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Environmental Decision Support Systems

-Truth or Dare!-

Quantitative Risk Assessment in Spain

by Jordi Boronat



MediTerra
consultors ambientals, s.l.

Sant Maximià, 2 - E-17300 Blanes (GIRONA)

Tel: [+34] 972 35 85 36 Fax: [+34] 972 35 85 37
mediterr@mediterr.es · www.mediterra.es



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- The Quantitative Risk Assessment as key tool in the Spanish Soil Policy
- Challenges for the development of Soil Policy in Spain

Soil policy framework

- Law 10/1998 of 21 April on Waste
- Royal Decree 9/2005, which establishes a list of potentially soil polluting activities and the criteria and standards to declare a soil as contaminated
- Technical Guideline for implementation of RD 9/2005
- Law 26/2007 on Environmental Liability

Soil policy framework

- Regional level: Basque Country, Madrid, Canary Islands, Andalucía, Galicia, etc (Catalonia has a draft for a Decree on Soil Contamination)
- Spanish Soil Policy includes the main issues of the Soil Protection Framework Directive
- Groundwater contamination is not developed in this RD

Risk assessment: key factor in DMP

Numerous decisions have to be made before, during and after conducting a quantitative risk assessment.



The importance of site characterization

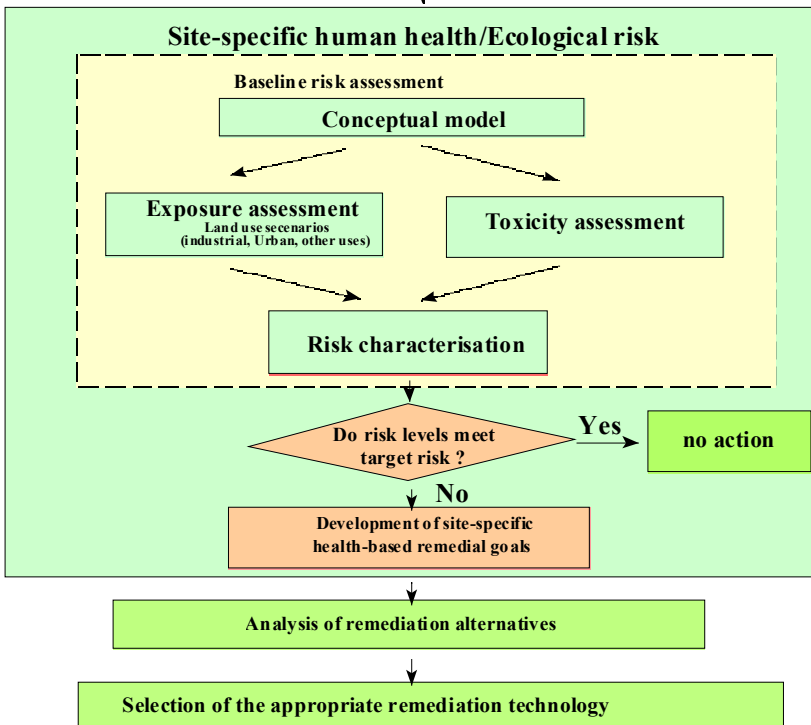
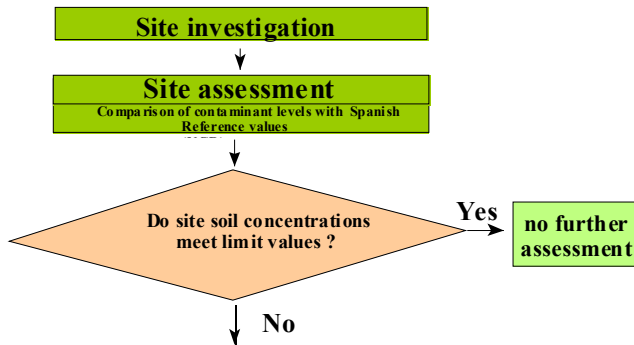
Risk assessment is based on the information gathered previously:

- Historical information (Phase I)
- Site investigation (Phase II)
- Toxicological information
- Characterization of receptors (definition of present and future uses)
- Definition of a conceptual site model

The use of the results

- The results of the risk assessment will be the basis for taking decisions for developing **remediation activities**
- Output has to be in a form that allows authorities and other stakeholders (owners, site users, neighbours, investors, etc) to **easily take decisions**
- Importance of a robust **Conceptual Model** and a **detailed sensibility analysis** of the data used in the Risk Assessment.
- Proper scientific **expertise** is required both for characterization of input parameters and for the assessment of model results.

When to perform a risk assessment in Spain?



Follows US EPA site-specific risk assessment procedures

Non-carcinogenic effects - Hazard Quotient
 $HQ = CDI/RfD$

Carcinogenic effects
 $Cancer Risk = CDI \times CSF$

$$\sum HQ \leq 1$$
$$\sum \text{Cancer risk} \leq 10^{-5}$$

Generic Reference Levels (NGR)

- Royal Decree includes Generic Reference Levels for 60 **organic compounds**
- **Human health** levels have been classified according to the **use of the soil** (Industrial, Urban and Other uses)
- **The ecosystem protection** values have been derived for **soil organisms, aquatic organisms and terrestrial vertebrates**
- **Metal** trigger values have to be developed by the Autonomous Communities.
- If **no reference values exist**, they have to be developed project by project

When to perform a risk assessment in Spain?

- Soil concentrations of oil hydrocarbons (**TPH**) higher than 50 mg/kg
- Analytical evidence that the concentration of any of the substances listed in **Annex V** of Royal Decree exceeds the generic reference level (Trigger Value) for the current or future use
- Analytical evidence that the concentration of any chemical contaminant not listed in Annex V of Royal Decree is higher than the **generic reference level calculated** in accordance with the criteria established in Annex VII.

