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by

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ABSTRACT

This document reports on the results of a study on the public availability of data in the IUCLID database. IUCLID is a comprehensive chemical data base. The data which it contains has been collected in a structured fashion through an obligation put on producers and importers of high production volume existing chemicals by the Existing Chemicals Regulation, Reg. 793/93. This data base is the central European instrument to collect, distribute and disseminate data on existing chemicals to authorities, including the Commission Services, industry, interest groups and the general public.

Much of the public discussion on chemicals over the last couple of years has centred around one, or both, of the themes "the problem of un-tested chemicals" and "the problem of un-assessed chemicals". The results of this study show that 14% of the EU High Production Volume Chemicals have data at the level of the base-set, 65% have less than base-set and 21% have no data. This indicates that there is more data publicly available than most previous studies have shown. However, it also shows that there are still considerable data gaps.

1. Introduction

There are vast amount of chemicals existing in the world. The Chemical Abstracts Service has attributed a Chemical Abstracts Service Registry Number (CAS RN) to approximately 16 million chemical substances [1]. Substances are usually entered into the CAS registry if they have been referred to in scientific literature. These chemicals can however exist in many forms: at the design stage, as a research chemical, as a pesticide, a pharmaceutical or as an industrial chemical. In determining the need for chemical inherent data for chemicals in general, in particular the need for toxicological and eco-toxicological data, it is important to realise that a chemical can only pose a risk to man or the environment if there is exposure. Generally, therefore, the more exposure of humans or the environment to a chemical, the more data is needed in order to determine to what extent the potential risk posed by the chemical really is.

The concern regarding the potential risks of chemicals and in particular existing chemicals, was already a policy priority in the late 1980's. The Council of the European Communities, in

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approving the Fourth Community Action Programme on the Environment (1987-1992), stated that one of the priority areas was the evaluation of the risks to the environment and human health posed by chemical substances [2]. This Action Programme underlined the need for a legislative instrument, which would provide a comprehensive structure for the evaluation of the risks posed by "existing" chemicals. In particular, the Action Programme stated that such a legislative instrument "will establish a procedure for treating priority lists of chemicals for immediate attention, as well as setting out the means for gathering information, requiring testing and evaluating the risks to people and the environment". Consequently, the European Commission proposed a series of legal instruments which were aimed at meeting the objectives outlined in the Action Programme.

In the Organisation for Economic Co-operation and Development (OECD), the importance of the work carried out on "existing" chemicals had already been recognised with the 1987 Decision-Recommendation of the OECD Council on the Systematic Investigation of Existing Chemicals [3]. This OECD Act stated that "Member Countries should establish or strengthen national programmes to systematically investigate existing chemicals". In 1988 the OECD launched an extensive programme on "existing" chemicals, an area in which some EC Member States were already active.

In the last two years the interest in and the concern for the potential risks posed by chemicals to man and the environment has increased, both by the general public and by policy makers (e.g. [4-5]. This interest has to some extent been influenced by reports regarding the lack of toxicological data on a large number of chemicals which are deemed to be on the market (e.g. [6-10]). It has also been confounded by new studies on potential long term effects to man and the environment, resulting from exposure to low concentrations of chemicals. This concern has, for example, been expressed in the recent studies relating to the potential effects of endocrine disrupting chemicals (e.g., [11-13]).

This report is intended to present a contribution to the discussion on existing chemicals by presenting the results of a comprehensive investigation into the public availability of information relevant to the hazard assessment and the risk assessment of existing chemicals. This report attempts to

- present an overview of the amount of publicly available data in order to provide information to qualify and to balance the discussions regarding the issues of “un-tested chemicals” (also called “toxic ignorance” [10]) and “un-assessed chemicals”;
- provide a clear, concise and well defined starting point for developing hazard and risk assessments by giving an overview of available data.

The information forming the basis for this report is also publicly available through the Internet[2].

2. The Existing Chemicals Regulation

In order to establish a systematic review of all new chemicals which are to be placed on the EU internal market, it was necessary to establish an inventory of all chemicals already on the market. The European Inventory of Existing Commercial Chemical Substances (EINECS) is this inventory and contains 100,195 chemical substances [14].

EINECS was drawn up by the European Commission in application of Article 13 of Directive 67/548 [15], as amended by Directive 79/831 [16], and in accordance with the detailed

[2] Internet Address: http://ecb.ei.jrc.it/.

provisions of Commission Decision 81/437. It lists and defines those chemical substances which were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. In terms of Article 1(4) of the amended Directive 67/548, these are substances to which the pre-marketing notification provisions of the Directive do not apply.

EINECS includes a large variety of chemical substances, for example (cf. [17-19]):

- industrial chemicals;
- substances produced from natural products by chemical modification or purification, such as metals, minerals, cement, refined oil and gas and their products including pitch;
- substances produced from animals and plants, such as lanolin, turpentine, rosin oil and resin acids, except where they are used solely in foodstuffs;
- food additives;
- ingredients or active substances of pesticides, medicaments, such as aspirin and paracetamol, and cosmetic products;
- monomers;
- natural polymers, including natural rubber and starch ;
- some waste and by-products, including some by-products of processed coal, such as coke and coal tar pitch.

EINECS does not include

- synthetic polymers (these are registered in EINECS under their building blocks, monomers);
- impurities as such, although some may be on EINECS in their own right;
- intentional mixtures;
- medical products, cosmetic products and pesticide products as intentional mixtures;
- food, feedstuffs;
- alloys, such as stainless steel, but includes most individual components of alloys;
- most naturally occurring raw materials, including coal and most ores.

All substances not on the EINECS are required by the 6th and the 7th Amendments to Directive 67/548 [16,21] to be notified and assessed prior to receiving permission to be marketed. In order to set up a similar system for assessing the chemicals listed in the EINECS, the Council, as a result of the Fourth Community Action Programme and based on the experiences gained in the OECD programme, adopted Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances on 23 March 1993 [22]. The Regulation, generally known as the "Existing Substances Regulation", entered into force 60 days after its publication in the Official Journal of the EC, on 4 June 1993. It is based on Article 100A of the Treaty of Rome [23] and is therefore based on the principle of maintaining the functioning of the internal market, while maintaining a high level of protection for man and the environment.

Regulation 793/93 aims at the protection both of man from exposure to dangerous substances via all possible exposure routes and of all the compartments of the environment. "Man" comprises in this context "workers, consumers and man exposed via the environment". The basic principle of the Regulation is that controls on hazardous chemicals should be based on an assessment of the actual or potential risks to human health and the environment, rather than the hazardous properties of the substance alone.

The aim and the scope of the Regulation, as defined in Article 1, is

1. the collection, circulation and ***accessibility*** of information on existing substances;
2. the evaluation and control of the risks of existing substances to man (…) and to the

environment (…).

Therefore, in 1993, it was already seen that accessibility and making data available on existing chemicals were high priorities.

The Regulation introduces a four step procedure to achieve it's aim, namely

- the collection of data on "existing" substances produced in or imported into the Community;
- the preparation of lists of priority substances for which the need for assessment is greatest;
- the assessment of risks; and,
- the identification of any measures needed to control those risks.

The obligation to submit data to the Commission under the data collection step lies with the producers and importers of the existing chemical. The data collection process is divided into three separate data collection phases.

PHASE I: Collection of information for those substances with a production or import volume in excess of 1000 tonnes/year which are included in Annex I of the Regulation. Annex I was produced as a pragmatic list of High Production Volume Chemicals (HPVCs) which were expected, but not known, to be HPVCs. For these substances, a complete summary data-set of all available information had to be submitted by manufacturers or importers over a 12-month period, ending on June 4, 1994.

