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Chemicals and Genetically Modified Organisms - Overview

1 Introduction and Overview

This Section of the Handbook deals with EC legislation related to Chemicals and Genetically Modified Organisms. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation. The fiches are presented according to their TAIEX numbering.

1.1 EU Policy

The adoption of the directive on the classification, packaging and labelling of dangerous substances (67/548/EEC) provided the first controls over the marketing and use of hazardous chemicals placed on the market. Today it provides for a common system for the classification and labelling of such substances according to their physico-chemical and toxicological properties which might present a risk under conditions of normal handling and use. The directive has undergone a number of amendments reflecting changes to its scope and purpose. It has also undergone numerous “Adaptations to Technical Progress” (ATPs) by means of Commission Directives that implement and change items of a more technical nature from within the Directive and its major amendments. The broad thrust of this legislation is to establish a common system across EU Member States and so prevent barriers to trade by the introduction of different national standards with regard to (mainly chemical) substances and while ensuring a high level of protection for man and the environment.

As first conceived the Directive on the classification, packaging and labelling of dangerous substances was concerned with specifying and providing a warning system for certain classes of intrinsic hazard, pertaining to chemical substances. These hazards were, in the first instance related either directly to human health (toxicological properties) or indirectly to human health from so-called “physico-chemical” properties such as flammability or explosivity. In this context, the Directive (that is all the various Amendments and ATPs) lays down specific classes of hazardous properties and also specific criteria and specific test methodology by which it may be ascertained whether the substance in question should be classified according to its hazardous properties. Once classified, the substance shall be labelled to warn the user of the hazard and in some cases how the substance shall be packaged to reduce the hazard to specific parts of the population (for example, to children or the blind).

Except for “priority” substances under the “Existing Substances Regulation” (793/93 – see later), “existing substances” are classified only on the basis of what is known about the substance. That is, there is no legal requirement to generate new data specifically for classification purposes. This classification is either carried out by a committee of experts of the Member States chaired by the Commission or by the manufacturer in accordance with the data in his possession. In the former case, the classification decision and the consequent label, are recorded within Annex I of the Directive after adoption by the Commission. Annex I is the sole basis on which hazard labelling is applied to a listed substance within the EU. For existing substances not listed in Annex I, there is a requirement that the manufacturer determines what is known about the substance and then apply the classification, packaging and labelling rules within the Directive before continuing to market the substance.

The 6th amendment of the Directive (79/831/EEC) introduced for the first time requirements for the notification of new substances. The purpose of this is to gather information on each new substance, before it is placed on the market in the EU including its identity, toxicological, ecotoxicological and physico-chemical characteristics. The European Commission has developed two lists for the purposes of the directive: the European Inventory of Existing Commercial Chemical Substances (EINECS) and the European List of New Chemical Substances (ELINCS). EINECS was published in 1990 and lists all substances placed on the market in the EU between 1971 and 1981. ELINCS is also published regularly in the Official Journal of the European Communities and contains substances placed on the market for the first time since 1981 (= new substances).

The 6th Amendment also introduced for the first time the classification “Dangerous for the Environment” which was brought into effect with the publication of the criteria for this classification in the 18th ATP (93/21/EEC). As part of the notification procedure, substances are considered for classification (including the classification “Dangerous for the Environment”).

The seventh amendment of the Directive (92/32/EEC) besides harmonising the requirements for the notification of small quantities of new substances, also introduced the requirement that the data obtained in the notification process should be used to assess the risk of the substance to man and the environment. This requirement was implemented by the Directive 93/67/EEC on the “Principles of Risk Assessment of New Chemicals”.

As indicated above, the Directive 67/548/EEC, through its subsequent amendments, has requirements to develop data and perform risk assessments for new substances. The Existing Chemicals Regulation (EEC/793/93) brought into effect a system whereby all existing substances, manufactured or imported above certain tonnage thresholds, must be reported to the Commission. Among other requirements, this report must include the amount of substance manufactured/imported, all available data on physico-chemical, toxicological and ecotoxicological studies and the manufacturer’s classification and labelling proposals (if the substance is not listed in Annex I of Directive 67/548/EEC). Based on this information, together with the views expressed by Member States, the EC, through a regulatory Committee, is required to produce formal lists of “priority” chemicals. A Member State rapporteur is allocated to each priority chemical and this rapporteur can require the manufacturer(s) to supply such information as is necessary to evaluate the risks to man and the environment posed by the use of that substance. Following the discussion and finalisation of the rapporteur’s risk assessment report by the Member States, a decision is taken as to whether restrictions are required on the marketing and use of the substance assessed.

Although the sale to developing countries of chemicals, particularly pesticides that were banned in developed countries became an issue in the 1970’s with a call for “prior informed consent” before export, the European Community did not place controls on exports until 1988. The first Regulation (EC/1734/88) was replaced in 1992 by Regulation EC/2455/92 which requires importing countries to be informed before exports are made of a number of substances banned or severely restricted in the EU. These are listed in the Annex 1 of the Regulation. In addition, for chemicals subject to the PIC procedure and listed in Annex II of the regulation, exports may not take place to countries participating in the “Prior informed consent procedure” established by UNEP and FAO without the countries’ specific consent. Finally, the Regulation also provides that dangerous chemicals and preparations, when exported, must be labelled as for their marketing within the EU.

The introduction of restrictions on the marketing and use of substances is an example of the “substance orientated approach” to chemicals control. This approach was put forward in the fourth environmental action plan, and early examples of such an approach were the directives on the prevention and reduction of environmental pollution by detergents (73/405/EEC, 82/242/EEC and 82/243/EEC) and by asbestos (87/217/EEC), which were aimed at controlling pollution of air, water and land by detergents and asbestos (although the detergent directives are still in force, they are largely historical). Similarly, Regulation EC/3093/94 aims to combat ozone depletion by placing restrictions on the production, sale and use of ozone depleting substances.

Given the potential hazards of chemicals, a central requirement of the European Community chemicals legislation is the obligation to conduct thorough high quality tests on potential hazardous properties before a new chemical substance may be placed on the market. Whilst this legislation lists the methods that should be used to conduct these tests (listed in Annex V of Directive 67/548), it does not make any general provisions relating to laboratory practices. Therefore, the need arose to introduce a system providing for mutual recognition of safety data in order to avoid the duplication of safety tests on chemical products due to differences in laboratory practices from one Member State to another.

Such a system of mutual recognition must be based on a scheme guaranteeing reliability and high quality of safety data. Under the auspices of the OECD, good laboratory practice (GLP) principles have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemical products. Through Council Directive 87/18/EEC and Council Directive 88/320/EEC, the GLP Principles were integrated into European Community legislation. Moreover, it was considered necessary to monitor the activities of laboratories conducting safety tests for regulatory purposes. Therefore, Council Directive 88/320/EEC requires Member States to set up a monitoring authority to inspect all laboratories claiming to apply GLP Principles and to verify whether the tests are actually conducted in compliance with GLP Principles. The purpose of this system of mutual recognition is twofold: first, the abolition of non-tariff barriers impeding trade between Member States and secondly, the guarantee of a high degree of protection of human health and the environment.

Although Council Directive 86/609/EEC also deals with certain aspects of safety tests required under European Community chemicals legislation, it is mainly concerned with the harmonisation of the protection of animals used for certain experimental purposes. The significant differences between the legal systems of Member States with respect to the protection of animals used for experimental purposes presented a risk of distorting the functioning of the internal market. Another major aim of the directive is the reduction of the number of animal experiments. This should be achieved by the mutual recognition of test results.

In contrast to the legislation on chemical control, concern about the environmental hazards of genetically modified organisms (GMOs) is more recent. While there was early concern, in the 1950s, when the potential of genetic engineering became apparent, this concern was directed at potential risks to people and subsided when measures to control GMO hazards by containment were introduced. In recent years concern has been expressed by environmental non-governmental organisations (NGOs) about the potential dangers of releasing GMOs, and especially plants, to the environment. This is beginning to be shared by the general public and taken into account by governments.

As a result of the public interest in GMOs, the area is highly politicised. Legal control of GMOs is based on whether the GMO is intended for contained use or deliberate release into the environment and, if intended for deliberate release, whether it is for the purposes of research and development or the placing on the market of products containing GMOs. The Contained Use Directive (90/219/EEC) covers the human health and environmental risks associated with genetically modified micro-organisms, defined as being any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. The Deliberate Release Directive (90/220/EEC) covers the human health and environmental risks associated with the release into the environment of genetically modified organisms, defined as being any biological entity capable of replication or of transferring genetic material in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. The Directives list techniques which, if used, lead to genetic modification as well as techniques that do not lead to genetic modification, and there are differences between the two directives.

The Deliberate Release Directive imposes differing requirements where the release is firstly for research and development purposes and, secondly where it is for the placing on the market of products containing GMOs. The provisions relating to the placing on the market of products containing GMOs do not apply to products covered by Community legislation which provides for a specific risk assessment similar to that laid down in the Deliberate Release Directive (e.g. Regulation EC/258/97 concerning novel foods and novel food ingredients).

Both Directives 90/219 /EEC and 90/220/EEC use terms such as “harm” and “environment” that are not defined and it is therefore open to individual Member States to apply their own definitions. However both directives include procedures to adapt the technical annexes in the light of developments.

Harm to the environment may be interpreted widely - for instance as including the consequences to wildlife of growing GMO crops that are subsequently sprayed with the weed killer to which they are resistant. Harm to people may be interpreted narrowly as potential to cause disease, or more widely as involving the social and economic implications of the growth of GMO crops. Some Member States wish to include ethical considerations in their assessments of hazard while others do not. As a result of these problems, the intention of the directive, that approval of release in one Member State should lead to Community-wide release, has not been achieved.

It is clearly important to resolve these disagreements and the Commission has tried to do this recently by proposing a revision of the deliberate release directive. However, at present this proposal does not resolve the definition problems referred to above and it seems that disagreement between Member States is likely to continue. The matter is complicated by the obligations accepted by the European Union as a member of the World Trade Organisation (WTO). The WTO specifically forbids barriers to trade being erected except in exceptional cases. The need to protect human safety may constitute such a case but, as there is no hard evidence that harm is caused by GMO plants, attempts to ban imports of GMO crops into the Community from the USA have failed.

1.2 EU Legal Instruments

The chemical and GMO sector considered in this Handbook covers ten pieces of legislation, consisting of seven directives and three regulations. This legislation can be subdivided into three categories, chemicals, GMOs, and good laboratory practice and animal experiments (see Box 1 below).

Box 1 Legislation Considered in the Sector on Chemicals and GMOs

Chemicals

- The Asbestos Directive (Council Directive 87/217/EEC).
- Directive on the Classification, Packaging and Labelling of Dangerous Substances (Commission Directive 67/548/EEC).
- Regulation on Evaluation of Risks of Existing Substances (Council Regulation EEC No. 793/93) and related Regulations.
- Regulation on the Export and Import of Dangerous Chemicals (Council Regulation EEC/2455/92).
- Regulation on Ozone Depleting Substances (Council Regulation EC/3093/94).

GMOs

- Directive on Contained Use of Genetically Modified Micro-Organisms (Council Directive 90/219/EEC and 98/81/EC).
- Directive on Deliberate Release of Genetically Modified Organisms (Council Directive 90/220/EEC).

Animal Experiments and Good Laboratory Practice

- Directive on the Protection of Animals Used for Experimental and Other Scientific Purposes (Council Directive 86/609/EEC).
- Directive on the Application of the Principles of Good Laboratory Practice (Council Directive 87/18/EEC).
- Directive on the Inspection and Verification of Good Laboratory Practice (Council Directive 88/320/EEC).

The overall objective of all the legislation on chemicals and GMOs is to minimise risk to health and, or, the environment. The GLP Directives have the principle aim of ensuring that specified health, environmental and safety tests carried out in different laboratories in different countries are all performed to acceptable and audited standards. Through the OECD implementation of the Mutual Acceptance of Data (MAD) agreement, this should ensure the world wide acceptance of GLP derived data, avoid the duplication of safety tests and within the EU achieve the abolition of non-tariff barriers. The mutual recognition of safety test data avoids the duplication of safety tests and, therefore, facilitates the trade in chemicals and chemical products. In contrast, the main objective of Council Directive 86/609/EEC is to minimise the suffering of animals used for experimental purposes.

Legislation on Chemicals

As indicated under Section 1.1, the Directive 67/548/EEC has a very wide ranging scope and *inter alia* regulates the classification, packaging and labelling of dangerous substances for

direct and indirect danger to people and danger to the environment. Regulation EEC/2455/92 standardises notification and information procedures for importing and exporting dangerous chemicals, and a number of regulations, primarily EEC/793/93, are concerned with the assessment of risks from chemicals. Directive 87/217/EEC (asbestos) and Regulation EC/3093/94 (ozone-depleting substances) are primarily concerned with the environment. However, each of these measures is concerned with wider impacts than are indicated above, with environmental measures affecting public health and vice-versa.

The legislation documented in this section is related to other legislation included in the environmental *acquis* as indicated in Table 1. Moreover, the legislation on environmental hazards of chemicals is also a sub-set of other legislation on chemicals. For example, the control of asbestos is the subject of several other directives aimed at protecting the health and safety of people, and their adoption has indirectly assisted environmental protection.

Legislation on GMOs

The principal directives on GMOs are Council Directive 90/219/EEC on contained use of GMOs and Council Directive 90/220/EEC on deliberate release of GMOs.

These two directives are not closely related to other legislation within the environmental *acquis* but are closely linked with other EU legislation, such as Council Directive 90/679/EEC on the protection of workers from risks relating to exposure to biological agents at work. Although this directive does not deal with GMOs, it contains provisions on the classification of micro-organisms with regard to the hazards they present. The controversies about released GMOs, mentioned above, have led to further legislation which impinges on the GMO sector. These include Regulation (EC) No. 258/97 concerning novel food and novel food ingredients and Regulation (EC) No. 1139/98 concerning the compulsory indication of the labelling of certain foodstuffs produced from GMOs. These regulations relate to the protection of the human health and to consumer information. It is important to implement legislation in the GMO section discussed here at the same time as implementing the principal regulations and directives mentioned above.

Legislation on Good Laboratory Practice (GLP) and Animal Experiments

There are only two directives dealing with Good Laboratory Practice: Council Directive 87/18/EEC and Council Directive 88/320/EEC. The former requires Member States to ensure that laboratories carrying out tests on chemicals or chemical products for regulatory purposes apply GLP Principles. The latter adds various requirements with respect to the monitoring and inspection of laboratories applying GLP Principles to ensure compliance with the principles.

Both directives must be read in conjunction with various directives regulating chemicals and chemical products. The following directives and regulations are of particular importance: Council Directive 67/548/EEC (classification, packaging and labelling of dangerous substances), Regulation (EEC) No. 793/93 (risks of existing chemicals), Council Directive 88/379/EEC (dangerous preparations), Council Directive 75/318/EEC (medicinal products), Council Directive 87/20/EEC (veterinary medicinal products), Council Directive 76/768/EEC (cosmetics), Council Directive 83/228/EEC (animal feed), Council Directive 89/397/EEC (food), Council Directive 91/414/EEC (pesticides) and Council and EP Directive 98/8/EC (Biocides).

All these directives and regulations require the performance of comprehensive safety tests before the respective product or chemical may be placed on the market. Council Directive 87/18/EEC provides (for each of these directives and regulations) that the required safety tests

must be carried out in compliance with GLP Principles. This interrelationship between the GLP directives and legislation concerning specific chemicals must be carefully considered when drafting national implementing legislation.

Council Directive 86/609/EEC is mainly concerned with the protection of animals used for experimental purposes. It is applicable to any testing carried out in the framework of any legislation requiring testing on animals. In addition to chemical legislation, as for example, Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, it contains several provisions beneficial to animal protection, including a prohibition of the marketing of cosmetics containing ingredients or combinations of ingredients tested on animals.

Table 1 Summary of Key Relationships between the Chemical and GMO Sector and EU Legislation in the Environmental Acquis and Legislation

Related Sector Legislation	Relevance to Chemical and GMO Sector
Horizontal	
Reporting Directive (91/692/EEC)	This directive standardises reporting requirements for certain other directives
Air Quality	
Montreal Protocol (Depletion of the Ozone Layer) Council Decision (88/540/EEC)	The EU has ratified the Vienna Convention and Montreal Protocol to limit and phase out production and use of compounds which destroy the ozone layer. The Regulation on ozone depleting substances (EC No. 3093/94) implements the Montreal Protocol.
Waste Management	
Framework Directive (75/442/EEC)	This directive sets out a framework for handling and disposing of waste. This will affect installations handling dangerous chemicals.
Hazardous Waste Directive (91/689/EEC)	This directive sets out a framework for handling and disposing of hazardous waste.
Water Sector	
The Dangerous Substances Directive (76/464/EEC)	This directive controls emissions of dangerous substances to waters.
IPPC and Risk Management	
IPPC Directive (96/61/EEC)	The IPPC Directive introduces an integrated system of pollution prevention and control for a range of specified industrial activities. It established an integrated system of permits, which contain specific conditions including emission limit values and the application of Best Available Techniques (BAT).
Seveso II Directive (96/82/EC)	This directive aims to prevent major accidents involving dangerous substances and to limit their impacts on people and the environment.

2 Development of a Sectoral Strategy and Implementation Plan

2.1 Key Factors Influencing Strategy Development

In Section 2.4 of the Introductory Chapters of this Handbook, the key activities to be undertaken in preparing a plan to implement environmental legislation are summarised in the Implementation Planning Framework checklist.

The chemicals and the GMO sector is regulated through a wide range of measures. These include requirements for prior notification to and authorization from the competent authority, risk assessment procedures, the classification, packaging and labeling of regulated substances, and restrictions on control and supply. The following text outlines key considerations to be taken into account when planning the implementation strategy for the chemical and GMO sector:

- Identify stakeholders and arrange discussions between them, especially on the choice of a competent authority or (authorities);
- Following consultation, appoint a competent authority to implement the requirements of each directive and/or regulation;
- Specific provision has to be made for dealing with potentially hazardous chemicals or GMOs at the planning stage. Issues to be resolved will include how and where a substance is to be kept or used, the times when the substance may be present and the permanent removal of the substance;
- Provision must be made for controlling potentially dangerous activities before they commence, with competent authorities having appropriate powers to impose safety requirements. Substances falling within the scope of the controls are usually defined by reference to their hazardous qualities as well as threshold quantities;
- Provide financial resources for undertaking the monitoring and other forms of assessment, checking, and for collating and disseminating the results;
- Appoint an appropriate institution (or institutions) to undertake inspections and monitoring;
- Where relevant, once emission limits and/or product specifications have been established, introduce regulations and/or other legislative measures to implement and enforce them;
- Set up suitable quality assurance and technical advice and guidance for the assessment/inspection/monitoring programme, to include third party accreditation for the analytical services;
- Prepare and implement action programmes to reduce adverse human and environmental health effects in the short-term, when emission or critical limit values are in danger of being exceeded;
- Prepare and implement integrated plans covering all the hazards concerned; and

- Prepare a report at specific time intervals informing the Commission (and sometimes also other Member States, national authorities or the public) about implementation of the legislation throughout the national territory.

