

(Tentative Translation)

Report from the Government of Japan

on the EU-Japan Business Dialogue Round Table (the BDRT)

Recommendations

March 2007

(The contents of this report are based on the situation in Japan as of 26 January 2007.)

Contents

WP 1 Trade and Investment	4
1. Concrete and focused actions to follow up the investment framework agreement to enhance foreign direct investment	4
2. The optimization of returns on investment	6
3. Supporting timely development of business	10
4. Facilitating business reorganisation from a legal and tax point of view	14
5. Promotion of regulatory reforms	15
6. Corporate Governance	18
7. Maintaining stable rules for legal presence of foreign companies	19
8. Promoting economic growth through decisive reform	20
9. Modernising legal and tax systems to support foreign investment	22
10. Advance openness by promoting good corporate governance	23
11. Promoting Public-Private Partnership Schemes	24
12. Privatisation of Japan Post	27
13. Facilitating business development through regulatory reform	29
14. Ensuring transparency and consistency in the regulatory process	31
15. Modernising Japan's food additives list	32
16. Facilitating the use of overseas clinical trial data for certification of medical equipment in Japan	34
17. Improving flexibility in setting airfares between Europe and Japan	36
18. Improved access in and out of Japan for Foreign Residents	37
19. Strengthening market mechanisms in the telecommunications sector	38
20. Strengthening market mechanisms in the procurement of aircraft	40
21. Promoting EU-Japan cooperation in commercial aircraft development and production	41
WP 2 Accounting & Tax Issues	43
22. CFC rules	43
23. Accounting Issues	44
24. Tax Issues	46
WP3: Information & Communication Technology	48
25. Benefits from ICT for the society	48
26. Security (including e-government) issues	52
27. R&D Cooperation with particular focus on international standardization initiatives	56

28. Regulatory environment allowing a dynamic development of the ICT-World	58
29. IPR-Policy	63
WP4: WTO	65
30. Policy Statement concerning the World Trade Organisation	65
WP 5: Life Sciences & Biotechnology (LS&BT)	69
31. General Recommendations	69
32. LS&BT for Health	72
33. LS&BT for Industrial/Environmental Uses	75
34. LS&BT for Plants	77

WP 1 Trade and Investment

1. Concrete and focused actions to follow up the investment framework agreement to enhance foreign direct investment

BDRT recommendations

- (1) The heads of governments of the EU and Japan should follow up and expand the ‘Cooperation Framework for Japan-EU Two-Way Investment Promotion’ adapted at the EU- Japan summit in Tokyo 2004. Concrete measures with substantial impact on investment between the EU and Japan should be elaborated.
- (2) Such measures should be assessable and clearly focused on the following four priorities: the optimisation of the returns on investment; supporting timely development of business; supporting timely and smooth business reorganisation; and promotion of regulatory reforms.
- (3) Its progress should be communicated to EJ BDRT as well as to the general public on a regular basis.

State of the measures taken thus far

Discussions have been underway on specific proposals related to the ‘Cooperation Framework for Japan-EU Two-Way Investment Promotion’ issued in June 2004 on the occasion of the regular Japan-EU Summit. Venues of such discussion include the meetings of the EU-Japan Dialogue on Regulatory Reform and the Action Plan Steering Group. In the Joint Press Statement of the Japan-EU Summit in April 2006, the leaders of Japan and the EU confirmed that the two sides will further enhance their dialogue and cooperation to promote trade and investment so that they reach their full potential. Furthermore in the annex of this statement, the two sides also identified the following three sets of events as part of further progress in implementing the Cooperation Framework for Promotion of Japan-EU Two-Way Investment, under the subtitle of the Review of Implementation of the Action Plan for EU-Japan Cooperation: 1) the 3rd World Investment Conference held in June 2005, the Meeting of Experts on Investment Promotion between Japan and the EU held in September 2005 and the Japan-EU dialogue on Corporate Social Responsibility held in December 2005; 2) progress towards the entry into force of the Social Security Agreements between Japan and France and between Japan and Belgium; and 3) the signature of the new Japan-U.K. Tax Treaty in February 2006. Following this, January 2007 saw the enactment of the Japan-Belgium Social Security Agreement and the signing of the Protocol amending the

Income Tax Treaty between Japan and France. Japan will continue its efforts toward the conclusion of social security agreements with countries with which such treaties are deemed necessary.

From the mid- to long-term perspective, Japan decided on the Program to Accelerate Direct Investment into Japan in June 2006 to double the GDP ratio of such direct investment by 2010, with the aim of utilising inward investment to develop the Japanese economy and improve people's life. As such, Japan continues to expect to see a further expansion of investment from the EU.

The results of the above-mentioned Regulatory Reform Dialogue and the Joint Press Statement of the Japan-EU Summit were both announced publicly without delay.

Future outlook

Japan and the EU continue to promote the measures set out in the above Japan-EU Cooperation Framework based on the commitment of the leaders of Japan and the EU.

(Note) Please refer to subsequent items 2. to 5. concerning the four priorities mentioned in (2) of the BDRT Recommendations.

2. The optimization of returns on investment

BDRT recommendations

(1) Avoidance of double taxation

- ① The Governments of Japan and Europe should ensure that dividend payments from subsidiaries to parent companies and royalty and interest payments between related companies are, to the greatest possible extent, exempt from withholding taxes. In addition, the Japanese Government should introduce measures to avoid the reduction of the ceiling of foreign tax credits as a result of such exemption.
- ② The European Commission should promote co-operation between Member States in their efforts to conclude bilateral tax treaties with third countries. The Japanese Government should strive to substantially revise all outdated bilateral agreements with EU Member States. Furthermore, particular priority should be given to initiating negotiations with those EU Member States with which Japan has, as yet, no double-taxation treaty.

(2) Reducing compliance costs associated with transfer pricing

A reduction of compliance costs of transfer pricing through simplification and rationalization of transfer pricing regimes in a coordinated manner will increase the international competitiveness of businesses in the EU and Japan. The respective Governments should establish a joint forum, similar to the Joint Transfer Pricing Forum (JTPF) established among EU Member States, for the following purposes:

- ① to harmonise and simplify interpretation and documentation requirements between the EU and Japan and among the EU Member States in order to reduce the costs of compliance with the various transfer pricing taxation regimes.
- ② to make the conclusion of bilateral and multilateral APAs (advance price agreements) between the EU Member States and Japan easier and cheaper by improving procedures. The work and progress made in the EU's JTPF on the acquisition procedures of APAs should be communicated to BDRT and the Japanese government so that APAs between the EU Member States and Japan could benefit from the progress made in the JTPF.

(3) Participation exemption

The Governments of the EU, the EU Member States and Japan should, as a medium to long-term objective, consider the introduction and/or expansion of capital participation exemption regimes in order to promote direct investment between the EU and Japan.

State of the measures taken thus far

(1) ① For Japan's general stance on the tax reform, see the appendix.

② In terms of avoiding double taxation, Japan has been seeking to enhance the tax convention network with European countries based on the perspective of actively promoting investment exchanges to reflect the close economic ties between Japan and Europe. In February 2006 Japan signed a new Income Tax Convention with the United Kingdom (UK) to entirely renew the existing convention, which entered into force in October 2006. The new convention allows a significant reduction of the withholding taxes on investment incomes (Dividends, Interests and Royalties) in the source country. In addition to such expansion in tax reduction, it will also enhance measures to prevent fiscal evasion.

Also with France, Japan signed a protocol to partially revise the existing bilateral convention, which will allow, as in the case with the UK, a reduction of withholding taxes in the source country. Furthermore, for the first time for a relevant convention signed by Japan, the protocol is designed to introduce rules for Japan and France to mutually allow income deduction for social security payments that are incurred by expatriates from the two countries staying in either of them under the respective social security system.

(2) The implementation of transfer pricing taxation regimes is being examined from various aspects with a focus on the discussions of the OECD Tax Committee as described below. Therefore, the GOJ believes that the creation of a new Japan-EU joint work group is unnecessary.

