

## MINISTRY OF THE PRESIDENCY

**895** *ROYAL DECREE 9/2005 of 14 January which establishes a list of potentially soil contaminating activities and criteria and standards for declaring that sites are contaminated.*

Soil is one of the most sensitive and vulnerable receptors of contamination. The importance of protecting soil and its potential uses within the context of sustainable development, particularly from human actions and activities, was recognized as early as 1992 at the Rio Summit. Within the framework of the European Union, the European Parliament's mandate to the Commission to develop a thematic strategy for soil protection (work on which was initiated during the six-month period of the Spanish Presidency in 2002) stresses the same point: the need to adopt measures that prevent, limit or reduce the impact of human activities on soil.

In 1999, the European Environment Agency (EEA) estimated the number of contaminated sites in Western Europe at between 300,000 and 1,500,000. These figures, in themselves indicative of the seriousness of the problem, also point to the serious ecological and legal consequences that result from an absence of standardized methodologies for identifying and characterizing contaminated soils. Indeed, the extent of the difference between the two figures is due precisely to a lack of uniformity in the criteria used in different countries for defining contaminated sites, quantifying acceptable risks and adopting instruments and characterization methodologies.

Despite the clear ecological vulnerability of soils, legislation in Europe and Spain has not provided adequate legal instruments to promote its protection. Prior to the enactment of the Spanish Wastes Law 10/1998 of April 21 there were no legal regulations in place to ensure that soils were effectively protected from contamination or to allow for the identification and characterization of already contaminated sites based on a standardized and technically rigorous methodology.

The absence of an effective legal framework has clearly placed limits on the implementation of the National Plan for Soil Remediation (1995-2005), in which 4532 potentially contaminated sites were inventoried. In view of accumulated experience and the situation with respect to this problem in other countries, it is likely that the number of sites in Spain that have been degraded by human activity is even higher. In order to facilitate the correct characterization of sites (as a starting point for future inventories of contaminated sites in Spain's autonomous communities and at a national level), it is essential to have in place standardized criteria for the assessment

of contamination, such as those established in this royal decree.

Articles 27 and 28 of the Wastes Law 10/1998 of April 21 govern the environmental aspects of contaminated soils and provide that the Spanish Government, following consultation with the governments of the autonomous communities, shall determine the criteria and standards to be applied in assessing risks to human health and the environment, while taking into account the nature of soils and the uses to which they are put. Applying these criteria and standards, the autonomous communities shall declare, delimit and make an inventory of existing contaminated sites within their territories, and shall establish a list of action priorities based on the level of risk to human health and the environment in each case.

The Wastes Law 10/1998 includes a mandate instructing the Spanish Government to approve and publish a list of potentially soil-contaminating activities, and establishes specific obligations that apply to the owners of activities and of properties where the specified activities are carried out or have been in the past.

This royal decree fulfils the provisions of the Wastes Law 10/1998 of 21 April, subject to prior consultation with the autonomous communities. The royal decree gives greater specification to the definition of contaminated soil in Article 3.p) of the Law and makes reference to the presence of dangerous chemical substances of human origin that are capable of altering the chemical, physical or biological characteristics of soil, and which therefore constitute a risk that must be quantified in order to assess possible harm that may result to human health and the environment. Sites shall be declared contaminated by express decision if, in accordance with the standards set out in this royal decree, said risk is deemed unacceptable for human health and the environment.

Annex 1 of this royal decree sets out a list of activities that may cause soil contamination, and Annexes III, IV, V, VI, VII and VIII present the criteria and standards to be applied in determining whether or not a site is contaminated, including the technical requirements that must be taken into account. This decree also regulates the form and content of the preliminary situation report that owners of potentially contaminating activities or of property where such activities have been carried out in the past must present to the autonomous communities. Annex II outlines the minimum information that must be included in such reports.

Generic reference levels are also regulated by this decree. These levels are the basic parameter that shall be used for assessing soil contamination for specific substances. Substances that represent a threat to human health are grouped together in Annex V, and those that pose threat to ecosystems in Annex

VI. Annex VII specifies the criteria for calculating reference levels for substances not included in Annexes V and VI, and for assessing contamination by metals.

In addition, the form in which a site shall be declared decontaminated following environmental remediation work on soil is defined. The scope and performance of remediation actions shall be such as to guarantee that any remaining contamination translates into acceptable risk levels in relation to current land use and anticipated future uses.

The general criterion for determining the level of soil contamination and for identifying possible environmental mediation measures for sites that have been declared contaminated involves assessing environmental risks linked to the existence of contaminants in soils. In line with the provisions of Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risk to man and the environment of existing substances in accordance with Council Regulations (EEC) No 793/93, Annex VIII indicates the points that must be covered in risk assessments.

