

# Glossary

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## 1. INTRODUCTION

### 1.1 Purpose

The purpose of this Glossary is to provide a common and unified terminology to the project.

### 1.2 Scope

This work is taking place as part of the REACH-IT project (Specific Agreement 4, dubbed SA4 but officially numbered #111 in the framework contract n° DI02411).

### 1.3 References

References to external documents or information are enumerated in this section. When mentioning such a reference in the present document, the “Reference ID” value will be used, like in [REACH\_PR1], which refers to the REACH Proposal, Volume I or [REACH\_PR1, 9 (1)], which refers to Article 9, Paragraph 1 of that document. (Article references in quotes from the Proposed Regulation are kept as in the original text, not using this notation).

**Table 1-1 References**

| Reference ID | Description  |
|--------------|--|
| [REACH_Q&A]  | <p>“<i>Q and A on the new Chemicals policy REACH</i>”<br/>Date: 29/11/2003.<br/><a href="http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.getfile=gf&amp;doc=MEMO/03/213 0 RAPID&amp;lg=EN&amp;type=PDF">http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.getfile=gf&amp;doc=MEMO/03/213 0 RAPID&amp;lg=EN&amp;type=PDF</a></p>  |
| [WP_CHEM]    | <p>“<i>WHITE PAPER Strategy for a future Chemicals Policy</i>”<br/><a href="http://europa.eu.int/eur-lex/en/com/wpr/2001/com2001_0088en01.pdf">http://europa.eu.int/eur-lex/en/com/wpr/2001/com2001_0088en01.pdf</a></p>   |
| [REACH_PR1]  | <p>“<i>Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation</i>”<br/><a href="http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/1.pdf">http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/1.pdf</a></p>  |
| [REACH_PR2]  | <p>“<i>Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH) [Annexes I to IX]</i>”<br/><a href="http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/2.pdf">http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/2.pdf</a></p>   |
| [REACH_PR6]  | <p>“<i>Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} [Annexes XI to XVII]</i>”<br/><a href="http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/6.pdf">http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/6.pdf</a></p> |

| Reference ID | Description  |
|--------------|--|
| [OECD_HPVS]  | <p>“Manual for investigation of HPV chemicals”<br/>September 2004<br/><a href="http://www.oecd.org/document/7/0,2340,en_2649_201185_1947463_1_1_1_1,00.html">http://www.oecd.org/document/7/0,2340,en_2649_201185_1947463_1_1_1_1,00.html</a> [last accessed 10.03.2005]</p> |
| [RAC, 1995]  | <p>“Risk Assessment of chemicals: An Introduction”<br/>Edited by C.J. van Leeuwen and J. L. M. Hermans<br/>Published by Cluver Academy Publishers, 1995</p>  |
| [JRC, 2003]  | <p>“Report of JRC Expert Group on Chemical Intermediates”<br/>Brussels, 23 January 2003; BSS/DS (2003) 1187B</p>   |

Table 1-2 Technical references

| Reference        | Description  |
|------------------|--|
| [CRYPT]          | <p>“Cryptography decrypted”<br/>H.X.Mel and D. Baker<br/>Addison-Wesley, 2001, ISBN 0-201-61747-5</p>  |
| [PKI_GLOSS]      | <p>“A Glossary of Common PKI Terms”<br/><a href="http://www.cio-dpi.gc.ca/pki-icp/beginners/glossary/glossary_e.asp">http://www.cio-dpi.gc.ca/pki-icp/beginners/glossary/glossary_e.asp</a><br/>[last accessed 23.01.2004]</p>   |
| [WFMC_GLOSS]     | <p>“Workflow Management Coalition - Terminology &amp; Glossary”<br/>Document Number WFMC-TC-1011<br/>Document Status - Issue 3.0<br/><a href="http://www.wfmc.org/standards/docs/TC-1011_term_glossary_v3.pdf">http://www.wfmc.org/standards/docs/TC-1011_term_glossary_v3.pdf</a></p> |
| [Dictionary.com] | <p>The <i>Dictionary.com</i> web site<br/><a href="http://dictionary.reference.com">http://dictionary.reference.com</a></p>  |

Table 1-3 IUCLID 4 references

| Reference     | Description   |
|---------------|---|
| [IUCLID_GUID] | <p>“IUCLID Guidance Document”, Version 1.1, 14 December 2000<br/>Prepared on behalf of the European Chemical Industry Council (CEFIC)<br/>by the Fraunhofer Institute of Toxicology and Aerosol Research.</p> |
| [IUCLID_GS]   | <p>“IUCLID 4.0 Getting Started” Version 1<br/>Prepared on behalf of the European Commission JRC by Technidata.</p>  |
| [IUCLID_RM]   | <p>“IUCLID 4.0 Reference Manual” Version 1<br/>Prepared on behalf of the European Commission JRC by Technidata.</p>   |

## 1.4 Overview

The Glossary is organised as follows:

- Abbreviations and acronyms are listed in section 2.

They are separated in business and technical domains. They are listed using a tabular format like in:

|            |                                  |
|------------|----------------------------------|
| <b>PKI</b> | <b>Public Key Infrastructure</b> |
|------------|----------------------------------|

When necessary additional information is provided or a reference to the definition section is added, like in

|             |  |
|-------------|--|
| <b>IHCP</b> | <b>Institute for Health and Consumer Protection</b><br>The IHCP is one of the seven Institutes of the Directorate General Joint Research Centre (DG JRC) of the European Commission<br>See <a href="http://ihcp.jrc.it/">http://ihcp.jrc.it/</a> |
|-------------|--|

- Terms and concepts are provided in sections
  - 3 “Business definitions”.
  - 4 “Technical and IT-related definitions”.

They are listed in alphabetic order. Definitions related to a common concept are grouped under a unique subsection.

- UML Stereotypes are defined in section 5.

A stereotype can be seen as an annotation to a UML element that provides additional semantics for this element.

Hyperlinks inside the document are used whenever it is useful to refer to other abbreviations and/or definitions. Being underlined, hyperlinks are visible even in a printed document.

## 2. ABBREVIATIONS AND ACRONYMS

### 2.1 Domain abbreviations and acronyms

Table 2-1 Domain abbreviations and acronyms

| Abbreviation      | Meaning   |
|-------------------|---|
| <b>BIA</b>        | <b>Business Impact Assessment</b><br>Study carried out for the Commission to estimate the costs of REACH  |
| <b>CAS</b>        | <b>Chemical Abstracts Service</b><br>Chemical Abstracts Service maintains the most comprehensive list of chemical substances. Each substance registered in the CAS Registry is assigned a CAS Registry Number. The CAS Registry Number is widely used as a unique identifier of chemical substances.<br>See <a href="http://www.cas.org">http://www.cas.org</a> |
| <b><u>CBI</u></b> | <b><u>Confidential Business Information</u></b>   |
| <b>CEFIC</b>      | Conseil Européen de l'Industrie Chimique / European Chemical Industry Council<br>See <a href="http://www.cefic.be">http://www.cefic.be</a> and <a href="http://www.cefic.org">http://www.cefic.org</a>  |
| <b>C&amp;L</b>    | <b>Classification &amp; Labelling</b>   |
| <b><u>CMR</u></b> | <b><u>Carcinogenic, Mutagenic or toxic to Reproduction</u></b>  |
| <b>CSA</b>        | <b>Chemical Safety Assessment</b>   |
| <b><u>CSR</u></b> | <b><u>Chemical Safety Report</u></b>  |
| <b>CSTEE</b>      | <b>Scientific Committee on the Toxicity, Ecotoxicity and the Environment</b><br>See<br><a href="http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_en.htm">http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_en.htm</a>  |
| <b>DNEL</b>       | <b>Derived No-Effect Level</b><br>Level of exposure to the substance above which humans should not be exposed. [REACH_PR1, (Annex I)]   |
| <b>ECA</b>        | <b>European Chemicals Agency</b><br>Name for the future agency in charge of the day-to-day management of REACH.   |
| <b>ECB</b>        | <b>European Chemicals Bureau</b><br>The ECB is one of five research units of the IHCP of DG JRC, located in Ispra, Italy. The ECB provides scientific and technical support in preparatory work for REACH. It will prepare the ground for the new Agency that will then manage the REACH system.<br>See <a href="http://ecb.jrc.it/">http://ecb.jrc.it/</a>     |
| <b>EFSA</b>       | <b>European Food Safety Authority</b><br>See <a href="http://www.efsa.eu.int/">http://www.efsa.eu.int/</a>  |

