COUNCIL OF THE EUROPEAN COMMUNITIES
GENERAL SECRETARIAT

PRESS RELEASE

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1634th Council meeting

- INTERNAL MARKET -

Brussels, 17 and 18 December 1992

President: Mr Richard NEEDHAM

Minister of State
Department of Trade
and Industry of the
United Kingdom

The Governments of the Member States and the Commission of the European Communities were represented as follows:

Belgium Mr Robert URBAIN:	Minister for Foreign Trade and European Affairs
Denmark: Mrs Anne Birgitte LUNDHOLT Mr Christopher Bo BRAMSEN	Minister for Industry State Secretary for Industry
Germany: Mr Johann EEKHOFF	State Secretary, Federal Ministry of Economic Affairs
Greece: Mr Georges THEOFANOUS	Secretary-General, Ministry of Trade
Spain: Mr Carlos WESTENDORP	State Secretary for Relations with the European Communities
France: Mrs Elizabeth GUIGOU	Minister for European Affairs
Ireland: Mr Bertie AHERN	Minister for Finance
Italy: Mr Raffaele COSTA	Minister for Community Policies
Luxembourg: Mr Georges WOHLFART	State Secretary for Foreign Affairs and Foreign Trade
Netherlands: Mr Piet DANKERT	State Secretary for Foreign Affairs
Portugal: Mr Vitor MARTINS	State Secretary for European Integration
United Kingdom: Mr Richard NEEDHAM	Minister of State, Department of Trade and Industry

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Commission: Mrs Christiane SCRIVENER Mr Karel VAN MIERT	Member Member

FUTURE SYSTEM FOR THE FREE MOVEMENT OF MEDICINAL PRODUCTS IN THE COMMUNITY

The Council adopted common positions on

- the amendments to Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to medicinal products;

- the repealing of Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology;

- the amendment of Directives 81/851/EEC and 81/852/EEC on the harmonization of the laws of the Member States in respect of veterinary medicinal products.

The Council also gave its political agreement to the Regulation laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

This legislative package is aimed at ensuring that there is a genuine single market in medicinal products, and it supplements the technical harmonization in the pharmaceuticals sector begun in 1965 and completed at the beginning of this year with the adoption of the Directives on the rational use of medicinal products for human use.

The main features of this new system for the free movement of medicinal products are summarized below:

- It establishes a new centralized procedure leading to a Community authorization directly valid in all the Member States for the most innovative medicinal products. The Community is, moreover, responsible for monitoring medicinal products authorized under this procedure and for the technical updating of the authorizations.

  The centralized procedure is compulsory for biotechnological and veterinary medicinal products intended to increase productivity and is optional for other innovative medicinal products.

- The decentralized procedure, which is based on the principle of mutual recognition of national authorizations and which enables marketing authorizations issued by one Member State to be extended to other Member States, has been reinforced.

  The decentralized procedure is based on experience acquired using the multi-State Community procedure set up in this sector in 1983, and will enable a firm which has obtained an authorization in one Member State to apply for one or more Member States to accept that authorization, with binding arbitration at Community level in the event of non-acceptance by one of the Member States concerned.

  After a period of three years during which the decentralized procedure would remain optional, this procedure will become compulsory whenever a request for authorization concerns more than one Member State, in order to ensure that decisions are uniform throughout the internal market.

- A European Agency for the Evaluation of Medicinal Products supplying appropriate logistical support for the proper functioning of these two procedures is established. The new Agency will encompass in particular the present Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, which will be at the head of its scientific structures.

- Co-operation and, where appropriate, co-ordination procedures regarding pharmacovigilance (monitoring of the side effects of medicinal products) have been introduced.

It should be pointed out that, following discussions at recent meetings of the Internal Market Council, the legal basis envisaged for the Regulation is Article 235 of the EEC Treaty, and the European Parliament will be consulted anew on this subject. The common positions will be sent to the European Parliament for a second reading, in the normal framework of the co-operation procedure.

