

IUCLID: An Information Management Tool for Existing Chemicals and Biocides[†]

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Received October 3, 2002

Because of the large number of chemicals to be risk assessed within the European Union, an electronic data reporting and management tool, IUCLID, was developed supporting all three steps of the risk assessment process, namely data collection, priority-setting, and risk assessment. This paper gives an overview of the IUCLID software, which has been updated and adapted to also be used for the notification phase of the Biocides Program of the European Commission.

INTRODUCTION

Achieving sustainable development in the chemicals sector is the main objective of the Commission's White Paper on a future chemicals strategy.¹ This objective is complex to reach and involves a balancing between the social and economic importance of the industry with the potential harmful impacts on environment and health from the industry and its products.

The EU (European Union) chemicals industry today accounts for 29% of the world's chemicals production with a value of €458 billion. It is the third largest manufacturing industry in Europe, generating €42 billion which is the largest trade surplus of all industrial sectors.² The fact that approximately 30 000 chemicals are used in quantities above 1 tonne/year/manufacturer¹ in the EU illustrates the breadth of the industry.

The use of chemicals in our society is thus widespread, but it is not well controlled. Chemicals are used in almost all manufacturing industries, generating products which are used in almost all trade sectors and by all consumers. Therefore there is considerable potential for environmental or health impairment due to exposure from chemicals throughout their life cycle.

Thus, the strategy for implementing an environmentally sound management of toxic chemicals as outlined in Chapter 19 of Agenda 21, which is the final declaration of the "Earth Summit", the United Nations Conference on Environment and Development (UNCED) in 1992 in Rio de Janeiro³, has been a basis for further European development.

Initiative was taken, and later reinforced by the White Paper, to collect data on chemicals for their risk assessment

leading to, where necessary, risk reduction. For the vast number of chemicals to be assessed, an electronic data reporting and management tool has been developed supporting all three steps (namely data collection, priority-setting and risk assessment) of the risk assessment process. The tool is the International Uniform Chemical Information Database, IUCLID. An earlier article⁴ describes the initial development of the system. The developments and current status are described in the following.

Why it is necessary to submit IUCLID data sets instead of word-processed documents?

The authors were asked this question by risk assessors who are used to working with word processors:

- IUCLID keeps all data together in one system. Studies not considered at the moment when the report is written can become important later. When additional studies become available from industry and are loaded up, the used modelling tools can be applied immediately, a new report can be printed and discussed if the outcome of the risk assessment would change.
- Alerting systems can be easily implemented. For example, if a certain threshold in production volume were exceeded that would change an environmental concentration to a value of concern, an 'alarm bell' would inform the assessor.
- All documents related to the substance or chemical category in question are kept in one system and are exported only when needed. There is no need to set up a file system for different versions of documents. Finalised risk assessment reports can be stored together with the data they are based on.
- Standard flags and user-defined criteria for individual records allow safe management of confidential data and support the evaluation process.
- Harmonisation: IUCLID provides a common frame for the work with different governmental, non-governmental and industrial institutions, even with different cultural backgrounds. Data are exchanged and reports are generated in a well-defined format.

A DATA MANAGEMENT SYSTEM FOR "EXISTING" CHEMICALS – IUCLID

Enhancement of a Proven System versus Development of a New One. Since 1993 the Commission has operated a data management system for existing chemicals, called IUCLID, which is based on a previous system from the 1980s developed by and for major European chemical companies. It has been continuously upgraded and adapted through a working group with experts from chemical companies and from the competent authorities for environment and health in the Member States; this working group is called the "IUCLID Expert Panel". The panel is chaired by the Commission's European Chemicals Bureau, the institution responsible for the technical and scientific work under European legislation on chemicals.

As required by the Existing Substances Regulation,⁵ data must be reported directly by the companies to the Commis-

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[†] Abbreviations: CEFIC, European Chemical Industry Council; ECB, European Chemicals Bureau; EU, European Union; EUR-OP, the European Commission's Publication Office; HEDSET, Harmonized Electronic Data SET; HPVC, High Production Volume Chemical; HPV, High Production Volume; ICCA, International Council of Chemical Associations; IUCLID, International Uniform Chemical Information Database; LPVC, Low Production Volume Chemicals; MITI, Ministry of International Trade and Industry (Japan); OECD, Organization for Economic Cooperation and Development; SQL, Structured Query Language; U.S. EPA, United States of America Environmental Protection Agency; WWW, World Wide Web.