| Abbreviation   | Meaning   |
|----------------|---|
| <b>EINECS</b>  | <b>European Inventory of Existing Commercial Chemical Substances</b><br>It concerns chemicals deemed to be on the EU Market between 1 January 1971 and 18 September 1981. It is a closed list of 100.106 'existing' chemicals governed by Regulation 793/93   |
| <b>ELINCS</b>  | <b>European List of Notified Chemical Substances</b>  |
| <b>EMEA</b>    | <b>European Agency for the Evaluation of Medicinal Products</b><br>See <a href="http://www.emea.eu.int/">http://www.emea.eu.int/</a>  |
| <b>ESIS</b>    | <b>Existing Substances Information System</b><br>See <a href="http://ecb.jrc.it/ESIS/NOMAP/esis.htm">http://ecb.jrc.it/ESIS/NOMAP/esis.htm</a>  |
| <b>GHS</b>     | <b>Globally Harmonised System</b> for classification and labelling of chemicals   |
| <b>HPV</b>     | <b>High Production Volume</b><br>Substances produced annually in volumes of more than 1.000 tonnes.   |
| <b>ICCA</b>    | <b>International Council of Chemical Associations</b><br>See <a href="http://www.icca-chem.org/">http://www.icca-chem.org/</a>  |
| <b>ICCA TS</b> | <b>ICCA HPV Chemical Tracking System</b><br>Monitors the progress of the global chemical industry's commitment to Product Stewardship and Responsible Care by evaluating the voluntary progress of completing hazard assessments on HPV chemicals.<br>See <a href="http://www.iccahpv.com">http://www.iccahpv.com</a> |
| <b>IFCS</b>    | <b>Intergovernmental Forum on Chemical Safety</b><br>See <a href="http://www.who.int/ifcs/">http://www.who.int/ifcs/</a>  |
| <b>IHCP</b>    | <b>Institute for Health and Consumer Protection</b><br>The IHCP is one of the seven Institutes of the Joint Research Centre Directorate General (DG JRC) of the European Commission<br>See <a href="http://ihcp.jrc.it/">http://ihcp.jrc.it/</a>  |
| <b>IP</b>      | <b>Intellectual Property</b>  |
| <b>IRPTC</b>   | <b>International Register of Potentially Toxic Chemicals</b><br>See <a href="http://www.chem.unep.ch/irptc/">http://www.chem.unep.ch/irptc/</a>   |
| <b>IUCLID</b>  | <b>International Uniform Chemical Information Database</b>  |
| <b>IUPAC</b>   | <b>International Union of Pure and Applied Chemistry</b><br>See <a href="http://www.iupac.org/dhtml_home.html">http://www.iupac.org/dhtml_home.html</a>   |
| <b>JRC</b>     | <b>Joint Research Centre (Directorate General)</b><br>See <a href="http://www.jrc.org/">http://www.jrc.org/</a>   |

| Abbreviation | Meaning  |
|--------------|--|
| <b>LOAEL</b> | <p><b>Lowest Observed Adverse Effect Level</b></p> <p>Lowest concentration or amount of a substance, found by experiment or observation, which causes an adverse alteration of morphology, functional capacity, growth, development, or life span of a target organism distinguishable from normal (control) organisms of the same species and strain under defined conditions of exposure.</p> <p>See IUPAC Compendium of Chemical Terminology – <a href="http://www.iupac.org/goldbook/L03633.pdf">http://www.iupac.org/goldbook/L03633.pdf</a> [last accessed 2005.03.09]</p>         |
| <b>LOEL</b>  | <p><b>Lowest Observed Effect Level</b></p> <p>Lowest concentration or amount of a substance, found by experiment or observation, that causes any alteration in morphology, functional capacity, growth, development, or life span of target organisms distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure.</p> <p>See IUPAC Compendium of Chemical Terminology – <a href="http://www.iupac.org/goldbook/L03634.pdf">http://www.iupac.org/goldbook/L03634.pdf</a> [last accessed 2005.03.09]</p>                 |
| <b>NCD</b>   | <b>New Chemicals Database</b>  |
| <b>NLP</b>   | <b>No-Longer Polymer</b>   |
| <b>NOAEL</b> | <p><b>No Observed Adverse Effect Level</b></p> <p>Greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target organism under defined conditions of exposure.</p> <p>See IUPAC Compendium of Chemical Terminology – <a href="http://www.iupac.org/goldbook/N04208.pdf">http://www.iupac.org/goldbook/N04208.pdf</a> [last accessed 2005.03.09]</p>   |
| <b>NOEL</b>  | <p><b>No Observed Effect Level</b></p> <p>Greatest concentration or amount of a substance, found by experiment or observation, that causes no alterations of morphology, functional capacity, growth, development, or life span of target organisms distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.</p> <p>See IUPAC Compendium of Chemical Terminology – <a href="http://www.iupac.org/goldbook/N04209.pdf">http://www.iupac.org/goldbook/N04209.pdf</a> [last accessed 2005.03.09]</p> |
| <b>OECD</b>  | <b>Organisation for Economic Cooperation and Development</b>   |
| <b>OSOR</b>  | <b>One Substance One Registration</b>  |
| <b>PBT</b>   | <b><u>Persistent, Bio-accumulative and Toxic</u></b>   |
| <b>PIC</b>   | <p><b>Prior Informed Consent</b></p> <p>The Rotterdam Convention on Prior Informed Consent sets up a system to control international trade in certain hazardous substances.</p>  |

| Abbreviation       | Meaning  |
|--------------------|--|
| <b>PNEC</b>        | <b>Predicted No-Effect Concentration</b><br>Concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur.<br>[REACH_PR2, Annex I] |
| <b><u>POP</u></b>  | <b><u>Persistent Organic Pollutant</u></b>   |
| <b>PPORD</b>       | <b>Product and Process Orientated Research and Development</b><br>Substances used in PPORD will have time limited exemptions from testing requirements.  |
| <b>PPP</b>         | <b>Plant Protection Product</b>  |
| <b><u>QSAR</u></b> | <b><u>Quantitative Structure Activity Relationship</u></b>   |
| <b>RA</b>          | <b>Risk Assessment</b>   |
| <b>REACH</b>       | <b>Registration, Evaluation and Authorisation of CHemicals</b>   |
| <b><u>RIP</u></b>  | <b><u>REACH Implementation Project</u></b>   |
| <b><u>SDS</u></b>  | <b><u>Safety Data Sheet</u></b>  |
| <b>SIDS</b>        | <b>Screening Information Data Set (OECD Existing Chemicals Programme)</b>  |
| <b>SIEF</b>        | <b>Substance Information Exchange Forum</b>  |
| <b>SME</b>         | <b>Small and Medium sized Enterprises</b>  |
| <b><u>SVHC</u></b> | <b><u>Substance of Very High Concern</u></b>   |
| <b>TSCA</b>        | <b>Toxic Substance Control Act</b><br>Inventory in the USA   |
| <b>UNCED</b>       | <b>United Nations Conference on Environment and Development</b><br>See <a href="http://www.un.org/geninfo/bp/enviro.html">http://www.un.org/geninfo/bp/enviro.html</a>                           |
| <b>UNEP</b>        | <b>United Nations Environment Programme</b><br>See <a href="http://www.unep.org/">http://www.unep.org/</a>   |
| <b>US-EPA</b>      | <b>United States Environment Protection Agency</b><br>See <a href="http://www.epa.gov/">http://www.epa.gov/</a>  |
| <b><u>VPVB</u></b> | <b><u>Very Persistent Very Bio-accumulative substance</u></b>  |
| <b>WTO</b>         | <b>World Trade Organisation</b>  |