The seat of the future Agency will be decided later.

EXPLOSIVES FOR CIVIL USES

The Council adopted the common position on the Directive on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses. The purpose of the Directive is to lay down both the conditions necessary for the supervision of such explosives, particularly at the stages of manufacture and placing on the market - to which end the Directive follows ln particular the provisions of the 1985 Resolution on the new approach to standards - and the conditions under which explosives may be transferred within the Community.

Regarding transfer, the Directive provides for the establishment of a system making transfers within the Community subject to the possession of a specific authorization. Annex I to the Directive contains a list of essential safety requirements which explosives covered by the Directive must satisfy.

It should be noted that, as it will not be possible for the Directive to enter into force by 1 January 1993, the Council has agreed to a statement establishing a procedure for co-operation among the Member States which will involve exchange of the information necessary to supervise transfers of explosives after 1 January 1993.

MEDICAL DEVICES

The Council gave its political agreement to the adoption of a common position on the proposal for a Directive relating to medical devices.

This proposal, which was submitted in connection with the white paper on completion of the internal market, is intended to harmonize, following the "new approach" procedure, the conditions for placing medical devices on the market and putting them into service, in order to ensure the safety and health protection of patients and users.

Devices must comply with the essential requirements in Annex I to the Directive and follow the classification system laid down in Annex 9 for certification of conformity with the provisions of the Directive.

The Permanent Representatives Committee was instructed to finalize the texts with a view to formal adoption of the common position without further debate at a forthcoming Council meeting.

COPYRIGHT AND NEIGHBOURING RIGHTS APPLICABLE TO SATELLITE BROADCASTING AND CABLE RETRANSMISSION

The Council held a detailed discussion on the few problems which must be resolved before a common position on the Directive on the co-ordination of certain rules concerning copyright and neighbouring rights applicable to satellite broadcasting and cable retransmission can be adopted.

The purpose of the proposal is to supplement the Directive on television without frontiers (EEC/89/552) by Community provisions on copyright, making a distinction between the fields of satellite broadcasting and cable retransmission and limiting its objective to the harmonization necessary for the exercise of cross-border activities.

With regard to satellite broadcasting, the proposal makes broadcasting subject to authorization by the rightholder and stipulates that the authorization must be obtained in the country of origin of the broadcast. It also provides that the level of protection for performers, phonogram producers and broadcasting organizations is that provided for by Directive 92/100/EEC of 19 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property.

Cable retransmission rights must be negotiated exclusively through the intermediary of collecting societies representing the different categories of rightholders, with the exception of broadcasting organizations.

In the light of the points made during its discussion, particularly in connection with co-production contracts and cable retransmission rights, the Council instructed the Permanent Representatives Committee to seek appropriate solutions to the questions outstanding with a view to the adoption of a common position at its next meeting.

COMMUNITY TRADE MARK

Following a very detailed discussion, which concerned the rules governing the languages of the Office, the Council, having failed to reach a consensus, instructed the Permanent Representatives Committee to continue examining this problem.

LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Pending receipt of the re-examined proposal which the Commission is to submit in the light of the amendments proposed by the European Parliament, the Council took note of a progress report from the Presidency on the discussions on the proposal for a Directive on the legal protection of biotechnological inventions.

The purpose of the proposal is to protect biotechnological inventions and to foster the innovatory potential and competitiveness of Community science and industry in this field. It makes it compulsory for Member States to ensure that their legislation on patents is in accordance with the provisions of the Directive, which establishes the possibility of patenting living matter, determines the extent of the protection of patented biotechnlological inventions, deals with licences to market plants and the deposit of, access to and redeposit of micro-organisms and other self-reproducing matter.

CHECKS ON THE CONFORMITY OF PRODUCTS IMPORTED FROM THIRD COUNTRIES

The Council held a policy debate on the proposal for a Regulation on checks on the conformity of goods imported from third countries with the rules applicable in the field of product safety.

