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"State-of-the-practice-light"

Notes from workshop 1 within project *EXPOSED?*

Human health risk assessment of contaminated soils – Current practices and experiences in some European countries

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Background

Assessment of the risks associated with contaminated soil is essential for protecting human health and the environment, as well as for making decisions about remediation measures. To improve the accuracy of human health risk assessments (HHRA), it is important to gain a deeper understanding of actual exposure and uptake of soil pollutants in the human body. The *EXPOSED?* project (Appendix 1), funded by a research grant from the Swedish Environmental Protection Agency, focuses on challenges related to HHRA of lead and arsenic contaminated soil. One important part of the project is to exchange knowledge and experiences with other European countries. For this purpose, a Policy Advisory Group (PAG) was formed, with members (including experts and policy makers) from several European countries (Appendix 1).

Except for the United Kingdom all countries in the PAG are EU members. However, contaminated soil risk management procedures are not, or at least not yet, covered or defined by EU regulations. Moreover, EU directives have historically been implemented differently in different countries. In addition, how the work with contaminated soils is organized as well as the historical context impact the national framework used in each country. Consequently, there are considerable differences in how challenges related to risk assessment and management of lead and arsenic contaminated soils are addressed. In this context, the proposal for an EU Directive on Soil Monitoring and Resilience[1] will, if adopted, be an incentive to increase harmonization between European countries. The proposed directive specifically mentions risk assessment of contaminated sites[2].

To gather information on practices in different countries on 1) HHRA of contaminated soils, 2) the assessment and use of bioavailability in HHRA and 3) use of biomonitoring in HHRA of contaminated soils, the PAG was invited to an online workshop (WS1) in November 2024. Before WS1 a questionnaire was distributed to all participants. The answers were compiled and formed the basis for WS1. This "State-of-the-practice light" is based on questionnaire answers and discussions in WS1. While not a comprehensive comparison of all aspects, this document highlights important similarities and differences, opportunities for learning from each other, and potential areas for harmonization.

[1] Proposal for a Directive on Soil Monitoring and Resilience - European Commission

[2] For example: "Member States shall lay down the specific methodology for assessing the site-specific risks of contaminated sites" (Art 15 of proposed Directive on Soil Monitoring and Resilience)

How is HHRA carried out in different countries?

HHRA is a critical component in management of contaminated soils as it involves evaluating the potential health risks posed by contaminants. There are important differences between countries regarding models and approaches used in HHRA of contaminated soil. The aspects discussed at WS1 are summarized in Table 1 and further developed under the following headings.

Table 1. Health risk assessment of contaminated soils in different European countries. SGV = Soil Guideline Value, TRV = Toxicological Reference Value. The HHRA models are briefly described in Appendix 1.

	Are "SGV-type" values calc. with generic model?	HHRA model for cont. soil	Special approach for Pb, As (or Cd)?	Other exposure considered in HHRA?
Nether-lands	Yes, with CSOIL	CSOIL	Yes, ALARA*-based for Pb. As currently under evaluation.	Not for intervention values, but for reuse of soil.
Wallonia	Yes, S-Risk for VSH**, the older RISC Humaan for VS**	S-Risk	Pb under evaluation. VS** (old TRVs) higher than VSH**.	In S-Risk possible but not used.
Flanders	Yes, with S-Risk	S-Risk	SGV and HHRA of Pb and As are currently under evaluation.	Yes, background concentrations in food and drinking water.
France	No, always site-specific assessment. There are values (not "SGV-type") for some specific contaminants and scenarios ***.	MODUL'ERS is one of the used tools	Always site and contaminant specific risk assessment	Not in national methodology for management of contaminated land*****
UK	No SGVs for As or Pb but "generic assessment criteria". S4UL**** for As, C4SL**** (Pb and As)	CLEA model	The type of generic assessment criteria may be different for different compounds.	Yes, max 50% of the TDI can be allocated to other exposures.
Sweden	YES with "SEPA model"	SEPA model	Yes, policy-based SGVs for Pb. For As adjusted to national soil background.	Yes, for threshold subst. For Pb and Cd 80% of TDI (generic 50%).

*ALARA = As low as reasonably achievable

**VSH = "threshold values for protection of human health", VS = "fixed threshold values"

*** "Rapid action" and "Vigilance" values for some specific contaminants in soil (e.g As, Cd) and scenarios proposed since 2022 by the High Council for Public Health (HCSP)

****S4UL = "Suitable for use Level", C4SL = "Cat. 4 Screening Levels"

*****Concerns only health risks associated with contaminated soil and other impacted media e.g. not dietary background exposure. However, note that e.g. for the As Vigilance and Rapid action values, inclusion of the dietary background exposure would lead values exceeding the tolerable intake.