With regard to ①,

The GOJ understands that taxpayers have been bearing certain costs in order to conform to the standards for transfer pricing documentation imposed by various taxation authorities. It also understands that through the standardisation of transfer pricing documentation, taxation authorities will be provided with the materials beneficial for the analysis of relevant overseas transactions and disputes arising from transfer pricing will be reduced.

With respect to this issue, a Transfer Pricing Documentation Package was developed among the Member States of the Pacific Association of Tax Administrators (PATA), consisting of Australia, Canada, the United States (US) and Japan. While this package was not one that was implemented between Japan and the EU, it illustrates three principles and sets forth in detail contemporaneous documentation for materials required during examinations (of the documentation that existed at the time the relevant transactions were conducted or documentation

that was created up to the deadline for submitting tax returns in accordance with the stipulations of each state, those which contain the relevant information on transactions that have arisen by the deadline).

- i) Multinational enterprises (MNEs) need to make sufficient efforts, in accordance with the rules determined by the tax administration agencies of each PATA Member State, to establish transfer pricing in compliance with the arm's length principle.
- ii) MNEs need to produce and maintain contemporaneous documentation during the process of establishing transfer pricing in accordance with the arm's length principle.
- iii) MNEs need to submit the documentation promptly in accordance with the request of the tax administration agencies of PATA Member States.

Taxpayers are not forced to use this model documentation package related to transfer pricing, and they are not subject to any obligation beyond the obligation imposed by domestic rules of the PATA Member States. While Japan has not laid down any legislation for contemporaneous documentation regarding transfer pricing, the materials required for a transfer pricing examination in Japan are generally consistent with the PATA model documentation package.

As Japan and the majority of EU Member States are OECD Member States, international rules on transfer pricing taxation regimes have been enforced through the OECD Tax Committee. Therefore, the interpretation of the regimes is an issue to be discussed at the OECD in the coming months as well, with the discussions to be in line with the OECD Transfer Pricing Guidelines.

With regard to ②,

The GOJ recognises the effectiveness of bilateral and multilateral APAs and it has been actively promoting them in order to ensure the smooth implementation of transfer pricing taxation regimes, to reduce the workload of businesses dealing with transfer pricing taxation regimes and to enhance the predictability of business management. In addition, mutual discussions concerning bilateral and multilateral APAs have been progressing smoothly with the EU Member States, and no particular issues have arisen.

APAs require the confirmation by the tax authorities of the calculation method for the arm's length price quoted by businesses, but in order to confirm this appropriately, it is essential that the tax authorities receive certain required information from the taxpayers, including an outline of business and relevant

financial data. In addition, the process requires a certain time to be completed. APA application procedures are not too complicated in themselves, neither do they entail the collection of costs from the taxpayer.

The administration and operational guidelines for Japan's advance price agreements have already been announced and publicised, and the National Tax Agency has released the APA Program Report on its website since 2003 (the reports are also available in English). They should be referred to for information on Japan's advance price agreements and their state of implementation.

- (3) For Japan's general stance on the tax reform, see the appendix.

Future outlook

- (1) ① (For Japan's general stance on the tax reform, see the appendix.)

② While working to put into effect the protocol of the convention with France, the GOJ is also advancing negotiations with the Netherlands to revise the bilateral tax convention. With other European countries, the GOJ is further committed to endeavouring to respond to necessities.

- (2) With regard to ①

The GOJ believes that both Japan and the EU must continue to make efforts to further clarify the international rules on transfer pricing in the context of the discussions at the OECD. With regard to the documentation issue, the GOJ believes that it should actively contribute to the discussions at the OECD in the future, having agreed to the model documentation package of PATA.

With regard to ②

As stated above, although no specific problems have arisen concerning procedures or pricing, as the number of bilateral and multilateral APAs is forecast to rise in the future, the GOJ will continue to make efforts to deal with such issues promptly and appropriately.

- (3) For Japan's general stance on the tax reform, see the appendix.

3. Supporting timely development of business

BDRT recommendations

(1) Smoother and swifter transfer of personnel

(a) Social security contributions

The respective governments should introduce measures to avoid intra-company transferees having to make double contributions to the social security systems of both home and host countries, by the accelerated introduction of social security agreements. In addition, they should introduce an interim measure: the host country should either exempt contributions to pension funds unilaterally or should refund in full when expatriates return to the home country.

(b) Work and residence permits

(i) Japan and EU Member states should make an agreement to simplify and accelerate the procedure for obtaining a work and residence permit – or a residence permit in the case of self-employed statutory directors – for intra-company transfers between the EU and Japan. The procedure should include the possibility of submitting an application for a work-residence permit or a residence permit for self-employment after entering the assigned country. Furthermore, spouses should, upon their arrival, be automatically granted the same rights as the holder of the permit, such as a work-resident permit and a residence permit for self-employment.

(ii) The Government of Japan should abolish the requirement that foreigners with a visa must renounce it and return their Alien Registration Card whenever leaving the country. The separate system of applying for and issuing re-entry permits should be abolished, so that permission to freely leave and re-enter the country is automatically granted when the visa is issued.

(2) Data Protection: International Data Transfer

Japan's Data Protection Law should be amended in a way that it could satisfy the level of protection required by the EU's Data Protection Law to permit the transfer of personal data from the Member States to Japan

State of the measures taken thus far

(1) Smoother and swifter transfer of personnel

(a) Social security contributions

(i) Japan is keenly endeavouring to conclude social security agreements with EU countries. It has already concluded such agreements with Germany, the UK and Belgium, while having signed one with France.

Furthermore, Japan is negotiating with the Netherlands and actively exchanging views and information with Spain and the Czech Republic to conclude social security agreements.

(ii) With regard to an interim measure, the GOJ already has in place a system whereby foreigners who have paid into the national pension scheme and have returned to their home country after a short-term stay in Japan, may receive the Lump-sum Withdrawal Benefit for Non-Japanese citizens, which gives consideration to the premiums they have paid into the national pension scheme.

(b) Work and residence permits

(i) The GOJ is taking various measures to simplify and accelerate the said procedure (for details of the specific measures taken, please see the last but one progress report).

Concerning those people wishing to engage in activities related to the status of residence of “Intra-corporate Transferees” (engagement in work), the GOJ allows those people to work at the stage of landing permission, provided that such people satisfy relevant landing conditions, such as that they possess valid visas at the stage of the landing examination, and that they are approved for the status of residence of “Intra-corporate Transferee” by the immigration officer. Conversely, when an applicant enters (lands in) Japan with a status of residence of “Temporary Visitor” (non-work status), and thereafter seeks to apply for a work status in Japan, the applicant is not allowed to work until he/she gets the desired status of residence. Taking this series of procedures into consideration, it can therefore be said that the quickest possible procedure would be made by the acquisition of an adequate visa before entry into Japan and the application for landing.

Concerning work activities of the spouses of intra-corporate transferees, please refer to our latest progress report.

(ii) When foreign residents in Japan who have obtained a valid re-entry permit temporarily leave Japan, intending to re-enter into Japan for the same purpose as upon their original stay, they need not return their alien registration certificate issued by the heads of their municipalities. The Alien Registration System is designed to clarify matters pertaining to the residence and status through the registration of foreign nationals staying in Japan. Therefore, except when they

have re-entry permits, bearers of alien registration certificate must upon their leaving Japan return their alien registration certificate to the immigration officer.

The re-entry permit system is also aimed at simplifying the procedures for entry into and landing in Japan and at benefiting the foreign nationals residing in Japan. Namely when foreign nationals leave Japan temporarily with the intention of re-entering, they do not need to apply for a visa on each occasion of entry so long as they have obtained a re-entry permit in advance. Therefore, the re-entry permit system is absolutely necessary and reasonable as a system which contributes to facilitating smooth entry and landing procedures.

The Ministry of Justice is also working to facilitate the landing examination further by means of introducing the automated gate system, in addition to the extension of the valid period of the re-entry permit (The period was extended from one year to three years by the amendment of Immigration Control and Refugee Recognition Act in 1999.).

