

14365/02 (Presse 360)

2467th Council meeting

- COMPETITIVENESS (Internal Market, Industry, Research) -

Brussels, 26 November 2002

President : **Mr Bendt BENDTSEN**, Minister for Economic
Affairs, and

Mr Helge SANDER, Minister for Science,
Technology and Innovation

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- *Where declarations, conclusions or resolutions have been formally adopted by the Council, this is indicated in the heading for the item concerned and the text is placed between quotation marks.*
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Minister for Higher Education, Further Education and Scientific Research (French Community)

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Minister for Economic Affairs, Trade and Industry

Mr Helge SANDER

Minister for Science, Technology and Innovation

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* * *

Commission :

Mr Mario MONTI
Mr Erkki LIIKANEN
Mr Philippe BUSQUIN

Member
Member
Member

ITEMS DEBATED

Horizontal issues

COMPETITIVENESS AND THE BUSINESS ENVIRONMENT - Council conclusions

The Council took note of the presentation by the Commission of its communication entitled "*Better environment for enterprises*" and related working papers. It held an exchange of views on the use of quantitative targets in pursuing the economic reform strategy established by the European Council at Lisbon in March 2000 and in strengthening efforts to enhance growth and competitiveness in the Union. The Council adopted the following conclusions :

"THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLING

- the Conclusions of the Lisbon European Council on the strategy for making the EU the world's most competitive and dynamic knowledge-based economy, capable of sustainable economic growth with more and better jobs and greater social cohesion by 2010, and the further elaboration of this strategy by the Stockholm, Gothenburg and Barcelona European Councils;
- the Conclusions of the Stockholm European Council, requesting Member States and the Commission to improve statistical information necessary for benchmarking, and inviting the Commission to reflect on the use of quantitative targets in enterprise policy;
- that the Lisbon European Council decided to apply an open method of co-ordination which involves establishing, where appropriate, quantitative and qualitative indicators and benchmarks against the best in the world and tailored to the needs of different Member States and sectors as a means of comparing best practice;
- the European Charter for Small Enterprises which calls for the creation of the best possible environment for small enterprises;
- the Council Decision on a Multiannual Programme for Enterprise and Entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005);

2. WELCOMES

- the Commission's Communication "Better Environment for Enterprises" and related Staff Working Papers, which point to progress as well as the need for strengthened efforts in many areas of enterprise policy, and which also include information on the candidate countries and indicators on sustainable development;
- the Commission's intention to review industrial policy in the light of the globalisation and the advent of enlargement;
- the Commission's intention to present a green paper on entrepreneurship;

3. EMPHASISES

- the need to redouble the efforts to promote growth and competitiveness in order to meet the Lisbon goal, noting that the slowdown in economic growth should not be allowed to detract attention from the implementation of the commitments of the Lisbon strategy;
- that structural reforms and the improvement of the framework conditions for enterprises are crucial to growth and that raising public awareness on these matters is essential;
- that necessary improvements in the business environment require further work at the appropriate level in a wide range of areas relevant for competitiveness, noting that the conditions for SMEs remain a task of critical importance;
- the need to ensure the competitiveness of European enterprises with the appropriate balance between the three pillars – social, economic and environmental – of sustainable development, and STRESSES in particular the need in all policy areas to assess effects on competitiveness, with reference to global markets;
- that improving the quality of rules and regulations is crucial to the Union in becoming more competitive and that achieving better regulation is an important responsibility for the Community Institutions and Member States;
- that learning from best practices can further improve the performance of Member States;

4. RECOGNISES

- the progress in developing a framework of quantitative targets which may be set by Member States on a voluntary basis in seven areas of enterprise policy crucial to competitiveness: entrepreneurship, regulatory and administrative environment, access to finance, access to human capital, innovation and knowledge diffusion, access to ICT and open and well-functioning markets;
- that quantitative targets can be a useful contribution to achieve concrete objectives and to increase focus and momentum in enterprise policy, noting that most Member States see a need to continue the work on such targets, in order to build on the targets already declared and further integrate their use in enterprise policy;

5. INVITES THE MEMBER STATES TO

- further develop quantitative and qualitative targets on a voluntary basis in areas where Member States consider it relevant and with due consideration to structural differences;
- develop a more systematic dissemination of best-practices in enterprise policy and, when developing policies, to take into account identified best-practices, emphasising in particular the results of the Best Procedure projects;

6. INVITES THE COMMISSION TO

- adopt a comprehensive and strategic approach to competitiveness, and to focus its work on the structural determinants of enterprise competitiveness in all sectors;
- facilitate the exchange of best practices in order to enable the Member States to learn more efficiently from each other;
- refine its analytical framework for competitiveness policy, and, in that respect, take into account in the work on quantitative targets, the results from other reports and procedures;
- report within a streamlined approach to the Council on a regular basis on the progress in the quantitative targets in order to contribute to a strategic discussion on competitiveness in the Council;
- continue to include information on candidate countries in benchmarking exercises with a view to ensuring comparability of data across countries;

7. INVITES THE MEMBER STATES AND THE COMMISSION TO

- further develop the work on identifying, benchmarking and exchanging best practises in the area of enterprise policy across the Union and candidate countries;
- continue the work on a voluntary basis on quantitative and qualitative targets with the aim of further integrating their use in enterprise policy;
- discuss enterprise policies developed in the Member States and in this regard to consider the possibilities to organise periodic monitoring, evaluation and peer review as mutual learning processes on a voluntary basis."

SUSTAINABLE DEVELOPMENT

The Council heard a report from the Commission on its planned strategy on the follow-up to the World Summit on sustainable development, held at Johannesburg in September 2002, and on work underway on the establishment of a Community chemical products policy. It confirmed its intention to reexamine these matters once the Commission has presented, during the first half of 2003, a package of measures on industry policy and the environment and on chemical products.