What guideline/threshold/screening values and calculation tools are used?

In risk assessment of contaminated soils, different types of "soil guideline values - SGVs" (e.g soil guideline/threshold/screening values), expressed as total contaminant concentrations in soil, are often used to evaluate the severity of soil contamination at a contaminated site and determine the need for further investigations, or in some cases intervention[3]. Risk based SGV-type values for human health are often based on toxicological reference values (TRV) that define an "acceptable" exposure. Several of the PAG countries use generic models to calculate SGVs or similar for many contaminants. Others do not use SGVs but use exposure models for

[3]When intervention values exist

calculations of risk in terms of potential exposure doses that are compared to the TRVs (so called forward calculations).

However, it has been acknowledged that it is often challenging to use risk-based models for lead and arsenic as they have some toxic effects already at low exposure. Moreover, the SGVs often become very low (below national background concentrations in soil), in particular when exposure not directly related to the contaminated soil (such as diet) is taken into consideration. Therefore, several countries have developed or are exploring other approaches.

In the Netherlands, a generic exposure model, CSOIL, is used to calculate human-health based "risk limits" for about 130 pollutants in soil (Appendix 2). Together with ecology-based "risk limits", they are integrated into SGV ("Intervention values"). For lead and arsenic, it has been recognized that unacceptable risks cannot be excluded at soil concentrations lower than the CSOIL risk limits. Therefore, a management framework, based on more recent studies and an ALARA (as-low-as-reasonably- achievable) principle is employed for lead. The framework focuses on limiting exposure (clean hands, clean house, clean garden, clean children's playgrounds). Within the framework more strict values may be used for lead. A similar approach is in progress for arsenic (deadline 2026).

Wallonia has fixed thresholds (VS) for pollutants. These are included in the Walloon soil decree, hence legally binding. The VS values are set to the lowest of the three risk-based components (protection of soil organisms/processes; groundwater and human health) and used both to determine if sites are polluted and to trigger further soil investigations. For lead and arsenic VS values were established using the previously used model RISC-Humaan which gives higher values than the newer S-Risk (Appendix 1), mainly because older TRVs were used in RISC-Humaan. When further investigations are triggered, S-Risk is used to calculate threshold values for the protection of human health (VSH). However, the resulting VSH for lead and arsenic are below background concentrations in soil and are not used directly. There is also a web-based tool called SANISOL, that is used to provide recommendations for gardening in trace metal contaminated vegetable gardens (Appendix 2). SANISOL use non-risk-based trigger values for lead and arsenic.

Flanders also use the S-Risk model but with different data for some parameters than Wallonia. Consequently, the output values are different. Flanders calculates BSN values (Bodemsanerings-normen, soil remediation values) which are part of the Flemish soil Decree. For the BSN value a criterium for human health protection and a criterium based on ecological risk is derived. The most stringent of these is chosen as the BSN. The BSN for arsenic is calculated (with S-Risk), taking into account non-carcinogenic effects for oral routes, and carcinogenic effects with a threshold for the inhalation route. Flanders has the tool 'Gezond uit eigen grond' (Appendix 1) to provide recommendations for people that want to grow vegetables in their own garden.

In the United Kingdom, SGVs are no longer in use for most compounds including lead and arsenic. The CLEA (Contaminated Land Exposure Assessment) model (Appendix 2) is used to calculate "generic assessment criteria". Generic assessment criteria have been developed for lead, arsenic and many other contaminants. There are "Suitable for use Levels" (S4UL) representing "minimal risk" based on epidemiological studies for arsenic and "no appreciable risk" for cadmium. In addition, there are "Cat. 4 Screening Levels" (C4SL) for both lead and arsenic to identify land posing a so-called low level of toxicological concern (higher than minimal/no appreciable levels of risk). By their advocates, the C4SL are claimed to be more pragmatic than SGVs and S4ULs, but still precautionary.

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In Sweden there is a list of generic soil guideline values derived with a generic model (Appendix 2). The model includes an adjustment that ensures that SGVs does not to fall below national background levels, which affects generic guideline values for "Sensitive land use" (residential areas) for arsenic and lead. However, the generic guideline value for lead is "policy-based" and higher than the value calculated by the model. In in-depth investigations the same model is frequently used to calculate site specific SGVs, but other approaches can also be used.

