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.

Overview of EU policy: Chemicals

Chemicals policy

The European Union (EU) chemicals policy dominates the national policy in all Member States more completely than other sectors of EU environmental policy for two reasons. Firstly, EU policy developed before Member States had established coherent policies of their own and secondly, the controls on chemicals are often linked to the free movement of goods, something that has always been the underlying objective of the EU. As a consequence, the EU policy is in many respects original and not modelled on pre-existing national schemes.

EU legislation on chemicals precedes the first action programme on the environment with several years and started with Directive 67/548/EEC, which sets out provisions for classifying dangerous substances and for packaging and labelling. This Directive was intended to prevent barriers to trade being erected by different national standards on the classification, packaging and labelling of dangerous substances. However, it was the sixth amendment in 1979 of the original 1967 Directive that has given EU chemicals policy the claim to being original. This sixth amendment introduced a prior notification system for new chemicals. The manufacturer of a new chemical had to submit the results of tests to evaluate possible harmful effects and its assessment of the results to a competent authority, which then passes the results to the Commission and in turn to authorities in the other Member States. If no objections were raised within a given period, the manufacturer had assured access to the whole EU market. The Directive is thus an example of the precautionary or preventative approach to environmental policy, while at the same time serving the purposes of the common market. No Member State had a similar scheme although several were contemplating one and part of the success of the Directive comes from its adoption before conflicting national rules developed.

The 'sixth amendment' also resulted in the establishment of a European Inventory of Existing Commercial Chemical Substances (EINECS) and this provided a base for further EU legislation.

Where the 1980s saw a systematic and proactive approach to new chemicals which were not allowed into the market before they had been tested, the 1990s developed the evaluation of existing chemicals but only about 140 chemicals were included into priority lists and of these only a few were evaluated and even fewer restricted. This disappointing progress in evaluating existing chemicals was one of the main reasons for the development of Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH).

Following a request from the European Council in June 1999, the Commission published the White Paper on the Strategy for a Future Chemicals Policy (COM(2001)88) on 25 February 2001. The White Paper elicited numerous reactions, including from the Council and the European Parliament, including proposals to simplify the strategy or to reinforce the protection of the environment and health it would provide. The Commission met with stakeholders and established expert groups before publishing a draft proposal for a Regulation on 7 May 2003. This was strongly criticized by Governments of three Member States (Britain, Germany and France) as well as non-Member States (USA, Asia). A joint

letter written by President Chirac, Chancellor Schroeder and Prime Minister Blair was sent to Commission President Prodi before the Commission had even finalized the Proposal. This letter warned of the possible impacts REACH might have on the competitiveness of the European chemical industry. At the time of the letter, these three Member States together could constitute a blocking minority and hence, it was a powerful expression of opinion. Consequently, the letter may have influenced the Decision that the proposal would be examined by both the Competitiveness Council and the Environmental Council.

The publication of draft legislation for consultation was unprecedented and emphasizes how contentious the Proposal was. Following the consultation and following further studies, discussions, position papers, lobbying and negotiations, the Commission formally proposed REACH on 29 October 2003. This Proposal was substantially modified from the earlier draft and overall these changes led to a reduced burden on industry and the weakening of environmental provisions. The Regulation came into force in June 2007.

Consequently, REACH and the legislation on classification, labelling and packaging (CLP), which have evolved from the original Directive from 1967, are the two main strands of EU chemicals policy. These are summarized here and discussed in more detail under the testing authorization and marketing of chemicals section. Legislation on inland transport of dangerous goods, maritime transport of dangerous goods, export and import of chemicals and substances depleting the ozone layer are discussed in more detail under the dangerous substances section.