When to perform an Ecological risk assessment?

- Where the concentration of any of the substances listed in Annex VI of RD exceeds the generic reference level for the group of organisms to be protected
- Analytical evidence that the concentration of any chemical contaminant not listed in Annex VI of RD is higher than the **generic reference level calculated** in accordance with the criteria established in Annex VII of the RD.
- Where **toxicity is demonstrated** based on any of the biotests referred to in Annex III.2 of RD, carried out using soil or leachate in undiluted samples.
- The competent body of the autonomous community shall determine when the protection of the ecosystem is needed

Soil contamination declaration

- After carrying out a risk assessment, the owner of the activity or property shall inform the competent body of the autonomous community
- A site shall be declared contaminated by the regional authorities when an unacceptable risks with regard to the protection of human health or ecosystems is identified.

Soil contamination declaration

The site can also be declared contaminated when:

- The concentration of any of the substances listed in Annex I of RD exceeds **100 times** the established generic reference level for the protection of human health in accordance with land use.
- The concentration of any contaminant not included in Annex V of RD exceeds **100 times** the generic reference level calculated in accordance with the criteria established in Annex VII of RD.

Soil contamination declaration

If the protection of ecosystems is the main priority the site can be declared contaminated when:

- The lethal or effective median concentration, L(E)C50, for **soil organisms** obtained in toxicity tests is lower than 10 mg of contaminated soil/gram of soil.
- The lethal or effective median concentration, L(E)C50, for **aquatic organisms** obtained in toxicity tests is lower than 10 ml of leachate/litre of water.

What is required for a Risk Assessment in Spain

A detailed description of the **sources** of contamination

- A characterization of the **geological** properties and components of the soil
- A description of the **physical environment** (pathways including groundwater)
- Identification and characterization of **potential receptors** and their level of exposure to contamination
- If no data is available, the parameters used for calculating the Reference values in the RD can be used

What is required for a Risk Assessment in Spain

- Identification of potential **exposure pathways**. The exposure pathways initially considered shall be those indicated in **Annex VII**. However, possible pathways may be added or eliminated
- Quantification of the **exposure dose** received via each pathway. For the quantification of exposure dose, the calculations used to develop reference levels or similar recognized methods may be used.

Exposure pathways

At minimum, the following exposure pathways shall be considered:

Exposure pathway	Land use scenario		
	Industrial	Urban	Other uses
Soil Vapour Inhalation	√	√	√
Inhalation of soil particles	√	√	√
Soil Ingestion	√	√	√
Dermal contact		√	√
Ingestion of contaminated food			√

Some Exposure Factors

This factors are not completed and may vary from one region to another.

Description	Unit	Industrial	Urban	Other
Body Weight	kg	70	15/70	70
Exposure Duration	years	25	6/30	30
Exposure Frequency	days/yr	250	350	350
Exposure Averaging Time	yr	25/75	6/30/70	30/70
Ingestion Rate for soil	mg/day	50	200	450
Target Hazard Quotient	unitless	1	1	1
Target Risk for carcinogens	unitless	1,00E-05	1,00E-05	1,00E-05

How to perform a Risk Assessment in Spain

- A **toxicity value** for each contaminant identified
- A **quantification of risk**. In cases where contaminants that have the same action mechanism, the **combined risk** shall be considered
- An **analysis of the uncertainties** associated with the risk assessment must be performed.

Main challenges in application of quantitative risk assessment in Spain

Risk assessment is a relatively **new issue** in Spain

- Many decisions are still in the hands of the **Autonomous Communities**. The degree of details on how the risk assessment has to be performed shall be established by the competent body of the autonomous community
- Only a few of the 17 Autonomous (Basque Country, Catalonia, Madrid and Andalucía) have published their own **Generic Reference Values for metals**
- Input data (exposure factors, toxicological data, etc) for developing a risk assessment are also very **heterogeneous** from one region to another

Main challenges in application of quantitative risk assessment in Spain

- **Human resources** in the Autonomous Communities are very limited
- Furthermore, **experience** in risk assessment application is limited both in the regional authorities and in part of the consultancy sector
- The **accreditation process** is very time consuming and economically costly and it would be preferable for all the autonomous communities in Spain to use a homogenous accreditation process.

The use of a Risk Assessment Software

The development of an **unified adapted software** would facilitate the application of risk methodology for the users (consultancy firms) and for the valuers (authorities)

- Tool for the **storage and management of data**
- Increase of **confidence** in calculations
- Improvement of accuracy analysis of input values in relation with the outputs of the program (**sensibility analysis**)

A unified tool in Spain will reduce the risk of non expert users or reviewers accepting outputs as the real truth, without knowing the functioning of the software and the assumptions and parameters that are the most sensitive.

The use of a Risk Assessment Software

- The outputs of the risk assessment have to be in a form that **facilitates** the authorities and other stakeholders (owners, site users, neighbours, banks, etc) in the process of decision making.

If the decision making process is a challenge to soil contamination in Spain, when we deal with **groundwater** it becomes more critical due to the lack of regulations and the fact that soil and groundwater issues are dealt with by different authorities inside each autonomous community.

Necessity of harmonization?

- Only few of the autonomous communities are dedicating resources for the development of the Royal Decree
- Harmonization would be especially helpful for the development of reference values for **metals**, development of a risk assessment **software tool**, definition of the **accreditation process**, etc.
- Risk assessment in the hands of the promoter and/or inexperienced people could be critical, especially if we consider that some regions do not have enough technical capacity to evaluate them.

The Ultimate Dare
is to tell the Truth.



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*Muchas
Gracias!!!*



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