2.2 Potential Difficulties in the Implementation Process

The main problems likely to be faced in the implementation of these Directives are likely to be related to the administrative arrangements required, which are extensive, and the trained manpower required in both for the administration of the Directives and in the industrial sectors to which they apply.

In addition, the costs incurred by industry, both as regards additional manpower and testing, in achieving full compliance with these regulations will be very significant. Thus, consideration must be given to the speed with which they may be implemented.

2.3 Key Stages in Strategy Development

The development of an effective strategy for the implementation of the legislation relating to the control of chemicals and GMOs involves the following key stages:

1. Establishment of a strategy development project team;
2. Review and analysis of the existing situation;
3. Development and evaluation of options;
4. Preparation of a draft strategy and options paper for consultation with stakeholders;
5. Review of strategy and options following the consultation process; and
6. Preparation of strategy and implementation plan.

The main considerations for each of these stages are outlined below.

2.3.1 Strategy Development Project Team

The project team should be drawn mainly from existing senior staff within the main pollution control organisation(s) and from governmental departments related to health and safety and trade and industry. However, it would also be useful to bring in, or at least consult with, senior technical and managerial staff from industry.

Essentially the team needs to have in depth knowledge of the following:

- the current framework for the control and assessment of chemicals and GMOs and its development;
- the current levels of chemical and GMO risk assessment conducted by industry;
- the capacity of industry to absorb costs relating to the testing of chemical substances and GMOs;
- national and international legislation in the field of chemicals and GMOs; and

- the functioning and relationships of national, regional and local governmental organisations.

It is likely that the team will need to be together for a number of years with at least a core of staff dedicated to the project on a full time basis.

2.3.2 Review and Analysis of the Existing Situation

This stage involves compiling information relating to the control and assessment of chemicals and GMOs. The review should include:

- a review of current legislation and its implementation;
- a review of authorisation and notification procedures with particular reference to application procedures and documentation requirements. The review should also include an assessment of who is responsible for issuing permits and licences and handling notifications and at which level it is most appropriate for these tasks to be carried out (national, regional or local);
- an examination of current guidance made available to industry in these areas;
- an examination of control procedures and enforcement practices;
- an examination of resources/expertise available for performing testing and risk assessments.

2.3.3 Development and Evaluation of Options

Once the review and analysis is complete sufficient information should be available to allow options for implementation to be put forward. The options put forward will include suggestions as to:

- how the requirements of the legislation may be met by the relevant institutions;
- how the existing permitting, licensing, notification, monitoring and control procedures could be improved;
- how the existing institutions may be strengthened, and whether combinations of disciplines would improve compliance;
- how to ensure effective co-ordination between the controlling authorities, and designation of responsibility;
- how to manage relationships with industrial concerns during their applications for permits and licences and submission of notification, and what those permits, licences and notifications should cover;
- what guidance should be made available to industry on how to comply with this legislation;
- how to monitor and control permitted or licensed processes, and ensure that they remain within the limits imposed by the permits; and

- how to manage the archive of notifications and similar material, and ensure proper dissemination.

The initial options put forward should vary from doing the minimum relative to the existing situation (whilst still complying with the requirements of the relevant directives and regulations) to introducing more extensive reforms.

For each of the options put forward there will need to be an assessment of the resource implications of implementation, which will include itemisation of the training, staffing and fixed resources required to complete the implementation. In addition the time scales associated with the options will need to be established.

2.3.4 Preparation of a Draft Strategy and Options Paper for Consultation with Stakeholders

As part of the initial stages of implementation it is advisable to undertake a series of consultation exercises in order to canvass the opinions of the various stakeholders. This would include the regulatory bodies, central, regional and local government, industry and industrial organisations, environmental organisations and NGOs. It would initially involve the preparation of a consultation document to be circulated to the various interested parties. The document would discuss the key issues associated with the implementation of the legislation relating to chemicals and GMOs, potential difficulties and possible options. Experience has shown this type of exercise to be very beneficial in smoothing the way forward for implementation, and in helping the preparation of all those likely to be involved.

2.3.5 Review of strategy and options following the consultation process

Following the consultation process and feedback from the stakeholders the strategy can be refined and the preferred options developed so that a detailed implementation plan can be drawn up.

2.3.6 Preparation of Strategy and Implementation Plan

At this stage the main tasks, roles and responsibilities of the key bodies to be involved in the implementation process and the operation of the systems need to be defined. Possible bodies that could be involved are as follows:

- the Government;
- the Competent Authority (CA);
- the Permitting Authority (PA) if required; and
- the Regulatory Body (RB) (in some cases this may be the same body as the PA).

A Technical Committee could be set up to co-ordinate the development of guidance notes and to act as an advisory body for policy issues.

3 Institutions and Relevant Parties

3.1 Stakeholders

A large number of stakeholders have an interest in, or may be affected by, the legislation covered in the Chemicals and GMOs sector. The principal stakeholders, and their role in the implementation of the legislation in this sector, are summarised in Box 2 below. The following subsections focus on particular issues concerned with key groups of stakeholders.

3.2 Central Government

Several ministries must be directly involved in the implementation of the legislation on chemicals, GMOs and GLP, while others will need to be informed and consulted.

The principal ministries involved directly in implementation will be those responsible for the environment, health and welfare, labour, agriculture and industry. Implementation of the GLP legislation will also involve the ministry with responsibility for veterinary affairs.

There will also be a need to liaise with other ministries on the implementation of the legislation. Ministries responsible for industry need to be consulted given the economic importance of the chemicals sector, the significance of GMO legislation to the emerging biotechnology industry, and the desire to avoid the prohibition of certain chemicals in Member States due to concerns over testing procedures. The ministry with responsibility for foreign affairs will have an interest because of the interactions of EC legislation with international organisations and treaties, such as the World Trade Organisation, Montreal Protocol, and the Biodiversity Convention which is currently formulating a Biosafety Protocol, as well as the implications for exporting and importing dangerous chemicals derived from the Rotterdam Convention. The ministry with responsibility for agriculture would be concerned with legislation on GMOs and animal welfare, and the ministry responsible for labour protection would have interests in all legislative groups chemicals, GMOs and GLP.

A well structured mechanism to provide governments with external advice is essential to meet the need for specialist inputs. Many matters arising in implementation in this sector require expertise which is not routinely present in government departments or being spread over many departments. In areas like chemicals and GMOs it could be beneficial to create formal advisory committees to ensure the participation of the affected departments.

Box 2 Principal stakeholders and their roles in the sector on chemicals and genetically modified organisms

<i>Stakeholders</i>	<i>Roles</i>
Central Government (e.g. a Ministry or Department)	→ Implementation and maintenance of compliance with EU policies and legislation on chemicals, GMOs, GLP and animal experiments
Environmental agencies working on behalf of central government (e.g. regulatory authority, national standards laboratory, veterinary service)	→ Provision of planning, regulation and technical assistance Enforcement of legislation
Regional and local government, municipalities	→ Planning consent and agreement of localised activities. Air emission control and waste disposal. Notification to higher bodies with respect to water supply. Trade descriptions. Forum for public concerns
Chemical industry (dangerous substances, manufacture of products including asbestos)	→ Import, export, transport and manufacture of dangerous substances. Use of animals in experiments
Construction industry	→ Demolish buildings and develop 'brown field' sites which may be contaminated with asbestos
Private laboratories	→ Chemical waste discharge. Carry out experiments on animals and with GMOs
Public	→ Health and safety concerns for workers handling dangerous substances and residents living near chemical installations. Lobby government on issues such as the release of GMOs to the environment and animal welfare
NGOs	→ Represent specific interest groups such as GMOs and animal welfare. Lobby government about the siting and activities at chemical plants and experimental activities
Research institutions (e.g. Universities)	→ Technical research, inter alia, into GMOs

3.3 Competent Authorities

The choice of competent authority will depend on the existing structure of government and the remit of the different ministries within the Candidate Countries.

In the chemicals area it could be useful to establish a chemicals supervisory service as competent authority responsible for risk assessments, notification, prior informed consent procedures etc. Such service could rationalise the administration. Also responsibilities under Council Directive 87/18/EEC on the application of GLP could be covered by the competent authority responsible for chemicals.

Where two or more competent authorities are appointed, there must be clear agreement about spheres of responsibility.

Competent authorities will be required to undertake a variety of activities as illustrated in Box 3 below. Many of these tasks require specialist technical knowledge.

3.4 Regional and Local Government

In general, regional and local governments are playing a minor role in relation to the implementation of legislation related to chemicals, GMOs and GLP. However, where the implementation will affect issues related to air quality, waste disposal, water management and integrated pollution prevention control, the regional and local governments will be involved. Also, activities that involve the handling of hazardous substances are often regulated at the stage of planning and development control at the regional and local levels.

3.5 Private Sector Involvement

Industrial companies working in chemicals, pharmaceuticals, biotechnology, laboratory research, and their significant sub-sectors, will have legitimate interests in legislation covering chemicals and GMOs. Major industries will often make individual representations to government, but a principal contact should be made with the relevant trade and branch organisations.

The interests of workers should be considered through consultation with trade unions and with relevant professional bodies.

3.6 Communication and Consultation

There is a requirement to inform and consult with the public in much of the EC legislation in this sector. In addition to providing information directly to the public by radio, TV and press, some legislation requires data to be made available in public registers.

Consultation with NGOs is also important. Although NGOs may present a wide range of views consultation with them is invaluable in demonstrating the transparency of legislation and its implementation.

Box 3 Examples of Activities Undertaken by Competent Authorities

Planning

- Design procedures for e.g. licensing, compliance programmes, notification, inspection and verification, safety requirements (67/548/EEC, 87/18/EEC, 88/322/EEC, 90/219/EEC, 3093/94, 90/220/EEC, 98/8/EEC, 91/414/EEC).
- Establish a list of safe genetically modified micro-organisms, a classification system, containment conditions and waste disposal methods for GMMs (90/219/EEC).

Regulation

- Set limits for discharges from installations processing asbestos (87/217/EEC).
- Monitor emissions and ensure controls are in place (87/217/EEC).
- Ensure that manufactures of controlled substances reduce and cease production (3093/94).
- Ensure that installations keep the required records, issue test certificates etc (86/609/EEC, 87/18/EEC).
- Inspect laboratories to verify compliance with procedures (86/609/EEC, 87/18/EEC, 88/320/EEC, 90/219/EEC).
- Arrange inspections at GMO sites (90/220/EEC).
- Set up a data collection system and publish statistical information (86/609/EEC).
- Evaluate data supplied by manufacturers and importers on chemical substances (67/548/EEC, 98/8, 91/414).
- Evaluate risks to human health and the environment (793/93, 90/219/EEC, 90/220/EEC, 67/548/EEC, 98/8, 91/414).
- Develop a strategy to limit risks (793/93) and ensure emergency plans are in place (90/219/EEC).
- Control the placing of dangerous substances on the market and the import and export of certain chemicals (67/548/EEC, 3093/94, 2455/92, 98/8, 91/414, 76/769, 79/117).

Reporting

- Ensure compliance with rules on confidentiality of information (86/609/EEC, 87/18/EEC, 793/93, 90/220/EEC, 67/548, 98/8, 91/414).
- Ensure that third parties comply with notification requirements (2455/92, 90/219/EEC, 90/220/EEC, 67/548, 98/8, 91/414).
- Publicise requirements to relevant manufacturers, importers, exporters, etc (67/548/EEC, 87/217/EEC, 793/93, 90/220/EEC, 98/8, 91/414).
- Ensure health and safety information is available to workers (90/219/EEC, 67/548).
- Ensure the public is informed (90/219/EEC).
- Report to the Commission (all legislation).

4 Technical Issues

Technical standards and guidelines are important in providing maximum compatibility across and between industries. They provide detailed technological information on, for example, methodologies for testing, construction, or use of materials. This type of information is not normally incorporated into primary legislation, often being very detailed and complex, and requiring periodic updates as technology advances.

Relevant standards may be prepared at different levels. The international level includes those produced by worldwide organisations such as the International Standards Organisation (ISO) or WHO, and European standards such as the European Standards Organisation CEN. European Standards must be applied in Member States and national standardisation bodies commonly adopt them as national standards. Standards do not have legal force in many European countries; in spite of this they are widely regarded by regulatory bodies as indicating best practice and their use often becomes obligatory for this reason.

A list of bodies producing standards which are significant in the Chemical and GMO Sector in Europe include:

- International e.g. World Health Organisation (WHO) guidelines and standards and ISO standards (e.g. ISO 14001);
- OECD Guidelines for testing methodologies;
- European e.g. EU guidelines and standards;
- National e.g. technical instructions/regulations developed and introduced by government; formal standards issued by national standards bodies; and
- Sectoral e.g. technical guidelines or specifications developed by industrial or professional associations applicable to a particular sector or type of activity.

In the Chemicals and GMOs sector, competent authorities are required to set standards and prepare procedures on a variety of issues. As an example, Commission Decision 92/146/EEC sets out the format for the notification to the competent authority by manufacturers or importers who intend to place a product containing a GMO on the market.

Technical standards prepared for other environmental sectors are also relevant here. For example, some Member States have prepared technical guidance on integration pollution control, which may be relevant to the implementation of legislation in this sector such as the Asbestos Directive.

The adoption of standards and guidelines to meet performance requirements will inevitably create the need to train staff and this must be recognised by regulatory authorities. In some cases, it might be difficult to implement legislation fully until training needs are met.

5 Regulation and Enforcement

5.1 Licensing, Inspection and Monitoring

The regulatory requirements in this sector relate mainly to notification of substances and authorisation of certain activities involving substances. In either case, monitoring and enforcement are key components of implementation of the legislation.

The main aspects of regulation are the same for most environmental legislation in this sector. Specific issues include:

- authorisation of establishments such as laboratories;
- the collection and evaluation of written or computerised information such as notifications from manufacturers, and exporter/importers;
- inspection and monitoring of activities to check that the correct procedures are being carried out; and
- enforcement action.

5.2 Data Collection and Reporting

Several pieces of legislation require Member States to gather and analyse data, for example to collect statistical information on laboratory experiments on animals or to assess the risk of certain substances.

The legislation requires Member States to inform the Commission about the text of legislation to transpose directives and actions taken to implement the legislation. There are also requirements to report other types of information to the Commission, for example:

- lists of licensed laboratories;
- instances of non-compliance;
- summaries of statistical data;
- sampling and analytical methods;
- alternative action taken;
- derogations;
- notifications and authorisations.

The frequency of reporting varies: sometimes reporting is required once, in other cases reports must be submitted annually, or three-yearly to the Commission. A number of Directives, including Council Directive 87/217/EEC on asbestos, require that reporting be carried out in accordance with the Reporting Directive (Council Directive 91/692/EEC).

Other Member States must also be informed of certain actions taken by an individual Member State, for example, when environmental or single market issues are involved. In some cases, a Member State has the power to object to a decision taken by another, for example, granting permission to market a GMO throughout the Community.

Member States also have to provide information to various third parties, particularly manufacturers, exporters, importers, trade unions, workers, and the public. The main reasons for publication of such information are to ensure that the relevant bodies are aware of their duties under the legislation, and to advise people of health and safety issues.

Further information on reporting requirements is provided in the relevant fiches following this sector overview.

6 Priorities and Timing

6.1 Prioritising the Implementation Tasks

In the chemical sector, the prioritisation of implementation tasks may be influenced by the economic importance or size of the industry, in particular asbestos and ozone depleting substances; the potential health risks from that industry; and the existing degree of concordance between EC and national legislation. Major risks to the population and the environment arise from chemical use, and the harm they cause is more clearly recognised and defined compared with the GMO sector.

In many Member States, there is great public concern about GMOs and especially about the release of transgenic¹⁾ plants to the environment. Public pressure encourages placing a high priority on implementing GMO legislation. The absence of regulatory control may encourage experimentation with these organisms and create a substantial hostility towards governments.

It is very important to ensure that the GLP directives are implemented in conjunction with other chemicals legislation. All of the directives dealing with chemicals and chemical products are closely related with the GLP directives. Tests on all those chemicals and chemical products regulated by EC directives must be carried out in compliance with GLP Principles.

The implementation of Council Directive 86/609/EEC can be a highly sensitive issue, since animal testing is a subject that is likely to cause strong public concerns. However, this can vary significantly from one Member State to the other. Governments should be prepared that animal rights groups may push for the quick adoption of legislation implementing this Directive.

6.2 Timescales

Considerable time is required to implement legislation fully, even for countries that aim to implement it as soon as possible. New Directives must usually be implemented within two years from the date of their publication in the Official Journal, whereas Regulations come into effect immediately on the date of their publication in the Official Journal. In principle, the Candidate Countries will need to ensure that the requirements of all the existing Directives and Regulations are in place by the date of accession. However, there may be instances where implementation of a specific requirement cannot be achieved by the desired date of accession, and in these cases Candidate Countries will have to negotiate appropriate transitional arrangements with the Commission.

The programme for implementing the legislation in this sector would be influenced considerably by the extent to which Candidate Countries have already adopted the measures and procedures required. For example, countries which have already ratified international conventions and protocols, such as the Montreal Protocol on substances that deplete the ozone layer, or which already have an established, regulated chemical industry, may be well placed to implement some of the legislation in this sector.

¹⁾ transgenic plants contain genes from other species

Implementation tasks that will tend to be especially time-consuming in the chemical and GMO sector are:

- Procedures for implementation and enforcement of licences/permits;
- Inventory of all affected industry and their individual functions or requirements;
- Data collation and statistical interpretation.

7 Economic and Financial issues

7.1 Principal Cost Areas

The principal cost areas associated with the implementation of legislation in the chemical and GMO sector consists of costs of establishing the implementation systems, the day to day costs of maintaining them and on-going costs for tasks such as the classification of new chemical substances, dealing with notifications of GMOs, and employing specialist advisors/consultants. Costs will also be incurred by the competent authority to manage notifications.

In general, costs to industry will be orders of magnitude greater than those borne by the regulatory authority. In the chemical sector, manufacturers of new substances will bear the major part of the ongoing costs of implementation. The costs to the biotechnology industry of implementing the GMO regulations, including for instance the costs of providing the information required by the notification procedures are also high.

It is critical in assessing the costs of the regulatory authority to consider the expected development in the sector in the future. For example, in the GMO sector, a relatively large implementation organisation will be necessary if the government, as a matter of policy, wishes to encourage research and development in biotechnology and the introduction of transgenic plants into agriculture. If it does not, a much smaller body will be appropriate.

