COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.05.1995
COM(95) 163 final /2

ADDENDUM: ANNEXE

WHITE PAPER

PREPARATION OF THE ASSOCIATED COUNTRIES OF CENTRAL AND EASTERN EUROPE FOR INTEGRATION INTO THE INTERNAL MARKET OF THE UNION

(presented by the Commission)

Environment

Direct Taxation

Free Movement of Persons

Public Procurement

Financial Services

Pages 214 - 304

ENVIRONMENT

TABLE OF CONTENTS :

GENERAL INTRODUCTION

Environmental policy is an essential component of the creation of the Internal Market. Both policies are mutually supportive. This special relationship is already recognised in the Single European Act (Article 100a, paragraphs 3 and 4) and is reinforced by Article 2 of the Treaty on European Union, where it is clearly indicated that the completion of the Internal Market will be an important means to reach, inter alia, "a sustainable and non-inflationary growth respecting the environment".

Article 130r (2) provides, inter alia, that Community environment policy shall aim at a high level of protection and that it shall be based on the *precautionary principle*, of the *polluter pays principle,* and that environmental damage, as a priority, should be rectified at the source. It goes on to stipulate that environmental protection requirements must be integrated into the definition and implementation of other Community policies.

These tasks are in particular addressed in the 5th Community programme of policy and action in relation to the environment and sustainable development ("Towards Sustainability"), endorsed by the Council on 1 February 1993, which embodies a strategy and programme for environmental action to the end of the present century and beyond. The guiding principles are "shared responsibility", in terms of a broadly-based involvement, active participation and "integration" into all policies of all economic and social players, including local, regional and national administration.

An integrated approach, to enable a more sustainable path of social and economic development, is not only vital for the environment itself but also for the long-term success of the Internal Market. Its success is dependent on the sustainability of the policies pursued in the fields of industry, energy, transport, agriculture and tourism, which are in turn dependent on the capacity of the environment to sustain them.

1. Environment and the Central and Eastern European countries

These considerations are of particular relevance in the perspective of creati
European market between the European Union and the CEECs. In view also of the transeuropean, transboundary nature of environmental problems, it is of utmost importance that environmental considerations are from the very beginning part of the process of the commercial and economic integration of the Associated Central and Eastern European countries, as part of the pre-accession strategy. This is clearly expressed in the Europe Agreements where, in relation to 'Economic co-operation', it is stated that "policies and other measures will be guided by the principle of sustainable development. These policies ensure that environmental considerations are incorporated from the outset..." (Title VI, Article 1).

The necessity to give a high priority to the structured dialogue in the environmental field was particularly highlighted at the Joint Meeting of the Union's Council of Environment Ministers and the Environment Ministers from the Associated Central and Eastern European countries, which took place on 5 October 1994. Meetings of this kind are agreed to be held on an annual basis. In the conclusions, the Ministers recommend notably "to evaluate priorities for a programme aiming at the convergence of environmental policies and the approximation of the environmental legislation of the Associated states of Central and Eastern Europe."

2. EU environmental legislation

To date, EU legislation in the field of the environment comprises about 200 legal acts which cover a wide range of sectors , including water and air pollution, management of waste and chemicals, biotechnology, radiation protection and nuclear safety, and nature protection. Further to that, several horizontal measures relating, *inter alia,* to the environmental impact assessment of certain public and private projects and access to environmental information, have been adopted. Sector a) of the following is covered in depth in the following fiches. Sectors b), c), d) and e), a very important part of environmental legislation, falls outside the scope of this White Paper, and is therefore not included in the annex.

a) Product-related environmental standards

A substantive number of product-related harmonisation measures follow an environmental objective, whether they are based on Article 100a, or Article 130s. Under this heading comes legislation on chemicals (restrictions on marketing; classification and labelling; environmental control of existing and new substances; export/import of certain dangerous chemicals; ozone-depleting substances; genetically modified organisms; motor vehicle emissions, fuel standards, product-related noise, radiation protection and radioactive contamination of foodstuffs, and the transfer of waste.