Finally, the provisions of the Wastes Law 10/1998 of 21 April are developed with respect to the manner in which a record is to be created in the Land Register of administrative rulings concerning the declaration of contaminated sites, and of declarations made by property owners carrying out potentially contaminating activities, giving effect to the legal provision by specifying the formal title by virtue of which a marginal note is to be recorded, its content, effects, duration and corresponding requirements for cancellation.

By virtue of their jurisdictional authority and at the proposal of the Minister of the Environment and the Minister of Health and Consumer Affairs, with the agreement of the Council of State, and subject to prior deliberation by the Council of Ministers in a meeting held on 14 January 2005,

## I HEREBY DECREE:

### Article 1. *Purpose*

The purpose of this royal decree is to establish a list of activities that may cause soil contamination, and to adopt criteria and standards for declaring that sites are contaminated.

### Article 2. *Definitions*

The following definitions shall apply for the purposes of this royal decree:

a) Soil: the upper layer of the earth's crust, situated between underlying bedrock and the surface, composed of mineral particles, organic material, water, air and living organisms, and constituting the interface

between earth, air and water, as a result of which it has the capacity to perform natural functions and serve for human use. This definition shall not apply to surfaces permanently covered by water.

b) Industrial land use: that whose main purpose is the carrying out of industrial activities, excluding agricultural and livestock-raising activities.

c) Urban land use: that whose main purpose is to be used for the construction of homes, offices, and public facilities and services infrastructure, as well as for recreational and sport activities.

d) Other land uses: those which are neither urban nor industrial, and which are suited for carrying out agricultural, forestry and livestock-raising activities.

e) Potentially soil-contaminating activities: industrial or commercial activities that may result in soil contamination due to the use of hazardous substances or the generation of waste products. For the purposes of this royal decree, substances and waste products considered hazardous shall include those listed in the Spanish National Classification of Economic Activities (CNAE-93), modified by Royal Decree 330/2003 of 14 March, as indicated in Annex 1, as well as those covered by the cases described in Article 3.2.

f) Criteria: criteria for assessing prima facie evidence that make it possible to assume or rule out the existence of soil contamination, and, in cases where there is analytical evidence of such contamination, to establish maximum levels of admissible risk.

g) Generic reference level (GRL): the concentration of a contaminant in soil that does not result in a level of risk higher than the acceptable maximum for human health or ecosystems, calculated according to the criteria contained in Annex VII.

h) Standards: the set of generic reference levels for contaminants of relevance for a site. Standards are established with a view to protecting human health and, where appropriate, ecosystems.

i) Risk: the probability of a contaminant present in soil coming into contact with a receptor with adverse consequences for human health or the environment.

In terms of protection of human health, for carcinogenic substances a situation of risk is regarded as that in which the expected frequency of the occurrence of cancer in the exposed population does not exceed one per one hundred thousand cases; for substances with systemic effects, a situation of acceptable risk is regarded as that in which, for each substance, the ratio of the long-term exposure dose to the maximum admissible dose is less than one.

In terms of protection of ecosystems, a situation of acceptable risk is regarded as that in which, for each substance, the ratio between the level of exposure, expressed as a concentration, and the ecotoxicological threshold, defined by the maximum

concentration at which effects on ecosystems are not expected, is less than one.

j) Contaminated soil: soil whose characteristics have been negatively altered by the presence of man-made chemical components of a hazardous nature in concentrations that imply an unacceptable risk for human health or the environment, and that have been declared contaminated by express decision.

### Article 3. *Situation reports*

1. Owners of the activities listed in Annex I shall be required to submit to the competent body of the corresponding autonomous community, within a period not exceeding two years, a preliminary situation report for each of the sites where the activity in question is carried out, with the minimum scope and content indicated in Annex II.

2. Preliminary situation reports shall also be presented by companies that produce, handle or store more than 10 metric tons per year of one or more of the substances included in Royal Decree 363/1995 of 10 March, which approves the regulatory scheme for notification of new substances and classification, packing and labelling of hazardous substances. This requirement shall also apply to companies with facilities for the storage of fuel for own use in accordance with Royal Decree 1523/1999 of 4 October, which modifies the regulatory scheme for oil installations, approved by Royal Decree 2085/1994 of 20 October, and complementary technical instructions MI-IP03, approved by Royal Decree 1427/1997 of 15 September, and MI-IP04, approved by Royal Decree 2201/1995 of 28 December, with an average annual consumption greater than 300,000 litres, and with a total storage volume equal to or greater than 50,000 litres.