- (2) The Act on the Protection of Personal Information, based on the eight OECD principles, was promulgated and enacted in May 2003, and entered into full enforcement in April 2005. The full enforcement of the Act has enhanced the Japanese people's awareness of the protection of personal information and business entities' efforts at such protection. In addition, ministries and government agencies, in charge of the business entities concerned, have also been making appropriate efforts including formulation and review of the guidelines, etc. based on the actual circumstances of each business field, as well as guidance for and supervision of the business entities.

Future outlook

- (1) Smoother and swifter transfer of personnel

- (a) Social security contributions

In concluding social security agreements, the GOJ intends to advance the exchange of information with a view to launching negotiations to conclude social security agreements with countries in order of priority, by giving comprehensive consideration to the scale of insurance premiums levied under the social security systems of the countries concerned, the situation of Japanese nationals and companies based in those countries, demands from the business community, and bilateral relations, as well as differences between Japan's social security system and the systems of the countries concerned.

In order to accelerate the moves of concluding agreements, the GOJ plans to submit to the current Diet session a “Bill concerning Special Measures etc. for Employees’ Pension Insurance Law etc. in line with the Implementation of Social Security Agreements” (tentative name), with the aim of establishing a domestic legal environment that is able to respond to the conclusion of relevant agreements with any given countries.

(b) Work and residence permits

We will continue our review on a timely basis concerning the facilitation of accepting foreign workers and acceleration of relevant procedures, taking Japan’s immigration control system into consideration.

- (2) The Act on the Protection of Personal Information was formulated, based on international approaches to the protection of personal information, as the result of various nation-wide discussions regarding the harmony between the proper way of personal information protection and the several requirements of the Constitution. Chapter 4 of this Act, which provides the duties of business entities, has materialized the eight OECD principles with considering the particular situations of Japan.

We believe Japan will ensure an adequate level of protection that satisfies international criteria, as each party’s efforts continue based on the Act, the Basic Policy concerning the Protection of Personal Information (Cabinet Decision on April 2, 2004) and guidelines of relevant ministries, etc, leading to their effectiveness ensured.

4. Facilitating business reorganisation from a legal and tax point of view

BDRT recommendations

- (1) Changes of company laws underway in the EU and Japan should be carried out in such a way as to fully facilitate smooth cross-border reorganisations between the EU and Japan that involve exchange of shares and transfer of assets.
- (2) Tax rules should be improved in order to expand the scope of tax deferral on unrealised profits resulting from business reorganisations, including those involving exchange of shares and transfer of assets.

State of the measures taken thus far

- (1) The Corporate Code enacted in 2005 allows any asset to be used for merger considerations, which will make triangular mergers available. The provisions of the Corporate Code related to this “deregulation of merger considerations” will enter into force on 1 May 2007.
- (2) (For Japan’s general stance on tax reform, see the attached appendix).

Future outlook

- (1) The provisions mentioned above are due to enter into force on 1 May 2007 as scheduled.
- (2) (For Japan’s general stance on tax reform, see the attached appendix)

5. Promotion of regulatory reforms

BDRT recommendations

The EU and Japan should abolish unreasonable authorisation procedures related to products and services, and continue to pursue mutual recognition of product standards, certification and notification. It is equally important that the respective Governments cooperate when introducing new standards to assure standard convergence and to avoid the creation of future barriers to trade.

The Working Party believes that the best way to accomplish this is through a further intensification of the on-going EU-Japan regulatory reform dialogue.

When appropriate, more expert sub-groups could be established, reporting to the main working group, to promote liberalisation in highly technical areas as well, such as medical equipment, animal health and food safety

State of the measures taken thus far

The GOJ has implemented the reviews on mutual recognition of product standards, certification and notification in line with “Three-Year Plan for the Promotion of Regulatory Reform and the Opening-Up of Government-Driven Markets for Entry into the Private Sector (re-revised)” (see Item 19 (Standards, Certification and Others) of III (Specific Measures)). Drastic reviews have been undertaken as to whether the government involvements are genuinely needed in those standards/certification systems that can be viable through voluntary actions by enterprises. From a viewpoint of international harmonisation on standards and upon validity studies on such harmonisation, the GOJ has worked for making its domestic standards consistent with existing international standards. In areas where international standards do not exist, the GOJ has proposed and promoted the adoption of such international standards as in accordance with the Japanese ones. The GOJ has also promoted the acceptance of overseas data and the mutual recognition. To further those efforts, the GOJ will also take measures to reduce the burdens on business. This includes the elimination of duplicating inspections for similar inspection items.

To date, the Agreement on Mutual Recognition between Japan and the European Community (hereafter referred to as “MRA”) has seen the implementation on four areas of products: Telecommunications, Terminal Equipment and Radio Equipment; Electrical Products; Good Laboratory Practice (GLP) for Chemicals; and Good Manufacturing Practice (GMP) for Medicinal Products. Measures taken in 2006 include

new registration of conformity assessment bodies under the MRA and exchanges of the laboratory lists under GLP for Chemicals. In October 2006, the fourth meeting of subcommittee of GMP for Medical Products was convened, where the GOJ and the EC discussed issues including smooth operations in these areas.

Japan-EU Regulatory Reform Dialogue started in 1994. It gains positive evaluation by the FY 2005 Japan-EU Summit as referred to as “ (it has) continued to deliver concrete outcomes, such as in finding practical solutions to facilitate the living and working environment of expatriate nationals.” The Japan-EU Summit in 2006 follows by stating that “Japan and the EU will further enhance their dialogue and cooperation to promote trade and investment so that they reach their full potential, including by addressing the interests and remaining concerns of either side through the Japan-EU Regulatory Reform Dialogue.” The summit also positions the dialogue as one of the priority actions to be taken by the next Japan-EU Summit in 2007.

The Brussels Meeting of Japan-EU Regulatory Reform Dialogue in December 2006 mainly discussed the EU Proposals to Japan on Regulatory Reform. The EU side expressed their appreciation to the commitment by the Japanese side on the following areas: the public comment procedures; promotion of competition in the ICT sectors; reviews on regulations for banking/insurance services; privatisation of Japan Post; improvement of the approval process for pharmaceuticals and medical devices; facilitation of expert meetings on wood standards; and introduction of new testing methods for safety verification of retort packages.

The meeting also introduced Japan’s Proposals to the EU on the following priority areas on which the GOJ requested proactive actions by the EU side: assessment of equivalence between Japanese GAAP and International Accounting Standards (IFRS); food safety (request of lifting the ban on the export of Japanese meat and meat products to European countries); trade and customs (exclusion of camcorders and box cameras from the scope of anti-dumping investigation); the new chemical regulations in the EU (REACH); and speeding-up and simplification of the issuing process for residence/work permits.

The next meeting in Brussels in March 2007 will mainly discuss Japan’s Proposals to the EU. The GOJ will, in due consideration to voices from Japanese companies advancing to Europe, make further requests to the EU for its positive actions on a wide

range of areas as follows: the cross-sector issues including commercial laws and business practices; the sector issues including the equivalence assessment between Japanese GAAP and the IFRS; environmental regulations; and the fundamental matters related to business environment including residence/working permits.

Japan and the EU, taking opportunities of the above Tokyo Meeting, held expert-level discussions at the Expert Meetings and Directors Meeting for the respective issues including healthcare and cosmetics, animal health products, food safety and agricultural products. Japan and the EU also held expert-level dialogues on wood standards in March 2006 (Brussels) and in October 2006 (Tokyo), with a view to promoting information/opinion exchanges among the experts.

Future outlook

Further reviews are scheduled on the areas of standards and certification in line with the above-mentioned “Three-Year Plan for the Promotion of Regulatory Reform and the Opening-Up of Government-Driven Markets for Entry into the Private Sector (re-revised).”

Japan and the EU intend to further strengthen their cooperation through the framework of the Japan-EU Regulatory Reform Dialogue, with a view to reaching their full potential for mutual trade and investment.

6. Corporate Governance

BDRT recommendation

Rules of corporate governance and disclosure of corporate information should be applied consistently within the EU. For companies conducting business in both Japan and the EU, it is important that there should be no double compliance; i.e. companies should not be required to comply both with the home country rules regarding corporate governance and with the host country rules. Compliance with the home country rules should be sufficient.