Few studies have been undertaken on the cost of implementing legislation in the chemical sector. A DISAE project in Lithuania²⁾ estimated that the implementation of the chemicals legislation would require an investment of EUR 476,000 (for institutions, laboratories etc.) in the public sector and EUR 12.1 millions in the private sector (hazard communication unit, safety data sheets, modification of equipment for transport of dangerous goods etc.). A report published by the Danish Environmental Protection Agency³⁾ estimated that implementation of ozone-related legislation in the ten CEECs would cost just under DKK 1 billion (EUR 133 million) and were considered to be insignificant.

In a separate study⁴⁾, the implementation of the chemicals legislation sector in Bulgaria alone was estimated at EUR 63 million.

A study by EDC⁵⁾ failed to find reliable information on the use of asbestos in the construction industry in CEECs. However they point out that asbestos was used in construction in the

²⁾ DISAE Project LIT-109. *Development of Action Programme for Implementation of EU Legislation on Chemicals in Lithuania*. Soil & Water Ltd. November 1999.

³⁾ DEPA, 1997. *EU's udvidelse mod øst - miljømaessige perspektiver*. Miljøstyrelsen.

⁴⁾ DISAE, 1998. *Review of the Assessment of Accession Costs*. Seminar Paper, June 1998.

⁵⁾ EDC, 1997. *Compliance costing for approximation of EU environmental legislation in the CEEC*.

CEECs, and that it is extremely expensive to control asbestos emissions during demolition and land clearance operations.

7.2 Cost Recovery and the Application of Economic Tools

Candidate Countries need to decide whether charges will be introduced for GMO notifications. For high levels of activity, charging may be adopted, sufficient to meet all the running costs of a notification scheme. If little activity is expected the costs of setting up and operating a charge scheme may be much larger than the income from the scheme. In part, such considerations explain the wide range (from zero to about EUR 10,000 per notification) for notification work about release of GMOs for marketing. Similar considerations as those above apply to costs in the chemicals sector.

The expenditures caused by the implementation of the GLP directives can at least partly be recovered by charging a fee for the inspection of the laboratories. There are different schemes possible. The Member State might charge a fee for every single inspection performed in a specific laboratory. The other alternative is the creation of a so-called monitoringprogramme with obligatory membership of all laboratories applying GLP. Then an annual membership fee might cover part of the costs for the monitoringprogramme.

8 Summary of Key Issues

Implementation of EU legislation in this sector requires a large number of activities as described in more details in the fiches.

A checklist of key-questions to be considered in preparing and implementing EC legislations for chemicals and GMOs is presented below.

Box 4 Checklist of Key Questions to be Considered in Preparing and Implementing EC Legislation for Chemicals and GMOs

- Has a national strategy for implementation in the sector been developed?
- Has framework and secondary legislation to allow implementation been produced?
- Has a competent authority or authorities been designated?
- Is the competent authority adequately staffed and equipped?
- Has the competent authority taken steps to consult stakeholders and has it prepared and published guidance notes for stakeholders?
- Has the competent authority demonstrated that it can manage notification and authorisation procedures?
- Is the competent authority able to monitor compliance with the regulations and carry out enforcement measures?
- Has it the competent authority established adequate data collection and data handling procedures to allow it to meet the reporting requirements of the directives and regulations?
- Has the competent authority created formal reporting procedures?
- Has the competent authority taken measures to provide a summary of the collected statistical information?
- Can the competent authority ensure that commercially sensitive information is not published?

The Directive on the Protection of Animals Used for Experimental and Other Scientific Purposes

Official Title: Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 358, 18.12.1986)

TAIEX Ref. No.: 100

1 Summary of Main Aims and Provisions

The Directive establishes minimum standards for the use of animals for experimental or other scientific purposes. It applies to animal experiments that are conducted for one of a number of specified purposes, including the safety testing of drugs, foodstuffs and other substances or products. Procedures need to be established for the advance notification of experiments to the competent authority. An experiment must not be performed if the aim can also be achieved by an alternative method which does not entail the use of an animal. The Directive specifies detailed requirements for accommodation and care of animals, welfare requirements for the avoidance of pain or stress, and the humane treatment of animals at the end of an experiment. Establishments using animals for experiments, as well as breeding and supplying establishments, must be registered with, or approved by, the competent authority. The Member States must ensure that these establishments are run in compliance with the terms of the Directive.

2 Principal Obligations of Member States

2.1 Planning

- Designate the competent authority responsible for verification purposes (Art. 6).
- Set up an authorisation or registration system for establishments conducting animal experiments and breeding and supplying establishments. Ensure that establishments keep detailed records regarding the animals sold, supplied, and used in experiments, to be kept for a minimum of three years and subject to inspections by the authority. (Art. 15, 17, 19).
- Set up a control system guaranteeing the inspection of the user, breeding, and supplying establishments on a regular basis and publish the collected statistical information; ensure that the confidentiality of commercially sensitive information is protected (Art. 13, 17, 19).

2.2 Regulation

- Ensure that animal experiments are performed only by competent, authorised persons, and only if another suitable method is not available. Experiments must be carried out in a way that avoids distress and unnecessary pain and suffering; general and local anaesthesia is required, subject to certain exceptions set out in the Directive (Art. 7).

- Ensure that persons carrying out or taking part in animal experiments, or the care of experimental animals, are suitably educated and trained (Art. 14).
- Prohibit experiments using endangered species listed in Appendix 1 of the Convention on International Trade in Endangered Species of Fauna and Flora (CITES) unless they comply with Regulation (EC) No. 3626/82 and the animals are used for research aimed at the preservation of the species in question or for essential biomedical purposes, where this species is the only suitable one for those purposes (Art. 4).
- Ensure that the choice of species is carefully considered; the methods using the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity and are most likely to provide satisfactory results must be chosen (Art. 7).
- Ensure that wild animals are not used for experiments unless other animals would not suffice for the aims of the experiment (Art. 7).
- Ensure that stray animals of domestic species are not used in experiments (Art 19).
- Ensure that dogs, cats and non-human primates are provided with a unique identification mark before they are weaned or as soon as they are taken into an establishment (Art. 18).
- Ensure that experimental animals are provided with appropriate housing, freedom of movement, food, water and care, and that their environmental conditions are checked daily (Art. 5).
- Ensure that animals can satisfy their psychological and ethological needs to a maximum (Art 5).
- Ensure that the state of health of experimental animals is observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm; any defect or suffering must be eliminated immediately (Art. 5).
- Ensure that animals are treated humanely at the end of the experiment. A decision must be made by a competent person as to whether the animal will be kept alive or killed by a humane method. Animals may not be kept alive if they are likely to remain in lasting pain or distress or if they cannot be kept under the appropriate conditions in Article 5 (Art. 9).
- Ensure that experimental animals are only set free subject to conditions relating to the animal's well-being and where there is no danger to public health and the environment (Art. 11).
- Ensure that re-use of animals is only permitted in accordance with the Directive and that animals are not used more than once in experiments entailing severe pain, distress or equivalent suffering (Art. 10).
- Establish procedures whereby experiments are notified in advance and ensure that experiments exposing animals to severe and prolonged pain may be conducted only after they are justified to, or specifically authorised by, the authority (Art. 12).
- Encourage research into the development and validation of alternatives for animal experiments and monitor trends in experimental methods (Art. 23).

- Recognise the validity of data generated by experiments carried out in other Member States, unless further testing is necessary to protect public health and safety (Art. 22).

2.3 Reporting

- Report to the Commission on:
 - legislation and administrative practice and factual information relating to animal experiments (Art. 22);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 25); and
 - measures taken in the field covered by the Directive (Art. 26).

2.4 Additional Legal Instruments

This Directive is the first legislative measure the Community adopted in order to harmonise legislation regarding the conduct of laboratory tests on animals. It was followed by Directives 87/18/EEC and 88/320/EEC, both on Good Laboratory Practice (GLP). The three Directives establish a system of harmonised test methodologies and quality standards which allow the mutual recognition of test results.

Commission Decision 90/67/EEC setting up an Advisory Committee on the Protection of Animals Used for Experimental and Other Scientific Purposes, was adopted pursuant to Article 22 of the Directive.

Following the Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, the Community has become Party to the Council of Europe Convention ETS 123.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this directive are summarised in the checklist below. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

DIRECTIVE ON ANIMAL EXPERIMENTS – KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority.
1.2	Set up an authorisation or registration system for establishments using, breeding or supplying animals for experimental purposes.
1.3	Establish a data collection system regarding the use of animals in experiments and publish the statistical information periodically.
1.4	Set up procedures to ensure that laboratory staff are adequately trained to perform experiments on animals or to care for animals used for experimental purposes.
2	Regulation

- | | |
|-----|--|
| 2.1 | Set up a control system to verify that establishments are run in compliance with the terms of the directive. |
| 2.2 | Set up a notification procedure for animal experiments. |
| 2.3 | Ensure that commercially sensitive information is not published. |

3	Reporting
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- | | |
|-----|---|
| 3.1 | Reporting to the Commission on: <ul style="list-style-type: none"> · legislation and administrative practice relating to animal experiments; and · the measures taken in this area and statistical information collected according to the harmonised set of statistical tables agreed between Member States and the Commission in 1997. |
|-----|---|

3.2 Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this directive are:

- transposing the requirements of the directive into national legislation and policy due to possible extensive discussions in the public;
- preparation of a registration or authorisation system for animal experiments, user, breeding and supplying establishments; and
- instituting an authority responsible for monitoring user, breeding and supplying establishments.

These tasks should, therefore, be planned to commence during the initial phase of implementation.

During the whole transposition process, it should be borne in mind that legislation on animal experiments is a very controversial and political sensitive issue. The Government should be prepared for strong intervention by animal rights groups. Moreover, the public is likely to follow the legislation process very closely. Therefore, a well reflected communications and public participation policy should be developed during the legislative process.

4 Implementation Guidance

The directive aims to abolish trade barriers between EU Member States arising from the different legal requirements for the treatment of animals used for experimental purposes. Furthermore, the directive is designed to limit the use of animals in scientific experiments to a minimum. In cases where there are no suitable alternatives animal experiments must be conducted so that the animal's pain, suffering and distress during the experiment is minimised as much as possible.

Member States must introduce an authorisation or registration system for all establishments using, breeding or supplying animals for experimental purposes. These establishments must be subject to inspections to ensure compliance with the requirements of the directive. Member States and the Commission are to co-operate in research matters. Research on the development and validation of alternative techniques that involve fewer animals or entail less painful procedures must be encouraged.

Implementation of the specific requirements of this directive will be influenced by the present status, needs and conditions concerning animal experiments in each Candidate Country. However, drawing upon the collective experience of the Member States, a number of general observations and 'good practice' suggestions for implementing this directive are presented below.

Regulation

- Article 12 requires the notification of every animal experiment to the authority in advance, and in certain cases also a justification or specific authorisation. In practice, most laboratories in the Member States have internal ethics committees which review and sanction proposed work.

Example of Practice in Member States

In most Member States the Ethics Committees have only advisory tasks. At least two Member States (NL and S) have given the Ethics Committees more power. In both of these countries, an animal experiment may be conducted only after an Ethics Committee has recommended the experiment. In one of these countries (NL), the Ethics Committees are not part of the public administration. They are private institutions admitted by the State to assess applications for animal experiments licences. In most other Member States, the Ethics Committees are integrated into the public administration, sometimes on regional and sometimes on local level.

- Member States have the option either to introduce an authorisation or a registration system. Whereas the former requires a formal permit prior to the operation of an establishment, the latter requires only the entry of details of the establishment into a register.

Examples of Practice in Member States

One Member State (UK) has introduced a specific three-tiered authorisation system. According to this system, an animal experiment must be part of a programme of work authorised by a project licence, the person applying the regulated procedures must hold a personal licence and the establishment at which the experiment will take place must have a certificate of designation. Such a certificate of designation is issued to a senior representative of an establishment after the place has been assessed as meeting the requirements of the Directive. A project licence is granted to an individual for a period up to five years, if the project is in compliance with the requirements of the Directive. The authorities issue a personal licence (valid for life but subject to five year review) if the individual is a suitable and competent person to carry out specified procedures on specified animals.

In another Member State (S) animal experiments are regulated within the framework of the general Animals Protection Act (APA) which applies to the care and treatment of domestic animals and other animals kept in captivity. The APA and several regulations based on the Act have been in force since 1988 but were amended early this year to incorporate several provisions implementing the requirements of Directive 86/609/EEC. Accordingly, this Member State decided not to enact a specific law dealing only with animal experiments.

Section 19a of the APA requires a prior permit for every animal experiment. The applicant must submit the application to a local Ethics Committee, which consists of laymen, research workers and representatives of the personnel who handle laboratory animals. Once approved, the application must be brought before the national Board for Laboratory Animals (NBLA), which is responsible for the final decision. The NBLA will investigate whether the proposed experiment is in compliance with the requirements of the APA and the Animal Protection Ordinance. The notification procedure guarantees the participation of specialists and laymen in the decision-making process through the Ethics Committees and, therefore, the decision-making in such a politically sensitive area becomes more transparent and accepted. However, the required approval by the Ethics Committee makes the application procedure lengthy, comprehensive and expensive for the applicant.

Reporting

- Member States must provide the Commission regularly with statistical information collected on the use of animals for experimental purposes. Due to the differences in compilation of the statistical material in Member States in 1997, Member States agreed to a set of 8 harmonised tables on how the information should be presented to the Commission.

5 Costs

The implementation of this directive will entail costs for the European Commission, the Member States, science/academia, industry and private testing laboratories.

The creation of an authorisation and control system for all establishments related to animal experiments can generate high costs for the Member States, in particular if they have not had any or only a less developed control system regarding the treatment and use of animals in experiments. The main expenditures are expected to emerge from the permitting, monitoring, and investigative work required under the directive. The employment of additional staff, in particular of specialists qualified in the area of veterinary medicine, is probably the most important cost driver for the Member States. Part of the costs might be recovered from businesses through fees for permits, investigations and inspections.

The establishments covered by this directive are forced to make investments in order to meet the directive's requirements for accommodation and care of animals. The costs for a modernisation

programme can vary enormously, depending on the current condition of the animal facilities. It is anticipated that industry together with academic and scientific institutions will have to bear some (or all) of the additional costs for experiments involving animals under this directive.

Checklist of the Types of Cost Incurred To Implement the Directive

Initial set-up costs:

- Designate competent authority;
- Establish data collection system;
- Set up an authorisation system and licensing procedures;
- Set up a control system;
- Training and recruitment of inspectors and veterinary staff.

On-going costs:

- Collecting data for reporting to the Commission;
- Monitoring compliance with standards;
- Issuing of permits and registration of establishments;
- Compilation of statistical information.

The Directive on Contained Use of Genetically Modified Organisms

Official Title: Council Directive 90/219/EEC on the contained use of genetically modified microorganisms (OJ L 117, 8.5.90) as amended by Directive 98/81 EEC (OJ L 330 5.12.98)

TAIEX Ref. No.: 102

1 Summary of Main Aims and Provisions

The Directive aims to protect human health and the environment from any adverse effects arising from using genetically modified microorganisms (GMMs) in containment. It lays down common definitions and rules for use of GMMs in research laboratories and industrial facilities, for systems of risk assessment and notification.

2 Principal Obligations of Member States

2.1 Planning

- Designate an authority or authorities to implement the requirements of the Directive and to receive and assess notifications (Art. 11).

2.2 Regulation

- Ensure that users apply the general principles and protective measures laid down in the Directive to ensure a high level of safety, and that they review the risk assessment and protective measures as required (Art. 6 and Annex IV).
- Ensure measures are taken to avoid adverse effects on human health and the environment that might arise from contained use of GMMs (Art. 5).
- Ensure that “users” (persons responsible for the contained use of GMMs) carry out risk assessments of the contained use and classify the contained use in accordance with the procedure laid down in the Directive (Art. 5 and Annex III).
- Ensure measures are taken to protect human health and the environment from the disposal of waste and effluents (Art. 5).
- Ensure that users comply with the requirements relating to notification to the competent authorities of a proposed contained use, prior to proceeding with the use, in accordance with the notification requirements of the Directive (which vary according to the class of contained use) (Arts. 7, 8, 9, 10 and 12).
- Ensure that users keep, and make available to the competent authority on request a record of assessments carried out in respect of the use (Art. 8).

- Ensure that competent authorities receive and assess notifications of contained use and authorise contained use in accordance with the criteria and deadlines laid down in the directive (Arts. 11 and 12).
- Ensure that certain measures are taken in the event of an accident (an incident involving a significant and unintended release of GMMs in the course of their contained use which could present a hazard to human health or the environment) including the provision of information to the competent authority (Art.15).
- Ensure that competent authorities receive and assess requests from notifiers to keep information confidential, in accordance with the conditions laid down in the directive and in Council Directive 90/31/EEC (Art. 19).
- Ensure that inspection and other control measures are established to ensure compliance with the Directive (Art. 17).
- Ensure that emergency plans are drawn up, and the plans and information relating to them are made available to relevant national authorities and the public (Art. 14 and 16).

2.3 Consultation and Reporting

- Provide for public consultation on contained use, where considered appropriate (Art. 13).
- Report to the Commission on:
 - Class 3 and Class 4 contained uses (annually) (Art. 18);
 - experience in implementing the directive (every three years) (Art. 18);
 - accidents (Art. 16);
 - implementation of the directive (Art. 2 of Council Directive 98/81/EC); and
 - transposition with text (Art. 2 of Council Directive 98/81/EC).

2.4 Additional Legal Instruments

The following legislation should be taken into consideration when implementing this directive:

- Council Directive 90/220/EEC on the deliberate release of genetically modified organisms.
- Council Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work.
- Council Directive 90/313/EEC on access to environmental information.
- Commission Directive 94/51/EC adapting to technical progress Council Directive 90/219/EEC.
- Commission Decision 91/448/EEC concerning the guidelines for classification referred to in Article 4 of Directive 90/219/EEC, as amended by Commission Decision 96/134/EC.

3 Implementation

3.1 Key Tasks

The key tasks required to implement this directive are summarised in the checklist below. The Table is arranged under sub-headings in chronological order whenever possible.

