

# The ISS Reclamation Data Bank

Loredana Musmeci<sup>(a)</sup>, Mirella Bellino<sup>(a)</sup>, Roberto Binetti<sup>(a)</sup>, Federica Ceccarelli<sup>(a)</sup>,  
 Francesca Marina Costamagna<sup>(a)</sup>, Antonella D'Angiolini<sup>(a)</sup>, Alessandra Fabri<sup>(a)</sup>,  
 Fabrizio Falleni<sup>(a)</sup>, Maurizio Ferri<sup>(b)</sup>, Augusta Piccardi<sup>(a)</sup>, Paolo Roazzi<sup>(b)</sup>,  
 Daniela Trucchi<sup>(b)</sup> and Ida Marcello<sup>(a)</sup>

<sup>(a)</sup>Dipartimento di Ambiente e Connessa Prevenzione Primaria;

<sup>(b)</sup>Servizio Informatico, Documentazione, Biblioteca ed Attività Editoriali,  
 Istituto Superiore di Sanità, Rome, Italy

**Summary.** Since the issue of the first regulations concerning the remediation of contaminated sites, the Istituto Superiore di Sanità, on the basis of specific requests, has drawn up various technical opinions regarding the proposed reference values (quality standards) for soils and underground waters, to be achieved when remediating contaminated sites, for substances for which no standard limit values did not exist at that time. These reference values, widely used throughout the country and accepted and adopted as “remediation aim” values by various territorial bodies responsible for the approval and monitoring of remediation projects, have been collected in a specific reclamation oriented data bank known as the “Banca Dati Bonifiche (BDB)” (Reclamation Data Bank). The BDB contains the related standardized “rationale” for each reference value, in order to serve as a useful reference for the national bodies concerned with the remediation of contaminated sites.

*Key words:* database, contaminated site, limit values.

**Riassunto** (*La banca dati bonifiche*). In seguito alla pubblicazione del primo regolamento riguardante la bonifica dei siti contaminati, l'Istituto Superiore di Sanità, sulla base di richieste specifiche, ha redatto diversi pareri tecnici relativi a valori di riferimento proposti (standard di qualità) per suoli e acque sotterranee per sostanze per le quali in quel momento non erano disponibili valori limite standard, da raggiungere in caso di bonifica di siti contaminati. Questi valori di riferimento, usati diffusamente in tutto il paese e accettati e adottati come “valori obiettivo di bonifica” da diversi organi territoriali responsabili della approvazione e del monitoraggio di progetti di bonifica, sono stati raccolti in una banca dati orientata specificatamente sulle bonifiche, denominata “Banca Dati Bonifiche (BDB)”. La BDB contiene per ciascun valore di riferimento il “razionale” standardizzato allo scopo di fornire un utile riferimento per gli organismi nazionali deputati alla bonifica dei siti contaminati.

*Parole chiave:* basi di dati, siti contaminati, valori limite.

## INTRODUCTION

Ministerial Decree, DM 471/1999 [1], now replaced by Legislative Decree (DL.vo 152/2006, Part IV, Title V) [2], gives the limit values for the substances mainly found in contaminated soils as a consequence of many types of industrial activity. For substances not included in the Table 1 of Annex 5 to DL.vo 152/2006, Part IV, Title V the regulation requires the acceptable limit concentration values for “the most toxicologically similar substance” to be adopted. In fact, it would not be feasible for the decree to identify limit values for every substance potentially present at the various sites therefore it was deemed advisable to provide in the regulation a very general criterion for defining the concentration limit to be adopted for substances for which no limit values were specified.

In this framework, many bodies – Ministry of the Environment, Regions, Provinces, Municipalities, Local Health Units (AUSL), Regional Environmental Protection Agencies (ARPA), etc. – considered the Istituto Superiore di Sanità (ISS) as the most competent organization for proposing new reference limit values for the remediation of contaminated sites, taking into account the hygiene-health relevance of the subject, in all cases where a specific limit value is not available and the above mentioned general criterion is not easily applicable.

We set out below some of the reference criteria adopted for defining the concentration limits currently given in DL.vo. 152/2006 Part IV, Title V; these criteria can be a useful aid for understanding the procedures adopted by the ISS over the years for proposing reference values for substances not regulated.