Registration, evaluation, authorization and restriction of chemicals (REACH)

REACH is the longest, most detailed and complicated item of EU environmental legislation. It introduces a single system for all chemicals and abolishes the distinction between ‘new’ (introduced to the market after 1981) and ‘existing’ chemicals (listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) before 1981). Hence, it incorporates into its remit all existing chemicals about which sufficient information was often lacking for effective assessment and control. It also transfers the burden of proof of risk assessments of substances from the public authorities to industry and places much more responsibility on manufacturers, importers and downstream users to provide useful information about the chemicals on the market. REACH also calls for the substitution of the most dangerous chemicals when suitable alternatives have been identified. The REACH process consists of four main stages, namely registration, evaluation, authorization and restriction.

All chemicals produced/imported to the EU in quantities over 1 tonne/year need to be registered. The aim of the registration provisions is to assess the risks related to these substances and to develop appropriate risk management measures. These provisions vary depending on the amounts imported/produced. The European Chemicals Agency (ECHA) is responsible for the evaluation of these registration dossiers. Based on these, ECHA will identify what substances will be evaluated. The first list of substances for evaluation is due to be published by December 2011 and the evaluation will start in 2012. Unlike the registration and evaluation stages, authorizations and restrictions are not dependent on amounts imported/produced. The aim of the authorization process is to identify substances meeting criteria of very high concern, which are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), carcinogenic, mutagenic or toxic for

reproduction (CMRs) or substances of equivalent concern. Through a complicated process, involving candidate lists, priority lists and then the comitology procedure, substances are added to the so-called Annex XIV list. Once a substance is included on this list, those using or making available such a substance will need to apply for an authorization for each use of the substance. Those applying for authorization are required to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. For some of the substances of very high concern an authorization can be granted if the risk to human health or the environment is considered to be adequately controlled. However, even if an authorization cannot be granted because the substance is not adequately controlled, an authorization can still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment and if there are no suitable alternatives. The restrictions procedure is a safety net to catch any substances, not only those covered by the authorization criteria, which have 'unacceptable risks' to human health and the environment. Substances are nominated to ECHA by Member States and then they have 12 months to submit the restriction dossier. Preparation of a dossier for restrictions will require considerable effort, since there is a need to identify unacceptable risks for the uses where risks are identified. Until data from registration dossiers become available, it is likely that only substances that were subject to risk assessment will be nominated for restrictions. It is therefore unlikely that a large number of substances will be initially proposed for restrictions.

Classification, labelling and packaging of chemical substances and mixtures

EU legislation on CLP aims to ensure a high level of protection of human health and the environment and the functioning of the internal market. It does so by laying down EU-wide criteria that must be applied to determine whether a substance or mixture which is manufactured or imported into the European market has properties which could damage human health or the environment. The EU legislation on CLP consists of three acts: The Dangerous Substances Directive 67/548/EEC (DSD), the Dangerous Preparations Directive 1999/45/EC (DPD) and Regulation (EC) No 1272/2008 on CLP of substances and mixtures.

DSD has been constantly adapted by Commission Directives and amended by Council Directives. The amendment to adapt DSD to the REACH Regulation (EC) No 1907/2006 introduces the same registration requirements for new chemicals as for existing substances, which means that the rules for notification of new chemicals will be replaced by those of REACH. In addition, the amendment will repeal requirements on testing and assessment and confidentiality of data. However, since REACH does not include rules on the CLP of dangerous substances, the requirements set by DSD regarding these matters will continue to apply.

DPD covers dangerous preparations that are mixtures or solutions of two or more substances (including paints, solvents, alloys and pesticides). The DPD was made necessary by the new category 'dangerous for the environment' introduced into DSD. The opportunity was therefore taken to consolidate in one Directive the existing requirements for CLP of dangerous preparations and pesticides, and to also include other substances such as explosives.

While the main features of classification and labelling are similar under DSD/DPD and CLP, there are some differences which are due to the integration of the terminology, classification criteria and labelling elements of the UN GHS and to procedures taken over from REACH.

