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Towards consistency in Risk assessment tools for contaminated sites management in the EU

The HERACLES strategy from the end of 2009 onwards

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Contaminated sites, harmonisation, HERACLES, Repository, Risk assessment tool, Soil Framework Directive, Toolbox

Rapport in het kort

Momenteel gebruiken Europese landen verschillende *Risk assessment tools* om de risico's van bodemverontreiniging te beoordelen. Dit is onwenselijk, omdat hierdoor in Europa verschillende risicokwalificaties ontstaan voor vergelijkbare gevallen van bodemverontreiniging. Om de consistentie van deze tools te vergroten hebben een aantal Europese onderzoekinstituten die actief zijn binnen HERACLES een strategie ontwikkeld. HERACLES (Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States) is een internationaal netwerk, opgezet om deze consistentie te vergroten.

De strategie omvat twintig activiteiten voor de korte en lange termijn. Aangezien vooralsnog geen budget beschikbaar is, kan op korte termijn alleen een digitaal archief (*Repository*) worden geopend, welke gevuld kan worden met beschikbare *Risk assessment tools*. Als budget beschikbaar komt, kan op de langere termijn een *Toolbox* worden ontwikkeld met *Risk assessment tools* die grondig zijn geëvalueerd.

Abstract

EU Member States currently use a range of different *Risk assessment tools* for the appraisal of contaminated sites. This is an undesirable situation since it results in different risk qualifications for comparable cases of soil contamination. A number of European research institutions that are active participants in HERACLES have therefore developed a strategy aimed at improving the consistency of these tools. HERACLES (Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States) is an international network that was established with the express purpose of improving this consistency. The developed strategy includes twenty activities for the short and long term. Since no financial resources are allocated at the present time, it is only possible to launch a digital archive (*Repository*) that can be filled with available Risk assessment tools. When financial resources are eventually allocated, a *Toolbox* with intensively evaluated Risk assessment tools can be developed for use over the long term.

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Summary

HERACLES (*Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States*) is an international long-term Research framework, established by the European Commission Joint Research Centre (JRC). The *purpose* of HERACLES is “the improvement of the consistency of *Risk assessment tools* for human health and ecological risk-based soil quality assessment in the EU Member States”. The reason for improving the consistency is that it is generally recognised that the variety of Risk assessment tools (*i.e.*, instruments such as models, equations, databases, graphs, manuals or protocols that contributes to the stepwise approach for risk-based soil quality assessment) used in Europe, results in widely differing risk estimates at comparable contaminated sites. Moreover, the *Thematic Strategy for Soil Protection* and the announcement of a *proposal for a European Soil Framework Directive* stimulate the development and further improvement of Risk assessment tools. A joint approach in further development of Risk assessment tools may lead to a *Toolbox* in Europe, which allows for more consistent risk assessment approaches in an efficient way.

“Improvement of the consistency of Risk assessment tools” does not mean that there must be one unique procedure for dealing with contaminated sites all over Europe. It *does* mean, however, that the *technical part* (without geographical, cultural or political factors) of risk-based soil quality assessment should be based on a similar approach, when practically feasible. The concept of a *Toolbox* with Risk assessment tools will provide support to all relevant stakeholders (decision makers, industrials, environmental consultants, et cetera) involved in the development or revision/updating of Soil Quality Guideline Values, site-specific risk assessments, et cetera.

This report describes a *strategy* for achieving a higher degree of consistency of Risk assessment tools in the short and the longer term. In the short term, without financial resources, the launch of an electronic Repository will be investigated, which can be filled with existing Risk assessment tools. When financial resources are eventually allocated, a *Toolbox* with evaluated Risk assessment tools can be constructed after thorough evaluation of the Risk assessment tools in the Repository, in the longer term. Twenty activities have been defined to come towards a *Toolbox*.

The most important target groups of this report within the European soil quality community are the decisions makers (in particular the Common Forum), the scientists and the consultants, involved with contaminated sites. Other important target groups are the NICOLE and CABERNET networks. Results from several projects, networks, meetings and documents that could be useful for improving the consistency in Risk assessment tools will be included. These are the former CARACAS and CLARINET networks, the REACH Guidance Documents on Chemical Safety Assessment Technical Guidance Document, The ISO/ Technical Committee 190 “Soil Quality”, the SETAC workshops on derivation of Soil Quality Guideline Values in 2005 (Fahringdon) and 2008 (Sydney), the EPA (Network of the Heads of the European Environmental Agencies) network and several relevant international projects. Besides, a close communication with the *European Union/ DG Environment* and the *European Commission/ Joint Research Centre (JRC)* is important.

