



EUROPEAN COMMISSION

**Commission Services Progress Report**  
**on the**  
**EU-Japan Business Dialogue Round Table 2005 Recommendations**

**Brussels, April 2006**

Under the heading “*A Continued Innovative Approach to Address New Common Challenges*”, the European Union – Japan Business Dialogue Round Table (BDRT) issued in 2005 its recommendations to the leaders of the EU and Japan.

Adopted during the BDRT annual meeting held in Brussels on 7 and 8 July 2005, those recommendations have been duly studied by the European Commission Services.

The following document outlines progress made in considering or implementing the various recommendations put forward by the BDRT.

For each recommendation (or set of recommendations concerning the same issue / topic), a summary is proposed before describing the action taken and the state of play. As appropriate, a paragraph is dedicated to the prospects for implementation.

The progress report is divided into 6 parts dealing with the following issues:

- Trade and Investment,
- WTO,
- Accounting and Taxation,
- Information and Communication Technologies,
- Life Sciences and Biotechnology,
- Sustainable Development.

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## 1. TRADE AND INVESTMENT

### 1.1. Supporting timely development of business (1-EJ-3): Social security contributions

#### 1.1.1. Summary of recommendation

Social security agreements between all Member States of the EU and Japan should be concluded at an accelerated pace (within a period of five years) to avoid double contributions.

An interim measure should be introduced when social security agreements are not yet concluded.

Research work should be outsourced to external think tanks to provide adaptable agreement texts and facilitate the negotiations.

#### 1.1.2. Action taken and state of play

Member States of the EU are responsible for the funding and organisation of their social security systems. They are therefore free to determine details of their own social security systems, including which benefits shall be provided, the conditions for eligibility and the value of these benefits, as long as they adhere to the basic principle of equality of treatment and non-discrimination as laid down in the Regulation (EEC) 1408/71 on the application of social security schemes to employed persons and their families moving within the Community. It is also the exclusive competency of Member States to conclude social security agreements with third countries.

In this context, the Commission welcomes the recognition of a need for action with regards to the question of double contributions. The EU acknowledges that bilateral social security agreements constitute an appropriate solution, and welcomes the willingness of Japan to conclude such agreements with each of the EU Member States. A number of bilateral social security agreements with some EU Member States have been concluded, or are being negotiated at present. The EU also welcomes the efforts of exchange of information to launch negotiations with other EU countries.

It will take a considerable time at the current pace of progress before the problem of dual pension membership and wasted premium payments can be solved. The foreign workers living in Japan must contribute to the Japanese pension system along with their employers. When leaving Japan, they can receive a partial refund of pension contributions of exceptional and temporary nature, adopted by the Japanese government in the Pension Law in 1994, capped at 3 years, if they have worked in Japan for longer than 6 months and less than 25 years.

The EU has reiterated its suggestion that departing expatriates not yet covered by a bilateral agreement should receive a full refund of the actuarial equivalent of all mandatory pension contributions paid to date, or at least the period and the amount for the refund should be extended to 5 years in line with recent

developments to extend the length of stay of certain foreign workers (e.g. those working in Special Zones for Structural Reforms).

### *1.1.3. Prospects for Implementation*

Given the competencies in this area, the conclusion of social security treaties between Member States and Japan has to be discussed on a bilateral basis. Accordingly, the possibility to involve think tanks is to be addressed by Member States.

## **1.2. Promotion of regulatory reforms (1-EJ-5)**

### *1.2.1. Summary of recommendation*

The EU and Japan should continue to cooperate with each other through their ongoing regulatory reform dialogue with the goal of creating an open environment for trade and investment.

### *1.2.2. Action taken and state of play*

The Regulatory Reform Dialogue between the EU and Japan has been acknowledged by Summit Leaders both at the Luxembourg EU-Japan Summit on 2 May 2005 by stating that it “*continued to deliver concrete outcomes, such as in finding practical solutions to facilitate the living and working environment of expatriate nationals. In that context, they underlined the usefulness of the ongoing dialogues and information exchanges on important economic issues, in particular on the REACH regulation and on government procurement.*”

The two-way dialogue continued to deliver results in the two meetings in November 2005 in Tokyo and in March 2006 in Brussels respectively. In both meetings prominence was given to facilitating access of products and services to the markets by early provision of information on new legislative undertakings and by cooperating on standards and conformity assessments, including the acceptance of test data. This continues to be a key element of the Regulatory Reform Dialogue and an important component of the two-way Investment Framework that was adopted at the Summit in 2004. On the latter, continuing working contacts have taken place in 2005 regarding the European Securities Regulators’ provision to provide technical advice on the equivalence of Japanese accounting standards with international accounting standards. Other issues related to provisions of the new Japanese Corporate Law pertaining to mergers and acquisitions as well as the privatisation of the Japan Post.

### *1.2.3. Prospects of implementation*

Regarding international harmonisation and mutual acceptance of technical regulations and standards, some progress can be noted on pharmaceuticals’ approval procedures and data protection, building standards (first meeting of the EU-Japan Wood Forum in Brussels on 22 March 2006), banking and insurance services (even if problems persist regarding reinsurance legislation), mergers and acquisitions (even if no final confirmation had been obtained

regarding new rules on tax deferral and shareholders' rights), and food additives and flavourings (limited progress).

No progress, however, was achieved regarding phytosanitary issues (simplification of control lists and procedures), EU import restrictions on ovine and bovine products, public procurement, legality of branches (Art. 821 Corporate Law), air service agreements, organic food certification system and telecommunications.

Both sides will continue work to promote and enhance the acceptance, recognition or harmonisation of standards, certification and notification, where appropriate, in the context of the Regulatory Reform Dialogue, by implementing the Investment Framework and through bilateral meetings and working groups between the Japanese Government and the services of the European Commission. Active participation in public consultation procedures in new legislative projects is thereby also of the essence.

### **1.3. The policy of the EU on taxation (1-E-1)**

#### *1.3.1. Summary of recommendations*

(a) Concerning the EU Transfer Pricing Documentation – the EU TPD – the EU and the Member States should commit themselves to exemption from penalties (i.e. penalties related to non-compliance with documentation requirements, penalties related to transfer pricing adjustments and interest related to adjustments) if a company submits an EU TPD acting in good faith and in a timely manner.

(b) Although VAT is a common taxation system in the EU, difference among Member States is so large that companies find it very difficult to centralise VAT administration. The EU and the Member States should simplify and harmonise it to the extent that companies can centralise VAT administration easily without employing people with expert knowledge of the VAT regime in each country in which it is operating.

(c) The European Commission and the Member States should make swift progress in realising the cross-border offset of losses against profits.

#### *1.3.2. Action taken and state of play*

(a) With the EU TPD, Member States have indicated that a multinational enterprise which follows the EU TPD will be unlikely to attract documentation related penalties. However, penalties and interest related to transfer pricing adjustments are something quite different. It is not in the interest of the tax paying community as a whole that merely documenting something exempts a taxpayer from penalties even if the tax return is wrong.

We take reducing compliance costs associated with transfer pricing very seriously. The work of the Joint Transfer Pricing Forum (JTPF) is conducted very much within this framework. By encouraging Member States and Business to adopt similar approaches to transfer pricing problems, the Forum seeks to reduce compliance costs caused by Member States having different approaches

within the EU. The JTPF is already looking at Advance Price Agreements (APAs) and seeking to formulate a pan-European framework for APA procedures to both encourage their use and to reduce the costs associated with APAs. The framework should apply for APAs within the EU and also between EU countries and, for instance, Japan.

(b) The EC put forward VAT simplification proposals (notably the One Stop Shop) which are aiming at reducing the VAT compliance burdens for non-established traders (in the Japanese case, an establishment would be required in one Member State at least to benefit from this). Negotiations on this proposal continue in the Council. Full harmonisation of VAT in the EU is currently unrealistic.

(c) Business considers the lack of cross-border loss relief as one of the remaining important tax obstacles to the Internal Market and the Commission is taking its concerns into account. The Commission has the intention to address this issue by a targeted measure in the form of a Communication in the near future also in line with the re launch of the Lisbon Strategy.