### CRITERIA ADOPTED FOR ESTABLISHING THE LIMIT VALUES FOR SOILS AND WATERS GIVEN IN DL.VO 152/2006

The limit concentrations shown in Table 1 of Annex 1 to DM 471/1999 were drawn up on the basis of the following criteria:

- comparison with limit values for substances in the soils drawn up at the international level (The Netherlands, United Kingdom, Germany, United States of America, Canada etc.);
- comparison with limit values for substances in the soils drawn up by Italian regional authorities (Regione Toscana, Regione Piemonte, Regione Emilia Romagna, Provincia Milano, etc.);
- evaluation of the health and environmental risk.

In accordance with the above, a comparison was made with the limits laid down for a certain set of substances at the international level and then, by means of mathematical risk assessment models, it was verified that the concentration values selected guaranteed the health of humans and the environment, even in the “worst case”, *e.g.*, soil ingestion, skin contact, inhaling vapours, entering the food chain through the use of drinking water, all at the same time. The mathematical model chosen for risk assessment was the RBCA (Risk Based Corrective Action) methodology established by the ASTM (American Society for Testing and Materials) on the basis of the US Environmental Protection Agency’s instructions and guidelines for health risk analysis [3-6]. A check was also made to make sure that the limit concentrations chosen for the various substances in soils used for “public green areas” and for “industrial use” ensured compliance with the limit concentrations laid down for deep waters. These evaluations were done by means of mathematical models for the transport and assessment of health risk (verified by bodies of international repute), always with reference to “worst case” conditions (*e.g.*, low content of clay and of organic matter, in other words, in fact, with reference to the case of soil that can be defined as permeable).

On this basis it is understandable how these criteria, used for establishing the limit concentrations set out in Table 1 of Annex 5 to DL.vo 152/2006, Part IV, Title V, need to be taken into account for establishing the limit concentrations of substances not included in Table 1 [2].

As far as underground water is concerned, the limit values set out in Table 2 of Annex 5 to Part IV, Title V of DL.vo 152/2006 were fixed on the basis of the criterion that underground or surface water quality, must allow in all legitimate ways, including for drinking whenever pertinent (in particular deep underground water). Since the use for drinking is the most restrictive use, the concentration limits for deep waters were established taking that quality criterion into account. When limit values for drinking water were not available for the substances under consideration, the reference level has been set in accordance with the above mentioned criteria, (in par-

ticular) on the basis of international regulations and guidelines [7, 8]. It should be pointed out that those objectives are to be achieved by remediation and are not to be considered as a quality criterion for the drinkableness of water. In this case also, in addition to the matters set out in Presidential Decree (DPR) 236/88, subsequently amended by DL.vo 2 February 2001, number 31, regarding water intended for human consumption and by DL.vo 152/99, regarding protection of water from contamination, the contents of the international regulations and guidelines were taken into account, with particular reference to US regulations on drinking water [7].

Starting with the issue of the first specific regulations on the subject of remediation of contaminated sites [1] the ISS on the basis of specific requests from Regions, Provinces, Municipalities, AUSL, APAT, ARPA, proposed reference values (quality standards) for soils and underground waters, to be achieved within the framework of remediation of contaminated sites, for about 250 substances not regulated by DM 471/1999 and subsequent amendments. Each reference value was backed up by an opinion drawn up on the basis of the above mentioned criteria, consulting data banks with good scientific reputations, including the ISS’s Inventario Nazionale delle Sostanze Chimiche (National Inventory of Chemical Substances), in order to evaluate the environmental and toxicological behaviour of the substances for which a proposed reference value needed to be expressed, always making conservative estimates.

These reference values proposed by the ISS have been adopted by various territorial bodies responsible for the approval and control of projects for remediating contaminated sites, as “remediation objective” values. It must be pointed out that these parameters were specifically established for remediation activities and not for other fields already regulated by the competent authorities (quality standards for drinking water, for instance).

### CONTENTS OF THE RECLAMATION DATA BANK

The Reclamation Data Bank – Banca Dati Bonifiche (BDB) – is prepared and kept up to date by the Soil and Waste Section and the Dangerous Substances and Preparations Section of the Department of the Environment and Primary Prevention of the ISS, with the assistance of Sector I – Information Technology of the Information, Documentation, Library and Publishing Activities Service.

The BDB supplies non-confidential, validated, up-to-date and complete information on substances concerned in the procedures of remediating contaminated sites (whether included in the regulations or not).

At present it includes 325 items:

- 112 related to substances or families for which a concentration limit in the soil, subsoil and/or un-

derground water is available, which are included in DL.vo 152/2006;

- 213 related to substances or classes for which DL.vo 152/2006 has not set a concentration limit but which have been found on remediation sites and for which the ISS has been asked to propose a reference concentration.

