



# Lowell Center for Sustainable Production

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## An introduction to the current system for regulating chemicals in the European Union

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**There has been much discussion of the European Union's plans for a new chemical regulatory system, REACH. However, many people are unaware of the extent to which REACH is built on the currently operating regulatory system for chemicals in the EU. This briefing explains this system.**

### 1. Introduction

The bulk of the regulation of chemicals use in European Union (EU) Member States is controlled at an EU level, with legislation starting in 1967:

*"..when it was recognised that provisions relating to the classification, packaging and labelling of substances on the market, in particular dangerous industrial chemicals, should be harmonised throughout the Community in order to eliminate the barriers to trade that national provisions in the Member States could represent." [1]*

It is important to note that these regulatory systems refer to "substances" rather than "chemicals" – in many cases a substance will be one chemical, but it may also be a mixture of chemicals, for example a crude oil fraction. In addition, this paper is discussing the regulation of industrial chemicals; within the EU. Certain other groups of chemicals are regulated separately, for example pharmaceuticals, veterinary medicines, pesticides, and radioactive substances.

Many technical aspects of the current European chemicals regulatory system are administered by the European Chemicals Bureau (ECB), part of the

European Commission's Joint Research Centre in Ispra, Italy. Regulatory investigation and decision making is usually carried out by government experts and officials from the EU Member States, working with the European Commission (in particular DG Environment and DG Enterprise) and the ECB.

The key elements of the regulatory system can be divided into four types of regulation, explained in more detail in the following sections: [1]

- Classification and labelling
- Restrictions on marketing and use
- Notification of 'New' (post-1981) chemicals
- Regulation of 'Existing' (pre-1981) chemicals

#### 1.1 Classification and labelling

Council Directive 67/548/EEC, the earliest EU chemicals legislation, created a system for standardising classification, packaging and labelling of dangerous substances (both industrial chemicals and pesticides), and has since been amended a number of times. Directive 88/379/EEC covers similar areas for 'preparations' – a mixture of substances e.g. paint – rather than substances.

Producers are obliged *"to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances"* [2].

The legislation also specifies the criteria to be used when classifying the dangerous properties of the substance [2].

It should be noted that producers are under no obligation to actually perform any tests; the legislation includes no test or data requirements, and classifications need only be made on the basis of available data. Given that a producer can classify a substance with no safety data, and that more safety data may result in a higher classification, this system actually creates an incentive for a producer to avoid safety testing [3].

In addition to classification by producers, for substances of special concern Member State regulatory authorities work together to produce harmonized classifications. To date around 8000 substances have been classified in this way and added to Annex 1; the results are available on the ECB website [4].

Producers of substances and preparations that meet the criteria for classification as dangerous are also required to create a safety data sheet (SDS) containing information about the substance's properties; this SDS must be passed on to their customers [5].

## 1.2 Restrictions on marketing and use

Directive 76/769/EEC (often known as the 'limitations directive') harmonises restrictions on the use of chemicals. This directive tends to be used as a reactive tool, after a Member State has raised concerns about a specific chemical. Restrictions agreed under this directive usually only limit substances for specific uses, rather than banning them completely.

Chemicals with certain classifications, for example class 1 and 2 carcinogens, mutagens and reproductive toxins (CMRs), are automatically restricted in that they cannot be sold to the public as substances or in preparations.

The restrictions are listed in Annex 1 of the Directive, which is frequently amended. The latest list is available from the European Commission web site [6].

## 1.3 New Chemicals regulation

All those chemicals which have been introduced to the market at greater than 10 kg/year since 19<sup>th</sup>

September 1981 (and are therefore not on the EINECS list, below) have had to go through the 'new chemicals' notification procedure. This process was introduced as an amendment to 67/548 (above). All new substances are listed on the European List of Notified Chemical Substances (ELINCS) [7].

The new substances notification includes specific pre-market testing and assessment, with testing requirements increasing with tonnage per notifier on the market, in 6 different tonnage bands.

Examples of test requirements are given in the following list – note that this list only covers the toxicological and related studies, and is a summary – for a more detailed explanation see the UK Health and Safety Executive web site, (<http://www.hse.gov.uk/nons>):

- Substances marketed at 10 kg/annum or more, but less than 100 kg/annum, Annex VII C: acute toxicity
- Substances marketed at 100 kg/annum or more, but less than 1000 kg/annum, Annex VII B: acute toxicity, skin irritation, eye irritation, skin sensitization, mutagenicity (bacterial, with and without metabolic activation), biotic degradation
- Substances marketed at 1 tonne per annum or more require the 'Base Set' of information, Annex VII A: acute toxicity (two routes), skin irritation, eye irritation, skin sensitisation, 28 day repeat dose, mutagenicity (two tests; if one positive then further testing), reproductive toxicity, fish acute toxicity, daphnia acute toxicity, algae growth inhibition, bacteriological inhibition, biotic and abiotic degradation
- Additional 'Level 1' data is required for substances marketed at 100 tonnes per annum or more, and 'Level 2' data is required in addition if the substance is marketed at 1000 tonnes per annum or more. At both levels, tests may be waived if reasons are given. 'Level 1' data may also be requested for 10 tonnes per annum and above chemicals.