The legal basis for any legislative action in the area of taxation has to be based on Art. 94 of the EC Treaty. This provision requires unanimity in Council which makes any progress politically extremely difficult.

#### **1.4. The policy of the EU on company law (1-E-2)**

##### *1.4.1. Summary of recommendations*

###### (a) Directive on cross-border mergers (10<sup>th</sup> Company Law Directive)

The proposal for a Directive of the European Parliament and of the Council on cross-border mergers of companies with share capital (10<sup>th</sup> Company Law Directive) should be adopted and implemented without delay.

###### (b) Proposal for a 14<sup>th</sup> Company Law Directive

A 14<sup>th</sup> Company Law Directive on the cross-border transfer of the registered office of limited companies without liquidation and incorporation should be proposed, adopted and implemented as soon as possible.

###### (c) Statute for a European Private Company

A Statute for a European Private Company should be introduced as a short-term priority.

##### *1.4.2. Action taken and state of play*

###### (a) Directive on cross-border mergers (10<sup>th</sup> Company Law Directive)

The Directive was adopted in a single reading by both the Council and the European Parliament on 26 October 2005. It is to be implemented by the Member States by 15 December 2007.

The Directive will facilitate mergers of limited-liability companies on a cross-border basis, which at present are impossible or entail prohibitive costs. It sets up a simple framework drawing largely on national rules applicable to domestic mergers and avoids the winding up of the acquired company. The Directive fills an important gap in company law.

The Directive covers all limited-liability companies, with the exception of undertakings for collective investment in transferable securities (UCITS). Also, there are special provisions for cooperative societies. Given the diversity of cooperatives in the EU, Member States can, with the Commission's agreement, prevent a cooperative from taking part in cross-border mergers for a limited period of five years.

Under the adopted Directive, employee participation schemes should apply to cross-border mergers where at least one of the merging companies already operates under such a scheme. Employee participation in the newly created company will be subject to negotiations based on the model of the European Company Statute.

#### (b) Proposal for a 14<sup>th</sup> Company Law Directive

The proposal for a 14<sup>th</sup> Company Law Directive has been included in the consultation on the future of the Action Plan on Company Law and Corporate Governance carried out by the Commission from 20 December 2005 to 31 March 2006. According to the preliminary results of the consultation, there is a strong support for this initiative among stakeholders. However, a final decision on the proposal would only be taken after the in-depth analysis of the results of the consultation and the costs/benefits impact assessment have been completed by the Commission services.

#### (c) Statute for a European Private Company

The proposal for a European Private Company Statute has also been included in the consultation on the future of the Action Plan on Company Law and Corporate Governance mentioned in point 1.5. The preliminary results showed considerable support from the stakeholders for this initiative as it would facilitate the mobility of companies, in particular small and medium-sized, in addition to other European measures and would be in line with a better regulation principle by creating more choice for the companies without imposing any new burdens on them.

The final decision on the proposal will be taken after an in-depth analysis of the results of the consultation and the costs/benefits impact assessment have been completed by the Commission services.

### **1.5. Corporate Governance (1-E-3)**

#### *1.5.1. Summary of recommendation*

The European Commission should coordinate EU Member States and introduce a guideline in order to make sure that corporate governance and its disclosure is regulated at the level of listed companies. Adoption of a code should be

voluntary and companies should comply with the adopted code on the principle of "comply or explain".

#### *1.5.2. Action taken and state of play*

In accordance with the recently adopted amendments to the 4<sup>th</sup> and 7<sup>th</sup> Accounting Directives, due to enter into force mid-2008, listed EU companies will be required to produce an annual corporate governance statement. In particular, listed companies, in application of the "comply or explain" principle, will have to indicate whether they follow a code of corporate governance, which one, and if they depart from it, where and why. The decision of companies to follow a code will remain entirely voluntary.

Whilst, in principle, the European Commission agrees with the idea that corporate governance rules and adjacent disclosure rules should be implemented throughout a group of companies in a consistent way, it seems neither feasible nor appropriate to mandate at EU level a "home-country" principle in the field of corporate governance.

The Commission does not intend to go beyond the two corporate governance recommendations respectively on directors' remuneration and independence adopted at the end of 2004. In particular, it is not in the intention of the Commission to develop a European Code of Corporate Governance but rather to promote the convergence of corporate governance practices in the EU through the European Corporate Governance Forum.

The role of the Forum is to allow exchange of information and best practices existing in Member States in order to enhance the convergence of national codes of corporate governance. The Forum can also provide strategic advice to the Commission – including areas of priority, concerns etc – taking into account the global dimension.

### **1.6. Japanese expatriates (1-E-4)**

#### *1.6.1. Summary of recommendation*

The EU should introduce a fast track procedure for Japanese nationals who are already legally resident in a Member State when he or she moves to another Member State for economic activities or other reasons.

#### *1.6.2. Action taken and state of play*

With regards to the movements of third country nationals (i.e. also Japanese citizens) within the Community, three Directives offering this possibility have been adopted so far.

According to Directive 2003/109/EC on long-term residence status, a third country national who fulfils the conditions provided by Articles 4, 5 and 6 of the Directive can acquire an "EC long-term residence status". Once acquired, the status grants a possibility to go to another MS upon fulfilment conditions provided for in Chapter III of the Directive (i.e. sufficient resources, health insurance, as well as in some cases integration conditions and accommodation;

for economic activities there might be further conditions required: e.g. application of national procedures to filling a vacancy such as work permit as well as application of community preference).

The deadline for transposition of this act expired on 23 January 2006 and the Commission is now closely monitoring how particular Member States are implementing it.

The possibility of Intra-Community movement is also recognised by further two Community Directives i.e. Directive 2004/114/EC on third country students and Directive 2005/71/EC on third country researchers. According to these two acts, third country students or researchers who were admitted to reside in one of the Member States under the conditions of these respective Directives have the possibility, upon fulfilment of certain conditions prescribed by the acts, to pursue their studies or research in another Member State.

For the moment the deadlines for transposition of these Directives have not expired yet (12 January 2007 and 12 October 2007 respectively). Consequently we are assisting Member States in their preparations made in order to implement them in the national legal order.

Directives 2003/109/EC and 2004/114/EC are not applicable to UK, DK and IRL. Directive 2005/71/EC is not applicable to UK and DK. This means that third country nationals residing in these MS may not apply the Directives to their situations and in consequence are not able to go to another MS. It also means that third country nationals residing in those MS where the Directives are applicable will not be able to go to respectively three or two MS where the Directives are not applicable.

All other scenarios which are not covered by above Directives are for the moment regulated by national legislations.

### *1.6.3. Prospects for implementation*

As for the future and as explained in the Policy Plan on Legal Migration (COM(2005)669 of 21 December 2005), the Commission plans to put forward in 2007 a proposal for a directive on the conditions of admission of highly skilled third-country workers to the EU, which, in the Commission's intentions, should include provisions on intra-EU mobility. Another possibility would be to create an EU green card for highly skilled workers, issued by the Member State of first admission, but valid throughout the EU. Such a scheme would be applicable to all highly skilled third-country workers, therefore also for Japanese nationals who would fall in this category.

## **1.7. Pensions (1-E-5)**

### *1.7.1. Summary of recommendation*

Double taxation related to occupational and supplementary pensions should be eliminated as soon as possible.

### *1.7.2. Action taken and state of play*

Member States of the EU are responsible for the funding and organisation of their social security systems. The conclusion of bilateral agreements will be conducive to a solution in the longer term to solve the problem of dual pension membership and wasted premium payments.

Japan has already concluded social security agreements with Germany and the United Kingdom. In February 2005, Japan signed social security agreements with France and Belgium, and the agreements were approved by the Diet in July 2005. Negotiations are on-going to conclude a social security agreement with the Netherlands. Exchange of information with all other EU Member States are foreseen with a view to launching negotiations to conclude social security agreements in order of priority, according to the situation of exchanges of people between Japan and these countries and the need for social security agreements.

### *1.7.3. Prospects for Implementation*

Given the competencies in this area, the conclusion of social security treaties between Member States and Japan has to be discussed on a bilateral basis.

## **1.8. Community Patent (1-E-6)**

### *1.8.1. Summary of recommendation*

The proposal for a Council Regulation on the Community Patent should be adopted and implemented as soon as possible.