PHASE II: Collection of information for all other substances of a production or import volume in excess of 1000 tonnes/year, which do not appear in Annex I. For these substances a complete summary data-set of all available information had to be submitted by manufacturers or importers over a 24-month period, ending on June 4, 1995.

PHASE III: Collection of information for substances of a production or import volume between 10 and 1000 tonnes/year (Low Production Volume Chemicals (LPVCs)). For these substances a limited data-set had to be submitted by manufacturers or importers within a period of 24 months, starting between June 4, 1996 and June 4, 1998.

Approximately 70 "existing" substances - ranging from Vitamin C and castor oil to limestone, nitrogen and carbon dioxide - do not require reporting because it is generally supposed that there are no risks associated with them. They are listed in Annex II to the Regulation. The Community may decide though, at a future date, to request information to be reported on any of these substances, but this would only be done if there were valid reasons to believe that the substance presents a serious risk to people or the environment.

The data reporting from manufacturers and importers represents an important and necessary step as it gives a complete picture to the authorities of the Community market in HPVCs and LPVCs and the data base for these chemicals.

The data which is required to be submitted to the Commission on HPVCs includes:

- the name of the substance;
- produced and/or imported quantities;
- classification and labelling information under Directive 67/548;
- reasonably foreseeable uses;

Furthermore, the Regulation requires that available data in the following areas be submitted:

- physico-chemical properties;
- information related to chemical fate and pathways;
- toxicological and ecotoxicological properties.

Companies are obliged by the Regulation to make every reasonable effort to obtain information on HPV chemicals which they produce or import. In this phase of data reporting, chemical companies are allowed, when appropriate, to present jointly substance-related data, in order to avoid any duplication of work. Data-sets produced in this way are called consolidated data-sets.

For substances of lower volume - exceeding 10 tonnes/year but not greater than 1000 tonnes/year - a smaller information package is acceptable. The data to be submitted on these substances includes

- the name of the substance,
- produced and/or imported quantities,
- classification and labelling information under Directive 67/548,
- reasonably foreseeable uses.

The summary information regarding the properties of the substance, behaviour and effects do not require reporting for LPVCs. In a subsequent stage, on the basis of the experience gained with the HPV substances, it will be decided what other data are necessary on LPVCs for the priority setting.

3. The HEDSET and the IUCLID

For the data collection a special computer program was developed by the European Commission Services, the HEDSET software package (Harmonised Electronic Data-set) [24,25]. Industry is required to use the software for the compilation of the data-sets which they submit under the Regulation. It has been designed to run on standard PC's and is available in 9 of the official EU-languages. It is mainly glossary driven, which makes it possible to define a specific structure and to allow an automated translation from one language to another.

The goal of the development of the HEDSET software was (1) to make the data collection as efficient as possible using little or no paper, (2) to provide an easy to use data-entry-screen system which allows for the entering of the required data and (3) to have the software program run on a standard PC, available even in smaller companies. The HEDSET software presents a choice e.g. test species or test methods, from a list of values, appearing in the appropriate language. An explanatory note accompanies the software as a guide on how to compile the data. After having completed the data-set the export function creates an export-file in the HEDSET data exchange format. This file can be imported into other HEDSET installations for data exchange.

The data is sent on a diskette or a CD ROM to the Security Office of the Joint Research Centre in Ispra, Italy and then forwarded to the ECB (European Chemicals Bureau) for data processing, storage and eventual further distribution. Here all HEDSET export files are loaded onto the database IUCLID (the International Uniform ChemicaL Information Database). The IUCLID database management software was developed in parallel with HEDSET by the European Commission Services. This database is the basic tool for the priority setting and risk assessment steps under the Regulation.

The goal of the development distribution of the IUCLID was to develop a database management software which would enable the European Commission Services, the Member States Authorities, Industry and other organisations to handle, organise, exchange and use the

enormous amount of data collected under the Regulation. The European Commission Services developed the database system with the following requirements in mind:

(1) it should hold all data submitted by Industry;
(2) it should allow interface programs to query the database for specific properties in the standard SQL-Retrieval language;
(3) it should allow data exchange between several installations;
(4) it should be able to create reports on the substances;
(5) it should be able to run in different hardware environments under the most common operating systems.

These features form the basis for the efficient implementation of the data collection process under the Regulation. IUCLID is divided into a number of chapters and sub-chapters. Tables 1 and 2 give an overview of the type of information collected in the IUCLID, ordered according to the IUCLID structure.

TABLE 1. IUCLID chapters and sub-chapters: Producer Related Part (Chapter 1)

Chapter	Chapter Description	Availability
1	**General Information**	
1.1*	General Substance Information	99.63%
1.2	Synonyms	94.20%
1.3*	Impurities	71.85%
1.4*	Additives	45.40%
1.5*	Quantity	100.00%
1.6.1*	Labelling	97.93%
1.6.2*	Classification	97.36%
1.7*	Use Pattern	99.59%
1.8	Occupational Exposure Limit Value	76.15%
1.9*	Source of Exposure	67.14%
1.10	Water Pollution	41.74%
1.11	Major Accident Hazards	33.59%
1.12	Air Pollution	25.72%
1.13*	Additional Remarks	55.01%

Parts of the information in the '*' marked sub-chapters are currently regarded as confidential, but disclosure may be done in the future.

TABLE 2. IUCLID chapters and sub-chapters: Substance Related Part (Chapter 2 - 5)

Chapter	Chapter Description	Availability
2	**Physico-chemical Data**	
2.1	Melting Point	75.46%
2.2	Boiling Point	68.76%
2.3	Density	84.54%
2.4	Vapour Pressure	61.14%
2.5	Partition Coefficient	58.38%
2.6	Water Solubility	76.23%
2.7	Flash Point	65.56%
2.8	Auto Flammability	41.38%
2.9	Flammability	40.37%
2.10	Explosive Properties	44.83%
2.11	Oxidizing Properties	27.42%
2.12	Additional Remarks	51.03%

3	**Environmental Fate and Pathways**	
3.1.1	Photodegradation	47.59%
3.1.2	Stability in Water	40.81%
3.1.3	Stability in Soil	23.16%
3.2	Monitoring Data (Environment)	22.88%
3.3.1	Transport between Environ. Compart.	25.48%
3.3.2	Distribution	31.24%
3.4	Mode of Degradation in Actual Use	25.52%
3.5	Biodegradation	60.57%
3.6	BOD5, COD or BOD5/COD Ratio	26.29%
3.7	Bioaccumulation	29.94%
3.8	Additional Remarks	25.23%
4	**Ecotoxicity**	
4.1	Acute/Prolonged Toxicity to Fish	67.95%
4.2	Acute Tox. to Aquatic Invertebrates	54.65%
4.3	Toxicity to Aquatic Plants e.g. Algae	45.56%
4.4	Tox. to Microorganisms e.g. Bacteria	56.92%
4.5.1	Chronic Toxicity to Fish	13.71%
4.5.2	Chronic Tox. to Aquatic Invertebrates	17.77%
4.6.1	Toxicity to Soil Dwelling Organisms	30.30%
4.6.2	Toxicity to Terrestrial Plants	31.76%
4.6.3	Tox. to Other Non-mamm. Terr. Species	32.70%
4.7	Biological Effects Monitoring	25.80%
4.8	Biotransformation and Kinetics	26.98%
4.9	Additional Remarks	35.82%
5	**Toxicity**	
5.1.1	Acute Oral Toxicity	76.96%
5.1.2	Acute Inhalation Toxicity	50.75%
5.1.3	Acute Dermal Toxicity	52.94%
5.1.4	Acute Toxicity, Other Routes	35.01%
5.2.1	Skin Irritation	73.27%
5.2.2	Eye Irritation	72.90%
5.3	Sensitisation	48.32%
5.4	Repeated Dose Toxicity	58.17%
5.5	Genetic Toxicity in Vitro	66.94%
5.6	Genetic Toxicity in Vivo	37.89%
5.7	Carcinogenicity	43.89%
5.8	Toxicity to Reproduction	26.00%
5.9	Developmental Toxicity/Teratogenicity	32.01%
5.10	Other Relevant Information	51.93%
5.11	Experience with Human Exposure	55.94%

The IUCLID structure enables the entry of any type of data which is relevant for the risk assessment. In particular the structure covers all the Annex VIIA elements of Directive 67/548 (the so-called “base-set”) and the OECD SIDS elements [26]. It is due to this capability, along with the easy data exchange possibilities, that the OECD has chosen to use the HEDSET as the data format for the OECD SIDS programme.

