

The Current Regulation of Environmental Chemicals

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1 Introduction

Man-made chemicals and naturally occurring chemicals used in industrial processes or in consumer products may enter the environment at any or all stages of their life cycle from the stage of production/manufacture through formulation and use and including disposal of a used product. The potential for harm to be caused to the environment or to human health via the environment will be dependent on the basic physico-chemical and toxic properties of the chemical, the amount that enters the environment and its distribution between different environmental compartments. The physical properties of a chemical will also determine whether the route of entry is likely to be via air, water or to the terrestrial environment.

The scope of this chapter is largely restricted to industrial chemicals that are not subject to a positive approval system, for example, pesticides, biocides and veterinary medicines, but these may be briefly touched on where appropriate. It will also be restricted to considering the regulation of impacts of chemicals on the environment and on human health via the environment. A consideration of the protection of humans in the work place is also not included.

It is proposed to consider both legal and other frameworks that have been put in place to prevent harm to the environment or to human health via the environment that arises out of the production, use or disposal of hazardous chemicals. Much legislation has been introduced to prevent damage occurring to the environment and human health from chemicals but other approaches including voluntary approaches from government and industry have been adopted.

2 Protection of the Water Environment

Many chemical production facilities have been located historically adjacent to rivers and estuaries frequently to allow ready extraction of water and raw materials (e.g. salt) for industrial processes and for the discharge of waste effluent to the receiving water posing a potential risk to the aquatic environment. The chemical industry has been very successful and thousands of products used in a multitude of commercial and consumer products have been developed and marketed around the world. The UK has become a major player in the international chemical industry. In the past, it was often the case that many chemical production facilities discharged poorly or even untreated waste streams to fresh or marine water bodies resulting in extensive damage to the water quality and resulting in harm to aquatic organisms. In some cases, effluents are discharged directly into the sewage system and pass through a sewage treatment works (STW) before entry into a river or the marine environment. This had the potential to cause harm to the treatment plant itself or for inadequate degradation of the chemical before entering into the receiving water body.

2.1 Control of Chemical Discharges to the Environment

The regulation or control of dangerous chemicals or substances to the environment, particularly to water, from industrial plants or STW has been implemented by various pieces of legislation derived from the Dangerous Substances Directive (76/464/EEC)¹ and Daughter Directives, The Environmental Protection Act (EPA)1990² and the Integrated Pollution Prevention and Control (IPPC) Directive (96/61/EEC)³. More recently, the Water Framework Directive (WFD) has been introduced to regulate the quality of all water resources in the European Union (EU).

Directive (76/464/EEC) was implemented to control discharges of dangerous substances to inland surface waters, territorial waters, inland coastal waters and ground water. Chemicals identified as the most hazardous to the aquatic environment are in list 1 of the Directive and the legislation requires that these chemicals be completely eliminated from discharges to water. The chemicals in this list are toxic and persist in the environment and accumulate in biological systems causing harm to aquatic life. Dangerous substances in list 2 were thought to be less hazardous than those in list 1. Chemicals in list 2 have an Environmental Quality Standard (EQS) set according to a standard methodology. EQSs represent a concentration limit that must not be exceeded in any controlled water in the UK and the dangerous substance is not believed to be harmful to the aquatic environment at concentrations below this limit.

Where there are uncertainties arising from lack of information, for instance on salt water organisms, larger safety factors are used for the derivation of the EQS. The standards apply to the receiving water and not to the discharge itself. These are statutory standards and the environment agencies (i.e. the Environment Agency, the Scottish Environmental Protection Agency and Environment and Heritage Service, Northern Ireland) have a legal obligation to ensure that they are met. Where special areas for conservation are concerned, the relevant enforcing agency should examine whether an EQS is sufficient to protect the species at the site. The adequacy of EQSs for substances in list 2 has been addressed by Grimwood and Dixon (1997).⁴

Regulatory monitoring for EQS compliance will be carried out at sites from industrial plants and STW where there is the possibility that the discharge effluent will contain dangerous substances. All major rivers will also have background monitoring sites just upstream of their tidal limits, the so-called National Network monitoring sites in the UK.

Discharges to controlled waters from STWs and industrial sites will also be monitored for compliance with their consents to discharge dangerous substances. These consents set limits for individual substance concentrations to ensure that the concentrations in the watercourse downstream do not exceed the EQS.

In 1980 the protection of groundwater was taken out of directive 76/464/EEC and regulated under the separate Council Directive 80/68/EEC⁵ on the protection of groundwater against pollution caused by certain dangerous substances.

Broader thinking to address European water policy was addressed in 1988 at the Frankfurt Ministerial seminar on water which resulted in a series of directives after the 1976 Dangerous Substances Directive to fill gaps identified in the existing regulations. This resulted in the introduction of the Urban Wastewater Treatment Directive,⁶ the Nitrates Directive in 1991,⁷ a Directive for IPPC⁸ in 1996 and a new Drinking Water Directive in 1998.⁹

2.2 *Water Framework Directive (WFD)*

Pressure from the EU Council and the European Parliament to consider water in a more holistic way led to a new European Water Policy, which was developed with extensive consultation with a broad group of stakeholders. The outcome was an agreed way forward for a single piece of legislation to bring together the fragmented pieces of legislation on protecting water. The Commission presented a proposal for a WFD with broad aims. This resulted in a proposal for a single system of management for river basins representing natural features of the hydrological landscape.