### *1.8.2. Action taken and state of play*

There has been no progress on the Community patent since spring 2004, when agreement in Council was blocked because of two issues relating to translations of patent claims. The Community patent remains a priority objective under the renewed Lisbon strategy on more growth and employment. Therefore, on 16 January 2006 the Commission launched a consultation on the future patent policy in Europe, focusing on the structure of the European patent model without yet touching upon issues of substantive patent law.

The main aim of this exercise is to gain new momentum on patent matters which will hopefully lead to the adoption of Community Patent.

Pending the outcome of this effort, the Commission is also seeking views on what measures could be taken in the near future to improve the patent system in Europe. The consultation is intended to ensure that any new proposals in the area of EU patents policy reflect stakeholders' needs.

Deadline for submitting replies to the consultation expired on 12 April 2006. Participation rates from a large range of stakeholders exceeded all expectations (some 2000 replies were received). Japan has contributed to the consultation by submitting a response to the questionnaire.

Preliminary findings from this consultation will be presented and put forward for discussion at a hearing in June 2006 in Brussels. The Commission will then decide on the steps to follow.

## **1.9. Fight against counterfeited, pirated and contraband goods (1-E-7)**

### *1.9.1. Summary of recommendation*

The BDRT calls for a serious fight against counterfeited, pirated and contraband goods. With respect to the EU, it calls for a reinforced action at the new and extended border of the EU.

### *1.9.2. Action taken and state of play*

Internal actions have been taken both in the EU and Japan in order to better fight against counterfeiting and piracy.

On the EU side, the following actions have been undertaken:

- implementation of Directive n° 2004/48 on IP Enforcement by Member States due before the end of April 2006),
- Commission’s proposal to harmonize criminal sanctions in the EU,
- Implementation of the Commission’s Strategy for the Enforcement of IP rights in Third Countries (in particular by defining a list of “priority countries” where its action should be targeted through a worldwide survey; report to be issued in March),
- Moreover, the Commission has launched a consultation on the future patent policy in Europe to which Japan has been invited to respond.

At bilateral level, the EU and Japan have also pursued their Dialogue on Intellectual Property and Joint Initiative on Enforcement in Asia, in particular by collaborating and having in-depth exchanges on multilateral and bilateral respective work in order to make things progress on the ground. The third session of the EU-Japan Dialogue on IP took place on 21 February 2006 in Tokyo.

- The issue of counterfeiting was discussed at the G8-IP Experts’ meeting in Moscow at the end of March 2006. Experts agreed on the need to reinforce the IP international legal framework.
- EU initiative on IP Enforcement in the TRIPs Council, started in October 2005 and discussed at every TRIPs Council at the EU’s request since then. The objective of this exercise is to examine the implementation of enforcement provisions of TRIPs and find solutions to possible problems in this implementation.
- Japan’s proposal for a Treaty on Non-Proliferation of Counterfeit and Pirated Goods made in September 2005.

- EU and Japan have also finalised the negotiations of a Customs Co-operation Agreement.
- In parallel, the EU has conducted an extensive survey of the situation of IP enforcement in third countries, the results of which will be released soon, and both sides have worked in close connection with other third countries, by mechanisms of specific co-operations on IP or dialogues.

### *1.9.3. Prospects for implementation*

The EU is committed to pursue and deepen co-operation in international fora where counterfeiting and piracy are discussed (WTO, G8, WIPO, WCO, etc.) and, in particular, actively participate in examination of the implementation of enforcement rules taking place in the TRIPs Council.

The EU will also continue to contribute to the implementation of G8-IP experts' recommendations and to the realization of an OECD study on the economy of counterfeiting;

Furthermore, it will pursue bilateral talks with third countries concerned by counterfeiting and piracy (source, transit and consumption countries). In this respect, Japan and EU are committed to keep each other informed about developments.

## **1.10. Tariffs and Tariff classification (1-E-8)**

### *1.10.1. Summary of recommendation*

- (a) The tariff rates of the EU on certain manufactured goods (e.g. audiovisual electrical appliances or passenger vehicles) are very high compared with those of other developed countries and should be lowered.
- (b) Tariff classifications must be appropriate, timely and transparent, based on the primary function of the manufactured good at the time of import. Importers find that classification remains unpredictable because of inconsistencies in the interpretation of the tariff schedule by the EU. This situation should be improved.

### *1.10.2. Action taken and state of play*

EU tariffs on manufactured products are largely comparable with those of other industrialised countries. According to WTO figures (2001), EU average bound tariff for industrial products is 4.1%, against 3.9% in the U.S. and 3.5% in Japan. The EU share of lines with tariff peaks (with duties above 15%) is 1.5%, against 3.5% in the U.S. and 1.8% in Japan.

Certain duty rates in the EU tariff are higher than those of other developed countries. However, it should be recalled that the duty rates in question are the outcome of GATT and then WTO negotiations for the post-UR Information Technology Agreement (ITA), and reflect an equitable balance between what the EU gave and was offered in terms of market access.

Within the current WTO Round, negotiations on tariffs and non-tariff barriers to trade in non-agricultural products remain a priority for the EU. All WTO Members should contribute to this process according to their level of economic development and capacities.

With reference to the EU tariff classification system, the BDRT recommendation seems to reflect an incorrect understanding of the purpose of classification. As already stated in previous reports, EU classification is made in accordance with the Harmonised System (HS) Convention rules. Its objective is to find the correct heading in the EU nomenclature, according to the physical characteristics of each product. Classification is not based on the duty rates associated with the Community subdivisions to HS nomenclature. The objective of classification is not to make new tariff concessions without proper trade negotiations. This is in conformity with Article 9 of the HS Convention which states that “The Contracting Parties do not assume by this Convention any obligation in relation to rates of Customs duty”.

With reference to digital technology products, the BDRT request reflects the misunderstanding that all so-called “IT products” are covered by the ITA. Thus, it must be stressed that the ITA covers many IT products but not all products using IT, in particular consumer electronics which were excluded from the start. The suggestion to apply ITA rates for all so-called IT products whether or not covered by the ITA by means of reclassification is not viable. Duty rates are fixed by the European Council in accordance with the EU’s multilateral and bilateral tariff commitments.

### *1.10.3. Prospects for implementation*

The multilateral market access negotiations for non-agricultural products within the current WTO Round provides an opportunity for both the EU and Japan to reduce overall tariff levels and tariff peaks as well as to seek harmonised and simpler tariff structures for all WTO Members. In this respect, as far as the current WTO Round is concerned, the EU insists on an approach that maintains the high levels of ambition set out in the Doha mandate.

The EU agrees with Japan that tariff classification must be timely and transparent based on the HS nomenclature rules. The EU is of the view that importers have a crucial role to play by declaring imported goods correctly with due respect of EU law and jurisprudence. The Commission remains committed to intervene whenever it discovers inconsistencies in the manner in which products are classified in the EU.

## 2. WTO

### 2.1. Policy Statement concerning the World Trade Organization

#### 2.1.1. Summary of recommendation

The BDRT confirms its strong support to the WTO Doha Round and asks for a balanced and significant result as well as for a rapid conclusion of the Round. The BDRT calls for:

- An ambitious market opening on industrial goods and supports the Swiss formula to reduce tariff peaks.
- Flexibility from WTO Members in order to advance on agriculture
- An ambitious and specific set of rules for Trade Facilitations
- Developing countries' concerns to be addressed, including on capacity building and market access, to ensure that Least Developed Countries (LDCs) participate in the DDA.

On services, the BDRT expresses its concerns for the negotiations lagging behind other negotiating areas.

The BDRT encourages the EU and Japan to work closely at bilateral level and to coordinate their position to achieve a successful conclusion of the negotiations.

#### 2.1.2. Action taken and state of play

The second half of 2005 was devoted to the preparation of the WTO Ministerial in Hong Kong in December 2005. In this respect, the EC is pleased to note that the Ministerial meeting marked a step forward towards the successful conclusion of the DDA possibly by the end of 2006. While it did not manage to fulfil all its initial objectives, i.e. the agreement on full modalities on all negotiating items, the Ministerial Declaration included important elements.