3. After examining a preliminary situation report, the corresponding autonomous community may request that the activity or property owner submit more detailed complementary reports, data or analyses to facilitate assessment of the level of soil contamination. Such reports, data and analyses shall be carried out in accordance with the criteria and standards established in this royal decree.

4. Similarly, the owners of potentially contaminating activities shall be obliged to submit regular situation reports to the competent body. The content of situation reports and the frequency with which they are to be submitted shall be determined by the competent body of the autonomous community in question, particularly in cases that involve the establishment, expansion or closure of an activity.

5. Owners of sites where potentially contaminating activities have been carried out in the past shall be obliged to submit situation reports when applying for licenses or permits for the establishment of an activity that differs from the potentially

contaminating activity or activities previously carried out, or that supposes a change in land use.

6. For the purposes of the provisions of this article, and in relation to the activities to which this royal decree applies, and which are also subject to Law 16/2002 of 1 July on Integrated Pollution Prevention and Control, the autonomous communities may regard the reporting requirements referred to in the preceding sections as having been met if required content is covered in the documentation presented together with an application to obtain an integrated environmental permit.

### Article 4. *Contaminated sites*

1. Taking into account the information received based on the application of Article 3, as well as that obtained from other available sources of information, the competent body of the autonomous community in question shall declare a site contaminated for specific uses on the basis of the criteria set out in Annex III. The assessment of this information shall take into account the object of protection in each case, whether human health or ecosystems.

2. 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.

3. Sites where one of the circumstances indicated in Annex IV holds shall be subject to a detailed assessment of possible risks they may pose to human health or ecosystems. 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. In all cases, the assessment of risks to human health or ecosystems shall be carried out in accordance with the content of Annex VIII.

### Article 5. *Contamination of groundwater*

Without prejudice to the content of applicable regulations regarding groundwater, if the assessment processes referred to in Articles 3.3 or 4.3 reveals evidence of groundwater contamination resulting from soil contamination, the competent water authority shall be notified immediately.

### Article 6. *Generic reference levels*

1. The generic reference levels to be used for assessing soil contamination by specific substances are indicated in Annex V and Annex VI.

2. The competent body of the autonomous community in question shall determine which set of

generic reference levels are to be applied in each case, taking into account the current use to which each site is put and any anticipated future uses.

3. The responsible autonomous community authorities may determine, with reasonable grounds, which substance or substances included in Annexes V and VI chemical characterization work on soils should focus on, taking into account the activities carried out at the site that may have led to contamination. They may also, with reasonable grounds, extend the scope of the characterization work done to other substances not included in these annexes.

#### Article 7. *Decontamination of sites*

1. When a site is declared contaminated, this shall establish an obligation to carry out the actions necessary for its environmental remediation under the terms and within the periods dictated by the competent body.

2. The scope and performance of remediation actions shall be such as to guarantee that any remaining contamination implies acceptable risk levels in accordance with the use to which the site is put.

3. Remediation of contaminated sites shall be carried out by applying the best available techniques in accordance with the specific characteristics of each case. Remediation actions shall ensure that permanent solutions are achieved, and, to the greatest extent possible, shall give priority to *in situ* treatment techniques that avoid the generation, transfer and elimination of wastes.

4. Whenever possible, remediation shall be aimed at eliminating the focal points of contamination and reducing the concentration of contaminants in soil. When there are justified technical, economic or environmental reasons why this type of remediation is not possible, solutions aimed at reducing exposure may be accepted, provided that they include measures for containing or enclosing affected sites.

5. Contaminated sites may cease to be classified as such for a particular use when decontamination actions carried out on them are such as to ensure that they no longer pose an inadmissible risk to the designated object of protection, human health or ecosystems. Moreover, a site shall cease to be classified as contaminated for a specific use when a final administrative ruling to this effect has been made, subject to prior verification of the effectiveness of remediation actions carried out.

#### Article 8. *Registry disclosure*

1. Owners of properties where potentially contaminating activities have been carried out shall be obliged to declare this circumstance in public deeds documenting the transfer of rights over such properties. The existence of such a declaration shall

be recorded in the Land Register by means of a marginal note to the registration associated with the transfer.

2. At the request of the corresponding autonomous community, the land registrar shall issue a certificate of title and land charges for the registered property or properties on which the site that is to be declared contaminated is located. The registrar shall record the issuance of said certificate by means of a marginal note to the latest title registration, indicating the initiation of the proceedings and the fact that the certificate has been issued.

Said note shall remain in effect for a period of five years and may be cancelled at the instance of the government authority that originally ordered that it should be recorded.