The major part of the data in IUCLID is non-confidential and is therefore in the public domain.

4. Methods

The reason for requiring industry (producers and importers of existing chemical substances) to submit all available summary information to the Commission Services for the HPVCs was to enable the Commission Services, in collaboration with the Member States, to select substances of highest priority for risk assessment and potential risk reduction. In order to base the priority setting step on sound information, industry was requested to perform a screening of the

available data and refrain from submitting data which was clearly invalid.
IUCLID therefore contains substantial amounts of information of varying quality. In order to definitively address the aim of this report, namely to evaluate the public availability of chemical data, a careful evaluation and validation of all the data submitted should be carried out. It is however recognised that the data evaluation and validation is a very labour intensive task. In fact it is this recognition which provided the stimulus to evaluate and control the risks of existing chemicals through the four step procedure, whereby the data evaluation and validation exercise makes up part of the risk assessment step. Clearly, therefore, it was not possible to validate the data for the purpose of this paper. In order still to get an impression of the public availability of data, it is necessary to make a number of assumptions regarding the submitted data and attempt to describe the resulting uncertainties.

The fundamental assumption made in this report is that industry has fulfilled its obligations responsibly by submitting valid data to the Commission Services on HEDSET. The methodology for determining if a specific data is "available" or not to the study, is therefore one of developing criteria for exclusion rather than inclusion of the data in the study. The criteria developed can be applied to exclude studies from the analysis and label them as being not valid. This assumption is in line with the instructions given to industry prior to compiling the HEDSETs and the requirement to submit a summary of the available information.

This assumption results in a "best case" evaluation of the data availability. Therefore, there will inevitably be data elements identified in this study as being "available", which, after validation, are determined to be "not valid" for the purpose of a hazard or risk assessment. This assumption could therefore, to a certain extent, work counter to the first main aim of this report (cf. Section 1). On the other hand, by categorising such data as "available", the user of the results of this paper, will evaluate this data carefully and may possibly, by taking an integrated and holistic approach, considering the weight of evidence, determine that there is no need to fill the data gap by a test result, thereby contributing to the second main aim of this report (cf. Section 1).

The criteria used in this study to exclude chemicals, i.e., to label them as "not available" are based on two observations:

- Users of the HEDSET programme have, by accident, entered a value in a sub-chapter of the programme and were not experienced enough to delete the data from the programme;
- Users of the HEDSET programme have entered in a free text field that no data is available for this substance.

In order to be able to eliminate these two cases from the study the following definitions were developed and implemented for the purpose of this study:

> Data in a specific sub-chapter of IUCLID is considered to be *"Not available"* for this study if (1) there is only free-text information and this information was less than 50 characters long and after manual screening the information indicated that there was no relevant information in the text or (2) if there is only one field in the structured part of the sub-chapter which has been filled in. All other data is considered to be *"Available"*.

This definition clearly does not safeguard against inclusion into the study of all invalid data (e.g., several typing errors in one sub-chapter), but does provide a simple definition which, based on a number of samples of the database, seems to be appropriate.

In the next sections an overview is given of the data availability in IUCLID using this definition, both for each individual end-point, i.e., each IUCLID sub-chapter and for combinations of end-points. In order to put the results of these studies into perspective, realising that the above definition is biased towards providing the "best case" situation, information has been included describing the "worst case" situation, using a very restrictive definition of available data.

As described in Section 2, EINECS contains a large number of entries, which, using a narrow definition, would not be considered as being chemicals. Six classes of such EINECS substances are of particular interest for this study, namely:

- Discrete organic chemicals;
- Mixtures of discrete organic chemicals;
- Organo-metallic compounds and mixtures;
- Petroleum and coal based substances;
- Inorganic compounds (incl. salts);
- UVCBs (Unknown or Variable composition, Complex reaction products or Biological material).

Many substances in the three last substance classes can not be tested with conventional test systems, due to either the complex and possibly variable composition of the substances or the difficulty in conducting a test for the particular chemical at all. This is also partially true for the second class. Therefore, in order for the conclusions of this study to be drawn in an informed fashion, a number of the statistics calculated have been sub-divided according to these substance groups. The composition of the EU HPVC list according to these classes is given in Table 3 (cf. [27]).

TABLE 3. EU HPVC List Composition

Chemical Class	Abbreviation	Number Chemicals
Inorganic	Inorganic	345
Coal and Petroleum based	Petroleum	416
UVCBs	UVCB	280
Discrete Organic	Organic (Sin)	1166
Mixtures of Discretes	Organic (Mix)	224
Organo-metallic	Organic (Met)	34
Total		2465

For simplicity of representation, a number of the results given in the next sections use the IUCLID sub-chapter number (cf. Tables 1 and 2) as the description of the end-point considered, rather than the full end-point name.

The basis of this study was the data available in IUCLID as of December, 1998.

5. Availability of End-point Data

In a first step to determine the data availability in IUCLID, an analysis was carried out regarding the number of chemicals having available data for each end-point (i.e., sub-chapter) in IUCLID. The complete results of this analysis are given in Tables 1 and 2 with a more detailed description in the Annex to this paper. In this section an extract of the results from the Annex has been made regarding specific selected end-points which are mandatory in either the EU or the OECD existing chemicals programmes.

The following table summarises the number of substances which have available data using the definition (IUCLID Def.s) given in Section 4. In order to put these results in perspective the table also includes the results of a data availability search made using the more stringent rules outlined in [28,29]. This is referred to as the EURAM Def.s. These rules generally require numeric values and a number of constraints on test conditions and test methods.

TABLE 4. IUCLID data availability for selected sub-chapters

		IUCLID Def.s		EURAM Def.s	
Environmental Fate					
3.1.1	Photodegradation	1,173	47.59%		
3.1.2	Stability in Water	1,006	40.81%		
3.1.3	Stability in Soil	571	23.16%		
3.5	Biodegradation	1,493	60.57%	827	33.55%
3.7	Bioaccumulation	738	29.94%	366	14.85%
Ecotoxicity					
4.1	Acute/Prolonged Toxicity to Fish	1,675	67.95%	1,286	52.17%
4.2	Acute Tox. to Aquatic Invertebrates	1,347	54.65%	1,083	43.94%
4.3	Toxicity to Aquatic Plants e.g. Algae	1,123	45.56%	765	31.03%
4.4	Tox. to Microorganisms e.g. Bacteria	1,403	56.92%	645	26.17%
4.5.1	Chronic Toxicity to Fish	338	13.71%	266	10.79%
4.5.2	Chronic Tox. to Aquatic Invertebrates	438	17.77%	545	22.11%
Acute Toxicity					
5.1.1	Acute Oral Toxicity	1,897	76.96%		
5.1.2	Acute Inhalation Toxicity	1,251	50.75%		
5.1.3	Acute Dermal Toxicity	1,305	52.94%		
5.2.1	Skin Irritation	1,806	73.27%		
5.2.2	Eye Irritation	1,797	72.90%		
5.3	Sensitization	1,191	48.32%		
Chronic Toxicity					
5.4	Repeated Dose Toxicity	1,434	58.17%	1,328	53.87%
Mutagenicity					
5.5	Genetic Toxicity in Vitro	1,650	66.94%	1,506	61.10%
5.6	Genetic Toxicity in Vivo	934	37.89%	380	15.42%
Developmental / Reproductive Toxicity					
5.8	Toxicity to Reproduction	641	26.00%		
5.9	Developmental Toxicity/Teratogenicity	789	32.01%		

NOTE: For the purpose of this study, "Chronic Toxicity", covers sub-acute, sub-chronic and chronic studies. The Annex VIIA equivalent would be a 28-day repeat dose study.