In agriculture, agreement was achieved to phase out all forms of export subsidies by 2013, with the parallel elimination of all forms of export subsidies and the establishment of disciplines on all export measures with equivalent effect, including export credits, State Trading Enterprises and Food Aid. On NAMA, it was agreed that the negotiations would proceed on the basis of a Swiss formula for tariff reduction, as requested by BDRT, although the question of the number of coefficients still remained and remains open. On services, WTO members agreed to expedite of the request-offer negotiations, with second revised offers to be submitted by 31 July 2006 and final draft schedules by 31 October 2006.

As far as Trade Facilitations are concerned, the text coming out of Hong Kong set out a number of recommendations which constitute a sound basis for developing multilateral commitments in 2006.

The Hong Kong meeting agreed a number of measures in favour of the LDCs, as wished by the BDRT. Developed country members and those "developing country members declaring themselves in a position to do so" (paragraph 47) have agreed to implement duty-free and quota-free market access for products originating in LDCs, although the scheme applies to 97% of their tariff lines. Moreover, both the EU and the US announced increases in their financial efforts in the area of aid for trade. In addition, the Ministerial meeting confirmed the agreement reached on 6 December 2005 concerning the Amendment to the TRIPS Agreement on compulsory licensing of medicines in the context of TRIPs and Public Health.

Regrettably, on Geographical Indications (GIs) no progress in any direction was made.

### *2.1.3. Prospects for implementation*

The EC fully shares the BDRT's strong support for the multilateral trading system and the Doha Development Agenda (DDA).

At this stage, it is not possible to foresee any outcome of this negotiating round. The Hong Kong Ministerial set a series of ambitious deadlines in 2006 which now need to be met. Progress in all areas is a necessary condition for the conclusion of the Round. In order to drive the DDA forward, the EC has shown a high level of flexibility in sensitive sectors such as agriculture. The EC expects other WTO Member to do the same in the next months. Issues that have not been addressed in Hong Kong, such as geographical indications, need to be addressed.

The EU and Japan need to work closely. Only a constructive co-operation across all issues, as urged by the BDRT, can guarantee a meaningful outcome.

The EU and Japan have both remained fully committed to further open up markets and develop trade rules within a multilateral framework, to make progress in the DDA negotiations on process and on substance and to ensure their successful conclusion.. Ensuring support from business through close dialogues on trade and investment issues of concern to them will remain one of the key aspects to the successful conclusion of these talks.

### 3. ACCOUNTING AND TAXATION

#### 3.1. International Accounting Standards (2-E-1; 2-EJ-1; 2-EJ-2)

##### 3.1.1. Summary of recommendations

(a) The BDRT asks the European Commission to make every effort to adopt a prompt decision on equivalence of IAS/IFRS and Japan GAAP well before the 1<sup>st</sup> January 2007 deadline. The final decision on equivalence should be taken after careful consideration to minimise the cost and inconvenience to users and providers of Japan GAAP following receipt of CESR's final technical advice.

(b) The BDRT asks that the public authorities in Japan and the EU make steady progress towards adoption and implementation of IAS/IFRS.

(c) The BDRT ask the public authorities to observe closely the process of rule setting and revision by the International Accounting Standards Board (IASB) and to have regard for the interests of companies and investors (whether European or Japanese) in the opinions they transmit to the IASB, in particular in its Performance Reporting project.

##### 3.1.2. Action taken and state of play

(a) The Commission is making a proposal for postponing the equivalence decision in relation to US GAAP, Canadian GAAP and Japanese GAAP until 2009. The deferral also includes other third country issuers who prepare their financial statements using GAAPs which are consistent with IFRS. The proposal is available at:

[http://europa.eu.int/comm/internal\\_market/accounting/committees\\_en.htm#060424](http://europa.eu.int/comm/internal_market/accounting/committees_en.htm#060424)

The European Securities Committee is the main committee advising the Commission and it is expected that a decision will be made in June 2006.

(b) The EU adopted IFRS for mandatory use in all listed companies' financial statements from 1 January 2005. Therefore, IFRS is fully implemented in the EU. The IAS Regulation also permits Member States to extend the use of IFRS in individual company financial statements and for unlisted companies.

(c) The Commission takes a very close interest in the corporate governance arrangements concerning the IASB and believes that the 2005 review of the IASCF's Constitution brought significant improvements. It is currently discussing with the IASCF its future funding arrangements as the current arrangements expire on 1 January 2008. The Commission Services monitor all projects of the IASB.

### **3.2. Convergence of international standards of accounting, auditing and disclosure (2-E-2; 2-EJ-3; 2-EJ-4)**

#### *3.2.1. Summary of recommendations*

(a) Given that the European Union's Emissions Trading Scheme ('ETS') is now in operation, the BDRT asks the European Commission to endorse widely accepted accounting rules on emission rights.

(b) Concerning research on the introduction of reports on internal control over financial reporting, the BDRT asks that both governments sufficiently discuss the function of internal control, correlating with each mechanism to improve credibility of financial reporting, such as corporate governance, audits on financial statements and oversight over companies and independent auditors.

(c) Recognising that convergence of international standards of accounting, auditing and disclosure is an objective, the BDRT asks that the public authorities adopt mutual recognition as a short-term target on a course toward convergence in the future.

#### *3.2.2. Action taken and state of play*

(a) The IASB issued IFRIC Interpretation 3 Emission rights in December 2004 to give guidance on how to account for the EU's ETS scheme. The IASB subsequently withdrew this Interpretation in July 2005, stating that whilst it was a correct interpretation of the standards, it creates unsatisfactory measurement and reporting mismatches.

The IASB has placed this issue on their agenda so that it can be dealt with in a comprehensive manner. At present, the project has been deferred pending conclusion of work on other projects that will affect this project, such as revenue recognition.

The Commission, with advice from EFRAG (European Financial Reporting Advisory Group), supported the withdrawal of IFRIC 3. This means that European companies must determine what the most appropriate accounting policy for emission rights is for their company.

(c) The IASB and the FASB have drawn up a Memorandum of Understanding (MoU) which was published on 27 February 2006. It describes the projects they intend to undertake jointly. It also includes an estimated timeline. The Commission welcomed the MoU in a press release on the same day and the following day the SEC welcomed the MoU.

There are also a number of important projects which are on the IASB's work programme that are important for Europe but are not included in the convergence programme. These include emission rights and service concession arrangements.

The Commission wishes the IASB to focus firmly on business need before making any further changes to the accounting standards as companies need a period of relative stability in order to implement IFRS. There are certain projects in the work programme do concern complex and controversial accounting areas. Accordingly these areas have a particular need for wide consultation and from an early stage in the project. The work programme also needs to be reviewed regularly with companies, auditors and market participants all playing a part.

## 4. INFORMATION AND COMMUNICATION TECHNOLOGIES

### 4.1. Promotion of broadband usage (3-EJ-1)

#### 4.1.1. Summary of recommendation

Widespread availability and use of broadband networks are driving factors for the improvement of competitiveness of both economies. E-entertainment services are important for the take-up of broadband access. Another way to enhance broadband take-up is the development of large-scale e-public services. The public sector is a service intensive sector, which would gain a huge benefit by further implementing ICT.

Both authorities should enable development of mass market e-entertainment services and give priority to large-scale public e-services.

#### 4.1.2. Action taken and state of play

Broadband take-up is growing fast in the EU, where almost 25% of households subscribe to broadband and there are almost 60 million broadband lines, a number that has quadrupled in three years.

Within this context, the development of new services and applications at the base of new business opportunities emerging from web-services requires a clear legal framework and actions to promote interoperability. The effective implementation of the European regulatory framework for electronic communications will contribute to extend markets and promote the use of broadband services. In this respect, the Commission will continue to enforce the EU telecom rules rigorously and promote competition as well as commercial investment.

As media content consumption changes and new services appear on the market, the Commission is also aware of their potential for growth, but also for creativity, diversity and democracy. However, the divergent rules on on-demand content and the lack of a consistent IPR regime across Europe risked to hold back innovative services. The Commission has taken the first steps to accompany this important evolution of the content consumption modes with a proposal to modernise the "Television without Frontiers" Directive. The modernised directive therefore, founded on the Country of Origin principle, will tackle part of this problem by allowing on-demand audiovisual media services to fully exploit the EU internal market. Furthermore, in order to tackle the question of IPR, a Commission communication on "Content On line" will be prepared before the end of the year.