In France, there are no generic soil guideline values. Instead, site- and pollution-specific assessments are adapted to the specific conditions of each site following national approaches. The "State-of-media quality assessment" (Interprétation de l'Etat des Milieux, IEM) helps to evaluate for a given site if there is compatibility between the current state of its environmental media quality and its current land use. The IEM is performed for each relevant medium (e.g. water, food, soil, air) and contaminant. If measured contaminant concentration(s) exceed background levels or other relevant values (e.g. drinking water criteria) a quantitative HHRA is conducted, which may be performed with the IEM grids provided by the Ministry of the Environment, with site specific parameters. Each hazard quotient (HQ)[4] and/or excess individual risk (ERI)[5] is interpreted in relation to risk-level intervals (3 for HQ and 3 for ERI) associated with various types of actions (no actions, simple actions, or remediation). Then, a "Management Plan" (Plan de Gestion, PG), can be implemented to act on environmental media and/or make changes to land uses. Quantitative HHRA is performed, and if there is a residual exposure after remediation, a HHRA named "Analysis of the Residual Risk" (Analyse des Risques Résiduels, ARR) is conducted. The ARR respects the risk additivity rules. A HQ level of 1, an ERI level of 10^{-5}, and the reference values given by the regulations in force also taken into consideration. MODUL'ERS is one of the tools available for HHRA.

What are the toxicological reference values?

Toxicological reference values (TRV) are values defining the level of a particular substance to which people can safely be exposed over a specified period, for example, the acceptable daily intake. With new knowledge TRVs may need to be updated. In several countries there is still an ongoing discussion on how to implement the latest toxicity and carcinogenicity assessments for lead and arsenic in HHRA. Even if based on the same toxicity assessment, the TRV implemented may differ between countries. The differences might be explained by, among other things, differences in what is regarded an acceptable excess cancer risk.

Lead: So far only Sweden have implemented a TRV for lead that is based on the latest evaluation from EFSA[6] in the HHRA model for contaminated soil (Table 1). However, for sensitive land-use a policy-based generic SGV is used instead of the SGV calculated with the model. In France, the TRV used is the ANSES value of 2013[7] (based on the reasoning of EFSA, 2010). Although not implemented in the SGV, in practice a TRV based on the EFSA 2010 report is often used for HHRA in the Netherlands. In Wallonia and Flanders, the TRV for lead used in S-Risk is under evaluation for update. In the meantime, Flanders has taken specific regulatory measures for lead, to take into account the EFSA 2010 evaluation. The EFSA 2010 evaluation has been implemented in Wallonia's Sanisol tool.

[4]Hazard quotient, HQ, for contaminants with threshold effects
[5]Excess individual risk. ERI, for contaminants without threshold effects
[6]Scientific Opinion on Lead in Food, EFSA Journal 2010; 8(4):1570
[7]Opinion of the French Agency for Food, Environmental and Occupational Health & Safety (No 2011-SA-0219). French Agency for Food, Environmental and Occupational Health & Safety (i.e. ANSES, Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail)

Arsenic: Arsenic have both threshold and non-threshold toxic effects. All countries surveyed use TRVs that take carcinogenic effects in consideration, but threshold effects may also be considered[8]. In Wallonia, Flanders, the Netherlands and France, the TRV for arsenic is currently being assessed and may be updated. In the Netherlands, a lower TRV than the one implemented in CSOIL has been proposed and is already used in practical application. In the approach currently evaluated in the Netherlands, evaluation of the EFSA 2024[9] and JECFA[10] (in progress) studies on TRVs will be taken into consideration.

Is other exposure, such as from diet, accounted for?

Because a major part of the overall exposure for lead and arsenic comes from sources that are not directly related to contaminated soil (often mainly the diet) it is important if risk assessment models take this "background" exposure into account. Risk assessment models that include other sources helps to understand the total exposure. However, for some metals the background exposure may fill up more or less the whole TRV.

In Sweden and United Kingdom background exposure, such as dietary intake, are taken into account in HHRA models as a percentage of the TRV (Table 1) for contaminants with threshold dose-response behavior. Flanders includes background exposure via food (commercially available) and drinking water. In the Netherlands, France and Wallonia, it is not routinely included but there are exceptions. For example, the Netherlands includes background exposure when the possibility of soil re-use is evaluated, while Wallonia includes background exposure in its Sanisol tool. In France, exposure from locally cultivated vegetables is included when people cultivate their own vegetable garden.

What are the challenges and considerations related to HHRA?

Human Health Risk Assessment (HHRA) of contaminated soil is complex and comprises science, expert judgements and valuation, leading to continuous developments, updates and debates. Although experts usually agree that assessments should be risk-based there is not always agreement on best approaches and practices. Moreover, national legislation demands may affect the potential for harmonization of risk-based approaches.