– FOLLOW-UP TO THE JOHANNESBURG SUMMIT

The Council was briefed by the Commission on the preparation of measures aimed at integrating environmental protection and sustainable development into the industrial aspects of competitiveness policy. This follows on from the report on the internal market aspects adopted by the Council at its meeting on 14 November.

Following the Göteborg European Council in June 2001, and the creation in July 2002 of the Competitiveness Council with the aim of taking a more strategic view of internal market and industry issues, environmental protection and sustainable development have become an integral part of competitiveness policy.

– CHEMICAL PRODUCTS

The Council was briefed on the preparation of measures that the Commission plans to present in the first half of 2003, providing for the establishment of a new Community chemical products policy.

The strategy on environmental protection and sustainable development endorsed at Göteborg deals also with the chemicals policy which, further to the Commission's White Paper of February 2001, will aim to ensure a high level of health and environmental protection whilst stimulating innovation and the competitiveness of Europe's chemical industry. It is envisaged that the current dual authorisation system for chemicals products, which distinguishes between existing substances and new substances for the purpose of testing requirements, will be converted into a single, more coherent system for treating the majority of chemical substances.

The long-term aim is to ensure that chemicals are only produced and used in ways that do not lead to a significant impact on human health and the environment, so as to meet current economic needs without compromising those of future generations.

STATE AID - Council conclusions

The Council held an exchange of views, on the basis of a progress report from the Commission on the reduction and reorientation of state aid, and took note of a report from the Presidency on the seminar, "*Towards efficient and effective state aid : best practices in establishing the need and measuring the effects of state aid*", held in Maastricht (Netherlands) on 20 November.

The Council also adopted the following conclusions :

"THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLING

- the conclusions of the Lisbon European Council aiming at making the EU the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion;
- the conclusions of the Stockholm European Council in particular the Member States' commitment to continue their efforts to reduce the general level of State aid expressed as a percentage of the gross domestic product (GDP) by 2003, and the need to redirect aid towards horizontal objectives of common interest, including cohesion objectives;
- the conclusions of the Barcelona European Council which renewed the call on Member States to reduce the overall level of State aid as a percentage of GDP by 2003, and onwards, and to redirect such aid towards horizontal objectives of common interest, including economic and social cohesion, and target it towards identified market failures;
- the State aid scoreboards presented by the European Commission following up on the Stockholm and Barcelona European Council conclusions;
- the Council conclusions of 12 March 2001, 5 December 2001 and 1st March 2002 reaffirming the need to continue efforts to reduce State aid, especially the most distortive ones in terms of competition and to further develop "*ex ante*" and "*ex post*" evaluations of State aid;
- the conclusions of Nice, Laeken and Sevilla European Councils regarding services of general economic interest;

2. RECOGNISES the importance of maintaining as seen in recent years the downward trend in State aid as a percentage of GDP and the reorientation of aid towards horizontal objectives of common interest including economic and social cohesion;

3. UNDERLINES that less and better targeted State aid towards identified market failures can be a key part of effective competition within the process of improving the efficiency of State aid as an instrument of competitiveness policy, recognizing its importance for achieving horizontal objectives;

4. REAFFIRMS the need to closely evaluate State aid in order to identify and reduce the most distortive types of State aid, underlining that monitoring and follow-up of State aid expenditures are essential components of State aid policies in Member States and Community State aid policy;
5. EMPHASISES the need to continue to modernise, simplify, and clarify EU State aid rules in order to make them more effective, also with a view to enlargement, and to elaborate methods to accelerate procedures, while increasing ex-post control;
6. WELCOMES the efforts made by the European Commission in order to improve transparency and underlines the responsibilities of Member States to also contribute to increased transparency;
7. RECOGNISES the downward trend in State aid as explained in the Commission State aid scoreboard 2002 and points made in the Commission report on the evaluation of progress made in 2002, in particular the need:
 - to improve statistical tools and indicators;
 - to develop a methodology for analysis of State aid impact on markets, competition, competitiveness, employment and cohesion objectives as well as intra-Community trade;
 - to enhance exchange of experience between Member States concerning the effort to monitor reduction and reorientation of State aid;
8. INVITES MEMBER STATES TO
 - commit themselves to continue their efforts to reduce the overall level of State aid, in particular those aids which imply the greatest risk of competition distortions;
 - consider before granting State aid whether it is targeted on a clearly identified market failures or directed at horizontal objectives of common interest, including economic and social cohesion objectives, and whether an intervention in the form of State aid is the most appropriate and effective way to address these issues;
 - continue to develop the use of “*ex-ante*” and “*ex-post*” evaluations of individual State aid and State aid schemes in order to monitor impact on competition and effectiveness of the aid;
 - contribute to the report of the Commission to the European Council in spring 2003 on the steps taken concerning the reduction and reorientation of State aid with a view to developing in the long term perspective an analytical framework for the evaluation of State aid impact on markets and economic development;
9. INVITES THE COMMISSION TO
 - in close co-operation with the Member States and without delay, continue to modernise, simplify, and clarify the scope and content of EU rules on State aid, including making them more effective in terms of the length of process and the administrative resources involved and include in the autumn edition of the State aid scoreboard each year a section on the results of these considerations;
 - clarify the economic criteria used to assess the effects of aid whether in established or in new areas of activity;

10. INVITES MEMBER STATES AND THE COMMISSION, in their respective areas of competence,
- to exchange experiences, starting in 2003, notably through meetings and seminars, on their efforts to reduce State aid; the results of this work will be reported in the framework of the scoreboard and could ideally include an evaluation of the State aid trend based on the following indicative list of themes and issues:
 - development of statistical measures and indicators;
 - methodologies and tools used to evaluate impact and effectiveness of State aid;
 - national targets and results of efforts to reduce State aid;
 - experience in using “*ex ante*” and “*ex post*” evaluations of aid;
 - other concrete measures in order to fulfil the targets set in the conclusions of the Stockholm and Barcelona European Council concerning a reduction and reorientation of aid, including suggestions for further work and initiatives;
 - to develop within the State aid scoreboard a web-based network for the exchange of information and experience between Member States and the Commission, and continue to increase transparency."