State of the measures taken thus far

Future outlook

(Please refer to “23. Accounting Issues (2)” in this report for internal control with regard to financial reporting)

7. Maintaining stable rules for legal presence of foreign companies

BDRT recommendation

The Government of Japan should use all means available, including revision of Article 821 of the Corporation (Law, to ensure legal certainty for foreign companies established as branches in Japan. The Government should take measures to make sure that rules of fundamental importance to foreign companies are not altered without prior notice and consultation.

State of the measures taken thus far

The stipulation of Article 821 of the Corporate Code regarding pseudo-foreign companies is equivalent to Article 482 of the previous Commercial Code. Article 821 is favourable to pseudo-foreign companies as compared with Article 482 of the previous Commercial Code, since, among other reasons, it treats such companies as legal entities while the definition of pseudo-foreign companies remains the same. Therefore, it is clear that Article 821 does not adversely affect foreign companies, as long as they have been conducted their operations in Japan in a lawful manner under the previous Commercial Code. This aspect is clearly stated in the concurrent resolution adopted at the House of Councillors at the time it passed the Corporate Code, as well as in the internal notification issued by the Ministry of Justice in March 2006.

Future outlook

The above-mentioned concurrent resolution of the House of Councillors requires consideration to be given to an amendment to Article 821 of the Corporate Code, if necessary, based on any impact of Article 821 on foreign companies after the Corporate Code has entered into force. Thus, the GOJ intends to continuously monitor any possible impacts on foreign companies caused by the stipulation of Article 821 of the Corporate Code. However, no amendment is scheduled at this stage with respect to Article 821.

8. Promoting economic growth through decisive reform

BDRT recommendation

It is important that the Japanese Government continues pursuing its structural reform agenda so that the economic recovery can be maintained. Current economic conditions represent a unique opportunity for Japan to fully realise its ambitious reform goals.

State of the measures taken thus far

Under a medium-term policy of promoting structural reform without relying on public spending, reform has been promoted across the whole economic society, such as the disposal of non-performing loans. Now, major banks have managed to normalize their non-performing loan problems, and the “Three excesses” problems of industry, i.e., excesses in employment, capital stock and debt, have been largely resolved. The economy started improving after bottoming out at the beginning of 2002, and even though there is imbalance between regions, a sustained recovery is continuing. With a breakaway from deflation coming into sight, the Japanese economy is finally ready to offer bright prospects for the future.

Future outlook

As Japan has become a society with a declining population, it is essential to increase productivity and strengthen growth potential. In light of this, it is important to elevate the Japanese economy to a new stage for economic growth over the medium to long term, and toward that end, the GOJ has formulated the "Direction and Strategy for the Japanese Economy," which sets forth the directions of reform Japan should undertake within the next five years. Japan will strongly advance a new growth strategy under this policy so that people can truly sense for themselves that they are achieving real growth. This will be realized through innovation which brings about cutting-edge technologies, products and services, and an open approach which brings the vitality of Asia and the world into our country.

In order to maintain economic growth, fiscal consolidation is indispensable as being both inseparable and necessary. Given this view, the GOJ will steadily promote

Integrated Reform of Expenditures and Revenues. The GOJ will also strongly promote fundamental administrative reform to realize a simple yet efficient government in a bid to create systems suitable for the 21st century, mainly based on the Administrative Reform Promotion Law, and realize various reforms.

9. Modernising legal and tax systems to support foreign investment

BDRT recommendation

The Japanese Government should ensure stock swaps occurring under the triangular merger scheme to be introduced in May 2007 will be given the same treatment as swaps involving only Japanese stocks. Capital gains under the scheme should be tax deferred.

State of the measures taken thus far

In relation to the deregulation of merger consideration which will make triangular mergers available, the provision of the Ministerial Regulation of MOJ defining the scope of “Transfer Restricted Shares, Etc. (jouto seigen kabushiki tou)” is scheduled to be reviewed pursuant to the supplementary provision of the above Ministerial Regulations in terms of whether it should be amended, taking into consideration the circumstances after the entry into force of the Corporate Code.

The necessity of review of the above provision is currently discussed at the Commercial Law Sub-Committee of the Liberal Democratic Party , the Company Law Project Team of New Komeito and other groups concerned.

(For Japan’s general stance on tax reform, see the attached appendix)

Future outlook

The GOJ will take adequate responses in time before 1 May 2007, the effective date of the deregulation of merger considerations, in line with the outcomes of the deliberations being progressed at the above mentioned sub-committee, the project team of the ruling parties and other groups concerned, and taking into consideration the system of the Corporate Code that basically requires an “extraordinary resolution”(instead of a “super extraordinary resolution”) of shareholders’ meetings to approve mergers, etc. If it is decided that the relevant provision of the Ministerial Regulations should be amended, the ministry will launch the public comment procedure, securing 30 days or more for the period of soliciting opinions pursuant to the applicable law.

(For Japan’s general stance on tax reform, see the attached appendix)

10. Advance openness by promoting good corporate governance

BDRT recommendation

The Government should encourage transparent governance by forcefully inhibiting undue entrenchment of vested corporate interests. Guidelines on takeover defenses produced by the Ministry of Economy, Trade and Industry and Ministry of Justice are sensible and should be given legal force.

State of the measures taken thus far

On 27 May 2005, the Ministry of Economy, Trade and Industry and the Ministry of Justice jointly announced the Guidelines Regarding Takeover Defense for the Purpose of Protection and Enhancement of Corporate Value and Shareholders' Common Interests. The Guidelines hold no legally binding force. However, the objective of the Guidelines is to promote the formation of a set of fair rules with regard to takeovers, explaining legitimate and rational modalities for takeover defense measures, while bearing in mind what is currently considered to be the "standard" for defense measures, based on legal precedent and theory concerning takeover defenses.

The GOJ has been closely monitoring takeover defense measures taken since it drew up the said Guidelines.

Future outlook

The GOJ understands that the Guidelines are recognised as part of the rules of conduct to be followed by most of those companies covered in the target scope of these Guidelines. Also in court, there has been an increased number of cases in which judgments were made in conformity with the Guidelines.

The GOJ intends to review the Guidelines constantly, looking into how they are actually operated, and will launch any necessary revisions. The GOJ expects the Guidelines to be continuously respected by those parties concerned and serve as a code of conduct for the Japanese business community.

11. Promoting Public-Private Partnership Schemes

BDRT recommendation

More private sector involvement in the delivery of public services should be encouraged through the use of true PFI/PPP schemes.

State of the measures taken thus far

The GOJ carries out procurement in a fair, transparent and non-discriminatory manner in accordance with the World Trade Organization (WTO) Agreement on Government Procurement and the Action Plan on Reform of the Bidding and Contracting Procedures for Public Works (approved by the Cabinet on January 18, 1994), which the GOJ formulated on its own initiative.

As of the end of December 2006, implementation outlines were established to implement 260 PFI projects throughout Japan and these projects are underway. The GOJ will continue to promote PFI projects actively.

<Number of PFI projects in progress (cumulative total)>

	End of FY2000	End of FY2001	End of FY2002	End of FY2003	End of FY2004	End of FY 2005	End of December, 2006
No. of projects	15	43	90	137	188	230	260
No. of projects thereof, which entered the operational phase	1	3	13	20	44	93	130

<Number of projects by area (as of end of December 2006)>

Sector	No. of projects
Education and culture (elementary and junior high schools, universities, libraries, etc.)	82
Living and welfare (welfare facilities for the elderly, etc.)	12
Health and environment (hospitals, waste disposal facilities, water supply facilities, etc.)	48
Industry (wholesale market, tourist facilities, etc.)	15
Urban development (parks, sewer facilities, port facilities, etc.)	32
Safety (police facilities, prison facilities, etc.)	17
Government offices and housing (housing for civil servants, etc.)	26
Other	28
Total	260

(Compiled by the Cabinet Office)

Based on the effects including the promulgation and enactment in August 2005 of the law to partially amend The Law Regarding to Promote Provision of Public Facilities and Other Related Services by Use of Private Capital and Other Resources (PFI (Private Finance Initiative) Law) (Law No. 117 of 1999), there have been an increasing number of projects in recent years, such as those for hospitals and prisons, whose major purposes are to realize comprehensive and effective services in the operation phase after the completion of relevant facilities. There have also been a number of large-scale, financially-independent projects based on the private sector's funds and expertise, such as one for improving and operating the passenger terminals of Tokyo International Airport (Haneda). These projects have introduced new attempts in public-private partnership, free from the conventional project methods. Based on such development, and also referring to the competitive dialogue model used by the EU, the GOJ drew up in November 2006 an arrangement paper of Liaison Conference of the Relevant Ministries and Agencies. The paper shows concrete ways to facilitate smooth communication between procuring entities and private businesses through dialogue as well as specific measures on the screening phases. Japan also exchanged opinions with the Republic of Korea by holding 1st Annual Meeting for PFI/ PPP Promotion between Japan and Korea in July 2006. The GOJ furthermore endeavours to grab the current situation of the implementation of PFI/PPP (Public Private Partnership) in various

countries and international market practices of PFI/PPP, as well as to provide adequate information about Japan's PFI to other countries.

