

## Quantitative Risk Assessment in Spain

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### 1 Introduction

Environmental Quantitative Risk Assessment is one of the key factors in the Decision Making Process for contaminated sites. Numerous decisions have to be made before, during and after conducting a quantitative risk assessment.

Risk assessment is based on the information gathered previously:

- Historical information (Phase I)
- Site characterization (Phase II)
- Toxicological information
- Characterization of receptors (definition of present and future uses)
- Conceptual site model

The more information there is in the investigation phases, the fewer uncertainties there are in the decision making process. Reliable results require proper characterization of site-specific input parameters.

During site risk assessments many decisions have to be made that will influence the output of the assessment. In order to facilitate the decision making process, it is important to have data transparency during the process that documents and justifies all the inputs used in the risk assessment.

The results of the risk assessment will be the basis for making decisions for developing remediation activities. Output has to be in a form that allows authorities and other stakeholders (owners, site users, neighbours, banks, etc) to easily take the last decision.

Proper scientific expertise is required both for characterization of input parameters and for the assessment of model results.

### 2 Soil Framework Policy in Spain

Until Law 10/1998 of 21 April on Waste, Spain has had no legal rules for the protection of soil against contamination. However, this Waste Law was incomplete and it was of high importance to have a more defined regime.

On January 14th 2005, when the Royal Decree 9/2005 which establishes a list of potentially soil polluting activities and the criteria and standards to declare a soil as contaminated was approved. The current legal regulations establish a number of phases in which the parties involved will have to comply with a number of procedures and legal requirements:

- Information to the competent authorities.
- Declaration of a soil as contaminated. Based upon the information received, a soil will be declared as contaminated, according to the criteria and standards set on the rule (Generic Reference Values and Environmental Risk Assessment).
- Obligation to remediate a contaminated soil.
- Publicity of soil contamination situations.

### **3 When to perform a risk assessment in Spain?**

According to the Royal Decree 9/2008, sites that meet any of the following conditions shall be subject to a Risk Assessment:

- a. Where sites present soil concentrations of oil hydrocarbons higher than 50 mg/kg.
- b. Where there is analytical evidence that the concentration of any of the substances listed in Annex V of Royal Decree exceeds the generic reference level for the current or anticipated use for the site.
- c. Where there is analytical evidence that the concentration of any chemical contaminant not listed in Annex V of Royal Decree is higher than the generic reference level estimated in accordance with the criteria established in Annex VII.

In those cases in which the main priority is the protection of an ecosystem, a ecological risk assessment will be compulsory if any of the following conditions applies:

- a. Where the concentration of any of the substances listed in Annex VI of RD exceeds the generic reference level established therein for the group of organisms to be protected in each case: soil organisms, aquatic organisms or terrestrial vertebrates.
- b. Where there is analytical evidence that the concentration of any chemical contaminant not listed in Annex VI of RD is higher than the generic reference level estimated in accordance with the criteria established in Annex VII of the RD.
- c. 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 delimit sites where the protection of the ecosystem of which they form part is regarded as the main priority. In each case of this type, the competent body shall determine which group or groups of organisms are to be protected. Normally corresponds to Nature Protected Areas.

After carrying out a risk assessment, the owner of the activity or property shall inform the competent body of the autonomous community with a view to facilitating a decision regarding whether or not the site is contaminated.

#### **4 Soil contamination declaration**

A site shall be declared contaminated when it is determined that there are unacceptable risks with regard to the protection of human health or, as may be the case, ecosystems due to the presence of any of the contaminants listed in Annexes V and VI of RD or of any other chemical contaminants.

When a corresponding risk assessment is not available, the competent bodies of autonomous communities may assume that the level of risk is unacceptable and, consequently, declare a site contaminated when any of the following circumstances holds true:

1. In cases in which the protection of human health is regarded as the main priority:
  - a) When the concentration in soil 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.
  - b) When the concentration in soil at the site of any chemical 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.
2. In cases in which the protection of ecosystems is regarded as the main priority:
  - a) When the lethal or effective median concentration, L(E)C50, for soil organisms obtained in toxicity tests OECD 208 (Test of Seedling Emergence and Growth of Terrestrial Plants), OECD 207 (Acute Earthworm Toxicity Test), OECD 216 (Soil Micro-organisms: Nitrogen Transformation Test), OECD 217 (Soil Micro-organisms: Carbon Transformation Test), or such tests as may be regarded as equivalent for assessment purposes by the Minister of the Environment, is lower than 10 mg of contaminated soil/gram of soil.
  - b) When the lethal or effective median concentration, L(E)C50, for aquatic organisms obtained in toxicity tests OECD 201 (Algal Growth Inhibition Test), OECD 202 (Daphnia Magna Immobilization Test), OECD 203 (Fish – Acute Toxicity Test), or such tests as may be regarded as equivalent for assessment purposes by the Minister of the Environment, carried out with leachates obtained using the standard DIN-38414 method, is lower than 10 ml of leachate/litre of water.