- Countries may have a similar risk-based basis but still get different results depending on country, models and settings. Calculated values mean different things in different countries.
- Human exposure from other sources than soil is high and toxicological reference values are low – there is little or no "room" for added exposure from contaminated soil – this is the case for both lead and arsenic. The need to still deal with these contaminants in practice has resulted in different approaches in different countries and regions.
- Differences in national legislation makes it difficult to harmonize HHRA. It is important to discuss (and try to define) what can and should be harmonized.
- Distinguishing between naturally occurring and anthropogenic sources of pollutants may be difficult, yet it remains important for risk management policies and remediation decisions.
- The relationship between consistency and specificity needs to be considered. In the Netherlands, for example, implementation of the new Environment and Planning Act gives more freedom to regional authorities, which may increase specificity but hampers

[8]E.g. Flanders Bodemsaneringsnormen, BSN, for arsenic consider non-carcinogenic effects for oral routes, and carcinogenic effects with a threshold for the inhalation route. In France, threshold and non-threshold toxic effects are considered for oral and the inhalation routes. The TRVs should be updated in 2025 for oral route.
[9]Update of the risk assessment of inorganic arsenic in food, EFSA Journal 2024; 22(1)
[10]JECFA = Joint FAO/WHO Expert Committee on Food Additives

consistency. Since the introduction of this act (2024), it is not obligatory to use the RIVM toolboxes anymore.
- There is no "safe" level of exposure for lead – rather a general need to decrease exposure of the population.
- Little is known about the contribution from lightly or moderately contaminated soils to blood lead levels in relation to total blood lead.

How can bioaccessibility be used in risk assessments?

Bioavailability refers to the part of a contaminant that is released from a matrix, absorbed in the human body and reaches the bloodstream when ingested, inhaled, or in contact with the skin. The discussion in WS1 focused on oral bioavailability of contaminants in involuntarily ingested soil and more specifically on the determination of oral bioaccessibility (summarized in Table 2). Understanding oral bioaccessibility is important as it determines the potential dose that may affect human health when soil is swallowed.

Table 2. Use of oral bioaccessibility (BA) in HHRA in different European countries. UBM=Unified Barge Method; RBA= relative bioaccessibility.

	Is BA defined in HHRA?	Default RBA	Is BA adjusted site-specifically?	Lab protocol prescribed or used	National guidance on BA in HHRA?
Nether-lands	Yes, in RIVM tools	As=1, Cd=1, Pb=0.74	Yes, mentioned in tier 3 in decision support tool Sanscrit (but not often done)	No recommend-dation, UBM is generally known.	No
Wallonia	Yes, in S-Risk	In S-risk As, Cd, Pb=1, in Sanisol As=0.6	Possible but not used in practice.	No recommendation. UBM used in some projects	No
Flanders	Yes, in S-Risk	As, Cd, Pb=1 (0.8 proposed for Pb)	Possible but rarely used in practice.	No recommendation.	No
France	Yes, specific protocol and methodology is used	Total (pseudo-total) concentration*	Yes.	UBM/ISO17924 recommended. A simplified method is developed**	Yes, a framework that is currently revised**.
UK	Yes, in CLEA model	As=1, Cd is complex, Pb=0.6	Yes, usually conservative value chosen.	Usually UBM/ISO17924, but also SBRC/RBALP.	Yes, for regulators but also useful to risk assessors.
Sweden	Yes, in SEPA model	As=1, Cd=1, Pb=0.6	Possible and used (but not routinely).	Usually UBM/ ISO17924, simplified method tested.	Limited

*Currently, HHRA is based on the total (or pseudo-total) concentration in soil, which corresponds to RBA =1. For initial pollution diagnostics without BA implementation soil sample is sieved to 2 mm, then milled to <250 µm. For the UBM protocol sample is sieved <250 µm without mechanical milling.
**French framework (As, Pb and Cd) from 2012[11] is currently revised by a national working group. New French national guideline will be published 2025. Standard for simplified method for prediction of oral bioavailability (ISO/DIS 7303) finalized 2025 will be recommended in screening of the "predicted bioaccessibility" in the guideline.

[11] InVS-Ineris (2012) Quantités de terre et poussières ingérées par un enfant de moins de 6 ans et bioaccessibilité des polluants, https://www.santepubliquefrance.fr/determinants-de-sante/pollution-et-sante/sols/documents/rapport-synthese/quantites-de-terre-et-poussieres-ingerees-par-un-enfant-de-moins-de-6-ans-et-bioaccessibilite-des-polluants.-etat-des-connaissances-et-propositions

Is bioavailability/bioaccessibility used in HHRA and can it be adjusted?