Some river basins will cross national boundaries but a 'river basin management plan' will be required and updated every 6 years. With regard to chemical protection, a general requirement for 'good chemical status' was introduced to cover all surface waters. This is defined in terms of compliance with all the quality standards established for chemical substances at European level. The Directive allows for updating existing standards and introducing new ones for priority hazardous substances.

Directive 76/464/EEC will be integrated into the WFD (2000/60/EC).¹⁰ This is a new piece of substantial legislation, which introduces a new integrated approach to the protection of Europe's rivers, lakes, estuaries, coastal waters and groundwater from deterioration and seeks to improve and sustain their quality. The Directive requires all inland and coastal waters to reach 'good status' by 2015. It aims to achieve this through identifying river basins and demanding environmental quality objectives to be set including ecological targets for surface waters.

With regard to dangerous substances, there are transition arrangements from the 1976 Directive. The list 1 of dangerous substances was repealed with the entry in force of the WFD and has been replaced by a List of Priority Substances. Other provisions of the earlier directive, including the reduction of emissions of dangerous substances to controlled waters will continue in place until 2013. The WFD was

transposed in the UK through a series of regulations including the Water Environment (WFD) (England and Wales) Regulations 2003¹¹ and others for specific river basins.

Within the WFD there is also an element of 'good ecological status' which considers the biological, hydrological and chemical characteristics of the catchment area. The biological characteristics will clearly vary from region to region but this is approached by considering what the biology of any particular area would be expected to look like in the absence of minimal human impacts although this is not a simple exercise due to the wide range of ecological variability.

In dealing with groundwater, the WFD presumes that the water body should not be polluted at all being a potential source of water for drinking. For that reason, the approach is to prohibit the discharge of any potential pollutant to groundwater and at the same time carry out monitoring to determine ingress of chemicals from indirect sources and take remedial action where necessary.

The new Directive essentially seeks to combine the two aspects of previous legislation that have sought on the one hand to control the entry of hazardous substances into water bodies and on the other to set quality objectives for the receiving environment. It will rationalise the EU's regulations on water by replacing seven existing directives, those on surface water and the related directives on measurement methods, sampling strategies and information requirements on fresh water quality, the fish water, shellfish water and groundwater directives and the directive on dangerous-substance discharges.

2.3 *Pollution Prevention and Control Regulations*

Pollution from industrial installations is controlled under rules set out in the EC Integrated Pollution Prevention and Control (IPPC) Directive of 1996 (96/61/EC)⁸ and this was introduced into England and Wales through the Pollution Prevention and Control (PPC) Regulations 2000¹² and other instruments in Scotland and Northern Ireland. The PPC regulations will replace the pollution control regime set up under Part 1 of the EPA 1990² and the transition is due to be completed by 2007.

The EPA introduced to the UK the concepts of Integrated Pollution Control (IPC), which aimed to control releases of hazardous substances to all environmental media, air, land and water and Local Air Pollution Control (LAPC), which controlled releases to air only. The act requires the authorisation to operate the relevant 'prescribed' industrial process from the appropriate regulatory body. Local Councils have responsibility for authorising prescribed processes that emit pollutants to air only (Part B processes) and the Environment Agency or the Scottish Environment Protection Agency authorise processes that may emit pollutants to air, land or water.

In April 2000, Part IIA of the EPA came into force and this introduced a new regime for the regulation of contaminated land. The main purpose is to make provision for the identification of land that poses unacceptable risks to the environment or human health from polluting chemicals and to enforce remediation where the risks cannot be reduced by other means.

The PPC Regulations 2000 introduce three linked systems for pollution control. These relate to the potential of the industrial site or installation to pollute the environment and are graded A (1) (highest) through A (2) to Part B (lowest). A1 sites are

regulated by the Environment Agency and A2 and Part B installations are regulated by local authorities.

A (1) installations are subject to IPPC, A (2) installations to Local Authority IPPC (LA-IPPC) and B processes to LA-PPC. All three systems require the operators of the installations to obtain a permit to operate.

IPPC and LA-IPPC introduce an integrated environmental approach to the control of certain industrial processes. The IPPC Directive seeks to achieve a high level of environmental protection and to prevent or reduce to an acceptable level emissions to the environment. A guiding principle under the PPC regulations is the use of 'Best Available Techniques' (BAT), which is designed to balance the cost of compliance to the operator against the benefits to the environment. The PPC regulations increase the scope of control above the EPA regime to cover energy efficiency, site restoration, accident prevention, noise, odour, waste minimisation and heat and vibrations and they cover a wider range of activities to include food and drink manufacturers, intensive live-stock production and landfill sites. LA regulated Part B installations extend only to emissions to air but BAT also applies.

Guidance documents have been published on the PPC regulations to help installation operators to understand and meet the requirements.

2.4 Direct Toxicity Assessment

The control of point source discharges by the regulatory agencies has been predominantly through the consents procedure for individual substances. This procedure is set out in Schedule 10 of the Water Resources Act 1991.¹³ A consent may be issued subject to certain conditions dependent on the location of the discharge, the design and construction of the outlet, the composition and quantity of the effluent and sampling requirements.