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sion in electronic form. The Regulation obliged Industry to submit to the European Chemicals Bureau all readily available data on "High Production Volume Chemicals" [High Production Volume Chemicals (HPVCs) are defined as being placed on the EU market in volumes greater than 1000 tonnes/year/company.] in phase one and two and, in a third phase, data on "Low Production Volume Chemicals". [Low Production Volume Chemicals (LPVCs) are defined as being placed on the EU market in volumes between 10 and 999 tonnes/year /company.]

Ideally, IUCLID would have been used as the data reporting software and thus installed in all involved companies and public institutions. However, a complex database system requires an underlying powerful database management system, which was and still is for IUCLID based on Oracle. Furthermore, at that time, when powerful computers were still expensive and therefore not common, the Commission could not request approximately 2000 companies to purchase both propriety data management software and possibly upgrade to an adequate computer to operate IUCLID. A simple, license free data entry tool was therefore developed, which could generate data files for loading up to IUCLID. This tool was called HEDSET (Harmonized Electronic Data SET), 2500 copies of which were distributed.

The data structure and the main functionality of the IUCLID system and the HEDSET tool were described in an earlier article,⁴ which gives the detailed background for development of the IUCLID database for "Existing Substances" and the state-of-the-art in 1996. (For reprints see reference and contact authors.)

Since 1996 the IUCLID database has undergone a continuous process of development and enhancements to address the further needs and useful functionalities that have been identified by the users. Furthermore, the rapid progress in hardware and software development has facilitated the improvement of the user interface and the database as such.

From the European to the International Arena. A major breakthrough was the acceptance of the IUCLID format by the "OECD Task force on existing chemicals" in 1999: to use IUCLID as the data management tool under the OECD chemicals program. The original EU-IUCLID working group was enhanced with participants from the non-EU OECD member countries; the "IUCLID Expert Panel" now defines the future developments within the work of the OECD.

Robust study summaries⁶ [Robust study summaries are intended to provide sufficiently detailed information to allow a technically qualified person to make an independent assessment minimizing the need to go back to the full study report (see reference).] are being prepared with IUCLID by sponsor countries for the OECD and Industry under their ICCA (International Council of Chemical Associations) initiative,⁷ which opened the doors of the Environmental Protection Agency in the United States (U.S.-EPA) or the Japanese Environment Ministry (MITI) for data sets in the IUCLID format. Numerous IUCLID reports can be found on the EPA's Web site [<http://www.epa.gov/opptintr/chemrtk>] as substance reports under the "Chemical Right to Know Initiative's HPV Challenge Program".⁸

In 2000 new legislation on chemical safety led to major modifications of IUCLID, which is described in the following.

CAN SERVE FOR OTHER CHEMICALS AS WELL – IUCLID FOR "BIOCIDES"

The Scope: Harmonize Reporting and Management Tools. In addition to the legislation on general industrial chemicals, the Community has set up special legislation addressing particular uses of chemicals, among others, the Commission Directive 91/414/EEC,⁹ concerning the placing of plant protection products (agricultural pesticides) on the market. For pesticides registration the use of electronic tools is currently limited to submission of test reports as document files.¹⁰

The placing on the market of "nonagricultural pesticides", the "Biocides", is regulated by Directive 98/8/EC, which is commonly referred to as the "Biocides Directive".¹¹

Within the frame of this Directive, the first review regulation has been published, Regulation (EC) No. 1896/2000.¹² It has the dual purpose of establishing a list of all existing active substances used as biocides and to establish priority lists for their review through a prioritization process based on substance data. Notification regarding substances which will be supported by Industry with the intent of keeping them on the market must be made under the Biocides Directive.

Since a large number of active ingredients in biocides have been reported as industrial chemicals under the Existing Substances Regulation,⁵ and given that Industry and Authorities have built up a solid experience with IUCLID, it was found reasonable to use the IUCLID software for the notification process for biocides as well.