The BDB is a factual bank in which the information, immediately usable and presented in a concise form, is accompanied by bibliographic references to enable users to go to the original source and, in some cases, to connect directly to it on the web.

### CRITERIA FOR SELECTING THE SUBSTANCES INCLUDED IN THE BDB

DL.vo 3 April 2006, number 152 regarding "Standards for environmental matters" sets out, in Table 1 of Annex 5 to Part IV, Title V, a list of substances for which a threshold concentration of contamination in the soil and subsoil has been set, in relation to the specific purpose of use of the sites to be remediated (use for public and residential green areas, business and industrial use). These substances (there are a total of 112 items), are the ones most often present in contaminated soils and waters, because they are related to many types of industrial activity.

Nevertheless, this list cannot be considered as exhaustive since, as pointed out in the note to Table 1 of Annex 5 to DL.vo 152/2006, Part IV, Title V, the substances for which that DL.vo gives a contamination threshold for the soil and the subsoil in relation to the specific purpose of use of the sites to be cleaned up are only *for each chemical category, some substances frequently found in contaminated sites*. For substances *not specifically shown in the Table* but present in a contaminated site, like the case foreseen at the foot of Table 1 of Annex 1 to DM 471/1999, the note specifies that *the acceptable concentration limit values are obtained by adopting those given for the most toxicologically similar substance* [9]. Since the standard came into force the ISS has often been asked by the bodies responsible for evaluating and/or authorising the remediation project to propose reference concentration values for substances not covered by DM 471/1999 and, subsequently, by DL.vo 152/2006.

According to the current criteria given in DL.vo 152/2006, even though such reference values proposed by the ISS do not have a specific regulatory force, they can be regarded as contamination threshold concentrations (CSC). What is more, the chemical-physical and toxicological properties of the substances shown in the reference documents related to each substance studied by the ISS can be useful for the purpose of evaluating the risk threshold concentration (CSR), as laid down in the aforementioned DL.vo 152/2006.

Experience gained points to the advisability of making the data and criteria on which such proposed reference values have been based available to outside users.

This was the basis for setting up the Reclamation Data Bank (BDB), accessible from the ISS website,

which currently contains over 325 items related to substances involved in remediation procedures (whether included in the regulations or not). For the values proposed by the ISS, the related standardised rationale is also given, as well as the evaluations and classifications done by reference international institutions, such as the European Union (EU), the International Agency for Research on Cancer (IARC) and the US Environmental Protection Agency (USEPA).

### PROCEDURES FOR DEFINING REFERENCE CONCENTRATIONS FOR THE PURPOSE OF REMEDIATING NON-REGULATED CONTAMINANT SUBSTANCES

The "toxicologically similar criterion", as laid down in DM 471/1999, now amended by DL.vo 152/2006, makes reference to all the characteristics of the substance under consideration and, therefore, to actually toxicological ones and also to environmental behaviour ones. This is in the light of what has been said above regarding the criteria according to which the concentration limits given in Tables 1 and 2 of Annex 5 to DL.vo 152/2006, Part IV, Title V, were established [9].

During the first phase of the evaluation process, both toxicological and environmental data banks are consulted and the various evaluations are then made, taking into consideration data available and deemed to be scientifically valid.

The data banks most frequently consulted include:

- the Integrated Risk Information System (IRIS) [10];
- the Health Effects Assessment Summary Tables (HEAST) [11];
- the Hazardous Substances Data Bank (HSDB) [12]; and
- the Inventario Nazionale delle Sostanze Chimiche (National Inventory of Chemical Substances) of the ISS [13].

The IRIS is an electronic database prepared and maintained by the US Environmental Protection Agency (USEPA), containing information on human health effects that may result from exposure to various chemicals in the environment [10]. It contains data in support of human health risk assessment. It is compiled by the USEPA and contains over 500 chemical records. The IRIS contains descriptive and quantitative information in the following categories: oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic non-carcinogenic health effects; hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. The IRIS data is reviewed by working groups of USEPA scientists and represents an USEPA consensus. The toxicity values listed in IRIS are considered to be validated and have undergone rigorous peer review. The completion of IRIS assessments is a multi-step process including internal peer review, USEPA program and

regional office review, federal interagency review, and external peer review with a public notice and comment period. The various steps are described in the IRIS Track, if one opens and reviews the status of any assessment currently presented.

The HEAST are for use at both Superfund and RCRA sites [11]. They are maintained by the Environmental Protection Agency's National Center for Environmental Assessment and provide a comprehensive listing of provisional risk assessment information relative to oral and inhalation routes of exposure for chemicals. In this document, slope factors are calculated by the EPA to assist HEAST users with risk-related evaluations and decision-making at various stages of the remediation process. It is updated every three months and contains ample references to the studies made of the substance. It contains provisional as well as verified data on the Reference Dose and Slope Factor.