#### **5 How to perform a Risk Assessment in Spain**

The Royal Decree states that without prejudice to any subsequent development of requirements by the autonomous communities, the elements that shall be included in assessment of the risks associated with contaminated sites, or sites where any of the circumstances described in Annex IV of the RD holds true, are as follows:

1. A detailed description of the focal points of contamination, identifying the contaminating substance(s) and determining significant concentration values (maximum measured, p95 or another duly justified statistic).
2. A characterization of the textural properties and components of the soil
3. A description of the immediate physical environment for the purpose of identifying mechanisms that may transfer contaminants from focal points to potential receptors and relevant contamination exposure pathways for such receptors, including groundwater.
4. Identification of potential receptors of contamination and an assessment of the characteristics or habits that determine their level of exposure to contamination

In the absence of other information concerning such characteristics or habits, this assessment may make use of the parameters utilized to define reference levels. The existence at the site in question or in adjacent areas of relevant ecological receptors shall also be taken into account.

5. Identification of foreseeable exposure pathways and quantification of the exposure dose received via each. The exposure pathways initially considered shall be those indicated in Annex VII. However, possible pathways may be added or eliminated based on the expert opinion of the technicians responsible for carrying out an assessment, subject to previous consultation with the autonomous community official in charge. For the quantification of exposure dose, the expressions used to develop reference levels or similar methods deemed appropriate by the autonomous community officials in charge may be employed.

At minimum, the following exposure pathways shall be considered:

- a) Industrial land use: inhalation of soil vapours, inhalation of contaminated soil particles, and ingestion of contaminated soil.
- b) Urban land use: inhalation of soil vapours, inhalation of contaminated soil particles, ingestion of contaminated soil, and dermal contact with soil.
- c) Other land uses: inhalation of soil vapours, inhalation of contaminated soil particles, ingestion of contaminated soil, ingestion of contaminated food products, and dermal contact with soil.

6. A toxicity value and justification of its choice for each of the relevant contaminants identified
7. A quantification of risk. In cases where contaminants with the same action mechanism are found together at a single site, the combined risk that they pose shall be considered.
8. An analysis of the uncertainties associated with the risk assessment carried out, including appropriate conclusions regarding the validity and reliability of the results of the assessment.

The degree of detail with which these points are to be covered shall be established by the competent body of the autonomous community in question, based on reasonable criteria and taking into account the specific circumstances that apply in each case

## **6 Criteria for calculating generic reference levels**

### **6.1 *Criteria for calculating generic reference levels for the protection of human health. Such calculations shall be carried out by applying the following methodology described in the Royal Decree 9/2005:***

Determination of toxicological threshold values based on land use:

1. Relevant exposure pathways shall be identified and defined.
2. The characteristics of the type of individual whom it may reasonably be assumed is subject to the highest level of exposure shall be defined, and the dose to which such an individual is exposed shall be determined for each exposure pathway considered. Levels of exposure shall be determined using models developed by well-recognized technical, scientific or academic institutions, such as the European Commission's Joint Research Centre, the US Environmental Protection Agency, or similar bodies.
3. The maximum admissible soil concentration for particular substances shall be calculated based on the following considerations:
  - a. For substances with carcinogenic effects (genotoxic) the maximum admissible soil concentration shall be that associated with an increased risk of occurrence of cancer no greater than 10<sup>-5</sup>.
  - b. For a substance with systemic effects, the maximum admissible level shall be that verified based on the ratio applicable, in accordance with its chemical nature, between the long-term exposure dose due to soil contamination and the maximum acceptable dose:

0.05 for plant protection products

0.2 for organochloride compounds

0.05 for polycyclic aromatic hydrocarbons

0.1 for monocyclic aromatic hydrocarbons

A criterion of contiguity shall be applied, resulting in the reduction, where necessary, of levels for urban and industrial land use. According to this criterion, the reference level for urban land use may not be more than 10 times higher than the reference level for other land uses, and the reference level for industrial land use may not be more than 10 times higher than the reference level for urban land use.

For synthetic substances, a reduction criterion may be applied, consisting in the adoption of a generic reference level of 100 mg/kg in cases where the calculated value exceeds this level.

## **6.2 Criteria for calculating generic reference levels for the protection of ecosystems: Such calculations shall be carried out by applying the following methodology:**

Determination of toxicological threshold values.

