ENVIRONMENTAL IMPACT ASSESSMENT IN THE PHARMACEUTICAL INDUSTRY

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Abstract

Environmental Impact Assessment in the Pharmaceutical Industry

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Environmental Impact Assessment is a process for identifying the likely effects that a proposed development will have on the environment and mans health and welfare. The process was first introduced in the United States under the National Environmental Policy Act of 1969 which introduced legislation to protect the environment.

The European Community set out in its second environment programme a requirement for the assessment of the effect of development projects on the environment and a Directive was approved in 1985 for this purpose. Member States were allowed 3 years to implement the Directive but the Irish Government did not introduce any new legislation for the purpose of implementing the Directive until the European Communities (Environmental Impact Assessment) Regulations 1989 were introduced. In the case of the pharmaceutical industry, the regulations required that an Environmental Impact Assessment be performed for all development projects prior to development consent being granted. Since 1988 twenty-eight Environmental Impact Statements have been submitted to the competent authorities covering developments in the pharmaceutical sector. Practically all of the EISs were prepared by consultants on behalf of the developer with 21 of these prepared by Eolas. Analysis of the EISs show that they comply well with the requirements of the regulations although a number of them are considered too long for public consideration of their contents. In general, the EISs stated that the developments would have little impact on the environment either due to the scale of the development or because of mitigating measures designed to eliminate any possible adverse impacts.

The European Commission has assessed how Member States have implemented the Directive and plans to introduce an amendment to Directive 85/337/EEC which will introduce more formal scoping into the process.

With the establishment of the Environmental Protection Agency and its role in the area of integrated pollution control licensing, there will be greater control over the pharmaceutical industry. The publication of guidelines by the agency for the preparation of EISs and its central role in the scoping process will lead to an improvement in the quality of EISs in the pharmaceutical sector.

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Chapter 1

Background to Environmental Impact Assessment

1.1 Introduction

For a number of years there has been growing public concern on the interactions between development and the subsequent environmental consequences. This has led to the situation in developed countries that environmental factors are taken into account in the decision-making process. Early types of project assessment included Technical Feasibility Studies and Cost Benefit Analysis (CBA). With CBA there was a problem in that an attempt was made to express the impact in monetary terms. These problems with placing monetary values on environmental intangibles led to the development of a new evaluation approach that was to become known as Environmental Impact Assessment (EIA). This new process was seen by environmental groups as a useful source of information to fight their cause and it is also seen by developers as an important management tool.

Originally the EIA process was conceived as an additional component of the Cost Benefit Analysis process. Table 1 outlines the evolution of the EIA process from pre-1970 to the present day.

1.2 Environmental Impact Assessment - Definition

Munn's (1979) definition of EIA can be paraphrased as being a process for identifying the likely consequences for the biogeophysical environment and for mans health and welfare that could result from a proposed development. The process also includes an onus on the developer to convey this information to those responsible for sanctioning the decision at a stage where the information can be used to influence their decision. The ultimate aim of the

EIA process is to provide decision makers with an indication of the consequences of their decision.

Table 1. Developments in EIA procedures. Based on Sadler (1988)

DATE	DEVELOPMENT IN PROCEDURES
PRE 1970	Analytical techniques largely confined to economic and engineering feasibility studies; narrow emphasis on efficiency criteria and safety of life and property; no real opportunity for public review.
circa 1970	Multiple objective benefit-cost analysis; emphasis on systematic accounting of gains and losses and their distribution; reinforced through planning, programming and budgeting review; environmental and social consequences not incorporated
1970-1975	Environmental impact assessment (EIA), primarily focused on description and prediction of ecological/land use change; formal opportunity for public scrutiny and review established; emphasis on accountability and control of project design and mitigation.
1975-1980	Multi dimensional (EIA), incorporating social impact assessment of changes in community infrastructure, services and lifestyle; public participation becomes integral part of project planning; increased emphasis on project justification in review process; risk analysis of hazardous facilities and unproven technology.
1980-present	Attention given to establishing better linkages between impact assessment and policy-planning and implementation-management phases; research focus on effects monitoring, post project audit and process evaluation; search for more disciplined scoping and focusing procedures and less protected forms of consultation based on negotiation and mediation.

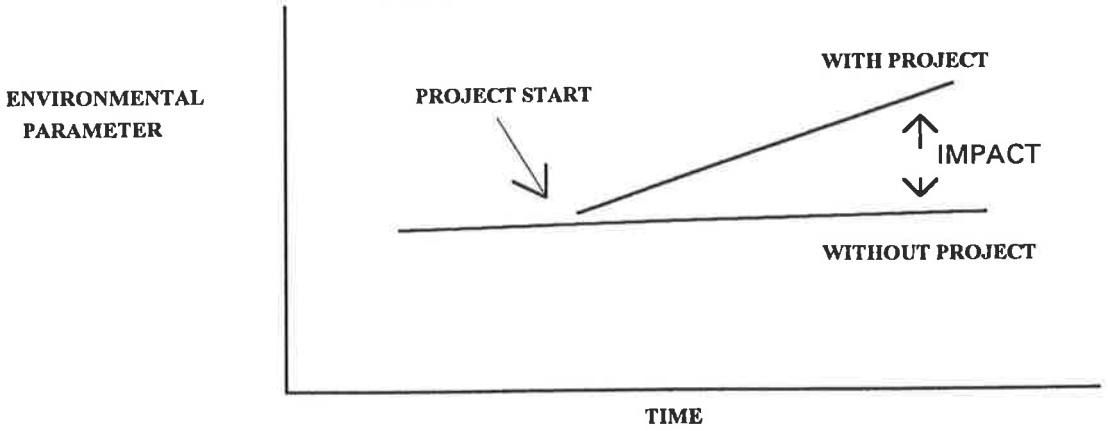
1.3 Environmental Impact Statement

The outcome of an EIA results in the publication of a formal document that contains a discussion of the beneficial and adverse impacts considered to be relevant to the proposed project. The usual term for this report is 'Environmental Impact Statement'(usually abbreviated to EIS).

1.4 Environmental Impact

The terms 'impact' and 'effect' are both used to define the consequences of a development. An impact can have both temporal and spatial components and can be described as the change in an environmental parameter, over a specified period and within a defined area, resulting from a particular activity compared with the situation that would have occurred had the activity not been initiated. The consequences of an impact can be represented graphically as in figure 1.

FIGURE 1. IMPACT DIAGRAM



Impacts can be further broken down into those which are direct (primary) and those which are indirect (secondary or higher order). Examples of the different types of impact are shown in table 2 for the action of a company discharging cooling water to a river.

Table 2: Types of impact

ACTION	IMPACT	TYPE OF IMPACT
Discharge Of Cooling Water To River	Water Temperature Increases	Primary First Order Direct
	Dissolved Oxygen Level Falls	Second Order Indirect
	Reduction In Fish Stock Levels	Third Order Indirect
	Loss Of Earning For Fishermen	Fourth Order Indirect

1.5 Eia Process

EIA is a procedure to provide information about the potential impact on the environment of a proposed development.

EIA can:

- Consider alternative to the project.
- Consider policy and resource issues.
- Consider mechanisms of reducing impacts and related costs.
- Provide a mechanism for all interested parties to be consulted.

- Provide a framework within which agreement may be reached between the developers causing the impacts and those affected by them.

EIA is a management tool providing information to those responsible for decision making.

It should:

- Enable government agencies, planners, developers and affected groups understand the implication of a development and help them make an informed decision.
- Provide details of the important impacts.
- The significance of these impacts.
- Mitigating measures available to counteract adverse impacts.

The main stages in the environmental impact assessment process as it has been adopted in many countries are shown in Figure 2 . Although there may be variation in the detailed procedure adopted within a particular country, most countries adopt a pattern similar to that shown in the diagram.

The steps are:

1.5.1 Screening

This is the process used to decide the types of development that should be subject to full environmental impact assessment. The type of criteria used include the type of project, size of project and the sensitivity of the local environment.

1.5.2 Scoping

This defines the key issues that should be included in the environmental impact assessment. The purpose of scoping is to focus on the key issues that can be included in the process from the beginning.

1.5.3 EIA Preparation

This is the scientific and objective analysis of the scale, significance and importance of the impacts that have been identified.

1.5.4 Review

The project developer is usually responsible for the preparation of the environmental impact assessment and it is usual that a review of the data gathered is undertaken by a government agency. The review panel guides the study and assesses the prepared environmental impact statement.

1.5.5 Monitoring

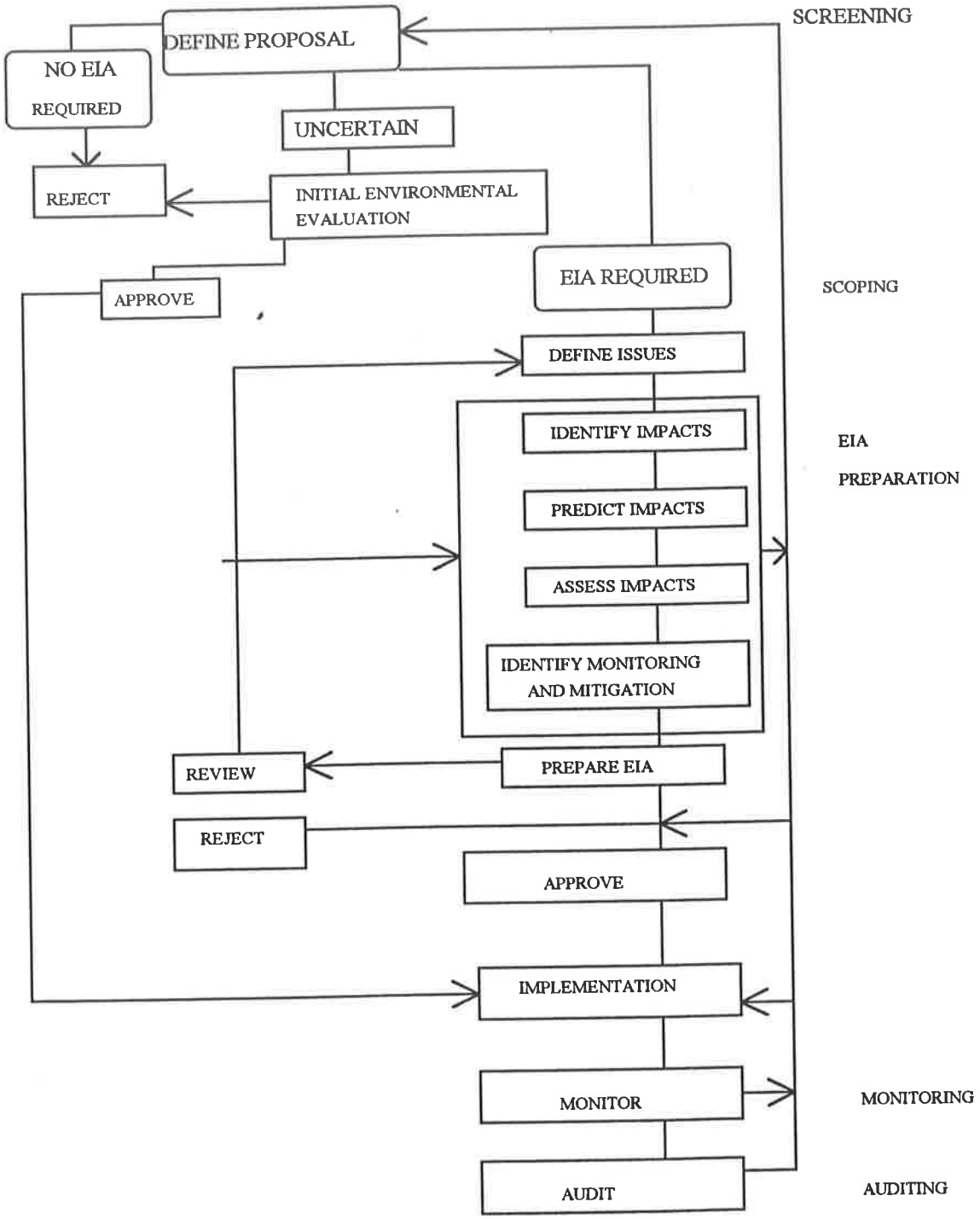
The key issues identified during the assessment will need to be monitored through the lifetime of the project to ensure that the project is conforming with the predictions made in the assessment. Monitoring also ensures that any conditions imposed on the project are being enforced and that there are no adverse effects on the environment.