BIOTECHNOLOGY - Council conclusions

The Council held an exchange of views, on the basis of the Commission's communication "*Life sciences and biotechnology - a strategy for Europe*", and adopted the following conclusions.

"THE COUNCIL OF THE EUROPEAN UNION,

1. RECALLS

- the European Council's conclusions of Stockholm recognising the important contribution that biotechnology can make towards achieving the target set at the Lisbon European Council for Europe to become the most competitive knowledge-based economy with thus more and better jobs while ensuring that those developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles and in full compliance with the existing legislative framework;
 - the European Council's conclusions of Barcelona calling for the development of measures and a timetable which enable Community businesses to exploit the potential of biotechnology while taking due account of the precautionary principle and meeting ethical and social concerns; and recalling that overall spending on R&D and innovation in the Union should be increased with the aim of approaching 3% of GDP by 2010 and that two-thirds of this new investment should come from the private sector;
 - the Council conclusions of June 2002 requesting an operational roadmap of measures to this end, indicating priorities, the various actors' responsibilities and a timetable for implementation;
2. WELCOMES the Commission Communication on a life sciences and biotechnology strategy and action plan that provides a comprehensive basis for implementation of a roadmap; AGREES with the main lines of the Commission's analysis of strengths and weaknesses of the EU biotechnology sector and of policies and actions related hereto, as well as the identification of main areas that need action to improve further policy coherence;
 3. UNDERLINES the necessity for adequate and appropriate approaches, taking into account biosafety issues related to new technologies and societal needs as well as the aim to ensure consumer freedom of choice and the safety of consumers;
 4. RECOGNISES that life sciences and biotechnology offer a considerable potential in areas such as health care, agriculture/food, industrial products and processes and environmental protection, and may contribute to sustainable development; UNDERLINES that this potential should be continuously assessed on the basis of benefits and risks anticipating health, economic, social and environmental consequences and ethical aspects and that the successful development of a competitive biotechnology sector in the EU requires a comprehensive and co-ordinated approach covering all major areas of application of biotechnology;
 5. ACKNOWLEDGES that any effective approach which would allow harvesting the potential of biotechnology in Europe should engage all Member States and encompass all policy areas and instruments available for the sector's promotion taking into account international aspects, be balanced, including a continuing societal dialogue, a high-standard regulatory framework which is science-based, and respect diversity of views and freedom of choice;

6. ACKNOWLEDGES that the European research and innovation area will be particularly helpful in providing a structuring effect and in overcoming the fragmentation of resources and the lack of critical mass. It will also stimulate – on a voluntary basis - enhanced co-ordination of research and development policies and actions and greater involvement of the private sector. Research in life sciences and biotechnology may serve as a model for integrating activities addressing ethical and social aspects from the earliest possible stage;
7. ACKNOWLEDGES that a science-based, transparent, effective and proportionate regulatory framework respecting the precautionary principle is a major requirement for establishing societal, in particular consumer confidence, which should prevent unnecessary administrative burden in particular on small and medium-sized enterprises and stimulate responsible innovation;
8. UNDERLINES that biotechnology could, to a certain degree, contribute to sustainable progress and economic growth in developing countries while decreasing the use of resources and environmental degradation; however, the biotechnology applications must correspond to the desires of the countries concerned;
9. ACKNOWLEDGES that the Cartagena Protocol on Biosafety represents an important global legal instrument to secure the protection of biodiversity while taking into account human health and ACKNOWLEDGES the importance of the Community's participation in capacity building in third countries;
10. UNDERLINES that a comprehensive strategy needs a continuous effort to ensure policy coherence and monitoring; RECOGNISES the need for a monitoring and a regular exchange of views and experiences between Member States about creating framework conditions for the biotechnology industry and the well-functioning of markets; WELCOMES the Commission's intention to present its regular life sciences and biotechnology report including a report on the implementation of the following roadmap for the strategy on life sciences and biotechnology, together incorporating the elements listed in the following roadmap;
11. INVITES the Commission to co-ordinate –with the active contribution of Member States – the implementation of the road map including:
 - monitoring the competitiveness of the EU biotechnology sector and related industries, in particular the EU framework conditions, entrepreneurship and functioning of markets, the legal framework, access to and dissemination of knowledge and technological counselling, research and innovation, access to capital, including venture capital, and public – private co-operation, societal dialogue and ethical concerns;
 - monitoring and driving the implementation of the following roadmap for the strategy on life sciences and biotechnology, taking into account its social, health, environmental, safety and ethical aspects;
 - working for cross-sectoral co-ordination within fields of relevance to biotechnology.

Based on a yearly report from the Commission the Council once a year should hold an in depth discussion, beginning in 2003, on the implementation of the following roadmap for the strategy on life sciences and biotechnology;

12. CALLS UPON THE COMMISSION, THE MEMBER STATES AND THE PRIVATE SECTOR AS WELL AS OTHER STAKEHOLDERS, within their respective competencies and responsibilities, to engage in defining and implementing measures in a co-operative way within the framework of the following roadmap for the implementation of the strategy on life sciences and biotechnology which sets out priorities within an indicative timetable.