1. Introduction

1.1 Background and purpose

1.1.1 EU policy

It is generally recognised that Risk assessment tools used in Europe result in widely differing risk estimates for the same contaminated site scenarios (e.g., Swartjes, 2002; Arcadis, 2004 for human exposure calculations). The main trigger for establishing the HERACLES (*Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States*) network, however, was the *Thematic Strategy for Soil Protection* and the announcement of a *proposal for a European Soil Framework Directive*. The Thematic Strategy for Soil Protection consists of a Communication from the Commission to the other European Institutions (Commission of the European Communities, 2006a), a proposal for a framework Directive (Commission of the European Communities, 2006b) and an Impact Assessment (Commission of the European Communities, 2006c and 2006d). “Soil contamination” is recognised as one of the eight soil threats by the Thematic Strategy for Soil Protection. The proposed Soil Framework Directive, which was first issued in 2006, recommends using a *risk-based approach* for contaminated site assessment and remediation (SD, 2006).

As yet, this proposal has not yet been adopted and is still a matter of debate at the policy level. In spite of considerable amendments introduced by the European Parliament during the first reading, provisions for a risk-based approach for contaminated sites still remained in the adopted text (European Parliament, 2007).

In the amendments of the European Parliament (EP) of the draft Soil Framework Directive (European Parliament, 2007), it was considered necessary that European reference values, based on risk assessment, for dangerous substances on or in the soil shall be established (Chapter III, Article 11, paragraph 6). Moreover, it states that the Commission will set up a platform for the exchange of information and coordination between Member States, regional and local authorities and stakeholders on risk assessment methodologies for polluted sites currently in use or under development (Chapter IV, Article 18, paragraph 1). The methods used for assessing the threat of soil contamination must be more consistent or the Directive needs to be adapted in line with technical and scientific advances; the Commission shall propose common criteria for assessing the risk of soil contamination or implementing the requisite adjustments (Chapter IV, Article 18, paragraph 3).

The above mentioned provisions and discussion at the policy arena indicate that improvement of the consistency of Risk assessment tools in Europe is required, whereas the level of consistency needs to be considered carefully and differentiated. In many Member States, there is, at least, certain reluctance in the development and use of a more standardized approach.

1.1.2 The HERACLES network

HERACLES (*Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States*, see Fig. 1.1 for the logo of HERACLES network) is an international long-term Research framework established by the European Commission Joint Research Centre (JRC). The *purpose* of HERACLES is “the improvement of the consistency of Risk assessment tools for human health and ecological risk-based soil quality assessment in the EU Member States”. HERACLES focuses on both human health and ecological Risk assessment tools.



Fig. 1.1: The logo of HERACLES network

1.1.3 Purpose of this report

The purpose of this report is to describe a strategy for improving the consistency of Risk assessment tools in the short term, without financial resources, and in the longer term, when financial resources are eventually allocated.

1.2 Risk assessment tool, Toolbox and Decision Support System

With a Risk assessment tool is meant: a technical (scientific) instrument such as a model, equation, database, graph, manual or protocol that contributes to risk-based soil quality assessment. A combination of evaluated Risk assessment tools is called a Toolbox. A Toolbox differs from a *Decision Support System* (DSS), or other risk assessment frameworks. A DSS guides risk assessors through an assessment, for example the assessment of the soil quality, according to a fixed procedure. Usually, policy aspects have been implicitly incorporated in such a DSS. A Toolbox is not such a fixed procedure, but offers a number of Risk assessment tools for performing assessments in different ways and

for different purposes. A Toolbox for soil quality assessment, for example, offers not only Risk assessment tools for the derivation of Soil Quality Guideline Values, but also for the performance of detailed site-specific risk assessment, or the development of a potentially contaminated sites priority system. The Toolbox could contain a number of alternative Risk assessment tools for a specific part of a risk assessment. This will enable the risk assessor to choose the most appropriate tool for the risk assessment. It is possible to develop a DSS on the basis of specific Risk assessment tools from the Toolbox, usually in combination with (political and /or socio-economic) boundary conditions.

1.3 Harmonisation

To improve the consistency of Risk assessment tools in the EU Member States some harmonisation must take place. “Improvement of the consistency of Risk assessment tools” does *not* mean, however, that there must be one unique procedure for dealing with contaminated sites all over Europe. It is not the purpose of HERACLES, for example, to derive a DSS for risk-based soil quality assessment, for use in all 27 Member States. Harmonisation certainly does *not* imply the use of the same Soil Quality Guideline Values in all 27 EU Member States. Obviously, political choices (*e.g.*, the selection of protection targets, or the determination of the human health protection level for genotoxic carcinogenic compounds¹) are the responsibility of the national governments and will not be part of harmonisation. Improvement of the consistency of Risk assessment tools Harmonisation *does* mean, however, that the *technical part* of the risk-based soil quality assessment should be based on a more consistent and transparent approach, which needs to be developed on scientific evidence.

Since in many EU Member States Soil Quality Guideline Values, DSSs and Risk assessment tools have been implemented in policy frameworks, or have been developed to support laws or acts, it is politically impractical to implement other Risk assessment tools as soon as these become available. However, the availability of evaluated and more consistent Risk assessment tools offers great possibilities for policy makers, industry, environmental consultants, et cetera, who will develop Soil Quality Guideline Values or other risk assessment approaches in the future. They could make use of more consistent evaluated Risk assessment tools, with a broad European scientific basis. Besides, the developed/applied Soil Quality Guideline Values, DSSs and Risk assessment tools should be regularly revised/updated, taking into consideration new knowledge, in all countries. At such times, it should be strongly encouraged to review the evaluated more consistent Risk assessment tools and either to implement them or to describe the reasons for rejecting them. When a Toolbox is available, Member States also might be encouraged to consider revision of Soil Quality Guideline Values.