Concerning the provision of public services, the GOJ newly created the Public Service Reform Act (Act concerning Reform of Public Services through the Introduction of Competition) and enacted it in July 2006, in an aim to provide the Japanese people with more quality and less costly public services by the use of competitive biddings between the public and private and among private entities and thereby adequately reflecting innovative efforts of private businesses into these services. Furthermore, the GOJ decided the targeted services in the Basic Policy of Public Services Reform in September 2006, and added new targeted services in December 2006.

Future outlook

Concerning PFI, 130 projects have already entered the operational phase, accounting for a majority of those projects being worked on. In light of this, the GOJ will continue to adequately address issues posed in the operation phase.

Concerning the provision of public services, the GOJ will further revise the Basic Policy on Public Service Reform, to reflect requests from private businesses and also to add new targeted services from time to time. The GOJ will further continue its endeavours to adequately reflect innovative efforts of private businesses in order to reform public services.

12. Privatisation of Japan Post

BDRT recommendation

The Working Party is pleased with the improvements made, and encourages the Government to ensure a level playing field for private sector competitors in Japan Post's three core business lines - insurance, banking and delivery services - throughout the privatisation process. Cross shareholding between the holding company and the entities (mail services, postal savings, postal life insurance and the branch network) should not be accepted, as it will enable centralized group management after full privatisation in 2017, with the risk of cross-subsidised financial products appearing on the market. Japan Post should be regulated in a manner identical to other carriers and the postal monopoly should be limited to basic delivery of correspondence, and regulated by an independent agency.

State of the measures taken thus far

- (1) In line with the Laws related to the Privatization of the Postal Services(PPS), promulgated on 21 October 2005, the Headquarters for the Promotion of PPS was established within the Cabinet in November 2005 with an aim of performing comprehensive adjustment for the promotion of the privatisation, under the leadership of the Prime Minister. In April 2006 the Headquarters had a Postal Services Privatization Committee, which is tasked with performing comprehensive reviews on the progress of postal privatization and making proposals to the Prime Minister based on the results of these reviews.
- (2) Any future expansion of scope of business of the Postal Savings Bank and Postal Insurance Company after the privatisation requires a series of transparent and fair procedures to be implemented to rule on the expansion. This involves the Prime Minister (who entrusts his authority to the Commissioner of the Financial Services Agency) and the Minister of Internal Affairs and Communications seeking the opinion of the Postal Services Privatization Committee and deciding on whether to approve business expansion, based on what the operating status of the new company would be, and whether it would be established on an equal footing with other private sectors companies.
- (3) The Japan Postal Services Holding Company, the Postal Service Company, the Post Office Company, the Postal Savings Bank and the Postal Insurance Company shall, likewise with any other private companies, disclose their financial information

pursuant to the competent regulation encompassing the Corporate Code, the Banking Law, the Insurance Business Law and any other relevant legislation. Should these entities be traded on public exchanges, they would be subject to the disclosure regulation of the Financial Instruments and Exchange Law (Securities and Exchange Law). Transactions between the Postal Savings Bank the Postal Insurance Company and the Post Office Company, etc. shall be adequately made under the supervision of the Financial Services Agency and upon the application of the arm's length rules, as well as pursuant to the Banking Law and the Insurance Business Law. In applying the accounting rules under the Banking Law and the Insurance Business Law, these companies are identified with the conditions of the "specific parties" set forth by these two laws. The cross shareholding between the holding company and the four business companies is restricted in the same way as for private sector companies and financial organisations under the general regulations of the Anti-Monopoly Act and the Banking Law, among others. The point raised about the risk of cross subsidised financial products entering the market is therefore groundless.

- (4) Neutrality is ensured for the regulation of Japan Post, the entity in charge of postal services, since fair and transparent procedures are applied to the implementation of regulation to Japan Post by the Ministry of Internal Affairs and Communications, independent from Japan Post, pursuant to relevant legislation.
- (5) The correspondence delivery service business has already been fully liberalised under certain conditions since 1 April 2003, pursuant to the Law Concerning Correspondence Delivery Provided by Private-Sector Operators. Hence the business is currently allowed to entities other than Japan Post. In fact, in the areas of high value-added services, competition is being enhanced by the entry of private companies.

Future outlook

Toward postal privatisation scheduled in October 2007, the GOJ is due to approve the relevant implementation plan scheduled to be filed for approval around April, and accordingly establish relevant ministerial ordinances.

13. Facilitating business development through regulatory reform

BDRT recommendation

The Japanese Government's regulatory reform programme should be strengthened by giving the new Regulatory Reform and Privatisation Promotion Council extra powers to implement the Government's "Three-year Plan for the Promotion of Regulatory Reform" and by expanding the special deregulation zone initiative. Special attention should be paid to regulatory reform recommendations made in the context of the EU-Japan bilateral regulatory reform dialogue and recommendations submitted by European business organisations such as the European Business Council in Japan.

State of the measures taken thus far

The Government further revised the "Three-year Plan for the Promotion of Regulatory Reform" (Cabinet Decision on March 31, 2006), in accordance with which it has been promoting regulatory reform and opening up to the private sector. Council for the Promotion of Regulatory Reform, established in April 2004 as an advisory body to the Prime Minister, has monitored the implementation status of this Plan and worked to promote the reforms detailed within it. The Council submitted the "Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector" to the Prime Minister on December 25, 2006, and the Cabinet Decision to respect the measures in the report was made on the following day.

As a part of this process, the GOJ has taken into consideration recommendations on regulatory reform submitted by the EU at the Japan-EU Regulatory Reform Dialogue, as well as opinions and requests from within Japan and overseas including those of the European Business Community (EBC). The Council for the Promotion of Regulatory Reform was reorganized in the Cabinet Office on January 26, 2007 in order to address to critical issues such as the creation of an open, energetic economic society.

Concerning commitments to the special zones for structural reform, as many as 576 cases of regulatory reform have been realized, covering those areas that had been seen as difficult for deregulation, such as agriculture, education, medical services and welfare, based on proposals by local public entities and private businesses. By the use of regulatory exceptions, which were established through these cases of regulatory reform, a total of 910 special zones for structural reform have been created so far. When a regulatory exception is implemented for a year, it is to be expanded countrywide, after

being evaluated by evaluation committee consisting of people from the private sector and experts. A total of 121 regulatory exceptions have been implemented nationwide, helping a steady expansion of the fruits of the special zones for structural reform.

Future outlook

The GOJ is scheduled to lay out a new three-year plan on regulatory reform around June 2007, based on the results of the “Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector” and of the deliberations made by the new Council.

The GOJ will also continue to promote regulatory reform taking into consideration proposals from EC raised at the Japan-EU Regulatory Reform Dialogue and recommendations submitted by EBC.

As for the system of special zones for structural reform, the GOJ will solicit proposals on special zones from local public entities and private businesses including foreign companies, based on which the GOJ will add new items to the special zone list applicable to local areas. The GOJ also plans to submit a bill for revising the relevant legislation in order to strengthen the system’s functions through the first overall review of the special zone system since its foundation in 2002 and make the solicitation of proposals a legal procedure.