I. STRENGTHENING THE VALUE CREATION CHAIN

A. HUMAN RESOURCES

Member States should keep under review and assess, before mid-2003, future requirements in specific skills in the EU for scientists, technicians, engineers and managers within the various life science specialities.

Member States and the Commission should

- cooperate in identifying tools, such as education modules or curriculum elements, and compare best practices to fill those needs, particularly relating to:
 - initial education: life science education at secondary school level, university and technical education resources, strengthening science interest, reduction of drop-out rate;
 - continuous professional development and lifelong learning related to biotechnology, as well as management and legal skills needed by entrepreneurial companies;
 - mobility, attraction and retention of researchers;
 - collaborate with academia and industry to establish and disseminate best practices to match workforce with available positions, and improve mobility.
- These measures should be operational by 2004.

Member States and the Commission call upon industry and academia to assist in developing tools and contribute within their own areas of competence, e.g. staff exchanges and in-house training and "research academy" partnerships. The Commission is invited to monitor this process and report to the Council before the end of 2004.

B. FROM KNOWLEDGE TO MARKET

Research

The Council invites the Member States and the private sector to increase or continue to increase the research resources allocated to life sciences and biotechnology, and improve the efficiency and effectiveness of national research by working to implement the European Research Area in those aspects of science, technology and engineering which specifically underpin and support biotechnology developments.

Member states should make the best use of the areas which have been identified under the 6th Framework Programme (2003-2006) to benefit of the EU life sciences and biotechnology industries so as to enhance their competitiveness in a coordinated manner, while taking into account views on ethical standards and social, health and safety concerns.

Intellectual Property

The Council recognises the vital importance of the proposed Community Patent for a dynamic biotechnology sector and will - in line with the Barcelona conclusions of 2002 - resolve the outstanding issues as soon as possible and invites Member States to:

- continue the transposition of Directive 98/44 on the legal protection of biotechnology inventions taking into account the Commission report on the development and implications of patent law in the field of biotechnology and genetic engineering. The status of transposition and practical experience in application should be reported every year to the Council – beginning in 2003;
- discuss - in close cooperation with academia - national plans for increasing awareness of the strategic uses of intellectual property in a responsible manner.

Technology transfer

Member States and the Commission should in 2003 establish an inventory of best practises for the promotion of technology transfer and subsequent support of the dissemination through networks and pilot projects.

Finance

Member States, the Commission and financial institutions should consider how to improve the financial framework for biotechnologies, and in particular:

- use the results of the collaboration between the Commission and the European Investment Bank/Fund to improve innovation finance including venture capital availability in their own innovation policies and increase investments in this area, e.g. through EIB/EIF instruments supporting late stage investments or consolidation funds;
- intensify work on a cross-national basis, e.g. by building networks between existing structures, sharing experience and exploring best practices. Results will be reported before the end of 2004.

C. NETWORKING AND CLUSTERS

The Council welcomes the Commission support for the creation of a self financed biotechnology portal for Europe, providing free access to information on available networking Internet platforms. In addition, the Commission, as it has indicated, should further develop its own website in order to provide a broad entry platform into the Commission's work on biotechnology giving all relevant actors easy access to information. This portal and the entry platform should be operational before the end of 2003.

In order to create mutual learning and develop best practices, representatives from biotechnology clusters are encouraged to exchange experiences yearly. The Commission is invited to report yearly to the Council on best practices related to biotechnology clusters.

Member States, regions and the Commission should take initiatives to stimulate interregional co-operation between biotechnology companies and institutions – including biotechnology clusters and centres of excellence.

The Commission is invited to monitor the process and the development of clusters and co-operation between clusters and report yearly to the Council beginning in 2003.

D. A PROACTIVE ROLE FOR PUBLIC AUTHORITIES

Member States and the Commission should prepare and implement on a voluntary basis a benchmarking programme in 2003, highly focussed on areas of special relevance, to assist the development of biotechnology policy through identification and exchange of best practices. Such a programme may for example include measurement of the extent of commercial development of biotechnology: the resource base (human and financial), public policies (national and sub-national) to promote the development of commercial biotechnology (e.g. technology transfer and SME support), regulatory factors including transparency and other (national and sub-national) factors affecting the business climate for commercial biotechnology, and the use of the precautionary principle.

The programme should make full use of already existing measures and involve all interested stakeholders.

The Member States and the Commission should continuously monitor and assess economic, social, health, environmental, ethical and safety factors.

II. RESPONSIBLE GOVERNANCE

A. PARTICIPATION OF SOCIETY

Societal scrutiny and dialogue

The Council joins the Commission's commitment to support an open and transparent as well as comprehensive, structured and focussed dialogue and information exchange, including all stakeholders, notably through a broadly-based Stakeholders Forum starting at the latest in 2003 as well as other targeted measures, as indicated in the Commission Science and Society Action Plan.

Member States, the Commission, academia, industry and civil society should take part in a continuous dialogue on issues of societal concern, by encouraging discussion-fora at the appropriate levels, starting at the latest in 2003.

Member States and the Commission should initiate and support the promotion of awareness of scientific paradigms underlying regulatory oversight, as well as an open and transparent public dialogue on biotechnology between all stakeholders, focussing on technological developments and potential benefits and risk. Balanced and informed debates should take place in each Member State starting at the latest before the end of 2003.

Member States and the Commission will take into account the output emerging from the above-mentioned initiatives.

Ethics

The Council notes that the ethical acceptability of some areas of biotechnology is related to the diversity among Member States and is governed by national law in accordance with the principle of subsidiarity. An increased dialogue between ethical bodies in the EU, including the European Group on Ethics in Science and New Technologies, and with the general public should facilitate the identification of different ethical standpoints and contribute to mutual understanding of their basis and exploration of where common views are possible and desirable. It is important to promote the understanding of ethical, legal and social aspects in the scientific community.