DIRECTIVE ON CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS – KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish a fully functional competent authority to oversee the implementation of the directive, and to receive and assess notifications.
1.2	Publicise the requirements of the directive and the national implementation measures to the community of GMM users, the public and other stakeholders.
2	Regulation
2.1	Ensure that GMMs are classified in accordance with Commission Directive 91/448/EEC and the Directive.
2.2	Establish containment conditions for each class of GMMs.
2.3	Establish waste disposal methods for class 2, 3 and 4 GMMs and if desired, class 1 GMMs.
2.4	Inform the public about containment work being carried out under the directive.
2.5	Establish inspection and control measures, including conducting inspections and ensure that containment measures, good laboratory practice and good occupational safety and hygiene are observed.
2.6	Examine the conformity of the notifications received with the requirements of the directive with regard to: <ul style="list-style-type: none"> • accuracy and completeness; • correctness of risk assessment; • proposed containment; and • waste management and emergency measures.
2.7	Interact with the applicant regarding any modifications required and inform them about approval or rejection of the application, within the time scales set out in the directive.
2.8	Ensure that GMM users comply with the following obligations with regard to their activities: <ul style="list-style-type: none"> • conduct a risk assessment, taking into account risk to human health and environment according to Annex III, sections A and B; • keep records of activities; • ensure that control over the level of containment is exercised and reviewed; • apply the general principles and protective measures set out in Annex IV to ensure a high level of safety; • notify the competent authority of the first use of premises for the contained use of GMMs; • notify the competent authority of the first and subsequent Class 2, 3, and 4 contained uses in accordance Art.7, with the information listed in Annex V, Part B; • notify the competent authority/authorities where new information regarding the contained use and risk becomes available; • take measures in the event of an accident; and • provides full details to the competent authority of accidents.
2.9	Establish criteria for emergency plans to be adopted by users in the event of an accident and develop procedures to advise other Member States affected.
2.10	Through discussions with the notifier define which items in a notification (which under directive 90/313/EE are normally required to be made available to the public) may be deemed confidential and are not to be released to the public.
3	Reporting
3.1	Set up a document management system and a related database to hold information relating to implementation of the directive
3.2	Meet reporting obligations to provide information to the Commission and the other Member States on the implementation of the directive.

3.2 Phasing

It is important to implement this directive as soon as possible for two reasons:

- a) there is growing public concern about genetically modified organisms and governments will be expected to have introduced regulations to control them; and

- b) in many Candidate Countries, there are large numbers of GMMs in use in universities and other academic institutions, without any regulatory control. Such control needs to be introduced rapidly. The technical expertise necessary to implement the directive is likely to be present in these academic organisations.

4 Implementation Guidance

4.1 Planning

- The details of implementation vary from one country to another as a consequence of national administrative structures. Sometimes the legislation used to implement both this directive and Directive 90/220/EEC on GMOs Deliberate Release has been based on one primary legal act. However, usually separate legislation is used for each directive.

Examples of Practice in Member States

In one Member State (NL), a Gene Technology Act was introduced in June 1986 amended in June 1991 and implementing regulations were produced including the Genetically Modified Organisms Decree pursuant to the Chemical Substances Act and the Ministerial Order on the Contained Use of Genetically Modified Organisms.

In another Member State (S) the two principal directives in the GMO sector, Directive 90/220/EEC and Directive 90/219/EEC, are implemented by the Genetically Modified Organisms Act and the Genetically Modified Organisms Ordinance, both from 1994. The implementation of the directives involves participation of 7 national authorities, i.e. the National Board of Occupational Safety and Health, the Chemicals Inspectorate, (KEMI), the National Board of Agriculture, the National Food Administration, the National Board of Fisheries, the National Board of Forestry, and the Medical Products Agency. Within their respective area the authorities are responsible for, inter alia, issuing permits and receiving notifications, issuing regulations on precautionary measures and investigations, and for conducting supervision of compliance with the legislation. EU membership gave rise to the creation of a new authority, the Gene Technology Advisory Board, which is functioning as an advisory body on ethical questions connected with the introduction of genetically modified organisms on the market. Although there is satisfactory co-operation between the involved authorities, the involvement of so many bodies is seen as cumbersome due to the time consuming consultation procedure.

- The role of the competent authority is to implement the directive via notification, monitoring and enforcement measures. One organisation is selected to become the competent authority in some countries; in others two are involved.

Examples of Practice in Member States

In one Member State (UK) the competent authorities are the Health and Safety Executive (HSE) and the Department of Environment, Transport and the Regions (DETR).

In another Member State (DK), the Ministry of the Environment and the Ministry of Labour share the responsibility.

In a third Member State (NL) the Ministry of Housing, Spatial Planning and the Environment is the sole competent authority.

In the first two mentioned Member States, two competent authorities were named because the directive covers both the risk to human safety, especially in the work-place, and a risk to the environment. In the third mentioned Member State it was decided that one organisation could meet the needs.

Regulation

- The implementation of the notification and risk assessment procedures in this directive is straightforward, with few options for national variation. Procedures for classification of GMMs into four classes, risk assessment and notification are set out in the Articles and the Annexes. Candidate Countries should use forms to facilitate notification and copies are readily available from the competent authorities in Member States.
- The competent authority has many tasks to perform and to carry them out successfully requires specialists in many disciplines. For inspection and monitoring, the expertise must reside within a government body with legal powers and the best solution is to add the expertise to the staff of this body. Inspectorates are vitally important and high quality staff are required with authority and technical competence which allows them to negotiate with those wishing to carry out trials and market products.

Examples of Practice in Member States

In one Member State (UK) the Inspectorate is the Health and Safety Executive. In a second Member State (DK) the Environmental Protection Agency fills the role, and in a third (NL) the Department for the Enforcement of Environmental Legislation is responsible.

- For activities not involving inspection and monitoring, a specialist advisory committee with members who cover the range of expertise required has been found to be a useful approach. This committee may include *ex officio* government officials. The use of an advisory committee ensures that the widest range of expertise can be obtained while retaining the ultimate decision within the competent authority itself. It is also a measure that contributes to transparency.

Examples of Practice in Member States

In one Member State (UK) the advisory body is the Advisory Committee on Genetic Manipulation (ACGM) and in another Member State (NL) it is COGEM. In a third Member State (DK), by contrast, there is no specialist advisory committee; individual ministries and specialists are consulted as necessary.

Reporting

- To meet the obligations on reporting to the Commission and other Member States, it is necessary to establish a high quality information system to collect data, to incorporate it into a database and to distribute it as required. This is an office and document management issue.
- In addition to the well defined reporting obligations set out above, experience shows that it is advisable to provide information to the users of GMOs and to the public about the national implementation of the directives, so as to ensure transparency. A multifaceted approach, using press releases, information leaflets, public meetings, private meetings with representative bodies, radio and television programmes, and publicity via the internet is recommended. Information is more easily distributed to the users of GMMs, who acknowledge the obligation to conform to regulations, than to the general public, who welcome transparency but may not understand the terminology used. The public may need much reassurance that great care is being taken, though concern is much less than in the case of deliberate release of GMOs under Directive 90/220/EEC.

5 Costs

The main costs to government of implementing this directive consist of indirect/overhead costs of establishing the implementation systems, the day to day costs of maintaining it and the payments to specialist advisors/consultants for attendance at committee meetings and for special events. The monetary value of these will vary greatly from country to country. Once the system is established, the total costs must depend on the number of cases needing consideration. The best guide to the cost is the charges made to applicants for dealing with notifications, for these are commonly designed to cover the costs of notifications. However, this approach is only practicable when a considerable number of notifications are received - otherwise the cost per application is prohibitive.

The costs of implementation to industry and academia are substantial. However, the majority of the costs would be incurred even if notification were not required, since stringent precautions are required under other safety legislation for any work involving potentially or actually harmful GMMs.

The Asbestos Directive

Official Title: Council Directive 87/217/EEC on the prevention and reduction of environmental pollution by asbestos (OJ L 85, 28.3.87)

TAIEX Ref. No.: 104

1 Summary of Main Aims and Objectives

The aim of the Directive is to prevent and reduce pollution by asbestos, in order to protect human health and the environment. It requires Member States to restrict emissions of asbestos into the air and discharges of asbestos into water, and to take precautions when carrying out certain activities involving asbestos, such as the demolition of buildings and the transport and disposal of waste. It also lays down monitoring requirements.

2 Principal Obligations of Member States

2.1 Regulation

- Take measures to prevent and reduce emissions of asbestos into the air, discharges of asbestos into water, and the production of solid asbestos waste (Art. 3).
- Ensure that asbestos is used in accordance with the Best Available Techniques Not Entailing Excessive Cost (BATNEEC), and that emissions of asbestos into the air comply with specified limit values (Arts. 3 and 4).
- Where asbestos cement or asbestos paper or board is manufactured, ensure that the effluent is recycled or, in the case of asbestos cement, that it is disposed of in accordance with specified conditions (Art. 5).
- Ensure that activities involving asbestos, including the demolition of buildings, the removal of asbestos, and the transport and disposal of waste containing asbestos, are carried out in accordance with the requirements of the Directive to ensure that they do not cause pollution (Arts. 7 and 8).

2.2 Monitoring

- Monitor emissions of asbestos into the air and discharges of asbestos into water, in accordance with specified methods of sampling and analysis (Art. 6).

2.3 Reporting

- Report to the Commission on:
 - methods of sampling and analysis (Art. 6);
 - implementation of the Directive (Art. 13 and Council Directive 91/692/EEC);

- measures taken to comply with the Directive (Art.14); and
- transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 14).

2.4 Additional Legal Instruments

A number of other legislative instruments are relevant to the implementation of this directive.

- Council Directives 76/769/EEC and 83/478/EEC contain provisions to restrict the marketing of crocidolite (blue asbestos) and products containing crocidolite fibres, as well as provisions concerning the labelling of products containing asbestos.
- Council Directive 83/477/EEC lays down provisions to protect workers from the risks of exposure to asbestos at work.
- Several directives are concerned with the disposal of waste, and controlling pollution to air, e.g.: the Waste Framework Directive, 75/442/EEC; the Hazardous Waste Directive, 91/689/EEC; Directive on Air Pollution from Industrial Plants, 84/360/EEC, and the IPPC Directive, 96/61/EEC.
- Reporting requirements have to be in accordance with the Reporting Directive, 91/692/EEC.
- Methods of sampling and analysis in the Annex refer to Council Directives, 82/883/EEC and 79/869/EEC.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this directive are summarised in the following checklist. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

THE ASBESTOS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate the competent authority to be responsible for implementation.
1.2	Ensure that the competent authority is adequately staffed with trained personnel.
2	Regulation
2.1	Publicise the requirements of the directive to those affected by it (e.g. relevant manufacturers and others working with asbestos).
2.2	Enforce the requirements of the Directive re: discharge, recycling, handling, disposal, etc. of asbestos.
3	Monitoring
3.1	In consultation with manufacturers and other relevant parties, set limits for total discharges and the solid content of liquid wastes, ensure that liquid wastes containing asbestos are recycled and that the sampling and analytical methods set out in the Annex to the directive - or equivalent measures - are used.
4	Reporting
4.1	Supply the Commission with information about the implementation of the directive.
4.2	Report to the Commission on: <ul style="list-style-type: none"> • methods of sampling and analysis and related information; and • transposition and implementation.

3.2 Phasing Considerations

It is important to control the hazards of inhalation of asbestos by implementing the appropriate directives. The relative urgency of implementing this directive, together with those relating to worker protection and marketing will depend on the current situation for controlling asbestos in the country. Where production, use and marketing are relatively well controlled, attention should be focused on the removal of asbestos from buildings and other sources of contamination. This will point to the implementation of this directive as of the greater urgency. However, in certain Member States, the implementation of the various directives lead to interlocking regulations and, recently, the regulations have been extended to deal with all types of work which may lead to exposure. It may be beneficial to implement all the asbestos-related directives at the same time, rather than to deal with them separately.

Issues which may affect or retard the implementation programme would be related to a) the lack of necessary technical skills to measure dispersal of asbestos in the atmosphere and water, which may not be widely available, and b) the fact that asbestos is an essential commercial material for some purposes and that alternatives are less effective or much more expensive. This latter point indicated the need for substantial and possibly lengthy consultation as a preliminary to implementation.

4 Implementation Guidance

Health problems caused by asbestos are primarily associated with the lungs, where inhalation of asbestos fibres can cause cancer. In the UK, the number of deaths attributable to asbestos is expected to rise from the existing level of ca. 3,000 at present to 10,000 per annum in the next millennium. This rise will primarily reflect past exposures rather than increased exposure. Nevertheless, there are still substantial risks and UK research has shown that workers in building related trades are most at risk from asbestos.

This directive is one of a group of measures to control hazards which asbestos presents to people and the environment. This directive supplements the provisions of Council Directive 76/769/EEC to prevent, as far as possible, emissions of asbestos to the environment by reduction at source.

Member States are allowed to introduce more stringent measures than those laid down in the Directive, in order to protect health and the environment. In this connection, the Council of Ministers (Employment and Social Affairs) has asked the Commission to bring forward its proposals for amending current asbestos directives so as to tighten restrictions and set higher standards. Future developments should be monitored.

A number of general observations and 'good practice' suggestions for implementing this directive are presented below based upon the collective experience of Member States.

Regulation

- The implementation of this directive has had relatively few implications for current Member States, due to the existing system of controls in those countries. For some of the Candidate Countries, it seems that current controls are less satisfactory and that implementation of this and related legislation is urgent.

- It is important that the directive requires the use of the Best Available Technologies not Entailing Excessive cost (BATNEEC) to reduce or eliminate asbestos emissions. This allows the possibility of discussion with the competent authority about the use of one or other technology when the costs of these differ significantly.

Examples of Practice in Member States

In one Member State (UK), asbestos control regulations have been produced in 1983 and 1987 to implement earlier asbestos control directives. Regulations implementing the present directive have been introduced from 1989 to the present day using the existing framework legislation. All regulations have been exposed to lengthy consultation procedures. The latest consultation related to proposals to tighten the original asbestos licensing regulations of 1983 and the control of asbestos at work regulations of 1987. Two codes of practice were also revised. The subsequent implementation of these new regulations made it necessary for laboratories which carry out asbestos related work to be accredited to the standard EN 45001. In reality, there is substantial interaction between the regulations implementing the various asbestos directives and current UK regulations apply to all types of work which may lead to exposure to asbestos. The competent authorities are the Department of the Environment, Transport and the Regions (DETR) and the Health and Safety Executive (HSE) who jointly undertake monitoring and enforcement. The Environment Agency also is involved as an enforcement body.

In another two Member States (DK and NL), this directive has been implemented through existing legislation dating from the late 1980s. In both countries detailed inspection and monitoring work has been carried out by organisations with responsibilities for the health and safety of workers.

- In enforcing the requirements of this Directive, competence in the technical skills of analysis and sampling is required. Training will be needed in many cases for technicians and technical managers to ensure that sensitivity and precision targets are achieved. Staff carrying out this work will possess technical qualifications and their laboratories must be operating Good Laboratory Practices.
- Current Member States encourage public awareness of the directive by use of the media. As a result the public is very well aware of the possibility of harm arising from contact with asbestos and that much of the impetus for remedial action in buildings has arisen from public pressure. The use of asbestos has decreased considerably in recent decades as the effects of asbestos on health have become more widely understood. Nevertheless, the consequences of past uses of asbestos are that many houses and commercial buildings contain substantial quantities of dangerous asbestos and that remedial work is still underway. Asbestos remains to be relevant within certain types of industries, in demolition of buildings containing asbestos, clean-up of sites contaminated with asbestos e.g. old landfill sites.
- A complication of media exposure is that the public has come to believe that all uses of asbestos are harmful. Thus, there is unjustifiable concern that asbestos water pipes are unsafe, though there is no evidence that this is true. The World Health Organisation publication guidelines for drinking water quality supports this view of its safety.

Example of Practice in a Member State

In one Member State (S) asbestos was extensively used for many years, particularly in the 1940s and 1950s. Imports peaked in the 1950s at 20,000 tonnes per year. In the mid 1970s a ban on asbestos use was introduced, due to suspicions concerning its effect on human health, based on research on worker exposure and disease. The National Board of Occupational Health and Safety (NBOHS) was created in 1949 and in 1963 the ordinance was extended to include protection against asbestosis. The NBOHS has since been responsible for regulating, monitoring and permitting the handling and usage of asbestos in the work place. They monitor the health of workers and produce statistics on behalf of government. In general the import and use of asbestos is very heavily restricted, apart from specialised products, for which substitutes cannot be found.

Monitoring

- The directive lays down emission limit values for emissions to air and water, and requires that measures be taken to ensure that asbestos is not released in the course of work such as demolishing buildings or transporting waste containing asbestos. Other limits (e.g. volume of discharges of suspended matter) must be set by the competent authority. The competent authority will also need to carry out monitoring to ensure that the emission and discharge limits are complied with.

5 Costs

The main regulatory costs consist of establishing and implementing the legal framework. The ongoing costs for monitoring and enforcement can be substantial. In addition to these, there are high compliance costs, which will be borne by the asbestos using industry and equally by the owners of buildings that require remedial treatment.

The Directive on Classification, Packaging and Labelling of Dangerous Substances

Official Title: Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ No. 196, 16.8.67)

TAIEX Ref. No: 105

1 Summary of Main Aims and Provisions

A summary of the background to the Directive and its evolution is given under Section 1.1. of the overview of legislation in the sector. As indicated in this overview, the Directive distinguishes between new and existing substances. Existing substances are those that were placed on the Community market before 18 September 1981 and that are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), and new substances are those that are not listed in EINECS.

The Directive lays down rules on the classification, packaging and labelling of all chemical substances, which are placed on the market in the Community, including rules on the notification of new substances, the exchange of information on such notified substances, and the assessment of the potential risks of new substances to humans and the environment.

The Directive requires Member States to ensure that producers and importers who place new substances on the market notify the competent authorities. This notification is progressive in that the data requirements increase stepwise as the tonnage levels of the notified substance cross specific thresholds. The “base set” notification should provide information so that the substance may, as necessary, be classified for any health, environmental and physico-chemical hazards. Any identified hazards must then be assessed as to their risk to man and the environment according to specified procedures. Annex I to the Directive lists the “harmonised” classification and labelling of new and existing substances as officially agreed at Community level.

2 Principal Obligations of Member States

2.1 Planning

- Appoint a competent authority (or authorities) to receive and assess information from manufacturers and importers about new substances to be placed on the market, and ensure that competent authorities carry out their duties in accordance with prescribed principles (Art. 16, and Commission Directive 93/67/EEC).

2.2 Regulation

- Do not allow substances to be placed on the market unless:
 - In the case of new substances they have been notified in accordance with specified criteria and procedures (Arts. 5, 7, 8 and 9, 10 and 15) subject to the exemptions listed in Article 13; and
 - In the case of all substances, they have been classified, packaged and labelled in accordance with specified criteria and procedures (Arts. 5, 22, 23, 24 and 25).
- Do not restrict the placing on the market of substances that comply with the Directive, for reasons relating to notification, classification, packaging or labelling, unless the restriction is temporary and is imposed in accordance with specified conditions (Arts. 30 and 31).
- Prohibit the advertisement of substances belonging to categories of dangerous substances without reference to the category (Art. 26 and Art 2).
- Ensure that notifiers of substances that they have already notified inform the competent authority of changes in quantities placed on the market and of new knowledge about the substance (Art. 14, subject to exemptions listed in Article 13).
- Ensure that manufacturers, importers and distributors:
 - comply with their obligations to supply safety data sheets to users of dangerous substances (Arts. 5 and 27);
 - understand and apply the rules on industrial and commercial secrecy (Arts. 16 and 19); and
 - carry out investigations into the properties of dangerous substances that appear in the EINECS, but which have not yet been introduced into Annex I of the Directive (Art. 6).