The EURAM Def.s data availability densities can be taken as the absolute minimum densities. The values in Table 4 represent an update to the data availability results given in [7]. The EURAM Def.s for biodegradation assume for example that the glossary field for "ready", "inherent" or "non degradable" has been filled in. As these result values are directly related to the test systems, namely the set of OECD test guidelines, then for most of the non standard test systems, e.g. the older tests, this glossary has not been filled in by industry. Industry has given a description of the test results in the remark fields. The results reported in the remark fields can though often be translated into one of the three glossaries, by an expert.

The EURAM Def.s are also very selective regarding the Ecotoxicity data. Table 5 summaries the criteria for determining if data is available for the EURAM. It follows for example that short term LC_0 and a long term EC_{50} are not counted as available for the EURAM.

TABLE 5. EURAM Definitions for Aquatic Toxicity

Standard end-point	Allowed Duration Range		Allowed Range for $L(E)C_X$	
	Lower limit	Upper limit	Lower limit	Upper limit
96 hour LC_{50} to Fish	48 hour	∞	10	50
48 hour EC_{50} to Daphnia	24 hour	∞	10	50
72 hour EC_{50} to Algae	48 hour	∞	10	50
28 day NOEC to Fish	14 day	∞	0	10
14 day NOEC to Daphnia	14 day	∞	0	10
72 hour NOEC to Algae	24 hour	∞	0	10

A closer analysis of the eco-toxicity results show that only 6 substances have a chronic fish study, but no acute fish test available. For daphnia there are only 12 substances with this data pattern.

There are only 6 substances with rodent acute toxicity test results via the inhalation and dermal routes and not via the oral route. For mutagenicity there are only 17 substances having in-vivo data with out having any in-vitro data. Utilising the stringent selection criteria used for mutagenicity in the EURAM (cf. [29]), where only selected test methods, covering certain gene-mutation tests, somatic cell tests and germ cell test systems are used, we find 82 substances unambiguously in-vitro positive, 111 in-vivo positive, 925 in-vitro negatives and 203 in-vivo negatives.

Another measure for data availability are the R-phrases submitted by industry for all HPVCs. Following Directive 67/548, all producers and importers are obliged to either classify and label a substance according to Annex I of the said Directive or, if it is not listed, to provide a provisional classification and labelling. Both types must be submitted to the Commission Services under the Regulation. Over 97 percent of the substances have statements regarding the R-phrases. These statements can be either “not classified due to lack of data”, “not classified due to no dangerous properties”, “classified according to the Directive” or “provisionally classified’. This is an indication that industry as a whole does have an insight as to how well tested the chemicals are which they produce or import. The following two figures (Figure 1 and 7) give an overview of the number of R-phrases per substance and the number of substances per R-phrase.

FIGURE 1. Frequency Distribution of Number of R-phrases

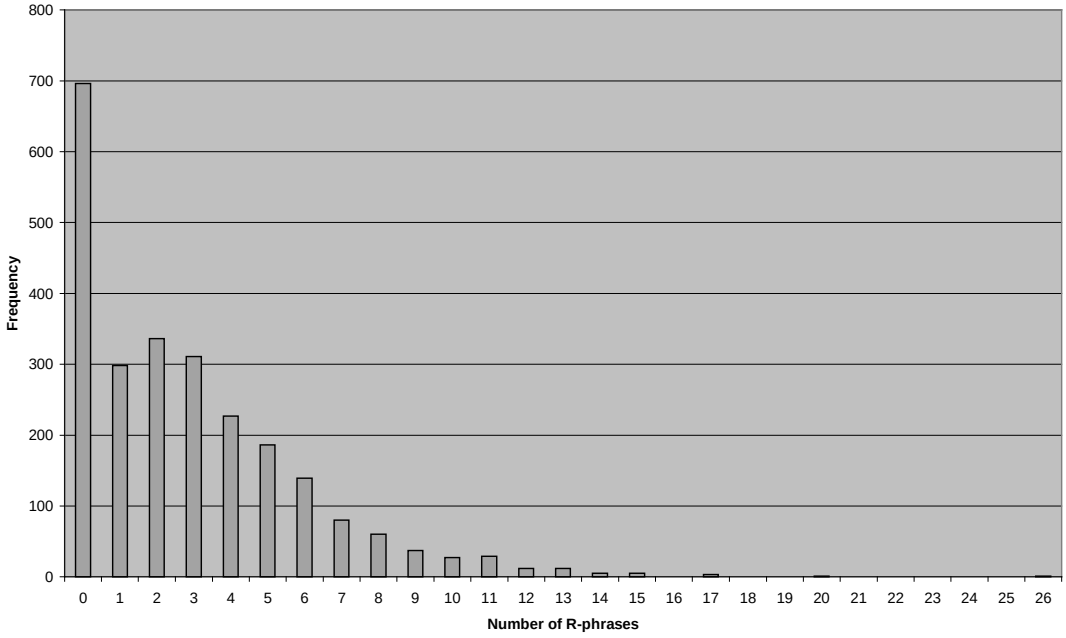
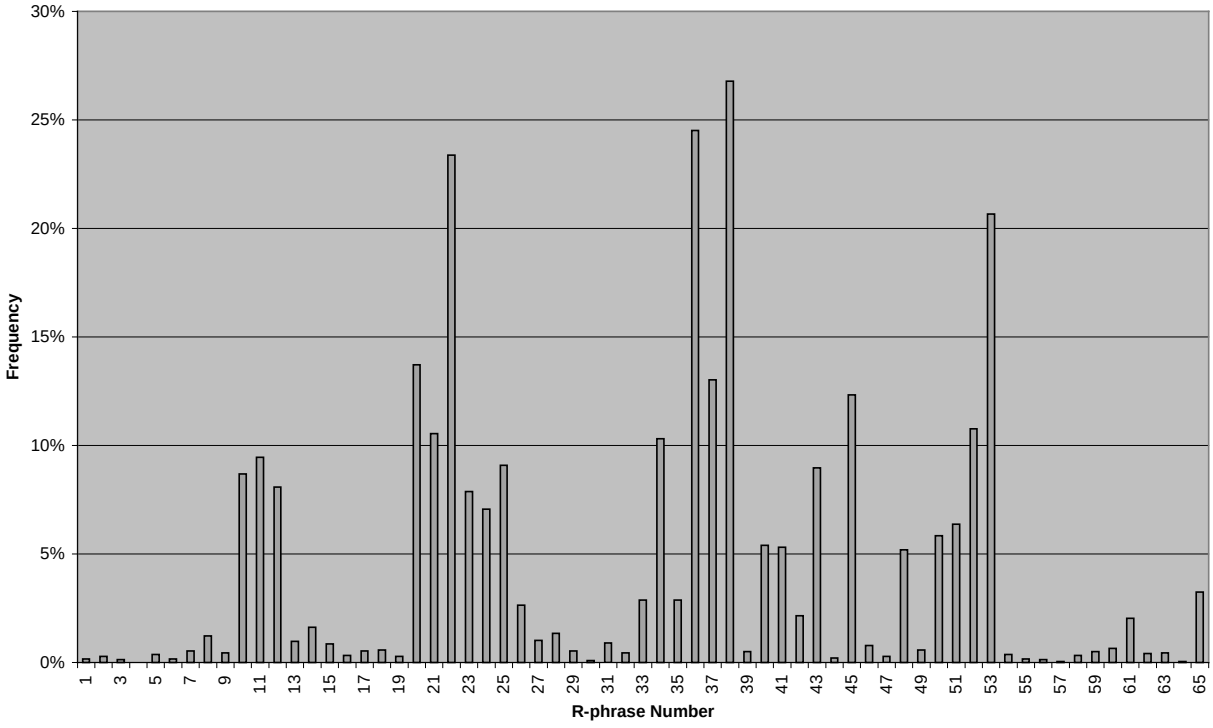