14. Ensuring transparency and consistency in the regulatory process

BDRT recommendation

Japanese regulators should make more efforts to improve the transparency and consistency of regulation, including for tax-related matters. When new laws are formulated, they should be immediately accompanied by clarifying orders. Public Comment procedures should be made meaningful by giving the industrial circle opportunities to express their opinions, not about approximate plans but about detailed ones.

State of the measures taken thus far

Council for the Promotion of Regulatory Reform carried out research and deliberation pursuant to themes such as “Reviewing regulations based on the review criteria after the passage of a certain period of time.” The deliberation results were covered in “The Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector” which was submitted by the Council to the Prime Minister on 25 December 2006.

The revised Administrative Procedure Act, entered into force on 1 April 2006, which covers the legislation for the Public Comment procedures. In the BDRT recommendation above, it is not clear what “plans” refer to. If they refer to the concept of “Administrative Orders, etc.” under the Administrative Procedure Act, proposed “Administrative Orders, etc.” publicly notified shall have “concrete and clear contents” pursuant to Paragraph 2, Article 39 of the said Law.

Future outlook

Council for the Promotion of Regulatory Reform was reorganized on January 26, 2007. The GOJ is scheduled to lay out a new three-year plan on regulatory reform around June 2007, based on the results of the “Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector” and of the deliberations made by the new Council.

The Ministry of Internal Affairs and Communications will conduct and publish comprehensive annual surveys on the implementation of Public Comment Procedures by Ministries and Agencies and will maintain close communications with relevant administrative organs on this matter.

15. Modernising Japan's food additives list

BDRT recommendations

The remaining 43 as yet unapproved food additives in the list of 46 submitted by the Ministry of Health, Labour and Welfare (MHLW) to the Food and Sanitation Control Council on December 19, 2002 should be reviewed and approved for use in Japan without further delay. The time schedule for approval should be made public by the Food Safety Commission.

State of the measures taken thus far

- (1) In Japan, like the EU, food additives (including flavouring agents) are not permitted to be used unless they are designated by the Minister of Health, Labour and Welfare under the Food Sanitation Law as substances that are unlikely to cause health hazards.

Also, the Food Safety Basic Law requires that the Minister hear the opinions of the Food Safety Commission before newly permitting the use of any substance as a food additive (or a flavouring agent), and the Food Safety Commission conducts risk assessment in due course when receiving a request from the Minister of Health, Labour and Welfare.

- (2) The GOJ has been proceeding with the examination of 46 food additives, including those proposed by the EU, which have been proven safe internationally and are widely used, with a special priority under the leadership of the Government. The Minister has already asked the opinions of the Food Safety Commission on the 33 food additives for which full documents have been prepared, and procedures for designation such as risk assessment have been initiated.

In addition, among these 33 food additives, 7 have been designated and permission has been obtained to be used in Japan, after the evaluation by the Food Safety Commission and consideration by the Pharmaceutical Affairs and Food Sanitation Council.

Should the Food Safety Commission request additional data for scientific evaluation, certain time will be required for additional tests.

- (3) Since March 2005, the Ministry of Health, Labour and Welfare has announced the schedule for initiating the risk assessment of the remaining food additives out of the 46 items including the above-mentioned items requested by the EU, which are not yet submitted to the Food Safety Commission for assessment, and the ministry will make efforts to work to that schedule.

Future outlook

(1) Looking towards the designation of those food additives in the future, the Ministry of Health, Labour and Welfare will continue to prepare the necessary documents and engage in consideration, and then make them prioritized items for consideration by the Food Safety Commission and the Pharmaceutical Affairs and Food Sanitation Council. When the Food Safety Commission asks for additional data, the ministry will endeavour to realize additional tests without delay. Especially concerning polysorbate, for which the United States and EU urge a prompt approval, the ministry will submit additional data to the Food Safety Commission in spring this year.

(2) The GOJ continues to expect that related information such as documents used for scientific evaluation in the EU will be provided, in order to expedite assessment in Japan.

(Reference) Concerning flavouring agents, 15 items have been put under evaluation tests by the Food Safety Commission, 12 of which have already been led to conclusions by the Commission and gone through deliberations by the Pharmaceutical Affairs and Food Sanitation Council. The 12 have now been designated as food additives and allowed for use in Japan.

16. Facilitating the use of overseas clinical trial data for certification of medical equipment in Japan

BDRT recommendation

The application procedure for certification of medical equipment to be sold in Japan must be made shorter. The GOJ should unconditionally accept clinical data generated overseas, in line with the guidelines issued by the Ministry of Health, Labour and Welfare as long ago as 1997.

State of the measures taken thus far

The following outlines the state of measures taken for applications for approval of medical device:

- (1) In its notice dated March 31, 2006, the GOJ once again presented its basic policy of accepting clinical trial data conducted outside Japan in an application for approval of medical device, in line with a revision of the Pharmaceutical Affairs Law, under which the Good Clinical Practice (GCP) was newly stipulated in a ministerial order. In advance of this notice, the GOJ had already presented such policy in notices such as one issued in 1997.
- (2) Specifically, under condition that the GOJ lays out the standards for performing clinical trials for medical device, based on these standards, when a clinical trial is deemed to reach a level that is equivalent or superior to the GCP adopted in Japan, such trial can be used as data submitted in the application.
- (3) When the data of such trial, designated in (2), further proves its competency to ensure effectiveness and safety after its prospective approval in Japan, it will naturally be possible that the medical device in question will be approved in Japan without undergoing a further domestic clinical trial. An additional domestic clinical trial will be required for those cases in which effectiveness and safety fail to be assessed in the records of the clinical trial that has been performed outside of Japan.
- (4) Among 50 medical devices that were approved in FY2005 based on data of their respective clinical trials, 33 were reviewed based on only overseas clinical trial data, without any additional trial in Japan.

Future outlook

We encourage active use of the Pharmaceuticals and Medical Devices Agency, which is available for consultation on individual items. The GOJ intends to further expand this consultation system.

17. Improving flexibility in setting airfares between Europe and Japan

BDRT recommendation

The distribution, pricing and settlement of airfares in Japan should be deregulated so that carriers can offer fares in a transparent fashion directly to the consumer, including over the Internet.

State of the measures taken thus far

Concerning international airfares, since bilateral agreements concluded between Japan and other countries require approval by aeronautical authorities of both parties, Japan has adopted the approval system based on the Civil Aeronautics Law.

With regard to individual airfare authorization criteria, however, aviation authorities of Japan implement their operation flexibly; in the case of PEX fares (i.e. discount Y-class fares applied to air tickets directly available for individual passengers at the airline ticket counter, etc.), individual fares set by each operator are approved on the condition that the price level is not under 30% of the IATA PEX fares. As a result, flexible fare setting reflecting market trends is possible.

There are no special restrictions on Internet sales within the framework mentioned above and settlement of airfares.

Future outlook

Air service issues, including those related to airfares, have been and will be discussed in individual civil aviation talks with the aviation authorities of each EU Member State.

18. Improved access in and out of Japan for Foreign Residents

BDRT recommendation

The Government of Japan should abandon the requirement that foreigners with a visa must renounce it and return their Alien Registration Card whenever leaving the country and also abolish the separate system of applying for and issuing re-entry permits, so that permission to leave and re-enter the country freely is automatically granted when the visa is issued.

State of the measures taken thus far

Please refer to (1)-(b)-(ii) of “3. Supporting timely development of business.”

Future outlook

Please refer to “3. Supporting timely development of business.”

19. Strengthening market mechanisms in the telecommunications sector

BDRT recommendation

Japan should reform the institutional structure of its telecommunications regulatory environment. A regulator independent from both commercial interests and the Government should be installed. Less emphasis should be placed on detailed micro-management, and more emphasis on explicit macro-level economic criteria designed to promote economic efficiency, innovation, investment, and effective competitive outcomes.