¹ For genotoxic carcinogenic compounds there is no threshold for acceptable exposure. Therefore, the determination of the level of human health protection (*e.g.* no more than 1 additional tumour is case of 100.000 exposed individuals; “10⁻⁵”) concerns a political decision

As well, the concept of a European network discussing scientific improvement of contaminated land Risk assessment tools will clearly result in a more cost-efficient way of revision or updating the tools. At present, countries are mostly addressing the same aspects of contaminated soil risk assessment in an independent way, while combining the scientific expertise will result in an efficient process with common acceptance by the broader community involved, as well leaving the freedom to countries for own implementation.

1.4 Target group of this report

This report will be presented to a large group of international experts from the following constituencies:

- Representatives of the relevant international projects (*e.g.*, FP program) that have a relation with Risk assessment tools.
- The *policy community* in Europe involved with contaminated sites. These experts will include national coordinators for HERACLES, which have been indicated by several countries. An important target group is the *Common Forum*², an umbrella organisation that includes the policy makers of a substantial number of European countries. The *policy community* must be involved with the purpose to increase the political consensus on the development of the Toolbox. Besides, it might stimulate the involvement of national decision makers, which increases the chance for using the evaluated Risk assessment tools. It also might trigger decision makers to allocate a part of the national budgets for the improvement of the consistency of Risk assessment tools.
- The scientific soil quality community in Europe involved with contaminated sites, from universities and research institutes, which have a relation with Risk assessment tools.
- The consultants. An important target group are the NICOLE³ and CABERNET⁴ networks.

² The Common Forum on Contaminated Land, established in 1994, is a network of contaminated land policy makers and advisors from national ministries in European Union member states and European Free Trade Association countries (Common Forum, 2009).

³ The Network on Industrially Contaminated land in Europe (NICOLE) is a leading forum on contaminated land management in Europe, promoting co-operation between industry, academia and service providers on the development and application of sustainable technologies (NICOLE, 2009).

⁴ The Concerted Action on Brownfield and Economic Regeneration Network (CABERNET) is a multidisciplinary network comprising of 6 expert Working Groups that aims to facilitate new practical solutions for urban Brownfields. Its vision is to: 'Enhance rehabilitation of Brownfield sites, within the context of sustainable development of European cities, by the provision of an intellectual framework for coordinated research and development of tools.' (CABERNET, 2009)

This report will be made public to all stakeholders (*e.g.*, on EUGRIS and on the internet sites of the national coordinators). The decision makers and experts in the EU Member States will be informed in this way and will be asked to give their opinion on the strategy. The results of these actions could be a revision of the strategy. To obtain both a wide distribution and to ensure the reliability of the findings, ideally an article should be submitted to an international peer reviewed journal.

2. Developments so far

2.1 Meetings

Within the HERACLES network the following meetings were organised, with the following purposes:

- HERACLES meeting February 2005 (Ispra): discussing the needs for improving the consistency of Risk assessment tools, and philosophy and approach of the HERACLES network;
- HERACLES meeting February 2007 (Ispra): discussing the methods for deriving soil screening values in Europe, on the basis of the draft document, and brainstorming on the procedure to improve the consistency of Risk assessment tools;
- HERACLES technical meeting February 2009 (Amsterdam): concretising the strategy towards the improvement of the consistency of Risk assessment tools.

Moreover, in September 2007 the EUR report n.22805 “Derivation method of soil screening values in Europe. A review and evaluation of national procedures towards harmonisation” (Carlson, 2007) was published. This report gave the state-of-art in regard to Risk assessment tools and soil screening values in the European Member States.

The conclusions of the February 2005 Ispra meeting were as follows:

- In general there was a lot of support for improvement of the consistency of Risk assessment tools, *i.e.*, focusing on the technical elements of risk-based soil quality assessment. However, it was also acknowledged that the process towards a higher degree of consistency is time-consuming and difficult, since there are many players (25 countries at the time, today 27 countries), certainly without a project structure and without financial resources.
- A problem is that when in the future a Toolbox with evaluated Risk assessment tools will become available they may not be compatible with the national Risk assessment tools and, hence, with national approaches. However, more consistency in Risk assessment tools, a broad European consensus and an improved scientific basis might encourage the acceptance of these Risk assessment tools on the longer term.
- The results of past initiatives on harmonisation must be included.
- The term “harmonisation”, the keyword in HERACLES at that time, needs an exact definition, which excludes the standardisation of political decision making. (Today, rather the term “consistency of Risk assessment tools” is used).
- The Human health risk assessment working group classified Risk assessment tools into three categories: Risk assessment tools that could be standardised, Risk assessment tools that offer flexibility and Risk assessment tools which at best can be described in general terms.
- The Ecological Risk Assessment working group referred to several widely accepted procedures that could be a basis for more consistent ecological Risk assessment tools.