FIGURE 2. Frequency Distribution of allocated R-phrase



From Figure 2 and Table 4 it follows that for those R-phrases where there is a relatively high percentage of substances which satisfy the classification criteria, also have relatively large amounts of data available. This is seen in particular for acute toxic effects (R-phrases between 20 and 28), irritation effects (R-phrases between 36-38) and the environmental effects (R-phrases between 50 and 53).

6. Availability of Basic Data-sets

In this section the results of a more comprehensive analysis into the data availability is given. This analysis determines the amount of available data in IUCLID for each of the EU HPVC chemicals for a set of relevant end-points (i.e., sub-chapters). The relevance of an end-point in this context depends on the framework within which the data is to be used. As this varies within and outside the OECD Member Countries, a number of different definitions for what makes up a set of data been taken in this paper. Table 6 defines the data elements which must be available for the specific data-set to be defined as full. The Minimal Data-set corresponds to the definition used in [9] and [10], SIDS data-set is that of the OECD SIDS programme (cf. [26]) and the Annex VIIA data-set corresponds to the base-set defined in Annex VIIA of Directive 67/548 and used in the EU Existing Chemicals Programme under Regulation 793/93. A full data-set is one where all relevant data on all relevant end-points is available.

TABLE 6. Data-set Definitions

	Minimal	SIDS	Annex VIIA	Full
Envir. Fat/Bio		**Environment**		
Photodegradation				x
Stability in Water				x
Stability in Soil				x
Biodegradation	x	x	x	x
Bioaccumulation				x
Ecotox.		**Environment**		
Acute/Prolonged Toxicity to Fish	o	x[2]	x[2]	
Acute Tox. to Aquatic Invertebrates	o	x[2]	x[2]	
Toxicity to Aquatic Plants e.g. Algae	o	x	x	x
Tox. to Microorganisms e.g. Bacteria			x	x
Chronic Toxicity to Fish				x
Chronic Tox. to Aquatic Invertebrates				x
Acute Toxicity		**Human Health**		
Acute Oral Toxicity	o	x[1]	x[1]	x
Acute Inhalation Toxicity	o	x[1]	x[1]	x
Acute Dermal Toxicity	o	x[1]	x[1]	x
Skin Irritation			x	x
Eye Irritation			x	x
Sensitization			x	x
Chronic Toxicity		**Human Health**		
Repeated Dose Toxicity	x	x	x	x
Mutag.		**Human Health**		
Genetic Toxicity in Vitro	o	o	o	x
Genetic Toxicity in Vivo	o	o	o	x
Dev/Repr.		**Human Health**		
Toxicity to Reproduction	o	o	o	x
Developmental Toxicity/Teratogenicity	o	o	o	x

x = must be available; o = one of the data elements in the group must be available

[1]Any two of the three data elements

[2]If chronic data is available, then the acute need not be available

Table 6 groups the fate and (eco-) toxicity data into six groups of end-points, analogous to [9]. The physico-chemical properties of the chemicals have not been included in the data-set definitions for a number of reasons,

- If the data is missing, it is relatively inexpensive to generate;
- If fate and effects data has been generated, then a number of physico-chemical properties must be known.

This grouping reflects to a large degree the data requirements for the SIDS and follows closely Annex VIIA. For mutagenicity and reproductive/developmental toxicity it was how ever not possible to implement the exact definitions of the dossiers in the data availability search programmes. The requirement for a full SIDS or a full Annex VIIA is that two (different) in-vitro systems be utilised, which could not easily be implemented in the search programmes without being too stringent. It therefore suffices for this data availability study that only one test result is available, in order for the chemical to fulfil the SIDS and the Annex VIIA for this end-point. For reproductive/developmental toxicity it is sufficient if only one study is performed, e.g., OECD 421. As this data has been entered by industry in both the IUCLID Chapters 5.8 and 5.9, data on this the end-point is available for this study if there is data in either of the two sub-chapters.

The results of the analysis of the availability in IUCLID of data on the 2465 EU HPVCs is given in Table 7.

TABLE 7. Availability of Data on EU HPVCs

Test Type	Full Dataset		Annex VIIA		SIDS Dataset		Minimal Dataset	
Envir. Fat/Bio	736	30%	1493	61%	1493	61%	1493	61%
Ecotox.	217	9%	888	36%	1033	42%	1778	72%
Acute Toxicity	716	29%	966	39%	1485	60%	1999	81%
Chronic Toxicity	1434	58%	1434	58%	1560	63%	1434	58%
Mutag.	917	37%	1667	68%	1667	68%	1667	68%
Dev/Repr.	504	20%	926	38%	1102	45%	1102	45%
Tests Per. 0	903	37%	525	21%	461	19%	373	15%
Tests Per. 1	472	19%	192	8%	185	8%	144	6%
Tests Per. 2	333	14%	282	11%	240	10%	143	6%
Tests Per. 3	355	14%	351	14%	345	14%	223	9%
Tests Per. 4	218	9%	366	15%	338	14%	402	16%
Tests Per. 5	100	4%	393	16%	390	16%	490	20%
Tests Per. 6	84	3%	356	14%	506	21%	690	28%
Environment	125	5%	770	31%	880	36%	1398	57%
Human Health	287	12%	554	22%	723	29%	816	33%
All Data	84	3%	356	14%	506	21%	690	28%

The first part of the table summarises the number of chemicals having a “full data-set” according to the definitions in Table 6 for each of the six end-point groups. Clearly, the more stringent the definition in Table 6, the less data is found to be available. The second part of Table 7 defines seven data availability categories, labelled “Test Per. X” (Test Performed for all of the end-points in X of the six end-point groups). For X between 0 and 6, the table shows the number of chemicals which have full data-sets for X of the 6 end-point groups defined in Table 6. The third part of the table gives the data availability for all the end-point groups relevant to the environment and relevant to human health (cf. Table 6) and finally also the

number of chemicals having all data as defined in Table 6.
Figure 3 below illustrates the results given in the second part of Table 7 and Figure 4 the results of the first part.