New Chapters and Functions To Make It Happen. The biocides work area in the European Chemicals Bureau established its own IUCLID steering group with participants from the Member States and Industry in order to define what is needed.

A comparison was carried out to identify those chapters in IUCLID which could remain unchanged and would "only" require guidance for the users and the areas which would require additional chapters, subchapters, and test guidelines in the glossaries.

The data structure of IUCLID 4.0 has been redesigned and reorganized from earlier versions, and the data set is now divided into 10 main chapters (identified by unique chapter numbers) each of which has several subchapters. A chapter is defined as a set of information that covers a specific subject (e.g. physicochemical data (Chapter 2) or toxicity (Chapter 5)). Each chapter has a number of subchapters that describe the specific properties within the subject (e.g., melting point (Chapter 2.1)). There are a total of 107 subchapters (one chapter per property class/end point). A complete list can be found on the Web site of the European Chemicals Bureau [<http://ecb.jrc.it>].

These changes have made the system far more complex than the earlier versions since they were for existing substances only and mainly for EU regulatory purposes. IUCLID is now being used for different regulatory programs for existing chemicals: the EU Existing Chemicals Program, the OECD program, the ICCA initiative, and the U.S.-EPA Challenge program. The new "biocides version" of IUCLID v.4.0 is compatible with the former versions. The start-up screen is shown on Figure 1.

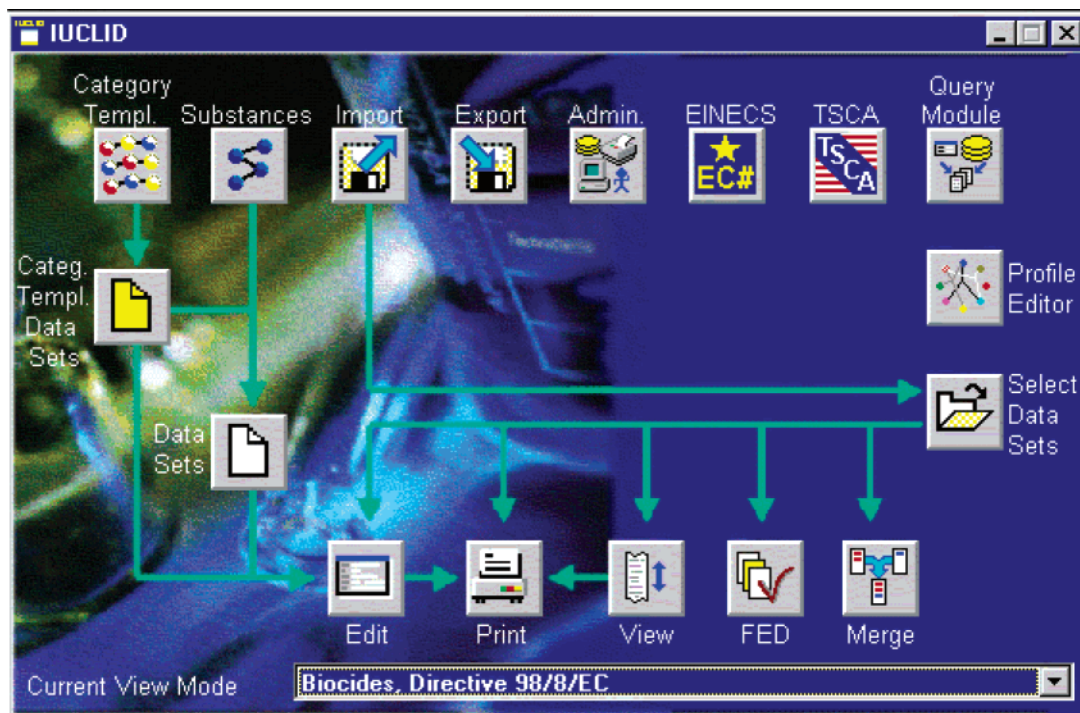


Figure 1. The IUCLID start-up screen: the user can select the various functions and the view to work.

Data providers could become confused about the chapters they would have to fill in, and evaluators who work under the OECD program do not need the extensions for biocides. Therefore, to reduce the numbers of screens needed in the actual IUCLID session, the concept of “Views” has been introduced: the user can select the chemicals program for which data shall be entered or consulted, and only the required chapters will appear. Views can be predefined for individual users by the system administrator.