However, there are some industrial discharges which contain a mixture of components creating a complex effluent that is entering the receiving water. These circumstances place difficulties on setting an appropriate consent for the whole effluent. The difficulties may arise through the potential high cost of analysis of all of the chemical components, scarce data for ecotoxicological end points for many substances and the difficulty in predicting how chemicals will behave in complex combinations. Such a situation calls for an alternative approach to assess the toxicity of the whole effluent and this approach is termed Direct Toxicity Assessment (DTA). To improve the assessment and control of complex effluents, the UK through the Environment Agency and the Scottish Environmental Protection Agency has been developing an approach for DTA.

The DTA approach will use a suite of well-established toxicity tests on algae, invertebrates and, where necessary, fish which can be used as a direct assessment of the biological quality of an effluent or environmental compartment such as the water column or sediment. The testing methods will also permit the identification of toxic waste streams discharging to a watercourse or to sewer and their source within a production facility. In some cases toxicity tests are already used for licensing of discharges and DTA has important implications for regulation as a component of IPC. The Scottish Environmental Protection Agency has issued a Technical Guidance Manual¹⁴ for DTA for licensing discharges to water.

The assessment and control of effluent toxicity currently relates to acute toxicity only. It is acknowledged that the approach could be extended to the assessment of chronic toxicity and endocrine disrupting effects. The combined use of biological effects measures, which includes the use of biomarkers, substance-specific assessment and biological surveillance will provide a robust system for identifying, characterising and controlling the effects of hazardous chemicals on the environment.

3 Classification and Labelling of Chemicals

In the 1960s, the European Economic Community (EEC) recognised a need to provide protection from dangerous substances of human health and in particular workers handling them. This resulted in the publication in 1967 of Directive 67/548/EEC (The Dangerous Substances Directive)¹⁵ relating to the classification, packaging and labelling of dangerous substances and provides another mechanism for managing the risk to the environment and human health from chemicals. The Directive covers all substances and preparations which are placed on the market in Member States of the Community and substances are defined as chemical elements and their compounds either in their natural state or as produced by industry. The original Directive did not require labelling substances as 'dangerous for the environment' but this was introduced with the sixth amendment of the Directive in 1979.

In the UK, the Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP)¹⁶ implement the Dangerous Substances Directive and later directives including 1999/45/EC¹⁷ relating to dangerous preparations and the Safety Data Sheets Directive (91/155/EEC and related directives).¹⁸ Under CHIP, substances have always required an environmental classification but the latest set of regulations, CHIP 3, which came into force in July 2002, requires both substances and preparations to be labelled if they have the potential to cause harm to the environment. Preparations are defined as mixtures or solutions composed of two or more substances so there may be considerable implications for the new requirement under CHIP 3. The CHIP regulations require those who supply dangerous chemicals to identify the hazards of the chemical, to provide this information to downstream users and customers via the label or in a safety data sheet and to package the chemical safely. In the context of CHIP, 'supply' is used in a broad sense wherever a chemical is supplied to another person and can include retailers, wholesalers, distributors, importers or manufacturers of chemicals.

Guidance on the classification of substances and preparations is provided in Annex VI of the Dangerous Substances Directive which is updated to reflect technical progress. Changes are agreed by experts from Member States known as the Technical Progress Committee (TPC) supported by the European Chemicals Bureau (ECB), which also engages interested stakeholders, including industry, in the discussions. Resulting measures are known as Adaptations to Technical Progress which are formally adopted as a Commission Directive. The TPC is also responsible for Annex I of the Dangerous Substances Directive, which is the published list of substances with a harmonised classification and labelling which contains information on approximately 8000 substances.

The classification currently has 15 categories of danger including explosive, very toxic, harmful, irritant, carcinogenic and dangerous for the environment. The criteria for

the latter are set out in Annex VI of Directive 67/548/EEC¹⁵ and comprise risk phrases indicating toxicity, harm or long-term adverse effects to the aquatic environment.

The regulations are administered in each Member State by the 'Competent Authority'(CA), which in the UK comprises the Health and Safety Executive and the Environment Agency acting jointly.

A Globally Harmonised System(GHS) of Classification and Labelling of Chemicals¹⁹ was adopted in December 2002 and is being implemented worldwide with a target for completion of 2008. The purpose of the GHS is to provide a common system to cover the wide range of languages, ages and social conditions that people face around the world. The intention is to communicate information on the hazards posed by chemicals particularly through the provision of safety data sheets. Agenda 21 adopted at the United Nations Conference on Environment and Development (UNCED) in 1992 provided the mandate to complete this system. It was managed under the auspices of the Interorganisation Programme for the Sound Management of Chemicals (IOMC).

4 The Notification of New Substances Regulations

Notifications schemes for new chemical substances which are manufactured or imported into the EU were first introduced during the 1970s by individual member states. This allowed a system for potential assessment of risks to consumer and occupational health and the environment. A sixth amendment to the Dangerous Substances Directive (DSD) (79/831/EEC)²⁰ introduced a European notification system in 1981. A seventh amendment to the DSD (92/32/EEC)²¹ was adopted in April 1992 with effect from November 1993 and introduced a risk assessment for new notified substances. This Directive was implemented in the UK as the Notification of New Substances Regulations 1993 (NONS 93).²² Over 6000 notifications have been made since 1981 covering more than 3700 substances of which some 2500 have been notified under the seventh amendment since 1993. The seventh amendment is a single market directive, which ensures that notification requirements are the same in all EC Member States and that a notification accepted in one Member State is valid for all of them. The notification requirements are harmonised across the Member States, which is intended to save notifiers, mostly industrial organisations and companies, time and money.