1.5.6 Auditing

This is now being developed to test the scientific accuracy of impact predictions and as a check on environmental management practices.

Figure 2

Environmental Assessment Process. Source:Wathern (1985)



1.6 Baseline studies

It is necessary to perform baseline measurements of environmental parameter before the proposed development commences operations. This is necessary to show that a proposed development will not have any impact on the environment or that mitigating measures taken will prevent an impact. Specific information and data on various environmental parameters is collected so the degree of any change is known. The baseline study is an important part of an EIA process because any monitoring carried out after the project commences must be compared to the situation that existed before the development commenced.

Chapter 2

Environmental Impact Assessment in the United States.

2.1 Origins of EIA

Until 1970, serious consideration was not given to the potential Environmental impacts of Federal projects. Cost Benefit Analysis was usually carried out to ensure public funds were spent wisely. There was in some cases a form of technical assessment of the project but the term Environmental Impact Assessment was not in use. There had been a type of Environmental assessment carried out as early as the late 1930's when, for example, a study was carried out on the environmental and social effects of the Grand Coulee Dam on the Columbia river in Washington.

2.2 National Environmental Policy Act

In the late 1960's there was growing public concern over the increased incidence of environmental incidents and this led to Environmental Impact Assessment being given national attention. The federal Government controls approximately one third of the land in the United States and this led to the U.S. congress enacting legislation in recognition of the need for care in the use of the country's national resources. This legislation: the National Environmental Policy Act of 1969 (referred to as NEPA) was signed into law by the late President Richard Nixon on the 1 January 1970. The enactment of NEPA sought to reverse 'a clear and intensifying trend towards environmental degradation' and 'to remedy the lack of environmental awareness of many federal agencies whose policies were in conflict with the general public interest'. Its main function was to hold the federal government responsible for the American environment (Holland 1985).

2.3 Purpose of NEPA

The purpose of the act was to:

- Declare a national policy that would encourage productive and enjoyable harmony between man and his environment.
- To promote efforts that would prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man.
- To enrich the understanding of the ecological systems and natural resources important to the nation.
- To establish a Council on Environmental Quality.

Section 102(2)(c) of the NEPA is one of the most important sections of the act in that it requires the preparation of an Environmental Impact statement (EIS) for major federal actions significantly affecting the quality of the human environment. The points to be addressed in an EIS are shown In Table 3.

Table 3. Requirement of an EIS under NEPA

1	The probable environmental impact of the proposed action.
2	Any adverse environmental effects that cannot be avoided if the proposal is implemented
3	Alternatives to the proposed action.
4	The relationship between local short term use of Man's environment and the maintenance and enhancement of long-term productivity.
5	Any irreversible and irretrievable commitment of resources required by the proposal.

2.4 Council On Environmental Quality.

The council on Environmental Quality issued guidelines to Federal agencies in 1973 that outlined the procedure for:

- The preparation of environmental impact statements.
- The concept of a draft Environmental statement.
- The minimum 45 day review and comment period before release of a final EIS
- The waiting period before an action could begin.

Up to 1977 a number of problems emerged in relation to prepared EIS's. President Carter in his first Environmental message addressed these problems by speaking of NEPA as follows:

> " In the seven years since its passage, it has had a dramatic and beneficial influence on the way projects are planned. But to be more useful to decision- makers and the public, environmental impact statements must be concise, readable and based on competent professional analysis. They must reflect a concern with quality not quantity. We do not want impact statements that are measured by the inch or measured by the pound."

As a result the President gave the Council on Environmental quality a directive to reform the act with the purpose of:

- Reducing paperwork.
- Reducing delay.
- To see that the process resulted in better, more environmentally sensitive decisions.

The council on environmental quality issued its final regulations on 28 November 1978 and the changes introduced by the new regulations were as follows:

- The length of Environmental impact statements should not exceed 150 pages except in the case of complex proposals where the length should not exceed 300 pages.
- A requirement for scoping was introduced which would determine the proper content of the statement. This process would allow for the decision-

making authority to join with other interested parties, including potential proponents and opponents to the proposal, to ensure that the major issues were identified and irrelevant ones dismissed.

- Alternatives to the proposed project should be identified. The 1978 regulations described the alternative section as 'the heart of the environmental impact statement'.

The requirements under the 1978 regulations are summarised in Table 4.

Table 4

Content required for an EIS under 1978 regulations

Summary

Statement of purpose and need.

Alternatives including proposed action.
- Discussion of all options considered.
- Discussion of no action option.
- Identification of agency preferred option.
- Discussion of mitigation measures.

Affected environment.
- Baseline environmental description of each area affected by each alternative.

Environmental consequences.
- Environmental impact of each alternative.
- Unavoidable effects.
- Relationship between Local short term use of environment and enhancement of long term productivity.
- Irreversible and irretrievable commitment of resources.

List of preparers.

2.5 Litigation and NEPA.

In the United States, recourse to law has often been the first rather than the last resort and this has resulted in a large amount of litigation concerning the implementation of NEPA. Kennedy (1984) quotes a total of 1602 NEPA related lawsuits (almost 10 % of the total number of federal project for which EIS's had been prepared). This represented a one in ten chance that a particular EIS would be challenged in the courts. Canter (1984) reported that almost 40 % of lawsuits were filed by environmental groups. The fear of litigation resulted in the quality of EISs improving as the courts have clearly shown that NEPA is a full disclosure law that places a responsibility to investigate fully and to reveal the likely consequences of their actions.

2.6 Quality of EIS's.

There have been few investigations of the quality of Environmental Impact Statements submitted. However the Environmental Protection Agency has rated both draft and final EISs submitted to it and between 1975 and 1982 91% of all final EIS's were rated to be in the top two categories. Kennedy (1984) reported that over the same period, the percentage of draft EISs that were in the top two categories rose from 59 % to 76 %.

Chapter 3

European Community Directive

3.1 Background

European environmental policy has been affirmed in general terms in the Communities Environmental Action programmes that have been adopted since 1973. A preventive policy was mentioned in the 1973 action programme, but the first reference to Environmental Impact Assessment was in the Second Action Programme(Council of European Communities 1977).

The communities Action Programmes are basically a statement of intent.

The various legislative means to convert this intent into specific provisions are:

- Regulations - most effective and directly applicable in member states
- Directives - specify binding policy objectives but the means of achieving the objectives are left to the individual member states
- Decisions - binding only on those specified
- Recommendations - carry no mandatory obligations

In the area of environmental policy the primary method of legislation has been the directive. Draft directives are generally formulated by European civil servants based on community statements and research. In the case of the directive on Environmental Impact Assessment over 5 years elapsed between the commissioning of a research project on EIA in 1975 and the publication of a draft directive in 1980. During this period there were more than 21 versions of the directive. There was also a period of 5 years between the publishing of the first draft directive and the adoption of the final draft into community law by the Council of Ministers in 1985. During the period 1980 to 1985 there were a series of changes made to the proposed directive under pressure from various governments and as such the final directive should be seen as a compromise document.

3.2 Directive

The directive as approved by the Environment Council in March 1985 was formally issued on June 27 1985 as Directive 85/337/EEC titled: *On the assessment of the effects of certain public and private projects on the environment* in the *Official Journal* No. 175 of July 5, 1985. It was felt that the directive was a complex piece of legislation and as such Member States were given three years to implement the directive. The directive consists of 14 Articles (appendix 1), some of which are purely procedural, and three Annexes.

Article 1 defines the terms and scope of the Directive and is worded to include a wide range of projects. The term developer includes both public authorities and private developers. Article 1 excludes national defence projects.

The spirit of the directive is contained in Article 2(1):

> Member States shall adopt all measures necessary to ensure that, before consent is given, projects likely to have significant effect on the environment by virtue *inter aliae* of their nature, size or location are made subject to an assessment with regard to their effects.

Article 2(3) indicates the procedure for exemption of projects where in certain cases a Member State may exempt projects from all or part of the requirements of the Directive.

Article 3 of the Directive defines the scope of the assessment process. The potential scope of an assessment is broad in that the Article refers to:

> The direct and indirect effects of a project
> on the following factors:
>
> - human beings, fauna and flora,
> - soil, water, air, climate and the landscape,
> - the interaction between the factors mentioned in the first and second indents,
> -material assets and the cultural heritage.

A detailed list of the information that may be required is provided in Annex III

of the directive and this includes descriptions of the site, project and planning context. It also includes a description of aspects of the environment likely to be significantly affected by the development and a description of the impacts. Detailed proposals to minimise these impacts should also be included. There is also a requirement for a non-technical summary of all information provided.

Article 4 and the two Annexes referred to in it define the types of project that will be subject to the directive. Projects in Annex I are subject to the full requirement of the directive. The projects listed in Annex I are major industrial projects and national infrastructure projects such as major roads and airports. These types of projects would normally have been subject to very rigorous planning control in any case. The list of projects in Annex II is much longer but was compiled with the intention that they would be subject to assessment only where 'Member States consider that their characteristics so require'. This allowed the Member States the discretion what projects, and under what conditions they would require an EIA.

Article 5 details the type of information to be supplied by the developer as follows:

- a description of the project comprising information on the site, design and size of the project,
- a description of the measures envisaged in order to avoid, reduce and, if possible remedy significant adverse effects,
- the data required to identify and assess the main effects which the project is likely to have on the environment,
- a non-technical summary of the information mentioned in indents 1 to 3.

Member States should also ensure that any authorities with relevant information, may make this information available to the developer.

Article 6 of the directive allows that the public will be informed of a request for approval by a developer. The public concerned must also be allowed an opportunity to express an opinion prior to the project commencing. The Article allows the Member State scope in how the detailed arrangements for public consultation are decided but the requirements include:

- determine the public concerned
- specify places where information can be consulted
- specify how the public may be informed
- determine the manner in which the public shall be consulted
- fix appropriate time limits for stages in the procedure.

Article 7 concerns the requirement to consult with other Member States if the project is likely to effect the environment in that Member State.

Article 8 requires that any information gathered shall be taken into account in the development consent procedure.

Article 9 requires that the Member States shall make arrangements to inform the public concerned about the contents of any decision and of any conditions attached.

Article 10 allows for Member States to have regard to commercial secrecy and the safeguarding of the public interest.

Article 11 requires Member States to inform the Commission of any criteria and/or thresholds adopted in relation to Annex II projects. The Member States and the Commission are also required to exchange information on experience gained in applying the directive.

Article 12 of the Directive allows the Member States 3 years to comply with the requirements of the Directive and the texts of national law adopted should be communicated to the commission.

Article 13 gives Member States the right to apply stricter provisions for the assessment procedure.

Chapter 4

Implementation of the Directive in Ireland

4.1 Assessment in Ireland - pre 1988

It was felt that the planning and development acts in force in 1988 adequately addressed the assessment of the environmental impact of development projects (Archer 1990). The 1963 Planning and Development Act of 1963 set out a framework for a form of Environmental Impact Assessment in that it included phrases such as:

> 'to make provision for the common good'
>
> 'shall be restricted to considering the proper planning and development of the area ... including the preservation and improvement of the amenities thereof'

There was also provision under section 26 of the Act to impose conditions on developments prior to approval being given. Given that the act also required that the proposal be described both verbally and graphically and that permission could be refused on grounds such as lack of adequate services, indicates that the 1963 Act made some provision for a form of Environmental Impact Assessment.

