Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

The Manual was published by Earthscan/Routledge from 2010 to 2012. It was designed as an on on-line interactive reference work and annual printed versions were also produced.

This section is the text of the Manual as published in 2012. It is therefore important to note the following:

- The contents have not been updated since 2012 and no guarantee is given of the accuracy of the contents given potential subsequent developments.
- The sections include links to external websites (e.g. to legal texts). These links continue to work as long as those links are not broken by those websites.
- The sections also include the original links that enabled interactivity within the published on-line version of the Manual. These links no longer work.

The Manual should be cited as follows:

Farmer, A.M. (2012) (Editor). Manual of European Environmental Policy. 1043pp. Routledge, London.

Historical Legislation: Testing existing chemicals

Formal references	
Regulation (EC) No 793/93 (OJ L105 28.4.77)	Regulation on the evaluation and control of the risks of existing substances
Proposed 14.9.90 – COM(90)227	
Legal base	Article 114 TFEU (originally Article 95 TEC)
Binding dates	
Entry into force	4 June 1993
National legislation on non-compliance:	23 March 1994
Screening to be included	30 June 1991
Manufacturer to report high-volume production data on Annex I substances	4 June 1994
Manufacturer to report high-volume production data on other substances	4 June 1995
Manufacturer to report low-volume production data:	4 June 1998
Repealed	1 June 2008

Note: This Regulation was repealed on 1 June 2008.

Purpose of the Regulation

The scheme for testing 'new' chemicals did not apply to 'existing' chemicals that is those on the market before 18 September 1981 and listed in EINECS. This Regulation, also called the Existing Substances Regulation (ESR), required manufacturers or importers, who make or import more than certain quantities of 'existing' substances (including pesticides), to send the Commission existing data relevant for an evaluation of risk. These data were used to draw up priority lists of substances which needed to be examined in more detail. These were then assessed to see whether they posed a particular risk to man or the environment, the work being divided between the Member States. If necessary, proposals could then be made for restrictions on marketing and use.

Summary of the Regulation

Data collection and reporting

An obligation was placed on manufacturers and importers of existing substances that is listed in EINECS, to assemble information relevant to the evaluation of risks and to submit it to the Commission, and provide updates at least every three years. More information was required for 'high-volume' production or import (more than 1,000 tonnes/year at least once in the three years preceding March 1993 and/or in the year

following) than for ‘lower-volume’ production or import (more than 10 tonnes/year).

Information for the approximately 1,900 substances listed in Annex I was to be supplied by June 1994 and for other ‘high-volume’ substances by June 1995. For ‘low-volume’ substances the information was to be supplied by June 1998.

For ‘high-volume’ substances the information was to include available data on uses and on physico-chemical properties; pathways and environmental fate; ecotoxicity; acute and sub-acute toxicity; carcinogenicity; mutagenicity and/or toxicity for reproduction; and any other relevant information. Manufacturers had to obtain existing data but did not need to carry out further tests on animals. For ‘lower-volume’ substances all the information above did not have to be supplied but only information on quantity produced and uses. However, extra information could be requested.

Substances in Annex II were exempt, but the information could be requested. The information was to be submitted to the European Chemicals Bureau (ECB) on a special software package known as HEDSET (Harmonised Electronic Data Set). Manufacturers/importers had to update the information. The Commission was to send the information to all Member States. The ECB managed IUCLID (International Uniform Chemical Information Database).

Priority lists and rapporteurs

On the basis of the information submitted, and on national lists of priority substances, the Commission was to draw up lists of priority substances requiring immediate attention. These lists were to be adopted by a committee established under the Regulation. (The lists published are shown in Table 1.) The factors to be taken into account in drawing up the priority lists were effects, exposure, lack of data on effects, work already carried out in other international fora, other Community legislation and/or programmes relating to dangerous substances. Special attention was to be paid to substances which may be carcinogenic or have chronic effects. Each substance on the priority list was allocated for evaluation to a Member State which designated a rapporteur for that substance.

Table 1. Priority lists of substances to be evaluated for risks. By Regulation (EC) No 2592/2001 further information and testing requirements were imposed on the manufacturers or importers of certain substances listed in the first three Regulations set out below.

List no	Regulation (EC) No	OJ reference	No of substances
1	1179/94	L131 26.5.94	42
2	2268/95	L231 28.9.95	36
3	143/97	L25 28.1.97	32
4	2364/2000	L273 26.10.2000	31
Total			141

Risk assessment

Within six months of publication of the list, manufacturers/importers of listed substances were to submit to the rapporteur all available information relevant for risk assessment. If any of the 'base set' of data were not available for a priority substance, the manufacturers/importers had to carry out the necessary testing and report to the rapporteur within 12 months. Rapporteurs could grant exemptions but had to inform the Commission which informed the Member States. If the exemption was contested the committee took a decision. Where there were valid reasons for believing that a substance presented serious risks the committee could request information and testing. Where a substance was produced or imported by several manufacturers/importers testing could be carried out by one on behalf of the others who should contribute to the costs. Tests on animals were to be avoided.

The rapporteur was to evaluate the information and decide whether the manufacturer/ importer was to be required to supply further information or carry out further testing. The Committee decided whether the request for further information was to be imposed and the time limits.