These sectors, which are part of the core of the 'Internal Market' legislative body, are outlined in more detail in the descriptive part of to this contribution.

However, these product-related legal acts cannot be seen in isolation from the overall environmental framework required to ensure the sustainability of the Internal Market. To illustrate this with the example of the waste sector, alignment of rules relating to the free circulation must go hand in hand with the establishment of a sound waste-management policy and legislation. This comprises, in particular, an integrated network of treatment facilities as well as the harmonisation of standards for the treatment of waste.

b) Legislation in relation to pollution from stationary sources

In general terms, approximation of legislation in relation to stationary sources is of importance not only from an environmental point of view, but also with a view to remedying to distortions of competition which would be created by differing environmental standards and regulations.

EU legislation on the environmental control of industrial installations includes :

- Council Directive 76/464/EEC (OJ L129 - 18/5/76) on pollution caused by certain dangerous substances in the aquatic environment of the Community, and its "daughter Directives;
- Council Directive 84/360/EEC (OJ L188 - 16/7/84) on combating air pollution from industrial plants, and its daughter Directives on large combustion plants, municipal waste incineration plants and hazardous waste incineration plants;
- Council Directives 78/176/EEC (OJ L54 - 25/2/78), 92/112/EEC (OJ L409 - 31/12/92) on waste from the titanium dioxide industry;
- Council Directive 88/604/EEC of 24/11/88 (OJ L336 - 7/12/88) on major accident hazards of certain industrial activities.

An important proposal on the integrated pollution prevention and control, to deal with all forms of pollution from stationary sources, is under discussion in the Council.

These measures are complemented by Council Regulation 1836/93/EEC of 28/6/93 (OJ L168 - 10/7/93) establishing a voluntary eco-audit scheme enabling firms to have their environmental performance certified.

c) Further legislation on air and water pollution

Legislation on emissions to the air from mobile and stationary sources is completed by air quality standards relating to SO2/particulates, NO2 and lead and Council Directive 92/72/EEC of 21 September 1992 (OJ L297 - 13/10/92) on air pollution by ozone, which also provide for monitoring and information exchange.

In relation to water pollution, in addition to those Directives relating to discharges from stationary sources, or pollution from specific industries, a number of legal acts lay down quality objectives or other requirements for water intended for specific uses; water for human consumption, bathing waters and the quality of water required for fish or shellfish.

Council Directive 91/676/EEC of 12 December 1991 (OJ L375 - 31/12/91) concerning the protection of waters against pollution caused by nitrates from agricultural sources relates again to a specific sector, whereas Council Directive 91/271/EEC of 21 May 1991 (OJ L135 - 30/5/91) on urban waste water treatment constitutes a departure from these problem-specific measures.

d) Nature protection

The first steps in instituting a Community level of protection of species were taken in 1979, with the adoption of Council Directive 79/409/EEC of 2 April 1979 (OJ L103 - 25/4/79) on the conservation of wild birds. Another key element of legislation in this field is Council Directive 92/43/EEC of 21 May 1992 (OJ L206 - 22/7/92) on the conservation of natural habitats of wild fauna and flora.

In relation to international trade, Council Regulation 82/3626/EEC of 3 December 1982 (OJ L384 - 31/12/82), implementing the Washington Convention on inter-national trade in endangered species of wild fauna and flora (CITES), subsequently added to by a series of modifications, is a central piece of EU legislation in this area.

e) Horizontal measures

A fundamental tool of environmental legislation is Council Directive 85/337/EEC of 27 June 1985 (OJ L175 - 5/7/85) on the assessment of the effects of certain public and private projects on the environment ('Environmental impact assessment'), which requires Member States to ensure that an environmental impact assessment is carried out before development consent is granted for the types of project specified in the Directive. Therefore, it is a basic tool to uphold the implementation of environmental legislation in general.