Furthermore, new technologies to deliver this content, such as mobile TV, will also require that harmonised spectrum is available across Europe to make possible the development of efficient business models. The Commission is working with the Radio Spectrum Policy Group of the EU Member States to ensure a minimum harmonisation of radio bands at European level to allow Mobile TV services to get started and to accelerate discussions on the use of the digital dividend derived from the switch-off of analog TV, including the

possibility to harmonise some of it at EU level. The “Regional Radio Conference 2006” (RRC 06) and the “World Radio Conference 2007” are important milestones for this debate, because they will define frequency plans for the future.

Finally, the Commission agrees that ICTs are a key element in generating tangible improvements in the areas of health, education, public administration, business, accessibility and social inclusion. Hence the importance attached to the build-up of citizen and business-centred eGovernment. First, the Commission is fostering the exchange and promotion of good practices coming from all over Europe through a Good Practice Framework with more than 600 experts. Second, as eGovernment reaches a critical juncture the step from information-only online services to fully personalised and transactions can only be made if certain key enablers, such as Electronic identification and authentication in public services, are in place.

Today’s incompatibility of public sector electronic identification and authentication systems is a barrier to using public services across borders, but the Manchester Ministerial Declaration has set the important target that by 2010 European citizens and businesses shall be able to benefit from secure and convenient electronic identifications for access to public services in their own or in any other Member State. However, electronic identification has also to be complemented by electronic document authentication and electronic archiving. In the same Ministerial Declaration, Member States have set the 2010 goal for setting up a framework for authenticated electronic documents across the EU.

To achieve these goals, EU Governments at all levels and industries will have to co-operate. For its part the European Commission will support these efforts and promote research and innovation in eGovernment, on user centred design and user satisfaction, exchange of good practice, and support to deployment in large-scale pilots to electronic identification and electronic public procurement. This Spring, the Commission will also present an eGovernment 2010 Action Plan which will look at the further challenges: ensuring inclusion, making efficiency and effectiveness a reality, strengthening participation in democratic decision-making, delivering high impact applications, and putting key enablers in place.

## **4.2. Establishment of a seamless ubiquitous network environment (3-EJ-2)**

### *4.2.1. Summary of recommendation*

Both authorities should promote the development of seamless ubiquitous network environments to allow users to access networks “anytime, anywhere” regardless of which kind of network is used.

Both authorities should coordinate as widely as possible when it comes to the preparation of the next World Radio Conference in 2007.

### *4.2.2. Action taken and state of play*

Technological development has brought a vast choice of technologies and applications to the user, resulting in a growing appetite for spectrum. At the

same time it has become increasingly difficult to predict new developments. In addition, those risking considerable investments to develop and introduce new technologies ask for large markets. This translates in a claim to have reasonably easy access to spectrum and similar conditions on spectrum use throughout the entire European internal market.

Against this background, the Commission efforts are directed at lowering the access hurdles to radio resources and to empower the spectrum users to decide on the usage they make of spectrum. This means reducing the present administrative constraints commonly imposed on spectrum usage to the minimum necessary to ensure an interference free environment and empowering market players to decide on an optimal usage of radio resources.

To achieve these goals, the Commission is working on a new Communication to Council and the Parliament later in the year that will underline the need to adopt technology neutrality and service neutrality as the general rule when managing spectrum, with any further restrictions having to be clearly justified. As the Commission reviews the current regulatory framework for electronic communications, the necessary provisions to support this approach will receive due consideration.

In addition, the Commission expressed already last year, in its Communication on a market-based approach to spectrum management in the European Union, that managing spectrum for commercial use should include allowing secondary trading of spectrum under certain circumstances. The Commission is gradually putting into place the conditions to this extent. In particular, the Review of the regulatory framework should allow for establishing the necessary provisions to allow for a coherent approach to spectrum trading at EU level.

Finally, other paradigms in spectrum management such as the more pervasive use of license exempt bands are currently being analysed to determine if this approach could be a valid option. The Commission is currently investigating the benefits and limits of this approach, in order to decide whether a further expansion of unlicensed spectrum resources is required.”

This being said, besides offering more flexibility to spectrum use, the Commission will continue to examine the need to harmonise spectrum usage conditions in specific cases. In this respect, the Commission has already introduced legally binding spectrum usage technical provisions in order to pursue important public policy objectives, for instance regarding anti-collision radar in cars, and will continue in the future to determine the spectrum needs for car-to-car and car-to-road infrastructure communication systems. Furthermore, spectrum harmonisation measures are also being used to enable economies of scale (as could be the case, for instance, to create an environment favourable to the deployment of radio tags or ultra wide band devices).

Finally, the switchover from analogue to digital TV will make available large quantities of very valuable spectrum, providing an opportunity to apply some of the principles described above if the conditions of access to this spectrum are coherently established in Europe and that sufficient spectrum is made available to allow pan European services to develop.

In the field of research, the Commission has already supported efforts in this area within its 5th and 6th Framework Programs for research. The 7th Framework program (the European Union's main instrument for funding research and development as of 1 January 2007) will build on the achievements of its predecessors. In this context, the European Commission has fostered and provided political support to the set-up of a Mobile and Wireless Communications Technology Platform which will allow industrial stakeholders to debate and commit to the implementation of an strategic research agenda within the 7th Framework Program. The European Commission will take this important contribution into account when preparing its work programme for research in this field.

### **4.3. Ensuring secure ICT infrastructure (3-EJ-3)**

#### *4.3.1. Summary of recommendation*

Both authorities should have continuous talks to raise their awareness of the quality of ICT infrastructure for ensuring secure ICT infrastructure, by promoting highly reliable and secure system/products, information exchange and matching regulations between them, and establishing a framework that can draw lessons from terror events and disasters.

#### *4.3.2. Action taken and state of play*

Achieving the objectives of the Lisbon agenda – that is, creating a competitive, sustainable and socially-inclusive Europe – largely depends on the take-up of secure and dependable ICT. As ICT and electronic communications networks become ubiquitous in everyday economic and social life, the Commission is aware of the need to address this issue. In this respect, trust and security are an integral part of its i2010 initiative that highlights the urgent need to coordinate efforts at European level to develop policies, regulations, technology and awareness to build trust and confidence of businesses and citizens in electronic communications and services and announces a new strategy to be proposed by the Commission this year.

Such an strategy will require that a structured process of consultation and dialogue on network and information security is be established with relevant stakeholders, including public administrations, private sector and civil society, and ENISA, as appropriate. This approach should promote greater coherence between the various public policies affecting information security, as well as a greater awareness and a better understanding of the roles and responsibilities of all actors involved. However, the Commission agrees that given the cross-border nature of many security problems and threats, international cooperation is essential for creating, fostering and enhancing a global culture of security, in particular as part of the approach agreed at the World Summit on Information Society in Tunis in 2005.

These and other related issues will be addressed in a series of policy documents planned for 2006, including a Communication on a strategy for a secure Information Society; a Communication specifically addressing spam, spyware and malware, and a Communication on cybercrime.

In addition, the 2006 review of the regulatory framework for electronic communications will provide with an opportunity to assess the need of any additional Regulatory measure, if considered necessary.

#### **4.4. Bridging the digital divide (3-EJ-4)**

##### *4.4.1. Summary of recommendation*

Both authorities should adopt every possible measure to improve ICT literacy, especially by promoting ICT education in schools. We encourage an exchange of information between Japan and Europe on the success of these initiatives in order to mutually benefit from experiences gained by the partner country when developing future initiatives.

##### *4.4.2. Action taken and state of play*

The promotion of an inclusive European information society is a central element of the i2010 initiative launched by the Commission in 2005. The i2010 presents three main action lines to allow the EU to take advantage of the mass deployment of ICTs and the latest waves of technological convergence: creating an open and competitive EU single market for Information Society and media services, considerably increasing investment in research on ICTs in the EU and promoting an inclusive European Information Society, with a strong focus on activities relating to the digital divide, on a territorial and on a social scale.