State of the measures taken thus far

The Ministry of Internal Affairs and Communications (MIC) is completely separated from any telecommunications carriers. It is the Ministry of Finance (MOF) that holds part of NTT shares. The responsibility and authority of MIC and MOF are clearly divided by law. MOF is in the position of merely holding the NTT shares as part of national assets. It is MIC that supervises NTT from the perspective of regulating NTT's telecommunications business pursuant to the NTT Law.

Telecommunications is a segment that commands drastic technological renovation and strongly requires an approach of a national strategic nature. In light of this, Japan believes it is reasonable to provide the said segment with an institution that can respond rapidly and strategically under the strong leadership of a minister with exclusive authority over telecommunications. With the current institution, MIC has made highly significant achievements such as the realization of the world's fastest and low-cost broadband environment and the prevalence of the third-generation mobile phone.

Article 1 of the Telecommunications Business Law defines the purposes of the Law as "to promote fair competition" and "to protect the interests of users (of telecommunications services) and to thereby [abbreviated] seek to secure the convenience of the people." The article thus puts legal provisions into an already competitive market environment, and the promotion of consumer interests. The article also stipulates that the Law intends to make the operation (of the telecommunications business) adequate and reasonable. The Law further provides legal explicitness for the consideration of economic factors in decision making.

Future outlook

MIC undertook a review of competitive rules in the telecommunications segment in pace with the major changes unfolding in the market structure, such as the increasing utilization of the IP method in telecommunications networks and the changes in business models generated by the maturing broadband market. In September 2006, based on the review, MIC laid out in its New Competition Promotion Program 2010 a series of measures which are to be taken by 2010 to further promote competition. MIC will continue to formulate competitive policies from the perspective of promoting competition and ensuring its fairness.

20. Strengthening market mechanisms in the procurement of aircraft

BDRT recommendation

- (1) The Japanese government should promote competition in the field of large (more than 100 seat) commercial aircraft procurement. Historical circumstances have created practices which have distorted the market mechanism. As a result, Japanese airliners buy almost exclusively from one supplier.
- (2) The Japanese government should set a positive example to the private sector of the advantages of sourcing from more than one aircraft manufacturer by considering buying large aircraft for official government use from an alternative supplier.

State of the measures taken thus far

- (1) It is the management of each airliner that decides aircraft procurement. The GOJ is in no position to be involved in such decisions.
- (2) If the “large aircraft for official government use” in this recommendation refers to the Japanese government’s “special aircraft,” the current model in the possession of the GOJ is a B747-400 type, which was purchased in 1987 (and delivered in 1991) after taking into account a variety of considerations, including flight range capability, transport capacity and support structures.
Besides, the special helicopters owned and used by the GOJ at the moment, e.g., for the transportation of VIP guests from foreign countries, were purchased from a European company.

Future outlook

- (1) The position of the GOJ is presented above and will remain the same in the future: it will not take any specific action on airliners regarding their decisions on aircraft procurement. Each aircraft manufacturer should make decent efforts for business opportunities with airliners.
- (2) The GOJ maintains no principle that government planes should be purchased from a specified country or region. On the other hand, the GOJ currently has no plans to purchase a new “large aircraft for official government use,” and given the stringency of the fiscal situation, the GOJ intends to utilise the existing government plane to maximum effect.

21. Promoting EU-Japan cooperation in commercial aircraft development and production

BDRT recommendation

The Japanese government should promote fair competition by providing similar support to European-Japan Cooperation programs in the field of commercial aircraft development as is currently given to the cooperation between Japanese manufacturing companies and their U.S. counterparts. European companies can offer technology, know-how, and production and management techniques that can benefit Japanese manufacturing companies and capitalize on their strengths, for the benefit of both Japan and the EU.

State of the measures taken thus far

- (1) In June 2005, the Society of Japanese Aerospace Companies (SJAC) and the French aerospace industries association (GIFAS) agreed on a cooperation program on Supersonic Transports (SSTs). The Japanese side consists of Japan Aircraft Development Corporation (JADC); Engineering Research Association for Supersonic Transport Propulsion System (ESPR); and Japan Aerospace Exploration Agency (JAXA). The French side consists of the European Aeronautic Defence and Space Company (EADS); Snecma; and ONERA (Office National d'Études et de Recherches Aérospatiales). The two sides held a workshop in Tokyo in October 2006.
- (2) In July 2006, R&D Institute of Metals and Composites for Future Industries (RIMCOF), which plays a central role in the development of the material-related basic technologies at Japan's METI, and Airbus agreed on cooperative study for development of Structural Health Monitoring Technology (SHM) for aircraft.
- (3) The International Aero Engines (IAE) was established by a group of companies including Japanese Aero Engines Corporation (JAEC); Rolls-Royce; and MTU of Germany, in order to jointly develop and manufacture V2500 aircraft engines. Japanese companies are also participating in the joint development of aircraft engines in Trent 1000 project by Rolls-Royce.
- (4) Twenty-one Japanese companies are participating in the development of Airbus' next generation super jumbo aircraft A380.

Future outlook

It is a welcoming event that steady progress has been made in the cooperation between Japanese and European companies in recent years. The GOJ expects further development of such cooperation and thus will continue its support for the collaboration between the aerospace industry of Japan and abroad, including Europe.

WP 2 Accounting & Tax Issues

22. CFC rules

BDRT recommendation

We recommend the following three points concerning Japanese CFC rules.

- (1) To exempt profits for re-investment
- (2) To increase certainty in their application
- (3) To reconsider Exception

State of the measures taken thus far

(For Japan's stance on comprehensive tax reform, see the attached appendix)

Future outlook

(For Japan's stance on comprehensive tax reform, see the attached appendix)

23. Accounting Issues

BDRT recommendations

- (1) The European Commission's decision regarding the US has facilitated the EU efforts in pressing for reciprocal rights. To accelerate progress towards convergence, we ask the European Commission to ensure that all parties engaged with this matter in the EU, the US and Japan will engage in mutually beneficial dialogue.
- (2) Research on the introduction of reports on internal control over financial reporting is now being examined. We ask that the public authorities discuss the function of internal control fully and thoroughly consult stakeholders before endorsing internal control systems, paying careful attention to the balance of benefits and costs and interaction between the audit of an internal control and the audit of the financial statement.
- (3) We ask that public authorities provide opportunities for companies to contribute to international rule setting and revision on capital markets, to increase the transparency of the rule-setting process, thereby reducing costs for market participants and burdens on regulators alike.

State of the measures taken thus far

- (1) In July 2006, the Business Accounting Council (BAC) of the Financial Services Agency (FSA) released an opinion report entitled "Towards the International Convergence of Accounting Standards." Based on this report, the following activities have been carried out: In October 2006, the Accounting Standards Board of Japan (ASBJ) released a time-framed convergence programme with a view to EU's equivalence assessment. ASBJ is currently proceeding the programme for the convergence of accounting standards. In November 2006, FSA held a meeting with the European Commission to monitor the progress of the convergence. FSA plans to hold such meetings on more than two occasions annually.
- (2) The Financial Instruments and Exchange Law, enacted in June 2006, requires relevant companies to have an assessment and audit of the internal control over their financial reporting. Aiming to promote the implementation of such assessment and auditing, BAC published in February 2007 an opinion report entitled "About the Setting of the Standard and Practice Standard for Management Assessment and Audits of Internal Controls over Financial Reporting";

Pursuant to the Financial Instruments and Exchange Law, foreign companies are allowed to submit to the Japanese authority their internal control reports, even if prepared under the rules of their home country, on condition that the Cabinet Office Ordinance or any other relevant legislation stipulates that such reports provide sufficient protection for public interests or general investors.

- (3) Concerning international rules of capital markets, it is important that the principle of due process is appropriately complied with when such rules are established or revised. Specific instances include the project of Financial Statement Presentation by the International Accounting Standards Board (IASB), in which the Accounting Standards Board of Japan (ASBJ) plays a central role in giving Japan's opinions concerning individual accounting standards. The GOJ also provides its opinions to IASB as appropriate

Future outlook

The GOJ will continue to support the ASBJ's positive efforts towards convergence. While EU has postponed its decision on the equivalence of Japanese GAAP by two years, the GOJ hopes to continue to encourage active dialogue between the competent authorities of Japan and EU towards the equivalence assessment. The GOJ also hopes that the Japanese GAAP will continue to be accepted in EU markets, with regard to the assessment of equivalence.