The rapporteur assessed the risks on the basis of principles set out in Regulation (EC) No 1488/94, which made the same distinction between 'hazard' and 'risk' as is made when assessing new chemicals. The Commission published technical guidance document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and 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. The rapporteur then sent conclusions to the Commission. The Risk Assessments were published on the European Chemicals Bureau web site[1].The results of the risk evaluation and risk reduction strategies were noted in Commission Recommendations (Table 2).

Table 2 Risk evaluation and risk reduction strategies published by the Commission

EC Recommendation	Chemicals	Rapporteur
1999/721/EC	2-(2-butoxyethoxy)ethanol	Netherlands
	2-(2-methoxyethoxy)ethanol	Netherlands
	Alkanes, $C_{10–13}$, chloro (SCCPs)	UK
	Benzene, $C_{10–13}$, alkyl derivs	Italy
2001/194/EC	Diphenylether/pentabromo derivative	UK
	Cumene	Spain
2001/838/EC	Acrylaldehyde	Netherlands
	Dimethyl sulphate	Netherlands
	Nonylphenol	UK
	Tert-butyl methyl ether	Finland

2002/575/EC	o-Anisidine, 1,4-Dioxane	Austria Netherlands
2002/576/EC	Ethyl acetoacetate, 4-Chloro-*o*-cresol Dimethyldioctadecyl- ammonium chloride	Germany Denmark Germany
2002/735/EC	Diphenyl-ether, octobromo derivative	France and UK
2004/394/EC	Acetonitrile Acrylamide, butadiene Acrylonitrile Acrylic acid, methacrylic acid, Methyl methacrylate Hydrogen fluoride Hydrogen peroxide Toluene, trichlorobenzene	Spain UK Ireland Germany Netherlands Finland Denmark
Total	28	

Risk reduction

The rapporteur could suggest a strategy for limiting risks including control measures and/or surveillance programmes. Technical guidance on development of risk strategies has been published by the Commission. Any proposed restriction on marketing or use had to be accompanied by an analysis of the advantages and drawbacks of the chemical and the availability of replacement chemicals (a risk–cost benefit analysis). The recommended strategy could be adopted by the Committee and published. If there were to be restrictions on marketing and use these could be proposed by the Commission under Directive 76/769/EEC (the restrictions are listed Table 3).

Table 3. Substances restricted as a result of evaluations under the Existing Substances Regulation (these restrictions are made under Directive 76/769/EEC)

Directive No	
2002/45/EC	Short-chain chlorinated paraffins (SCCPs) (listed in Table 2 as Alkanes, $C_{10–13}$, chloro
2003/11/EC	PentaBDE and octaBDE (listed in Table 2 as diphenylether/pentabromo and diphenylether octobromo)
2003/53/EC	Nonylphenol, nonylphenol ethoxylate and cement

Commercial confidentiality

A manufacturer/importer could indicate that certain information was to be kept secret and the competent authority decided on this. Some information could not be kept secret.

Non-compliance

By 23 March 1994, Member States had to introduce appropriate legal and administrative measures to deal with non-compliance.

Development of the Regulation

In the United States the Toxic Substances Control Act of 1976 applies to both new and existing chemicals. In contrast, the EC began by requiring the testing of new chemicals and proposed a Directive in 1976. The scheme for existing chemicals developed more slowly.

The second Action Programme of 1977 briefly mentioned the environmental difficulties due to the use of some existing chemicals and proposed a systematic review. The idea of a priority list was suggested in the third Action Programme of 1983 and the fourth Programme of 1987 suggested that a Directive would be proposed 'to provide a comprehensive structure for risk assessment and regulation of existing chemicals'. The Directive would 'establish a procedure for treating a priority list of chemicals for immediate attention, as well as setting out the means for gathering information, requiring testing, and evaluating the risks to people and the environment. It could also be a mechanism to coordinate the development of chemical specific control strategies, where this proves to be necessary'.

The Regulation proposed in 1990 differed from earlier drafts which would have involved much more of the work being done by the Commission itself. These early drafts were modified as a result of criticism from industry and the Member States. A much more extended period for the supply of information was another change.

The development of the Regulation owed much to work done in the OECD which had established a programme on existing chemicals in 1982 and a programme to share the burden of testing among different countries in 1988.

In 1997 the European Council of Vinyl Manufacturers called for the risk assessments currently under way for five phthalates to be accelerated as a result of concern about the safety of soft toys that are chewed by children. A temporary (3 month) ban on toys and 'teethers' containing phthalates was introduced in December 1999 through Decision 1999/815/EC and regularly renewed pending agreement of a Directive on this subject. The latest renewal – Decision 2004/781/EC – extended the ban until 20 September 2005. A proposal for a permanent ban was made (COM(1999)577) – which proposed to be the 22nd amendment to the Directive 76/769/EEC and was agreed in principle by the Council

in September 2004 (see also Appendix II) and in April 2005 a Common Position was reached to ban three phthalates (at concentrations greater than 0.1 per cent of mass) from all toys and childcare products – DEHP (bis (2-ethylhexl) phthalate), DBP (dibutyl phthalate) and BBP (benzyl butyl phthalate) – which had been identified as reprotoxic substances and to ban the use of toys and childcare articles intended for children under three years of age that could be placed in the mouths of them of DINP (di-isononyl phthalate), DIDP (di-isodecyl phthalates) and DNOP (di-*n*-octyl phthalate). The European Parliament second reading was on 5 July 2005.

Reference

1. See the "risk assessments" section in JRC, 'existing chemicals', European Commission webpage, http://ecb.jrc.it/existing-chemicals