## 2.2 Commission specific abbreviations and acronyms

Table 2-2 Commission specific abbreviations and acronyms

| Abbreviation | Meaning                                    |
|--------------|--|
| <b>CA</b>    | <b>Competent Authority</b>                 |
| <b>DIGIT</b> | <b>Directorate General for Informatics</b> |
| <b>EC</b>    | <b>European Commission</b>                 |
| <b>ECA</b>   | <b>European Chemicals Agency</b>           |
| <b>ENTR</b>  | <b>Enterprise Directorate General</b>      |

| Abbreviation | Meaning                                     |
|--------------|---|
| <b>ENV</b>   | <b>Environment Directorate General</b>      |
| <b>EU</b>    | <b>European Union</b>                       |
| <b>JRC</b>   | <b>Joint Research Centre</b>                |
| <b>MS</b>    | <b>Member State</b>                         |
| <b>MSCA</b>  | <b>Member State Competent Authority</b>     |
| <b>SLRP</b>  | <b>Standardised List of REACH Processes</b> |

## 2.3 Technical abbreviations and acronyms

**Table 2-3 Technical abbreviations and acronyms**

| Abbreviation   | Meaning   |
|----------------|---|
| <b>API</b>     | <b>Application Program Interface</b>  |
| <b>BPEL</b>    | <b>Business Process Execution Language</b>  |
| <b>CA</b>      | <b>Certification Authority<sup>1</sup></b>  |
| <b>CERT</b>    | <b>Computer Emergency Response Team</b><br>The CERT Coordination Center (CERT/CC) is a major reporting center for Internet security problems<br>See <a href="http://www.cert.org/nav/index_main.html">http://www.cert.org/nav/index_main.html</a>                                   |
| <b>COTS</b>    | <b>Commercial Off-The-Shelf software</b>  |
| <b>D&amp;B</b> | <b>Dun &amp; Bradstreet</b>   |
| <b>DBMS</b>    | <b>Database Management System</b>   |
| <b>DOI</b>     | <b>Digital Object Identifier</b><br>See <a href="http://www.doi.org">http://www.doi.org</a>   |
| <b>DOS</b>     | <b>Denial of service</b>  |
| <b>D-U-N-S</b> | <b>Data Universal Numbering System</b><br>A D&B D-U-N-S Number is a unique nine-digit sequence recognized as the universal standard for identifying and keeping track of over 80 million businesses worldwide.<br>See <a href="http://www.dnb.ca/duns/">http://www.dnb.ca/duns/</a> |
| <b>EJB</b>     | <b>Enterprise JavaBeans</b>   |
| <b>GPL</b>     | <b>GNU General Public License</b>   |
| <b>HTTP</b>    | <b>Hypertext Transfer Protocol</b>  |

<sup>1</sup> CA is also used for “Competent Authority”. We advise the use of MSCA for “Member State Competent Authority”.

| Abbreviation | Meaning  |
|--------------|--|
| <b>HTTPS</b> | <b>H</b> ypertext <b>T</b> ransfer <b>P</b> rotocol over <b>S</b> SL<br>The secure version of HTTP. Instead of using plain text socket communication, HTTPS encrypts the session data using either a version of the <b>SSL</b> (Secure Socket Layer) protocol or the <b>TLS</b> (Transport Layer Security) protocol. The default TCP/IP port of HTTPS is 443 |
| <b>HTML</b>  | <b>H</b> yper <b>T</b> ext <b>M</b> arkup <b>L</b> anguage   |
| <b>ICT</b>   | <b>I</b> nformation and <b>C</b> ommunication <b>T</b> echnology   |
| <b>IETF</b>  | <b>I</b> nternet <b>E</b> ngineering <b>T</b> ask <b>F</b> orce<br>A large open international community of network designers, operators, vendors, and researchers concerned with the evolution of the Internet architecture and the smooth operation of the Internet.<br>See <a href="http://www.ietf.org">http://www.ietf.org</a>                           |
| <b>ITU</b>   | <b>I</b> nternational <b>T</b> elecommunication <b>U</b> nion<br>Formally the CCITT (Consultative Committee for International Telegraph and Telephone), a worldwide telecommunications technology standards organisation.<br>Standard body for the X.509 certificate.<br>See <a href="http://www.itu.int/home/">http://www.itu.int/home/</a>                 |
| <b>J2EE</b>  | <b>J</b> ava <b>2</b> <b>E</b> nterprise <b>E</b> dition   |
| <b>JAAS</b>  | <b>J</b> ava <b>A</b> uthentication and <b>A</b> uthorization <b>S</b> ervice<br>See <a href="http://java.sun.com/products/jaas/index.jsp">http://java.sun.com/products/jaas/index.jsp</a>   |
| <b>JAXB</b>  | <b>J</b> ava <b>A</b> rchitecture for <b>X</b> ML <b>B</b> inding  |
| <b>JDBC</b>  | <b>J</b> ava <b>D</b> atabase <b>C</b> onnectivity<br>See <a href="http://java.sun.com/products/jdbc/">http://java.sun.com/products/jdbc/</a>  |
| <b>JDO</b>   | <b>J</b> ava <b>D</b> ata <b>O</b> bjects  |
| <b>JSF</b>   | <b>J</b> ava <b>S</b> erver <b>F</b> ace<br>See <a href="http://java.sun.com/j2ee/javaserverfaces/index.jsp">http://java.sun.com/j2ee/javaserverfaces/index.jsp</a>  |
| <b>JVM</b>   | <b>J</b> ava <b>V</b> irtual <b>M</b> achine   |
| <b>NUTS</b>  | <b>N</b> omenclature of <b>T</b> erritorial <b>U</b> nits for <b>S</b> tatistics   |
| <b>PAM</b>   | <b>P</b> luggable <b>A</b> uthentication <b>M</b> odule  |
| <b>PDF</b>   | <b>P</b> ortable <b>D</b> ata <b>F</b> ormat   |
| <b>PKCS</b>  | <b>P</b> ublic <b>K</b> ey <b>C</b> rypto <b>S</b> tandards  |
| <b>PKI</b>   | <b>P</b> ublic <b>K</b> ey <b>I</b> nfrastucture   |
| <b>RDF</b>   | <b>R</b> esource <b>D</b> escription <b>F</b> ramework   |
| <b>RSS</b>   | <b>R</b> ich <b>S</b> ite <b>S</b> ummary<br>May also stand for “ <b>R</b> DF <b>S</b> ite <b>S</b> ummary”  |
| <b>RUP</b>   | <b>R</b> ational <b>U</b> nified <b>P</b> rocess   |

| Abbreviation | Meaning   |
|--------------|---|
| <b>SSL</b>   | <p><b>Secure Socket Layer</b></p> <p>SSL is a commonly-used protocol for managing the security of a message transmission on the Internet. SSL uses a public-and-private key encryption system, which also includes the use of a digital certificate. SSL is an integral part of most Web browsers (clients) and Web servers (see also TLS)</p>  |
| <b>TLS</b>   | <p><b>Transport Layer Security</b></p> <p>TLS is a protocol that ensures privacy between communicating applications and their users on the Internet. When a server and client communicate, TLS ensures that no third party may eavesdrop or tamper with any message.</p> <p>TLS is the successor to the Secure Sockets Layer (SSL).<sup>2</sup></p>   |
| <b>UML</b>   | <b>Unified Modelling Language</b>   |
| <b>URI</b>   | <b>Uniform Resource Identifier</b>  |
| <b>URL</b>   | <b>Uniform Resource Locator</b>   |
| <b>URN</b>   | <b>Uniform Resource Name</b>  |
| <b>UUID</b>  | <b>Universal Unique Identifier</b>  |
| <b>VPN</b>   | <p><b>Virtual Private Network</b></p> <p>A VPN works by using the shared public infrastructure (e.g. the Internet) while maintaining privacy through security procedures and “tunnelling protocols”. By encrypting data at the sending end and decrypting it at the receiving end, VPN sends the data through a “tunnel” that cannot be “entered” by data that is not properly encrypted.</p> |
| <b>WFMS</b>  | <b>Workflow Management System</b>   |
| <b>XML</b>   | <b>eXtensible Markup Language</b>   |
| <b>XPath</b> | <b>XML Path Language</b>  |

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<sup>2</sup> Netscape developed SSL in 1994 and subsequently transferred control of the protocol to the Internet Engineering Task Force (IETF). The IETF renamed SSL to Transport Layer Security (TLS), and released their first specification in January 1999. TLS 1.0 is a modest upgrade to the most recent version of SSL, version 3.0, and the differences between the two are minor.