The HSDB is a toxicology data file on the national Library of Medicine's (NLM) Toxicology Data Network (TOXNET). HSDB focuses on the toxicology of potentially hazardous chemicals and is enhanced with information on human exposure, industrial hygiene, emergency handling procedures, environmental fate, regulatory requirements, and related areas. All data are referenced and derived from a core set of books, government documents, technical reports and selected primary journal literature. The HSDB is peer-reviewed by the Scientific Review Panel (SRP), a committee of experts in the major subject areas covered by the data bank, and is organized in individual chemical records, and contains over 5000 such records [12].

The National Inventory of Chemical Substances (INSC) is a factual data bank on chemicals, prepared and maintained by the ISS. The INSC provides extensive information on chemical identification, toxicological and ecotoxicological data, occupational health and safety, environmental fate, standards, evaluation, and classification for over 3000 entries. In addition, for approximately 2000 other substances, raw data (consisting of bibliographic information and specific articles collected in the open and grey literature) are available [13].

During the second phase the information collected is evaluated for the purpose of using information of a significant toxicological and environmental nature for defining and classifying the substances under consideration.

During the third phase the information collected and evaluated is compared with the toxicological and environmental purpose/behaviour characteristics of the substances listed in Tables 1 and 2 of Annex 5 to DL.vo 152/2006, Part IV, title V with a view to finding the "most similar" ones where possible. Obviously this third and last phase has to involve a certain amount of approximation, since it is extremely difficult to assign absolutely identical behaviours to the substances (in fact, we speak of "similarity"). When a substance similar to the one under consideration has been found among those shown in Tables 1 and 2 of Annex 5 to DL.vo 152/2006, Part IV, Title V,

that substance will, wherever possible, be assigned the same concentration limit for the various sectors foreseen in the decree for the similar substance.

If the toxicological characteristics and the environmental behaviour of the substance are substantially different from those of the substances listed, or are similar from the toxicological point of view but not from that of environmental behaviour, or vice versa, new evaluations are done to lead to the identification of concentration limits other than the ones listed in Tables 1 and 2 of Annex 5 to DL.vo 152/2006, Part IV, Title V. For example, it could happen that a substance is quite similar toxicologically to a substance listed but its environmental behaviour is characterised by greater mobility in the soil and solubility. In this case a concentration limit equal to that of the toxicologically similar substance listed in DL.vo 152/2006 could be assigned, but it would have to be subdivided by a correction factor (normally between 1 and 100) in view of the risk of higher environmental diffusion than the similar substance listed in the tables of the decree.

#### INFORMATION AVAILABLE IN THE BDB

For each agent taken into consideration by the BDB, the information available is standardised and structured in the following sections.

##### *Names and synonyms*

This section includes names and synonyms such as:

- the EINECS name for existing substances contained in the European Inventory of Existing Commercial Chemical Substances (EINECS). For substances officially classified within the framework of Directive 67/548/EEC, the EINECS name usually corresponds to the name in Annex I;
- the ELINCS name, for new substances, contained in the European List of Notified Chemical Substances (ELINCS);
- the name(s) in Annex I, available for substances officially classified as dangerous, corresponding to the name with which the substance appears in Annex I of Directive 67/548/EEC;
- the IUPAC name, name of the substance according to the nomenclature rules of the International Union of Pure and Applied Chemistry;
- the CAS name, name given by the Chemical Abstract Service (CAS);
- synonyms, *i.e.*, other chemical, common or conventional names that can provide a further key to identification or search substances not included in the EINECS or ELINCS list are designated by an internationally recognised chemical name (ISO for example). In some cases the common name is also given.

##### *Identification codes*

This section includes:

- the CAS number – registration number assigned by the Chemical Abstract Service (CAS);

- the EC number – this corresponds: for existing substances listed in the EINECS (European Inventory of Existing Commercial Chemical Substance – G.U.C 146 A OF 15.6.1990), to the EINECS number; for new substances, listed in the ELINCS (European List of Notified Chemical Substances) to the ELINCS number;
- the Index number – number used in Annex I to Directive 67/548/EEC for indicating substances classified as dangerous by the European Union;
- the ISS number – identification code assigned to the substance by the Inventario Nazionale delle Sostanze Chimiche.