In HHRA models for contaminated soil, a factor called "relative bioavailability" (RBA) is used to include bioavailability in the assessment. The RBA factor relates the bioavailability of the contaminant in soil to the bioavailability included in the TRV. However, since it is not possible to measure the actual bioavailability of contaminants in soil, it is not obvious how to estimate this relative bioavailability by considering bioaccessibility and use it in HHRA. Moreover, bioavailability differs both between groups of people and between individuals. Even for a single individual bioavailability will vary, for example depending on if food is ingested simultaneously. In HHRA, the RBA is often considered equal to 1 (i.e. 100 %) by default, to be conservative.

All countries that use generic models for calculation of SGV-type values include bioaccessibility as RBA in their model, however the default values differ to some extent (Table 2). There are ongoing discussions about lowering the RBA in some countries, for example in Flanders and Wallonia that currently use a RBA of 100% for lead as default but are discussing lowering it to 60-80%. It is also possible to adjust RBA site specifically in the risk assessment models to account for site specific properties and conditions. It is not commonly done, except in the UK, where site specific values for bioaccessibility are used routinely.

France, which always uses a site-specific approach for HHRA, estimates bioaccessibility (for arsenic, cadmium and lead) on a site-specific basis. Research projects are also in progress to validate the UBM (Unified Barge Method) method for chromium and nickel (in vitro/in vivo validation).

In the Netherlands RBA values for lead have been derived for different types of soils, for example a value of 58% is used for artificial soils in the west of the Netherlands.

How is bioavailability/bioaccessibility estimated?

Animal-based tests which expose animals (mice or swine) to contaminated soil (so called in-vivo tests) have been developed to estimate the bioavailability but in Europe these are only used to validate laboratory in-vitro tests. Several different in-vitro laboratory tests where soil is leached with solutions that mimic body fluids have been developed. These in-vitro tests estimate how much of the contaminants that are released in body fluids but do not include the actual adsorption, or uptake, in the body (bioaccessibility). The "UBM" standardized test (ISO 17924:2019[12]) is the most commonly used method to measure oral bioaccessibility and estimate bioavailability in Europe. It is in-vivo validated for lead, arsenic and cadmium and can be used to estimate a site-specific bioaccessibility.

In the Netherlands, Wallonia, Flanders and Sweden there are no explicit recommendations regarding the methodology that should be used to estimate bioaccessibility. In France, UBM is considered as the reference method and is recommended. France has also developed a simplified method (extraction with HCl), aimed for site specific screening of "predicted bioaccessibility". An ISO standard for this method will be published during 2025. In the UK, UBM is commonly used, although the SBRC/RBALP protocol is also occasionally used. Just as the UBM, this protocol simulates bioaccessibility in the gastric and gastro-intestinal phases.

Is there guidance for the use of bioavailability/bioaccessibility in HHRA?

France has a bioaccessibility framework that is currently being revised and developed to give more detailed guidance. The new framework will include advice about use of the UBM and the

[12] Soil quality — Assessment of human exposure from ingestion of soil and soil material — Procedure for the estimation of the human bioaccessibility/bioavailability of metals in soil

simplified method. The UK provides guidance for regulators, which is also useful for risk assessors. In Netherlands, Wallonia, Flanders and Sweden there is little guidance on how to integrate results from bioaccessibility tests into risk assessments.

What are the challenges and considerations related to bioavailability/bioaccessibility in HHRA?

There are barriers that prevent the routine use of site-specific bioavailability/bioaccessibility in HHRA.

Firstly, the tests used to estimate bioaccessibility of contaminants, e.g. ISO 17924:2019 are complex and costly. To overcome this barrier, a simpler and less expensive method for screening has been developed and tested. French researchers have completed a draft for an ISO-standard for this method. However, for each site this simplified test needs to be validated site specifically with UBM on few soil samples and assessing bioaccessibility may still be perceived as costly. Secondly, several countries lack detailed guidance and consensus on how to estimate bioavailability/bioaccessibility and integrate it into risk assessments which limits its application. There are ongoing discussions, and work on guiding documents. The SOILveR expert group on bioaccessibility works to share practices and experiences between countries. In France, National Working Group – Oral Bioaccessibility of metal(loids) in soils - will publish a new guide in 2025. Thirdly, the extent to which bioaccessibility influences the results of HHRA can vary, affecting its perceived importance and use. If a low bioaccessibility does not influence, e.g. guideline values or conclusions on risks and need for mitigation, performing such test may be considered an unnecessary cost.

Is biomonitoring used in HHRA of contaminated soils?