2.3 Reporting

- Report to the Commission on:
 - notifications to place substances on the market and reports on risk assessment (Art. 17 and Art. 7 of Commission Directive 93/67/EEC);
 - the use of alternative labelling (Art. 25);
 - prohibitions or restrictions on the placing on the market of dangerous substances (Art. 31);
 - implementation of the Directive (Art. 32);
 - measures taken to comply with the Directive (Art. 3 of Directive 92/32/EEC);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 3 of Directive 92/32/EEC).

2.4 Additional Legal Instruments

This directive has been amended nine times and is frequently adapted to incorporate technical progress (26 such adaptations until the end of 1999). Commonly, amendments are made to single articles or to annexes. Council Directive 92/32/EEC substantially amended the original Directive, for the seventh time. As it has a central role in the control of chemicals through classification, labelling and packaging, it is referred to in almost all Directives and Regulations in the chemical sector. It is paralleled by Council Directive 88/379/EEC on the classification, labelling and packaging of dangerous preparations (recently replaced by Directive 99/45/EC).

Other legal instrument that should be taken into account when implementing this directive include:

- Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC;
- Council Regulation (EEC) No. 793/93 on the risks of existing substances;
- Council Regulation (EC) No. 1488/94, on the principles for risk assessment of existing substances; and
- Council Directives 76/769/EEC and 79/117/EEC, which restrict the marketing and use of certain chemical substances and preparations within the EU. These do not apply to products exported to third countries.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this directive are summarised in the checklist below. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

DIRECTIVE ON CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority or authorities to receive and assess information on new substances to be placed on the market.
2	Regulation
2.1	Establish a procedure for the notification of new substances by manufacturers, importers and distributors.
2.2	Establish a mechanism to ensure that all substances are classified, packaged and labelled in accordance with the directive.
2.3	Establish a mechanism to ensure that manufacturers, importers and distributors provide safety data sheets.
2.4	Provide information to manufacturers, importers and distributors to ensure they understand the requirements of the directive.
2.5	Establish a procedure for carrying out risk assessments.
2.6	Establish a procedure to ensure that dangerous substances are not advertised in breach of the Directive's requirements.
2.7	Establish criteria for placing temporary restrictions on substances.
2.8	Establish procedures and criteria for maintaining industrial and commercial secrecy.
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none"> • notifications to place new substances on the market; • the use of alternative labelling; • prohibitions or restrictions on the placing on the market of dangerous substances; and • transposition and implementation of the directive.

3.2 Phasing considerations

This is a key directive in the control of chemical hazards. It is likely to take a substantial amount of time to implement the directive because of its potential effect on a range of stakeholders. Lengthy consultation and information procedures may be a principal constraint on implementation.

4 Implementation Guidance

This directive plays a vital role in the protection of the public and the environment from chemical hazards. It also has important implications for the smooth functioning of the internal market, and it was

adopted under Article 100a of the EC Treaty (of Maastricht). Some industrial sectors are exempted from the provisions of the Directive because they are covered by provisions in other Community legislation, for example, medicinal products and cosmetics. Transport matters and substances supplied in small quantities are also exempt.

Implementation of the directive requires a system which:

- classifies chemicals according to the hazard they present;
- establishes safety procedures to minimise the likelihood of a hazard becoming a risk;
- provides an identification code for the chemical; and
- ensures that the chemical is packaged and labelled to minimise risk.

A number of general observations and 'good practice' suggestions for implementing this directive are presented below based upon the collective experience of Member States.

Planning

- This directive is one of a number that regulate the placing on the market of chemical substances.
- The choice of a competent authority will require care, because of the many government bodies with a legitimate interest in the directive. For example, a body concerned with worker safety may be considered to be the most appropriate, but it is essential that mechanisms for involving other departments and receiving input from them, particularly those with a remit for environmental protection, are established. Where more than one competent authority is appointed tasks must be clearly allocated, for example, receiving notifications, carrying out risk assessments and communicating with the Commission. Training or recruitment may be required to ensure that the competent authority/ies is adequately equipped, inter alia to complete the risk assessments required.

Examples of Competent Authorities in Member States

In one Member State (UK) the competent authorities responsible for implementation and enforcement of the Directive are the Health and Safety Executive (HSE) and the Environment Agencies. The HSE is the executive arm of the Health and Safety Commission. It is an independent body that reports to government but is not part of it. The HSE publishes a wide range of guidelines explaining the consequences of the national regulations and their amendments. The Environment Agencies are also non-governmental public bodies reporting to the Department of the Environment, Transport and the Regions (DETR) with responsibility for, amongst others, the regulation and enforcement of the most polluting industries and all discharges to surface waters. In UK the provisions of the directive relating to the notification of new substances is transposed through the Notification of New Substances Regulations 1993 whilst the provisions relating to the classification, packaging and labelling of dangerous substances (that is, Annex I of the Directive) are transposed through the Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) 1994.

In another Member State (S) the competent authority responsible for overseeing all aspects of chemicals related to EC Directive is the National Chemicals Inspectorate (KEMI). KEMI was established in 1986 and was the first independent body of its kind, under the Ministry of Environment, with specific responsibility for chemicals in the country.

Example of Practice in a Member State

One Member State (S), which recently acceded to the EU, had already implemented legislation for the control, labelling and packaging of dangerous chemicals and substances. Consequently there were few implications in implementing this directive. However, one area of concern was that under national law four categories of acute toxic substances were recognised, instead of the three categories in the EC Directive. This situation prompted much discussion at the time of membership to the EU, with some sectors suggesting that compliance to less stringent criteria may weaken the control on dangerous substances. The differences prompted derogations in some areas, which have been in existence for four years until 31 December 1998 which was the end of the accession treaty period. This Member State is still active in the area of chemical classification and has seen the inclusion of certain effects covering inhalation and de-fatting of the skin

- The directive has a potential impact on many stakeholders, and as a result great care must be taken to consult widely. For example, the stakeholders involved include not only companies and their workers, together with their representatives, but also environmental bodies, accident control authorities, emergency services, and wide range of NGOs and government departments. This large number of interested parties reflects the importance of chemical substances in everyday life.
- Governments may benefit from consultation with the Commission, international agencies concerned with chemicals such as the OECD, and other national governments by, for example, the exchange of information, discussion of best practices, or pooling of common resources.

Regulation

- A procedure must be established for the notification of new substances by manufacturers, importers and distributors. Such a procedure could involve the preparation of standard forms to assist notifiers in submitting data and the competent authorities in judging whether sufficient data has been received. A process for checking that the required data has been submitted will be required as will a mechanism for informing the notifier either of additional data requirements or that a dossier is satisfactory. A process for ensuring that when the production/import level of a notified substance reaches the specified trigger points that a dialogue is established with the manufacturer/importer to agree the “level 1” or “level 2 “ studies which are appropriate for the substance and the time frame in which those tests shall be performed. These procedures should maintain industrial and commercial secrecy.
- Requirements for the packaging and labelling of dangerous substances are laid down in the directive, and a mechanism will be required for ensuring that these requirements are met. This could be achieved at the same time as installations are inspected for other environmental or health and safety purposes, or could be achieved by a specific inspection. Packaging and labelling could also be inspected in the market place.
- There are also requirements relating to the provision of safety data sheets. These contain information for the user on the safe handling of the substance during storage, transport and disposal and information on hazards, fire fighting, first aid, accidental release measures and toxicological and eco-toxicological properties. Once again a system of compliance monitoring will be required to ensure that data sheets are both provided and accurate. This may partly be achieved at the notification stage as the notifier must provide a draft safety data sheet with the notification. Standard MSDs are available on the Internet.
- For the effective implementation of the directive, guidance should be issued to manufacturers,

importers and distributors on the notification procedure and the requirements relating to classification, packaging and labelling of dangerous substances. The guidance should provide information on:

- which substances are covered by the directive and which are exempt;
 - the information that must be submitted and under which circumstances;
 - how that information should be obtained (this should include the use of specified test methods, the sharing of information with other manufacturers etc.)
 - how the competent authority treats the information it has received;
 - when and under what circumstances additional information may be required;
 - how the risk assessment may be carried out, and what the results can lead to (see below);
 - when and where the substance may be placed on the market; and
 - how the substance should be packaged, classified and labelled.
- The directive requires that, once a new substance has been notified and the data set provided has been judged to be acceptable, the competent authority receiving the notification must carry out a risk assessment of the substance, based on the data provided. The procedure for carrying out this risk assessment has been laid down in Commission Directive 93/67/EEC and guidance on the procedure has been provided by the Commission (see References below). The risk assessment is prepared in four steps:
 - hazard identification;
 - dose- (concentration) response- (effect) assessment where appropriate;
 - exposure assessment; and
 - characterisation of the risk for human health and the environment.
 - A mechanism is required to prevent the advertisement of dangerous substances in contravention of the directive's provisions. Such advertisements could be placed in trade publications in addition to more general setting (billboards, national press etc.).
 - The directive allows for a Member State to restrict temporarily the marketing and use of a notified substance if, in the light of new information, it is believed that it presents a danger to people and the environment. Criteria against which such a decision will be made should be established and made available.
 - After the notification of a new substance the dossier must be circulated among the national competent authorities in order to maintain the information of notified substances at the same level. As the information within the dossier must be kept confidential, this is achieved via the Permanent Representations of the Member States in Brussels.
 - An adequate system of penalties for non-compliance will be required to provide an incentive for manufacturers and importers to meet the requirements of the directive.

Reporting

The Directive requires Member States to report to the Commission on several aspects of implementation.

- With respect to the notification procedure, the competent authority must forward copies of all notification dossiers, and certain related information, to the European Commission. This information is treated confidentially (see above);

- Once a notification has been supplied, the competent authority must complete a risk assessment (see above) the results of which must be forwarded to the Commission. This will be circulated amongst the Member States and, depending on its conclusions, may result in proposals for legislation controlling the use of the substance being put forward;
- The directive allows for labelling other than that specified to be used in certain circumstances (e.g. when containers are too small for the specified label to fit). Such variations must be approved by the competent authority and notified to the Commission;
- Any temporary prohibitions placed on the placing on the market of dangerous substances (see above) must be notified to the Commission; and
- Finally, Member States must report to the Commission on the implementation of the directive every three years.

5 Costs

The main costs of implementing this directive consist of the costs of establishing and running a regulatory authority and the costs incurred by industry.

For the regulatory authority, the costs are those of establishing the implementation systems, the day to day costs of maintaining it and managing notifications, for dealing with the risk assessment of new substances and the use of specialist advisors/consultants if required.

In industry, the manufacturers of new substances will bear major costs arising from the notification of new substances. The costs may include those of carrying out detailed toxicity tests as specified in the directive. Other costs will arise from the introduction of the packaging and labeling controls, as the existing requirements in Candidate Countries are harmonised with those within the EU. However, a recent study by the European Commission has found that despite a temporary reduction on the number of notifications of new substances during the initial implementation of Council Directive 92/32/EEC, the number of notifications on an annual basis was 350 in 1996.

The Genetically Modified Organisms Deliberate Release Directive

Official Title: Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (OJL 117, 8.5.90)

TAIEX Ref. No.: 111

1 Summary of Main Aims and Provisions

This Directive aims to protect human health and the environment from the risks arising from the deliberate release into the environment of genetically modified organisms (GMOs) either for research and development purposes or for the purpose of placing on the market products which contain or consist of GMOs. The Directive is also concerned with the smooth functioning of the internal market, and once the placing on the market of a GMO product has been authorised by one Member State, the other Member States may not restrict its marketing on their territory (unless there are justifiable reasons relating to the protection of the environment and human health). The provisions adopt a preventive approach requiring a system of prior risk assessment, notification and consent from the competent authority of the Member State in which the release of GMOs is proposed. The Directive does not apply to organisms obtained through certain listed techniques of genetic modification.

2 Principal Obligations of Member States

2.1 Planning

- Designate a competent authority (or authorities) to implement and enforce the requirements of the Directive (Art. 4).

2.2 Regulation

- Ensure that appropriate measures are taken to avoid adverse effects on human health and the environment that might arise from the deliberate release of GMOs (Art. 4).
- Ensure that competent authorities receive and evaluate notifications in accordance with the Directive's requirements, and only allow a release to proceed if satisfied that the notification complies with the Directive (Arts. 6, 12, 13).
- Ensure that the competent authority carries out inspections and other control measures to ensure that the legislation implementing the Directive is complied with (Art 4).
- Ensure that prior notification is submitted to the competent authority before the deliberate release / placing on the market of GMOs is undertaken, in accordance with the notification and risk assessment requirements set out in the Directive, and that notifiers proceed with the release only with the consent of the competent authority and in accordance with any conditions attached to the consent (Arts. 6, 10, 11).

- Ensure that notifiers provide certain information to the competent authorities with regard to the risks to human health or the environment of releasing GMOs into the environment (Arts. 5, 8, 11).
- Ensure that users of products consisting of or containing GMOs that are placed on the market comply with conditions attached to consents regarding their deliberate release, including conditions relating to packaging and labeling (Arts. 13, 14).
- Ensure that confidentiality of information and intellectual property rights are protected in accordance with the Directive's requirements (Art. 19).
- Do not prohibit, restrict or impede the placing on the market of products containing or consisting of GMOs which comply with the requirements of the Directive, on grounds relating to notification and written consent (Art. 15). This is subject to powers of Member States to provisionally restrict or prohibit use and/or sale of a product on grounds of risk to human health or the environment (Art. 16).

2.3 Reporting

Report to the Commission on:

- notifications received by the competent authority (Arts. 9, 12);
- final decisions of the competent authority regarding notifications (Arts. 9, 13);
- additional information received by the competent authority regarding the risks of a product (Art. 12);
- provisional restrictions/prohibitions on the use and/or sale of a product on grounds of harm to human health or the environment (Art. 16);
- control of the use of products placed on the market under the Directive (Art. 18);
- measures taken to implement the Directive (Art. 22); and
- transposition, with the texts of the main provisions of national law adopted in the field covered by the Directive (Art. 23).

Report to other Member States on:

- final decisions of the competent authority regarding notifications (Arts. 9, 13);
- additional information received by the competent authority regarding the risks of a product (Art. 12); and
- provisional restrictions/prohibitions on the use and/or sale of a product on grounds of harm to human health or the environment (Art. 16).

2.4 Additional Legal Instruments

The following legislation should be taken into consideration when implementing this Directive:

- Council Regulation (EC) No. 258/97 on novel food and foodstuffs (if the GMO is placed on the market as a food or food ingredient).
- Council Directive 98/95/EEC on genetically modified plant varieties and plant genetic resources.
- Council Regulation (EC) No. 1139/98 concerning labeling of foodstuffs produced from GMOs.
- Council Directive 90/219/EEC on the contained use of GMOs.
- Council Directive 90/313/EEC on the Freedom of Access to Information on the Environment.

3 Implementation

3.1 Key Tasks

The key tasks required to implement this directive are summarised in the following checklist. Tasks are arranged under sub-headings in chronological order whenever possible.

GENETICALLY MODIFIED ORGANISMS DELIBERATE RELEASE DIRECTIVE – KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to implement and enforce the requirements of the Directive. Establish a mechanism for receiving and evaluating notifications and ensuring that they comply with the requirements of the Directive.
2	Regulation
2.1	Interact with the applicant with regard to notifications and inform them about approval or rejection of applications within the time scales set out in the directive.
2.2	Through discussions with the notifier, determine which aspects of a notification may be deemed commercially sensitive and are to be protected.
2.3	Establish mechanisms for informing the public about deliberate releases to be carried out under the directive.
2.4	Circulate information to ensure that persons wishing to release a GMO: <ul style="list-style-type: none">• submit a notification to the competent authority prior to release of GMOs;• notify the competent authority of any new information with regard to the risks of a product;• do not proceed without the necessary written consent of the competent authority, and implement the deliberate release in conformity with any conditions in the consent; and• notify the competent authority about the results of the release.
2.5	Create formats to be completed by notifiers.
2.6	Examine the notifications to ensure conformity with the requirements of the directive.
2.7	Evaluate the risks from the proposed release.
2.8	Establish an inspection and monitoring mechanism to ensure the conditions of the directive are fulfilled.
2.9	Establish procedures for liaising with the Commission and Member States as required by the directive.
2.10	In accordance with the directive, establish procedures to implement, or object to, marketing permissions granted by other Member States.
2.11	Request from the Commission, when appropriate, the application of simplified procedures for the release of certain types of GMOs.
3	Reporting
3.1	Set up document management system and a related database to record relevant information relating to implementation.
3.2	Report to the Commission: <ul style="list-style-type: none">• notifications received from the competent authority;• final decisions taken by the competent authority;• new information received regarding the risks of products;• provisional restrictions/prohibitions on the use or sale of a product; and• transposition and implementation.
3.3	Report to other Member States on: <ul style="list-style-type: none">• final decisions taken by the competent authority;• additional information regarding the risks of a product;• provisional restrictions/prohibitions on the use or sale of a product.

3.2 Phasing

The growing public concern about risks to the environment and to the risks to the environment of released GMOs and to the food safety of ingredients derived therefrom, makes it essential that regulatory controls are introduced as rapidly as possible.

4 Implementation Guidance

The aim of the directive is to implement effective mechanisms to protect human health and the environment from the risks arising from the release of GMOs. The key actors are government ministries with responsibilities for the environment and health and safety. They will establish a competent authority with responsibility for implementing and enforcing the directive's requirements. It is

recommended that they should establish a specialist committee to ensure that a wide range of specialised scientific knowledge is available to the competent authority.

The directive defines a GMO as ‘an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’ (Art. 2). It also lists techniques which are, and are not, considered to result in genetic modification (Annex IA Parts 1 and 2 respectively). The Directive does not apply to organisms obtained through the techniques of genetic modification listed in Annex IB.

Planning

- When planning the implementation of the directive, it should be noted that there is no definition in the Directive of the term ‘adverse effects on human health and the environment’ and that the interpretation of this term is therefore very dependent on national attitudes; in this sense, national variations in approach are inevitable.
- Many countries already have existing environmental protection legislation that includes a reference to genetic engineering, and it may be possible to incorporate the requirements of the Directive into existing legislation rather than to enact separate legislation. Both Directives 90/220/EEC and 90/219/EEC could be implemented together.

Examples of Legal Systems in Member States

In one Member State (UK) the Environmental Protection Act 1990 was used as the basis for new regulations on GMOs. The competent authorities are the Health and Safety Executive and the Department of Environment, Transport and the Regions. To enable the competent authority to perform effectively it believes that it must have access to a range of specialist scientific information and technology and to advice from scientists, industry and other sectors of the community. The Advisory Committee established for deliberate releases is the Advisory Committee on Release to the Environment (ACRE). Such a committee provides a greater degree of transparency. The other important organisation for the competent authority to establish is the Inspectorate, for inspecting and monitoring to ensure regulations relating to GMOs are followed. This role is provided by the Health and Safety Executive.