A notification for a new chemical substance requires the presentation of a technical dossier containing information about the production and uses of the chemical and data about its physical, chemical, toxicological and ecotoxicological properties. There is a requirement for classification and labelling proposals with any necessary precautions that need to be taken and a draft assessment of any risks that the chemicals pose to human health or the environment. The amount of information required increases according to the quantity of chemical manufactured per year starting at 10 kg and with a 'base-set' of data for substances from 1 to 10 tonnes per year and with further toxicological and ecotoxicological testing required for quantities above 10, 100 and 1000 tonnes.

The regulations are administered in each Member State by a Competent Authority (CA), which in the UK is the Health and Safety Executive and the Environment Agency acting jointly. The function of the CA is to evaluate the technical dossiers, provide a risk assessment, request further information from the notifier if necessary

and liaise with European Chemicals Bureau (ECB) Work Area New Substances which manages the New Chemicals Data Base. There is a system whereby information exchange and discussion on dossier content and interpretation takes place between Member States through meetings chaired by the ECB or Directorate General (DG) Environment. The outcome of these meetings is recorded in a 'Manual of Decisions,' which provides information and guidance for industrial and other stakeholders with an interest in new substances and their risks to the environment and human health.

The definition of a New Substance is limited by the enforcement date of the sixth amendment to the Dangerous Substances Directive mentioned earlier (79/831/EEC), which differentiates between new and existing substances. Existing substances are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), which was published in the Official Journal of the European Union on 15 June 1990. The Inventory lists 100,196 entries, which were on the EU market between 1 January 1971 and 18 September 1981. Chemicals introduced after 1981 are listed in the European List of Notified Chemical Substances (ELINCS), which is periodically updated in an Official Journal (OJ). New chemicals in this category do not include pesticides, veterinary medicines, biocides, pharmaceuticals, cosmetics, foodstuffs, radioactive materials, chemical wastes and substances used only in scientific research in small quantities.

5 Existing Substances Regulations

Council Regulation 793/93/EEC²³ was adopted in 1993 and legislates on the evaluation and control of the risks from all existing substances, listed in EINECS, manufactured or imported into the EC. In the UK the Regulation is enforced by the Notification of Existing Substances (Enforcement) Regulations (1994).²⁴

Regulation 793/93/EEC was one outcome following concern over potential risks arising from existing chemicals towards the end of the 1980s and the Fourth Community Action Plan for the Environment (1987–1992) of the Council of the European Community highlighted as a major objective the evaluation of the risks to the environment and human health from chemical substances. The Fourth Action Programme proposed a means of prioritising chemicals for action and suggested how appropriate data should be gathered and assessed for risks to the environment and human health.

Just before the EC action programme was launched, the Organisation for Economic Co-operation and Development (OECD) had recognised the need for work on existing chemicals by recommending in 1987 a Systematic Investigation of Existing Chemicals and launched a programme of work in 1988. OECD and United Nations initiatives on chemicals are furthermore linked into the international arena through the development of strategy for the environmentally sound management (ESM) of toxic chemicals which was outlined in Chapter 19 of Agenda 21 of the Rio Declaration and adopted at the United Nations Conference on Environment & Development (UNCED) in 1992.

The Existing Substances Regulation complements the new substances element of the Dangerous Substances Directive Regulation and has four discrete phases to the assessment process; collection of data, setting priorities, risk assessment and risk reduction.

As a means of setting some priorities for dealing with the large number of chemicals in the EINECS, the Regulation initially looked at chemicals produced in high-production volumes (HPVs) as a surrogate for potential environmental exposure. In the context of the regulations, an HPV is a chemical which was either produced or imported into the EC in quantities exceeding 1000 tonnes per year in the period between March 23, 1990 and March 23, 1994. Subsequently, there was a requirement for submission of a reduced data package for chemicals in the 10–1000 tonne bracket by June 4, 1998. The Regulation requires that all data are in a standard format, the Harmonised Electronic Data Set (HEDSET) and all the information is stored in the International Uniform Chemical Information Database (IUCLID), which is required to be updated every 3 years by companies that have previously submitted data which is held on it.

The data collected is reviewed by the Commission and Member States and lists of chemicals requiring priority action drawn up. Four such lists have been drawn up since 1994 comprising 144 chemicals. Prioritised substances undergo an extensive assessment of their hazards and risks to man and the environment, the latter covering, aquatic, terrestrial and the atmospheric compartments and any tendency for chemicals to bioaccumulate in the food chain. The risk assessments are carried out according to the Technical Guidance Documents (TGD) on Risk Assessment for New and Existing Substances.²⁵ On the basis of the TGD, the ECB has produced a European Union System for the Evaluation of Substances (EUSES),²⁶ which enables users to assess risks rapidly and efficiently by looking at the relationship between a substance's expected emissions and its effects on organisms.

The outcome of a risk assessment may be categorised in one of three ways:

- (i) No need for further information/testing
- (ii) At present no need for further information and/or testing and no need for risk reduction measures
- (iii) Need for limiting the risks.