The essential purpose of this proposal is, with a view to the abolition of internal frontiers on 1 January 1993, to set up a legal instrument strengthening customs regulations so that a customs authority may intervene at an external frontier before the release for free circulation of a product imported from a third country where that product may be dangerous or not in conformity with existing Community or national rules. The customs administration would therefore act on behalf of all the Member States and the products in question would be able to move freely throughout the Community once they had crossed the external frontier.

After its debate, which concentrated mainly on the scope and legal basis of the Regulation, the Council agreed that discussions on this dossier should be resumed as soon as possible with the aim of adoption at the Internal Market Council meeting in February 1993.

ABOLITION OF BORDER CHECKS AND COMPLETION OF THE INTERNAL MARKET

Informally over lunch, the Council took note of two oral communications by the Commission on progress on, respectively, the abolition of checks at intra-Community borders and the completion of the internal market.

FOODSTUFFS - ADDITIVES AND SWEETENERS

Pending receipt of the Opinions of the European Parliament and the Economic and Social Committee on the proposal amending the framework Directive on additives (89/107/EEC), the Council held a policy debate on that proposal and on the proposal on sweeteners in foodstuffs. The proposal on sweeteners is a specific Directive pursuant to the comprehensive Directive 89/107/EEC on additives.

These proposals were submitted by the Commission following the European Parliament's rejection, in May 1992, of the common position on the Directive on sweeteners. In these circumstances, the proposal to amend the framework Directive provides for a procedure enabling derogations to be accorded from the general rules on additives in order to protect the national production of certain traditional foodstuffs, without prejudice to the principles of the single market, in particular the free movement of goods and freedom of establishment.

DUAL-USE GOODS AND TECHNOLOGIES

The Council took note of a Presidency report on progress on the proposal for a Regulation on the control of exports of certain dual-use goods and technologies and of certain nuclear products and technologies.

It also examined a draft statement dealing essentially with the type of controls to be carried out on these goods from 1 January 1993 pending the formal adoption of the Regulation.

Formal adoption of that statement was referred to the General Affairs Council scheduled for 21 December 1992.

LABELLING OF FOOTWEAR

The Council held a policy debate on the proposal for a Directive on the labelling of the materials used in the main components of footwear for sale to the final consumer.

The purpose of the proposal is to ensure the free movement of footwear and to provide the consumer with reliable information by means of a system of labelling of the materials used in the main components of such footwear.

The debate centred on the advisability of a Directive in this field, and on the principles on which the Directive should be based. Following the debate, during which most delegations were able to give their support to the idea of such a Directive, the Commission confirmed, as announced at the Edinburgh summit, that it would be reconsidering the approach to be adopted.

FRUITS AND FRUIT JUICES

The Council adopted the Regulation opening and providing for the administration of Community tariff quotas for certain fruits and fruit juices.

OTHER DECISIONS IN THE INTERNAL MARKET FIELD

Machinery

The Council adopted the common position regarding amendment of Directive 89/392/EEC (as amended by Directive 91/368/EEC) on the approximation of the laws of the Member States relating to machinery.

The purpose of this Directive is both to amend certain provisions of Directives 89/392/EEC (fixed machinery) and 91/368/EEC (mobile machinery and lifting equipment) and to supplement these two Directives with additional requirements for equipment, other than lifts, intended for raising or moving persons. More specifically, it lays down essential additional safety and health requirements for these kinds of machines.

Controls carried out in the field of road and inland-waterway transport

The Council adopted the Regulation on Community controls in the field of road and inland-waterway transport.

This Regulation forms part of the measures which must be implemented for completion of the internal market; in substance, it provides that controls carried out by the Member States concerning means of road and inland-waterway transport registered or put into circulation in a third country will no longer be performed as controls at the internal borders of the Community, but as normal controls carried out throughout Community territory.

Statistical units for the observation and analysis of the production system in the European Community

The Council adopted the common position on the Regulation on the statistical units for the observation and analysis of the production system in the Community.