Most data to be submitted for biocidal active substances and existing chemicals are of a similar structure, e.g. information about the applicant and the identity of the substance. The information collection format can remain unchanged. For various endpoints the collected information is based on the same internationally recognized test protocols (e.g. Annex V of Directive 67/548/EEC¹³ or OECD test methods for toxicity and ecotoxicity¹⁴). The underlying picklists (glossaries) for test types and guidelines were expanded to cover all required entries for biocides.

In addition, notifiers of biocidal active substances are obliged to quantify the effectiveness against target organisms and to provide analytical methods for identifying the substance in the human body and the environment.

A detailed technical description of all the features of the new IUCLID would go far beyond the scope of this article; the authors refer to the technical documentation, which can be downloaded from the ECB's Web site, but would like to highlight some new functions and highlights.

Highly Structured Data Entry. Data entered in IUCLID are administered according to a hierarchical structure as illustrated in Figure 2.

When entering structured data the user can pick from a list of values, which facilitates and harmonizes the data entry significantly, see Figure 3. Data which has been entered in the structured fields can be easily accessed for the use in screening tools in order to find substances with common

properties. For instance with the IUCLID query module the identification of all substances with positive test results in a certain test and for which a selected volume threshold has been reached can be identified. External modeling and scoring tools can use the structured data via the SQL interface.

IUCLID supports flags, which allow marking selected records, e.g., the key studies for “Robust Summaries” used for decision making in the risk evaluation, see Figure 4. Views and printed records can be limited to flagged records. The flags can be used when importing and exporting data from and to IUCLID as well. Several types of flags have been implemented to support data security, especially that of confidential data and data evaluation by the assessor.

Records can also be “flagged” as confidential, for sensitive data such as business information on sold volumes or the detailed descriptions of the manufacturing processes to make sure that these data will not become publicly available. The rules for confidential treatment of data are outlined in the ESR and the Biocides Directive and follow specific Community legislation.¹⁵

Flexible Freetext Management. The freetext part allows providing additional information in text format. The freetext part has been substructured into different so-called freetext types, see Figure 5: Information on the methods used is given in freetext type “TM” (Test method), further information on the substance used in “TS” (Test substance). The freetext type “CL” stands for Conclusions and can contain entire documents along with any summary tables. Of particular importance is the freetext type “AD” (attached document) which allows users to attach formatted documents such as MS Word files and graphics formats such as TIFF or JPG.

IUCLID has become a highly structured database. For a detailed description on how data are compiled within IUCLID see the compilation guidance document prepared

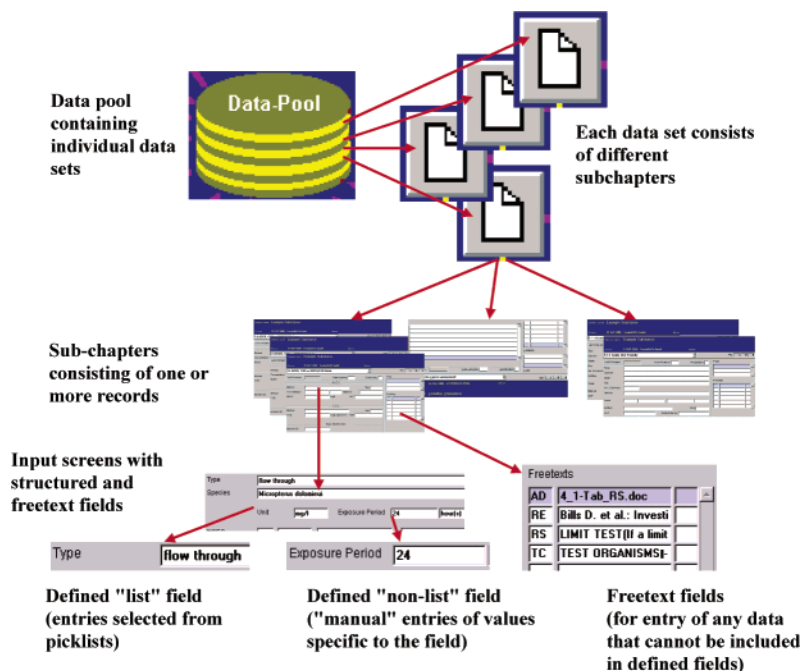


Figure 2. Structure of the data in IUCLID.