- To get towards concrete results, there must be a combination of institutes/ individuals with regular contribution for the more time-consuming activities, and voluntary contributions of other institutes/ individuals for less time-consuming activities.

The conclusions of the February 2007 Ispra meeting were as follows:

- The report “Derivation method of soil screening values in Europe. A review and evaluation of national procedures towards harmonisation” (Carlon, 2007), at the time as draft report available, is very useful as starting point towards improvement of the consistency. However, the most important work, the explanation of the differences and the evaluation of Risk assessment tools itself, still has to be done.
- It is proposed to construct a “*Repository*” for the storage of Risk assessment tools, *e.g.*, as an electronic database. In the longer term this Repository must result in a Toolbox including Risk assessment tools.
- Several working packages were formulated on which the Repository and the harmonisation could focus (*e.g.*, contaminant-specific database, soil screening level assessment, exposure assessment, background exposure, soil sampling strategies, criteria of soil quality assessment, dust emission, toxicological values, vapor intrusion, soil-to-groundwater migration, plant uptake). They correspond to “bricks” and “cement” of the contaminated site assessment process, *e.g.*, vapor intrusion, leaching to groundwater, plant uptake, bioassays, dermal exposure, contaminant specific database, screening level assessment, background exposure, soil sampling, toxicological values.
- A steering group was formulated (this group, however, never was operational), mainly due to lack of available capacity.

The general framework of the HERACLES process (see Fig. 1.2) includes the Repository and the Toolbox, which were defined as follows:

- Repository: a storage place for the information presently available on Risk assessment tools and the results of their evaluation.
- Toolbox: a compilation of evaluated Risk assessment tools.

This means that the Toolbox should be filled from the Repository, after evaluation of the available tools from the Repository. The process of harmonisation in the strictest sense happens when information moves from the Repository to the Toolbox. A combined use of both Toolbox and of the Repository could be considered: one can look back in the Repository for more justification.

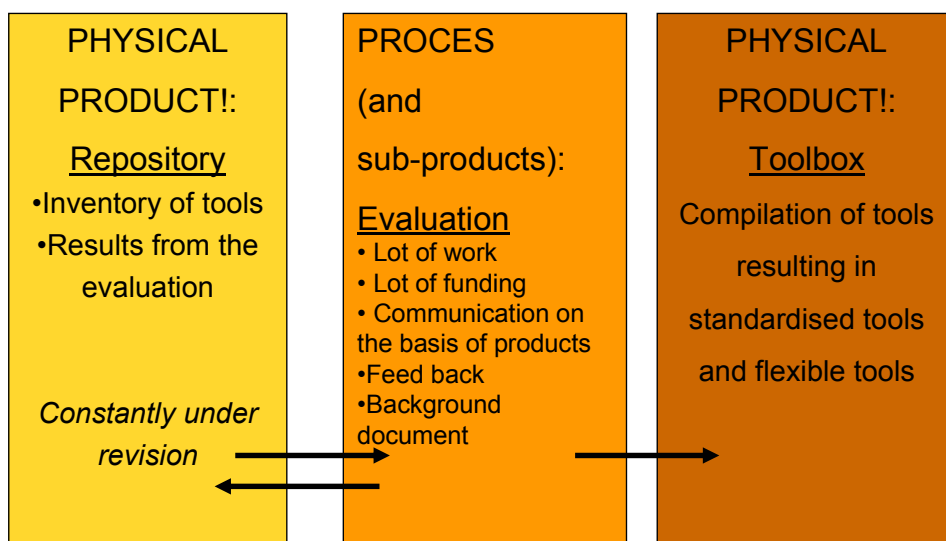


Fig. 1.2: General framework of HERACLES, as result of the discussion of the HERACLES meeting February 2007

The conclusions of the February 2009 Amsterdam technical meeting were as follows:

- From a technical perspective a higher degree of consistency in Risk assessment tools is important, even without a Soil Framework Directive, since there are many different Risk assessment tools in the EU for the same purposes that give widely differing results.
- We need to include all stakeholders, *i.e.*, scientists, policy makers, regulators and consultants. Since the authors of this report do not represent the whole EU community we will keep a close contact with the EU representatives. Besides, we will be in close contact with the Common Forum, representing the policy makers in the EU.
- The strategy to get towards improvement of the consistency of Risk assessment tools very much depends on the available capacity and, hence, the possibilities for funding. Currently, there is no funding; several experts can spend a limited amount of time on HERACLES using national budgets.
- In the short-term we will investigate the possibilities for launching a website, possibly connected to an existing website, on which the Repository could be realised. This concerns a low-profile activity, which could be done without financial resources.
- The longer term activities depend on funding. We will try to explore different possibilities for funding, *e.g.*, with regard to international projects and via national budgets (from 2010).
- Moreover, guidance must be published on how the harmonisation process can benefit from ongoing and future international projects and activities.
- On the longer term a higher degree of consistency in Risk assessment tools could be achieved following the steps 1 to 20, described in section 4.7 of this report.