Lastly, the Directive 90/313/EEC of 7 June 1990 (OJ L158 - 23/6/90) on access to environmental information is to contribute to more transparency for the individual citizen, and the voluntary ecolabel scheme, established by Council Regulation 92/880/EEC, of 23 March 1992, contributes to 'informed choice' of consumers in relation to the environmental performance of products.

Conclusion

As is illustrated by the above, the present exercise covers only a small part of EU environmental legislation, namely those acts directly related to the free circulation of products. An important part of the EU environmental acquis relating to air and water pollution, to nature protection, but also to the overall framework for waste management, and horizontal instruments, falls out of the scope of the present document.

The "Internal Market" approach needs to be complemented by an overall assessment of present EU environmental policy and legislation in relation to the future approximation of laws by the Central and Eastern European countries, in order to define priorities within a timescale. This process will take some time, and needs to be followed up closely and in a coherent way in the frame of the structured dialogue, and in other fora like the 'Environment for Europe' process. In the meantime, the PHARE programme will continue to be used to improve the situation.

The major task will be to assist the Central and Eastern European countries in such a way that they will be able to take over EU legislation together with a system capable of practical implementation and enforcement.

I. RADIOACTIVE CONTAMINATION OF FOODSTUFFS

DESCRIPTION OF THE LEGISLATION

All foodstuffs placed on the market for human consumption and all animal feedingstuffs offered for sale have been required to comply with contamination limits since the Chernobyl accident and as a precautionary measure in the event of any future accident.

It has been found to be necessary for the proper management of Regulation 737/90/EEC for the Member States to submit regular reports of the measures carried out to the central body (the Commission).

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

An inspection and control system is essential for the application of the legislation. It must be possible to carry out tests, in the event of any future accident, to determine the level of (radioactive) contamination of food products available on the national market. Regulation Euratom/90/737 applies in the present situation following the Chernobyl accident and requires similar controls to be carried out at the external frontiers to determine the level of contamination of imported foodstuffs.

KEY MEASURES

In view of the implications of this legislation for public health, it is not possible to separate its various parts. It is a body of legislation within which individual measures cannot be categorized, in a hierarchy of importance, as being essential, a priority (Stage I) or a lower priority (Stage II).

- *CHOICE OF STAGE I MEASURES*

DESCRIPTION & JUSTIFICATION :

Regulation EEC/90/737, which extends Regulation EEC/3955/87 and is due to expire on 31 March *2000*, lays down the present conditions governing imports of agricultural products processed within the European Union following the Chernobyl nuclear accident. It specifies maximum permissible levels of radioactive contamination for a limited list of products to be marketed *(for the products' list see Regulation EC/3034/94).*

Regulation Euratom/87/3954 defines the procedure to be followed for laying down maximum permitted levels of radioactive contamination of foodstuffs and feedingstuffs sold following a nuclear accident. Contrary to Regulation EEC/90/737, this Regulation does not apply to the current situation following the Chernobyl accident.

STAGE I MEASURES

Regulation EEC/90/737 OJ L 82 of 29.3.1990 as supplemented by *Regulation EC/3034/94* *OJ L321 of 14.12.94*	Council Regulation EEC/737/1990 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Tchernobyl nuclear power-station
Regulation Euratom 3954/87 OJ L 371 of 30/12/87 as supplemented by - Regulation Euratom 770/90 OJ L 83 - 30/3/90 - Regulation EEC/2219/89 OJ L 211 - 22/7/89 - Regulation Euratom 944/89 OJ L 101 - 13/04/89	Council Regulation Euratom/3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following nuclear accident or any other case of radiological emergency.

DESCRIPTION OF THE LEGISLATION

The purpose of radiation protection legislation is to protect the general public, workers and the environment against the dangers of ionizing radiation. Economic activities which involve the use of products that emit ionizing radiation are therefore subject to a reporting or authorization requirement.

Directive 80/836/Euratom provides for a general requirement for reporting and obtaining prior authorization and is due to be revised. This Directive does not constitute total harmonization since exemption is optional and because the Member States themselves decide whether to justify (or prohibit) an activity and are able, for some activities, to decide whether to require reporting or prior authorization.