Where the outcome is the need for limiting the risks, a risk reduction strategy must be developed. This is carried out according to the Technical Guidance Document (TGD) on Risk Reduction. The implementation of risk reduction strategies is primarily via the Marketing and Use (M&U) Directive (76/769/EEC),²⁷ which will specify in an amendment to the Directive the restrictions that need to be placed on using the substance in order to reduce the risk and prevent harm. For example, Directive 2003/53/EEC is a recent amendment to the M&U Directive that places restrictions on the use of nonylphenol and nonylphenol ethoxylates where those uses result in discharges, emissions or losses to the environment. The risk assessment, which identified a need to reduce risks, was identified by the Commission in March 2001 and the decision endorsed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), which has more recently become the Scientific Committee on Health and Environmental Risks (SCHER). Other chemicals recently controlled under the M&U Directive include the brominated flame retardants pentabromodiphenylether and octabromodiphenylether. In the past, substances such as polychlorinated biphenyls (PCBs), asbestos and cadmium have been subject to restrictions on their use via this directive.

6 New European Chemicals Policy (REACH)

It has been widely accepted across the EU Member States that since the Existing Substances Regulations were introduced in 1993, the number of chemicals which have progressed to some form of control or regulation has been slow even though around 140 have been prioritised as of high concern for the environment. This is only a very small proportion of those 100,000 or so chemicals on EINECS of which some 30,000 are thought to be produced or imported into the EU in quantities of over 1 tonne.

The need to reform the Community's chemicals policy was discussed at an informal meeting of EU Environment Ministers in Chester in 1998 and this prompted the Commission to issue a White Paper in February 2001 on a Strategy for a Future EU Chemicals Policy. Following much discussion and dialogue with all major stakeholders, the Commission issued a proposal for a New Regulatory Framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) on 29 October 2003. REACH aims to protect the environment and human health via the environment while at the same time maintaining the competitiveness and enhancing innovation within the chemicals industry in the EU.

REACH is proposed to cover both new and existing substances and will require industrial organisations that manufacture or import chemicals in excess of 1 tonne per annum to register the chemical in a central database.

Information to be provided on the chemical properties will be dependant on the quantity of chemical supplied or imported in a rather similar but less extensive manner to that required under the current UK New Substances Regulations. Emphasis for the registration procedure will be placed on the maximum sharing of data with the aspiration of one registration for each substance. This will have the effect of minimising costs to industry and also will be one way for achieving a key objective for the regulation of minimising the use of animals for the testing that will be necessary to provide the data required to ensure adequate protection of human health and the environment.

The Evaluation stage of REACH will examine the data provided during registration to determine whether any further information is required and the hazards and risks posed by the chemical substance.

Chemicals evaluated as of most concern which are likely to be, at least in the first instance, those produced in quantities of over 1000 tonnes and with certain toxic, persistent and bio-accumulative properties (PBT) or category I and II carcinogens, mutagens or reprotoxins will be subject to Authorisation. This will require the registrant to gain a specific approval for all uses to which any chemical is put. All other uses of the chemical would be banned. Implicit in its approach to dealing with chemicals of high concern, REACH includes the concept of chemical substitution. Substitution will require that, wherever possible, products or processes using chemicals of high concern should replace them with an alternative chemical or process which poses a lower risk to the environment.

The REACH proposals are currently being considered by the Council of the EU and the European Parliament for adoption under the co-decision procedure. The Commission has defined an Interim Strategy leading up to and after the entry into force of the Regulation. The strategy comprises three phases; an interim period running from 2004 to 2006 will put in place a number of preparatory actions to enable

the effective administration of the legislation immediately after it comes into force; a transition period covering 2006–2008 and a final phase commencing in 2008, when the proposed European Chemicals Agency takes over running REACH from the Commission. The interim strategy will prepare for REACH by developing Technical Guidance Documents (TGDs), software tools and infrastructure through a series of REACH Implementation Projects (RIPs), by re-evaluating current work on chemicals to make resources available for the development of REACH and by ensuring full stakeholder engagement, particularly with industry, to ensure that the various components of REACH are workable. Much of this work is the responsibility of the ECB, which provides support for the Commission on this new legislation on chemicals.

In the UK, a Government position statement on REACH was published in December 2002 and since then the Government has, among other activities, responded to the Commission consultation of May 2003, launched its own consultation process in March 2004, held a stakeholder conference in April 2004, carried out a series of regulatory impact assessments and been particularly active in developing a proposal for 'One Substance, One Registration' to optimise data sharing to minimise costs and the requirement for animal testing.

7 Other European and UK Regulations on Chemicals

7.1 OSPAR

The Convention for the Protection of the Marine Environment of the North-East Atlantic of 1992 (the OSPAR Convention),²⁸ of which the UK were one of 16 contracting parties, agreed that all should take measures to safeguard the marine environment against adverse effects of human activities, including pollution from hazardous chemicals to protect human health and to conserve the marine ecosystem. It entered into force in March 1998. It replaces the Oslo (1972) and Paris (1974) Conventions but decisions, recommendations and all other agreements adopted under those Conventions continue to be applicable unless terminated by new measures adopted under the 1992 Convention.

An OSPAR Commission was established to administer the Convention and to develop policy and international agreements. The Commission has reached a number of decisions, recommendations and other agreements relating to its Hazardous Substances Strategy²⁹ which was reaffirmed in 2003. The strategy aims to reduce pollution of the marine environment through a continuous programme of reducing discharges, emissions and losses of hazardous substances with the intention of eliminating them by the year 2020.