Furthermore, a Special Session on improvement of the consistency of Risk assessment tools was organised at ConSoil, June 2008. The purpose of this session was to inform the international soil community about HERACLES and to investigate the first rough ideas about the possibilities for more consistent Risk assessment tools. The Special Session resulted in “awareness raising” and a categorisation of Risk assessment tools, based on the opinions of individuals (no consensus).

During the production of this report discussion took place about the terminology that was used in the HERACLES framework. It was generally believed that the word “harmonisation”, although it was not meant as a process that should lead to one imperative unique procedure in the European Union, was associated with compulsory use of specific Risk assessment tools. Especially decision makers were often sceptical about “harmonised” Risk assessment tools. To avoid any misunderstanding, the purpose of HERACLES was rephrased in “improvement of the consistency of Risk assessment tools”.

2.2 *Relevant initiatives*

Many other projects, networks, meetings and documents are in some way related to the harmonisation process. Projects, in which Risk assessment tools are developed, for example, usually include the state of art and sometimes combine existing Risk assessment tools. Besides, the following initiatives, projects and documents have a relation with HERACLES:

- The former CARACAS (Contaminated Risk Assessment on Contaminated Sites; 1996-1998) and CLARINET (Contaminated Land Rehabilitation Network; 1998-2001) networks.
- The Technical Guidance Document (<http://ecb.jrc.it/TGD/>). This Technical Guidance Document is coordinated by the Consumer Products Safety & Quality (CPS&Q) Unit, formerly known as European Chemicals Bureau (ECB), which is part of the Institute for Health and Consumer Protection (IHCP) of the JRC of Ispra. It supports the Commission Directive 93/67/EEC on Risk Assessment for new notified substances, the Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and the Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. This Technical Guidance Documents is now being replaced by the REACH Guidance Documents on Chemical Safety Assessment (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1236267515), implementing Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
- The ISO/ Technical Committee 190 “Soil Quality” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=54328&development=on). This committee focuses on international normalisation related to soil issues. It includes the following six sub-commissions (SC’s): Evaluation

- of criteria, Terminology and codification; Sampling; Chemical methods and soil characteristics; Biological methods; Physical methods and Soil and site assessment.
- The NICOLE network. NICOLE considers itself a leading forum on contaminated land management in Europe, promoting co-operation between industry, academia and service providers on the development and application of sustainable technologies. Since NICOLE cares about the collaboration with other international networks it is interested in harmonisation of procedures for dealing with contaminated sites.
 - CABERNET, Europe's sustainable Brownfield regeneration network, recognised the value for consistent approaches to environmental risk assessment and management across Europe and lamented the poor take up of risk based land management in many member states.
 - SETAC workshops on derivation of Soil Quality Guideline Values in 2005 (Fahringdon) and 2008 (Sydney).
 - The EPA Network (Network of the Heads of the European Environmental Agencies) and its Interest Group on Contaminated Sites & Soil Protection (coordinated by ISPRA, Italy).
 - Several international projects that relate to contaminated sites management.

Besides, a close communication with the *European Union/ DG Environment* and the *European Commission/ Joint Research Centre (JRC)* is important.

3. Risk-assessment tools

3.1 A closer look at Risk assessment tools

Terminology is not univocal and can sometimes be mutually interchangeable. An exposure model, for example, is a Risk assessment tool, since it coincides with the definition “an instrument that contributes to risk-based soil quality assessment”. At the same time it includes several “smaller scale” Risk assessment tools, like algorithms and input parameters for the calculation of exposure through soil ingestion (or through other pathways), and can therefore be considered as a Toolbox. Moreover, when policy aspects have been included in an exposure model, it can be considered a DSS. With the purpose to improve the consistency, the most relevant principle is to focus on Risk assessment tools at the smallest scale possible. In case of exposure models, for example, the most useful entities for improving the consistency are either “the approach for the determination of exposure through the separate exposures pathways” (algorithms and input parameters), or maybe even “algorithms for the determination of concentrations in specific contact media” and “algorithms for the determination of the exposure through the separate exposures pathways, given the concentrations in the relevant contact media”.

At least two type of Risk assessment tools can be distinguished, *i.e.*, *Standardised Risk assessment tools* and *Standardised Risk assessment tools*

3.1.1 Standardised Risk assessment tools

Standardised Risk assessment tools relate to technical Risk assessment tools that are evidently suited for use within all EU Member States. Examples are:

Human health risk assessment:

- daily inhalation rates;
- tolerable exposure (Reference dose or tolerable daily intake) for non-carcinogenic effects (a critical dose that leads to adverse health effects is similar for humans from different countries); or unit risks for carcinogenic effects (the increase in excess cancer risk per unit of exposure).