In view of the flexibility given to the Member States, no major problems have arisen in the Member States with regard to the transposition of the Directive.

The recent application of the legislation regarding the shipment of radioactive substances and radioactive waste has also not given rise to any particular difficulties.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximations in this area presupposes the existence of a national regulatory authority with administrative powers of authorization, surveillance and inspection:

- Implementation of the requirements concerning the reporting and authorization of the production, processing, handling, use, holding, storage, transport and disposal of radioactive substances (Article 2 of Directive 80/836/Euratom) and authorization of the manufacture and importation of consumer goods, medicinal products and medical devices containing radioactive substances (Article 5 of the Directive) presupposes the existence of authorities of this kind;

- the total of the contribution of each of these activities to the exposure of the population as a whole must be kept under review (Article 13 of the Directive);

- each Member State is required to establish a system of inspection to supervise the protection of the health of the population (Article 45 of the Directive).

Infrastructure

The authorities must be able to call on the services of approved radiochemistry or radiophysics laboratories in order to measure the quantity of radioisotopes (radioactivity) present in products for which marketing authorization is planned.

The authorities must also have the necessary equipment so that, after marketing, they are able to keep a record of all radioactive sources above a certain radioactivity threshold which are used in industry, agriculture, the medical sector or for research purposes. It must also be possible to monitor the use of the most radioactive sources at all stages up to and including disposal.

The Directive on the shipment of radioactive waste requires that, in the case of shipments from the European Union to the CEEC, the latter countries have at their disposal the technical, legislative and administrative resources needed for the safe management of the radioactive waste (see Article 11 of the Directive).

KEY MEASURES

In view of the implications of this legislation for public health, it is not possible to separate its various parts. It is a body of legislation within which individual measures cannot be categorized,in a hierarchy of importance, as being essential, a priority (Stage I) or a lower priority (Stage II).

STAGE I MEASURES

Directive 80/836/EURATOM OJ L246 of 17.09.1980 as amended by Directive 84/467/Euratom (OJ L265 of 5.10.1984	Council Directive 80/836/EURATOM of 15.7.1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation. The Directive defines a system of reporting and obtaining authorization for any activity involving ionizing radiation, including the production and marketing of products. The Commission has submitted an amended proposal for the revision of the Directive (COM(94)298 final) aimed in particular at increasing the level of harmonization of the system of reporting and obtaining authorization in the context of the single market.

Directive 92/3/EURATOM OJ L35 of 12.12.1992 as supplemented by Decision 93/552/Euratom OJ L268 of 29.10.1993	Council Directive 92/3/EURATOM of 3.2.1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. This Directive has been supplemented by Commission Decision 93/552/Euratom establishing a standard document for transfers.

Regulation 93/1493/EURATOM OJ L148 of 19.6.1993	Regulation 93/1493/EURATOM: Following the abolition of frontier controls in the Community on 1 January 1993, the aim of this Regulation is to lay down a Community system for the declaration and provision of information relating to shipments of radioactive substances between the Member States. This system does not apply to radioactive waste covered by Directive 92/3/Euratom.

- ***CHOICE OF STAGE II MEASURES :***

  DESCRIPTION & JUSTIFICATION :

  Supplementary regulations may be found to be necessary for radiation protection in respect of the use of particular types of equipment or sources which emit ionizing radiation, e.g. medical devices, accelerators, consumer goods.

III. CHEMICAL SUBSTANCES

INTRODUCTION

Responsibility for the control of chemicals and their derivatives is allocated between several Directorates-General of the European Commission depending on the particular chemical properties and their use and impact on health and the environment.

This allocation is also due to the way in which specific tasks are assigned to each Directorate-General and the history of Commission policy in the chemical sector.

DG IX (Environment) is responsible for regulations concerning dangerous substances, the control of existing and new substances, non-agricultural pesticides (biocides) and the import/export of certain dangerous chemicals.