FIGURE 3. Distribution of Available Data

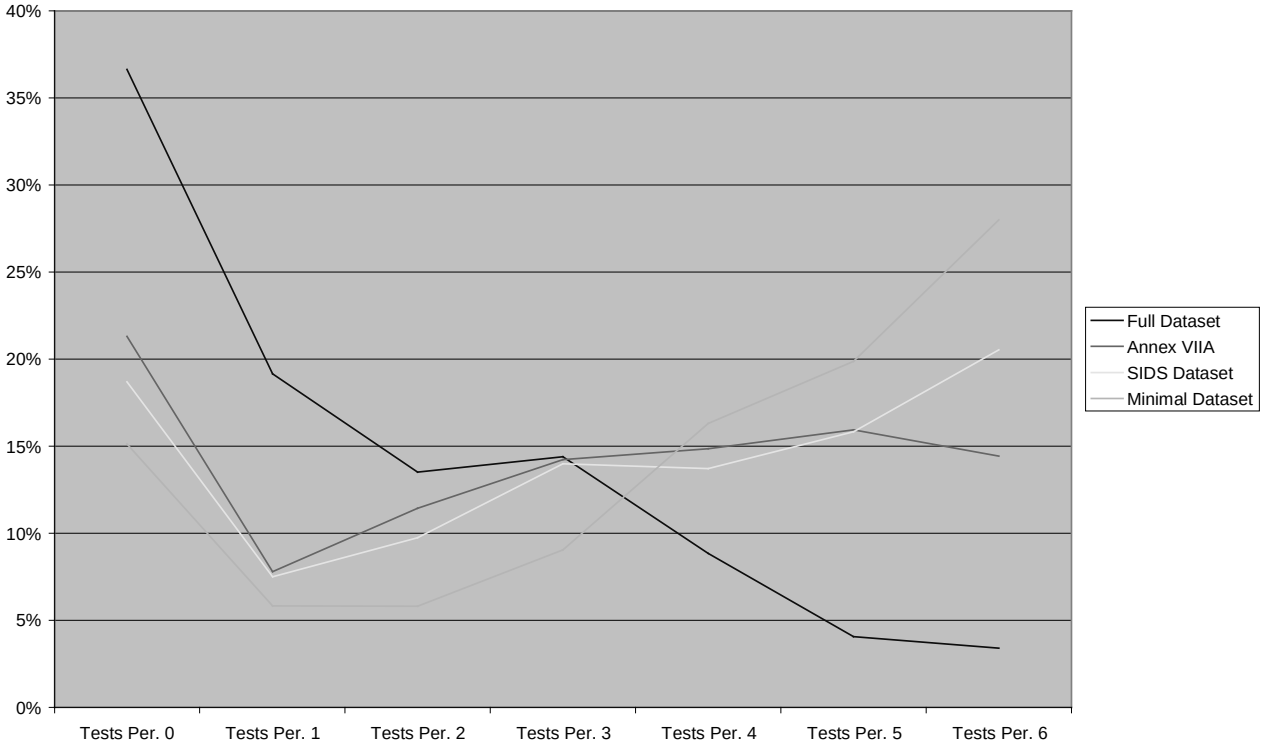
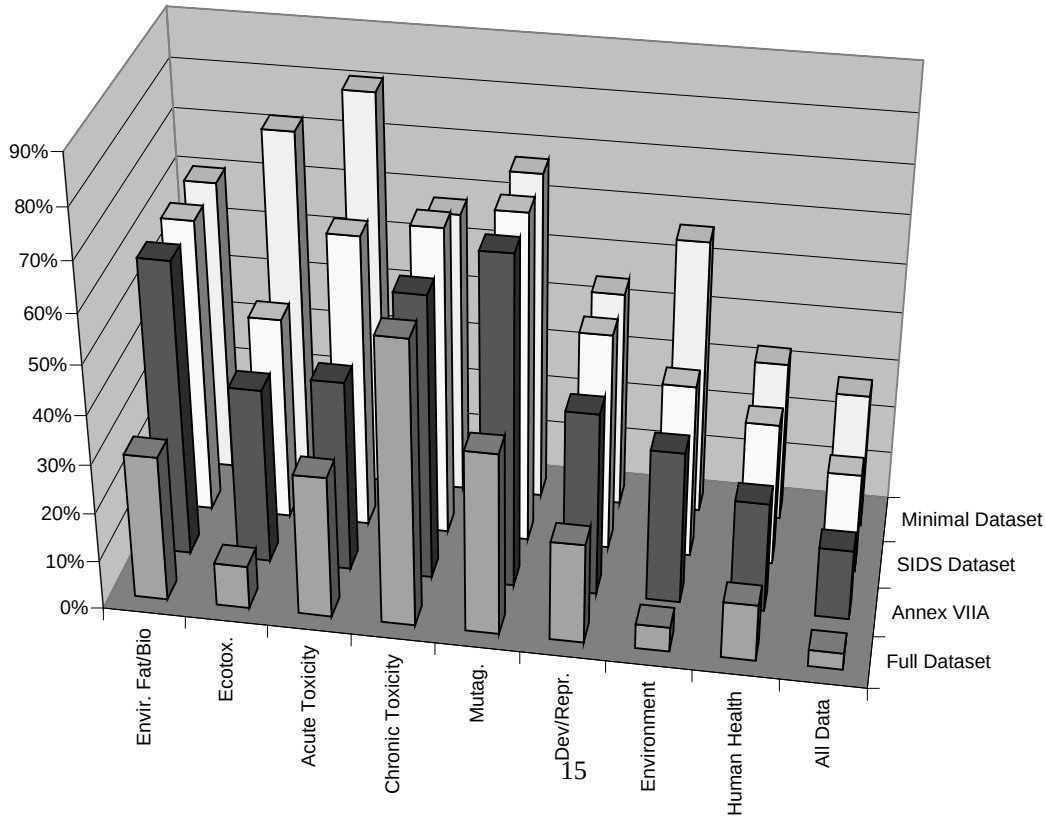


FIGURE 4. Distribution of Available Data According to Data Type



As mentioned in Section 4, it can be expected that the availability of data for a substance will depend on the type of substance under consideration. The following table gives the analogues results of Table 7 for the SIDS data-set (cf. Table 6) partitioned into the six substance type categories mentioned in Table 3.

TABLE 8. Availability of SIDS Data on EU HPVCs according to Substance Type

Test Type	Organic (Sin) (n=1166)		Organic (Mix) (n=224)		Organic (Met) (n=34)		In organic (n=345)		Petroleum (n=416)		UVCB (n=280)	
Envir. Fat/Bio	915	78%	148	66%	16	47%	124	36%	197	47%	93	33%
Ecotox.	624	54%	91	41%	14	41%	118	34%	139	33%	47	17%
Acute Toxicity	864	74%	115	51%	22	65%	165	48%	267	64%	52	19%
Chronic Toxicity	785	67%	101	45%	18	53%	164	48%	309	74%	57	20%
Mutag.	948	81%	139	62%	19	56%	188	54%	306	74%	67	24%
Dev/Repr.	553	47%	63	28%	11	32%	143	41%	123	30%	33	12%
Tests Per. 0	96	8%	34	15%	10	29%	86	25%	69	17%	166	59%
Tests Per. 1	71	6%	26	12%	0	0%	43	12%	20	5%	25	9%
Tests Per. 2	94	8%	31	14%	5	15%	52	15%	27	6%	31	11%
Tests Per. 3	135	12%	34	15%	3	9%	38	11%	121	29%	14	5%
Tests Per. 4	177	15%	48	21%	5	15%	39	11%	56	13%	13	5%
Tests Per. 5	241	21%	31	14%	5	15%	37	11%	58	14%	18	6%
Tests Per. 6	352	30%	20	9%	6	18%	50	14%	65	16%	13	5%
Environment	585	50%	83	37%	11	32%	73	21%	86	21%	42	15%
Human Health	470	40%	36	16%	8	24%	83	24%	109	26%	17	6%
All Data	352	30%	20	9%	6	18%	50	14%	65	16%	13	5%

From the Table it follows that UVCBs have, as could be expected, hardly any data. Substances which are difficult to test, i.e., petroleum substances, inorganics and organo-metallics have little data. Mixtures of discrete organic chemicals also have less data than the discrete organic chemicals. The following table gives the results of a similar analysis as that resulting in Tables 7 and 8 for the substances on the ICCA List [30].