## 3. BUSINESS DEFINITIONS

### 3.1 Actor in the supply chain

All [manufacturers](#) and/or [importers](#) and/or [downstream users](#). [REACH\_PR1, 3 (16)]

### 3.2 Agency

Agency is the shorthand for the European Chemicals Agency (ECA) which is established by REACH and will be responsible along with the Member State Competent Authorities for the implementation of REACH.

### 3.3 Animal testing

Use of the laboratory animals to detect how [chemicals](#) react in the living organisms. In the REACH proposal there is a clear distinction between testing on vertebrate animals and other (animal) tests.

### 3.4 Annex XIV

The REACH Annex XIV “sets out the requirements for a proposal for any [restriction](#), as well as proposals for harmonised classification and labelling, and the identification of substances as [PBT](#), [VPVB](#) or of equivalent concern.” [REACH\_PR1].

The Annex is located in volume VI of the proposed regulation [REACH\_PR6].

#### 3.4.1 Annex XIV dossier

A [IUCLID 5](#) data object which contains the different data elements specified by the regulation and can be exported from and imported to IUCLID 5, as well as being submitted to REACH-IT and thereby triggering the activities foreseen by the corresponding REACH business process.

#### 3.4.2 Annex XIV format

Refers to the structure and table of contents of the Annex.

For instance, a document in the “Annex XIV format” is a document whose internal table of contents respects the structure of an Annex XIV dossier as specified by the regulation. Such a document has often to be produced (or may be provided) as a justification for a decision. In this case, the decision does not require the generation of an Annex XIV dossier.

An Annex XIV dossier is obviously in the Annex XIV format.

### 3.5 Applicant

A general term that refers to anyone [submitting](#) an application to the REACH-IT system. For instance, a [company](#) submitting a registration dossier or an application for authorisation is an applicant.

## 3.6 Article

Article means an object composed of one or more [substances](#) or [preparations](#) which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does. [REACH\_PR1, 3 (3)]

## 3.7 Authorisation

Use-specific permission to use [substances](#) of [very high concern](#). [REACH\_Q&A]

## 3.8 Category

See [chemical category](#).

## 3.9 Chemical category

A chemical category is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of (structural) similarity. These structural similarities may create a predictable pattern in any or all of the following parameters: physicochemical properties, environmental fate and environmental effects, and/or human health effects. The similarities should be based on the following:

- a common functional group (e.g., aldehyde, epoxide, ester, etc.); or
- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals; and
- an incremental and constant change across the category. Within a category different members can be selected for the endpoint desired - i.e., those selected for a category approach for environmental effects endpoints may not be suitable for assessing human health effect endpoints. [OECD\_HP, section 3.2.2]

In a European context a category is a group of substances which have a different “[EC substance definition](#)” (i.e. considered to be different within the EU and having a different EC number) and therefore are always different “[real substances](#)” with different [profiles](#). They can be grouped because they have similar characteristics or properties.

**Synonym:** category, group, chemical group.

## 3.10 Chemical

A synonym for [substance](#).

## 3.11 Chemical Safety Report (CSR)

The chemical safety report (CSR) details a chemical safety assessment (CSA). This is a risk assessment in which the [registrant](#) takes account of the risk management measures that he either implements himself for his own uses or proposes to [downstream users](#) for their uses.

The uses addressed in the [registrant](#)'s CSA are known as identified uses. This is not the classic model of risk assessment as understood by persons involved in chemicals' regulation today. The terms "chemical safety report" and "chemical safety assessment" are chosen to make this change clear.

## 3.12 Company

A generic term that covers [manufacturer](#), [importer](#) or [only representative](#).

The term [M/I/R](#) is also used for the same concept.

## 3.13 Competent Authority

See [Member State Competent Authority](#).

## 3.14 Computer modelling

Development of a mathematical representation of the functioning of a system, implemented in the form of a computer program (computational algorithm).

## 3.15 Confidentiality

### 3.15.1 Confidential Business Information

Information that should not be provided to other companies.

Confidential Business Information is any information, in any form, developed or acquired by a company about a substance, and its production, sale or use, the disclosure of which could reasonably be expected to prejudice substantially a company's commercial interests.

### 3.15.2 Intellectual Property

Information that can only be provided within a consortium or to companies having been granted letter of access.

### 3.15.3 Confidential data

Data that may not be published on the REACH dissemination site.

Data that shall not be considered as confidential under REACH is specified by [REACH\_PR1, 116 (1)].

Data that shall always be considered confidential under REACH is specified by [REACH\_PR1, 116 (2)].

### 3.15.4 Non-confidential data

Data that can be published on the REACH dissemination site.

## 3.16 Consortium

Grouping of [companies](#) for the purposes of [registration](#).

### 3.16.1 Consortium leader

The [company](#) providing registration information on behalf of the other members of the consortium.

**Synonym:** also called “the one manufacturer or importer” in [REACH\_PR1, 10 (1)].

### 3.17 Downstream user

Any natural or legal person established within the Community, other than the [manufacturer](#) or the [importer](#), who uses a [substance](#), either on its own or in a [preparation](#), in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 4(2)(c) shall be regarded as a downstream user. [REACH\_PR1, 3 (11)]

Formulators and industrial users of [chemicals](#). [WP\_CHEM]

Companies that use a [substance](#) professionally or industrially (on their own, in [preparations](#)). Example: a manufacturer who mixes different [chemicals](#) to make ink, or uses the ink to print leaflets. [REACH\_Q&A]

### 3.18 End point

An end point is an [information requirement](#) according to the REACH Annexes. An example of an endpoint is “State of the substance at 20° C and 101,3 kPa” (under information on the physicochemical properties of the substance in Annex V).

An endpoint generally corresponds to a [subchapter](#) in IUCLID 4 and to an [endpoint](#) in IUCLID 5.

From a scientific point of view, an endpoint corresponds with or relates to an effect on organisms or the environment in general, e.g., carcinogenicity, biodegradation, aquatic toxicity. They are laid down in Annexes V to VIII. Such an endpoint must be supported by at least one test, being an actual test, a [QSAR](#), etc. The test result describes the magnitude of the effect, if there is an effect.

A look to Annex VI shows the structure of an endpoint:

- Section 6.1 covers the “Skin irritation” endpoint
  - “6.1.1. In vivo skin irritation” is the associated test method, which is associated to the [endpoint study](#) in IUCLID 5.
  - Another test method for the same endpoint can later be added under 6.1.2.

### 3.19 Evaluation

Qualitative assessment of [registration dossiers](#) and/or registered [substances](#). [REACH\_Q&A]

### 3.20 Exposure

To come into contact with a [substance](#). The amount of a [substance](#) someone/something comes into contact with is often modelled with a computer (see [computer modelling](#)). [REACH\_Q&A]

## 3.21 Exposure scenario

Exposure scenarios shall be developed for manufacture in the Community, [manufacturer](#)'s and [importer](#)'s own use, and all identified uses. An exposure scenario is the set of conditions that describe how the [substance](#) is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends [downstream users](#) to control, exposures of humans and the environment. These exposure scenarios may be as wide-ranging or specific as necessary. The exposure scenario shall be presented under the relevant heading of the [chemical safety report](#), and summarised in an annex to the [safety data sheet](#), using an appropriate short title giving a brief general description of the use.

