COUNCIL OF THE EUROPEAN COMMUNITIES
GENERAL SECRETARIAT

PRESS RELEASE

8635/92 (Presse 161)

1603rd Council meeting

- INTERNAL MARKET -

Brussels, 22 September 1992

President: Mr Richard NEEDHAM

Minister for Trade and Industry of the United Kingdom

Press Service ... Rue de la Loi 170 ... 1048 B...
Tel 2346... 2346319 ... 2345...

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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:	
Mr Bo BRAMSEN	State Secretary for Industry
Germany:	
Mr Johann EEKHOFF	State Secretary, Federal Ministry of Economic Affairs
Greece:	
Mrs Anna PSAROUDA-BENAKI	Minister for Culture
Mr Georges THEOFANOUS	Secretary-General, Ministry of Trade
Spain:	
Mr Carlos WESTENDORP	State Secretary for Relations with the European Communities
France:	
Mr Pierre SELLAL	Deputy Permanent Representative
Ireland:	
Mr Desmond O'MALLEY	Minister for Industry and Commerce
Italy:	
Mr Raffaele COSTA	Minister for Community Policies
Mr Alberto RONCHEY	Minister for Culture

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 for Trade and Industry
Mr Neil HAMILTON	Parliamentary Under-Secretary of State for Trade and Industry

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Commission:

Mr Martin BANGEMANN	Vice-President
Mr Jean DONDELINGER	Member

FUTURE SYSTEM FOR THE FREE MOVEMENT OF MEDICINAL PRODUCTS

The Council reached broad agreement on the principles of the future system for the free movement of medicinal products as drawn up by the Permanent Representatives Committee on the basis of the political guidelines laid down by the Internal Market Council on 18 June 1992.

The main aspects of the system are as follows:

- the creation of a new, centralized Community procedure for the most innovatory medicinal products, leading to a Community authorization valid in all Member States. The Community is, moreover, responsible for monitoring the medicinal product authorized in accordance with that procedure and for the technical updating of the authorization;

- a decentralized procedure, based on the principle of mutual recognition of national authorizations and allowing the extension of marketing authorizations from one Member State to other Member States.

  The above procedure, which is based on experience with the multi-State procedure introduced in this sector in 1983, should enable accompany which has obtained an authorization in one Member State to ask 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.

  The Commission proposes that, following an initial 3-year period during which the decentralized procedure would remain optional, the procedure should become compulsory each time the request for

authorization concerns more than one Member State, so as to ensure uniform decisions throughout the internal market;

- the establishment of a European Agency for the Evaluation of Medicinal Products, providing appropriate logistical support for the proper functioning of the two procedures. The new Agency will encompass in particular the current Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, which will be at the head of its scientific structures;

- co-operation is also envisaged and, where appropriate, co-ordination with regard to pharmacovigilance (monitoring of the secondary effects of medicinal products).

The Permanent Representatives Committee was called upon to finalize the texts with a view to their formal adoption in the near future.

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REGULATION ON THE COMMUNITY TRADE MARK

With a view to adopting the Regulation on the Community trade mark at its next meeting, or in December at the latest, the Council conducted a policy debate on certain basic issues still outstanding. The Council discussed the following questions in particular:

- form of the act to be adopted (Community Regulation or international convention);

- powers of the Court of First Instance (CFI) with regard to disputes;

- number and possible selection of working languages;

- level and means of protection of earlier Community and national marks;

- budgetary provisions (financial independence of the Office or inclusion in the Community budget);

- power to appoint the senior officials of the Office.

At the end of the discussion the Council recorded broad agreement on a number of options and points; as the details thereof remained to be defined, they were passed on to the Permanent Representatives Committee with a view to reaching an overall compromise proposal, possibly for submission to the meeting on 10 November.

UNFAIR TERMS IN CONSUMER CONTRACTS

The Council adopted a common position on the Directive on unfair terms in consumer contracts, further to the agreement reached at the Consumer Council on 29 June 1992 (see press release, 7459/92 presse 131).