TABLE 9. Availability of SIDS Data on the ICCA List

Test Type	All (n=880)		Organic (Sin) (n=591)		Organic (Mix) (n=73)		Organic (Met) (n=15)		In organic (n=127)		Petroleum (n=21)		UVCB (n=53)	
Envir. Fat/Bio	641	73%	481	81%	51	70%	6	40%	57	45%	14	67%	32	60%
Ecotox.	429	49%	315	53%	32	44%	5	33%	50	39%	11	52%	16	30%
Acute Toxicity	594	68%	455	77%	34	47%	7	47%	67	53%	13	62%	18	34%
Chronic Toxicity	562	64%	415	70%	31	42%	5	33%	79	62%	11	52%	21	40%
Mutag.	671	76%	495	84%	44	60%	6	40%	90	71%	12	57%	24	45%
Dev/Repr.	370	42%	275	47%	14	19%	3	20%	60	47%	8	38%	10	19%
Tests Per. 0	90	10%	40	7%	10	14%	7	47%	15	12%	6	29%	12	23%
Tests Per. 1	50	6%	27	5%	7	10%	0	0%	8	6%	0	0%	8	15%
Tests Per. 2	106	12%	47	8%	15	21%	2	13%	27	21%	2	10%	13	25%
Tests Per. 3	110	13%	67	11%	12	16%	1	7%	22	17%	2	10%	6	11%
Tests Per. 4	158	18%	112	19%	16	22%	2	13%	21	17%	2	10%	5	9%
Tests Per. 5	153	17%	122	21%	9	12%	1	7%	13	10%	3	14%	5	9%
Tests Per. 6	213	24%	176	30%	4	5%	2	13%	21	17%	6	29%	4	8%
Environment	390	44%	303	51%	30	41%	4	27%	29	23%	10	48%	14	26%
Human Health	293	33%	235	40%	8	11%	2	13%	34	27%	8	38%	6	11%
All Data	213	24%	176	30%	4	5%	2	13%	21	17%	6	29%	4	8%

On comparing Table 8 and 9 it becomes evident that the data availability of chemicals selected for the ICCA initiative is almost identical with that of all the EU HPVCs. This indicates that the substances selection for the ICCA initiative was not biased towards those substances which have more data. A similar analysis using the Annex VIIA definition as the basic set of data (cf. Table 6) results in the following table for the EU HPVCs:

TABLE 10. Availability of Annex VIIA Data on EU HPVCs according to Substance Type

Test Type	Organic (Sin) (n=1166)		Organic (Mix) (n=224)		Organic (Met) (n=34)		In organic (n=345)		Petroleum (n=416)		UVCB (n=280)	
Envir. Fat/Bio	915	78%	148	66%	16	47%	124	36%	197	47%	93	33%
Ecotox.	578	50%	75	33%	14	41%	100	29%	86	21%	35	13%
Acute Toxicity	549	47%	54	24%	15	44%	82	24%	227	55%	39	14%
Chronic Toxicity	785	67%	101	45%	18	53%	164	48%	309	74%	57	20%
Mutag.	948	81%	139	62%	19	56%	188	54%	306	74%	67	24%
Dev/Repr.	553	47%	63	28%	11	32%	143	41%	123	30%	33	12%
Tests Per. 0	120	10%	45	20%	10	29%	101	29%	78	19%	171	61%
Tests Per. 1	79	7%	24	11%	2	6%	45	13%	16	4%	26	9%
Tests Per. 2	121	10%	36	16%	4	12%	55	16%	37	9%	29	10%
Tests Per. 3	136	12%	48	21%	3	9%	32	9%	117	28%	15	5%
Tests Per. 4	213	18%	28	13%	6	18%	45	13%	62	15%	12	4%
Tests Per. 5	235	20%	30	13%	4	12%	32	9%	77	19%	15	5%
Tests Per. 6	262	22%	13	6%	5	15%	35	10%	29	7%	12	4%
Environment	547	47%	70	31%	11	32%	62	18%	48	12%	32	11%
Human Health	351	30%	24	11%	6	18%	56	16%	103	25%	14	5%
All Data	262	22%	13	6%	5	15%	35	10%	29	7%	12	4%

The EU list of marketed biocide active ingredients can be found in [31] (cf. [32]). The following table, which tabulates the data availability of the 244 EU HPVC biocide active ingredients, clearly shows that for this subset of EU HPVCs, considerably more data is available than is the case for all the HPVCs.

TABLE 11. Availability of Annex VIIA and SIDS Data on EU HPVC which are also Biocide Active Ingredients

Test Type	Annex VIIA		SIDS Dataset	
Envir. Fat/Bio	181	74%	181	74%
Ecotox.	145	59%	158	65%
Acute Toxicity	132	54%	192	79%
Chronic Toxicity	189	77%	189	77%
Mutag.	211	86%	211	86%
Dev/Repr.	168	69%	168	69%
Tests Per. 0	20	8%	16	7%
Tests Per. 1	12	5%	9	4%
Tests Per. 2	16	7%	16	7%
Tests Per. 3	13	5%	14	6%
Tests Per. 4	49	20%	34	14%
Tests Per. 5	57	23%	50	20%
Tests Per. 6	77	32%	105	43%
Environment	128	52%	138	57%
Human Health	108	44%	142	58%
All Data	77	32%	105	43%

7. Discussion

In [10] it was reported that, based on a random sample of 100 US HPVC, only 29% of the chemicals fulfilled the minimum data requirements (i.e., the SIDS) for health data. When in [9] the study was extended to include all the US HPVCs the figure was reported to be 8.5%. These numbers are in accordance with the original conclusions of a report from 1984, which stated that 22% of the US HPVCs had “minimal” toxicity data available [33]. The 100 substances selected in [10] were re-examined in [34], were the amount of publicly available data was determined to be 47%. The results of similar studies relating to the EU HPVCs (cf. [6-8]) report end-point specific values, which do not contradict the findings in the US. In comparing the figures from the US with those for the EU, it is important to note that the US HPVC list does not include petroleum substances, metals and UVCBs.

The results of this study show that there is more data publicly available than most previous studies have shown (e.g. [6-10]) and confirms to a certain extent the findings of [34], though the latter study was based on a limited sample of 100 chemicals. Table 7 shows that 28% of all EU HPVCs have some data relevant for the evaluation of the risk to man and the environment. These substances also have sufficient data to consider their EU classification and labelling for some of the main effects. 21% of the EU HPVCs have full SIDS and 29% fulfil the SIDS minimum data requirements for health.

There are however still considerable data gaps. From Table 7 it follows that only 3% of the EU HPVCs have a full data-set, including long term eco toxicity results, degradation behaviour in various environmental compartments and a complete mammalian toxicity profile (availability of carcinogenicity studies was not included in this report). A considerably larger amount of EU HPVCs, namely 15%, have no data at all. The SIDS dossier and the Annex VIIA dossier is completed for 21% and 14%, respectively, of all EU HPVCs. Some data is available in each of the six data categories for 29% of all chemicals. Turning these percentages into numbers of substances, this study shows that full SIDS data is available for 504 substances and a full Annex VIIA dossier for 356 substances of the 2465 EU HPVCs.

The contrary to this summary is though that 79% of all HPVCs lack data to fill a SIDS dossier and 86% to fill an Annex VIIA dossier. 71% of all EU HPVCs lack information in one of the six data areas defined in this study.

A partial explanation for the lack of data can be found when analysing the data availability for different substance classes. The UVCBs have, as can be expected, hardly any data. Substances which are more difficult to test or for which the test simply cannot be performed, e.g., petroleum and coal derived substances and inorganics have less data than the discrete organics. The study also shows that biocides have more data available than do the discrete organic compounds.

When considering the substances on the ICCA List, which have been chosen based on their widespread use with in OECD Member Countries, the data availability does not change. This indicates that there was no bias towards selecting substances with more data when ICCA developed their list.