In particular, an exposure scenario includes, where relevant, a description of:

- the processes involved in the production by the manufacturer and, if relevant, the further processing and use by the manufacturer or importer, including the physical form in which the substance is manufactured, processed and/or used;
- the processes involved in the identified use of the substance foreseen by the manufacturer or importer, including the physical form in which the substance is processed and/or used;
- the risk management measures implemented by the manufacturer or importer to reduce or avoid exposure of humans (including workers and consumers) and the environment to the substance;
- the risk management measures which the manufacturer or importer recommends to be implemented by the downstream users to reduce or avoid exposure of humans (including workers and consumers) and the environment to the substance;
- the waste management measures implemented by the manufacturer or importer and those recommended to be implemented by the downstream user or consumer to reduce or avoid exposure of humans and the environment to the substance during waste, disposal and/or recycling;
- the activities of workers related to the processes and the duration and frequency of their exposure to the substance;
- the activities of consumers and the duration and frequency of their exposure to the substance;
- the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment. [REACH\_PR2, Annex I, section 5.1.1]

A very simple example of exposure scenario might be:

- use gloves
- work outside
- not spraying
- < 2h per day

See also [use](#).

**Note:** The synonym “use scenario” should be avoided.

## 3.22 Glossary

A glossary is a list of standardised values. Examples of glossaries encompass:

- Substance use glossary. It contains values such as “cosmetic use”.

**Note:** This term is obsolete.

## 3.23 Group of substances

There are different ways to group [substances](#).

### 3.23.1 Category

See [chemical category](#).

### 3.23.2 Group

A synonym for [chemical category](#).

### 3.23.3 Set

In a set of substances the substances have the same “EC substance definition” (i.e. considered to be the same within the EU, they share or will share the same EC number) and might have a different purity/impurity [profile](#).

The table below provides an example of a set of substances; they are considered to be the ‘same’ substances.

| EC number | EC name | CAS number | Molecular formula             | Trade name          | Constituent     | Impurity                  |
|-----------|---------|------------|-------------------------------|---------------------|-----------------|---------------------------|
| 200-753-7 | benzene | 71-43-2    | C <sub>6</sub> H <sub>6</sub> | Benzenas pure       | 98-99 % benzene | 1-2% toluene              |
| 200-753-7 | benzene | 71-43-2    | C <sub>6</sub> H <sub>6</sub> | Bentseeni Mult Purp | 90-99 % benzene | 1-10 % toluene            |
| 200-753-7 | benzene | 71-43-2    | C <sub>6</sub> H <sub>6</sub> | Bentseeni Tech Grad | 85-99 % benzene | 1% water + 0-14 % toluene |

## 3.24 Importer

Any natural or legal person established within the Community who is responsible for import (The physical introduction into the customs territory of the Community). [REACH\_PR1, 3 (8-9)]

## 3.25 Information requirement

Annexes IV to IX specify the information requirements, the information that shall be submitted for [registration](#) and [evaluation](#) purposes according to Articles 9, 11 and 12, 39, 40 and 44. For the lowest tonnage level, the standard requirements are in Annex V, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added to the dossier and the updated dossier resubmitted. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care. [REACH\_PR2, Annex IV]

Relates to [end point](#).

## 3.26 Intermediates

See section 3.49.6.

## 3.27 In vitro testing

In glass, referring to studies in the laboratory usually involving isolated organs, tissues, cells or biochemical systems. [RAC, 1995]

## 3.28 Inventory

A list of entries providing information on a substance that pertain to a specific context. An inventory can have a scientific nature (e.g. CAS inventory) or a legislative nature (TSCA, EINECS).

Examples of inventories are:

- [ELINCS](#) (European List of Notified Chemical Substances)
- [EINECS](#) (European Inventory of Existing Commercial Chemical Substances)
- TSCA (Toxic Substance Control Act – Inventory in the USA)
- DSL (Domestic Substances List – Inventory in Canada)
- AICS (Inventory of Chemical Substances – Australia)
- ENCS (Existing and New Chemical Substances – Inventory in Japan)
- PICCS (Philippines Inventory of Chemicals and Chemical Substances)

See [nomenclature](#), [substance definition](#).

### 3.28.1 EC inventory

The “EC inventory” is a table that contains information on substances valid in the context of some EC regulations. It is the union of the [EINECS](#), [ELINCS](#) and NLP inventories.

It includes the following 5 attributes:

- EC number
- EC name
- EC CAS number, the CAS number associated to the EC number
- Molecular formula
- Description

## 3.29 IUCLID 4

Terminology specific to IUCLID version 4 are listed in this section.

IUCLID stands for International Uniform Chemical Information Database.

[IUCLID](#) 4 is a database and management system for the administration of data on chemical [substances](#). This system was initially developed to fulfil European requirements for the evaluation and control of the risks of existing chemical substances. It went through three major upgrades in the past. The current version is 4.0.2.

IUCLID 4 has been designed for entering and storing in a relational database the information on the properties of substances in an agreed upon format for use in regulatory submissions. IUCLID 4 can generate reports from information entered into the data base in formats suitable to meet the reporting requirements of the [US EPA HPV](#) Chemical Challenge program, the EU Existing Chemicals program, the EU Biocides program and the [OECD SIDS](#) program. [IUCLID\_GS]

### 3.29.1 Data set

In IUCLID 4, a data set consists of the following parts:

- Substance header

The substance header states for which substance the data set was created.

- Producer related part

The producer related part provides information about the origin of the company information in chapter 1.

- Substance related part

The substance related part provides information about the origin of the substance-specific data in chapters 2 – 8 and 10.

The division into data related to the producer on one hand and to the substance on the other hand makes it possible to refer to other companies' data sets, or to import other companies' data sets. Other companies' data sets can only be viewed, not edited.

Every data set is allocated to a single [substance](#), but each substance can have many data sets assigned to it. Data sets can be created by several companies and attached to the same substance. A data set can be associated to a category/template. [IUCLID\_RM], [IUCLID\_GUID]

### 3.29.2 Export file

An external representation of a [dataset](#) generated by IUCLID 4 and saved as an external file.

### 3.29.3 Harmonised data set

A [data set](#) is referred to as being harmonized if the [substance](#) related part (producer and creation date) is identical to the producer related part (producer and creation date) and other companies refer to this data set. In this case, the data is created on behalf of all the companies involved in the data set and the data set is submitted for all of them. However, it is essential to agree on the content of the data set with all the companies in question.

### 3.29.4 Subchapter

Related to [end point](#).

## 3.30 IUCLID 5

**IUCLID 5** is a major upgrade of IUCLID 4.

It will cover all functionalities already covered by IUCLID 4, plus: extended data structure, advanced user-friendliness, needs arising from the international use of IUCLID (OECD ICCA, US-EPA, etc.),...

IUCLID 5 provides a flexible way to configure [endpoints](#) in a hierarchic way.

### 3.30.1 Endpoint

The container for [endpoint studies](#) and [endpoint study records](#). For instance, “Skin irritation” is an endpoint.

### 3.30.2 Endpoint study

The container for all [endpoint study records](#) that correspond to a specific test method. For instance, the endpoint study “In vivo skin irritation” corresponds to a test method under the “Skin irritation” [endpoint](#).

### 3.30.3 Endpoint study description

An endpoint study description is the model for a general description of an [endpoint study](#). It defines its internal data fields and the structure of [endpoint study records](#).

### 3.30.4 Endpoint study type

Different [endpoint study descriptions](#) can be configured for the same [endpoint](#). They are called endpoint study types. For instance, the “repeated dose by oral route” and the “repeated dose by inhalation route” are two endpoint study types for the “repeated dose toxicity” endpoint.

### 3.30.5 Endpoint study record

An instance of [endpoint study](#) as it is stored in the IUCLID 5 database.

## 3.31 Letter of access

A document, signed by the owner or owners of relevant data protected under the provisions of this legislation which states that these data maybe used by the other [registrant](#) for the purpose of [registration](#).