Human biomonitoring (HBM) involves measuring the levels of contaminants in biological samples (such as blood or urine) to assess exposure and potential health risks. Biomonitoring is not commonly used in connection with the investigation of human exposure to contaminated soils except in France where HBM is used more frequently under certain conditions (Table 3). There are no known HBM studies that specifically target areas with low to moderate lead and arsenic contaminant concentrations, but such areas may be part of studies in contaminated areas, for example in the Campine area in Flanders. Also, people exposed to low-moderate lead and arsenic concentrations in soil may be included in national HBM but then information on concentrations in soil is not included.

Table 3. Use of human biomonitoring (HBM) in relation to contaminated soils in different European countries.

	Use of HBM in HHRA of contaminated soils	How or when is HBM initiated for contaminated soils?	Background values in biological matrices
Netherlands	Yes (rarely)	Mentioned in tier 3 in decision support tool Sanscrit.	International
Wallonia	Yes (occasionally)	Action protocol is being developed	National
Flanders	Yes (not routinely)	Sometimes when large area and population is affected	National. A HBM program since 2002.
France	Yes (if total Pb, total Cd or bioaccessible As in soil is above a certain level).	Mentioned in methodology. Triggered by total conc. in soil, dust, drinking water for Pb, by total conc. in soil for Cd and for As by bioaccessible conc. in soil.	National values from population impregnation studies.
UK	Very rarely	When the legal context requires a high level of confidence of a high level of risk.	There are studies
Sweden	Rarely (special cases)	Mentioned briefly in guidance	National

What triggers are there for biomonitoring?

HBM is mentioned in the French national methodology for the management of contaminated land, specifically in relation to management of former mining sites, but also around industrial sites. If there are concerns about exposure in such areas, health authorities can carry out HBM to clarify the actual exposure. In France, the High Council for Public Health (HCSP) published concentrations in soil that triggers biomonitoring for some elements; a "screening trigger level" for lead[13] and "rapid action values" for arsenic, cadmium and mercury. In addition, the French National Authority for Health (HAS) has published documents with recommendations regarding HBM screening strategies to evaluate possible overexposure to arsenic[14] and cadmium[15]. In the document for arsenic, the concentration in soil is expressed as bioaccessible arsenic while cadmium is given as total concentration in soil.

In the Netherlands, biomonitoring is sometimes used in the HHRA of contaminated soil, especially when there is societal concern or when initial risk assessments are uncertain. Biomonitoring is mentioned in the Dutch decision support tool Sanscrit. In Wallonia, biomonitoring is becoming more common, especially in response to societal and political pressures. Here an action protocol of measures is being developed to structure its use. In Flanders, biomonitoring is sometimes initiated when there is a widespread contaminated area

[13]There are also screening trigger values for drinking water and deposited indoor dust.
[14]Screening, care and monitoring of people potentially overexposed to inorganic arsenic due to their place of residence, https://www.has-sante.fr/upload/docs/application/pdf/2020-03/reco_arsenic.pdf
[15]Screening, care and monitoring of people potentially overexposed to inorganic arsenic due to their place of residence, https://www.has-sante.fr/upload/docs/application/pdf/2024-09/cadmium_recommandation_mel.pdf

with large population. Flanders is also exploring how HBM data can support development of soil threshold values for human health.

In the UK, biomonitoring is rarely used in this context but could be initiated by the risk assessor. In Sweden, biomonitoring is briefly mentioned as a possible tool in guidance documents but in practice it is only used in special cases, often as part of research studies.

What background values for concentration in biological matrices are used?

Wallonia, Flanders and France have national values for background concentrations in biological matrices from population studies (in France, values for As, Pb, Cd and some other compounds via ESTEBAN national biomonitoring program studies). In the UK, studies exist, but biomonitoring is not commonly used in this context, and there are no official national background concentrations. In Sweden, there are national measurements compiled from various ongoing studies since the 1970s, but no official national background levels for the general population. The Netherlands has not adopted specific background concentrations of metals in blood based on national data.

What are the challenges and considerations related to biomonitoring?

Human biomonitoring programs may be considered politically sensitive. Representatives of the countries surveyed have observed that they can cause social unrest and worry. On the other hand, social unrest and worry can also be a trigger to initiate human biomonitoring. Human biomonitoring is also sensitive as it entails handling of personal data. This may impact the possibility to share data between different projects and/or researchers and risk assessors.

For substances where the background exposure is high, the relative contribution from contaminated soil may be difficult to identify. If background exposure decreases, the relative contribution from contaminated soil will increase making it easier to identify. To statistically validate a small increase in blood levels a large study population is needed.