When any entry is made in the registry folio after the recording of the marginal note, its content shall be recorded in the corresponding note of deed issue.

3. The administrative ruling by virtue of which a site is declared contaminated shall be recorded on the folio of the registered property or properties affected by means of a marginal note to the latest registration of title.

The marginal note shall be recorded pursuant to the administrative certificate in which the ruling declaring the site contaminated is inserted verbatim, with a statement indicating that the ruling is final in terms of administrative action; and which constitutes the means by which notification has been given to all registered owners appearing on the certificate referred to in the preceding section.

Duplicate copies of said certificate shall be presented to the Land Register, and shall indicate, in addition to the circumstances required by applicable legislation, the circumstances required by mortgage-related legislation concerning the rights and properties affected by the agreement.

The marginal note concerning the declaration of the site as contaminated shall be cancelled by virtue of a certificate issued by the competent government authority, which shall incorporate the administrative declassification ruling.

#### Article 9. *System of sanctions*

Offences committed against the provisions of this royal decree shall be subject to the system of sanctions set out in the Wastes Law 10/1998 of 21 April, without prejudice to any other civil or criminal liability that may apply.

Single supplementary provision *Sites used for military installations or activities*

This royal decree shall not apply to publicly owned sites where military installations are located or where military activities are carried out.

Within a period of two years from the date on which this royal decree enters into effect, the Ministry of Defence shall approve, subject to previous acceptance by the Ministry of the Environment, a decontamination plan for such sites, which shall conform to the technical content of this royal decree.

Final provision [Article 1]. *Competencies*

This royal decree shall be regarded as basic legislation governing the protection of the environment, and as establishing basic conditions and general coordination measures for the public health system, with the exception of Article 8, which constitutes legislation concerning the organization of public registers, in accordance with the provisions, respectively, of Article 149.1 Clauses 23, 16 and 8 of the Spanish Constitution.

Final provision [Article 2]. *Authority for making developing provisions*

The Minister of Health and Consumer Affairs and the Minister of the Environment are empowered to adopt all such provisions in their respective areas of competence as may be necessary for applying and developing the provisions of this royal decree, as well as for modifying its annexes in accordance with advances in technical and scientific knowledge, subject to previous notification of the autonomous communities, or at their proposal.

Done at Madrid, 14 January 2005.

JUAN CARLOS R.

The First Vice-President of the Government and Minister of the  
Presidency  
MARÍA TERESA FERNÁNDEZ DE LA VEGA SANZ

## ANNEX I

## Potentially soil-contaminating activities

CNAE93-Rev1	Description
11.10	Extraction of crude petroleum and natural gas
11.20	Service activities incidental to oil and gas extraction, excluding surveying
13.20	Mining of non-ferrous metal ores, except uranium and thorium ores
15.40	Manufacture of vegetable and animal oils and fats
17.30	Finishing of textiles
17.542	Manufacture of textiles impregnated, hardened or covered with plastic materials
18.301	Dressing, tanning and dyeing of furs
19.10	Dressing, tanning and finishing of leather
20.10	Sawmilling and planing of wood; industrial preparation of wood
20.20	Manufacture of veneer sheets; manufacture of plywood, laminboard, particle board, fibre board and other panels and boards
21.1	Manufacture of pulp, paper and paperboard
21.24	Manufacture of wallpaper
22.2	Printing and service activities related to printing (1)
23.10	Manufacture of coke oven products
23.20	Manufacture of refined petroleum products
24.1	Manufacture of basic chemicals
24.20	Manufacture of pesticides and other agro-chemical products
24.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
24.4	Manufacture of pharmaceutical products
24.5	Manufacture of soap, detergents and other cleaning and polishing preparations
	Manufacture of perfumes and beauty and toilet products
24.6	Manufacture of other chemical products
24.70	Manufacture of man-made fibres
25.1	Manufacture of rubber products
26.1	Manufacture of glass and glass products
26.21	Manufacture of ceramic household and ornamental articles
26.3	Manufacture of ceramic tiles and flags
26.65	Manufacture of fibre cement
26.8	Manufacture of other non-metallic mineral products
27.10	Manufacture of basic iron and steel and of ferro-alloy products
27.21	Manufacture of cast iron tubes
27.22	Manufacture of steel tubes
27.3	Other first processing of iron and steel
27.41	Production and first processing of precious metals
27.42	Production and first processing of aluminium
27.43	Production and first processing of lead, zinc and tin
27.44	Production and first processing of copper
27.45	Production and first processing of other non-ferrous metals
27.5	Casting of metals
28.1	Manufacture of structural metal products
28.2	Manufacture of tanks, reservoirs and containers of metal
	Manufacture of central heating radiators and boilers
28.3	Manufacture of steam generators
28.40	Forging, pressing, stamping and roll forming of metals; powder metallurgy
28.5	Treatment and coating of metals
	General mechanical engineering on behalf of third parties
28.6	Manufacture of cutlery, tools and general hardware
28.63	Manufacture of locks and hinges
28.7	Manufacture of other fabricated metal products, excluding furniture
29.1	Manufacture of machinery, equipment and mechanical material
29.2	Manufacture of other general-purpose machinery, equipment and mechanical material
29.3	Manufacture of agricultural machinery
29.4	Manufacture of machine tools
29.5	Manufacture of other special-purpose machinery
29.6	Manufacture of weapons and ammunition
29.71	Manufacture of electric domestic appliances
30.0	Manufacture of office machinery and computers
31.1	Manufacture of electric motors, generators and transformers
31.2	Manufacture of electricity distribution and control apparatus
31.3	Manufacture of insulated wire and cable
31.4	Manufacture of accumulators and electrical batteries