If a substance has already been registered, a new [registrant](#) shall be entitled to refer to studies and test reports, hereinafter “[studies](#)”, for the same [substance](#) submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that he can submit a letter of access from the previous [registrant\(s\)](#) allowing the use of the studies. [REACH\_PR1, 12 (4)]

In the context of application for [authorisation](#), if an application has been made for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the

previous applicant, to the parts of the previous application submitted in accordance with Article 59(4)(d) and (5). [REACH\_PR1, 60 (1)]

If an authorisation has been granted for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the holder of the authorisation, to the parts of the holder's application submitted in accordance with Article 59(4)(d) and (5). [REACH\_PR1, 60 (2)]

### 3.32 Manufacturer

Any natural or legal person established within the Community manufacturing (producing and extracting substances in the natural state) a substance within the Community. [REACH\_PR1, 3 (6-7)]

### 3.33 Member State Competent Authority

Member State Competent Authority represents the authority or authorities or bodies established by the Member States to carry out the obligations arising from the REACH Regulation. [REACH\_PR1, 19]

### 3.34 M/I/R

M/I/R is a shortcut term to designate [manufacturer](#), [importer](#) or [only representative](#). The term [company](#) is also used with the same meaning.

### 3.35 M/I/R/DU

M/I/R/DU is a shortcut term to designate a [M/I/R](#) or a [downstream user](#).

### 3.36 Nomenclature

Rules on how to name chemical substances.

For instance, the [IUPAC](#) organisation is a source of rules for naming chemical substances.

See [inventory](#), [substance definition](#).

### 3.37 Only representative

A natural or legal person established outside the Community who manufactures a [substance](#) imported into the Community on its own, in [preparations](#) or in [articles](#) may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on [importers](#) regarding the [registration](#) of substances. [REACH\_PR1, 6a]

The representative shall also comply with all other obligations of importers under the Regulation.

The non-Community exporter shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as [downstream users](#) for the purposes of the Regulation.

## 3.38 Preparation

Mixture or solution composed of two or more [substances](#). [REACH\_PR1, 3 (2)]

A preparation is a deliberate physical mixture of more than one substance with the absent of chemical reaction(s) after mixing.

## 3.39 Quantitative Structure Activity Relationship (QSAR)

Models used to predict the properties of [chemicals](#) from the molecular structure. [WP\_CHEM]

A Quantitative Structure Activity Relationship is a set of methods that tries to find a mathematical relationship between a set of descriptors of molecules and their activity. The descriptors can reveal the shape, the electrostatic field, the hydrophobic propensity or other features of the molecules. The descriptors can be experimentally or computationally derived and can help to avoid animal testing.

## 3.40 REACH Implementation Project (RIP)

The aim of the REACH Implementation Projects (RIP's) is to ensure an efficient implementation of the future legislation through the development of guidance and IT-tools for the Agency, industry and the authorities. The RIP's include 7 main areas and a number of sub-subjects (See <http://ecb.jrc.it/REACH/>)

Two RIP's are important in the context of this project:

- RIP-1 is the project that analyses the procedures and workflows resulting from the new legislation.
- RIP-2, i.e. REACH-IT (The present project).

## 3.41 Registrant

The [manufacturer](#) or the [importer](#) submitting a [registration](#). [REACH\_PR1, 3 (5)], [REACH\_Q&A]

### 3.41.1 Potential registrant

A [manufacturer](#) or [importer](#) desiring to register his [substance](#) who is looking for already available data before submitting a [registration](#).

### 3.41.2 Previous registrant

A registrant of the same [substance](#) who has registered at a date prior to the registrant currently registering.

## 3.42 Registration

The [manufacturers](#) and [importers](#) submit information in a standardised format, to demonstrate that they are managing their chemicals safely. [REACH\_Q&A]

### 3.42.1 Registration dossier

Information to provide in the context of a registration defined in Article 9 or 15-16. [REACH\_PR1, 9, 15, 16]. It consists of a [technical dossier](#) and, when required, a [Chemical Safety Report](#).

Annexes IV to IX set out the requirements for generating information on the substance to be registered.

### 3.43 Restriction

Restriction means any condition for or prohibition of the [manufacture](#), [use](#) or placing on the market. [REACH\_PR1, 3 (29)]

### 3.44 Risk

The risk posed by a [substance](#) depends on hazard (the [intrinsic properties](#) of the [substance](#)) and exposure. [REACH\_Q&A]

### 3.45 Robust Study Summary (RSS)

See [Robust Study Summary](#) in section 3.47.

### 3.46 Safety data sheet (SDS)

The SDS is the instrument for conveying the relevant information from [manufacturer](#), [importer](#) or [downstream user](#) down the supply chain [REACH\_PR1, 29].

The safety data sheet is the main tool used in industry for communicating information on the risks of dangerous [substances](#) and [preparations](#) through the supply chain. Annex Ia is the old annex to the safety data sheet Directive (91/155/EEC) that explains what information should be included under each of the 16 safety data sheet headings.

### 3.47 Studies

#### 3.47.1 Robust Study Summary

Robust study summary means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. [REACH\_PR1, 3 (27)]

As defined by OECD4/US EPA5, robust study summaries are characterized as follows:

- The term “robust summaries” is used for [summaries](#) that include as much technical information as necessary to adequately describe an experiment or study.
- Hence, robust study summaries adequately reflect the objectives, methods, results, and conclusions of the full [study report](#).
- The term “robust” comes from the fact that an exhaustive description of the various study items or parameters is necessary together with evaluative comments made by the data reviewer.

- The objective of robust study summaries is to provide sufficient information to allow a technically qualified person to independently assess a given study report without having to go back to the full report, and to also allow evaluation of the proposed test plan. [IUCLID\_GUID]

### 3.47.2 Study Summary

The study summary is any summarizing description of a [study report](#). Study summaries can be very condensed or very detailed. In other words, the terminology "study summary" is not indicative of the documentation completeness in terms of the most relevant study elements. Very detailed study summaries are also termed [robust study summaries](#), if they address all relevant study items.

### 3.47.3 Study Report

A study report can either concern an experiment or in some cases an estimation or prediction method or any other information, e.g. exposure data or surveys, physicochemical data, etc.

## 3.48 Submission

A submission is a general term that encompasses any communication of information by an [applicant](#) to the Agency using the REACH-IT system. A submission is thereby restricted to an electronic communication. The [registration](#) of a substance is an example of submission.

## 3.49 Substance

A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. [REACH\_PR1, 3 (1)]

**Synonym:** also named [chemical](#) and real substance.

See also [grouping of substances](#).

### 3.49.1 Biocide (Biocidal product)

Active substances and [preparations](#) containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. [Directive 98/8/EC]

### 3.49.2 CMR (Carcinogenic, Mutagenic or toxic to Reproduction)

Substance of very high concern which is carcinogenic (causes cancer), mutagenic (causes damage to genes) or reproductively-toxic (causes either a decrease in fertility or problems with development of the foetus). CMRs category 1 and 2 are subject to [authorisation](#). [REACH\_Q&A]

### 3.49.3 Composition profile

The description of the composition of a substance in terms of its constituents: main constituents, additives and/or impurities.