In that respect, the Council welcomes the Commission's intention to:

- before the end of 2004 strengthen and focus Community support for research into socio-economic and ethical issues and dissemination of results, including criteria for assessing the cost and benefit of using biotechnology, in order to facilitate future reporting and provide a good basis for societal decisions on the application of life sciences and biotechnology;
- fund bioethics research and ensure that the ethical, legal and social implications are taken into account at the earliest possible stages of Community-supported research by providing an ethical review of research proposals received;
- to promote the dialogue between national ethical bodies and private and public partners with a view to examine - on a case by case basis - where it might be possible to work towards Common approaches to be used e.g. in decision-making processes and as a basis for public consultation and information, taking into account the experience obtained under the 6th Framework Programme.

B. REGULATORY FRAMEWORK

Pharmaceuticals

The Council welcomes the Commission's efforts to improve the regulatory framework for medicinal products that constitute one of the most important sectors of applied biotechnology, and will conclude discussion on the proposed review of the pharmaceutical legislation, including accelerated authorisation procedures, conditional approval and enforced scientific advice for applicant companies, in order to increase the competitiveness of the pharmaceutical sector with a high level of consumer confidence. The Commission is invited to yearly evaluate progress made in implementation and its impact.

The recommendations made by the High-Level Group on Innovation and Provision of Medicines, and the Commission's reaction to the recommendations should provide a basis to arrive at operational conclusions to be presented by 2003.

Genetically modified organisms (GMO) legislation

Directive 2001/18 on the deliberate release of GMOs into the environment has been applicable since 17 October 2002. Its objectives are to strengthen the regulatory approval system and to provide a high level of health and environmental protection, as well as to ensure individual choice. In this context, the Council is considering the outcome of the ongoing work concerning further GMO related legislation.

The Council encourages the Commission, Member States and other interested stakeholders to develop agronomic and other options to enable the coexistence of all different agricultural practices, considering the need to safeguard sustainability and diversity in Europe and fully apply the principle of freedom of choice for operators and consumers. Results in this respect should be included in the Commission annual report on the strategy for life sciences and biotechnology based on information coming notably from the Member States.

The Commission is invited to, as it has indicated, periodically – beginning in 2003 - publish a rolling regulatory work programme to further improve coherence, predictability, transparency and quality of the regulatory framework, applying notably the principles of:

- product authorisation on the basis of scientific risk management
- precautionary principle
- risk management measures also taking into account other legitimate factors as appropriate
- proportionality of risk management measures
- transparency of procedures assessments and, as foreseen by the Aarhus Convention, public participation
- consumer information and choice
- testing and validation of control methods
- regular reviews of legislation
- the functioning of the approval system

C. INTERNATIONAL/DEVELOPMENT COOPERATION

Member States and the Commission should provide strong EU support in order to enable developing countries and countries with economies in transition to assess and use the potential of biotechnology and to develop their own capacity for the adequate policy response, according to their needs and to the local conditions. Support should include international scientific cooperation, such as the establishment of effective research partnerships between public and private research organisations in developing countries and the EU. Assistance should be based on the express preferences of the developing partner. Apart from assistance for application purposes, this should reinforce assistance to implement the relevant international Conventions and Agreements, for example the International Treaty on Plant Genetic Resources for Food and Agriculture, the Convention on Biological Diversity including the Cartagena Protocol on Biosafety. By the end of 2003, the Commission should report on results in this respect."

THE EUROPEAN RESEARCH AREA - Council conclusions

The Council held a policy debate on the basis of the Commission's communication, "*The European Research Area: Providing new momentum - Strengthening, reorienting, opening up new perspectives*".

The President noted that, in the light of the debate, as regards EUREKA², the pan-European network for market-oriented, industrial research and development, COST³, European co-operation in the field of scientific and technical research, and the initiative concerning a "European Research Council",⁴ delegations:

- will continue discussions on a concrete basis, on the purpose and scope of a European Research Council and to explore options for its possible creation, in co-operation with relevant national and European research organisations;
- stressed the importance of EUREKA as an inter-governmental initiative of European states, focused on applied research and technology, and complementing the efforts of the European Union, undertaken, notably in the research Framework Programmes. The Commission is invited to use all the possibilities foreseen in the Sixth Framework Programme for strengthening cooperation between EUREKA and the Framework Programme, utilising the specific characteristics of both instruments to achieve optimum synergies in the spirit of ERA;

² EUREKA supports collaboration between European companies through links and networks for innovation, whilst remaining open to global co-operation, with the aim of bringing high quality research and development to the market.

³ COST is an intergovernmental framework supporting co-ordination of nationally funded research on a European level, with a scope going beyond the EU, including most central and eastern European countries and welcoming the participation of non-COST member states.

⁴ This initiative was examined at a scientific conference organised by the Presidency at Copenhagen in October. As proposed, it would be an autonomous funding organisation managed by scientists and oriented towards basic research. Funding decisions would be based exclusively on scientific criteria, with contributions welcome from public and private sources, but with no strict rules on co-financing.

- reaffirmed Community support for COST as a valuable and flexible instrument for bottom-up scientific co-operation in the context of ERA; the Council welcomes the partnership between COST and ESF, as well as the ongoing reforms of COST; invites the Commission to take the necessary measures to ensure the successful continuation and increased relevance of COST, in the framework of ERA, during the implementation of the Sixth Framework Programme, bearing in mind the indicative financial allocation set out in the Council decision on the first Specific Programme "Integrating and Strengthening ERA".