The 1976 Planning Act further strengthened the planning assessment process in that it transferred the appeal function to An Bord Pleanala.

4.2 Implementation

The Irish Government, although fully aware of the requirement to implement the Directive before 1 July 1988, and having 3 years to do so, did not enact any new legislation before the required date.

On the 1 July 1988 the Minister for the Environment issued a circular letter (PD/111/8/20) to all local authorities and government departments.

This circular letter entitled 'The EC Directive on Environmental Impact Assessment' set out to explain the Directive and the arrangement for giving effect to it. It was the Ministers intention that the circular letter would be sufficient to incorporate the Directive into Irish law. The fact that this circular letter did not give effect to the Directive in Irish law was clarified by the judgement of Mr. Justice Barron in the case of *Browne v An Bord Pleanala* which stated:

> 'Unless the principles of the Directive are already incorporated in the domestic law of the Member State, they do not have the force of law in the Member State unless they have been made legally binding by a domestic legislative process'

The above case referred to the proposed development of a pharmaceutical Manufacturing facility in Co. Cork by the American company Merrell Dow. The application was accompanied by an EIS that had been prepared by Eolas to satisfy the requirements of the European Community Directive (although the Directive was not in force at the time) and was submitted to Cork County Council in July 1988. A decision to grant planning permission was approved by the council, but this was appealed by objectors to the development to An Bord Pleanala who upheld the decision of the local authority to grant permission. The matter was appealed to the High Court on the grounds that the application did not meet the requirement of the Directive, but the High Court upheld the decision of An Bord Pleanala to grant permission.

The main findings of the decision were:

1. Directives can not be made law by circular letter.
2. The circular letter (PD/111/8/20) did not have the force of law.
3. The Directive was binding on Ireland.
4. If the Directive had been in force in Ireland at the time of the application, the application by Merrell Dow and the decision of both the local authority

and An Bord Pleanala would have complied with the provisions of the Directive.

After the unsuccessful attempt to introduce the Directive by circular letter, it was brought fully into operation by a total of 12 statutory regulations over the period 1988 to 1990. EIA was integrated into existing decision making procedures, notably the development control procedures established under the local government (Planning and Development) Act 1963.

The most important Regulations implementing the directive were the European Communities (Environmental Impact Assessment) Regulations 1989 and the Local Government (Planning and Development) Regulations 1990.

4.3 European Communities (Environmental Impact Assessment) Regulations 1989

The European Communities (Environmental Impact Assessment) Regulations 1989 requires EIA to be carried out for all projects as listed in the Directive except motor ways which were covered under specific regulations.

Initially there was a problem in relation to developments such as the proposed Merrell Dow facility in that it was not clear whether such a facility was to be regarded as an Annex I project: i.e. 'an integrated chemical facility' or an Annex II project. Although the court (Browne v An Bord Pleanala) did not rule on this issue, the 1989 regulation clearly stated that 'all installations for the production of pesticides and pharmaceutical products' and 'all installations for the production of chemicals' are subject to the EIA process. Whereas in the original Directive, the criterion for selecting an Annex II project was 'a likelihood that the project will have significant effects on the environment by virtue, *inter alia*, of its nature, size and location'; in the 1989 Regulations a large number of Annex II projects are, irrespective of their size or location, automatically

subject to mandatory EIA. Other projects have had criteria/thresholds set by the Minister for the Environment based on their size/ production capacity. Even if an Annex II project does not exceed the threshold/criteria, competent authorities have the discretion to require an EIA where they consider the development would be likely to have significant effect on the environment.

A comparison of the outline contents of the European Directive(85/337/EEC) and the 1989/90 regulation is given in table 5 below.

Table 5 Comparison of EEC Directive and Irish Regulations

EC Directive	**1989/1990 Irish Regulations**
Articles 1 to 14	Articles 1 to 26 (1989 regulations) Articles 1 to 48 (1990 regulations)
procedures relating to EIA	procedures relating to EIA
A Projects requiring an EIA	
Article 4(1) and Annex I EIA required	Article 24 and first Schedule Part I of 1989 Regulations(EIA required)
Article 4(2) and Annex II EIA may be required	Article 24 and first Schedule Part II of 1989 Regulations(EIA required)
B Information to be contained in EIS	
Article 5(1), 5(2) and Annex III	Article 25 and second schedule of 1989 regulations Information which 'shall' be included part 2 Information which 'may' be included part 3
C Use by the Competent Authority of EIA in decision making.	
Article 9	Article 8 of the 1989 Regulations

(Based on Meehan 1991)

4.4 Information required in an EIS

Article 5 (1) of the European Community Directive specifies that the developer should include the information specified in Annex III insofar as it is relevant and reasonable to do so. Article 5(2) goes on to specify the minimum that should be provided in any case.

The second schedule of the 1989 Regulations specifies the information to be contained in an EIS and relates this to Annex III of the European Community Directive. There is a distinction made between information that shall be included(which is based on Article 5(2) and parts of Article 3) and information that may be included (which is based on Annex III). Both lists are shown in table 6 and table 7.

Table 6 specified information **required** for an EIS

The **Specified Information** is:

(a) a description of the development proposed, comprising information about the size and the design and size or scale of the development;

(b) the data necessary to identify and assess the main effects which the development is likely to have on the environment;

(c) a description of the likely significant effects, direct and indirect, on the environment of the development, explained by reference to its possible impact on:

- human beings,
- flora,
- fauna,
- soil,
- water,
- air,
- climate,
- the landscape,
- the interaction between any of the foregoing,
- material assets,
- the cultural heritage.

(d) where significant adverse effects are identified with respect to any of the foregoing, a description of the measures envisaged in order to avoid, reduce or remedy those effects;

(e) a summary in non technical language of the information specified above

Table 7 Information that **may** be contained in an EIS

An Environmental impact Statement may include by way of explanation or amplification of any specified information, **further information** on any of the following matters:

(a) the physical characteristics of the proposed development, and the land use requirements during the construction and operational phases;
(b) the main characteristics of the production processes proposed, including the nature and quantity of the material to be used;
(c) the estimated type and quantity of expected residues and emissions (including pollutants of surface water and groundwater, air, soil and substrata, noise, vibration, light, heat and radiation) resulting from the proposed development when in operation;
(d) (in outline) the main alternatives(if any) studied by the applicant, appellant or authority and an indication of the main reasons for choosing the development proposed, taking into account the environmental effects;
(e) the likely significant direct and indirect effect on the environment of the development proposed which may result from-
    (i) the use of natural resources;
    (ii) the emission of pollutants, the creation of nuisance and the elimination of waste;
(f) the forecasting methods used to assess any effects on the environment about which information is given under subparagraph(e); and
(g) any difficulties, such as technical deficiencies or lack of knowledge, encountered in compiling any specified information.

In paragraph(e) 'effects' include secondary, cumulative, short, medium, long-term, permanent, temporary, positive and negative effects.

Where further information is included in an Environmental Impact Statement pursuant to paragraph 3, a non-technical summary of that information shall also be included.

Chapter 5
Proposed Amendment to Directive 85/337/EEC

5.1 Introduction

The European Commission prepared a document in 1993 (COM (93) 28 vol. 13 final) which assessed how various Member States had implemented the Directive. It was felt by the Commission that Ireland had implemented the Directive fully into Irish legislation and had included most Annex II projects as necessitating an EIS.

5.2.1 Criteria/ Thresholds

Where criteria or thresholds had been applied in the Irish legislation, the Commission felt that these were relatively strict. The Commission noted that there was some confusion in relation to projects not listed in the Irish Regulations and it was confirmed by the Department of the Environment that projects not listed cannot legally be subjected to the EIS requirement.

5.2.2 Monitoring

The Commission felt that there were no formal measures in place to monitor the implementation of the Directive in Ireland and that no single authority had to be informed of all EISs submitted.

5.2.3 Scoping

The Commission felt that the Irish regulations lacked a formal scoping procedure although it was felt that consultation on scoping generally did take

place between the applicant and the competent authority. The Commission felt that there was some confusion as what information should be included in an EIS.

5.2.4 Quality of EISs

The Commission felt that there was no definitive data on the quality of the submitted EISs. The Commission felt that the quality varied considerably and that there was a need for a comprehensive examination of this area.

5.2.5 Review

The Commission highlighted the fact that there was no formal review system provided for in the Irish Regulations. The Commission acknowledged that a process of notification had been established in that the Environmental Research Unit of the Department of the Environment would be notified of all EISs on an ongoing basis.

5.2.6 Monitoring and post-auditing

The commission felt that there was no formal provision for monitoring and post auditing in the Irish Regulations. It was acknowledged that the proposed Environmental Protection Agency would have a licensing and monitoring in respect of certain projects.

5.2.7 Assistance to Practitioners

The Commission felt that the publication of a number of guidelines by the Department of the Environment and the provision of seminars by the dept and Eolas provided adequate assistance to practitioners of EIA.

5.2.8 Effect on timescales and costs

The Commission felt that there was no evidence that the implementation of the Directive in Ireland had affected the costs or timescale of projects which required an EIS. It was felt that developers had welcomed the EIA process.

5.3 Proposed amendment to the Directive

The Commission Under Article 11 (4) of the Directive was required to assess the implementation of the Directive in the Member States. The findings of the Commission were published in a report (COM (93) 28) and circulated to the European Parliament and the Council. The Commission felt that there had been some practical difficulties in implementing the Directive owing to differences in interpretation between Member States and the Commission. The commission found that some Member States were not applying the Directive in its entirety and that an amendment to the Directive would be necessary.

5.3.2 Scope of Directive

The Commission felt that Member States had interpreted the provision of Article 4 (relating to the selection of projects requiring an EIS based on Annex I and Annex II) in different ways. This resulted in Annex II projects not being fully covered. The Commission also felt that where Member States had

applied low thresholds (or no thresholds at all), that this could result in large numbers of minor projects being subject to assessment.

5.3.3 Content

The Commission felt that there was considerable variation between Member States in determining the information provided for under Article 5. In most States the EIS was only required to contain the minimum information as required under Article 5(2). This failed to satisfy the requirement that the information must under certain circumstances be that specified in Annex III. To ensure the information is more relevant and to improve the quality of that information, the Commission believes that the introduction of the concept of scoping will improve the process. The process of scoping will be performed prior to the assessment beginning and will indicate to the developer, the information from Annex III that should be gathered and submitted.

5.3.4 Monitoring

The Commission felt that the Directive contained a technical inadequacy in that there was no provision for monitoring the effects on the environment due to the implementation of the project. It was felt that monitoring would ensure that competent authorities and developers would be able to soften any impacts at the earliest stage possible.

5.3.5 Costs and benefits

The Commission felt that there would be benefits from the proposed changes to the Directive:

- the information gathered would be more relevant and selective based on the scoping process;
- there would be easier access to existing data for those who need it;
- better control over the quality of impact assessments and the conclusion drawn from them;
- fewer assessments of smaller projects (where they are unlikely to have any environmental impact).

In relation to costs, the Commission felt that it would be difficult to estimate accurately whether the cost of performing an EIA would increase. However the Commission felt that the scoping exercise could result in savings. The Commission also felt that where mitigating measures were necessary, that when these were included at the beginning of a project design, that this could result in an overall reduction of the capital cost.

5.4 Amendments to 85/337/EEC

The main proposed changes to the directive are as follows:

The proposal is to amend Article 1 to transfer and clarify the definition of 'modification of projects' which appears as a project class in Annex II.