Human biomonitoring programs are expensive, especially when a large study population is required. In practice, HHRA for contaminated soil is often performed for sites or projects of limited geographical distribution. This means that finding a large study population exposed to contaminated soil from the (limited) area in question, may not even be theoretically possible. In addition, people are not always willing to participate in human biomonitoring studies. Participation rates has been a problem in some screening campaigns in e.g. France, as it not only limits the number of participants but also causes the study population to be biased. People who worry more about contamination may be more prone to participate and may also behave in a more conscious way with regards to the contaminated soil. Willingness to participate may vary between countries.

Another challenge related to the interpretation of results from HBM studies compared to investigations focused on contaminated soil is that people are very mobile, and behavior vary between individuals both in short term and in long term. For example, in the short term, individuals may visit the area under study more or less frequently and may behave differently while there. In the longer term, individuals may move resulting in significant variations in their residential time at the studied area. Furthermore, it is crucial to acknowledge that other behaviors may influence contaminant exposure from sources other than the contaminated soil under study. It is imperative that these factors are given due consideration during the interpretation of results from human biomonitoring studies.

Appendix 1. The *EXPOSED?* project

The project *EXPOSED?* is funded by a research grant from the Swedish environmental protection agency via the call for research proposals "Giftfria kretslopp" (Toxic-Free Cycles).

The project is led by the Swedish Geotechnical institute (SGI) and project partners are AMM (Occupational and Environmental Medicine) at the Academic Hospital, Uppsala University, ISSeP (The Scientific Institute of Public Service) in Wallonia, Belgium, and JUNIA, part of LGCgE, Laboratoire de Génie Civil et géo-Environnement, in France.

Website (during the project period): https://www.sgi.se/en/research-and-development/research-and-development-projects/forskning-renare-mark/exposed-risks-of-living-in-a-contaminated-area

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Appendix 2. HHRA models in some different countries

The various tools for health risk assessment mentioned in the text about HHRA are presented here briefly with links to where more information can be found.

The CSOIL model, Netherlands

The CSOIL was first launched in 1991 and since then several times updated. It is an exposure model that includes 12 different exposure pathways and a database for circa 130 pollutants. Basically, the model has three different parts: the calculation of the distribution of pollutants over the three soil phases; transfer to contact media and exposure calculations. Since the toxicological reference values are also included in CSOIL, the model enables the calculation of human health-based risk limits (or soil screening values) and to perform site-specific risk assessments.

More information:

CSOIL 2020: Exposure model for human health risk assessment through contaminated soil. Technical description RIVM letter report 2020-0165. https://www.rivm.nl/bibliotheek/rapporten/2020-0165.pdf

Responsible institution:

The National Institute of Public Health and the Environment (RIVM) https://www.rivm.nl/

The CLEA model, United Kingdom

The CLEA model (Contaminated Land Exposure Assessment) Model and CLEA software have been developed by the Environment Agency and DEFRA (the Government Department responsible for UK land contamination policy). The software is used to develop assessment criteria for many contaminants including metals and organic contaminants. With time contaminants such as halogenated organics and PFAS have been added. CLEA does not allow assessment of water contamination to be made – however there are numerous models available for this purpose. The Environment Agency has developed fact sheets available on their web site explaining the various models available.

More information:

Available for download from the UK Environment Agency Web Site:
https://www.gov.uk/government/publications/contaminated-land-exposure-assessment-clea-tool
(Only works on PC computers using the MS Windows operating system. There are currently no plans to make the software available for Apple Macintosh computers or any other PC operating systems.)

Responsible institution:

UK environment agency, http://www.environment-agency.gov.uk

The S-risk model, Wallonia and Flanders

S-Risk© has been put forward as the standard model for use in sustainable soil management in Flanders, Brussels, and Wallonia. Two regional versions of S-Risk© are available from April 2017, one following the Flemish and Brussels regulatory context and one following the Walloon regulatory context.

S-Risk© allow users to modify built-in land use scenarios. The model calculates concentrations of contaminants in the surrounding air (both indoor and outdoor) due to volatilization and soil resuspension, in drinking water through leaching or permeation, and in food through plant and animal uptake. Exposure predictions are made for inhalation (ambient, indoor, and bathroom air), oral (water, food, soil, and dust), and dermal (water, soil, and dust) routes across different age groups, ranging from children to adults.

To assess risk, the model compares exposure levels with toxicological reference values and concentrations with toxicological or legal reference concentrations. Users have flexibility in determining critical ages and performing simultaneous runs for local, systemic, threshold, and non-threshold effects.