The text in question should contribute to the completion of the Single Market, as it constitutes an important step towards improving consumer protection by approximating, by 31 December 1994 at the latest, the laws, regulations and administrative provisions of the Member States relating to non-negotiated unfair terms in contracts concluded between a consumer and a seller or supplier acting for purposes relating to his public or private trade, business or profession.

LABELLING OF HOUSEHOLD APPLIANCES

Following the procedure for co-operation with the European Parliament and consultation of the Economic and Social Committee, the Council adopted the Directive on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances.

The Directive, the text of which is in line with the common position adopted by the Council on 21 May 1992, should enable consumers to choose appliances with a better energy yield.

It represents an important aspect of the Community strategy to improve energy efficiency, in particular with a view to the completion of the internal market on 1 January 1993.

AFTER 1992

On the basis of a Presidency note, the Council held a policy discussion on the means required to ensure the proper functioning of the Single Market after the end of 1992.

Pending the report which the Sutherland Committee is to submit to the Commission in October, the Council decided to resume its examination of the issue at its meeting scheduled for 10 November 1992.

ABOLITION OF BORDER CONTROLS ON GOODS, CAPITAL AND SERVICES

The Council took note of an oral statement by Vice-President BANGEMANN on two Commission communications concerning:

- the abolition of border controls on goods, capital and services;

- progress towards completing the internal market.

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CULTURAL GOODS

The Council continued the discussion on the proposal for a Regulation on the export of cultural goods and the proposal for a Directive on the return of cultural objects unlawfully removed from the territory of a Member State.

At the end of the discussion the Council instructed the Permanent Representatives Committee to continue proceedings with a view to adoption of the Regulation and of a common position on the Directive at its meeting on 10 November 1992.

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OTHER DECISIONS IN THE FIELD OF THE INTERNAL MARKET

Medicinal products

Following completion of the procedure for co-operation with the European Parliament, the Council adopted:

- the Directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws, regulations and administrative provisions of the Member States on medicinal products and laying down additional provisions on homeopathic medicinal products;

- the Directive widening the scope of Directive 81/851/EEC on the approximation of the laws, regulations and administrative provisions of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products.

The purpose of these two Directives is to extend Community pharmaceutical legislation to homeopathic medicinal products for human and veterinary uses.

Foodstuffs

= Contaminants in food

The Council adopted a common position on the Regulation aimed at laying down harmonized Community procedures for the determination of the possible toxicity of contaminants in food.

The main objective of the Directive is to prohibit the placing on the market of food containing a contaminant in an amount which is unacceptable in public health and toxicological terms.

It should be noted that the Directive states that "contaminant" means any substance not intentionally added to food as a result of production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding, or as a result of environmental contamination.

= Co-operation in the scientific examination of questions relating to food

The Council adopted a common position on the Directive aimed at providing the Scientific Committee for Food with the necessary resources for carrying out the various scientific and pre-legislative tasks required by the programme on the internal market and by the implementation of existing legislation on food.

More specifically, the Directive stipulates that the Member States' competent authorities and bodies shall co-operate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest in the field of public health, through disciplines such as those associated with medicine, nutrition, toxicology, biology, hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques, physics and chemistry.

Action plan for the exchange of national officials who are engaged in the implementation of Community legislation required to achieve the internal market

Further to completion of the procedure for co-operation with the European Parliament, the Council adopted the Decision on the adoption of an action plan for the exchange, between Member State administrations, of national officials who are engaged in the implementation of Community legislation required to achieve the internal market.

It should be noted that the action plan uses as a model the "Matthaeus" programme, extending it to the internal market field as a whole. The objective of the exchanges is to allow a more homogeneous approach to the implementation of Community legislation, in particular by making national officials aware of the European dimension of their work and by building mutual confidence between Member State administrations. Exchanges between Member State administrations are in principle for a minimum of two months.

The action plan is spread over five years. The Community financial resources estimated as necessary for its implementation amount to ECU 17,3 million, corresponding to an overall figure of 1 900 participants. The financing of the programme is shared between the Community and its Member States.

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MISCELLANEOUS DECISION

Appointment

The Council replaced an alternate member of the Advisory Committee on Vocational Training.