It is proposed to amend Article 4 to initiate the screening procedure to be applied by Member States for identifying the Annex II projects that require assessment. This amendment requires that where an Annex II project could

have a significant effect on a special protection area, it will be subject to Articles 5 to 10. In all other cases of Annex II projects, they shall be examined by the competent authority based on any thresholds and the selection criteria in Annex IIa, as to whether their probable environmental impact necessitates assessment in accordance with Article 5 to 10.

It is proposed to amend Article 5 to introduce the concept of scoping to facilitate the exchange of information between the parties concerned and to improve the quality of the assessment procedure. Article 5(1) allows the competent authority to specify in consultation with the developer, what information from Annex III that the developer is required to provide. Article 5(2) is deleted. There is also a proposed change to Article 5(3) to ensure that authorities in Member States pass on any relevant information to the developer.

The proposed changes to Article 6 include provision for any authorities concerned with the project to express an opinion on the information supplied by the developer. There is also a change in the terms of public consultation on a project, in that the public will be allowed express opinions before 'development consent is granted ' rather than 'before the project is initiated' as the current Directive states.

The proposed amendments to Article 7 relate to improving the bilateral relations between the Member States when a project is liable to have significant adverse effect on the environment of another Member State.

The proposed amendment to Article 8 involves clarifying that opinions and information gathered pursuant to Articles 5, 6 and 7 must be taken into consideration in the consent procedure.

The proposed amendment to Article 9 requires that there must be justification for decisions taken by a competent authority. The competent authority must publish its decisions and inform the public of:

- the content of the decision and any conditions attached;
- the reasons and considerations on which its decision to refuse to grant development consent, or to grant development consent despite receiving unfavourable opinions pursuant to articles 6 and 7, is based;
- a description, where necessary of the measures to avoid, reduce and if possible, offset the major adverse effects.

Due to the proposed changes, Article 11 and 12 will become unnecessary and it is proposed that they will be deleted.

It is also proposed to delete Article 13 of the Directive as Article 130t of the Treaty on European Union now allows Member States to lay down stricter rules on environmental protection.

Annex I

It is proposed to amend Annex I by the addition of 2 categories relating to the nuclear industry. The definition of the term Integrated chemical installation is expanded.

Annex II

The amendment proposes to amalgamate certain categories and to tighten some of the definitions. A new category is included covering tourism and leisure.

Annex IIa

The proposed addition of this Annex is to allow application of the new provisions in Article 4(3). The new Annex lays down selection criteria to

allow Member States to appraise, on an identical basis, whether or not Annex II projects are likely to have a significant impact on the environment.

Annex III

It is proposed to amend point 2 of the annex to make the examination of the main alternatives to the project compulsory with the intention of making the Directive more effective and to harmonise the relevant national provisions.

Annex IV

The proposed addition of this new Annex is to define the procedure for consultation between Member States in relation to projects which have a transboundary impact.

Chapter 6

The Role Of The Environmental Protection Agency In Environmental Impact Assessment

6.1 Background

Because there was growing concern among the public about environmental matters, the environment was high on the agenda of the elected government of 1989. The situation as it existed was that there was a large amount of environmental legislation on the statute books and there was a trend for more complicated legislation in the future. The institutional arrangements for dealing with these new environmental controls had not been developed to the same level as the legislation. There was also a need for a uniform and consistent application of the legislation across the country. The government also felt that there was a need for a high level of expertise combined with sophisticated equipment to monitor modern developments to ensure compliance with new standards. It was felt that a national organisation would be best placed to meet the requirements of the government in this area and that a central organisation could offer significant cost advantages. The Government set about to establish the Environmental Protection Agency in 1989 and the outline of the Agency was announced on 5 December 1989 by the then Minister for Environmental Protection, Mary Harney. This was followed by a period of consultation between the Government and various interests including industrial, environmental, commercial, educational and state bodies. After 1 year a draft bill was published in December 1990. After a long and detailed debate in both the Seanad and the Dail, the Environmental Protection Agency Act of 1992 was passed into law on the 23 April 1992. The EPA was set up in 1993 as an independent body managed by a Director General and four directors. The agency has strong regulatory and enforcement powers relating to

all activities with potential for major pollution and provides supervisory and support services for public bodies.

6.2 Function of the EPA

The aim of the agency is to protect the environment through the following powers and functions.

Control

- Licensing major developments and enforcing compliance.
- Authorising certain public sector activities.
- Imposing conditions on marine development.

Monitoring

- Monitoring general environmental quality.
- Monitoring the quantity and quality of water resources.
- Monitoring specific problems.

Promotion

- Issuing guidelines on environmental issues.
- Issuing codes of practice.
- Encouraging environmental audits.
- Encouraging environmentally friendly products and services.

Assistance

- Co-ordination of environmental research programmes.
- Encouraging local authorities in environmental protection.
- Providing training in environmental protection.

Advice

- On policy matters.
- On the need for legislative change.
- On environmental quality standards.
- On emission standards.
- On environmental impact statements.

Supervision

- Supervising environmental monitoring by other authorities.
- Overseeing the environmental activities of local authorities.

Consultation

- Provide consultation for developers seeking licences.
- Consulting with public authorities about their environmental functions.

Information services

- Publication of monitoring results.
- Provision of public access to environmental databases.
- Publication of ' State of the Environment' reports.
- Holding of seminars and conferences.

International Co-operation

- Liaising with the European Environment Agency.
- Consulting with similar international bodies about environmental issues.

6.3 Licensing under EPA Act

The EPA Act of 1992 established the framework for the control of pollution in Ireland. The agency is responsible for the licence and regulation of large/complex industrial and other processes on the basis of Integrated Pollution Control (IPC) and having regard to the best available technologies for the purpose. Under the Environmental Protection Agency (Licensing) Regulations, 1994, this function commenced on the 16 May 1994 and will be expanded on a phased basis. With IPC there will be only one licence issued covering all aspects of air, water, noise and waste. In granting a licence, the EPA must be satisfied that the Best Available Technology Not Entailing Excessive Cost (BATNEEC) will be used to prevent or eliminate or, where that is not practicable, to limit, abate or reduce an emission from the activity. For an activity that is in the IPC licensed sector the EPA will control all discharges to water, sewers, air, land and will also be responsible for the control of noise pollution.

The IPC licensing function of the Agency will be related to both new and established activities. The Introduction of IPC licensing will be as follows:

(i) 16 May 1994

All new activities in the following categories will require an IPC licence:

1 Minerals and other materials
2 Energy
4 Mineral fibres and glass
5 Chemicals
7 Food and Drink
8 Wood, paper, textiles and leather
10 Cement
11 Waste

(reference numbers and categories from First Schedule to EPA Act)

In relation to the Pharmaceutical Industry all new activities will fall in under section 5 and require an IPC licence.

(ii) 1 September 1994

From this date established activities will require an IPC in the following classes:

5.6 * Activities for the manufacture of pesticides, pharmaceuticals or veterinary products and their intermediates

11.1 The incineration of hazardous waste

*In the case of activities in Class 5.6 the requirement for an IPC licence will only apply to activities where the number of employees exceeds 200.

(iii) 1 January 1995

From this date existing activities in class 5.6 will require an IPC licence where the number of employees exceeds 100 but is less than 200.

Under the terms of the established activities order, any licence applications or reviews underway in respect of any plant covered by the order will transfer to and be decided by the EPA with effect from 16 May 1994.

6.3.1 Requirement For An Environmental Impact Statement

In the case of new activities, the new licensing regulations separates the application for planning permission from the IPC licensing procedure. The application for an IPC licence can be made prior to, at the same time or after the application for planning permission. For IPC purposes an EIS will be required for most activities, including the pharmaceutical industry.

In the case of existing activities, where there is any reconstruction or alteration that would require a review of a licence, the EPA may require that an EIS be prepared.

In the case of IPC applications, the EPA is the competent authority for the assessment of an EIS insofar as the statement relates to environmental pollution matters and these matters will not be considered by the planning authority. The EIS must still comply with the requirements of the EIA regulations.

To allow the EPA to consider Environmental Impact Assessment procedures for activities that are licensable by the agency, another set of regulations were made by the Minister for Environmental Protection. These regulations are the European Communities (Environmental Impact Assessment) (Amendment) Regulations, 1994 . These Regulations make some amendments to the Planning Acts to facilitate the effective operation of the change in responsibility in relation to EIA between the EPA and the planning authorities. Where there is a requirement for an IPC licence the planning process will not deal with matters that relate to the pollution potential of the activity.

6.3.2 Monitoring

Under the IPC licence regulations there is a requirement that compliance monitoring be performed. The licence will include details of monitoring to be

performed by the applicant. The Agency will also carry out monitoring or have it done on its behalf. This monitoring will ensure that any licence conditions are being adhered to.

6.4 Guidelines for EIS

Under section 72 of the EPA Act the Agency may prepare guidelines for the information to be contained in an EIS. The purpose of these guidelines is to provide the necessary information to developers in relation to the preparation of an Environmental Impact Statement. It is hoped that with these guidelines, the resulting EISs will be credible, complete and useful documents which can contribute to the approval procedure for new developments. These guidelines are currently at a draft stage and have been circulated among various bodies for comment. The EPA hopes to publish the guidelines in due course.

Chapter 7

The pharmaceutical Industry and EIA

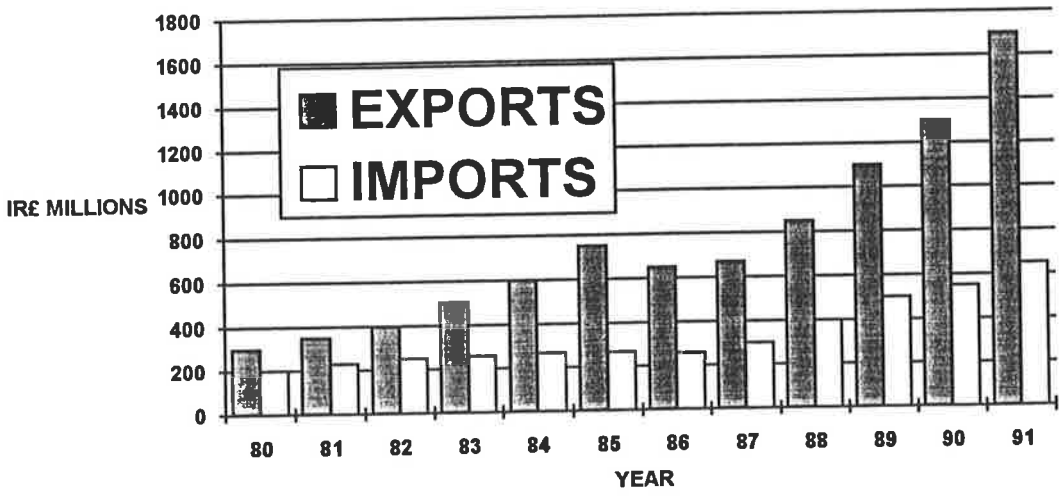
7.1 The Pharmaceutical Industry

According to the Federation of Irish Chemical Industries, over 60 pharmaceutical companies have established manufacturing operations in Ireland since 1970. This figure includes 11 of the world's leading companies.

The pharmaceutical industry contributes significantly to the country's balance of trade surplus as shown in figure 3 where the value of exports far exceeds that of imports for this sector.