Figure 3. Structured data entry in glossary driven fields and as freetext.

by the Fraunhofer Institute of Toxicology and Aerosol Research which is available for download at European Chemical Industry Council's (CEFIC) Web site [<http://www.cefic.be/icca>].

Individual Substances and Substance Groups. Risk assessments are carried out not only for individual substances but also for substance groups or categories. The new IUCLID version also allows for the creation of "template data sets" for such groups. Common data for all members of a chemical category have to be entered or updated only once but are shown when a category member's data set is open. Category data are also printed in the report of the category member substance.

Presentation of the Evaluated Data. IUCLID will assist data submitters and data assessors through the entire process. After having set the evaluation flags for the key studies entering the study summaries and conclusions have been entered, there is a need to present the results, either printed or for online distribution. IUCLID version 4.0 has a report generator to create MS Word documents with tables and graphs. The standard IUCLID report presents the data in monograph format; additional report formats can be defined.

A template for a risk assessment report can be generated with IUCLID, which provides a skeleton report with selected key data in tables, graphs, and can include images such as the chemical structure for the substance concerned. The

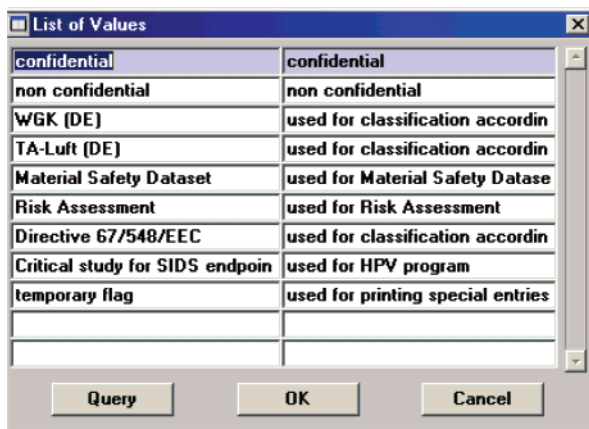


Figure 4. The selection box for flags.

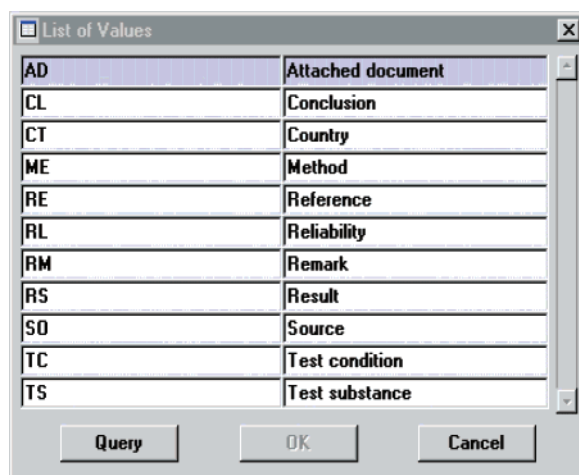


Figure 5. The freetext type selection box.

assessor receives a prefilled document in RTF format, which can be completed easily with word processors, in addition to MS-Word.

The acronym IUCLID is commonly used for a database software application and for the contents of the database as well, what has sometimes caused confusion:
 IUCLID stands for 'International Uniform Chemicals Information Database'
 IUCLID is:

- A software tool to compile, exchange and manage huge amounts of data on chemical substances. It can be installed in various configurations in different computing environments. After the installation the software does not contain data, unless data is put in. The software is distributed by a software house under contract of the Commission.
- The term IUCLID is also used for the contents of the database as such: e.g., as '... the substance is in IUCLID'. Technically, the IUCLID data is distributed in the IUCLID exchange format on DATA CD-ROMs by the European Chemicals Bureau.
- The IUCLID CD-ROM is a dissemination tool for the data collected under the existing substances programme. It contains substance reports for about 2600 high production volume chemicals substances, those risk assessment reports that have been completed and background information in Acrobat PDF™ format. A query tool allows retrieval of individual data sets by certain search criteria.