More information:

Model website S-Risk: https://www.s-risk.be/

Flanders substance data sheet for lead and arsenic: S-Risk substance data sheets – Part 1: metals and arsenic, https://www.s-risk.be/documents/VL-metals-en.pdf

Wallonian substance data sheet for lead and arsenic: S-Risk for the Walloon region - substance data sheets part 1: metals and arsenic, https://www.s-risk.be/documents/Metals-S-Risk_WAL.pdf

Responsible institution:

SPAQuE, https://spaque.be/

The MODULER'S tool, France

MODUL'ERS is a software for conducting protective health risk assessments as part of the analysis of the health effects of Classified Environmental Facilities (ICPE) and for conducting Residual Risk Analyses (ARR) of polluted sites and soils. By simulations with MODUL'ERS concentrations, exposures and health risks can be assessed.

MODUL'ERS consists of a modeling and simulation platform and a library of modules, and allows the user to build, adapted multimedia models based on the conceptual diagram of the site under study by arranging the predefined modules from the library. The user can analyze uncertainties and conduct deterministic, probabilistic simulations and sensitivity analyses on the results. Its flexibility allows it to be used in situations ranging from the simplest to the most complex.

Information on how the input data proposed by default in MODUL'ERS were chosen are provided in reports (defining data sources consulted, assumptions and choices made). Thereby users can decide if the values are suitable for their case study, and if not, the aim is also to help users complete the work of defining input data, based on the bibliographic research and analysis already carried out.

More information:

Website: https://www.ineris.fr/fr/recherche-appui/risques-chroniques/logiciel-modulers

General information about MODU'ERS and reports about the software and parameters used are available on this website. However, the software itself is not available for download on the website, it is obtained during the training number RC41 given by Ineris.

Responsible institution:

Ineris, Institut National de l'Environnement Industriel et des Risques, https://www.ineris.fr

The "Swedish EPA model", Sweden

Sweden has an excel calculation tool (Beräkningsverktyg or Beräkningsmodell) to calculate guideline values for contaminated soils. The tool calculates SGVs for two scenarios, sensitive landuse (känslig markanvändning, KM) which is mainly used for residential areas and less sensitive landuse (mindre känslig markanvändning, MKM) which is used for commercial areas. Several exposure routes for human exposure are included as well as a value for protection of the soil ecosystem. The Swedish generic guideline values are calculated with this tool, except for the KM lead value, which is a policy decision. Many parameters in the tool can be adjusted and it can be used to calculate site specific guideline values.

If guideline values fall below national background concentrations, they are adjusted to the background concentration (e.g. for arsenic).

More information:

Swedish EPA website about soil guideline values for contaminated soils (Riktvärden för förorenad mark): https://www.naturvardsverket.se/vagledning-och-stod/fororenade-omraden/riktvarden-for-fororenad-mark/

Link to calculation tool (Beräkningsmodell): https://www.naturvardsverket.se/498c56/contentassets/680d20b5c13d44a39521ba6597e7f3fb/version-2-2-nv-berakningsprogram-rv-mark-2023-02-22.xlsm

Link to report about SGVs for contaminated soil: Riktvärden för förorenad mark - Modellbeskrivning och vägledning: https://www.naturvardsverket.se/publikationer/5900/riktvarden-for-fororenad-mark/

Responsible institution:

Naturvårdsverket (NV), the Swedish environmental protection agency, https://www.naturvardsverket.se/

The Sanisol web-tool, Wallonia

A web-tool developed to give recommendations to gardeners in Wallonia regarding fruits and vegetables grown in gardens in or close to polluted areas. Sanisol helps the gardener assess the risks associated with consuming fruits and vegetables grown in their gardens based on metal concentrations in the garden soil, i.e. the specific soil must be analyzed to use the tool. The assessment consists of two parts:

Part 1: Assessment of health risks associated with gardening and the consumption of fruits and vegetables. The user's overall exposure to metals contained in their vegetable garden soil is assessed, particularly through the following main exposure routes:

- ingestion of soil particles and dust (hand-to-mouth contact)
- consumption of fruits and vegetables grown in the vegetable garden.

Part 2: Assessment of the quality of fruits and vegetables produced in my vegetable garden. The metal levels (estimated or measured) in fruits and vegetables produced in the vegetable garden are compared with:

- average levels found commercially in Belgium (Europe)
- maximum levels based on European marketing regulations.

More information:

Sanisol website: https://sanisol.wallonie.be/

The Gezond uit eigen grond tool, Flanders

Information and advice, including a web-tool, to help people assess if their soil is suitable for gardening.

More information:

Website: https://omgeving.vlaanderen.be/nl/klimaat-en-milieu/gezonde-veilige-en-aantrekkelijke-leefomgeving/gezond-uit-eigen-grond