Figure 3

EXPORTS AND IMPORTS OF PHARMACEUTICALS



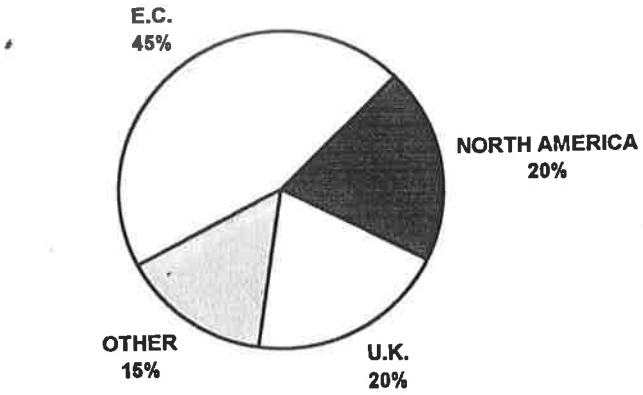
Source: F.I.C.I.

As can be seen from the above graph, the value of exports of pharmaceuticals has been growing steadily since 1987. The figures from the

FICI indicate that up to 85 % of the production is exported. Of this 85% that is exported, 75% is exported in bulk pharmaceutical form with the remaining 25% in finished dosage form. The destination of Irish pharmaceutical exports is shown in figure 4.

Figure 4

Export Destinations of Pharmaceuticals



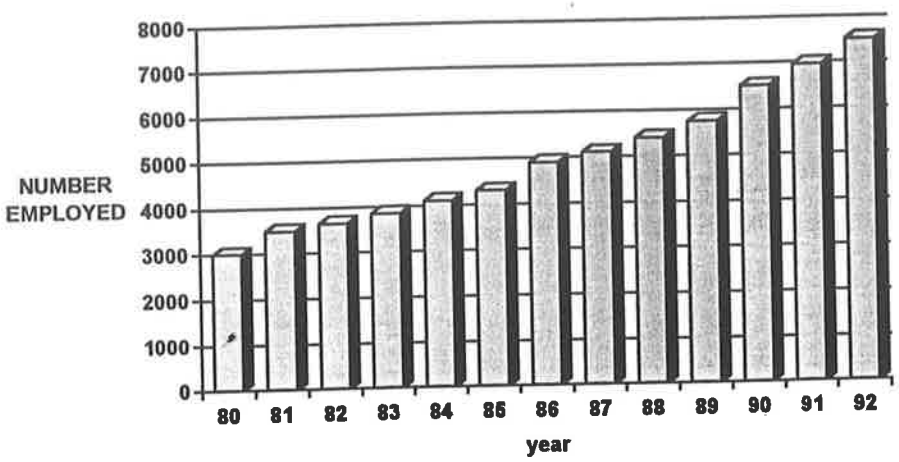
Source: F.I.C.I.

Figures produced by the FICI indicate that the growth in the Irish pharmaceutical sector over the period 1985 to 1992 was in excess of 100% which was far greater than that experienced by the sector in other European countries.

Employment in the pharmaceutical sector in Ireland has grown considerably over the period 1982 to 1992 as shown in figure 5. Employment in this sector is forecast to continue to rise and approximately 30 % of those employed in the sector are skilled craftsmen, technicians and graduates.

Figure 5

Employment in the Pharmaceutical Industry



Source: Central Statistics Office

7.2 Concerns in relation to the Pharmaceutical Industry

Within the sector known as the pharmaceutical sector, there is a wide variety of industrial activities from simple packaging operations to more complex manufacturing operations that may involve chemical or biochemical synthesis.

According to the World Bank, the following are the major concerns in relation to the impact of the pharmaceutical industry on the environment.

1 Many of the materials used in the manufacture of pharmaceuticals are toxic, hazardous or flammable. Many of the reaction processes also involve highly reactive compounds and there may be high temperature and pressure involved in the process.

2 Some materials may have long-term effects in low concentrations. The toxicological properties of many compounds may not have been fully investigated.

3 The industry has a requirement for large quantities of water for process, cooling and cleaning of plant and equipment. During manufacture, water often becomes contaminated with chemicals or by-products and this generally results in the construction of a treatment plant designed to reduce concentrations of pollutants to acceptable levels. This is generally achieved by biological treatment of wastewater.

4 There is potential to negatively impact on groundwater and surface water resources by the discharge of contaminated wastewater or by run-off from tank farms, production areas, pipe tracks, cooling water, flushing and cleaning water and accidental release of raw materials and finished products.

5 There is a potential for release of air pollutants such as particulate matter and gaseous compounds including sulphur oxides, carbon oxides, nitrous oxides from boilers. There is also the potential release of volatile organic compounds that may be used in the production process. These emissions could result from process equipment, storage facilities, pumps, valves, vents and leaking seals.

6 There is also potential for the production of solid waste streams which may include residues from raw materials and intermediates, sludges from boiler feed, tank cleaning or pollution control equipment. There may also be packaging waste that may be contaminated with chemicals.

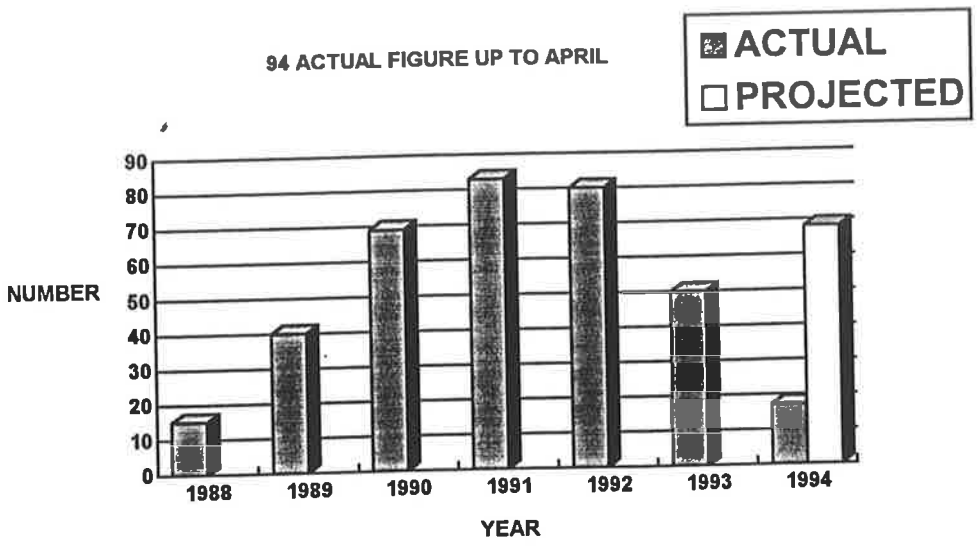
7.3 EIS inventory

The environmental research unit has maintained an inventory of all EISs submitted since 1988. The numbers of EISs submitted over the period 1988 to April 1994 was approx. 350 in total. Initially there was a marked increase in the numbers submitted up to 1991 but there has been a slight fall off in

numbers up to the present as shown in figure 6. The graph includes a projected figure for 1994 based on the number submitted to the end of April.

Figure 6

Numbers of EISs submitted 1988 to 1994

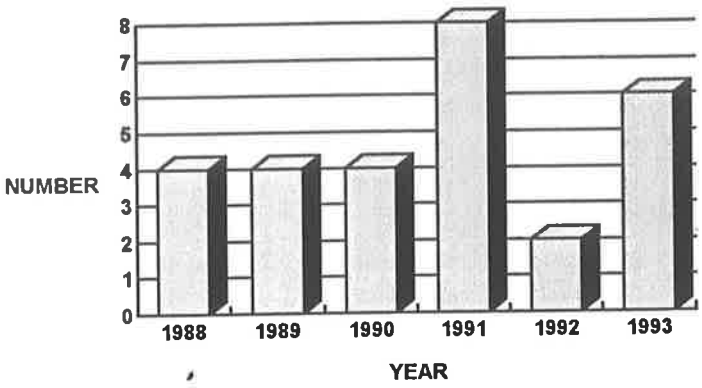


source: ERU inventory of EISs

7.4 Pharmaceutical EIS numbers

The category under the 1989 regulations for the pharmaceutical industry is Category II.6.b and the numbers of EISs submitted over the period 1988 to 1993 is shown in figure 7. The category includes ' all installations for the production of pesticides and pharmaceutical products, paints and varnishes, elastomers and peroxides'. The majority of EISs submitted under this category related to the pharmaceutical industry.

Figure 7
Number of EISs submitted in the pharmaceutical sector



Source: ERU inventory of EISs

7.5 Competent Authority

Over the period 1988 to 1994 there were 28 EISs submitted under category 2.6.b which were pharmaceutical related. In each case the EIS was submitted to the competent authority which was the local authority in whose area the proposed development was planned. Details of competent authorities that received EISs under category 2.6.b are shown in table 8 below. As can be seen from the table only 11 out of a total of 87 planning authorities had received an EIS in this category. The figures also show that the majority of EISs for the category were received by Cork County Council. As the majority of authorities in the country had not received an EIS in this category, one would question whether the necessary expertise was available to planning authorities to assess EISs that are pharmaceutical related and which could involve complex procedures.

Table 8

Planning Authorities that have received EISs under category 2.6.b

COMPETENT AUTHORITY	NUMBER OF EISs RECEIVED
Bray U.D.C.	1
Nenagh U.D.C.	1
Westport U.D.C.	1
Sligo B.C.	1
Dublin Corporation	3
Clare C.C.	1
Cork C.C.	13
Dublin C.C.	2
Galway C.C.	1
Kildare C.C.	1
Wicklow C.C.	3

Source: ERU inventory of EISs

7.6 EIS preparer

With the exception of one, all the developers in this category used the services of consultants to prepare the EIS. The details are shown in table 9 below. Eolas produced 75 % of the EISs in this group with each of the other consultants producing only one each. These figures would indicate that with the exception of Eolas, many consultants have little experience of preparing an EIS for the pharmaceutical sector to meet the requirements of the Irish regulations.

Table 9

Preparers of EISs

Preparer	Number of EISs
Eolas	21
BeMRA Consulting Engineers	1
Rorer International (own development)	1
Kenny and Associates	1
duQuesne Ltd.	1
Project Management Ltd.	1
Frank Murphy and Partners	1
Don Menzies and Associates	1

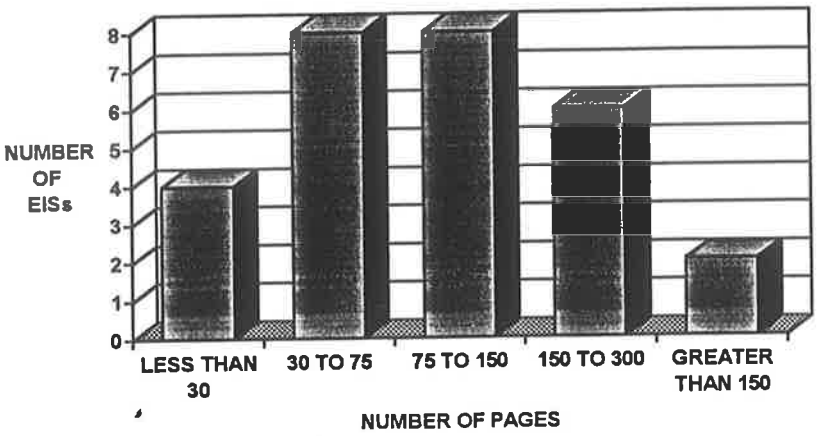
Source: ERU inventory of EISs

7.7 EIS: No. of pages

Over the period 1988 to 1993, the average length of EISs for the pharmaceutical sector was 124 pages. The shortest EIS was 13 pages (for an extension to an existing facility) and the longest was 500 pages (for a green field development of a large production facility). A breakdown of EIS lengths is shown in figure 8. Approximately 46% of EISs are less than 75 pages in length with approximately 18 % greater than 200 pages.

Figure 8

Length of EISs



Source: ERU inventory of EISs

7.8 Analysis of EISs

A number of the EISs submitted under category II.6.b were assessed as to their quality.