#### ***Threshold concentrations of contamination in the soil and subsoil and/or underground water***

- class: indicates the chemical class of the substance/item under consideration;
- remediation name. Indicates the name under which the item appears in DL.vo 152/2006, Part IV, Title V or in the opinion given by the ISS;
- limits: indicate 1) the threshold contamination concentrations in the soil and subsoil in relation to the specific purpose of use of the sites to be remediated (expressed in mg/kg of substance) set out in DL.vo 152/2006, Part IV, Title V, that is to say in sites for public, private and residential green areas and in sites for commercial and industrial use and the contamination concentration thresholds in underground water (expressed in µg/l) set out in DL.vo 152/2006, Part IV, Title V. In some cases only one of the concentrations might be available; 2) the reference concentrations proposed by the ISS in its opinions, for the soils (soils for use as public/private and residential green areas; soils for commercial and industrial use) and/or for underground water;
- bibliographic reference consisting of DL.vo 152/06 for the substances included in that decree and the documents prepared by the ISS for substances not included in Annex 5 to the Part IV, Title V of DL.vo 152/06;
- date: for the substances listed in DL.vo 152/2006 the date is that of the decree, for substances not included in Annex 5 to Part IV, Title V of DL.vo 152/2006 the date on which the opinion of the ISS was given is indicated;
- rationale: for substances whose reference concentration does not derive from the regulations, the document in which the ISS proposed the reference concentration is shown. The current version of this document, although it maintains the original content of the opinion of the ISS, may differ slightly in formal terms from that opinion.

#### ***Hazard classification***

This section includes the complete European Union Hazard Classification according to Directive 67/548/EEC, that is to say, hazard category(ies); risk phrases; concentration limits for the classification of dangerous preparations containing the substance; the last Community legislative measure (adaptation to

technical progress) by which the substance is classified, regardless of the formal national act of implementation.

#### ***Carcinogenesis evaluations***

This section includes:

- the evaluation of the IARC which includes the degree of evidence of carcinogenicity in humans; the degree of evidence of carcinogenicity in laboratory animals; the carcinogenesis category;
- the bibliographic reference of the most recent IARC Monographs in which the substance was taken into consideration and which refers to the carcinogenesis category;
- the evaluation of carcinogenicity which includes the carcinogenesis category adopted by the USEPA in accordance with the *Guidelines for carcinogen risk assessment* published in 1986, 1996, 1999, 2005 [14].

#### **PROCEDURES FOR ACCESSING AND QUERYING THE BDB**

The search can be done through one of the following key fields:

- CAS number;
- EC number;
- Index number;
- name or part of name.

If you search by CAS number, EC number, Index number, or name you get a specific result. If you are searching by part of name, the term searched for must be entered in the name or part of name field, followed or preceded by an asterisk, or between asterisks, and the result is a list of all the agents containing that term as the initial or final part of the name, or containing the term being searched for within the name itself. The search can be done in either Italian or English because these synonyms are entered in the data bank in both languages. The more information you enter the more restricted and therefore faster, is the search.

#### **RESULT OF THE QUERYING**

The result of the querying is a short form containing the reference concentrations as remediation objective of the soils and/or in underground water and all the classifications/evaluations available in the literature ascribed to the substance by the various bodies.

For some substances the information contained in the short form available on interrogation is fairly limited because reliable and referenced data were not found in the literature. This condition is pointed out.

#### **TECHNICAL CHARACTERISTICS OF THE BDB**

Data are stored in the BDB in a relational database. The following were taken into account when designing it:

- specific requirements regarding remediation problems;
- the need to implement the database to meet new, contingent requirements;
- logging the information so that its evolution can be studied;
- the possibility of integration with databases dealing with similar matters so as to optimise the resources as a whole;
- the process of validating and controlling the quality of the data entered;
- the possibility of making the information contained in it immediately available, on the web, so that it can be used by everybody that needs it.

### CONCLUSIONS AND FUTURE PERSPECTIVES

The BDB evolves constantly and is updated on the basis of new laws. The most recent measure on the

subject is DL.vo 152/2006, Part IV, Title V, which replaces the previous DM 471/1999.

Periodic updating of the data bank is also foreseen in relation to the proposal of new limit concentrations in the soil, subsoil and/or in underground water for substances not covered by DL.vo 152/2006.

Another possible updating of the BDB would be the definition, for the substances of greater health and environmental interest, whether included in the regulations or not, of the reference chemical-physical and toxicological characteristics for the use of software for health risk assessment for soils and water, in order to identify the risk threshold concentration (CSR), as laid down in DL.vo 152/2006, Part IV, Title V [15].

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