8. Acknowledgements

The authors would like to thank the thousands of HEDSET and IUCLID users in the chemical producing and importing industries, who have compiled and submitted the HEDSET/IUCLID export files to the Commission Services. In doing so they have made one of the two main aims of the Regulation reality, namely, making information on existing chemicals publicly available.

The authors would also like to thank Guiseppe Aina, Lutz Erdmann, Christian Heidorn, Dorte Linde, Grazia Pellegrini, Kirsten Rasmussen and Rene Seynaeve, all of whom have, for one or more of the data collection phases, been part of the Existing Chemicals Team loading HEDSETs into IUCLID.

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GLOSSARY OF TERMS/ABBREVIATIONS IN ALPHABETICAL ORDER

CAS RN: Chemical Abstracts Service Registry Number attributed by the Chemical Abstracts Service to substances referred to at least once in the scientific literature.

EINECS: European Inventory of Existing Commercial Chemical Substances, deemed to be on the European Market between 1st January 1971 and 18th September 1981. The definitive list of 100,106 "existing" chemicals which in principle are governed by Council Regulation (EEC) 793/93. Closed list.

Existing Substances: Substances listed in EINECS (100,106 substances, closed list).

Hazard assessment: Is the composite of hazard identification and determination of the dose-response relationship.

Hazard identification: Identification of the adverse effects which a substance has an inherent capacity to cause.

HEDSET: Harmonised Electronic Data-set. This is the Commission Data Entry Programme which has to be used under Council Regulation (EEC) 793/93 to submit summary information on chemicals.

HPV chemicals: High Production Volume chemicals. Chemicals placed on the EU market in volumes exceeding 1000 tonnes per year per producer or importer.

IUCLID: International Uniform Chemical Information Database. This is the Commission database used to store and distribute the information collected under Council Regulation (EEC) 793/93.

LPV chemicals: Low Production Volume chemicals. Chemicals placed on the market in volumes between 10 tonnes and 1000 tonnes per year per producer or importer.

New Substances: Substances not listed on EINECS. These substances are in the "European List of Notified Chemical Substances" (ELINCS) (> 2100 substances, ever growing list) following notification to Competent Authorities of placing on the market.

Notification procedure for a new substance: Submission of a technical dossier to the Competent Authority of a Member State, containing information specified by the sixth amendment to Directive 67/548/EEC.

OECD: Organisation for Economic Co-operation and Development.

PHASE I, II, III: The systematic approach for the collection of information to be submitted by industry in a step-by-step procedure according to production or import volume. Phase I concerned all HPV chemicals, which are listed in Annex I of Council Reg. (EEC) 793/93. The reporting period for Phase I ended June 4, 1994. For Phase II all HPV chemicals, which are not listed in Annex I, had to be reported by June 4, 1995. For Phase III a reduced HEDSET (Chapter 1 only) for all LPV chemicals had to be submitted by June 4, 1998.

Priority Lists*:* Lists of substances prioritised for risk assessment owing to potential concerns for man and the environment and for which a comprehensive risk assessment should be carried out, as defined under Regulation (EC) 1488/94.

Risk Assessment: A process to determine the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation.

SIDS : Screening Information Data-set. This is the internationally accepted minimum data-set required for carrying out a risk assessment.

UVCB: Unknown or Variable composition, Complex reaction products or Biological material

Voluntary agreement: For the purpose of this Regulation, the concept of voluntary approaches by Industry as a substitute or complement to legislation. The agreement concerns a well-defined scope of application and normally includes a timetable for implementation.

Annex

CHAPTER 1 General Information

	1.1	1.2	1.3	1.4	1.5	1.6.1	1.6.2	1.7	1.8	1.9	1.10	1.11	1.12	1.13	Chapter
RECORDS	13,490	44,055	14,289	4,088	19,029	13,823	19,577	52,044	11,125	6,089	2,294	1,893	1,382	5,230	208,408
SUBS. WITH RELEVANT RECORDS	2,456 99.63%	2,322 94.20%	1,771 71.85%	1,119 45.40%	2,465 100.00%	2,414 97.93%	2,400 97.36%	2,455 99.59%	1,877 76.15%	1,655 67.14%	1,029 41.74%	828 33.59%	634 25.72%	1,356 55.01%	2,465 100.00%
SUBST. WITHOUT RELEVANT RECORDS	9	143	694	1,346	0	51	65	10	588	810	1,436	1,637	1,831	1,109	0

CHAPTER 2 Physico-chemical Data

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10	2.11	2.12	Chapter
RECORDS	5,615	5,899	7,277	6,083	5,271	5,829	4,528	2,735	2,399	2,632	1,245	6,732	56,245
SUBS. WITH RELEVANT RECORDS	1,860 75.46%	1,695 68.76%	2,084 84.54%	1,507 61.14%	1,439 58.38%	1,879 76.23%	1,616 65.56%	1,020 41.38%	995 40.37%	1,105 44.83%	676 27.42%	1,258 51.03%	2,175 88.24%
SUBST. WITHOUT RELEVANT RECORDS	605	770	381	958	1,026	586	849	1,445	1,470	1,360	1,789	1,207	290

CHAPTER 3 Environmental Fate and Pathways

	3.1.1	3.1.2	3.1.3	3.2	3.3.1	3.3.2	3.4	3.5	3.6	3.7	3.8	Chapter
RECORDS	5,567	3,591	2,155	5,501	2,101	2,746	2,192	10,156	1,486	2,636	2,859	40,990
SUBS. WITH RELEVANT RECORDS	1,173 47.59%	1,006 40.81%	571 23.16%	564 22.88%	628 25.48%	770 31.24%	629 25.52%	1,493 60.57%	648 26.29%	738 29.94%	622 25.23%	1,943 78.82%
SUBST. WITHOUT RELEVANT RECORDS	1,292	1,459	1,894	1,901	1,837	1,695	1,836	972	1,817	1,727	1,843	522

CHAPTER 4 Ecotoxicity

	4.1	4.2	4.3	4.4	4.5.1	4.5.2	4.6.1	4.6.2	4.6.3	4.7	4.8	4.9	Chapter
RECORDS	14,448	10,799	5,842	7,468	1,056	1,991	1,351	2,050	2,205	1,275	1,237	6,269	55,991
SUBS. WITH RELEVANT RECORDS	1,675 67.95%	1,347 54.65%	1,123 45.56%	1,403 56.92%	338 13.71%	438 17.77%	747 30.30%	783 31.76%	806 32.70%	636 25.80%	665 26.98%	883 35.82%	1,970 79.92%
SUBST. WITHOUT RELEVANT RECORDS	790	1,118	1,342	1,062	2,127	2,027	1,718	1,682	1,659	1,829	1,800	1,582	492

CHAPTER 5 Toxicity

	5.1.1	5.1.2	5.1.3	5.1.4	5.2.1	5.2.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10	5.11	Chapter
RECORDS	14,861	10,313	6,549	5,761	10,558	9,190	6,099	19,044	24,301	8,670	12,060	2,074	4,543	18,694	14,120	166,837
SUBS. WITH RELEVANT RECORDS	1,897 76.96%	1,251 50.75%	1,305 52.94%	863 35.01%	1,806 73.27%	1,797 72.90%	1,191 48.32%	1,434 58.17%	1,650 66.94%	934 37.89%	1,082 43.89%	641 26.00%	789 32.01%	1,280 51.93%	1,379 55.94%	2,131 86.45%
SUBST. WITHOUT RELEVANT RECORDS	568	1,214	1,160	1,602	659	668	1,274	1,031	815	1,531	1,383	1,824	1,676	1,185	1,086	334

Data Source : Existing-Chemicals European Chemicals Bureau HPV Chemicals from October 1998.