The Council adopted the following conclusions :

"THE COUNCIL OF THE EUROPEAN UNION,

RECALLING the conclusions of the Lisbon European Council in March 2000, which, in the context of setting the strategic target for the European Union to become the most competitive knowledge-based society by 2010, and in underlining the significant role played by research and development in generating economic growth, employment and social cohesion, asked the Council and the Commission, together with the Member States where appropriate, to take the necessary steps as part of the establishment of a European Research Area (ERA), including to:

- develop appropriate mechanisms for networking national and joint research programmes on a voluntary basis around freely chosen objectives;
- encourage the development of an open method of coordination for benchmarking national research and development policies;
- remove obstacles to the mobility of researchers in Europe ;

RECALLING that the Barcelona European Council in March 2002 agreed that overall spending on R&D and innovation in the Union should be increased with the aim of approaching 3% of GDP by 2010, and that two thirds of this new investment should come from the private sector; NOTING that this initiative is an important element in contributing to the successful implementation of ERA;

RECALLING the Council's earlier resolutions of 15 June 2000 on establishing a European area of research and innovation, of 16 November 2000 on making a reality of the European area of research and innovation: guidelines for the European Union's research activities (2002-2006) in which it was considered that this must be the product of joint and voluntary effort and partnership between the EU, the Member States, the applicant countries, the associated countries and all scientific and technical research stakeholders, as well as the resolution of 10 December 2001 concerning the reinforcement of the mobility strategy within the European Research Area;

1. WELCOMES the submission of the Communication from the Commission entitled "The European Research Area: Providing New Momentum";
2. WELCOMES the progress achieved in developing the European Research Area, in areas such as benchmarking, networking and mutual opening up of national programmes, while noting the structural differences in Member States, as well as the varying pace of advance in the application of its different aspects;
3. WELCOMES the adoption of the 6th Framework Programme as an important and innovative strategic tool having a structuring effect on research and technological development in Europe and contributing to making a reality of ERA;
4. WELCOMES efforts currently being undertaken in the context of ERA to achieve closer linkage with other European co-operation initiatives such as COST, EUREKA and ESF, with a view to creating synergies while respecting their complementary roles;
5. AFFIRMS that a continuing strong commitment of the Member States is necessary for the successful implementation of ERA;
6. REAFFIRMS, in accordance with Article 165 of the Treaty, the importance that the Community and the Member States coordinate their research and technological development activities so as to ensure that national policies and Community policy are mutually consistent, and CONSIDERS that, while fully respecting the principle of subsidiarity, this coordination should take place at the national and European levels;
7. CONSIDERS that for achieving the objectives of ERA, as agreed in the Lisbon 2000 European Council conclusions, a method of open coordination on a voluntary basis could be developed;
8. ACKNOWLEDGES in addition the possibility of using legal measures where they can constitute the most appropriate and effective means of achieving the objectives of ERA, such as in the field of Intellectual Property Rights and RTD statistics;
9. INVITES CREST to recommend appropriate measures for strengthening the ongoing actions to advance ERA, in particular in its advisory capacity in relation to the coordination of the RTD activities of the Community and the Member States and in respect of the role of other European co-operation initiatives in ERA.
10. INVITES the Permanent Representatives Committee to study further the Communication from the Commission, with a view to assisting in the timely preparation of the necessary input for the Spring 2003 European Council. It is invited to pay particular attention to the following suggestions for improving conditions for encouraging better co-ordination:
 - Examining, for achieving the objectives of ERA, the concrete use of an open method of coordination in accordance with the Lisbon 2000 Council conclusions, based on joint and voluntary efforts and in full respect of the principle of subsidiarity and the independent role of national policies.
 - Strengthening the role of CREST in contributing to improved co-ordination within ERA, possibly by reviewing its mandate and working methods;

- Improving the mobility of researchers in the public and private sectors in Europe by the further identification and removal of persistent obstacles, where such obstacles span different policy areas, also taking into account other issues arising from the development of an effective mobility strategy for the European Research Area;
 - Measures to favour innovation in ERA, so that those who generate knowledge are brought together with those who use, exploit and finance it, thus stimulating the free movement of knowledge and innovation.
11. INVITES the Member States, in collaboration with the Commission where relevant through CREST and other appropriate existing bodies, to strengthen the actions being undertaken to develop ERA further, in particular by:
- improving career development for researchers, including issues such as recruitment and retention of researchers;
 - facilitating or continuing to facilitate entry and residence for researchers from third countries;
 - encouraging national research organisations in Europe to co-ordinate their activities, while taking advantage of opportunities existing in the Framework Programme, as well as strengthening cooperation at a strategic level between managers of major national research organisations by building upon existing fora;
 - making fuller use of the possibilities offered by the European Strategy Forum on Research Infrastructures for consulting and advising the Member States and the relevant European institutions;
 - in co-operation with relevant national and European research organisations, continuing discussions on the purpose and scope of a European Research Council and exploring options for its possible creation;
 - putting in place a more effective exchange of information and co-operation on international scientific co-operation policies;
 - stimulating technological innovation, utilisation of research results, transfer of knowledge and technologies and the setting up of technology businesses;
 - exploring the means for transferring knowledge of good practice and policies between regions in the European Research Area, including the regions of the Candidate countries;
12. INVITES the Commission, in consultation with relevant stakeholders, to facilitate the examination of all these issues, and to report to Council before the end of 2003 on the progress made in developing the European Research Area, with special emphasis on the issue of integrating other European co-operation initiatives."

INVESTMENT IN RESEARCH - 3% OF GDP OBJECTIVE

The Council held an exchange of views on the communication entitled "*More research for Europe: Towards 3% of the GDP*", following the presentation of this document by the Commission. It took note of the Commission's intention to engage with the other EU institutions, the Member States, regions and industry in order to identify actions to be undertaken to encourage more effective R&D investment in Europe, in the preparation of its synthesis report to the 2003 Spring European Council.