7.8.1 Scoping

Of the EISs assessed, approximately 40 % mentioned that consultation had taken place between the developer and the planning authority prior to the preparation of the EIS. In the other 60%, the document made no mention of a consultation process although consultation may have occured .

7.8.2 Project Description

The project description should include details of the site, design, size or scale of the development and should consider the development of the project

from its construction through to its operation. It should also consider alternative locations, designs and methods of production.

The majority of EISs provided an adequate description of the project, although most did not assess the option of alternatives in any detail. Alternative designs or processes were rarely mentioned, with alternative locations receiving slightly greater attention. In most cases, the location of the development was justified without assessment of alternative sites.

7.8.3 Operation of the project

This is one of the most important sections of an EIS in that it describes the principal processes and activities that will be performed on a site.
In practically all of the EISs submitted, the information supplied included full details of the production processes. Details of the materials used including amounts, storage /handling conditions and usage were well documented.

7.8.4 Description of the existing environment

In order to predict the likely impact of a new development on the environment it is necessary to provide an accurate description of all aspects of the existing environment. The regulations specify the topics which should be used to decribe the existing environment, which are: human beings, flora, fauna, soils, water, air, climate, the landscape, cultural heritage, material assets and the interaction between any of the foregoing.

All of the EISs covered these areas, although there was variation in detail. Many of the EISs contained baseline data in relation to areas such as water, soils, air, flora and fauna. Some of this baseline data was inadequate in that it was monitored over a single day which would not show any seasonal variations. The character and significance of each of the above aspects of the environment was generally well documented, although the assessment of their vulnerability was subjective.

7.8.5 Description of likely significant impacts

One of the purposes of the EIS is to give 'a description of the likely significant effects, direct and indirect, on the environment'.As these effects are in the future, impact prediction is a more appropriate term to describe the process. In theory, a new development could have a large number of possible impacts on the environment, but in relation to EISs submitted under Irish Regulations, it is necessary to address only the 'likely significant' impacts. Likely impacts are those that are planned to occur (e.g. the projected air emissions from the facility). In most cases (particularly small developments), the EIS stated that the operation was unlikely to have any significant effect on the environment. In the case of larger developments, the mitigating measures incorporated by the developer at the design stage, would reduce the negative impacts of the development to a level where they would be insignificant.

In many cases, the EIS stated that the development would have a positive impact on some areas, for example the positive effects on humans of increased employment in an area or the benefit to flora and fauna from the preservation of a green-field site around large pharmaceutical developments.

Chapter 8
Conclusions

8.1 Quality of EISs

Over the past number of years there have been 28 EISs submitted to statutory authorities in relation to developments under category 6.II.b of the EIA Regulations. The majority of these EISs were prepared by one consultant with several other consultants preparing single EISs in this area.

The length of EISs submitted is directly proportional to the size of the project with large projects producing excessively large EISs. There would be great difficulty for members of the general public to read, let alone assess the significance of information contained in such large volumes. It could also be said that some of the smaller projects are of little environmental significance.

EISs in the area of pharmaceutical developments comply well with the requirements of the regulations. The submitted EISs address all the key areas as required under the regulations.It is possible that there is a slight bias in favour of the developer in that most EISs do not record any significant adverse impacts and it must be remembered that the developer is paying the consultant to prepare the EIS. This is a slight deficiency in the Irish system, whereas if the assessment was performed by an independent body, this could possibly lead to a more impartial assessment of the likely impacts of the development. There is also a need for more monitoring of the existing environment prior to a development commencing so that monitoring that occurs after the operation begins can highlight any unforseen adverse impacts quickly so that mitigating measures may be implemented.

8.2 Competent Authority

The EPA will become the competent authority for the assessment of the information contained in submitted EISs. The fact that the EPA is preparing guidelines for the preparation of EISs should lead to greater awareness among developers as to the information required in an EIS. Under the proposed amendment to the E.C. Directive there will be a requirement for a more formal scoping stage prior to the preparation of an EIS and the EPA will also have a key role in this area. The introduction of the Integrated Pollution Control licensing system in 1994 combined with the EIA regulations will lead to greater control of the pharmaceutical industry. The assessment of the pollution potential of a proposed development by an independent EPA rather than by a local authority will lead to greater control of the industry.

8.3 Amendment to Directive

The European Commission had a number of minor concerns in relation to the implementation of the Directive in Ireland. The establishment of the EPA will deal with most of these concerns, particularly those in relation to scoping, monitoring and review of EISs. The proposed amendments will have some effect on EIA in the pharmaceutical industry in the area of scoping and consultation. This should lead to more concise and informative documents and eliminate the need for documents containing several hundred pages.

The amendment to Annex III may have an effect on pharmaceutical EISs in that the examination of the main alternatives to the project will become compulsory.

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APPENDIX A

Council Directive of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (85/337/EEC).

No L 175/40 Official Journal of the European Communities 5. 7. 85

COUNCIL DIRECTIVE

of 27 June 1985

on the assessment of the effects of certain public and private projects on the environment

(85/337/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 100 and 235 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the 1973 (4) and 1977 (5) action programmes of the European Communities on the environment, as well as the 1983 (6) action programme, the main outlines of which have been approved by the Council of the European Communities and the representatives of the Governments of the Member States, stress that the best environmental policy consists in preventing the creation of pollution or nuisances at source, rather than subsequently trying to counteract their effects; whereas they affirm the need to take effects on the environment into account at the earliest possible stage in all the technical planning and decision-making processes; whereas to that end, they provide for the implementation of procedures to evaluate such effects;

Whereas the disparities between the laws in force in the various Member States with regard to the assessment of the environmental effects of public and private projects may create unfavourable competitive conditions and thereby directly affect the functioning of the common market; whereas, therefore, it is necessary to approximate national laws in this field pursuant to Article 100 of the Treaty;

Whereas, in addition, it is necessary to achieve one of the Community's objectives in the sphere of the protection of the environment and the quality of life;

Whereas, since the Treaty has not provided the powers required for this end, recourse should be had to Article 235 of the Treaty;

Whereas general principles for the assessment of environmental effects should be introduced with a view to supplementing and coordinating development consent procedures governing public and private projects likely to have a major effect on the environment;

Whereas development consent for public and private projects which are likely to have significant effects on the environment should be granted only after prior assessment of the likely significant environmental effects of these projects has been carried out; whereas this assessment must be conducted on the basis of the appropriate information supplied by the developer, which may be supplemented by the authorities and by the people who may be concerned by the project in question;

Whereas the principles of the assessment of environmental effects should be harmonized, in particular with reference to the projects which should be subject to assessment, the main obligations of the developers and the content of the assessment;

Whereas projects belonging to certain types have significant effects on the environment and these projects must as a rule be subject to systematic assessment;

Whereas projects of other types may not have significant effects on the environment in every case and whereas these projects should be assessed where the Member States consider that their characteristics so require;

Whereas, for projects which are subject to assessment, a certain minimal amount of information must be supplied, concerning the project and its effects;

Whereas the effects of a project on the environment must be assessed in order to take account of concerns to protect human health, to contribute by means of a better environment to the quality of life, to ensure maintenance of the diversity of species and to maintain the reproductive capacity of the ecosystem as a basic resource for life;

(1) OJ No C 169, 9. 7. 1980, p. 14
(2) OJ No C 66, 15. 3. 1982, p. 89
(3) OJ No C 185, 27. 7. 1981, p. 8
(4) OJ No C 112, 20. 12. 1973, p. 1
(5) OJ No C 139, 13. 6. 1977, p. 1
(6) OJ No C 46, 17. 2. 1983, p. 1

Whereas, however, this Directive should not be applied to projects the details of which are adopted by a specific act of national legislation, since the objectives of this Directive, including that of supplying information, are achieved through the legislative process;

Whereas, furthermore, it may be appropriate in exceptional cases to exempt a specific project from the assessment procedures laid down by this Directive, subject to appropriate information being supplied to the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the assessment of the environmental effects of those public and private projects which are likely to have significant effects on the environment.

2. For the purposes of this Directive:

'project' means:

— the execution of construction works or of other installations or schemes,

— other interventions in the natural surroundings and landscape including those involving the extraction of mineral resources;

'developer' means:

the applicant for authorization for a private project or the public authority which initiates a project;

'development consent' means:

the decision of the competent authority or authorities which entitles the developer to proceed with the project.

3. The competent authority or authorities shall be that or those which the Member States designate as responsible for performing the duties arising from this Directive.

4. Projects serving national defence purposes are not covered by this Directive.

5. This Directive shall not apply to projects the details of which are adopted by a specific act of national legislation, since the objectives of this Directive, including that of supplying information, are achieved through the legislative process.

Article 2

1. Member States shall adopt all measures necessary to ensure that, before consent is given, projects likely to have significant effects on the environment by virtue *inter alia*, of their nature, size or location are made subject to an assessment with regard to their effects.

These projects are defined in Article 4.

2. The environmental impact assessment may be integrated into the existing procedures for consent to projects in the Member States, or, failing this, into other procedures or into procedures to be established to comply with the aims of this Directive.

3. Member States may, in exceptional cases, exempt a specific project in whole or in part from the provisions laid down in this Directive.

In this event, the Member States shall:

(a) consider whether another form of assessment would be appropriate and whether the information thus collected should be made available to the public;

(b) make available to the public concerned the information relating to the exemption and the reasons for granting it;

(c) inform the Commission, prior to granting consent, of the reasons justifying the exemption granted, and provide it with the information made available, where appropriate, to their own nationals.

The Commission shall immediately forward the documents received to the other Member States.

The Commission shall report annually to the Council on the application of this paragraph.

Article 3

The environmental impact assessment will identify, describe and assess in an appropriate manner, in the light of each individual case and in accordance with the Articles 4 to 11, the direct and indirect effects of a project on the following factors:

— human beings, fauna and flora,

— soil, water, air, climate and the landscape,

— the inter-action between the factors mentioned in the first and second indents,

— material assets and the cultural heritage.

Article 4

1. Subject to Article 2 (3), projects of the classes listed in Annex I shall be made subject to an assessment in accordance with Articles 5 to 10.

2. Projects of the classes listed in Annex II shall be made subject to an assessment, in accordance with Articles 5 to 10, where Member States consider that their characteristics so require.

To this end Member States may *inter alia* specify certain types of projects as being subject to an assessment or may establish the criteria and/or thresholds necessary to determine which of the projects of the classes listed in Annex II are to be subject to an assessment in accordance with Articles 5 to 10.

Article 5

1. In the case of projects which, pursuant to Article 4, must be subjected to an environmental impact assessment in accordance with Articles 5 to 10, Member States shall adopt the necessary measures to ensure that the developer supplies in an appropriate form the information specified in Annex III inasmuch as :

(a) the Member States consider that the information is relevant to a given stage of the consent procedure and to the specific characteristics of a particular project or type of project and of the environmental features likely to be affected ;

(b) the Member States consider that a developer may reasonably be required to compile this information having regard *inter alia* to current knowledge and methods of assessment.

2. The information to be provided by the developer in accordance with paragraph 1 shall include at least :

— a description of the project comprising information on the site, design and size of the project,

— a description of the measures envisaged in order to avoid, reduce and, if possible, remedy significant adverse effects,

— the data required to identify and assess the main effects which the project is likely to have on the environment,

— a non-technical summary of the information mentioned in indents 1 to 3.

3. Where they consider it necessary, Member States shall ensure that any authorities with relevant information in their possession make this information available to the developer.

Article 6

1. Member States shall take the measures necessary to ensure that the authorities likely to be concerned by the project by reason of their specific environmental responsibilities are given an opportunity to express their opinion on the request for development consent. Member States shall designate the authorities to be consulted for this purpose in general terms or in each case when the request for consent is made. The information gathered pursuant to Article 5 shall be forwarded to these authorities. Detailed arrangements for consultation shall be laid down by the Member States.