The notification should also include a suggestion for classification and labelling and may include a

preliminary risk assessment. The final risk assessment is prepared by the Competent Authority of the Member State where the notification occurs, and this notification is accepted by other Member States (though they do have a chance to comment on it).

If the risk assessment concludes that the substance is of concern, then recommendations may be made to modify classification and labelling (which may then be harmonised as described above), or the safety data sheet, or alternatively control measures could be recommended, for example a recommendation that certain uses should be restricted using the limitations directive [1].

#### 1.4 Regulation of 'Existing Chemicals'

The 'New Chemicals' regulations address those chemicals which have been placed on the market since 1981. Existing chemicals, those which were already on the market in 1981, are regulated through regulation 793/93: the 'Existing Substances' regulation. This legislation aims to seek out and investigate priority chemicals, rather than waiting for a concern to arise (as happens with the restrictions process) – however, in practice this regulation has not worked well.

All chemicals on the European market between 1<sup>st</sup> January 1971 and September 1981 have been listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) [8]. This is a closed database; no substances have been added since the 1981 inventory.

The EINECS database has 100,106 entries, though in reality there are fewer chemicals actually on the market. Recent data from the European Commission's Joint Research Centre [9] suggests that the numbers of substances in the different tonnage categories are as follows:

- 1-10 tonnes per annum (tpa) – 17,500 substances
- 10-100 tpa – 4977 substances
- 100-1000 tpa – 2641 substances
- >1000 tpa – 2704 substances

There is no requirement on industry to submit safety information for those chemicals on the EINECS database, however, they have been obliged to submit available data. Safety data of

chemicals produced or imported at more than 1000 tonnes per annum (High Production Volume (HPV) Substances), should have been submitted between March 23, 1990 and March 23, 1994. For substances produced or imported in quantities between 10 and 1000 tonnes per year (Low Production Volume (LPV) Substances) a reduced data-set was required by June 4, 1998 [8].

The aim of the Existing Substances regulation is to assess the environment and health risks of Existing Substances by setting priority lists for assessment using the data submitted by industry or other available data. There are currently 141 existing chemicals on the priority lists; once a chemical is on a priority list there is an obligation on producers to submit a "base set" of data, as described above in the New Chemicals notification section [8]. Chemicals on priority lists are then assigned to Member States who produce a risk assessment, and if necessary, risk management proposals which may then feed into the restrictions on marketing and use regulations.

The risk assessments produced under the existing chemicals programme are long and complex, requiring a significant workload from Member State and European Commission experts, who also have the burden of obtaining the necessary data on chemicals uses, exposures, and hazards. The detailed technical guidance documents (TGD) which Member State authorities use to guide their risk assessments are freely available on the European Chemicals Bureau web site [10].

The regulatory division between 'New' and 'Existing' chemicals does not exist for any scientific or risk-based reason. It is a general feature of regulatory systems that it is easier to put new requirements on something that is new (and hasn't happened yet) – e.g. a chemical, or a new building – than it is to put requirement on something that is already in use.

## 2. Problems with the existing EU system for regulating chemicals

In theory, the current EU system appeared to create an effective methodology for assessing and managing the risks posed by chemicals. However, this has not proved to be the case, and in 1998 a review of European chemicals policy was initiated

by a detailed analysis of the workings of the regulations [1].

Two of the key problems with the existing system are:

- a lack of available information on the hazards and uses of existing chemicals, due to a lack of an obligation on industry to deliver such data;
- an undue burden on the regulator to assess risks of existing chemicals.

These deficiencies are outlined in more detail below.

### 2.1 The information gap

In 1999 the ECB analysed the data it had received from industry on the properties of their HPV chemicals [11]. This study found that:

- Only 14% of the EU High Production Volume Chemicals had data publicly available at the level of the base set used for new chemicals marketed at 1 tonne per annum or above (see above);
- 65% had some data but less than base set;
- 21% had no data.

Without this data it was impossible to assess whether most existing chemicals fulfilled the criteria for prioritisation for further evaluation in the existing chemicals program. It was also unclear how industry was managing to carry out its responsibilities, such as classification and labelling of chemicals and assessing risks to workers, given the lack of safety information.