The Commission's communication reflects the agreement reached at the European Council at Barcelona in March 2002 whereby Member States agreed that investment in research and technological development in the EU must be increased with the aim of approaching 3% of gross domestic product by 2010, up from 1.9 % in 2000.

The communication examines the possible ways and means of reaching this aim, and identifies a number of areas where action needs to be taken or existing action needs to be strengthened. It emphasises the need to make conditions more conducive to business investment and to raise the effectiveness of public financing in R&D so as to close the ever-growing investment gap in relation to industrialised third countries.

Specific dossiers

REFORM OF COMMUNITY COMPETITION RULES

The Council reached a unanimous political agreement on the basis of a compromise suggested by the Presidency, on the draft Council Regulation aimed at introducing a new system for implementation of the competition rules laid down in articles 81 and 82 of the Treaty. The Regulation will be adopted at a forthcoming Council session, after finalisation of the text (*doc. 14471/02*).

The main issues covered by the Council's agreement concern the principles relating to application of articles 81 and 82, the burden of proof, the relationship between Community and national competition laws, exchange of information, inspections of undertakings and fines on associations. The Council also decided to enter into the minutes a joint statement by the Council and the Commission aimed at clarifying the functioning of the future network of competition authorities in order to ensure that Community competition rules are applied effectively and consistently.

The draft Regulation is intended to enable more effective implementation of Community competition law, introducing a decentralised system which allows for its application by both the competition authorities and courts of the Member States and the Commission, whilst maintaining consistency and preserving the Commission's specific role.

In particular, it provides for the introduction of a system of legal exception, based on the principle that agreements not contravening the competition rules are automatically lawful, replacing the current system which is based on the principle of prohibition and the use of individual notifications to the Commission. The Regulation is thus aimed at lightening the Commission's workload, in particular by removing the requirement for notification of agreements, so as to enable it to concentrate on the most important cases.

The Barcelona European Council in March 2002 gave priority to work on this new legislative framework and called on the Council to adopt it by the end of 2002. The new rules will apply as from 1 May 2004.

SHIPBUILDING - LATEST DEVELOPMENTS ON WORLD MARKETS

The Council took note of a report from Commission on the latest developments regarding the situation on world shipbuilding markets.

This report responds to a request from the Council, at its meeting on 6 June, to assess the latest developments. On 27 June, the Council requested the Commission to make a final effort to solve the problems arising from unfair business practices by shipyards in Korea and achieve an amicable settlement with Korea by 30 September.

Two rounds of talks with the government of Korea in August and September failed to achieve this, and in the absence of a negotiated solution, the Commission has now initiated proceedings at the World Trade Organisation (WTO).

On 27 June, the Council also adopted a Regulation establishing a temporary mechanism to protect EU shipyards from unfair commercial practices in Korea, until the conclusion of the WTO dispute-settlement proceedings or until 31 March 2004 at the latest. This Regulation allows for direct national aids to be granted, in certain conditions, up to a ceiling of 6% of the value of a contract for the construction of certain types of vessels.

Regulation 1540/98 on state aid rules for shipbuilding, adopted in June 1998, requires the Commission to report regularly to Council, assessing whether European shipyards are affected by anti-competitive practices.

MEASURING INSTRUMENTS

The Council took note of a progress report from the Presidency on the draft Directive of the European Parliament and the Council on measuring instruments. It requested the Permanent Representatives Committee to oversee further work on this proposal so as to enable it to reach a political agreement in the near future.

There is already broad agreement on the objectives and underlying concept of the Commission's proposal, but given the large number of technical annexes, examination of the text has been a complex task. Major adjustments have been made, including some resulting from amendments proposed by the Parliament, and the number of outstanding issues has been considerably reduced in recent months. Practically all of these issues concern technical details.

The proposed directive follows the so-called "new approach", aimed at unifying rules so as to enable measuring instruments to be marketed throughout the Community, whilst attributing responsibility to manufacturers with regard to the presumption of conformity with these rules.

COMMUNITY PATENT - Presidency procedural conclusions

The Council took note of the following Presidency procedural conclusions :

"The Council has examined the status of the proposed Community Patent Regulation, in accordance with the outcome of the Council meeting the 21 May 2002 during the Spanish Presidency, focusing on the jurisdictional arrangements for the Community Patent.

The Council noted that progress has been made on both the underlying general principles for the jurisdictional arrangements as well as on the structure of the Community Patent Court and the more technical - but essential - legal issues involved.

The Presidency believes the main principles in document 13881/02 is a basis for taking work forward on the jurisdictional arrangements for the Community Patent, on the understanding that nothing is considered as having been finally agreed until agreement has been reached on all aspects of the future Community Patent system.

Therefore the Permanent Representatives Committee should pursue work actively on and give high priority to finalising an agreement on the key elements of the jurisdictional system for the Community Patent and prepare an overall political agreement at the Council on the Community Patent as a whole. The Council will make all efforts to adopt this political agreement in good time before the European Council in Spring 2003. Work on the text of the proposed Community Patent Regulation should then be accelerated, as should detailed discussion on the Commission's working papers on jurisdiction and amendments to the European Patent Convention (EPC). The aim is - based on the overall political agreement - to finalise and adopt the Community Patent as soon as possible."

These conclusions follow on from examination of the jurisdictional arrangements for the proposed Community patent system at the Council's meeting on 14 November. On that occasion, the Council noted that further work was necessary on the jurisdictional system of the proposed patent system and on the dossier as a whole.

The Community patent system, which is provided for in a proposal for a Council Regulation, is aimed at creating a single patent that would be valid throughout the Community. Patents would be granted by the European Patent Office in Munich in accordance with the requirements and procedures laid down in the European Patent Convention and its implementing Regulation.