Until 1 December 2010, substances are to be classified, labelled and packaged in accordance with DSD. After that date, substances are to be classified according to DSD and CLP but labelled and packaged in accordance with the CLP only. However, a substance may also be classified, labelled and packaged in accordance with the provisions of CLP before 1 December 2010. In this case, the packaging and labelling provisions of DSD do not apply. Until 1 June 2015, mixtures are classified, labelled and packaged in accordance with DPD. Both DSD and DPD will be repealed by CLP as of 1 June 2015.

Pesticides policy

Amid growing public concern over the impact of pesticides, the Commission presented in July 2006 a set of proposals, the so-called pesticides package, aimed at protecting human health and the environment from dangerous or excessive use of pesticides in agriculture. The pesticides package included the Proposal (COM(2006)388) for a Regulation together with a Proposal for a Directive establishing a framework for Community action to achieve a sustainable use of pesticides (COM(2006)373). These Proposals were approved in 2009 and together with legislation on maximum residue levels on pesticides and the authorization and marketing of biocides, form the basis of EU pesticides policy.

Authorization and marketing of plant protection products

The purpose of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market is to ensure a high level of protection of both human and animal health and the environment and harmonize the rules on the placing on the market of pesticides, while improving agricultural production. The Regulation divides the EU into three zones (north, centre and south) inside of which mutual recognition of plant protection products will become the rule. The Regulation exists in parallel with two older Directives. The purpose of Directive 79/117/EEC is to ban the use or placing on the market of pesticides containing certain active substances and the purpose of Directive 91/414/EEC is to introduce a Community system for the authorization and placing on the market of pesticides. On 14 June 2011, Directive 79/117/EEC will be repealed in its entirety and Directive 91/414/EEC will be repealed in parts by Regulation (EC) No 1107/2009/EC.

Authorization and marketing of pesticides

Directive 98/8/EC on placing of biocidal products on the market sets controls over the marketing and use of biocides to manage the associated risks to the environment and to human and animal health. Directive 91/414/EEC on placing plant protection products on the market established a common European system for the authorization and placing on the market of plant protection products. Directive 98/8/EC establishes a similar common framework of rules relating to the authorization and placing on the market of biocidal products. The framework will replace existing rules and procedures in the Member States, removing potential barriers to trade in biocides and in products treated with them.

Sustainable use of pesticides

Directive 128/2009/EC establishing a framework for Community action to achieve the sustainable use of pesticides establishes a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the

environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides. The Directive applies to pesticides that are plant protection products as defined in Regulation (EC) No 1107/2009 on placing plant protection products on the market. These do not include biocidal products, as defined in Directive 98/8/EC on placing biocidal products on the market. However, it is anticipated that the scope of Directive 128/2009/EC will be extended to cover biocidal products as well. Member States are required to adopt National Action Plans to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of plant protection products. Member States are also required to ensure that the use of pesticides is minimized or prohibited in certain specific areas.

Maximum residue levels of pesticides

The purpose of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin is to protect consumers and animal health by setting limits and controls on the amounts of pesticides on food and animal feeding stuffs and to facilitate trade by setting common standards. The Regulation is not primarily intended to protect the environment. The Regulation establishes the maximum levels of pesticide residues permitted on food and feed of plant or animal origin that are intended for human or animal consumption. The Regulation concerns all commodities covered by previous repealed Directives, covering fruits, vegetables, dry pulses, oilseeds, cereals, spices, sugar plants and products of animal origins. This list of products is periodically revised.

Radioactivity policy

The Treaty establishing the European Atomic Energy Community, known as Euratom, was intended to promote the speedy establishment and growth of nuclear industries. At the same time, it contained several articles concerned with health and safety and with safeguards against fissile materials being diverted from their intended use. The issues covered under this section include legislation on radiation protection, radioactive emergencies, radioactive waste, shipment of radioactive waste, protection of foodstuffs and agricultural products, safeguards in record keeping as well as emergency planning.