This regulation establishes a list of statistical units relating to the production system, the criteria used, definitions of the units and explanatory notes. Its purpose, in the context of the internal market is to establish the statistical norms necessary to identify units, and the collection, transmission and publication of national and Community statistics in order to make reliable and comparable information available to enterprises, financial institutions, governments and all other operators in the internal market.

Customs agents

The Council adopted the Regulation on measures to adapt the profession of customs agent to the internal market.

This Regulation contains measures supplementing those taken by the Member States to facilitate the adaptation of the profession of customs agent to the internal market. In particular, the Community action is designed to supplement the measures taken under the Structural Funds by:

- providing assistance for the areas notified by each Member State to the Commission as being the hardest hit by the abolition of customs formalities;

- promoting the conversion and/or restructuring of weakened but viable enterprises to save the maximum number of jobs.

Braking of two or three-wheel motor vehicles

Following the adoption on 18 June 1992 of the framework Directive 92/61/EEC laying down the administrative details of type-approval of two or three-wheel motor vehicles and component type-approval, the Council adopted the common position on the individual implementing Directive on the breaking of such vehicles. The framework Directive drew up a list of the components and characteristics of these vehicles which must be the subject of individual Directives laying down the technical requirements applicable to them.

External projections forward of the cab's rear panel of motor vehicles of category N

Following the common position adopted at its meeting on 18 June 1992 and the completion of the co-operation procedure with the European Parliament, the Council adopted the Directive relating to external projections forward of the cab's rear panel of motor vehicles of category N.

The purpose of this Directive is, by means of technical provisions, to ensure that goods vehicles do not have sharp external projections, in order to reduce the severity of injuries sustained by a person coming into contact with the external surface of the vehicle in the event of an accident.

Extraction solvents

Following the common position adopted at its meeting on 29 June 1992 and the completion of the co-operation procedure with the European Parliament, the Council formally adopted the amendment to Directive 88/344/EEC on the approximation of the laws of the Member States relating to extraction solvents used in the production of foodstuffs and food ingredients.

The purpose of this amendment, provided for in Article 2 of Directive 88/344/EEC, is both to regulate certain substances hitherto governed by national legislation and to revise the existing provisions, in particular Annex II to the 1988 Directive.

The Community legislation in this field is generally intended to harmonize national legislation on extraction solvents in order to facilitate the free movement of foodstuffs, while ensuring health protection.

Hygiene of foodstuffs

The Council adopted the common position on the Directive on the hygiene of foodstuffs.

The purpose of the Directive is to supplement Directive 89/397/EEC on the official control of foodstuffs by laying down general rules aimed at improving the level of food hygiene in the Community at all stages of production and sale to the final consumer, and to verify that these rules are observed by operators.

MISCELLANEOUS DECISIONS

Telecommunications

Following the agreement in principle reached at the Telecommunications Council on 19 November 1992, the Council formally adopted the Resolution on the assessment for 1992 of the situation in the telecommunications sector - towards cost orientation and the adjustment of pricing structures and telecommunications tariffs in the Community (see Press Release 10085/92).

Customs union

The Council adopted the Regulation opening and providing for the administration of Community tariff quotas for certain agricultural and industrial products (first series 1993).

Consumer protection - cosmetic products

Following the agreement reached at the Consumer Protection Council on 3 November 1992 and after finalization of the texts, the Council adopted the common position on the Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

The amendment is designed to improve and harmonize information for consumers and supervisory authorities on cosmetic products marketed in the Community and thereby to eliminate the last remaining risks of barriers to the free movement of such products in the single market. It also deals with the banning of animal experiments in the cosmetics industry.

Fisheries

As the European Parliament had delivered its Opinion on 20 November 1992, the Council adopted the Regulation on the common organization of the market in fishery products, which had been the subject of political agreement at the Fisheries Council on 19 October 1992 (see Press Release 9041/92 Press 178).