Ecological Risk assessment:

- the use of the Species Sensitivity Distribution (SSD) concept⁵ for the derivation of ecologically-based Soil Quality Standards;
- a methodology to quantify a specific bioavailable fraction.

⁵ The Species Sensitivity Distribution (SSD) concept is based on an empirical relation between soil concentration and fraction of species affected. When an acceptable fraction of species protected (= 100 - fraction of species affected) is selected (a political task and hence not suited for standardisation), the SSD gives the corresponding risk limit that can be used as ecologically-based Soil Quality Standards.

General:

- a database with contaminant characteristics.

3.1.2 Flexible Risk assessment tools

Flexible Risk assessment tools relate to tools that must offer the possibility for flexible use throughout Europe, due to differences in geographical or cultural aspects and (*last but not least*) policy decision making. Examples of *Flexible* Risk assessment tools might be:

- vapour intrusion models, which are dependent on soil type and groundwater depth (geographical difference);
- the contribution of home-grown vegetables to total vegetable consumption (cultural difference) and food consumption data;
- time-activity patterns.

For the *flexible* Risk assessment tools “guidance for use” must be developed, in as far as possible. This guidance may be, for example:

- a manual which allows flexible use of the Risk assessment tool by choosing, for example, different input parameters;
- a series of optional Risk assessment tools;
- boundary conditions of their applicability.

Ideally, a *flexible* Risk assessment tool can be turned into a *standardised* Risk assessment tool on a national (or regional) level, by implementing geographical, cultural or political factors.

3.2 State of art

In all European countries many Risk assessment tools for the assessment of soil quality exist. Many of these Risk assessment tools are implemented in national policies.

In 2007 the state-of-art of derivation methods of soil screening values in Europe was extensively reviewed and evaluated in the EUR report n.22805 (Derivation method of soil screening values in Europe. A review and evaluation of national procedures towards harmonisation; see Carlon, 2007). In this report the following conclusions were drawn:

- There is a huge variation in Risk assessment tools in Europe. The magnitude of the differences in combination with the sensitivity of the Risk assessment tools for the derivation of Soil Quality Guideline Values is evaluated in the report. Also the reasons for differences are categorised in the following categories: geographical/cultural, technical/scientific, or political/ regulatory.
- In about 10 countries Soil Quality Guideline Values are based on risk assessment. Another five countries, mainly post-2004 EU Member States, Soil Quality Guideline Values are based on Soil Quality Guideline Values from other countries. For many countries the derivation methods are not published or not transparent (*e.g.*, only published in the national language).
- The main references used by EU countries are the European Commission Technical Guidance Document on Risk Assessment, the procedures developed by RIVM in the

Netherlands (RIVM reports), guidance published by the UK DEFRA, approaches adopted in United States (*e.g.*, US-EPA, ASTM) and Canada (CCME and Health Canada) and the former Soviet Union procedures.

- Several differences in Risk assessment tools can be attributed to lack of technical consensus. These Risk assessment tools are particularly interesting for improving the consistency in Risk assessment tools.

The information in this report represents the starting point for the improvement of consistency of Risk assessment tools.

4. The way forward

4.1 *Repository*

As a first step towards a Toolbox with evaluated Risk assessment tools it is proposed to set up a Repository of *available* Risk assessment tools within the European Member States. Many Risk assessment tools only can be used properly by the developer. For these reasons it is proposed to include *descriptions, manuals or evaluations* of existing Risk assessment tools in the Repository. A standard format must be developed for these *descriptions, manuals or evaluations*.

Many relevant research organisations will be asked to deliver input for the Risk assessment tools and make them available for the Repository. A problem could be that not all organisations are prepared to make the Risk assessment tools generally available.

4.2 *From Repository to Toolbox*

Subsequently, in-depth technical evaluation on Risk assessment tool must be performed accordingly to the work packages, so as to reach consensus on each Risk assessment tool or group of Risk assessment tools. To this purpose an international project must be organised, with one-day to one-week intensive technical sessions. The Repository is the basis for the further actions that must lead towards the Toolbox with evaluated Risk assessment tools. An information sheet must be developed with every object in the Repository stating its aim and structure, and other relevant information about it. The experts that contributed to the construction of the Repository will be involved as much as possible, either by direct participation or by email consultation. Also, direct or indirect involvement of the decision makers is important.

Since some very important developments in Risk assessment tools takes place outside the EU Member States, it would be a missed opportunity when the evaluation process strictly focused on existing Risk assessment tools in the EU member States. Therefore, also some sophisticated tools used in the USA, Canada, and in Australia will be evaluated.

4.3 *Toolbox*

There has been a lot of discussion about the format of the evaluated Risk assessment tools in the Toolbox. Initially, the focus was on two types of Risk assessment tools, *i.e.*, *standardised* Risk assessment tools and *flexible* Risk assessment tools (see Section 3.1). *Standardised* Risk assessment tools are suitable for use in every part of Europe, independent of geographical, cultural or political aspects. *Flexible* Risk assessment tools are not suitable for use in every part of Europe, but must be adapted in regard to geographical, cultural or political aspects. To this purpose, “guidance for use” must be developed for this *flexible* Risk assessment tools.