A COMPLEX SYSTEM BUT SHARED EXPERIENCE INCREASES ACCEPTANCE

Several courses and workshops with participants from EU and overseas were held in Europe, the United States, and Japan. They have been opportunities for the sharing of experiences with IUCLID. Lecturers from Industry, Government, and Research presented background information, while the participants were able to become familiar with the system in hands-on exercises. On the second day of a typical workshop data on human health effects and ecotoxicology, according to the expertise of the participants, would be entered. At the end, all data are exported and merged to a

common final report to be generated, tips and tricks are exchanged, and possible improvements discussed.

The initial objections against a complex system are then transformed into a real interest to continue work "at home". Courses are currently being organized by the ECB and the Fraunhofer Institute¹⁶ at different locations.

EXAMPLES OF USES OF IUCLID

An advantage of having the information stored in a database is the numerous possibilities for utilizing it for statistical analysis or applying it in computer programs. The EU has implemented several systems that use the IUCLID structure for analysis of information on HPV chemicals.

A study¹⁷ on the data availability was performed to understand European situation, i.e., the chemicals registered via the IUCLID database, of data availability and furthermore analyze if any special groups of chemicals would appear through such an analysis as having more or less data. The European results are compared to the corresponding analysis made for chemicals on the United States market.

The priority setting for the HPV program in Europe is performed by first applying EURAM¹⁸ (The European Union Risk Ranking Method) to the HPV Chemicals in IUCLID and then using expert judgment for the top-ranked substances. EURAM extracts the relevant data from predefined fields in IUCLID; if several studies appear the most relevant one can be flagged for data transfer and then calculates the "risk" in a same manner for all substances ensuring that the basis for selecting a chemical for Risk Assessment is as neutral as possible.

To support the Risk Analysis of the individual substances in the European HPV program, EUSES¹⁹ (European Union System for the Evaluation of Substances) was developed. It is a computer program implementing the calculations that are part of the risk assessment, which is described in detail in the Technical Guidance Document for Risk Assessment.²⁰ EUSES can operate with agreed default values or the information that has been submitted to IUCLID can be transferred automatically to EUSES which then calculates e.g., the predicted environmental concentrations of the chemical in question for several different environmental compartments. Where relevant, IUCLID information can be flagged so that only flagged values are transferred to EUSES.

NEXT STEPS

Technical Challenges. The main activity for the future will concentrate on better accessibility to the IUCLID software and the data for data submitters and the interested public.

The user interface will be converted from the current Oracle FORMS application to online forms, which can be opened in a standard Web browser, and a prototype has been developed, see Figure 6. This will resolve not only current difficulties with making the data available to the public but also such issues such as licensing and its costs.

Registered users will be able to decide if the application shall be installed in an Intranet environment for the preparation of data sets in-house or if the secure data transfer shall be used to connect directly to the central IUCLID database to update data, which serves as the basis for the Community programs on existing chemicals and biocides.