In another Member State (DK) the Act on Environment and Genetic Engineering (EGE) of 1986 (Act No 356, sec. 27 6/6/1991) authorises the Ministry of Environment to legislate by Statutory Order, thereby transferring powers relating to GMOs to the Environmental Protection Agency. The competent authorities are the Ministry of Environment and the Ministry of Labour. They have not created a specialist Advisory Committee, but when specialist scientific knowledge is required, individual specialists and ministries are consulted on an ad hoc basis. The Inspectorate for monitoring and inspecting to ensure regulations relating to GMOs are followed is the Environmental Protection Agency.

In a third Member State (NL) the directive was implemented by extending the Chemical Waste Act. The relevant Act is the Environmental Protection Act and implementing regulations include the Genetically Modified Organisms Decree pursuant to the Chemical Substances Act and the Ministerial Order on the Contained Use of Genetically Modified Organisms. The sole competent authority is the Ministry of Housing, Spatial Planning and the Environment. This has established a deliberations based approach involving relevant constituencies through individual membership of an Advisory Committee the COGEM. The Department for the Enforcement of Environmental Legislation is responsible for inspection and monitoring.

Regulation

- The competent authority has many tasks to perform and to carry them out successfully requires specialists in many disciplines. Access to a wide range of expert advice is required during

implementation of the directive and it is usually impracticable to provide the whole of this from within government. The formation of a specialist advisory committee with members who cover the range of expertise required may be the best approach. Government officials may *beex officio* members of such a committee. The use of an advisory committee ensures that the widest range of expertise can be obtained while retaining the ultimate decision within the competent authority itself. It is also a measure that contributes to transparency.

- Competent authorities may already exist in the Candidate Countries, for example in the Ministry of Environment, or Labour or Health Care or Social Welfare, which have experience of the sector and they could act with the assistance of an advisory committee or on specialist advice.
- The Commission has recognised that implementation of the directive has revealed a number of problems. In particular, it has proved difficult to reach a consensus in Member States on the acceptability of the release of GMO plants. It is hoped that a future revision of the directive will overcome this, and other, problems.

Examples of Risk Assessment Practices in Member States

In one Member State (UK) the competent authority defines the acceptability of the risk of GMOs in the context of conventional agricultural practice and assesses how far GMOs pose an additional risk by comparison with conventional agricultural practice. When considering its first proposal to release herbicide tolerant sugar beet the competent authority in another Member State defined its approach to assessment by using the criteria of "sustainable social development". While this was essential to enable them to achieve consensus within the country on GMO legislation, it caused problems with the other Member States. Furthermore in assessing the agronomic effect of this directive it evaluates the acceptability of products in view of sustainable development. Two other Member States (S and F) operate using very similar assessment criteria.

The approach to assessment in another Member State (NL) is to seek to establish through trial releases that plausible effects are manageable. When negative environmental effects can not be demonstrated in the field for a particular plant-gene combination it becomes a candidate for exemption from further risk assessment reviews by the Advisory Committee for a similar release. Inspection and monitoring organisations are vitally important and high quality staff are required with authority and technical competence which allows them to negotiate with those wishing to carry out trials and market products.

Reporting

- The obligations for reporting to the Commission and Member States are set out in the obligations and key tasks, above. To meet the obligations, it is necessary to establish a high quality information system to collect data, to incorporate it into a database and to distribute it as required. This is an office and document management issue.
- In addition to the well defined reporting obligations set out above, experience shows that it is advisable to provide information to the users of GMOs and to the public about the national implementation of the directives so as to ensure transparency. A multifaceted approach, using press releases, information leaflets, public meetings, private meetings with representative bodies, radio and television programmes, and publicity via the Internet is recommended.

5 Costs

The main costs to government of implementing this directive consist of indirect/overhead costs of establishing the implementation systems, the day to day costs of maintaining it and the payments to

specialist advisors/consultants for attendance at committee meetings and for special events. The monetary value of these will vary greatly from country to country. Once the system is established, the total costs must depend on the number of cases needing consideration. The best guide to the cost is the charges made to applicants for dealing with notifications, for these are commonly designed to cover the costs of notifications. However, this approach is only practicable when a considerable number of notifications are received - otherwise the cost per application is prohibitive.

The costs of implementation to industry are very much greater than to government. Not only are there the costs of trials to satisfy regulatory requirements but major costs have been incurred because of difficulties in obtaining Europe-wide permission for releases.

The Regulation on Risks of Existing Substances

Official Title: Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.93)

TAIEX Ref. No.: 127

and related Regulations:

- Commission Regulation (EC) No. 1488/94 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No. 793/93 (OJ L 161, 29.6.94). TAIEX Ref. No. 128
- Commission Regulation (EC) No. 1179/94 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No. 793/93 (OJ L 131, 26.5.94). TAIEX Ref. No. 129
- Commission Regulation (EC) No. 2268/95 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No. 793/93 (OJ L 231, 28.9.95). TAIEX Ref. No. 130
- Commission Regulation (EC) No. 142/97 concerning the delivery of information about certain existing substances as foreseen under Council Regulation (EEC) No. 793/93 (OJ L 25, 28.1.97). TAIEX Ref. No. 131
- Commission Regulation (EC) No. 143/97 concerning the third list of priority substances as foreseen under Council Regulation (EEC) No. 793/93 (OJ L 25, 28.1.97). TAIEX Ref. No. 132

1 Summary of Main Aims and Provisions

The main aim of the Regulation is to evaluate and control the risks of ‘existing’ chemical substances, i.e. those listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). The Regulation places obligations on manufacturers and importers to submit available data on substances produced or imported above certain quantities. Member States must carry out risk assessment (in accordance with Regulation (EC) No. 1488/94) for certain ‘priority’ substances. Additional data to carry out this risk assessment may be requested from the manufacturer. Lists of priority substances were established by the Commission in Regulations (EC) No. 1179/94, (EC) No. 2268/95 and (EC) No. 143/97, which also allocated responsibility to specific Member States for the evaluation of these substances.

2 Principal Obligations of Member States

2.1 Planning

- Establish competent authorities to implement the regulations, and a mechanism to evaluate the risks of priority substances assigned to the Member State (Arts. 10 and 13).

2.2 Regulation

- Ensure that manufacturers and importers, who produce or import existing substances above certain quantities, carry out the following tasks:
 - send and update information to the Commission (and to the government where required) on the substances and their potential serious risks. The information should include the classification of the substance according to Annex I of Directive 76/548/EEC or, where the substance is not in Annex I, any provisional classification determined by the manufacturer/importer (Arts. 3, 4, 5, 6, 7, Annex III and Annex IV);
 - send information to the competent authority on priority substances (Arts. 9 and 12, and Commission Regulation (EC) No 142/97);
 - carry out testing to obtain additional data on priority substances (Art. 9);
 - make arrangements with other manufacturers and importers for joint testing and reporting, if required (Arts. 6 and 12);
 - ensure that tests on animals are only carried out if essential and if carried out in accordance with relevant Directives (Art. 10); and
 - understand and apply the rules on confidentiality of data (Art. 16).
- Establish legal or administrative measures to deal with cases of non-compliance with the requirements of the Regulation (Art. 17).

2.3 Evaluation and Reporting

- Evaluate the risks to human health and the environment of certain priority substances, in accordance with the principles laid down in Council Regulation (EC) No. 1488/94, and propose a strategy for limiting those risks (Art. 10, and Commission Regulation (EC) No. 1488/94).
- Report to the Commission on:
 - cases of derogation from the requirements to carry out additional testing (Art. 9);
 - requests for further information and/or testing (Arts. 4 and 10); and
 - risk assessment and proposed strategies for limiting risks (Art. 10 and Commission Regulation (EC) No. 1488/94).

2.4 Additional Legal Instruments

The following legislation should be taken into account when implementing these regulations.

- Council Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this regulation are summarised in the following checklist.

REGULATION ON EVALUATION AND CONTROL OF THE RISKS OF EXISTING SUBSTANCES – KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority/ies to evaluate the risks of priority substances and to ensure that manufacturers/importers are complying with the requirements of the regulation.
1.2	Establish a procedure for completing risk assessments of substances allocated.
1.3	When a substance has been allocated for assessment, nominate a rapporteur competent authority.
1.4	Nominate an expert/s to sit on the technical committee for the purposes of the regulation.
2	Regulation
2.1	Issue guidance to manufacturers and importers to inform them of their obligations under the regulation and how these should be met.
2.2	Decide whether manufacturers and importers should submit information to the competent authority/ies in addition to the Commission.
2.3	Determine which information shall be covered by industrial and commercial secrecy and make this decision publicly available.
2.4	Establish a procedure for monitoring compliance with the Regulation by manufacturers and importers.
3	Evaluation and Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none"> • requests for additional information and/or testing; • derogations granted from requirements to carry out additional testing; and • risk assessment and proposed strategies for limiting risks.

3.2 Phasing Considerations

The main aims of this Regulation are to reduce risks to workers, the general public and the environment from certain dangerous substances and to avoid distortions in competition. The primary considerations, when implementing the Regulation, should be the appointment of the competent authority/ies and the development and publication of guidance to manufacturers and importers on their obligations under the terms of the regulation and how these should be met. Chemicals for which risk assessments must be completed are identified by Commission Regulations after consultation with the Member States.

4 Implementation Guidance

The control of chemical hazards is of major importance to workers, because as a group they are significantly exposed to industrial chemicals. Additionally, the presence of chemicals used in manufacturing in products sold to consumers present potential hazards. These factors make it necessary to collect data about the multitude of "existing chemicals" used in the Community and listed in the EINECS database.

In order to reduce the workload, compounds believed to have minimal risk and those used in relatively small amounts, are excluded from the data reporting requirements. As chemicals are used internationally and the same shortage of information is recognised in all industrialised countries, work is being carried out by other international bodies and should be taken into account by the Community in selecting existing chemicals for further study of risks.

These regulations are only a part of the broad area of legislation to ensure the safety of people and the environment with regard to the hazards presented by chemicals.

A number of general observations and 'good practice' suggestions for implementing this regulation are presented below based upon the collective experience of Member States.

Planning

- The type of organisation(s) appointed as the competent authority(ies) will vary depending on the administrative structure within the country concerned, but will usually be concerned with the safety of workers and the public and/or the assessment and control of chemicals in the environment. It is important to ensure that governmental bodies with expertise in the assessment of chemicals (e.g. environment and health ministries) are involved, although training or recruitment may be required.
- The rapporteur is the competent authority designated by a Member State to lead the risk assessment of a substance allocated to that Member State. Where more than one competent authority has been appointed, the Member State may decide that one should always lead the risk assessment, drawing on the skills of others. Alternatively, the lead authority could vary depending on the substance concerned and its properties.
- A decision should be made as to whether manufacturers and importers should copy information sent to the European Commission for the purposes of the regulation to the competent authorities in their own Member State. This will result in the competent authority being aware of data submitted but may place a heavy administrative burden upon them. If it is decided that the competent authority should receive copies of the information sent to the Commission, a suitable database should be developed.

Example of Practice in a Member State

In one Member State (UK) the framework legislation used to implement this Regulation is the Health and Safety at Work Act, 1974 and the Environmental Protection Act, 1990. The implementing regulations are made under these Acts. Currently, these are published in the Notification of Existing Substances (Enforcement) Regulations 1994.

The competent authorities are the Department of the Environment, Transport and the Regions (DETR) and the Health and Safety Executive (HSE). The enforcement agencies are the HSE and the Environment Agencies. DETR is the Governmental Department responsible for deriving policy on the environment, planning, local government and transport related issues. The HSE is the principal authority in the UK with regard to the protection of workers and the control of chemical and their hazards. The Environment Agencies are responsible, amongst other duties, for licensing and regulating emissions from the most polluting industries and all discharges to surface and groundwaters. All of the competent authorities publish information in print and electronic format and have Internet web sites.

Regulation

- The regulation will apply directly to manufacturers and importers and therefore, for the effective implementation of the regulation, it is important that guidance is provided on the obligations placed on them and how these obligations are to be met. Such guidance should include:
 - the information to be supplied to the Commission and under which circumstances;
 - the format in which the information may be supplied (e.g. electronic or on paper) and where electronic pro-formae may be obtained;
 - the testing guidelines that should be used to produce the information;
 - the procedure for supplying information, including whether information should be copied to the country's own competent authority;

- which company should report information when a substance is produced or imported by more than one company and how collaboration should be organised when additional testing is required;
 - the circumstances under which additional information must be provided and to whom it must be sent;
 - the circumstances under which additional testing will be required, when exemptions can be granted and procedures for checking that such information is required, that it is not available from other manufacturers or importers and that the use of animals for experimentation is reduced as far as possible; and
 - the rules relating to the protection of confidential information.
- In order to allow risk assessments of substances to be conducted efficiently, particularly if more than one competent authority is involved, a procedure should be developed. This should include clear accountabilities for each organisation involved (who is responsible for what) and should identify, where required, which organisation is responsible for the overall co-ordination of the risk assessment. Guidance has been published by the European Commission on how risk assessments should be carried out.
 - The European Chemicals Bureau (ECB) in Ispra, Italy, is the Commission's co-ordinating body for receiving the head set data, identifying priority chemicals and organising the meetings necessary to discuss the rapporteur's draft risk assessments.
 - For consistency, a policy should be determined regarding the confidentiality of data. This should be made publicly available so that manufacturers and importers can identify when they may be successful in applying for an exemption from disclosure of commercially sensitive information.
 - The regulation requires Member States to establish legal or administrative measures in order to deal with non-compliance of the regulation. Procedures should be developed to monitor compliance and to take appropriate action in cases of non-compliance.

Reporting

- Under the terms of the regulation, Member States are only required to report to the Commission on risk assessments when acting as rapporteur in respect of a particular substance.

Example of Practice in a Member State

In one Member State (FIN) the implementing authority for these regulations is the National Chemicals Inspectorate (KEMI), which reports to the Department of Environment.

Work in this area interfaces with the implementation of the Classification, Packaging and Labelling of Dangerous Substances Directive (67/548/EEC) and Regulation on Export and Import of Dangerous Chemicals Directive (EEC/2455/92). KEMI maintains a specialist division, which is responsible for conducting inspections at industrial locations to review safety sheets and procedures, as specified in the directives (67/548/EEC and 793/93/EEC).

Finland was already involved in a project researching the effect of substances on the environment, prior to accession and under the auspices of the Nordic Council of Ministers. Consequently EU membership did not cause an extensive increase in workload to implement these regulations.

The establishment and maintenance of a close working relationship with industry is seen as an important factor in implementation. KEMI is involved in providing training and organising workshops for industry.

The consideration of the environmental effect of substances has lagged behind the previous initiatives, which centred on their effect on human health and the safe handling of chemicals. In general, much work is required in this area, using the established biological test indicators (phytoplankton, daphnia and fish), particularly concerning new chemical substances.

This area of work is, by its nature, very demanding on the regulatory authority and KEMI is constantly engaged in answering questions from industry and the general public. In response, they have implemented a rolling programme, whereby department staff take turns in manning the answering facility.

Costs consist of indirect/overhead costs of establishing the implementation systems, the day to day costs of maintaining it and ongoing costs for tasks such as the classification of new substances, as well as for the use of specialist advisors/consultants. The manufacturers of new substances will bear the major part of this cost but the regulatory competent authority will also incur costs.

All the legislation and some related information are available on the Internet, on sites established by the Member State government. All published information is readily available to the general public.

5 Costs

These consist of the costs of the regulatory activities involved in implementation and the costs, which apply to the industry, which is regulated.

The regulatory costs are those of establishing the implementation systems, the day to day costs of maintaining them and ongoing costs for carrying out risk assessments of allocated substances. Costs will also be incurred for monitoring compliance with the regulation, but these can be reduced by incorporating such monitoring into existing inspection systems.

The manufacturers and importers of substances on the EINECS inventory for which data are required will bear a substantial cost in obtaining the information required. The sharing of costs between manufacturers and importers with common interests will reduce the burden on individual companies.

The Regulation on the Export and Import of Dangerous Chemicals

Official Title: Council Regulation EEC/2455/92 concerning the export and import of certain dangerous chemicals (OJ L 251, 29.8.92)

TAIEX Ref. No.: 133

1 Summary of Main Aims and Provisions

The Regulation establishes a common system of notification and information, for imports and exports of certain dangerous chemicals into and out of the European Union. The Regulation makes the Prior Informed Consent (PIC) procedure (established by the United Nations Environment Programme and the Food and Agriculture Organisation) mandatory within the EU. Under this PIC procedure, chemicals that are banned or severely restricted, in order to protect human health or the environment, should not be shipped internationally unless the importing country consents to the shipment. The Regulation also seeks to ensure that the rules on classification, packaging and labelling of dangerous substances, laid down in other Directives, also apply to exports of dangerous chemicals from the EU to third countries.

2 Principal Obligations of Member States

2.1 Planning

- Designate an authority (or authorities) to be responsible for implementing the notification and information procedures laid down in the Regulation (Art. 3).

2.2 Regulation

- Ensure that exporters of chemicals comply with their obligations under the Regulation, including obligations:
 - to package and label chemicals in accordance with Community legislation (Art. 7);
 - to ensure that exports of chemicals subject to notification are accompanied by the relevant EC Export Reference Number (Art. 4);
 - to notify the competent authority if chemicals subject to notification are being exported to a third country for the first time (Art. 4); and
 - to comply with the decision of the importing country regarding the import of chemicals subject to the PIC procedure (Art. 5).
- Establish legal or administrative measures to deal with cases of non-compliance with the requirements of the Regulation (Art. 6).
- Ensure that competent authorities comply with their obligations under the Regulation, including obligations:
 - to notify the appropriate authorities of the country of destination of the intended export, for the first time, of chemicals subject to notification (Art. 4);
 - to ban or restrict imports of chemicals in accordance with the decisions of the Commission

- (Art. 5);
 - to inform the Commission of notifications to/from third countries re: exports from/to the EC (Art. 4 and 8).
- Take account of the need to protect the confidentiality of data in accordance with the criteria set out in the Directive (Art. 4).

2.3 Information and Reporting

- Co-operate with the Commission in evaluating the risks posed by certain chemicals (Art. 5).
- Report to the Commission on:
 - the designation of competent authorities (Art. 3);
 - notifications regarding the export of chemicals subject to notification (Arts. 4 and 8);
 - information on the operation of the notification system (Art. 9); and
 - other export notification systems that are applied to chemicals not listed in Annex I (Art. 10).