### 2.2 An undue burden on the regulator to assess risk of existing chemicals

Even when there was sufficient data available to place a chemical on the priority lists for assessment by Member State and European Commission experts, difficulties remained as experts tried to complete the risk assessment and management studies. These studies frequently required more data than was available on hazards, and required use information that was either difficult to find or was not available at all.

As a result of these problems, at the end of 2004 only 141 of the over 100,000 existing substances

had been placed on priority lists, and only 126 of these 141 substances had at least a first draft risk assessment, with only 70 of these risk assessments being finalised. Of these 70, it was concluded that 57 needed risk reduction measures and 2 needed further information. For only 11 of the 70 substances were further risk reduction measures agreed to be unnecessary [12]. The fact that so many of the selected substances required further risk reduction measures clearly indicates the need for proper assessment of the risks posed by existing substances.

### 3. A new chemicals policy

As a result of the deficiencies identified in the existing legislation, a process of stakeholder debate led to the proposal of a new system, Registration, Evaluation and Authorisation of CHemicals, REACH, which was first outlined in a White Paper in February 2001 [13].

It's worth noting that many elements of the REACH system are based on the current system for regulating industrial chemicals in Europe, as described in this briefing.

It is currently predicted that REACH will enter into force in 2007 – most of the legislation defined in this briefing will be replaced by REACH. For more information about REACH, see the [www.chemicalspolicy.org](http://www.chemicalspolicy.org) website, and the Lowell Center briefing "*A Brief Introduction to REACH*".

*To find out more about the status of any chemical within the EU system, use the European Chemical's Bureau's "European Chemical Substances Information System":*

<http://ecb.jrc.it/esis/esis.php?PGM=ein>

### 4. References

1. European Commission, Report on the operation of Directive 67/548/EEC, Directive 88/379/EEC. Regulation (EEC) 793/93 and Directive 76/769/EEC. 18th November 1998, European Commission: Brussels.  
[http://europa.eu.int/comm/environment/chemicals/pdf/report-4-instruments\\_en.pdf](http://europa.eu.int/comm/environment/chemicals/pdf/report-4-instruments_en.pdf)
2. European Union, Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time

- Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, 1992: Brussels, Belgium.  
[http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31992L0032&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31992L0032&model=guichett)
3. Ove Hansson, S. and C. Rudén, Improving the incentives for toxicity testing. *Journal of Risk Research*, 2003. 6(1): p. 3-21.
  4. European Chemicals Bureau, Classification and Labelling website, 2005: Ispra, Italy.  
<http://ecb.jrc.it/classification-labelling/>
  5. European Commission, Safety Data Sheets website, 2005: Brussels, Belgium.  
<http://europa.eu.int/comm/enterprise/chemicals/legislation/sds.htm>
  6. European Commission, Marketing restrictions website, 2005: Brussels, Belgium.  
<http://europa.eu.int/comm/enterprise/chemicals/legislation/markrestr/>
  7. European Chemicals Bureau, New Chemicals website, 2005: Ispra, Italy. <http://ecb.jrc.it/new-chemicals/>
  8. European Chemicals Bureau, Existing Chemicals website, 2005: Ispra, Italy.  
<http://ecb.jrc.it/existing-chemicals/>
  9. Pedersen, F., J. de Bruijn, S. Munn, and K. van Leeuwen, Assessment of additional testing needs under REACH: Effects of (Q)SARS, risk based testing and voluntary industry initiatives. September 2003, European Commission Joint Research Centre, Institute for Health and Consumer Protection.  
[http://ihcp.jrc.cec.eu.int/DOCUMENTATION/IHCP\\_Reports/REACH%20testing%20needs%20final.pdf](http://ihcp.jrc.cec.eu.int/DOCUMENTATION/IHCP_Reports/REACH%20testing%20needs%20final.pdf)
  10. European Chemicals Bureau, Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market., 2003.  
<http://ecb.jrc.it/Technical-Guidance-Document/>
  11. Allanou, R., B.G. Hansen, and Y. van der Bilt, Public availability of data on EU High Production Volume chemicals. 1999 1999, European Chemicals Bureau: Ispra, Italy.  
[http://ecb.jrc.it/existing-chemicals/PUBLIC\\_AVAILABILITY\\_OF\\_DATA/](http://ecb.jrc.it/existing-chemicals/PUBLIC_AVAILABILITY_OF_DATA/)
  12. European Chemicals Bureau, European Chemicals Bureau Newsletter, 23rd December, 2004.  
<http://ecb.jrc.it/NewsLetter/newsletter200404.pdf>
  13. European Commission, White Paper: Strategy for a future Chemicals Policy. 27th February 2001, Commission of the European Communities: Brussels, Belgium.  
<http://www.europa.eu.int/comm/environment/chemicals/whitepaper.htm>

**[www.chemicalspolicy.org](http://www.chemicalspolicy.org)**