CNAE93-Rev1	Description
31.5	Manufacture of lighting equipment and electric lamps
31.6	Manufacture of other electrical equipment
32.1	Manufacture of electronic valves and tubes and other electronic components
32.2	Manufacture of television and radio transmitters and apparatus for line telephony and line telegraphy
32.3	Manufacture of sound or video reception, recording or reproducing apparatus
33.1	Manufacture of medical and surgical equipment and orthopaedic appliances
33.2	Manufacture of instruments and appliances for measuring, checking, testing, navigating and other purposes, except industrial process control equipment
33.3	Manufacturer of industrial process control equipment
34.10	Manufacturer of motor vehicles
34.20	Manufacturer of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers
34.30	Manufacture of parts and non-electrical accessories for motor vehicles and their engines
35.1	Building and repairing of ships and boats
35.20	Manufacture of railway and tramway material
35.30	Manufacture of aircraft and spacecraft
35.4	Manufacture of motorcycles and bicycles
36.1	Manufacture of furniture
36.63	Manufacture of other articles that use hazardous substances
37.10	Recycling of metal waste and scrap
37.20	Recycling of non-metal waste and scrap
40.1	Production and distribution of electricity
40.2	Manufacture of gas; distribution of gaseous fuels through urban mains, except gas pipelines
50.20	Maintenance and repair of motor vehicles
50.40	Sale, maintenance and repair of motorcycles and mopeds and related parts and accessories (2)
50.50	Retail sale of automotive fuel when the seller has storage facilities
51.12	Agents involved in the sale of fuels, ores, metals and industrial chemicals
51.51	Wholesale of solid, liquid and gaseous fuels and related products
51.52	Wholesale of metals and metal ores
51.532	Wholesale of paints and varnishes
51.551	Wholesale of fertilizers and chemical products for agricultural use
51.553	Wholesale of industrial chemicals
51.57	Wholesale of waste and scrap
52.486	Retail sale of fuels
60.10	Transport via railways
60.2	Other land transport
60.3	Transport via pipelines
63.122	Storage and warehousing of hazardous goods
63.22	Other supporting water transport activities
63.23	Other supporting air transport activities
74.811	Laboratories for developing, printing and enlarging photographs (1)
90.01	Collection and treatment of sewage
90.02	Collection and treatment of other waste
90.03	Sanitation, remediation and similar activities (3)
93.01	Washing, cleaning and dyeing of textile and leather garments (1)

(1) Except for retail trade

(2) Except for sales.

(3) Except for lands where remediation work is carried out for third parties.

**ANNEX II**

**Minimum scope and content of the preliminary situation report for a site**

The purpose of the preliminary situation report referred to in Article 3 is to assess the possibility that significant contamination has occurred or may occur at a site where one of the activities listed in Annex I has been carried out, or as a result of any of the activities covered in Article 3.2.

In those cases in which title to the property on which the site is located has been acquired after the cessation of the potentially contaminating activity, the site owners referred to in Article 3.5 shall be exempt from the requirements specified in Sections 2, 3, 4, 5 and 6 below.

The drafting of a preliminary situation report does not imply an obligation to carry out any type of specific test or analysis: such reports may be drafted based on information generated in compliance with legislation in effect with regard to wastes and hazardous substances. Nevertheless, the interested parties may include in the report any complementary information they regard as useful for accurately assessing the situation of the site(s) in question.