2.4 Additional Legal Instruments

EC legislation which needs to be taken into consideration in the implementation of this regulation includes:

- Directives 76/769/EEC and 79/117/EEC which restrict the marketing and use of certain chemical substances and preparations within the EU. These do not apply to products exported to third countries.
- Council Directive 67/548/EEC on the classification, packaging and labeling of dangerous substances. This is applicable to substances placed on the market in the Community.

3 Implementation

3.1 Key tasks

The key tasks involved in implementing this regulation are summarised in the checklist overleaf. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

3.2 Phasing Considerations

This regulation cannot be fully implemented until appropriate systems for classifying chemicals and managing their marketing within the EU are in place. Its implementation should therefore be carried out in parallel with Council Directive 67/548/EEC.

Some regulatory control of chemical import and export will already be in existence in Candidate Countries, especially those that are already participating in the international Prior Informed Consent (PIC) procedure.

REGULATION ON EXPORT AND IMPORT OF DANGEROUS CHEMICALS - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to take responsibility for the notification and information measures required for the import and export of chemicals requiring prior informed consent.
2	Regulation
2.1	Establish procedures and protocols to ensure that the competent authority complies with its obligations under the Regulation, including: <ul style="list-style-type: none"> · receiving notification of a proposed first export of a substance subject to notification at least 30 days before the intended export; · informing the appropriate authorities in the country of destination of the intended export at least 15 days before the intended export; · reporting to the Commission; · taking appropriate actions in response to reactions from the country of destination; · ensuring that dangerous substances for export to third countries comply with EC labeling and packaging requirements; and · monitoring compliance with the provisions of the regulation.
3	Obligations of the exporter
3.1	Develop and provide guidance to exporters on their obligations under the Regulation, including: <ul style="list-style-type: none"> · packaging and labeling of chemicals in accordance with EC requirements; · complying with the import decisions of countries of destination; and · notifying competent authorities of the proposed first export of chemicals subject to notification to third countries.
4	Information and Reporting
4.1	Co-operate with the Commission in evaluating the risks posed by certain chemicals
4.2	Report to the Commission on: <ul style="list-style-type: none"> · designation of competent authorities; · notifications received relating to exports of chemicals; and · information on the operation of the notification system.

4 Implementation Guidance

A number of general observations and 'good practice' suggestions for implementing this directive are presented below based upon the collective experience of Member States.

Planning

- The competent authority/ies will vary depending on the administrative structure within the country concerned, but may include government departments or agencies with responsibility for the chemical industry, trade and customs control. If more than one competent authority is established, it must be made clear who is responsible for which tasks.

Examples of Practice in Member States

In one Member State (UK) the Health and Safety Executive (HSE) administers the regulation under the "Export of Dangerous Chemicals" Regulation of 1992 and penalties can be levied under the Health and Safety at Work Act of 1974.

In another Member State (S) this regulation is primarily dealt with by the National Chemicals Inspectorate (KEMI) and the Customs Department. KEMI inspects permits and provides advice to the Ministry of Environment. This country had a small chemical manufacturing industry, and had been reliant on the importation of chemicals for some years prior to accession to the EU. This country had developed a rigorous regulatory system early on and subscribed to the voluntary UNEP scheme of 1992 which included 'prior informed consent' (PIC). Consequently implementation of this regulation had few implications for this Member State.

Regulation

- Once the competent authority has been designated, a procedure must be established for the notification of the export and import of dangerous chemicals. An exporter must notify the competent authority (in its own country) of its intention to export certain dangerous chemicals to a third country for the first time. This notification must be done at least 30 days before the export is to take place. Certain information must be included in the notification and this is laid down in Annex III of the Regulation, together with a standard form that should be used. On receipt of the notification the competent authority must notify the appropriate authorities in the country of destination at least 15 days before the export is to take place and inform the Commission. Exceptions from these notification requirements may be allowed in emergency situations.
- The Commission acts as the central authority for the PIC procedure. It notifies the competent bodies outside the EU of chemicals, which are banned or severely restricted within the Union. On receipt of information about the export from the EU of a dangerous chemical, it assigns a reference number to the export, which is used also for each subsequent export of the same chemical from the Community to that third country. Member States are informed of this number and it is published in the Official Journal.
- Once the Commission has issued the reference number to the Member State's competent authority, and the third country has indicated that it will accept the substance, the export may take place. The reference number issued by the Commission must be used for all subsequent exports of the substance to that country.
- In addition, when exported chemicals are subject to restrictions and/or conditions of import in the importing country, through the IPC Procedure, exporters must comply with these requirements and Member States must ensure compliance.
- The European Chemicals Bureau (ECB) at Ispra, Italy, is now responsible, on behalf of the Commission, for the exchange of information between the Member States, third countries and United Nations organisations (FAO and UNEP). It has created a useful database, EDEXIM, distributed to Member States in 1996, providing classification and labelling information about substances covered by the Regulation. EDEXIM is available in confidential form to Member States and a publicly accessible form is also available from the ECB web site.
- Dangerous chemicals that are exported from the EU must be packaged and labelled in accordance with Council Directive 67/548/EEC on the classification, packaging and labeling of dangerous substances.
- A monitoring system should be established to ensure that the provisions of the regulation are complied with. This may involve inspection of exports as they leave the country concerned as well as inspection of the records of known exporters of chemicals.
- In general, the Commission will act as the central authority in respect of imports of substances to the EU. However, where a Member State receives a notification of an import it is required to forward the notification to the Commission together with any additional information provided, and to prohibit or restrict the import in accordance with the decision of the Commission.

Obligations of the Exporter

- As the regulation is directly applicable for Member States (and Candidate Countries from day one of membership), guidance should be provided to exporters informing them of their obligations under the regulation to ensure successful implementation. This should specify:

- the information that must be included with a notification (as specified in Annex III of the Regulation);
- to whom the notification must be sent;
- guidance on what information is required to be included with the export;
- information on the packaging and labelling required by the national legislation implementing Council Directive 67/548/EEC;
- details of how to make subsequent exports; and
- information on the circumstances under which a new notification must be made.

It may be appropriate for a competent authority to operate a helpline to assist exporters in the completion of notifications. In addition, information could be provided to exporters on which substances destination countries will and will not accept. Guidance is available from FAO/UNEP Guidance Documents.

Information and Reporting

- The European Commission acts as the central authority for the import of chemicals into the Community under the PIC procedure. As such, when a request for import decision issued by the PIC Secretariat is made, the Commission must decide whether the import should be accepted, prohibited or restricted. In order to do this, the Commission forwards such notifications and any additional information to the Member States. This decision is taken through a Regulatory Committee with the Member States.
- A Member State must report to the Commission when a third country has responded substantially to a notification for the export of a dangerous chemical. The Commission will then notify other Member States.
- Member States are required to report regularly to the Commission on the implementation of the regulation. To date, the Commission has published two reports on the implementation of the Regulation, one in 1993 and the second in 1998.
- The international PIC procedure is currently a voluntary one, although the participation of the EC in this procedure is an obligation for Member States. However, on 10 September 1998, a new international convention on the PIC procedure (the Rotterdam Convention) was adopted. The Convention has been signed by over 60 countries as well as the European Community. The Convention will formalise the arrangements currently operated by UNEP and FAO. These already offer many Decision Guidance Documents to assist recipient countries in deciding whether to give prior informed consent for import of particular chemicals and maintain lists of the authorities responsible for making import decisions. Forms for making notifications of control actions to ban or seriously restrict the import of a chemical are available, as is a guidance document on the operation of PIC procedures for Chemicals. This is very useful and should be consulted for detail. The FAO web page relating to PIC should be consulted. The substantial guidance document for PIC procedures for chemicals is available at this site and should be consulted for detail.

5 Costs

The costs of implementing this regulation are concerned with establishing and running a notification and information system to support the import and export of dangerous chemicals.

A statutory import/export control system already exists in some countries. The additional costs to the regulatory authority to collect the information required by this regulation and to control the movement of chemicals is unlikely to be very large, particularly if the country already subscribes to similar schemes such as the UNEP or OECD schemes.

The costs to industry will be limited to additional administrative costs.

The Regulation on Ozone Depleting Substances

Official Title: Council Regulation (EC) No. 3093/94 on substances that deplete the ozone layer (OJ L 333, 22.12.94)

TAIEX Ref. No.: 134

1 Summary of Main Aims and Provisions

This Regulation establishes rules on the production, import, export, supply, use and handling of substances that deplete the ozone layer. It implements the Montreal Protocol to the Vienna Convention for the Protection of the Ozone Layer, but lays down more stringent requirements than the Protocol for phasing out CFCs (chlorinated fluorocarbons) and HCFCs (hydrochlorofluorocarbons). The Regulation also introduces an import licence system that is administered by the Commission.

2 Principal Obligations of Member States

2.1 Planning

- Appoint a competent authority (or authorities) to implement the requirements of the Regulation.
- Establish penalties for non-compliance with the requirements of the Regulation (Art. 19).

2.2 Regulation

- Ensure that producers of controlled substances reduce, and eventually cease, production and supply of controlled substances in accordance with specified targets and time limits; and allow producers to exceed the prescribed levels only in accordance with specified conditions (Arts. 3 and 4).
- Ensure that the use, import and supply of HCFCs and products and equipment containing HCFC's are controlled, in accordance with specified targets and time limits (Arts. 4 and 5).
- Ensure that only licensed controlled substances are imported and that used licenses are returned (Arts. 6 and 7).
- Ensure that the controls on import and export of controlled substances, and products containing these substances, to and from states that are not parties to the Montreal Protocol, or territories not covered by the Protocol, are enforced in accordance with specified conditions (Arts. 8, 9, 11, 12 and 13).
- Ensure that used controlled substances are recovered and are dealt with in accordance with specified conditions (Art. 14).
- Take precautionary measures to prevent emissions of controlled substances (Art. 15).

2.3 Reporting

- Report to the Commission on:
 - proposals to authorise the production of controlled substances (Art. 3);
 - the acquisition of rights to supply controlled substances (Art. 4);
 - the results of investigations carried out at the request of the Commission (Art. 18); and
 - information on activities involving controlled substances, including their production, import, export, supply and use (Art. 17).

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this regulation are summarised in the following checklist.

REGULATION ON OZONE DEPLETING SUBSTANCES - KEY IMPLEMENTATION TASKS	
1	Administrative Arrangements and Planning
1.1	Appoint a competent authority with responsibility for implementing the regulation and communicating with the Commission, including nominating a member of the committee operating under Article 16.
1.2	Evaluate the need for institutional strengthening, in particular training, determining qualifications for personnel handling ozone depleting substances.
1.3	Design an authorisation system for the production and importation of controlled substances for essential uses as licensed by the Commission.
1.4	Consider the scope for introducing voluntary schemes - as in the Netherlands and the UK- to meet the reduction targets.
1.5	Monitor leakage of controlled substances.
1.6	Prepare guidelines for industry and the public.
2	Regulation
2.1	Identify (via consultation) and nominate, annually, essential uses/users of controlled substances and apply to the Commission for licenses.
2.2	Design and implement a system of inspection of imports to ensure compliance with the regulation.
2.3	Establish and impose penalties for non-compliance with the requirements of the regulation.
2.4	Establish procedures to ensure that the producers of controlled substances meet the requirements to reduce their production of controlled substances.
2.5	Establish control mechanisms and procedures to ensure that the users of controlled substances meet the requirements on use in the regulation.
2.6	Ensure that controlled substances are recovered, recycled or destroyed.
2.7	Design and implement a system of monitoring and inspection for leakages and recovery operations to ensure compliance with the regulation.
3	Data Collection and Reporting
3.1	Establish reporting systems to ensure that the data required (see below) are collected.
3.2	Report to the Commission on: <ul style="list-style-type: none"> • proposals to authorise the production of controlled substances for essential uses prior to authorisation; • the acquisition of rights to supply controlled substances; • the results of investigations carried out at the request of the Commission; and • information on activities involving controlled substances, including their production, import, export, supply, use, storage, recycling and destruction.

3.2 Phasing Considerations

In the European Union, bans on the production and placing on the market of most ozone depleting substances are already implemented, except where they are licensed by the Commission for essential use. Since many of the requirements are also covered by the Montreal Protocol to the Vienna Convention, Candidate Countries, which have already implemented this protocol, are likely to be at least partly compliant with the regulation. However, the regulation contains stricter obligations than the Montreal Protocol and will impose new obligations, such as stricter standards and controls, different timescales for phasing out use and additional information requirements.

4 Implementation Guidance

Depletion of ozone in the upper atmosphere increases the irradiation of the earth's surface by ultra violet radiation and this has harmful effects on the biosphere. The depletion of ozone results from the liberation of substances into the atmosphere, which react with and destroy ozone. These substances are listed in the Annex to the regulation, and are referred to as 'controlled substances'.

The need to protect and restore the ozone layer led to two international agreements - The Vienna Convention for the Protection of the Ozone layer and the Montreal Protocol to this Convention which aim to limit and ultimately phase out consumption and production of all depleting substances.

Drawing upon the collective experience of Member States, a number of general observations and 'good practice' suggestions for implementing this regulation are presented below.

Administrative Arrangements and Planning

- Regulations are directly applicable in all Member States, and do not therefore need to be transposed into national legislation. However, some new legislation may be required, for example to designate competent authorities, assign enforcement powers, and establish penalties for non-compliance with the requirements of the regulation.
- This regulation falls between environmental and health and safety fields. In the Member States organisations from both fields have been nominated as competent authorities.

Examples of Practice in Member States

In one Member State (UK) the Department of the Environment, Transport and the Regions (DETR) acts as the competent authority for the control of ozone depleting substances. Under the COSHH regulations (Control of Substances Hazardous to Health), the Health and Safety Executive plays a role in enforcement. Banks for Halons and CFCs have been set up to serve as stores for recycled material required for essential purposes - such as Halons for fire extinguishers in critical uses, to reduce the need for their manufacture or import. Industry consortia are active in the management of the banks. Research has been undertaken by the government to develop non-ozone-depleting substances under contract from the DETR.

In another Member State (S) the competent authority is the national Environmental Protection Agency which reports to the Ministry of Environment. Other responsible bodies include the County Administration Boards (CABs) and the municipalities, who are involved in day to day implementation, supervision of industry and all aspects of recovery of Ozone Depleting Substances (ODS) and refrigerants.

- The regulation sets out the reductions in the production, supply, use, etc. of controlled substances, subject to exceptions for certain licensed essential uses. A control mechanism should be introduced

to ensure that these targets are met.

- Some Member States have introduced additional mechanisms to advance the phase out of ozone depleting substances, for example regulations and the use of voluntary agreements. Both types of scheme have been successful in achieving phase-out targets ahead of the EU schedule.
- The United Nations has produced a wide range of information to help countries implement the technical and policy requirements to reduce the use of ozone depleting substances.
- Member States have also produced extensive guidance for industry on alternatives for ozone depleting substances, recovery procedures and undertaking research to support the identification of non-ozone depleting alternatives.

Regulation

- The approach taken in this regulation is to phase out the use of controlled substances wherever possible. Therefore the licensing for essential uses is likely to become increasingly rare as alternatives become available.
- The information requirements of the regulation are extensive. Information is required on activities involving controlled substances, including their production, import, export, supply, use, storage, recycling and destruction. The accuracy of the information provided should be monitored by undertaking random spot checks to audit data.
- Leakages of controlled substances must be controlled, and this includes emissions of substances from household equipment, factories, and installations which recover ozone depleting substances. Leakages must be minimised by adopting precautionary measures. Operators should be monitored to ensure that the necessary measures are being taken and minimum staff requirements may be established.

Example of Practice in a Member State

The 1986 Montreal Protocol established an agreement to phase out Ozone Depleting Substances (ODS). This case study describes the route taken by one Member State (S) which became a signatory to the Protocol on 29 June 1988.

In 1986 this country's CFC consumption was about 5,300 tonnes per annum, of which around 1,500 tonnes was for the production of refrigerants. Annual emissions due to leakage from domestic and industrial equipment which used CFCs and other ODS were considered to be high, but no particular attention was focused on this area. In the early 1980s there was a significant increase in the development of heat pumps to provide heating for district and individual residences, most of which used CFCs.

Some time prior to EU membership, Sweden introduced comprehensive national legislation on the handling, usage and phasing out of ODSs, which was seen to be more stringent than the requirements of the EC legislation. The national legislation included the main national ordinance of 1995 (95/636) as amended, which was based on earlier ordinances. In accordance with EC policy, there is no national ban on the import of CFCs and HCFCs. EC regulations have prevented the production of and imports into the EU of virgin CFCs from 1 January 1995. Production and imports of HCFCs from non-EU countries are gradually being reduced and will finally be banned by 1 January 2015.

Sweden banned the use of CFC and HCFC refrigerants in new equipment from 1 January 1995 and restrictions were introduced for CFCs for recharging existing equipment from 1 January 1998. Furthermore, the use of all equipment with CFC refrigerants, except for private use, will be prohibited by 1 January 2000, even if they do not require recharge. This ban also applies to recovered CFCs and HCFCs, with the intention of encouraging the use of non ODS refrigerants.

The authorities worked extensively with industry to implement the ODS initiatives and a voluntary agreement was introduced under which suppliers are obliged to take back recovered refrigerants free of charge. Since 1997, permits have been required from the Environmental Protection Agency to export refrigerants and are only issued for destruction purposes. In 1988 the government took a policy decision to reduce the use and emissions of CFCs by 25% by 1 January 1991 and by 50% by 1 January 1993. Achievement of these targets required close co-operation with industry. The three largest trade associations formed an organisation (the national Refrigeration Foundation) the KYS, to promote higher standards in refrigeration, including those amongst the installation workers. Based on these discussions, the EPA issued a Refrigerants Order which accredited installation workers; promoted high production standards; promoted reuse of refrigerants, and promoted equipment maintenance. The accreditation system is regulated by (SWEDAC), the national accreditation body.

Reporting

- Mechanisms will need to be established for reporting to the Commission on measures to implement the regulation, including, for example, data on production, import and export of controlled substances.

5 Costs

The costs to Member States to implement this regulation are associated with:

- establishing and running the regulatory system; and
- costs to industry and the public related to the replacement of existing substances by non-ozone depleting substances in products and equipment.

The costs of regulation are likely to be incurred mainly in monitoring and enforcing compliance with the time tables for phasing out production and use of controlled substances and controlling imports and exports.

As alternatives to ODS's are becoming less costly, the compliance costs to industry and to purchasers are unlikely to be high.

The Directive on the Application of the Principles of Good Laboratory Practice

Official Title: Council Directive 87/18/EEC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 15, 17.01.87)

TAIEX Ref. No.: -

1 Summary of Main Aims and Provisions

The Directive harmonises the procedures under which specified tests are performed. All laboratory tests, which are required under Community chemicals control legislation to determine whether a chemical product presents a danger to man or the environment, must be carried out in compliance with the principles of good laboratory practice (GLP). (Tests must be carried out under Council Directive 67/548/EEC but also under other Community legislation). These principles are specified in the Annex to the Directive, which sets out the revised and updated Principles of Good Laboratory Practice of the Council of the Organisation for Economic Co-operation and Development (OECD) (which cancel and replace the original OECD Principles adopted in 1981).