Today, it is believed that this distinction in two classes is oversimplified and a third (or more) classes of Risk assessment tools will be needed. The evaluation process must show if this distinction in two classes is feasible, or if more classes and what type of classes are needed.

Standardisation mainly implies to Risk assessment tools that only differ due to lack of scientific consensus (see Carlon, 2007).

4.4 *Approach for evaluation of Risk assessment tools*

4.4.1 Basic principles

As a first step of an international project it must be defined what is meant with “evaluation” in the process of getting from Risk assessment tools in the Repository towards evaluated Risk assessment tools in the Toolbox. As a second step, either the type of Risk assessment tools must be discussed. Alternatively, the primary focus could be on Risk assessment tools that are evidently suited for standardisation. The principle could be: standardize what can be standardised (*standardised* Risk assessment tools) and develop guidance for the remaining tools (*flexible* Risk assessment tools and maybe other tools), as much as possible.

HERACLES focuses on existing Risk assessment tools and not on the development of new Risk assessment tools. However, revision of input parameter data could result in new proposals for optimal values or ranges.

4.4.2 Exclusion of political elements

A problem for harmonisation is that Risk assessment tools generally include technical as well as political elements. Algorithms, for example, may include empirical relations valid for specific conservative boundary conditions, *e.g.*, for (conservative) first tier risk assessment. Input parameters implicitly include a political element, since parameter identification is (often unconsciously) based on a specific level of conservatism or precaution.

One of the boundary conditions for Risk assessment tools in the Toolbox is that they are applicable for different purposes and with different levels of precaution. Users of the Toolbox must be able, for example, to choose a more conservative value of a specific input parameter for preventive purposes than for curative purposes. Possibilities to deal with this phenomenon are to either include *ranges* of input parameters or *probability density functions* in the Toolbox. For some Risk assessment tools it might be necessary to document the political elements which have been included as part of the Risk assessment tool. An example is whether the average or some conservative parameter values have been used.

4.5 *International basis*

This document on the HERACLES strategy was drawn up by a group of technical experts that have been intensively involved in the HERACLES Network. It is of the utmost importance to create a much wider basis for the Risk assessment tools and the Toolbox and, hence, for the strategy laid down in this document. Therefore, decision makers, other scientists, consultants and policy makers must be involved in the process.

4.6 *International projects*

Much of the technical work has to be done within international projects. It is important that the experts involved in ongoing projects, generally with other purposes than “improving consistency of Risk assessment tools”, are aware of and support the principle of the need for the improvement of consistency of Risk assessment tools. Moreover, they must know what kind of information is needed to support the harmonisation process. To this purpose a template or description must be developed that can be provided to project coordinators of any relevant international project. The template or descriptions format may need to be different for different kinds of tools.

4.7 *Activities*

To come towards a more harmonised Toolbox the following activities have to be performed:

CONTINUOUS ACTIVITIES:

International basis:

1. Selecting and approaching other relevant players within the scientific community, who can contribute to a wider technical basis of the harmonisation process.
2. Selecting and approaching relevant players within the political community, who can contribute to a wider political basis of the harmonisation process (among others via the Common Forum)
3. Communicating with the European Commission, DG Environment and the European Commission, Joint research Centre, about the possible “formal” involvement of all 27 EU Member States.

Collaboration:

4. Identification and evaluation of relevant networks, meetings and documents.
5. Contributing to meetings, reviewing of relevant documents and approaching relevant people from these initiatives.

Communication:

6. Presenting the strategy and inviting for comments.
7. Publishing about HERACLES, risk assessment methodologies, the Repository and the Toolbox

SHORT TERM ACTIVITIES:

Repository:

8. Scoping and structuring the Repository.
9. Launching the Repository (electronic).
10. Development of a format for the *descriptions* of Risk assessment tools and possible additional information in the Repository
11. Selecting and approaching organisations that are invited to send in descriptions of Risk assessment tools and supplementary information to the Repository.

Financial basis:

12. Investigating the possibilities for funding for the longer term (from 2010).

Involvement international projects:

13. Development of a template or description that can be provided to project coordinators of any relevant international project, with the purpose to invite them to contribute to the harmonisation process.
14. Identification of relevant international projects and contacting project coordinators.

LONG TERM ACTIVITIES:

Toolbox/ Risk assessment tools

15. Assessment and categorisation of Risk assessment tools into:
 - suitable for standardisation (standardised Risk assessment tools);
 - not suitable for standardisation, but need for development of guidance;
 - other *Risk assessment tools*;
 - lacking tools;
16. Development of standardised Risk assessment tools, on the basis of an evaluation of *Risk assessment tools* in the Repository.
17. Development of guidance for flexible Risk assessment tools, on the basis of an evaluation of Risk assessment tools in the Repository.
18. Developing a procedure to communicate about dealing with other Risk assessment tools and Risk assessment tools that are lacking.
19. Development of a Toolbox (electronic).
20. Implementation of a system for the continued development or updating of the Toolbox.