The actions undertaken by the European Commission aim at turning the risk of a digital divide into "digital cohesion" and "digital opportunities" across the Union. This means bringing the benefit of the Information Society into all segments of the population, including: people who are disadvantaged due to limited resources or education, age, gender, ethnicity, people with disabilities and those living in less favoured areas.

A concrete step towards building the digital cohesion is a Commission Communication on e-Accessibility, adopted in 2005 which builds on ongoing e-Accessibility activities in the R&D field (web accessibility, "design for all", and assistive technology) and addresses issues relating to public procurement, certification, and electronic communications legislation.

In 2006 the Commission issued a Communication on Bridging the Broadband Gap: while broadband stimulates economic growth, remote and rural areas have the most to gain from broadband deployment because it reduces the disadvantages of low population density and of physical remoteness from the main economic centres. The Communication underlines that Internet is a critical element in assisting local communities in attracting businesses, in providing healthcare, in improving education and access to government services.

Later in 2006 the Commission will adopt an eGovernment 2010 Action Plan. It will look at further challenges: ensuring inclusion, strengthening participation in democratic decision-making and delivering high impact applications.

From 11-13 June 2006 the European Commission with the Austrian Presidency is organising a Ministerial Conference on ICT for an Inclusive Information

Society in Riga, Latvia. It is expected that the Ministerial Declaration to be adopted at this Conference will address a range of topic related to digital divide and ICT for inclusion (eInclusion), including related to ageing, e-Accessibility, geographic digital divide, and digital literacy. The Commission will follow up on this Ministerial Conference by preparing an initiative on eInclusion for 2008, as part of i2010.

On the international arena, the European Union played an important role in the World Summit on the Information Society in Tunis 16-18 November 2005. It contributed to a balanced agreement on the way forward to bridge the digital divide on the global level. The Tunis documents encourage the adoption of programmes with a view to assisting developing countries to take advantage of ICTs in their pursuit of development.

#### **4.5. Ubiquitous and interoperable platforms (3-EJ-5)**

##### *4.5.1. Summary of recommendation*

Interoperability of software and systems should be a relevant matter in R&D programmes set up by governments.

##### *4.5.2. Action taken and state of play*

Interoperability is a key issue at every level: between network layers, systems and components; between home/organisational networks and global networks; between software systems; between different security and DRM systems; and between enterprise applications. As well as technical functionality, increasingly interoperability involves codifying a complete contract between a user and a provider. The promotion of interoperable software and systems based on open standards is at the heart of the IST R&D programme which focuses on the future generation of technologies in which computers and networks will be integrated into the everyday environment, rendering accessible a multitude of services and applications through easy-to-use human interfaces.

#### **4.6. IPR in a network society (3-EJ-6)**

##### *4.6.1. Summary of recommendation*

Governments should intensify their dialogue on the best way how to protect intellectual property rights e.g. by promoting the use of protection solutions such as DRMs.

##### *4.6.2. Action taken and state of play*

The European Commission has been active in contributing towards take-up of technologies which provide for the management of intellectual property rights (Digital Rights Management systems DRMs). The aim is double fold: to ensure adequate protection of copyright protected content, which is a condition for the availability of 'rich' online content and to ensure a high level of consumer protection and make sure that DRM are not under any circumstances used to lower consumers' rights (privacy, freedom of expression etc.), This is, in itself,

a condition for the take-up of the new services which are made possible by DRMs.

In its Communication on “i2010” the Commission announced that: “Under i2010, the Commission will also seek to establish a comprehensive approach for effective and interoperable digital rights management.” It is therefore planning to issue in 2006 a Communication on Content Online covering DRMs.

An important field of Commission’s activities is a dialogue with the film industry and the online services providers to ensure that online distribution takes place through legal supply. In order to accommodate this need, the “Film Online initiative” has been initiated at the Leadership Summit on Film Online on the “European Day” at the 2006 Cannes Film Festival.

The Summit is a first step towards framing the discussion between these two industries. The objective of the Summit is to discuss the new economic model and to identify, during the course of the year 2006, the opportunities and challenges involved in making film online take off in Europe. The goal is to work towards a European Charter for the Development and the Take-up of Film Online.

Finally, in the context of the 2001 Copyright Directive, the Commission will issue soon a Recommendation on copyright levies in the information society.

#### **4.7. Diverse working styles for ensuring quality of life (3-EJ-8)**

##### *4.7.1. Summary of recommendation*

Both authorities should take an active role in encouraging work-style conceptual frameworks by promoting societal experiments and their evaluation by experts in various areas of industry, academia, and government.

##### *4.7.2. Action taken and state of play*

The promotion of an advanced ICT utilisation for workers in workplaces is one of the strategic objectives of the IST R&D programme. A number of IST projects have been launched with the objective to develop next generation collaborative working environments, thereby increasing creativity and boosting innovation and productivity. These environments should provide collaboration services to make possible the development of worker-centric, flexible, scalable and adaptable tools and applications. This will enable seamless and natural collaboration amongst a diversity of agents (humans, machines, etc) within distributed, knowledge-rich and virtualized working environments. Professional virtual communities and nomadic personal access to knowledge are also supported.

## 5. LIFE SCIENCES AND BIOTECHNOLOGY

### General recommendations

#### **5.1. Continue to implement with urgency the Action Plans issued by the EU in 2002 and by Japan in 2002 (5-EJ-1)**

##### *5.1.1. Summary of recommendation*

Continuous review of these Action Plans is recommended to ensure that they keep pace with advances in Life Sciences and Biotechnology (LS&BT) and the changes of society. Further, project evaluation functions and inter-minister/inter-states coordination should be strengthened.

##### *5.1.2. Action taken and state of play*

The implementation of the Commission's biotechnology action plan continues to make good progress. In 2006-2007 a comprehensive mid-term review will be carried out, including a stocktaking of achievements and obstacles, priority setting, and possibly new proposals for action.

The coordination between the Commission and the Member States' ministries has improved by intensifying our cooperation in the Commission's network of Member State officials for biotechnology. Our joint work is expected to lead to concrete recommendations and proposals for action in 2006.

The Commission has requested the Joint Research Centre in Seville to carry out an assessment study on modern biotechnology, including a comprehensive evaluation of the consequences, opportunities and challenges of modern biotechnology for Europe, in terms of economic, social and environmental aspects. The results are expected to be presented in 2007.

#### **5.2. Encourage Governments to establish "National LS&BT Understanding Promotion Plans" (5-EJ-2)**

##### *5.2.1. Summary of recommendation*

This should be done by a strong governmental initiative in cooperation with industrial and academic sectors for promoting public understanding of biotechnology in the form of a strengthened education in biotechnology and in the form of more direct Communication programmes. Encourage the academic society to help by playing a greater role in fostering understanding in biotechnology.

##### *5.2.2. Action taken and state of play*

The Commission is in 2006 working together with EU Member States to develop concrete proposals on how to improve our communication with the public on matters relating to biotechnology and its applications. This process involves for example collecting good examples of initiatives that have led to a better public understanding, and a catalogue of good practices will be developed by the end of 2006.

The authorisation procedures for products involving biotechnology will, as far as possible, build on the principles of scientific assessment, transparency, and clear communication with the stakeholders.

In its regular contacts with industry and academia, the Commission is keen to underline the importance of improving our way of communicating with the public to explain the characteristics, benefits but also potential risks of biotech products.

### **5.3. Make research for LS&BT a priority in public research funding schemes e.g. Framework Programme 7 in the EU (5-EJ-3)**

#### *5.3.1. Summary of recommendation*

Adoption of the final EU FP7 programme should confirm the importance of research in biotechnology that was outlined in the initial Commission proposal of April 2005.

#### *5.3.2. Action taken and state of play*

A list of examples where progress has been made since 2005 is provided below:

- The Commission's proposal for the 7th Research Framework Programme will boost European research and development, where health is a major priority (second after ICT).
- The Council of the EU has recently confirmed the objective to spend 3% of GDP on research.
- A Commission proposal for a Competitiveness and Innovation Programme is designed to specifically benefit SMEs and start-ups by providing substantial financial means to innovation and bringing promising ideas to the market. More specifically, a risk capital instrument for High Growth and Innovative Companies will be created; and an instrument to securitize banks' SME loan portfolios. Biotech SMEs will likely benefit significantly from this.