The European Council has emphasised on several occasions that the Community patent must be an efficient and flexible instrument, obtainable by businesses at an affordable cost, whilst complying with the principles of legal certainty and non-discrimination between Member States.

RESEARCH TO COMBAT AIDS, MALARIA AND TUBERCULOSIS

The Council held an exchange of views on the proposal for a Decision of the European Parliament and the Council on Community participation in a research and development programme aimed at developing clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries.

The proposal provides for a Community contribution of 200 million euros from the 6th Research Framework Programme 2002-06, with the aim of bringing national activities together and providing added value in a partnership that will bring developing countries together with a number of Member States and Norway. The proposal is based on article 169 of the Treaty, which allows the Community to participate in research and development programmes undertaken by groups of Member States.

Following the debate, the Presidency drew the following conclusions:

"The Council confirmed its intention to pursue this proposal as a pilot programme for the use of Article 169, it being acknowledged that further detailed discussions with the European Parliament will take place. In this context, Ministers:

- underlined the importance of ensuring the commitment of financial and human resources at the national level, including, as appropriate, those of third countries, to carrying out these activities;
- stressed the importance of associating very closely the developing countries with all aspects of the programme, including in the decision making process, and reinforcing current collaboration in this area as well as ensuring the establishment of the necessary modalities for effective coordination between the different actors in this field.

Recognising the pioneering nature of this proposal, Ministers stressed the need for an in-depth examination of all aspects of this initiative and how best to link this programme to other activities in the implementation of the Sixth Framework Programme and the creation of ERA.

Ministers stressed the need for establishing the appropriate structure and effective management arrangements for carrying out the programme, bearing in mind the need to provide for a similar level of scientific excellence and protection of Community financial interests as in other instruments implementing the Sixth Framework Programme.

As to the way forward, therefore:

- the Permanent Representative Committee should continue the examination of this proposal in close cooperation with the European Parliament, with particular attention to the modalities of the Community participation in EDCTP and also the question of liability of the participants;
- the participating Member States should agree on the form of the legal entity and the common structure which will be responsible for the implementation and execution of the EDCTP activities, prior to the decision being taken by the European Parliament and the Council".

ITEMS APPROVED WITHOUT DEBATE

ECOFIN

Budget of the European Communities for the 2003 financial year

(doc. 14802/02)

The Council confirmed the outcome of the proceedings of the Ecofin Council of 25 November 2002; with regard budget issues. The Council consequently :

- established the amending letter N°2 to the draft budget for 2003;
- established the Council second reading of the general budget for 2003, and
- mandated the Presidency, assisted by the General Secretariat of the Council, to draw up the relevant budget documents and forward them to the European Parliament in accordance with the timetable established.

The Council also recorded in its minutes the statements annexed to document 13900/02, with the exception of statement N°3 and in the conclusions of the conciliation meeting of 25 November 2002.

For further information about the results of the Ecofin Council of 25 November, you can consult the Council web page at : <http://ue.eu.int/newsroom> .

Budget of the European Communities for the 2002 financial year

(doc. 14463/02)

The Council:

- established the supplementary and amending budget N°6 for 2002;
- instructed the Presidency to prepare the budget documents to be sent to the European Parliament.

EXTERNAL RELATIONS

Western Balkans – European Union Monitoring Mission (EUMM)

The Council adopted a Joint Action extending the mandate of the European Union Monitoring Mission (EUMM) in the Western Balkans until 31 December 2003 (14023/02). The reference amount for the implementation of the Joint Action is EUR 5,18 million.

On 22 December 2000 the Council adopted Joint Action 2000/811/CFSP concerning the EUMM, which was extended in November 2001 until 31 December 2002. The Mission had previously operated since 1991 as the ECMM (European Community Monitoring Mission) on the basis of a memorandum of understanding between the participating countries. The primary objective of the EUMM is to contribute, in a flexible manner, through information gathering and analysis in line with directions from the Secretary General/High Representative and the Council, to the effective formulation of Union policy towards the Western Balkans.

The Council also adopted a Decision extending the mandate of the Head of Mission of the EUMM, Mr Antóin Mac Unfraidh, until 31 December 2003 (14025/02).

Bulgaria / trade in fishery products* (11332/02)

The Council adopted a Decision on the conclusion of an additional Protocol on trade in fishery products with the Republic of Bulgaria. It authorised the President of the Council to designate the person empowered to sign this Protocol to the Europe Agreement with Bulgaria on behalf of the Community.

In May 2000, the Council authorised the Commission to open negotiations with the ten associated countries of central and Eastern Europe on reciprocal trade concessions for fishery products, in the general context of the accession process, to help prepare these countries for integration into the internal market. The Council has already approved the conclusion of additional Protocols with eight out of the ten countries.

TRADE

Anti-dumping/India (13733/02)

The Council adopted a Regulation imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of polyester textured filament yarn (PTY) originating in India.

Anti-subsidy/India/Indonesia*(13736/02)*

The Council adopted a Regulation imposing a definitive countervailing duty on imports of polyester textured filament yarn (PTY) originating in India and terminating the proceedings concerning imports of PTY originating in Indonesia.

Vietnam - Prevention of fraud in trade in footwear products

The Council agreed on a recommendation authorising the Commission to open negotiations for the renewal of a Memorandum of Understanding between the European Community and the Socialist Republic of Vietnam on the prevention of fraud in trade in footwear products.

COMMODITIES**International agreement on olive oil and table olives***(doc 14224/02)*

The Council adopted a Decision on the six month extension until 30 June 2003, of the 1986 International Agreement on Olive Oil and Table Olives.