At minimum, preliminary situation reports shall include the following sections:

1. General information on the activity
  - Business name.
  - Address, telephone, fax, e-mail
  - Owner
  - Spanish tax identification code (CIF), Industrial Registry Registration Number (NIRI)
  - Industrial activity classification (CNAE 93-REV 1)
  - Year in which the activity started and ended
  - Registry information for the property contained in the Land Register
  - Personnel
  - Installed power (kW)
  - Surface area occupied
  - Plans for and descriptions of facilities and their current condition
  - Pavement: type, condition, percentage of total surface covered
  - Drainage network
  - Wastewater treatment network
  - Accidents or irregularities that have occurred at the site
  - Year
2. Hazardous materials consumed (raw materials, secondary materials and auxiliary materials)
  - Type, nature
  - Annual quantity (volume, weight)
  - Aggregation state (solid, liquid, sludge)

- Form of presentation (loose, type of packing, etc.)
- Risk description associated with the material in accordance with regulations concerning the classification and labelling of substances
- Storage

3. Intermediate or end products of a hazardous nature
  - Type, nature
  - Annual quantity (volume, weight)
  - Aggregation state (solid, liquid, sludge)
  - Form of presentation (loose, type of packing, etc.)
  - Risk description associated with the material in accordance with regulations concerning the classification and labelling of substances
  - Storage

4. Wastes or by-products generated (1)
  - Denomination
  - Coding according to the European List of Wastes and Spanish regulations
  - Composition, main constituents
  - Annual quantity (volume, weight)
  - Aggregation state (solid, liquid, sludge)
  - Form of presentation (loose, type of packing, etc.)
  - Type of temporary storage and management system

5. Storage
  - For each material, product or waste product, the form of storage used and its characteristics shall be indicated.

5.1 Surface storage

- Surface area: average depth, volume
- Pavement/isolation: type, surface area covered by pavement or isolated
- Existence of coverings
- Presentation of material [loose or packed, type (drums, big bags, boxes, etc.), identification of materials]
- Separation of materials: by incompatible types, type of separation
- Access to site, access control
- Drainage network and collection of rainwater
- Leaks or spills: control, evacuation procedures, clean-up and management
- Safety equipment
- Site plan and installation layout

5.2 Surface tanks

- Type, number, volume, age, total capacity
- Identification
- Control of storage
- Retention ponds

Clean-up of leaks and spills  
Access and access control  
Site plan and installation layout

### 5.3 Underground tanks

Type, number, volume, age, total capacity  
Leaktightness: tests, results, year  
Identification  
Mechanisms for identifying and retaining leaks or spills  
Clean-up system  
Site plan and installation layout

### 6. Production areas

For areas where activities regulated by this royal decree are carried out, situation reports shall specify the presence of construction elements that reduce the possibility of soil contamination. Such descriptions shall give separate consideration to the various stages of the production process.

### 7. Historical activities

In cases where historical activities with the potential to cause contamination are known to have been carried out at the site, any available information concerning the following points shall be provided:

The name of the activity or activities carried out in the past at the site.

Type of activity carried out.

The dates on which each of the activities started and ended

Remarks: any other information that may facilitate the detection of historical contamination and its differentiation from possible current contamination.

(1) If wastes or by-products have been generated, a copy of the annual declaration made by the producer shall be attached to the preliminary situation report. This section shall also apply to all materials generated in treatment processes for emissions and effluents.

## ANNEX III

### Criteria for determining if a site is contaminated

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 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 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 exceeds 100 times the generic reference level calculated in accordance with the criteria established in Annex VII.

2. In cases in which the protection of ecosystems is regarded as the main priority:

a) When the lethal or effective median concentration,  $L(E)C_{50}$ , 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,  $L(E)C_{50}$ , 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.

## ANNEX IV

### Criteria for identifying sites that require risk assessment

1. Sites that meet any of the following conditions shall be subject to the terms of this annex:

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 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 is higher than the generic reference level estimated in accordance with the criteria established in Annex VII.

2. In those cases in which the main priority is the protection of an ecosystem, this annex shall apply to sites that meet any of the following conditions:

a) Where the concentration of any of the substances listed in Annex VI 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 is higher than the generic reference level estimated in accordance with the criteria established in Annex VII.

c) Where toxicity is demonstrated based on any of the biotests referred to in Annex III.2, carried out using soil or leachate in undiluted samples.