### Life Sciences and Biotechnology for Health

### **5.4. Ensure the communication mechanisms between industry and Government regarding pricing and evaluation system of medicines to address the barrier to innovation (5-EJ-4)**

#### *5.4.1. Summary of recommendation*

Work together to ensure that the value of innovation is recognised in the pricing of medicines in EU Member States and Japan.

Ensure that mechanisms in place for the evaluation of medicines are based on clear, transparent and objective criteria, and are subject to appeal.

#### 5.4.2. *Action taken and state of play*

To start a dialogue with EU Member States about possible measures to improve the climate in the EU for investment in European pharmaceutical-related innovation, the Commission has in 2005 launched a new initiative, the Pharmaceutical Forum. The Forum will deal with three major issues: pricing and reimbursement; relative effectiveness and information to patients.

Pricing and reimbursement of medicaments is a Member State responsibility. One issue is to study the impact that the fragmented pricing structure in Europe on competitiveness, and consider whether alternative approaches to establishing prices can provide benefits to governments and industry. A balance between three objectives must be achieved:

- (1) Member States' responsibilities to provide sustainable and affordable healthcare,
- (2) the need to provide a competitive environment and reward for innovation for industry, and most importantly,
- (3) the access for patients to good and innovative medicines.

There are no obvious solutions but a key to finding a way forward will be to change our perspective on medicinal prices. Investment in medicines can deliver long-term reductions in health care costs, e.g. a reduction in hospital stays, etc.

On relative effectiveness, the issue is to study ways to support Member States to develop effective ways of assessing added therapeutic value and cost-effectiveness of treatments. In particular, it would be beneficial for Member States to learn from each other's expertise and experience as well as to address those elements that are barriers for effective exchange of those experiences.

### **5.5. Enhance funding to the clinical research and facilitate regulatory harmonisation to enhance the integrity as well as the practicability of meaningful pre- and post-approval review (5-EJ-5)**

#### 5.5.1. *Summary of recommendations*

Support clinical research by addressing regulatory barriers, public involvement in clinical trials and facilitating development of an improved infrastructure for clinical research.

Continue to facilitate regulatory harmonisation where possible and practical by supporting international regulatory harmonisation. Review the regulatory requirements for vaccines between the EU & Japan.

Work with industry to make further improvements to the regulatory framework for medicines, such as supporting the development in biomarkers, surrogates, and predictive technologies to ensure development of regulatory competence and acceptance.

### 5.5.2. *Action taken and state of play*

Progress is continuously made in addressing the pharmaceutical regulatory framework and the infrastructure for clinical research. Examples of such progress in 2005 are the following points:

- The Technology Platform for Innovative Medicines is designed to accelerate the development of medicines by removing bottlenecks. It will foster the development a new “toolbox” of toxicology tests, biomarkers, clinical trials protocols, et cetera, for drug developers to reduce the risk of failure during clinical trials. It will also provide the infrastructure for the validation of these new tools.
- The EU’s pharmaceutical legislation was fully reviewed in 2004 and the new regulatory framework came into force at the end of 2005. It aims at enhancing innovation and channelling innovation into therapeutic areas and target populations where therapeutic gaps have been identified. Improvements in this area include e.g.:
  - Strengthened data exclusivity for medicines;
  - Enhanced access to market through accelerated, fast-track assessment procedures;
  - Improved availability of medicines through conditional marketing authorisations for medicines addressing unmet medical needs;
  - Reinforced scientific advice provided by the European Medicines Agency (EMA), as early as possible in the drug development process;
  - Introduction of financial and administrative incentives for SMEs (such as waivers and deferrals of the fees they have to pay).
- Other examples of key EU pharmaceutical legislation that can contribute to an improved competitiveness include:
  - The EU has created the world’s first regulatory framework for the assessment, authorisation and monitoring of similar biological medicinal products, i.e. “biosimilars”, also called “follow-on biologics” in the USA.
  - The EU Regulation on orphan medicines, adopted five years ago, has been very successful, both in terms of public health and to boost innovation, which was highlighted in a 2005 report.
  - Another major step forward has been taken recently, in the field of gene, cell and tissue-based products, in Europe called “advanced therapies”. A single European legal framework for all these advanced therapy products has been proposed by the Commission in November 2005. In this field it is desirable to try to achieve a genuine, global regulatory harmonisation together with other countries with experience in advanced therapies, such as Japan.

Life Sciences and Biotechnology for Industrial/Environmental Uses**5.6. Encourage Governments to work towards harmonisation of regulatory requirements for biotechnology products and processes (5-EJ-6)***5.6.1. Summary of recommendation*

The BDRT encourages the European Commission and Member States' governments to keep the present interpretation of EU Regulation 1829/2003 on Genetically modified Food and Feed that "Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation 1829/2003".

*5.6.2. Action taken and state of play*

A revision of the food and feed Regulation 1829/2003 is expected within short, so there is no decision yet on the issue of genetically modified micro-organisms (GMM) used for fermentation, where the final product does not contain any traceable GMM. The position of the industry, which will be duly taken into account, is that GMMs should continue to stay outside the scope of the food and feed Regulation, i.e. they would not be forced to indicate the use of GMMs on the product label.

**5.7. Provide incentives to enable industries to switch to more sustainable production processes (5-EJ-7)***5.7.1. Summary of recommendation*

Consider tax abatements and investment tax credits to incentivise and speed up the implementation of sustainable production technologies.

Provide financial support for highly promising Bio-based technologies at the proof-of-concept stage.

*5.7.2. Action taken and state of play*

The Commission has in 2005 started working together with Member States to formulate concrete recommendations and proposals aimed at realising the potential of plant science and develop a knowledge-based bio economy in the future. To do this, it may be necessary to identify and remove obstacles to putting into practice of more sustainable production technologies.

Thus, the Commission directs its efforts at identifying the needs for a better coordination of EU and Member State legislation, studying the economic effects of e.g. regulatory compliance and tax systems, and identifying possibilities to strengthen Europe's competitiveness in industrial and agriculture biotechnology. The need for introducing support schemes and incentive mechanisms will equally be addressed.

Financial support to research projects is given through the 6<sup>th</sup> and 7<sup>th</sup> Framework Programmes. The Technology Platform “Plants for the future” is a stakeholder forum on plant genomics and biotechnology and it is designed to address four challenges for society to which the plant sector can contribute. Those are:

1. Healthy, safe and sufficient food and feed
2. Sustainable agriculture, forestry and landscape
3. Green products
4. Competitiveness, consumer choice and governance

**5.8. Support setting up a few demonstration projects, either in the area of Bio-chemicals, Bio-materials and/or Bio-fuels, using the US Bio-refineries as a model (5-EJ-8)**

*5.8.1. Summary of recommendation*

See above (5.8).

*5.8.2. Action taken and state of play*

As mentioned, the Commission is working together with Member States to formulate proposals, and one idea that could be turned into a concrete proposal regards the dissemination of knowledge in biotechnology for industrial processing. Some bio-refineries already exist in Europe and the setting up of a demonstration project on the transition of lab-scale knowledge to pilot/pre-industrial scale, e.g. an integrated bio-refinery to provide a test-facility of technological and logistical solutions, would be an idea for the future.

A European pilot project could involve a processing plant where biomass feedstocks such as starch, glucose and vegetable oils are converted into intermediate and final products, ideally novel bio-products: biofuel, biomass, lubricants, cooling fluids, fibres, biodegradable plastics, paper, etc.

Life Sciences and Biotechnology for Plants

**5.9. Further implement and enforce existing regulatory frameworks on GMOs, both in the EU and in Japan (5-EJ-9)**

*5.9.1. Summary of recommendation*

We urge the Commission to ensure that all applications made in accordance with the EU legislation and that have received a positive safety assessment from the European Food Safety Authority (EFSA) receive a timely approval.

We would also like to see the Commission ensuring that Member States that have invoked bans based on “safeguard clauses” and that have failed to provide the required scientific justification to support these bans, withdraw these illegal bans immediately.

We are against linking European-wide legislation for coexistence (as a precondition) with GMO approvals for cultivation in the EU.