Member States must set up a control system to verify that laboratories performing safety tests for the above-mentioned regulatory purposes actually carry out their tests in compliance with the principles of GLP as set out in the Annex to the Directive. Council Directive 88/320/EEC specifies the detailed standards and procedures for the inspection of laboratories and the auditing of studies. Placing on the market of chemical products tested in conformity with the principles of good laboratory practice may not be prohibited, restricted or impeded on grounds of test methodology.

2 Principal Obligations of Member States

2.1 Planning

- Appoint a competent authority for verifying compliance with the principles of good laboratory practice and notify the European Commission (Art. 3).

2.2 Regulation

- Ensure that laboratories carrying out tests on chemical products comply with the principles of good laboratory practice as specified in the Annex to the Directive (Art. 1).
- Ensure that laboratories carrying out tests on chemical products certify that the tests have been carried out in conformity with the principles of good laboratory practice (Art. 2).
- Adopt control measures (including inspections and study audits) in accordance with the recommendations of the OECD to verify that the laboratories are operating in compliance with the principles of good laboratory practice (Art. 3).

- Ensure that the placing on the market of chemical products tested in accordance with the principles of good laboratory practice is not prohibited, restricted or impeded on grounds relating to the principles of good laboratory practice (subject to an exception for the provisional prohibition or restriction of substances that present a danger to man and the environment) (Art. 5).
- Ensure that the Commission and other Member States are informed if the marketing of a chemical product is provisionally prohibited or restricted under the article 5 exception (Art. 5).

2.3 Reporting

- Report to the European Commission on:
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 6);
 - the authority responsible for verifying compliance with the principles of good laboratory practice (Art. 3); and
 - Member State decisions to provisionally prohibit or restrict the marketing of dangerous substances (Art. 5).

2.4 Additional Legal Instruments

- Council Directive 88/320/EEC on the inspection and verification of good laboratory practice.
- Council Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, which requires tests to be carried out on chemical substances in order to enable their potential risk to man and the environment to be determined. In carrying out these tests it is necessary to comply with the principles of good laboratory practice.
- Other EC legislation that provides for the application of the principles of good laboratory practice in respect of tests on chemical products to evaluate their safety for man and the environment.
- Commission Directive 99/11/EC adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC. This publishes the full text of the OECD's revised principles of GLP.
- Council Decision 89/569/EEC on the acceptance by the EEC of an OECD Decision/Recommendation on compliance with principles of good laboratory practice. This approves the OECD Decision/Recommendation and attaches the text of it.
- Commission Directive 99/12/EC adapting to technical progress for the second time the Annex to Council Directive 88/320/EEC on the inspection and verification of good laboratory practice. This attaches the full text of the revised annexes on the inspection and verification of good laboratory practice (which form part of the OECD Council Decision/Recommendation on compliance with principles of good laboratory practice).

Directive 87/18 should also be read in conjunction with Council Directive 88/320/EEC, which establishes standards and procedures for the inspection and verification of GLP Principles.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this directive are summarised in the checklist below. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

PRINCIPLES OF GOOD LABORATORY PRACTICE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority for verifying compliance with the principles of GLP.
1.2	Ensure that tests carried out by foreign laboratories in accordance with the principles of good laboratory practice are fully recognised ('national treatment').
1.3	Establish a certification system for laboratories that comply with the principles of good laboratory practice.
2	Regulation
2.1	Develop a system for the inspection and control of laboratories (in accordance with the requirements of Directive 88/320/EEC).
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none">• transposition and implementation;• the authority responsible for verifying compliance with the principles of good laboratory practice; and• decisions to provisionally prohibit or restrict the marketing of dangerous substances.

3.1 Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this directive are:

- Transposing the requirements of the directive into national legislation and policy; and
- Designation of a monitoring authority and developing of a monitoring programme.

These tasks should, therefore, be planned to commence during the initial phase of implementation.

GLP legislation should be developed and drafted in conjunction with other chemicals legislation.

4 Implementation Guidance

The directive recognises the necessity to support the mutual acceptance of test results, to avoid further testing on chemical products that have already been tested in accordance with the principles of good laboratory practice. The mutual recognition of test results is an essential condition both for the reduction of costs caused by the marketing of chemical products and for the reduction of animal experiments. The directive supplements the Community legislation regarding chemicals and chemical products. Under several directives, laboratory tests of chemicals or chemical related products are required (e.g. industrial chemicals, biocides, plant protection products, food additives, drugs, explosives). These tests must be carried out in accordance with the principles of good laboratory practice. Moreover, the directive contains the general requirement to adopt measures necessary for verification of compliance with the principles of good laboratory practice. Council Directive 88/320/EEC specifies this general obligation and lays down standards and procedures for the inspection and verification of the principles of good laboratory practice.

Implementation of the specific requirements of this directive will be influenced by the present status, needs and conditions in each Candidate Country. However, drawing upon the collective experience of the Member States, a number of general observations and 'good practice' suggestions for implementing this directive are presented below.

Planning

Examples of Practice in a Member State

In most Member States the requirement to test chemical substances and products in compliance with GLP Principles is spread over various laws. Most Member States have decided to incorporate this requirement into each product specific law rather than adopting general GLP legislation that applies to all chemicals and chemical products.

One Member State (S) has adopted the following general provision on which such regulations can be based: "The Government, or such authority as the Government may designate, may issue such prescriptions on the handling, importation and export of chemical products as are needed in consequence of (the country's) membership of the EU." Such a general authority is an appropriate tool to facilitate the implementation of EC Directives.

- Those problems that occurred have tended to involve distrust by the EU Member States of each other's regulatory authorities. This problem of distrust has been largely assuaged by the "Mutual Joint Visit Programme" of GLP review set up under the auspices of the OECD Chemicals Programme. Here, regulatory authorities of two to three countries visit their counterpart in another OECD Member State to review the GLP programme there.

Examples of Practice in a Member State

In at least one Member State (D), the party who notifies a chemical or chemical product is obliged to submit a certificate of compliance issued by the competent monitoring authority. Such a certificate proves that the laboratory that has carried out the safety tests is operated in compliance with GLP Principles.

- In addition, the OECD conducted a comprehensive survey of implementation of the OECD requirements and guidelines on GLP Principles and Mutual Acceptance of Data (MAD). This included a comprehensive questionnaire that was sent to all OECD Member States for completion and which addressed the implementation by these States (which include all EU Member States) of GLP and MAD requirements.
- It may be appropriate to entrust the competent authority that is responsible for the enforcement of chemicals control legislation with the duties required under this directive.
- Training of laboratory staff and inspectors is an important part of implementation of the Directive, which competent authorities should arrange.

Examples of Monitoring Practice in Member States

The monitoring authority of at least one Member State (A) co-operates closely with the monitoring authority in another Member State (D). Since there are only a few laboratories applying GLP Principles in the former, there was the need for inspectors to gain experience abroad.

Regulation

- The requirement to recognise tests conducted by laboratories based in other Member States in accordance with the GLP principles has not always been implemented into national law. Although the administrative practice in Member States is mostly in compliance with the recognition requirements of the Directive, these requirements must be incorporated into binding legislation.

Reporting

- The Member States should designate a person or a department, most likely within the monitoring authority, to be responsible for the contacts with the Commission, other Member States and the OECD.

5 Costs

The main expenditures caused by the implementation of Council Directive 87/18/EEC are the costs of the inspection and control system. Member States have to employ a sufficient number of inspectors to guarantee an efficient control of laboratories and test results. These inspectors must have qualifications and practical experience in the field of chemicals testing, together with a thorough understanding of both manual and electronic systems for raw data collection and storage. Regular training is necessary to ensure that the inspectors are familiar with state of the art procedures and techniques. In addition, the Member State must employ staff for the administrative tasks related to the control system (e.g. certification). Part of the costs would normally be borne by industry and the laboratories licensed to carry out tests in compliance with the principles of good laboratory practice, and part of the costs recovered through a fee for certification and for inspections.

The expenditure of industry for product testing will substantially increase, especially as a result of the need to introduce a transparent internal audit system and a raw data archive such that an external audit may be performed at a later date. However, the mutual recognition of test results will lead to a reduction of tests and, therefore, to a reduction of test costs, if a product is marketed in more than one country.

Checklist of the Types of Cost Incurred To Implement the Directive

Initial set-up costs:

- Establishment of competent authority(s);
- Development of compliance programmes;
- Provision of training;
- Design of laboratory monitoring procedures;
- Preparation of guidance.

On-going costs:

- Periodic inspections of laboratories;
- Certification and inspection fees;
- Assessment of conformity with GLP.

The Directive on the Inspection and Verification of Good Laboratory Practice

Official Title: Council Directive 88/320/EEC on the inspection and verification of good laboratory practice (GLP) (OJ L 145, 11.06.88)

TAIEX Ref. No.: -

1 Summary of Main Aims and Provisions

The Directive establishes standards and procedures for the inspection and verification of Good Laboratory Practice (GLP), the principles of which are defined in Council Directive 87/18/EEC. Member States must control all laboratories within their territory which carry out tests required under Community chemicals control legislation to assess their effects on man, animals and the environment. (However, the Directive is not concerned with the interpretation and evaluation of test results). The control measures are to include the inspection of the laboratory and the auditing of tests carried out by the laboratory. The Annex to the Directive lays down detailed guidelines for the inspection and verification of good laboratory practice, extracted from the relevant parts of the revised Decision on compliance with principles of good laboratory practice, of the Council of the Organisation for Economic Co-operation and Development (OECD). Member States must apply rules on the protection of commercially sensitive and other confidential information to which inspectors have access during inspections. Inspections and audits carried out in other Member States must be recognised.

2 Principal Obligations of Member States

2.1 Planning

- Designate competent authorities for inspection and verification (Art. 3).
- Ensure that the competent authorities inspect laboratories and audit studies in accordance with the provisions laid down in the Annex (Art. 3).

2.2 Regulation

- Grant laboratories the right to use a specified formula confirming compliance with the Directive's requirements, if the results of an inspection and verification are satisfactory (Art. 2).
- Ensure that commercially sensitive and other confidential information to which inspectors have access as a result of the inspection is protected in accordance with the rules laid down in the Directive (Art. 4).
- Ensure that results of laboratory inspections and study audits on GLP compliance carried out by another Member State are recognised (Art. 5).
- Ensure that laboratories claiming to use GLP are inspected and that their compliance with GLP is verified in accordance with the provisions laid down in the annex to the Directive (Art. 2).

2.3 Reporting

Report to the Commission on:

- the implementation of GLP, including a list of inspected laboratories, annually (Art. 4);
- any laboratory that claims to, but does not, comply with GLP (Art. 5);
- the results of consultations with another Member State over claims that a laboratory in the other Member State has not carried out a test in accordance with GLP (Art. 6);
- transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 9).

2.4 Additional Legal Instruments

- Council Directive 87/18/EEC on the application of the principles of good laboratory practice.
- Commission Directive 99/12/EC adapting to technical progress for the second time the Annex to Council Directive 88/320/EEC on the inspection and verification of good laboratory practice. This attaches the relevant extracts of the revised OECD Decision/Recommendation on compliance with principles of good laboratory practice.

3 Implementation

3.1 Key Tasks

The key tasks involved in implementing this directive are summarised in the checklist below. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

DIRECTIVE ON THE INSPECTION AND VERIFICATION OF GOOD LABORATORY PRACTICE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to carry out inspections and verify compliance with GLP.
2	Regulation
2.1	Identify laboratories claiming compliance with GLP and ensure that their compliance is verified..
2.2	Design and implement a procedure for inspecting laboratories.
2.3	Establish procedures for enabling laboratories to formally claim compliance with GLP and for allowing appeals against decisions resulting from an inspection. Develop procedures for the protection of confidential information.
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none">• transposition and implementation;• implementation of GLP, attaching a list of laboratories inspected;• instances where a laboratory claiming GLP compliance does not in fact comply;• instances where a laboratory in another Member State claiming GLP compliance has not carried out a test according to GLP.

3.2 Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this directive are:

- Transposing the requirements of the directive into national legislation and policy; and
- Designation of a monitoring authority and developing of a monitoring programme.

These tasks should, therefore, be planned to commence during the initial phase of implementation.

GLP legislation should be developed and drafted in conjunction with other chemicals and product-specific legislation (e.g. industrial chemicals, biocides, plant protection products, food additives, drugs, explosives, and cosmetics).

4 Implementation Guidance

Following Council Directive 87/18/EEC, which lays down a general obligation to set up a control system for laboratories applying GLP, this directive lays down specific requirements for such a control system. The relevant parts of the OECD Guidelines on compliance with principles of GLP are incorporated into the annex to the directive. The directive creates a legal framework to ensure that chemicals tests which are carried out in different Member States to the same standards of GLP are recognised on a mutual basis by other Member States. By incorporating the OECD Guidelines into Community Law, the directive guarantees that tests carried out in the Community in accordance with GLP principles are also recognised in other OECD member countries.

The present status, needs and conditions concerning GLP in Candidate Countries will influence implementation of the specific requirements of this directive. However, drawing upon the collective experience of the Member States, a number of general observations and ‘good practice’ suggestions for implementing this directive are presented below.

Planning

- Those problems that occurred in implementing this directive have tended to involve distrust by the EU Member States of each other’s regulatory authorities. This problem of distrust has been largely assuaged by the “Mutual Joint Visit Programme” of GLP review set up under the auspices of the OECD Chemicals Programme. Here, regulatory authorities from two to three countries visit their counterpart in another OECD Member State to review the GLP programme there.
- In addition, the OECD conducted a comprehensive survey of implementation of the OECD requirements and guidelines on GLP Principles and Mutual Acceptance of Data (MAD). This included a comprehensive questionnaire which was sent to all OECD Member States for completion and which addressed the implementation by these Member States (which include all EU Member States) of GLP and MAD requirements.
- Laboratories applying GLP must be identified and a programme for inspecting them and verifying their compliance with GLP principles (including carrying out study audits) must be developed and implemented. The number of inspectors required will depend upon the number of laboratories involved and the frequency of inspections.

Example of Monitoring Authorities in a Member State

One Member State (D) has, due to its federal system, established 16 different monitoring authorities each responsible for one of the federal states (Bundesländer). In addition to these 16 monitoring authorities, a Federal GLP Bureau was created which is responsible for the international contacts and the co-ordination between the 16 monitoring authorities.

Regulation

- Setting up a laboratory monitoring system is a key task for ensuring GLP compliance. Inspectors must be trained to carry out inspections in accordance with the guidelines set out in the Annex. For example, inspectors should establish contact with the laboratory's internal quality assurance unit and should follow set procedures in carrying out inspections.

Example of Practice in a Member State

In one Member State (S), GLP Principles were introduced in 1979 (even before the OECD Decision on GLP was issued), as a tool for evaluating the integrity of non-clinical safety data. Two monitoring authorities operate in the Member State. The Medicinal Products Agency (MPA) has the exclusive responsibility for the control and monitoring of medicines, veterinary medicines, cosmetic and hygienic products. The responsibility for all other chemicals for which GLP is required (industrial chemicals, pesticides) is the responsibility of the national Board of Accreditation and Conformity (SWEDAC). The main disadvantage of having two monitoring authorities, SWEDAC and MPA, is the cost factor. The operation of two different monitoring authorities is likely to be more expensive and less efficient than having only one body responsible for all laboratories applying GLP for all products tested.

The power to issue implementing regulations regarding the requirements for safety data submitted to the authorities is also allocated between SWEDAC and MPA. MPA has been delegated the competence to adopt regulations with respect to testing of pharmaceuticals, and cosmetic/hygienic products, whereas the National Chemicals Inspectorate is responsible for regulations on testing requirements for industrial chemicals and pesticides. As a result of this division of competence, a large number of regulations, each applicable for specific products, deal with GLP.

Although both authorities run their own GLP Compliance Programme, the organisation of the programmes and the procedures are identical. A test facility enters the Monitoring Programme automatically when safety data generated by it have been submitted to the authorities as part of a registration or licensing procedure for a product for which testing in compliance with GLP is required. Then, the monitoring authority (MPA or SWEDAC) includes the laboratory in the programme and prepares an initial inspection of the facilities. Two weeks before the actual site visit, the monitoring authority informs the laboratory about its intention and requests general information on the facilities. After the initial inspection, the laboratory will be inspected approximately every two years.

- Member States must determine under which conditions a laboratory enters the national monitoring programme and how often inspections will take place. Laboratory inspections will generally include study audits, which review ongoing or completed studies, but specific study audits are also likely to be requested by regulatory authorities and can be conducted independently of laboratory inspections.

Example of Practice in a Member State

In one Member State (NL) also a laboratory which is not a member of the monitoring programme can submit safety tests for regulatory purposes. These tests are not immediately refused, even though the receiving authority does not have any guarantee that the laboratory is actually operated in compliance with GLP Principles. The receiving authority then directly asks the monitoring authority to inspect the laboratory. If the inspections prove that the laboratory is operated in compliance with GLP Principles, it will be included in the monitoring programme.

Reporting

- Various documents will need to be published relating to the adoption of GLP principles but also providing details of the national GLP compliance programme, including information on the legal and administrative framework within which the programme operates and references to published acts, normative documents (e.g. regulations, codes of practice).
- It would be advisable to designate a person or a department, most likely within the monitoring authority, which is responsible for maintaining contacts with the Commission, other Member States and the OECD, compiling data, and submitting reports as required (e.g. reports to the Commission on implementation).

5 Costs

The implementation of Directive 88/320/EEC mainly generates costs for the competent authorities of the EU Member States. They are obliged to set up a team of inspectors having the necessary technical/scientific expertise and experience. Further administrative costs are caused by the obligation to publish documents informing industry and interested third parties on the national GLP compliance programme and to maintain detailed records of the laboratories inspected. Part of the costs would normally be borne by the industry and the laboratories licensed to carry out tests in compliance with GLP. A fee for the right to use the compliance formula could also be levied to help to meet the costs to the authorities of carrying out inspections.

The expenditure of industry for product testing will substantially increase, especially as a result of the need to introduce a transparent internal audit system and a raw data archive such that an external audit may be performed at a later date. However, the mutual recognition of these tests leads to a reduction in the number of required tests and, therefore, to a reduction of costs, if a tested product is marketed in more than one country.

Checklist of the Types of Cost Incurred To Implement the Directive

Initial set-up costs:

- Establishment of competent authority (ies);
- Development of compliance programmes;
- Provision of training to inspectors;
- Design of laboratory monitoring procedures;
- Preparation of associated literature for technical and non-technical audiences.

On-going costs:

- Periodic inspections of laboratories;
- Collection and reporting of data;
- Assessment of conformity with GLP.