Certain other aspects are covered by other Directorates-General:

- the use of chemicals at the workplace is the responsibility of DG V (Social Affairs);
- the agricultural use of phyto-pharmaceutical products is managed by DG VI (Agriculture);
- the transport of dangerous chemical products is dealt with by DG VII (Transport).

Aspects of a more commercial nature concerning the marketing of products or dangerous preparations are covered by DG III (Industry). This Directorate-General is also responsible for Directives and Regulations concerning the placing on the market of dangerous substances and preparations, detergents and fertilizers and the framework regulations on dangerous preparations.

All of these legal instruments are therefore closely interlinked as regards the concept of control, the definitions and their scope.

Each Directorate-General that is responsible for one or more legal instruments (Regulations or Directives concerning the control of chemical products) works in close cooperation with the other Directorates-General concerned both in framing the proposal for a Regulation or amendments to it and in consulting the Member States or industries concerned.

1. *THE PLACING ON THE MARKET OF DANGEROUS SUBSTANCES*

INTRODUCTION:

The placing on the market of dangerous substances is governed at Community level by requirements concerning the labelling, packaging and classification of the products or preparations containing them.

The aim of the Community instruments is to achieve harmonization by laying down, in particular, general classification criteria and the individual classification of each substance on the basis of the risk to man and the environment.

The rules are laid down in Directive 67/548/EEC (OJ L 196 of 16.8.1967) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended (seven amendments so far), and adapted to technical progress (21 adaptations). See "Stage I measures".

DESCRIPTION OF THE LEGISLATION :

The aim of Directive 67/548/EEC is to harmonize the classification of dangerous substances according to risk, including the environmental risk, their labelling in order to ensure the safety of the people who handle them and their packaging.

These provisions in particular permit the application of Directive 88/379/EEC (OJ L 187 of 16.7.1988) relating to dangerous preparations (see also contribution on the free movement and safety of industrial products).

If the Directive does not specify the particular kind of control infrastructure to be set up, this together with the degree of control must be decided by the Member State itself.

It is importers and small or medium-sized enterprises (SME) which seem to have most difficulty and most work in applying the current provisions (including toxicological data searches, the preparation of appropriate labels and the drafting of appropriate "Safety data sheets").

There are also difficulties with regard to international trade in products and their authorization for use in third countries (these concern missing information, the improper interpretation of classifications, indirect measures to restrict the market and even economic dumping).

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

In principle, there are two aspects to the regulatory provisions of Directive 67/548:

- the classification, labelling, packaging and safety data sheets for all dangerous substances;
- the notification of new substances and their classification/labelling (see point 2).

The classification of a substance serves to identify the particular hazard it poses. It is based on the intrinsic properties of the substance (or preparation) in accordance with one of the hazard categories defined in Article 2 supplemented by the detailed information given in Annex VI.

The criteria in Annex VI include a general reference to the methods for the determination of the dangerous properties described in Annex V to the Directive.

The labelling depends on the classification of the substance and provides information on the hazard posed to the user of the product under normal conditions of use.

The information is given in the form of:

- hazard symbols, as described in Annex II;
- risk phrases ("R" phrases), as given in Annex IV;
- safety phrases ("S" phrases), as given in Annex IV.

The wording of the phrases must not be changed. Annex VI (Guide to classification and labelling) clearly stipulates the conditions for the use of the S and R phrases in order to guarantee a uniform system of presentation throughout the European Union.

For some substances, the classification and labelling are agreed at Community level, these being given in Annex I to the Directive concerned.

This Annex is not a definitive version since other substances are also being developed. A large number of adaptations to technical progress have already been made and more will follow.

If no Community classification of a particular product exists, the producer or importer is obliged, in accordance with the rules laid down in Annex VI (provisional labelling), to classify and label the substance on the basis of the information available to him.

Articles 22, 23 and 24 provide for the introduction by the Member States of national legislation on the labelling, packaging and classification of dangerous substances.