A List of Substances of Possible Concern to the marine environment has been drawn up and priorities for individual chemicals for risk assessment and any necessary action have been determined. The list is a dynamic list and is regularly revised, most recently in August 2004. The list was drawn up according to a Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC) developed by the Convention. The list, originally agreed in 2002, contains approximately 400 chemicals that meet specific criteria for persistence, toxicity and bioaccumulation potential. Industries are invited to bring forward data for each prioritised

chemical and each is adopted by a sponsor country which, in conjunction with OSPAR, produces a background document covering the properties of the chemical and likely pathways to the marine environment. The document provides an environmental risk assessment and is used to recommend any actions required to meet the aims of the Convention on hazardous substances.

OSPAR works with the European Commission to ensure that work is not duplicated on specific chemicals under other regulatory programmes (such as the Existing Substances Regulations) and carries out hazard and risk assessments according to the same guidelines as those used under the Existing and New Substances Regulations described earlier.

7.2 The UK Offshore Chemicals Notification Scheme and the Offshore Chemical Regulations

OSPAR also played a key role in the development of the Offshore Chemicals Notification Scheme (OCNS), which was originally introduced in 1979, and applies to all chemicals that are used in connection with the exploration and other offshore activities in the processing of petroleum and gas on the UK Continental Shelf. The UK Government introduced a revised scheme in 1993 to take account of test protocols approved by OSPAR and this was taken forward further in 1996 when OSPAR introduced a Harmonised Offshore Chemical Notification Format (HOCNF), which is used to define the testing requirements for offshore chemicals in the NE Atlantic sector.

OSPAR introduced a decision in 2002 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals, which are administered in the UK under the Offshore Chemical Regulations (OCR) 2002³⁰ which came into force on 15 May 2002. The Department for Trade and Industry administers the OCR with technical support from Defra's Centre for Environment, Fisheries and Aquaculture Science (CEFAS).

The regulations have been introduced to ensure better control, in a proportionate and cost-effective manner, of the use and discharge of offshore chemicals which inevitably contaminate the marine environment. The substitution of hazardous for lower impact chemicals is also a key element of these regulations.

The system for risk assessment of chemicals is similar to that used in other chemical regulatory regimes but uses data on marine organisms (algae, invertebrates and fish) and chemicals are ranked on the basis of a Hazard Quotient and their persistence and bioaccumulative properties. The regulation also places an obligation on authorities to use the Chemical Hazard Assessment and Risk Management (CHARM) hazard assessment module as the primary tool for ranking chemicals. Chemicals are placed on a List of Notified Chemicals for 3 years when they become due for re-certification. The hazard data are used by operators of exploration platforms to carry out site-specific risk assessments for the particular chemicals they propose to use.

7.3 Hazardous Waste Regulations

Hazardous chemicals can become hazardous waste at the end of their life and the issue of how to dispose of, transport, store or treat those wastes is addressed by various

regulations and directives within the EU. The European Hazardous Waste Directive (91/689/EEC)³¹ sets out the requirements for the controlled management of hazardous (special) waste. The Directive was implemented in England, Scotland and Wales by the Special Waste Regulations (1996)³² and various subsequent amendments to them. The regulations were substantially reviewed in 2000³³ and improvements have been developed and, following a consultation in 2004 on new Hazardous Waste Regulations for England, it is intended to introduce them during 2005. One particular requirement of the new regime will be for producers of hazardous waste to notify their premises to the Environment Agency and guidance on this process will be provided.³⁴

8 International Activities on Chemicals

8.1 OECD and ICCA HPV Chemicals Programmes

In 1990, OECD decided to embark on a system for evaluating the hazards from High Production Volume (HPV) Chemicals that would involve the co-operation and sponsorship of all member countries. HPV chemicals are defined as those chemicals reported to be produced or imported into member countries of OECD or the EU in quantities of over 1000 tonnes per year. Industry would be encouraged to provide the information needed to complete a Screening Information Data Set (SIDS) with an agreed number of initial toxicological and ecotoxicological end points. When the SIDS dossier is complete, an initial appraisal of the data is made (SIAR, SIDS Initial Assessment Report), potential hazardous properties of the chemical are identified and areas for further work are recommended if need be. Exposure information is taken into consideration based largely on the use to which the chemical is put to make a preliminary assessment of likely risks to the environment and human health. SIDS dossiers and assessments are made available worldwide through the United Nations Environment Programme (UNEP) when they have been agreed by all member countries at a SIDS Initial Assessment Meeting (SIAM).

In 1998 a major refocusing of the HPV programme took place to streamline various aspects of the selection of chemicals, to enhance the SIDS testing programme and to focus the SIDS work on hazard identification but to leave risk assessment to be looked at by a joint OECD/IPCS (International Programme on Chemical Safety) project.

Also in 1998 a major voluntary initiative was launched by the International Council of Chemical Associations (ICCA) to provide internationally harmonised data sets and hazard assessments for approximately 1000 HPV Chemicals. This programme effectively replaced the system by which member states sponsored individual chemicals through the system. The ICCA has been working in partnership with the refocused OECD HPV programme and using the OECD HPV Chemicals List to establish priority chemicals for action. The aim was to have SIDS completed by the end of 2004 but while this has not been met with only around 260 being assessed to date, all 1000 are being progressed. The ICCA are urging participating companies to complete work on the remaining chemicals as soon as practicable. Chemical companies have been providing data needed for the various physical and chemical properties and toxicological and ecotoxicological end points required under the OECD programme. Industry recognises the value of the availability of the hazard data to internationally

agreed guidelines to prevent duplication of testing, minimising the numbers of animals used for testing and costs to themselves and that it provides a framework for the risk assessment of the chemicals on a global, regional or national basis.