2. Member States shall ensure that :

— any request for development consent and any information gathered pursuant to Article 5 are made available to the public,

— the public concerned is given the opportunity to express an opinion before the project is initiated.

3. The detailed arrangements for such information and consultation shall be determined by the Member States, which may in particular, depending on the particular characteristics of the projects or sites concerned :

— determine the public concerned,

— specify the places where the information can be consulted,

— specify the way in which the public may be informed, for example by bill-posting within a certain radius, publication in local newspapers, organization of exhibitions with plans, drawings, tables, graphs, models,

— determine the manner in which the public is to be consulted, for example, by written submissions, by public enquiry,

— fix appropriate time limits for the various stages of the procedure in order to ensure that a decision is taken within a reasonable period.

Article 7

Where a Member State is aware that a project is likely to have significant effects on the environment in another Member State or where a Member State likely to be significantly affected so requests, the Member State in whose territory the project is intended to be carried out shall forward the information gathered pursuant to Article 5 to the other Member State at the same time as it makes it available to its own nationals. Such information shall serve as a basis for any consultations necessary in the framework of the bilateral relations between two Member States on a reciprocal and equivalent basis.

Article 8

Information gathefed pursuant to Articles 5, 6 and 7 must be taken into consideration in the development consent procedure.

Article 9

When a decision has been taken, the competent authority or authorities shall inform the public concerned of :

— the content of the decision and any conditions attached thereto,

— the reasons and considerations on which the decision is based where the Member States' legislation so provides.

The detailed arrangements for such information shall be determined by the Member States.

If another Member State has been informed pursuant to Article 7, it will also be informed of the decision in question.

Article 10

The provisions of this Directive shall not affect the obligation on the competent authorities to respect the limitations imposed by national regulations and administrative provisions and accepted legal practices with regard to industrial and commercial secrecy and the safeguarding of the public interest.

Where Article 7 applies, the transmission of information to another Member State and the reception of information by another Member State shall be subject to the limitations in force in the Member State in which the project is proposed.

Article 11

1. The Member States and the Commission shall exchange information on the experience gained in applying this Directive.

2. In particular, Member States shall inform the Commission of any criteria and/or thresholds adopted for the selection of the projects in question, in accordance with Article 4 (2), or of the types of projects concerned which, pursuant to Article 4 (2), are subject to assessment in accordance with Articles 5 to 10.

3. Five years after notification of this Directive, the Commission shall send the European Parliament and the Council a report on its application and effectiveness. The report shall be based on the aforementioned exchange of information.

4. On the basis of this exchange of information, the Commission shall submit to the Council additional proposals, should this be necessary, with a view to this Directive's being applied in a sufficiently coordinated manner.

Article 12

1. Member States shall take the measures necessary to comply with this Directive within three years of its notification (1).

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 13

The provisions of this Directive shall not affect the right of Member States to lay down stricter rules regarding scope and procedure when assessing environmental effects.

Article 14

This Directive is addressed to the Member States.

Done at Luxembourg, 27 June 1985.

For the Council

The President

A. BIONDI

(1) This Directive was notified to the Member States on 3 July 1985.

ANNEX I

PROJECTS SUBJECT TO ARTICLE 4 (1)

1. Crude-oil refineries (excluding undertakings manufacturing only lubricants from crude oil) and installations for the gasification and liquefaction of 500 tonnes or more of coal or bituminous shale per day.

2. Thermal power stations and other combustion installations with a heat output of 300 megawatts or more and nuclear power stations and other nuclear reactors (except research installations for the production and conversion of fissionable and fertile materials, whose maximum power does not exceed 1 kilowatt continuous thermal load).

3. Installations solely designed for the permanent storage or final disposal of radioactive waste.

4. Integrated works for the initial melting of cast-iron and steel.

5. Installations for the extraction of asbestos and for the processing and transformation of asbestos and products containing asbestos: for asbestos-cement products, with an annual production of more than 20 000 tonnes of finished products, for friction material, with an annual production of more than 50 tonnes of finished products, and for other uses of asbestos, utilization of more than 200 tonnes per year.

6. Integrated chemical installations.

7. Construction of motorways, express roads (1) and lines for long-distance railway traffic and of airports (2) with a basic runway length of 2 100 m or more.

8. Trading ports and also inland waterways and ports for inland-waterway traffic which permit the passage of vessels of over 1 350 tonnes.

9. Waste-disposal installations for the incineration, chemical treatment or land fill of toxic and dangerous wastes.

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(1) For the purposes of the Directive, 'express road' means a road which complies with the definition in the European Agreement on main international traffic arteries of 15 November 1975.

(2) For the purposes of this Directive, 'airport' means airports which comply with the definition in the 1944 Chicago Convention setting up the International Civil Aviation Organization (Annex 14).

ANNEX II

PROJECTS SUBJECT TO ARTICLE 4 (2)

1. Agriculture

(a) Projects for the restructuring of rural land holdings.

(b) Projects for the use of uncultivated land or semi-natural areas for intensive agricultural purposes.

(c) Water-management projects for agriculture.

(d) Initial afforestation where this may lead to adverse ecological changes and land reclamation for the purposes of conversion to another type of land use.

(e) Poultry-rearing installations.

(f) Pig-rearing installations.

(g) Salmon breeding.

(h) Reclamation of land from the sea.

2. Extractive industry

(a) Extraction of peat.

(b) Deep drillings with the exception of drillings for investigating the stability of the soil and in particular:

— geothermal drilling,

— drilling for the storage of nuclear waste material,

— drilling for water supplies.

(c) Extraction of minerals other than metalliferous and energy-producing minerals, such as marble, sand, gravel, shale, salt, phosphates and potash.

(d) Extraction of coal and lignite by underground mining.

(e) Extraction of coal and lignite by open-cast mining.

(f) Extraction of petroleum.

(g) Extraction of natural gas.

(h) Extraction of ores.

(i) Extraction of bituminous shale.

(j) Extraction of minerals other than metalliferous and energy-producing minerals by open-cast mining.

(k) Surface industrial installations for the extraction of coal, petroleum, natural gas and ores, as well as bituminous shale.

(l) Coke ovens (dry coal distillation).

(m) Installations for the manufacture of cement.

3. Energy industry

(a) Industrial installations for the production of electricity, steam and hot water (unless included in Annex I).

(b) Industrial installations for carrying gas, steam and hot water; transmission of electrical energy by overhead cables.

(c) Surface storage of natural gas.

(d) Underground storage of combustible gases.

(e) Surface storage of fossil fuels.

(f) Industrial briquetting of coal and lignite.

(g) Installations for the production or enrichment of nuclear fuels.

(h) Installations for the reprocessing of irradiated nuclear fuels.

(i) Installations for the collection and processing of radioactive waste (unless included in Annex I).

(j) Installations for hydroelectric energy production.

11. Other projects

(a) Holiday villages, hotel complexes.

(b) Permanent racing and test tracks for cars and motor cycles.

(c) Installations for the disposal of industrial and domestic waste (unless included in Annex I).

(d) Waste water treatment plants.

(e) Sludge-deposition sites.

(f) Storage of scrap iron.

(g) Test benches for engines, turbines or reactors.

(h) Manufacture of artificial mineral fibres.

(i) Manufacture, packing, loading or placing in cartridges of gunpowder and explosives.

(j) Knackers' yards.

12. Modifications to development projects included in Annex I and projects in Annex I undertaken exclusively or mainly for the development and testing of new methods or products and not used for more than one year.

ANNEX III

INFORMATION REFERRED TO IN ARTICLE 5 (1)

1. Description of the project, including in particular:

   — a description of the physical characteristics of the whole project and the land-use requirements during the construction and operational phases,

   — a description of the main characteristics of the production processes, for instance, nature and quantity of the materials used,

   — an estimate, by type and quantity, of expected residues and emissions (water, air and soil pollution, noise, vibration, light, heat, radiation, etc.) resulting from the operation of the proposed project.

2. Where appropriate, an outline of the main alternatives studied by the developer and an indication of the main reasons for his choice, taking into account the environmental effects.

3. A description of the aspects of the environment likely to be significantly affected by the proposed project, including, in particular, population, fauna, flora, soil, water, air, climatic factors, material assets, including the architectural and archaeological heritage, landscape and the inter-relationship between the above factors.

4. A description (1) of the likely significant effects of the proposed project on the environment resulting from:

   — the existence of the project,

   — the use of natural resources,

   — the emission of pollutants, the creation of nuisances and the elimination of waste;

   and the description by the developer of the forecasting methods used to assess the effects on the environment.

5. A description of the measures envisaged to prevent, reduce and where possible offset any significant adverse effects on the environment.

6. A non-technical summary of the information provided under the above headings.

7. An indication of any difficulties (technical deficiencies or lack of know-how) encountered by the developer in compiling the required information.

(1) This description should cover the direct effects and any indirect, secondary, cumulative, short, medium and long-term, permanent and temporary, positive and negative effects of the project.

4. Processing of metals
   (a) Iron and steelworks, including foundries, forges, drawing plants and rolling mills (unless included in Annex I).
   (b) Installations for the production, including smelting, refining, drawing and rolling, of non-ferrous metals, excluding precious metals.
   (c) Pressing, drawing and stamping of large castings.
   (d) Surface treatment and coating of metals.
   (e) Boilermaking, manufacture of reservoirs, tanks and other sheet-metal containers.
   (f) Manufacture and assembly of motor vehicles and manufacture of motor-vehicle engines.
   (g) Shipyards.
   (h) Installations for the construction and repair of aircraft.
   (i) Manufacture of railway equipment.
   (j) Swaging by explosives.
   (k) Installations for the roasting and sintering of metallic ores.

5. Manufacture of glass

6. Chemical industry
   (a) Treatment of intermediate products and production of chemicals (unless included in Annex I).
   (b) Production of pesticides and pharmaceutical products, paint and varnishes, elastomers and peroxides.
   (c) Storage facilities for petroleum, petrochemical and chemical products.

7. Food industry
   (a) Manufacture of vegetable and animal oils and fats.
   (b) Packing and canning of animal and vegetable products.
   (c) Manufacture of dairy products.
   (d) Brewing and malting.
   (e) Confectionery and syrup manufacture.
   (f) Installations for the slaughter of animals.
   (g) Industrial starch manufacturing installations.
   (h) Fish-meal and fish-oil factories.
   (i) Sugar factories.

8. Textile, leather, wood and paper industries
   (a) Wool scouring, degreasing and bleaching factories.
   (b) Manufacture of fibre board, particle board and plywood.
   (c) Manufacture of pulp, paper and board.
   (d) Fibre-dyeing factories.
   (e) Cellulose-processing and production installations.
   (f) Tannery and leather-dressing factories.

9. Rubber industry
   Manufacture and treatment of elastomer-based products.

10. Infrastructure projects
   (a) Industrial-estate development projects.
   (b) Urban-development projects.
   (c) Ski-lifts and cable-cars.
   (d) Construction of roads, harbours, including fishing harbours, and airfields (projects not listed in Annex I).
   (e) Canalization and flood-relief works.
   (f) Dams and other installations designed to hold water or store it on a long-term basis.
   (g) Tramways, elevated and underground railways, suspended lines or similar lines of a particular type, used exclusively or mainly for passenger transport.
   (h) Oil and gas pipeline installations.
   (i) Installation of long-distance aqueducts.
   (j) Yacht marinas.