**Synonym:** profile.

### 3.49.4 Endocrine disruptors

Substances of very high concern that mimic or inhibit the effects of hormones. Identified on a case-by-case basis and subject to [authorisation](#). Many of these substances are also CMRs. [REACH\_Q&A]

### 3.49.5 Existing substance

Substances in use within the EU before September 1981 and listed in [EINECS](#). EINECS contains 100.106 entries including chemicals, substances produced from natural products by chemical modifications or purification, such as metals, minerals, cement, refined oil and gas; substances produced from animals and plants; active substances of [pesticides](#), medicaments, fertilisers and cosmetic products; food additives; a few natural [polymers](#); some waste and by-products. They can be mixtures of different [chemicals](#) occurring naturally or as an unintentional result of the production process. 'Existing' substances do not include: synthetic [polymers](#) (which are registered in EINECS under their building block monomers), intentional mixtures, medical preparations, cosmetic preparations and pesticide preparations as intentional mixtures; food; feedstuffs; alloys, such as stainless steel (but individual components of alloys are included); most naturally occurring raw materials, including coal and most ores. [WP\_CHEM]

According to estimations, some 30.000 existing substances will be subject to registration in REACH. [REACH\_Q&A]

### 3.49.6 Intermediate

Intermediate means a [substance](#) that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. [REACH\_PR1, 3 (14)]

One distinguishes between:

- Non-isolated intermediate [REACH\_PR1, 3 (14) (a)]
- On site isolated intermediate [REACH\_PR1, 3 (14) (b)]
- Transported isolated intermediate [REACH\_PR1, 3 (14) (c)]
- Isolated intermediates supplied other than within strict contractual controls between the original supplier and recipient. (This type of intermediates should be treated as normal substances under REACH regulation as they are already being placed in the market). [JRC, 2003]

### 3.49.7 Intrinsic property (of a substance)

An intrinsic property of a chemical substance is categorised into [endpoints](#). For instance, "carcinogenic" is an intrinsic property of a substance.

Intrinsic properties are mentioned in the context of:

- [Registration](#) [REACH\_PR1, 9 and 12].

- [Authorisation](#) [REACH\_PR1, 54-55].

### 3.49.8 New substance

This term is used in the current European chemicals legislation.

Substances not in use in the EU before September 1981 and therefore not included in [EINECS](#). They must be notified before being placed on the market, after which they are registered in [ELINCS](#). New substances are governed by Directive 67/548, as amended by Directive 92/32. [WP\_CHEM]

There are around 3.400 ‘new’ substances currently on the market. [REACH\_Q&A]

In REACH the notion of ‘new substance’ does no longer exist. Substances which were notified as ‘new substances’ under the current legislation are in REACH referred to as ‘notified substances’.

**The term “new substance” should not be used in the context of the proposed new regulation!**

### 3.49.9 Notified substance

Notified substance means a [substance](#) for which a notification has been submitted and which could be placed on the market in accordance with Directive [67/548/EEC](#). [REACH\_PR1, 3 (21)]

### 3.49.10 PBT (Persistent, Bio-accumulative and Toxic)

Substances of very high concern that are persistent (difficult to break down), bio-accumulative in living organisms and toxic. PBTs are subject to [authorisation](#). [REACH\_Q&A]

Annex XII defines criteria for the identification of PBTs, and [vPvBs](#).

### 3.49.11 Pesticide

Pesticides, also know as “plant protection products”, are active [substances](#) and [preparations](#) containing one or more active [substances](#), put up in the form in which they are supplied to the user, intended to: 1) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below; 2) influence the life processes of plants, other than as a nutrient, (e.g. growth regulators); 3) preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives; 4) destroy undesired plants; or 5) destroy parts of plants, check or prevent undesired growth of plants. [Council Directive [91/414/EEC](#), 2 (1)]

### 3.49.12 Phase-in substance

A substance which over the 15 years preceding the entry into force of this Regulation meets at least one of the following criteria:

- a. it was manufactured in or imported into the Community, or the countries acceding to the European Union on 1 May 2004, by a [manufacturer](#) or [importer](#) and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

- b. it was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the [manufacturer](#) or [importer](#);
- c. it was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the [manufacturer](#) or [importer](#) and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a [polymer](#) set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC. [REACH\_PR1, 3 (20)]

### 3.49.13 Polymer

Polymer means a [substance](#) consisting of molecules characterised by the sequence of one or more types of monomer units. [REACH\_PR1, 3 (4)]

Large molecules consisting of repeated chemical units (monomers) joined together. Examples of polymers: plastic materials, two-component glue. [REACH\_Q&A]

### 3.49.14 POP (Persistent Organic Pollutant)

Persistent Organic Pollutants (POPs) are chemical [substances](#) that persist in the environment, bio-accumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. With the evidence of long-range transport of these substances to regions where they have never been used or produced and the consequent threats they pose to the environment of the whole globe, the international community has now, at several occasions called for urgent global actions to reduce and eliminate releases of these chemicals. [UNEP, <http://www.chem.unep.ch/pops/default.html>]

POPs are banned or severely [restricted](#) under [UNEP's](#) Stockholm Convention.

### 3.49.15 Spectra

The spectrum is the result of transforming a time domain signal to the frequency domain. It is the decomposition of a time signal into a collection of sine waves. The plural of spectrum is spectra. Chemical analysis with the aid of spectra is based on the procedure of doing this transformation.

The web site *Chemical Properties of Material* (<http://www.science.uwaterloo.ca/~cchieh/cact/-applychem/propertyc.html> - Last accessed 18.10.2004) an introduction to some types of spectrum: When a beam of light passes a medium, photons with appropriate wavelengths are absorbed. Plots of the transmitted intensity against frequency are called *spectra*. Depending on the region of the electromagnetic radiation used, these are called infrared (IR), visible, or ultraviolet (UV) spectra. Excited atoms or ions in the plasma also emit radiation, and plots of intensity against frequency are called emission spectra. Some molecules contain nuclei that are magnetically active, their absorption of radiation is affected by the strength of the magnetic field, in which they are placed. The technique is called nuclear magnetic resonance (NMR) spectroscopy. Using laser as light sources and analyzing scattered light pattern are techniques used in Raman spectroscopy. The technique based on the weight and charge of a particle is called mass spectroscopy. Spectroscopic techniques are useful for compound identification and chemical analysis.

### 3.49.16 Substances in articles

Hazardous substances that are released from articles as part of their function will generally have to be registered. If the release is not intentional, the substances may have to be notified. [REACH\_Q&A]

### 3.49.17 Sunset date

This concerns the inclusion of substances in Annex XIII: “[...] the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, hereinafter “the sunset date”; [...]” [REACH\_PR1, 55 (1) (c) (i)]

### 3.49.18 SVHC (Substance of Very High Concern)

Substances of very high concern are defined in the REACH Proposal as:

1. [CMRs](#) category 1 or 2;
2. [PBTs](#) and [vPvBs](#); and
3. substances of similar concern.

These substances have hazards which give rise to serious and irreversible effects on health or the environment. These substances have higher than normal uncertainties when drawing conclusions on the risk posed by the substances. The consequences of drawing the wrong conclusions are therefore more serious. Such substances are candidates for authorisation under REACH.

### 3.49.19 VPVB (Very Persistent Very Bio-accumulative)

Substance of very high concern that are very persistent (very difficult to break down) and very bio-accumulative in living organisms.

## 3.50 Substance definition

The collection of information identifying a substance. A substance definition is a “theoretical” description of a real substance and exists out of general substance information like [inventory](#) information or [nomenclature](#) names and numbers.

A substance definition includes the substance identification (names and/or identifying numbers or codes in international inventories like EINECS or TSCA), the name of a substance according to nomenclatural rules like IUPAC and the substance structure (molecular formula, molecular structure and smiles notation).

## 3.51 Substitution

Avoiding use of a hazardous [substance](#) by replacing it with another substance (a substitute) or by changing production methods. [REACH\_Q&A]

## 3.52 Technical dossier

Part of a [registration dossier](#) containing information on the [substance](#) and information on risk management measures. It does not include the [chemical safety report](#) that documents the choice of these measures. [REACH\_PR1, section 1.2]

The precise content of the technical dossier is defined in [REACH\_PR1, 9 (a)] as well as in the Annexes IV to IX.

## 3.53 Technical Expert Working Groups

Eight working groups consisting of stakeholder experts were convened in the winter of 2001/2002 to discuss and investigate technical issues. [REACH\_Q&A]

## 3.54 Tonnage threshold

Volume based criteria for different requirements under REACH, formulated as “X tonnes/year per manufacturer/importer”. The tonnage threshold will affect [registration](#) deadlines. [REACH\_Q&A]

## 3.55 Toxicity

The inherent potential or capacity of a [substance](#) to cause adverse effects on a living organism, seriously damaging structure or function, or producing death. [RAC, 1995]

## 3.56 Use

Use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. [REACH\_PR1, 3 (12)]

See also [exposure scenario](#).