8.2 *United Nations Environment Programme (UNEP)*

In addition to work carried out on chemicals by the OECD, the United Nations coordinates a wide range of international activities to control hazardous chemicals. The Stockholm Convention of 2001³⁵ is a worldwide treaty to protect the environment and human health from persistent organic pollutants (POPs). These chemicals, which include organochlorine insecticides such as DDT, aldrin and dieldrin, toxaphene, PCBs and dioxins and furans, are chemicals which persist in the environment for long periods of time, have the properties to become very widely distributed around the globe, bioaccumulate in the bodies of living organisms and are toxic to wildlife and humans. An assessment report on these chemicals was produced for the International Programme on Chemical Safety in 1996 and served as a basis for development of a work plan to complete the assessment process called for in the UNEP.

The Stockholm Convention, an international legally binding instrument, implemented international action on POPs and national governments are taking measures to reduce the release of POPs into the environment. The Convention entered into force in May 2004 and was ratified by EU in November 2004 and by the UK in January 2005. Regulation 850/2004/EEC³⁶ bans the intentional production, marketing and use of the substances listed in the Convention so far. The first Conference of the Parties of the Stockholm Convention was held in May 2005 to ensure effective implementation and further development of the Convention. One aim will be to set up a POPs Review Committee for adding new chemicals to the Convention. The adoption of guidelines on the minimisation of dioxin releases and the consideration of guidelines on the levels of POPs permitted in waste will also be considered.

In 1998 governments adopted the Rotterdam Convention³⁷ of the United Nations, which made the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade legally binding. From 1980 up to 1998, the PIC procedure was voluntary and required exporters of hazardous chemicals to obtain the PIC of importers before proceeding with the trade. The Rotterdam Convention gave importing countries the means to identify potentially hazardous chemicals and to withhold importation of any that they were unable to manage safely. Where hazardous chemicals are imported, the convention provides for support in terms of appropriate labelling and handling. It also enforces compliance on exporters to meet the requirements of PIC. The Rotterdam Convention entered into force on 24 February 2004 after the EU had implemented in January 2003 Regulation 304/2003/EEC³⁸ concerning the export and import of dangerous chemicals. The first conference of the parties to the Convention held in September 2004 agreed the addition of 14 hazardous chemicals to Annex III of the Convention and established a chemicals review committee.

A decision to create a Strategic Approach to International Chemicals Management (SAICM) was adopted by the UNEP Governing Council in February 2002. UNEP agreed to work with member governments and other stakeholders to review current actions to advance the sound international management of chemicals, to further

advance the approach of the Intergovernmental Forum on Chemical Safety (IFCS) Bahia Declaration on Chemical Safety and to propose specific projects and give them priorities. It is due to be adopted at an International Conference on Chemicals Management (ICCM) in February 2006.

The Bahia Declaration of 2000³⁹ set out some key goals for chemicals in the international arena. These were centred on the essential role of robust chemical management in sustainable development and the protection of human health and the environment and promoted a precautionary approach. Other objectives were to assist countries with issues of chemical safety, better provision of data on chemicals and control of illegal trade in hazardous chemicals.

8.3 Disposal of Hazardous Waste

The Basel Convention⁴⁰ adopted on 22 March 1989 in response to international concern about the shipping of hazardous waste, including waste chemicals, to developing countries when a tightening of legislation in the 1980s resulted in a steep rise in the cost of disposal. The Convention was initially concerned with setting up a mechanism to control the movement of hazardous waste across national boundaries and developed criteria for Environmentally Safe Management (ESM) of hazardous wastes. The Convention is now building on the framework for movement control to implement and enforce treaty commitments. It will also focus on the minimisation of hazardous waste generation.

The objective of ESM is to protect human health and the environment by minimising hazardous waste production. The concept invokes an 'integrated life cycle' approach where controls are placed at all stages in waste generation through to transport, treatment, re-use, recycling, recovery and final disposal.

A guiding principle of the Basel Convention is that hazardous wastes should be dealt with close to where they are produced. Under the Convention movement of hazardous waste across international borders can take place only upon prior written agreement between the state of export and the states of import. It is illegal to make shipments without such agreement and without appropriate documentation. An exception is granted where an exporting state does not have the capacity to deal with the waste in an environmentally acceptable manner.

The Secretariat of the Convention co-operates with individual national authorities to help them in developing national legislation, compiling waste inventories, assessing hazards and preparing waste management plans and policy tools. It also provides advice on dealing with accidents with hazardous waste and can provide expertise and equipment if necessary to national authorities.