APPENDIX B

Proposal for a
COUNCIL DIRECTIVE
amending Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 130s(1) thereof,

Having regard to the proposal from the Commission[1],

In cooperation with the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas the main purpose of the environmental assessment procedure under Council Directive 85/337/EEC[4] is to provide the competent authorities with relevant information to enable them to make a decision on a specific project in full knowledge of the facts regarding the project's probable impact on the environment; whereas the assessment procedure is therefore a fundamental instrument of environmental policy as defined in Article 130r of the Treaty;

Whereas a sufficient degree of environmental protection must be ensured at Community level by laying down a general assessment framework and criteria for defining those projects which must be submitted for an environmental assessment; whereas, however, in accordance with the subsidiarity principle, the Member States are in the best position to apply those criteria in specific instances;

Whereas the report on the implementation of Directive 85/337/EEC, as adopted by the Commission on 2 April 1993, shows that there are problems in applying the Directive; whereas certain provisions of the Directive should therefore be clarified so that the assessment procedure may produce greater benefits, but without altering the actual scope of the Member States' obligations under the Directive;

Whereas it would, nevertheless, appear necessary to introduce provisions designed to improve the rules on the assessment procedure;

Whereas additions should be made to the list of projects which have significant effects on the environment and which must on that account be made subject to systematic assessment;

Whereas it should also be made clear that such assessment is compulsory for the projects listed in Annex II to the Directive which may have a significant effect on the specific environmental protection objectives laid down by mutual agreement at Community level; whereas in all other cases, however, it falls to the Member States to determine whether assessment is necessary in accordance with the selection criteria set out in this Directive;

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(1) OJ No C
(2) OJ No C
(3) OJ No C
(4) OJ No L 175, 5.7.1985, p. 40.

Whereas some of these measures bring the provisions of the Directive into line with the Convention on environmental impact assessment in a transboundary context (Espoo Convention), which the Community signed at the same time as the Member States on 25 February 1991,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 85/337/EEC is hereby amended as follows:

I. In Article 1(2), the following definition is inserted after the first definition:

"'modifications to projects' means:

any restructuring of a project which affects it substantially or any substantial change in the conditions of execution or operation of a project;".

2. Article 4 is replaced by the following:

"Article 4

1. Subject to Article 2(3), projects listed in Annex I shall be assessed in accordance with Articles 5 to 10.

2. Subject to Article 2(3), projects listed in Annex II shall be assessed in accordance with Articles 5 to 10 where they are liable to have a significant effect on the special protection areas designated by Member States pursuant to Community law.

3. In all other cases, projects listed in Annex II shall be examined by the competent authority to determine, on the basis of thresholds set, where appropriate, by Member States and of the selection criteria laid down in Annex IIa, whether their probable environmental impact necessitates assessment in accordance with Articles 5 to 10.

Member States shall ensure that decisions taken by the competent authority are published."

3. Article 5(1) is replaced by the following:

"1. In the case of projects which, pursuant to Article 4, must undergo environmental impact assessment in accordance with Articles 5 to 10, Member States shall adopt the necessary measures to ensure that the competent authority defines, in agreement with the authorities referred to in Article 6 and in consultation with the developer, the information specified in Annex III which the developer is required to provide, in an appropriate form, in so far as:

(a) the information is relevant to a given stage of the development consent procedure and to the specific characteristics of a particular project or type of project, or those of the environmental features liable to be affected;

(b) a developer may reasonably be required to gather this information having regard, inter alia, to current knowledge and methods of assessment."

4. Article 5(2) is deleted.

5. Article 5(3) is replaced by the following:

"3. Member States shall ensure that any authorities holding relevant information, regard being had in particular to Article 3, shall make this information available to the developer."

6. Article 6(1) is replaced by the following:

"1. Member States shall take the measures necessary to ensure that the authorities likely to be concerned by the project by reason of their specific environmental responsibilities are given an opportunity to express their opinion on the information supplied by the developer and on the request for development consent. To this end, Member States shall designate the authorities to be consulted, either in general terms or on a case-by-case basis, when the request for development consent is made. The information gathered pursuant to Article 5 shall be forwarded to those authorities. Detailed arrangements for consultation shall be laid down by the Member States."

7. In Article 6(2), the words "before the project is initiated" are replaced by the words "before development consent is granted".

8. Article 7 is replaced by the following:

"Article 7

1. Where a Member State considers that a project referred to in Article 4 is liable to have significant adverse effects on the environment of another Member State, or where a Member State whose environment is liable to be significantly affected so requests, the Member State on whose territory the project is located shall communicate to the other Member State, at the latest when it informs its own nationals, the information specified in Annex IV.

2. The Member States concerned shall enter into consultations, setting a reasonable timetable for:

(i) the main alternative solutions to the project which have been examined;

(ii) the measures which may be taken to avoid, reduce and, if possible, offset the adverse transboundary effects;

(iii) possible forms of mutual assistance to lessen any major harmful transboundary impact caused by the proposed project;

(iv) the measures which may be taken to ensure the monitoring of the transboundary effects of the project at the expense of the Member State in which the project is proposed.

3. The authorities of the Member State whose environment is liable to be significantly affected shall hold consultations with the authorities concerned and with the public, in accordance with the provisions of Article 6 and shall, within the time limit provided for in paragraph 2, communicate their opinion on the project to the authorities of the Member State on whose territory the project is located.

However, failure by the authorities of the Member State whose environment is liable to be affected to deliver the opinion mentioned in paragraph 1 within the time limit and in the form specified above, those authorities having been properly informed pursuant to paragraph 2, shall not provide grounds which may be invoked in support of a challenge to the validity of the competent authorities' decision regarding the project."

9. Article 8 is replaced by the following:

"Article 8

The opinions and the information gathered pursuant to Articles 5, 6 and 7 must be taken into consideration in the development consent procedure."

10. Article 9 is replaced by the following:

"Article 9

When a decision has been taken, the competent authority or authorities shall publish it and, where appropriate, inform the other Member State which has been consulted pursuant to Article 7 thereof, indicating:

- the content of the decision and any conditions attached thereto;

- the reasons and considerations on which its decision to refuse to grant development consent, or to grant development consent despite receiving unfavourable opinions pursuant to Articles 6 and 7, is based;

- a description, where necessary, of the measures to avoid, reduce and, if possible, offset the major adverse effects."

11. Article 11(2) is hereby deleted.

12. Article 13 is hereby deleted.

13. The Annexes are amended as shown in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 1996 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. If a request for development consent has been submitted to a competent authority before 1 July 1996, the provisions of Directive 85/337/EEC prior to these amendments shall continue to apply.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX

1. Point 3 in Annex I is replaced by the following:

"3. (a) Installations for the reprocessing of irradiated nuclear fuel.

(b) Installations designed solely for the permanent storage or final disposal of radioactive waste and centralized temporary storage installations for radioactive waste or irradiated nuclear fuel."

2. Point 6 in Annex I is replaced by the following:

"6. Integrated chemical installations: installations located in a geographical area in which several units for the industrial production of chemical products, not necessarily belonging to the same company, are juxtaposed and are functionally linked to one another."

3. Point 8 in Annex I is replaced by the following:

"8. (a) Inland waterways which permit the passage of vessels of over 1 350 tonnes;

(b) Trading ports and port installations, including offshore installations, and ports and installations for inland-waterway traffic which permit the passage of vessels of over 1 350 tonnes."

4. Point 1 in Annex II is replaced by the following:

"1. **Agriculture**

(a) Projects for the restructuring of rural land holdings.

(b) Irrigation and land drainage projects.

(c) Afforestation, reafforestation, deforestation.

(d) Intensive stockfarming.

(e) Production of exotic species of flora and fauna.

(f) Intensive fish or shellfish farming."

5. Letter (h) under point 3 in Annex II is deleted.

6. Point 10 in Annex II is replaced by the following:

"10. **Infrastructure projects**

(a) Industrial estate development projects.

(b) Urban development projects, including the construction of shopping centres and car parks.

(c) Doubling, electrification and adjustment to standard gauge of railway lines or tracks for combined transport, construction of railway and intermodal transshipment facilities, and of intermodal terminals.

(d) Construction of airfields and extension of the airport capacity of airfields (projects not listed in Annex I).

(e) Construction and upgrading of roads (widening and alternative routes), harbours and port installations, including fishing harbours (projects not listed in Annex I).

(f) Inland-waterway construction, canalization and flood-relief works.

(g) Dams and other installations designed to hold water or store it on a long-term basis.

(h) Tramways, elevated and underground railways, suspended lines or similar lines of a particular type, used exclusively or mainly for passenger transport.

(i) Oil and gas pipeline installations.

(j) Installation of long-distance aqueducts.

(k) Coastal work to combat erosion and maritime works capable of altering the coast through the construction, for example, of dykes, moles, jetties and other sea defence works."

7. Point 11 in Annex II is replaced by the following:

"11. **Other projects**

(a) Permanent racing and test tracks for cars and motor cycles.

(b) Installations for the disposal of industrial and domestic waste (unless included in Annex I).

(c) Waste-water treatment plants.

(d) Sludge-deposition sites.

(e) Storage of scrap iron.

(f) Test benches for engines, turbines or reactors.

(g) Manufacture of artificial mineral fibres.

(h) Manufacture, packing, loading or placing in cartridges of gunpowder and explosives.

(i) Knackers' yards."

8. The following points are added to Annex II:

"11a **Tourism and leisure**

(a) Ski-runs, bobsleigh tracks and ski-lifts and artificial snow installations.

(b) Golf courses and associated developments.

(c) Marinas.

(d) Holiday villages, hotel complexes and associated developments.

(e) Camp sites and caravan sites.

(f) Leisure centres.

11b **Land-use projects**

(a) Changes in the use of uncultivated land, semi-natural areas and natural or semi-natural forests.

(b) Reclamation of land from the sea."

9. Point 12 in Annex II is replaced by the following:

"12. Modifications to projects listed in Annex I or Annex II and projects in Annex I undertaken exclusively or mainly for the development and testing of new methods or products and not used for more than two years."

10. A new Annex IIa is inserted, as follows:

"ANNEX IIa

SELECTION CRITERIA REFERRED TO IN ARTICLE 4(3)

1. Characteristics of the project

The characteristics of the project must be considered having regard, in particular, to:

- the size of the project[1];
- the use of natural resources;
- the production of waste;
- pollution and nuisances;
- the risk of accidents;
- the impact on the natural and historical heritage having regard to the existing functions of the areas likely to be affected (such as tourism, urban settlement, agriculture).

2. Location of the project

The environmental sensitivity of geographical areas likely to be affected by the project must be considered, having regard, in particular, to:

- the relative abundance, quality and regenerative capacity of natural resources in the area;

- the absorption capacity of the natural environment, paying particular attention to the following areas:

  (a) wetlands;
  (b) coastal zones;
  (c) mountain and forest areas;
  (d) nature reserves and parks;

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[1] The size of the project must be considered in relation to the duration, frequency and reversibility of its likely impacts.

(e) areas already classified or protected under Member States' legislation;
(f) areas in which the environmental quality standards laid down in Community legislation have already been exceeded;

(g) densely populated areas;
(h) landscapes of historical, cultural or archaeological significance."

11. Point 2 in Annex III is replaced by the following:

"2. A description of the main alternatives which might be envisaged and an indication of the main reasons for the developer's choice, taking into account the environmental effects."

12. A new Annex IV is added, as follows:

"ANNEX IV

INFORMATION REFERRED TO IN ARTICLE 7

1. A description of the project together with any available information on the possible transboundary impact.

2. Information on the nature of the decision which may be taken.

3. A reasonable time limit within which the other Member State must indicate whether it intends to take part in the assessment procedure. Notification of such intention shall be accompanied by all available relevant information on the environment in that part of the territory which might be affected.

4. The information gathered pursuant to Article 5.

5. An indication of the date on which a decision will be taken on the project and the time limit, calculated on a reasonable basis, within which the Member State likely to be affected must communicate its opinion to the Member State on whose territory the project is located."