**ANNEX V**

**List of contaminants and generic reference levels for the protection of human health based on land use**

*Protection of human health*

Substance	CAS number	Industrial use	Urban use	Other uses
		(mg/kg dry weight)		
Methylene chloride	75-09-2	60***	6***	0.6
1,1-Dichloroethane	75-34-3	100**	70***	7
1,2-Dichloroethane	107-06-2	5***	0.5***	0.05
1,1,2-Trichloroethane	79-00-5	10***	1***	0.1
1,1,2,2-Tetrachloroethane	79-34-5	3***	0.3***	0.03
1,1-Dichloroethene	75-35-4	1	0.1***	0.01
Trichloroethene	79-01-6	70***	7***	0.7
Tetrachloroethene	127-18-4	10***	1***	0.1
1,2-Dichloropropane	78-87-5	4	0.5***	0.05
1,3-Dichloropropane	42-75-6	7***	0.7***	0.07
Acenaphthene	83-32-9	100**	60***	6
Acetone	67-64-1	100**	10***	1
Aldrin	309-00-2	1***	0.1***	0.01
Anthracene	120-12-7	100***(1)	100**	45
Benz[a]anthracene	56-55-3	20***	2***	0.2
Dibenz[a,h]anthracene	53-70-3	3***	0.3***	0.03
Benzene	71-43-2	10***	1***	0.1
Chlorobenzene	108-90-7	35	10***	1
1,2-Dichlorobenzene	95-50-1	100**	70**	7
1,4-Dichlorobenzene	106-46-7	40***	4***	0.4
1,2,4-Trichlorobenzene	120-82-1	90***	9***	0.9
p-Chloroaniline	106-47-8	30***	3***	0.3
Chlordane	57-74-9	1***	0.1***	0.01
Chloroform	67-66-3	5	3	0.7
Chloroethene	75-01-4	1***	0.1***	0.01*
o-Cresol	95-48-7	100**	40***	4
Chrysene	218-01-9	100**	100**	20
p,p'-DDE	72-55-9	60***	6***	0.6
p,p'-DDT	50-29-3	20***	2	0.2
p,p'-DDD	72-54-8	70***	7***	0.7
Dieldrin	60-57-1	1***	0.1***	0.01*
Endosulfan	115-29-7	60***	6***	0.6
Endrin	72-20-8	1***	0.1***	0.01*
Styrene	100-42-5	100**	100**	20
Ethylbenzene	100-41-4	100**	20***	2
Phenol	108-95-2	100**	70**	7
2-Chlorophenol	95-57-8	100**	10***	1
2,4-Dichlorophenol	120-83-2	10***	1***	0.1
2,4,5-Trichlorophenol	95-95-4	100**	100**	10
2,4,6-Trichlorophenol	88-06-2	90***	9***	0.9
Pentachlorophenol	87-86-5	1***	0.1***	0.01*
Fluoranthene	206-44-0	100**	80***	8

Benzo[b]fluoranthene	205-99-2	20***	2***	0.2
Benzo[k]fluoranthene	207-08-9	100**	20***	2
Fluorene	86-73-7	100**	50***	5
Heptachlor epoxide	1024-57-3	1***	0.1***	0.01
Hexachlorobenzene	118-74-1	1***	0.1***	0.01*
Hexachlorobutadiene	87-68-3	10***	1***	0.1
α-Hexachlorocyclohexane	319-84-6	1***	0.1***	0.01*
β-Hexachlorocyclohexane	319-85-7	1***	0.1***	0.01*
γ-Hexachlorocyclohexane	58-89-9	1***	0.1***	0.01*
Hexachlorethane	67-72-1	9***	0.9***	0.09
Naphthalene	91-20-3 13-	10	8	1
PCB	36-36-3	0.8	0.08	0.01*
Pyrene	129-00-0	100**	60***	6
Benzo[a]pyrene	50-32-8	2***	0.2***	0.02
Indeno[1,2,3-cd]pyrene	193-39-5	30***	3***	0.3
Carbon tetrachloride	56-23-5	1	0.5***	0.05
Toluene	108-88-3	100***(2)	30***	3
Xylene	1330-20-7	100***(2)	100**	35

\* Lower limit of detection.

\*\* Applying the reduction criterion described in Annex VII.

\*\*\* Applying the contiguity criterion described in Annex VII.

(1) For this substance, autonomous communities may apply GRs higher than 100 mg/kg but no higher than 700 mg/kg, provided that an explicit justification is given citing the reasons for adopting the new values. The justification shall be included in declarations stating that sites are contaminated or not contaminated.

(2) For this substance, autonomous communities may apply GRs higher than 100 mg/kg but no higher than 200 mg/kg, provided that an explicit justification is given citing the reasons for adopting the new values. The justification shall be included in declarations stating that sites are contaminated or not contaminated.