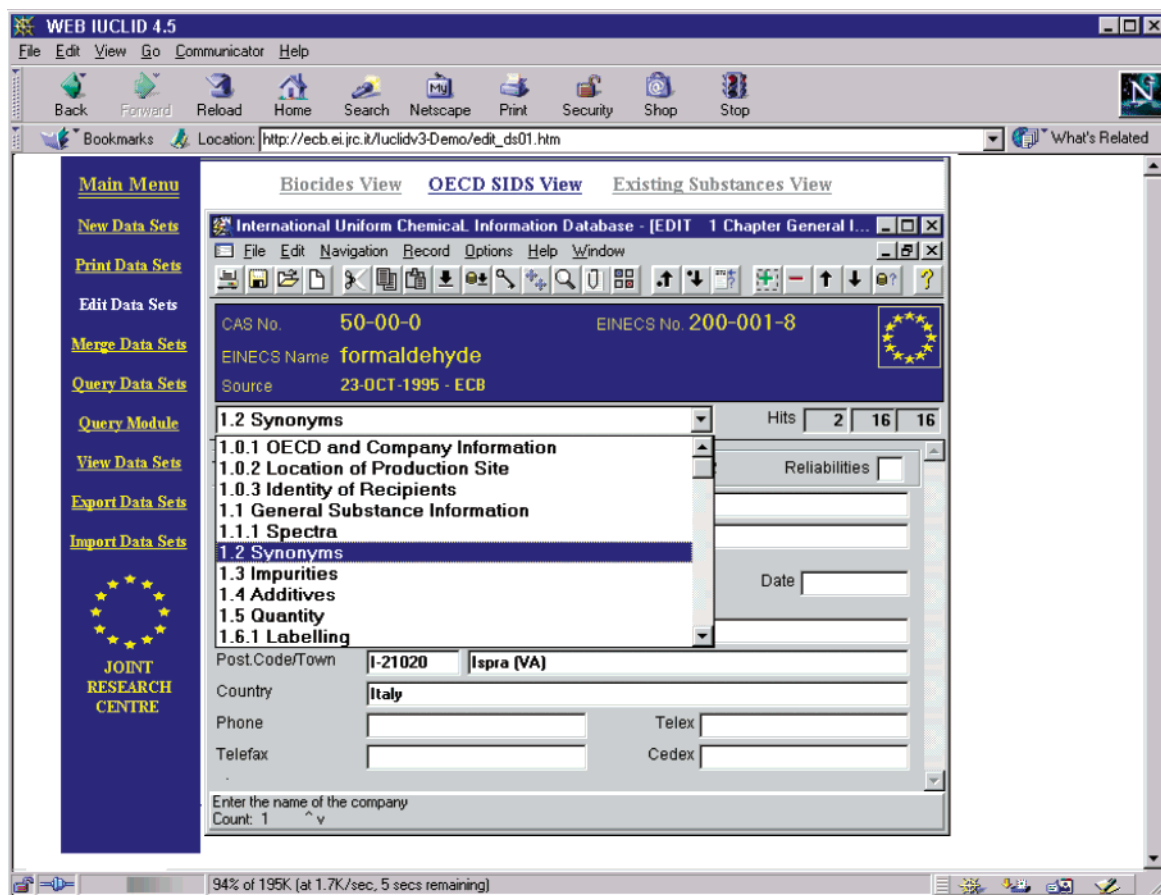


Figure 6. WEB-IUCLID prototype for data management via Intranet/Internet.

The template function will be further enhanced to enable the use of IUCLID for the management of information on and legal registration of chemical products, in particular for the further use under the biocides program and eventually in pesticides registration if decided.

In the long term the data exchange format will be standardized to the XML format, which would allow a more flexible exchange with other existing database applications. [XML: Extensible Markup Language (XML) is a universal format for structured documents and data.]

A New Policy on Chemicals. In June 2001, the Council of the European environment ministers approved a new "Strategy for a future chemicals policy".¹ The new legislation shifts the burden of proof concerning the safety of chemicals to Industry, importers, and, in the case of manufactured products containing chemicals, to the downstream users.

The so-called REACH (**R**egistration, **E**valuation, **A**uthorisation of **C**hemicals) system will ensure that chemicals are produced and used only in ways that do not pose significant threats to human health and the environment. It is estimated that approximately 30 000 chemicals will be covered by REACH. Substances of concern will have to be authorized before they can be further marketed, and Industry will have to prove that the foreseen use is safe. The previously mentioned 30 000 chemicals will have to be registered, to know how they are produced and used during service life and what their eventual fate is. Resources for management and enforcement of the new legislation is planned to be in place by 2004.

To support the REACH system, IUCLID will be enhanced to become the common database for "new" and "existing" chemicals and biocides. To become the data management tool for REACH, major amendments in the administration part of IUCLID will be necessary, including the tracking of the actual status of a substance in the risk assessment process. In addition to manufacturers and importers, downstream users will also have to register and report the amounts of chemicals and how they use them. This will increase data traffic significantly. Registrations will have a legal status within the process, which will have to be communicated to both the regulatory body and the data providers, while the new system will play an important role in informing the general public as well as keeping sensitive business information confidential where appropriate. An interface that will allow the generation of statistics on usage, volumes on the market, substance classes, and indicators on the progress made will have to be designed.

The Commission services and the two IUCLID working groups have started an intensive discussion and planning phase, to be ready with a fully tested system when the new legislation will be in place.