### 3.56.1 Registrant's own use

An industrial or professional use by the [registrant](#). [REACH\_PR1, 3 (24)]

### 3.56.2 Identified use

A use of a [substance](#) on its own or in a [preparation](#), or a use of a [preparation](#), that is intended by an [actor in the supply chain](#), including his own use, or that is made known to him in writing by an immediate [downstream user](#) and that is covered in the [safety data sheet](#) communicated to the [downstream user](#) concerned. [REACH\_PR1, 3 (25)]

Any use of a particular [substance](#) that the [registrant](#) has been made aware of. [Downstream users](#) have the right to demand from their suppliers that they register [substance](#) for all their uses. [REACH\_Q&A]

### 3.56.3 Undesirable use

A use by [downstream users](#) which the [registrant](#) advises against. [REACH\_PR1, 3 (26)]

## 4. TECHNICAL AND IT-RELATED DEFINITIONS

### 4.1 Communication network

#### 4.1.1 Intranet

A privately maintained computer network that can be accessed only by authorized persons, especially members or employees of the organization that owns it. [Dictionary.com]

#### 4.1.2 Extranet

An extension of an institution's [intranet](#), especially over the World Wide Web, enabling communication between the institution and people it deals with, often by providing limited access to its intranet. [Dictionary.com]

### 4.2 Internationalisation

Internationalisation is the process that occurs during application development that makes [localisation](#) easier by separating the details that differ between locales from the rest of the program that stays the same. If internationalisation is thorough, localisation will require no programming. [Dictionary.com]

The abbreviation “I18N” is often used instead of the word “internationalisation”. It means “I - 18 letters – N”.

### 4.3 Locale

A geopolitical place or area, especially in the context of configuring an operating system or application program with its character sets, date and time formats, currency formats, etc. [Dictionary.com]

Locales are significant for [internationalisation](#) and [localisation](#).

### 4.4 Localisation

Adapting a product to meet the language, cultural and other requirements of a specific target market. Localisation includes the translation of the user interface, on-line help and documentation. [Dictionary.com]

The abbreviation “L10N” is often used instead of the word “localisation”. It means “L - 10 letters – N”.

## 4.5 Security

### 4.5.1 Authentication

A security service that validates the claimed identity of a participant in an electronic transaction. [PKI\_GLOSS]

Authentication is assurance of the identity of the person at the other end of the line. [CRYPT]

### 4.5.2 Certification Authority

A Certification Authority is a trusted third party that issues [digital certificates](#) and validates the identity of the holder of a digital certificate.

### 4.5.3 Confidentiality

A security service that ensures that data is not disclosed to unauthorised parties. [PKI\_GLOSS]

Confidentiality is assurance that only owners of a shared secret key can decrypt a computer file that has been encrypted with the shared secret key. [CRYPT]

### 4.5.4 Digital certificate

A digital certificate is a secure electronic identity that certifies the identity of the holder. Issued by a [Certification Authority](#), it typically contains a user's name, [public key](#), and related information. A digital certificate is tamper-proof and cannot be forged, and is signed by the [private key](#) of the Certification Authority which issued it. [PKI\_GLOSS]

### 4.5.5 Digital signature

Produced by a sender using his or her private key to encrypt a message digest, a digital signature allows the message recipient to confirm both the identity of the sender and that the content of the message was not changed in transmission (see [integrity](#)). [PKI\_GLOSS]

### 4.5.6 Integrity

A security service that ensures that data cannot be deleted, modified, duplicated or forged without detection. [PKI\_GLOSS]

Integrity is assurance that a file was not changed during transit. This is also called [message authentication](#). [CRYPT]

### 4.5.7 Key pair

A pair of digital keys – one [public](#) and one [private](#) – used for encrypting and signing digital information. [PKI\_GLOSS]

### 4.5.8 Message authentication

A synonym for [integrity](#).

## 4.5.9 Non repudiation

1. A security service that ensures that a message sender cannot deny sending a message and that the recipient cannot deny receipt. 2. Irrefutable, unforgeable proof of an electronic message's origin or receipt. [PKI\_GLOSS]

According to [CRYPT], non repudiation is limited to the assurance that the sender cannot deny a file was sent.

## 4.5.10 Private key

A cryptographic key known only to the user, employed in public key cryptography in decrypting or signing information. One half of a [key pair](#). [PKI\_GLOSS]

## 4.5.11 Public key

The other half of a [key pair](#), a public key is held in a digital certificate. Public keys are usually published in a directory. Any public key can encrypt information; however, data encrypted with a specific public key can only be decrypted by the corresponding [private key](#), which the key owner keeps secret. A public key can also be used to verify the authenticity of a [digital signature](#). [PKI\_GLOSS]

## 4.6 Workflow

See [WFMC\_GLOSS] for a complete glossary on workflow terminology.

### 4.6.1 Notification

A notification is a message generated by the system towards one of its actors. It is automatically constructed based on information stored in a dossier and may be issued with or without a prior step for a visa.

## 4.7 XML






### 4.7.1 Schematron


A rule-based XML schema language that defines validation rules using [XPath](#) expression (<http://xml.ascc.net/resource/schematron/schematron.html>).

## 5. UML STEREOTYPES

### 5.1 RUP stereotypes

Table 5-1 RUP stereotypes

| Stereotype      | Description  | UML representation  |
|-----------------|--|---|
| Business actor  | A business actor represents a role played in relation to the business by someone or something in the business environment. | Actor, stereotyped as <<business actor>>, also represented by the  icon    |
| Business worker | An abstraction of a human that acts <u>within</u> the system   | Class, stereotyped as <<business worker>>, also represented by the  icon |
| Business entity | Business entities represent objects that business workers access, inspect, manipulate, produce, and so on.                 | Class, stereotyped as <<business entity>>, also represented by the  icon |
| boundary        | A boundary class models the interaction between one or more actors and the system  | Class stereotyped as <<boundary>>, also represented by the  icon         |
| control         | A class used to model behaviour specific to one, or several use cases  | Class stereotyped as <<control>>, also represented by the  icon          |

| Stereotype | Description   | UML representation  |
|------------|---|---|
| entity     | A class used to model information that has been stored by the system, and the associated behaviour. | Class stereotyped as <<entity>>, also represented by the  icon |

## 5.2 Additional stereotypes

Table 5-2 Model stereotypes

| Stereotype           | Description  | UML representation                               |
|----------------------|--|--|
| trace                | Usually represents an historical development of one element into another more developed version.   | Dependency relationship stereotyped as <<trace>> |
| use case realisation | Used to denote an activity (in an activity diagram) that corresponds to a use case realisation.  | Activity stereotyped as <<use case realisation>> |
| use case activity    | Used to denote an activity (in an activity diagram) that corresponds to a use case activity occurring <i>inside</i> a use case during the realisation of the use case. | Activity stereotyped as <<use case activity>>    |
| enumeration          | An enumeration is a list of named values used as the range of a particular attribute type.   | Class stereotyped as <<enumeration>>             |
| process              | An activity which is decomposed into sub-activities.   | Activity stereotyped as <<process>>              |

Table 5-3 User interface stereotypes

| Stereotype | Description                 | UML representation                  |
|------------|-----------------------------|-------------------------------------|
| screen     | Used to model a screen      | Class stereotyped as <<screen>>     |
| input form | Used to model an input form | Class stereotyped as <<input form>> |
| list       | Used to model a list        | Class stereotyped as <<list>>       |
| tree       | Used to model a tree        | Class stereotyped as <<tree>>       |

| <b>Stereotype</b> | <b>Description</b>   | <b>UML representation</b>                  |
|-------------------|--|--|
| button            | Used to denote the existence of a button (user interface) in a screen or a form. | Public attribute stereotyped as <<button>> |