### 5.9.2. *Action taken and state of play*

Since the completion of the EU's regulatory framework for biotechnology products, the Commission has run all authorisation procedures normally: product applications are being examined under the relevant authorisation procedures, on a case by case basis and on their own individual merits.

The Commission has played an active role in re-launching product approvals in the EU. In its orientation debates in January 2004 and in March 2005, the College endorsed the approach that pending decisions concerning the placing on the market of new GM products and the lifting of national safeguard measures (bans) should be progressed through the relevant comitology procedures without any further delay, in accordance with the provisions of relevant EU legislation.

In spite of improvements in the new regulatory framework, public and political concerns with GMOs are still a central issue and this is reflected in the Member States' opinions in Council.

At present, there are nine national safeguard clauses against the placing on the market of GMO products pending examination by the Commission to determine whether they are in accordance with Article 30 of the EC treaty. If found that there is a lack of scientific basis, the Commission shall act to have the safeguard clauses withdrawn.

On co-existence, the Commission's approach is to ensure that GMOs, which are authorised at EU level, may freely circulate and be used throughout the Community. It is nevertheless important to introduce co-existence measures to protect farmers of non-GM crops from the possible economic consequences of accidental mixing of GM-crops. The Commission adopted a Recommendation in 2003 on guidelines for the development of national strategies and best practices, to help Member States develop national legislative or other strategies for co-existence. It states that co-existence measures should not go beyond what is necessary to ensure that accidental traces of GMOs in non-GM products stay below EU labelling thresholds in order to avoid any unnecessary burden for the operators concerned. Measures should be science-based and proportionate and must not generally forbid the growing of GM crops.

Most Member States are still developing national approaches, with specific co-existence legislation adopted in four Member States (Germany, Denmark, Portugal and six of the Austrian Länder) by the end of 2005. An evaluation of the experience of co-existence measures taken in some Member States was made available to the Commission in January 2006. Monitoring programmes will be set up and implemented in order to verify the effectiveness and economic feasibility.

## **6. SUSTAINABLE DEVELOPMENT**

### **6.1. Effective Use of the Kyoto Mechanisms (6-EJ-1)**

#### *6.1.1. Summary of recommendation*

Authorities should use the Kyoto Mechanisms and create systems of internationally harmonised accounting and tax incentives to enable industry to easily utilise this mechanism.

#### *6.1.2. Action taken and state of play*

The European Commission is actively promoting the use of the Kyoto mechanisms by Member States and industry and is one of the key funders of the UN infrastructure managing the operation of these mechanisms. As part of the assessment of the first National Allocation Plans, the Commission encouraged Member States to present concrete figures on their investment in the Kyoto Mechanisms. The European Commission is furthermore actively encouraging the use of JI and CDM under the EU Emissions Trading Scheme (EU ETS).

### **6.2. Post-Kyoto Framework (6-EJ-2)**

#### *6.2.1. Summary of recommendation*

Setting different targets from the initial Kyoto Protocol would encourage USA, China and India to join the framework. This would include targets on energy efficiency or emission intensity by major sub-sectors on a cross-border basis. The EC and Japan should also work together to include technological development related to reducing GHG emissions, as an item for post-2012 negotiation.

#### *6.2.2. Action taken and state of play*

The EU and Japan have worked closely together in the run-up to and during the Montreal Climate Change Conference in November 2005 and successfully secured the agreement to start discussions on the post-2012 climate change regime, both under the Kyoto Protocol and under the UN Framework Convention on Climate Change.

### **6.3. Impact Assessment (6-EJ-3)**

#### *6.3.1. Summary of recommendation*

The impact of materials and products should be assessed in an extended manner which includes economic, social and environmental dimensions. Authorities should adopt the methods of life-cycle assessment and/or full value chain assessment in any impact assessment.

### 6.3.2. *Action taken and state of play*

The Commission's most relevant initiative is IPP which promotes life cycle thinking. IPP aims at reducing the environmental impacts of products through their life cycle in an integrated way. Life cycle thinking was taken up in other areas such as the Commission's resources and waste strategies. Another significant tool is the LCA which assesses the environmental impact of products. Other deliverables foreseen by 2008 are the European Reference Life Cycle Data System (ELCD) and Handbook of Technical Guidance Documents for LCA.

## 6.4. **Development of Energy-Saving Products and Services and Diffusion on a global basis (6-EJ-4)**

### 6.4.1. *Summary of recommendation*

Industries and people, with the support from the authorities should:

- adopt efficient electric and electronics equipment by using a top runner approach;
- use the full potential of IT society;
- adopt energy-saving offices and houses equipped with high performance insulators; diffuse fuel-efficient vehicles.

### 6.4.2. *Action taken and state of play*

Energy efficiency is a top priority for the EU and the Commission. Energy efficiency in all sectors is comprehensively addressed in the Commission's 2005 Green Paper "Doing more with less" and the Commission is currently preparing an EU Action Plan on Energy Efficiency as the follow-up to the Green Paper. In addition, the EU has adopted wide-ranging legislation on energy efficiency measures (such as minimum efficiency requirements and labelling of electrical appliances) and has recently adopted a Directive on promotion of end-use efficiency and energy services.

The EU has adopted the Energy Using Products (EuP) framework directive, which takes into account the environmental impacts of a product throughout its entire life-cycle. The Energy label is also significant.

Industry, in the EU and Japan has already made considerable efforts in GHG reduction but room for drastic improvements by using current technologies is limited. The EU recognises the potential for reducing GHG emissions by implementing those measures outlined by the EU-Japan BDRT.

### 6.4.3. *Prospects for implementation*

Co-operation between Japan and the EU in the area of energy efficiency is already ongoing, for example in the framework of the International Energy Agency and the G8. In addition, in January 2006, the Commission and Japan co-organised a regional seminar on energy efficiency in Tokyo in the framework of ASEM. The Commission is in favour of continuing co-operation on this high priority issue.

## **6.5. Cultivation for People and Initiatives of the Authorities (6-EJ-5)**

### *6.5.1. Summary of recommendation*

It is necessary to reduce emissions especially from households, and educate the general population in contributing to GHG reduction. Authorities should take initiatives to instigate this.

### *6.5.2. Action taken and state of play*

The Commission is starting in June 2006 a major public awareness campaign on climate change. This campaign will focus on what individuals can contribute to tackling climate change through their own actions.

## **6.6. Diversification of Energy (6-EJ-6)**

### *6.6.1. Summary of recommendation*

With a view to diversifying energy supply, to promote technological development of energy sources that can replace fossil fuels, including development of nuclear energy, renewable energy (wind, solar, biomass) and hydrogen.

### *6.6.2. Action taken and state of play*

As Japan, the EU relies to a large extent on energy imports, notably imports of oil and natural gas. Diversification of energy sources and development of alternative sources are thus key objectives of EU energy policy with a view to enhance security of supply. In the Green Paper adopted on 8 March 2006 (*A European Strategy for Sustainable, Competitive and Secure Energy*), the Commission comprehensively set out the main energy challenges and proposals to address these.

The EU has, for many years, promoted the development and the use of renewable energy and has put in place a framework aimed at reaching agreed targets in the area of electricity production from renewable sources of energy and in the area of biofuels. Nuclear energy is currently contributing with one third to the EU's electricity generation. Research into technological development in the field of hydrogen is a priority within the EU's research programmes and is also the subject of international co-operation in the International Partnership for the Hydrogen Economy (IPHE) in which both Japan and the EU participate.

The Commission has recently started a number of important new initiatives to promote specific technologies. In relation to CO<sub>2</sub> capture and storage the Commission has for instance initiated the Working Group on Carbon Capture and Geological Sequestration under the second phase of the European Climate Change Programme. The Commission has also set up the Technology Platform for "Zero Emission Fossil Fuel Power Plants" which aims to further stimulate the development and deployment of this technology.

### 6.6.3. *Prospects for Implementation*

Energy security, energy diversification and technological development of alternative energy sources are all issues which are at the top of the international political agenda, and issues on which progress can only be achieved through international co-operation. Given largely coinciding energy policy objectives, there are good prospects for EU and Japan working closely together in international fora, in particular the IEA and the G8. At the EU-Japan Summit, EU and Japan have agreed to step up their cooperation in the field of Climate Change.