HOW TO OBTAIN IUCLID

The easiest way to become familiar with IUCLID 4.0 is an installation on a stand alone PC. It can be installed by the user like any other Windows application. The PC should be well equipped with disk space (min. 1 GigaByte free) and at least 128 MB RAM (more would of course be better).

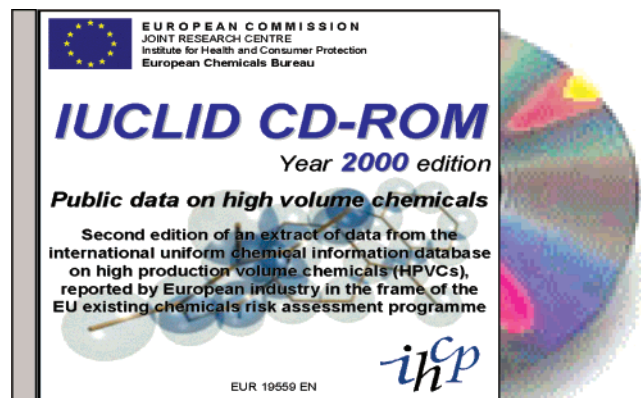


Figure 7. The most recent IUCLID CD-ROM.

In our experience, companies prefer to run IUCLID in Windows NT network environments. If a larger number of users need to be connected to a single IUCLID database, a client-server mode together with Unix based Oracle database servers is also supported. Details on hardware requirements, prices, assistance, and ordering information can be found on the ECB Web site [<http://ecb.jrc.it>].

The DATA CD-ROMs with the “nonconfidential” data sets on HPVCs and LPVCs as submitted by Industry can be ordered from the ECB as well. The DATA CD-ROMs contain the data in the IUCLID exchange format and can only be used together with an IUCLID installation. The data can be copied, merged, and used for the preparation of a company’s or an organization’s data sets and reports, under the condition that the reference to the original data source would be provided.

The “IUCLID CD-ROM Year 2000 edition”,²¹ see Figure 7, not to be confused with the “real” IUCLID, does not require an Oracle license. It is a read-only dissemination tool and does not have database functionality. It does include, however, an update facility: Additional substance data sets and reports can be downloaded from the ECB Web site, using a password found in the CD-ROM documentation. The CD-ROM can be ordered online from EUR-OP’s (the Commission’s Publication Office) Web site [<http://online.eur-op.eu.int>].

CONCLUSIONS

Systems such as IUCLID will continue to develop since new policy and new legislation on chemical safety define more data requirements and technical improvements become possible as computers become ever more powerful. Work under the biocides directive is at an initial stage, and further requirements will be defined soon by data submitters and assessors driving further the development.

Decisions on risk management should be based on sound data. Political decisions will in the future be based on data and followed up by indicators derived from these data. As a result, the public will be better informed and much more involved in the whole process.

IUCLID is already the major data source for risk assessment. The planned enhancements will increase its status as a data source under the future European chemicals policy. It will also be an important tool to provide data for the establishment of indicators on chemical risk in general,

whether it be it for biocides or industrial chemicals (and, if decided, also for agricultural pesticides).

With IUCLID, OECD countries have a common language for the exchange of chemical information. With the implementation of the system on the Internet, visibility and use are expected to increase significantly.

Following the 1992 “Earth Summit” held in Rio de Janeiro, IUCLID has been further developed and improved so that it became a major contributor for the fulfilment of the main goal of Chapter 19 of Agenda 21: to improve “Information exchange on toxic chemicals and chemical risks”.¹ This commitment was renewed at the Johannesburg World Summit for Sustainable Development in 2002, setting the stage for recognizing these achievements at the Rio +10 conference in 2002 in Johannesburg: “Minimize the harmful effects on human health and the environment from the production and use of all chemicals by 2020”.²² The commitment will stimulate further work on harmonization, exchange of data, and knowledge transfer from data-rich to less informed parts of the world, as recently requested by the Intergovernmental Forum on Chemical Safety (IFCS) at its recent conference in Bahia, Brasil.²³

The authors would like to encourage the interested readers to contact the referenced Web sites and institutions for further information.

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CI0202786