4.8 *Project risks*

Several risks are recognised that might threaten a successful harmonisation procedure:

- There are no financial resources for HERACLES activities available for activities in the short term. As a consequence, these short activities are dependent on the limited availability of a few individuals on an ad hoc basis. Therefore, the coordination and the execution of the HERACLES activities are not guaranteed.
- The long term activities must be performed within the framework of a project, including funding. Several possibilities will be investigated. The EU FP research program, however, does not offer a clear lead for harmonisation related projects. Without a project and funding, the long term activities are not possible.
- It is possible that several organisations are not prepared to make the Risk assessment tools generally available for the Repository. This may not necessarily be a problem, as long as a basis of Risk assessment tools from the contribution of several institutions is available.
- At present, some decision makers are not in favour of improvement of the consistency of Risk assessment tools. In some cases, the term “harmonisation” is too much associated with “losing every control over the procedures of contaminated sites management”. The position of harmonised Risk assessment tools is still under political debate. However, the harmonisation of Risk assessment tools described in this report is limited to the technical part of risk assessment procedures (not to geological cultural or political decisions making).

5. Preliminary results

5.1 *Introduction*

Some preliminary results are available from the first HERACLES meeting (February 2005), the second HERACLES meeting (February 2007) and the ConSoil Special session on harmonisation of Risk assessment tools (June 2008). These initial results concern a proposal for classification in type of Risk assessment tools. Since these preliminary results are the result from inventorising individual opinions, and not from consensus, they must be considered as examples. They could, however, be used as a starting point for harmonisation. This proposed classification must be evaluated within the wider international soil quality assessment community.

5.2 *Identification of Risk assessment tools*

A list of *Risk assessment tools*, including tools that were mentioned at any of the HERACLES related meetings, is included in Appendix A.

6. Conclusions

In this document a strategy has been described for improving the consistency of *Risk assessment tools* for contaminated sites management has been described, within the HERACLES (*Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States*) network. This strategy has been discussed in a workshop on 20 February 2009. The following conclusions can be drawn:

- Improvement of the consistency of Risk assessment tools is useful, since it is generally recognised that Risk assessment tools (*i.e.*, instruments such as models, equations, databases, graphs, manuals or protocols that contributes to risk-based soil quality assessment) used in Europe result in widely differing risk qualifications for the same contaminated site scenarios. Moreover, although there is an ongoing political debate, the *Thematic Strategy for Soil Protection* and the announcement of a *proposal for a European Soil Framework Directive* stimulates the development and further improvement of Risk assessment tools. International cooperation will lead to a more cost-effective approach for the further development of risk assessment tools which may lead to a common (and harmonised) toolbox of improved flexible risk assessment approaches in Europe. International cooperation will lead to a more cost-effective approach for harmonised technical tools.
- Improvement of the consistency of Risk assessment tools means that the *technical part* (no geographical, cultural or political factors) of the risk-based soil quality assessment should be based on a similar approach, as far as possible. It does *not* mean that that there must be one unique procedure for dealing with contaminated sites all over Europe.
- Twenty activities have been defined to work towards a *Toolbox* with evaluated Risk assessment tools. On the short term, without financial resources, the launch of a repository will be investigated, which can be filled with existing Risk assessment tools. In the long term, when financial resources are eventually allocated, a Toolbox with evaluated Risk assessment tools can be constructed after thorough evaluation of the Risk assessment tools in the Repository.
- The most important target groups of this report within the European soil quality community are the *policy makers and regulators* (in particular the Common Forum), the scientists and the consultants, involved with contaminated sites. Other important target groups are the NICOLE and CABERNET networks.
- The results from several projects, networks, meetings and documents, which have been identified in the report, will be included in the harmonisation process.
- A close communication with the *European Commissions/ DG Environment* and the *European Commission/ Joint Research Centre (JRC)* is important.

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Appendix A: List of Risk assessment tools that were mentioned in several HERACLES related meetings

<u>Contaminant characteristics</u>
Koc
Criteria for data quality
<u>Human behaviour</u>
Soil ingestion rate children
<u>Exposure:</u>
Procedure to determine the bioaccessibility in humans
Model algorithm for exposure through soil ingestion
Model algorithm for exposure through vegetable consumption
Model algorithm for exposure through the consumption of animal products
Model algorithm for dermal exposure
Model algorithm for soil particles or volatiles inhalation exposure
Model algorithm for vapour intrusion
Vegetable consumption rate
<u>Geological/ geographical parameters</u>
Soil type
Groundwater table
Organic matter content
Clay content
<u>Toxicological parameters</u>
Reference dose for non-carcinogens
Slope factors for carcinogens
The decision on whether or not contaminants have a threshold
The decision on whether or not contaminants are carcinogenic
<u>Risk characterisation</u>
Procedure to combine exposure with reference dose (critical exposure)
<u>General</u>
Standards for reporting
Approach to Toxicological Equivalent factors (TEFs)
Procedure on risk communication

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