9 Voluntary Approaches to Control of Chemicals in the Environment

9.1 UK Chemicals Strategy

In 1999 the UK Government set out its proposals for a Chemical Strategy on the Sustainable Production and Use of Chemicals.⁴¹ Its aim was to avoid harm to the

environment and human health via environmental exposure to chemicals. The strategy was designed to make information about the environmental risks of chemicals publicly available, to continue to reduce the risks to the environment from chemicals while maintaining the competitiveness of industry and to phase out those chemicals that pose an unacceptable risk to the environment and human health. A key feature of the strategy was the establishment of the UK Chemicals Stakeholder Forum (CSF) to promote a better understanding between stakeholders on issues of chemicals and the environment and to provide advice to the Government about chemicals in the environment to guide the development of policy. The Stakeholder Forum was established in 2000 with the following terms of reference:

- Act as a barometer for the views and opinions of stakeholders
- Advise on the selection of criteria for identification of chemicals needing priority attention and the risk management strategies required for them
- Report on such chemicals, advising on precautionary controls and restrictions and time scales for action
- Advise on the development of indicators of environmental exposure to hazardous chemicals, including targets for reducing overall exposure of the environment
- Conduct its business in an open fashion, making its documents, minutes and advice public.

The work of the CSF has been carried out in conjunction with technical support from the Environment Agency and the Advisory Committee on Hazardous Substances (ACHS), which added support to the CSF to its terms of reference in 2000. The ACHS is an independent Scientific Non-Departmental Public Body made up of 10 experts in the fields of toxicity, ecotoxicity and the properties and behaviour of chemicals in the environment.

An early task of the Stakeholder Forum was to decide on a set of criteria for chemical properties to enable selection of substances for priority action. The criteria were based on properties of likely persistence (P) in the environment, the potential to accumulate in biological systems (B) and toxicity (T) to environmental organisms or to humans. Chemicals meeting the criteria were then identified from HPV chemicals in the International Uniform Chemical Information Database (IUCLID) that was set up under the Existing Substances Regulations referred to earlier. This resulted in a list of approximately 120 chemicals potentially having PBT properties and the CSF 'list of chemicals of concern' was published on the internet in June 2003.

The CSF has selected chemicals from this list and engaged with industry to progress actions to gather data on hazardous properties and, where appropriate, asked for action to be taken to reduce risks to the environment. An early success of the CSF was to recommend a voluntary agreement between industry and the Government for the reduction of risks from nonylphenol, nonylphenol ethoxylates and to prevent any increase in risks from octylphenol and octylphenol ethoxylates and this was agreed in April 2004 with the chemical supply industry and downstream users.

Between 2002 and 2004, the CSF considered 10 chemicals on its list in some detail including tetraethyl lead, hexamethyldisiloxane, vinylneodecanoate, hexabromocyclododecane, tetrabromobisphenol-A, dodecylphenol and tertiary-dodecylmercaptan.

These chemicals are now all part of ongoing programmes of hazard and risk assessment and, where appropriate, risk reduction and progress is regularly reviewed by the Stakeholder Forum at its 3-monthly meetings. All of the work of the CSF is published in an Annual Report.

During 2004, the work of the CSF had a major review, which included an external consultation, and Ministers subsequently agreed a change of focus for the CSF work to include an advisory role to Government on the developing REACH regulation. The review also led to a reconsideration of how to speed up the consideration of individual chemicals and this resulted in moving from single substance consideration to looking at groups of chemicals at the same time. The ACHS identified nine groups from the CSF list of chemicals of concern and three of those, representing around 20 chemicals are now being considered by the CSF. The prime objective is to establish the PBT properties of the chemicals to determine whether they are of high concern and should be candidates for further action. Industry, in the form of individual companies and chemical sector organisations assist the CSF in the provision of data which feed in to European or international chemical programmes on hazard and risk assessment as described earlier. The UK Environment Agency does undertake National Risk Assessments, according to internationally agreed guidelines, to speed up action on particularly hazardous chemicals that have been identified as of concern to the UK environment and human health. Some of the chemicals from the CSF list of concern are being evaluated through this route which can lead to recommendations for local risk reduction measures being taken where unacceptable risks have been identified.

Since October 2004, the CSF has addressed two major issues that are part of the developing REACH regulation. It has considered the UK Government position papers on 'One Substance One Registration' and 'Substitution', the latter a crucial aspect of the process of chemical authorisation proposed under REACH. The CSF will continue to address further issues as the policy develops and the regulation moves towards the implementation phase.

9.2 *Royal Commission on Environmental Pollution*

The Royal Commission on Environmental Pollution is an independent standing body which was established in 1970 to advise the Queen, the Government and members of the public on environmental issues. Its 24th report published in June 2003 was entitled 'Chemicals in Products; Safeguarding the Environment and Human Health'⁴² and it sought to challenge current approaches to the regulation of chemicals and to make recommendations for future regulatory systems. The 54 recommendations focussed on a new approach to the management of chemicals in the environment some of which may be common to or complementary to the REACH proposals. The recommendations comprise a stepwise system for handling chemicals commencing with the compilation of a list of all marketed chemicals, sorting, selecting and evaluating chemicals of concern and introducing risk management action where necessary. The report emphasises the need to phase out animal experiments in regulatory testing and promotes the greater use of *in vitro* testing methods and the wider application of existing data and computational techniques to describe the hazardous properties of chemicals.

The Commission also considered aspects of how to manage a chemical assessment programme, international harmonisation of processes and procedures and various ways to encourage action from industry through, for example, the introduction of a charging scheme to encourage chemical substitution, further voluntary initiatives like those promoted by the CSF, better information supply and labelling and improvements to the regulatory process to stimulate innovation in the chemical industry.

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