**ANNEX VI**

**List of contaminants and generic reference levels for protection of ecosystems**

*Protection of ecosystems*

Substance	CAS number	Soil organisms	Aquatic organisms	Terrestrial vertebrates
		(mg/kg dry weight)		
1,1-Dichloroethane	75-34-3		0.06	4.18
1,2-Dichloroethane	107-06-2		0.16	0.24
1,1,2-Trichloroethane	79-00-5		0.16	0.3
1,1,2,2-Tetrachloroethane	79-34-5		0.04	0.02
Trichloroethylene	79-01-6		0.21	0.45
Tetrachloroethene	127-18-4	0.01*	0.06	0.15
1,2-Dichloropropane	78-87-5	4.24	0.07	0.43
1,3-Dichloropropane	42-75-6		0.01*	0.58
Acenaphthene	83-32-9		0.02	4.85
Acetone	67-64-1		0.54	6.71
Aldrin	309-00-2	0.01*	0.01	0.01*
Anthracene	120-12-7		0.01*	22
Benz[a]anthracene	56-55-3	3.8	0.01	
Benzene	71-43-2	1	0.2	0.11
Chlorobenzene	108-90-7	1	0.03	7.66
1,2-Dichlorobenzene	95-50-1		0.11	3.15
1,4-Dichlorobenzene	106-46-7	0.1	0.16	0.53
1,2,4-Trichlorobenzene	120-82-1	0.05	0.79	0.94
p-Chloroaniline	106-47-8	0.14	0.01*	0.09
Chlordane	57-74-9	0.04	0.01*	0.01*
Chloroform	67-66-3		0.01	0.01
p,p'-DDE	72-55-9	0.14	0.01*	0.01*
p,p'-DDT	50-29-3		0.01	0.01*
Dieldrin	60-57-1	0.13	0.01*	0.01*
1,4-Dioxane	123-91-1	1.45	13.9	
Endosulfan	115-29-7	0.01	0.01*	0.04
Endrin	72-20-8		0.01*	0.01*
Styrene	100-42-5	0.68	0.25	100**
Ethylbenzene	100-41-4		0.08	4.6
Decabromophenyl ether	1163-19-5		2.66	59.7

Pentabromodiphenyl ether	32534-81-9	0.32	5.18	0.01*
Octabromodiphenyl ether	32536-52-0		0.51	0.24
Phenol	108-95-2	0.27	0.03	23.7
2-Chlorophenol	95-57-8	0.04	0.01*	0.12
2,4-Dichlorophenol	120-83-2	0.2	0.06	0.02
2,4,5-Trichlorophenol	95-95-4	0.05	0.09	3.3
2,4,6-Trichlorophenol	88-06-2	0.4	0.012	0.03
Pentachlorophenol	87-86-5	0.02	0.01*	0.01*
Fluoranthene	206-44-0	1	0.03	1.96
Fluorene	86-73-7	0.22	0.02	2.84
Fluorides	7664-39-3	11	0.29	3.7
Hexachlorobenzene	118-74-1	5.7	0.01	0.01*
Hexachlorobutadiene	87-68-3		0.01*	
α-Hexachlorocyclohexane	319-84-6		0.25	0.05
β-Hexachlorocyclohexane	319-85-7		0.38	0.01*
γ-Hexachlorocyclohexane	58-89-9	0.01*	0.01*	0.23
Hexachlorethane	67-72-1		0.03	0.03
Naphthalene	91-20-3	0.1	0.05	0.06
Nonylphenol	25154-52-3	0.34	0.031	0.78
Pyrene	129-00-0		0.01*	1.2
Benzo[a]pyrene	50-32-8	0.15	0.01*	
Carbon tetrachloride	56-23-5		0.12	
Toluene	108-88-3	0.3	0.24	13.5
Xylene	1330-20-7		0.07	

\* Lower limit of detection.

\*\* Applying the reduction criteria described in Annex VII.

## ANNEX VII

### Criteria for calculating generic reference levels

1. Criteria for calculating generic reference levels for the protection of human health. Such calculations shall be carried out by applying the following methodology:

A) Determination of toxicological threshold values based on land use:

a) Relevant exposure pathways shall be identified and defined. At minimum, the following exposure pathways shall be considered:

1. Industrial land use: inhalation of soil vapours, inhalation of contaminated soil particles, and ingestion of contaminated soil.

2. Urban land use: inhalation of soil vapours, inhalation of contaminated soil particles, ingestion of contaminated soil, and dermal contact with soil.

3. 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.

b) 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.

c) The maximum admissible soil concentration for particular substances shall be calculated based on the following considerations:

1. 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  $10^{-5}$ .

2. 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

B) 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.

C) 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.

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

A) 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.

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.

## ANNEX VIII

### Assessment of environmental risks

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 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.

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.

**Not valid for legal purposes.**