At minimum, toxicity tests shall include information concerning the following groups of organisms:

- a. Soil organisms: plants, invertebrates, soil micro-organisms
- b. Aquatic organisms: fish, Daphnia species, unicellular algae
- c. Terrestrial vertebrates: birds and mammals

Validly obtained toxicological data shall be used, whenever possible based on tests carried out using protocols standardized by the European Union (EU) or the Organization for Economic Cooperation and Development (OECD). When other tests are used, a justification of their validity shall be required.

In the case of substances for which the EU has published risk analyses, the "probable no-effect concentrations" (PNEC) established therein shall be used, except in those cases in which more recent toxicological studies are available.

The generic reference level for each selected contaminant shall be determined in relation to the protected group or groups of organisms in each case: soil organisms, aquatic organisms and populations of terrestrial vertebrates. Concentrations shall be determined using the following procedures:

- a. For soil organisms: the maximum concentration of the contaminant in soil shall be equal to the "probable no-effect concentration" (PNEC) for soil organisms, as calculated in accordance with EU recommendations.
- b. For aquatic organisms: the maximum concentration of the contaminant in soil shall be that which, in conditions of equilibrium and for standardized European conditions, gives rise to a concentration of the contaminant in porewater that is equivalent to the "probable no-effect concentration" (PNEC) for aquatic organisms, calculated in accordance with EU recommendations.
- c. For terrestrial vertebrates: the maximum concentration of the contaminant in soil shall be that which, in conditions of equilibrium and for standardized European conditions, gives rise to a concentration of the contaminant in plants or soil invertebrates that is equivalent to the "probable no-effect concentration" (PNEC) for terrestrial vertebrates, calculated in accordance with EU recommendations. The described procedures shall be applied, but including processes of biomagnification through the food chain.

Assessment of potential bioaccumulation/biomagnification shall be based on the results of field studies and on monitoring of concentrations in plants, invertebrates

and vertebrates. When such information is not available, one of the models for estimating biomagnification developed by well-recognized technical, scientific or academic institutions shall be used.

B) For synthetic substances, a reduction criterion may be applied, consisting in the adoption of a generic reference level of 100 mg/kg in cases where the calculated value exceeds this level.

### **6.3 Generic reference levels for metals.**

In cases where for technical or other reasons is not feasible to apply the methodology described in Sections 1 and 2 above, autonomous communities that have not established generic reference levels for metals may adopt those which obtained by adding to the average concentration twice the typical deviation of concentrations existing in soils in nearby areas that are not contaminated and have geological substrates with similar characteristics. For the purposes of assessing soil contamination, the values calculated in this manner for metals shall constitute a single set, and, therefore, shall apply for any land use and be valid for both the protection of human health and of ecosystems.

## **7 Main challenges in application of quantitative risk assessment in Spain**

Risk assessment is a relatively new issue in Spain; no common framework was established before Royal Decree 9/2005 entered into force. Although this Royal Decree is defining Guidelines for developing Risk Assessment, many decisions are still in the hands of the Autonomous Communities such as the establishment of threshold values (Generic reference values) for metals or the delimitation of sites where ecological risk assessment is necessary. Only a few of the 17 Autonomous (Basque Country, Catalonia, Madrid and Andalucía) have published their own metals Generic Reference Values. The degree of details on how the risk assessment has to be performed shall be established by the competent body of the autonomous community.

Input data for developing a risk assessment are also very heterogeneous from one region to another. For example, there is different use of toxicological data, exposure factors (exposure duration, exposure frequency, dermal exposure, skin surface, soil-dermal adherence factor), transport modelling options, etc. from one region to another, and few autonomous communities have published such data.

Human resources in the Autonomous Communities are very limited compared with the amount of projects that are awaiting resolution. Furthermore, experience in risk assessment application is limited both by the regional authorities and in the consultancy sector due to the short period that this Royal Decree has been in force.

In order to partially solve these deficiencies, some regions are working according to accreditation processes. The Basque Country has published a Decree defining the accreditation process for companies that want to perform soil investigations, risk assessments and remediation works in that region. Other regions are working in the same direction, as is the Ministry of Environment. 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 Basque Country is the only region that has been working towards creating software for implementing risk assessment similar to that developed in countries like Italy, the Netherlands or Denmark. In the case of Spain, this type of adapted software would facilitate the application of risk methodology for the users (consultancy firms) and for the valuers (authorities). Furthermore, these types of tools are good for the storage and management of data and for increasing confidence in calculations.

The use of risk assessment software is also helpful for developing an accurate analysis of the input values assessing the different alternatives for the input parameters in relation with the outputs of the program.

Moreover, the use of an 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 outputs of the application of a 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.

Due to the different degrees of time and effort which each autonomous community is dedicating to the development of the Royal Decree, harmonization for the application and development of Royal Decree 9/2005 within the different regions in Spain is needed. Such harmonization would be especially helpful for some key aspects such as the development of reference values for metals, development of a risk assessment software tool, definition of the accreditation process, etc.