Concerning international rules of capital markets, it is important that the principle of due process is appropriately complied with when such rules are established or revised. Japanese authorities intend to closely monitor on this matter continuously. Specific instances for such include a project of Financial Statement Presentation by the International Accounting Standards Board (IASB), in which the Accounting Standards Board of Japan (ASBJ) will continue to play a central role in giving Japan's opinions concerning individual accounting standards. The GOJ will also continue to provide its opinions to IASB as appropriate.

The GOJ is scheduled to establish the Cabinet Office Ordinance related to the internal control reporting system for foreign companies.

24. Tax Issues

BDRT recommendations

- (1) We hope that the EU Member States will enter into common agreements on tax issues with the Government of Japan to enjoy fully the benefits of the single market.
- (2) We repeatedly asked last year that the Government of Japan quickly reforms the consolidated tax system to allow the carrying forward of tax losses in subsidiaries incurred before the system came into effect, exempting revaluation of subsidiaries at the initiation, and allowing inclusion of donation between consolidated corporations in expenses.
- (3) We ask the public authorities to ensure significant reduction in source country withholding taxes (dividends, interest, and royalties) similar to the Japan-US Taxation Treaty and taking into account the close economic relationship between Japan and the EU's Member States actively to promote mutual investment between the EU and Japan.
- (4) We ask that the tax administration of Japan, before taxes are assessed, reaches a common understanding with the tax administration of the second jurisdiction in which an associated enterprise operates in order for taxpayers in Japan to avoid the excessive burden of transfer price taxation (that is, to avoid double taxation).
- (5) Given the progress of convergence, as new deviations arise between corporate accounting and tax practice, we ask that the Government of Japan respond flexibly.
- (6) We ask the tax administration of Japan to review the tax haven rules.
We suggest that Japan's tax authority reviews the criteria rate for tax haven regulation, or expand the exemptions, such that companies in countries with tax treaties with Japan can be exempted from tax haven regulations.

State of the measures taken thus far

(Please refer to “2. The optimization of returns on investment” in this report for Taxation Treaty (avoiding double taxation, transfer price taxation, etc.). For all aspects of the tax reform, see the attached appendix)

Future outlook

(Please refer to “2. The optimization of returns on investment” in this report for Taxation Treaty (avoiding double taxation, transfer price taxation, etc.). For all aspects of the tax reform, see the attached appendix)

WP3: Information & Communication Technology

25. Benefits from ICT for the society

BDRT recommendation

- (1) Governments should promote ICT utilization to support the development of a dynamic society as a way to address social issues, such as the aging society, nursing/medical care, unemployment, crime/disaster prevention, and energy/environmental issues. ICT can provide remote medical care, telework, e-learning, and entertainment, and currently the following 3 areas should be emphasized.
- (2) Both governments should promote realization of an educational environment in which every child can achieve self-realization with support of ICT. EU-Japan-cooperation should be promoted so as to improve the information literacy of children and to develop an environment in which children can utilize the Internet with security and safety. Both governments should promote development of digital archives including pictures that encompass the cultural heritages, arts, and entertainment of the EU and Japan, for children to better understand cultures of the EU and Japan, and appreciate the worlds' finest arts and knowledge. Any digitisation, however, should be done with the explicit permission of the rightsholders, thereby fully respecting their exclusive rights.
- (3) For better resolution of inconveniences with international travel between the EU and Japan, and for promotion of further interaction between the EU and Japan, both governments should promote the development of multilingual information environment by utilizing ICT, such as development of multilingual websites and deployment of user-friendly intelligent and interactive displays that respond to individual needs.
- (4) Governments should act for practical application and spread of ITS to contribute to global climate by reduction of CO2 emissions as a result of resolution of urban traffic congestion, and the prevention of traffic accidents. Both governments should actively promote field tests and share the results of these trials.

State of the measures taken thus far

- (1) Through implementing the e-Japan Strategies in the past five years, Japan has promoted its IT strategy in combination with its structural reform, becoming one of

the world's top IT nations with the most advanced market and technological environment, both in terms of the broadband infrastructure and users' levels. In January 2006, the IT Headquarters compiled the "New IT Reform Strategy" with the aim of helping promote reform of the Japanese society by the use of IT's capabilities to address social challenges faced by 21st century Japanese society, such as countermeasures for a declining birthrate in an aging society, for environmental issues and the realization of a safe and reassuring society. The Strategy seeks "Realizing Ubiquitous and Universal Network Society Where Everyone Can Enjoy the Benefits of IT." This aim will be achieved by promotion measures that include the following: the promotion of full online processing of medical insurance claims, as part of structural reform for the medical field; the establishment of an environment covering e-learning systems with the aim of realizing abundant living throughout one's life span to provide learning opportunities at any convenient time for seniors, handicapped persons, carers, parents and unemployed youth; the establishment of a telework environment to allow for flexible work timetables; provision of disaster information by the use of terrestrial digital television broadcasting services; and energy use management by the use of IT.

(2) (Improvement of the ICT environment)

Based on its New IT Reform Strategy and other policies, the GOJ promotes the establishment of learning systems with the use of ICT. Specific instances include the promotion of ICT in the elementary and secondary education levels; development of high-level ICT human resources at universities; the promotion of remote education with the use of the Internet and other means; and the provision of other relevant institutions and e-learning services that cater to learners anytime at anyplace.

The GOJ is also advancing awareness-raising campaigns based on the recognition that safe and reassured use of the Internet must be well acknowledged by those who protect and educate children, such as parents and teachers, against the background that makes it increasingly easier for children to access mobile phones and the Internet in recent years.

Furthermore in response to the serious development of issues of information provided by the media that influence the youth, the GOJ is involved in the efforts by local community members to protect the youth from such information and programs to enhance media literacy for the youth and children's guardians. The GOJ is also conducting nation-wide awareness-raising campaigns and necessary research and studies.

(Development of digital archives for cultural assets)

Since April 2004 the GOJ has been opening a test version of cultural asset online disclosure in Japanese for domestic viewers. This site is based on the technical cooperation of the National Institute of Informatics and the cooperation of licensing digital images by independent administrative museums and museums of art and the National Research Institute for Cultural Properties, as well as other public and private museums, museums of art across the country and other relevant organizations. As of January 2007, 746 museums and entities participated in the site.

- (3) In a three-year plan since FY2006, the Ministry of Economy, Trade and Industry has been promoting R&D for speech recognition technology with the aim of a drastic improvement in usability of digital consumer electronics.

Two other R&D projects are also underway for overcoming barriers of language, culture and ability by developing a heart-to-heart communication technology: one project is for a text translation system using a bilingual translation data base; and the other for a bi-directional multi-lingual speech translation system. Both projects are being carried out by the National Institute of Information and Communications Technology (NICT), an affiliate organization of the Ministry of Internal Affairs and Communications, during NICT's five-year mid-term target period started in FY2006.

- (4) Concerning practical application and spread of ITS, the GOJ has been working based on e-Japan Strategy II compiled in July 2003. Specifically, the GOJ has been seeking to realize smooth traffic flows through enhanced provision of traffic information and the promotion of the electronic toll collection system (ETC). The GOJ has also been working to prevent traffic accidents through measures including the promotion of the driving safety support system. In the New IT Reform Strategy compiled in January 2006, the GOJ has further confirmed its continued commitment to solving urban traffic congestion through the use of the intelligent transportation system (ITS). Specifically in the area of traffic safety, this Strategy laid out a road map to bringing the driving safety support system into practical use by 2010 and measures to speed up emergency relief activities through the provision, etc. of location information of the callers of emergency help.

These efforts have led to smooth progress, as the shipment of vehicle information and communication system (VICS) reached about 16.6 million units (as of the end of September 2006), while the average ETC utilisation reached over 65% (as of the end of December 2006). Efforts for the driving safety support system has also advanced based on the above mentioned road map, with an ITS Promotion Conference established in April 2006 as a venue to link public and private sectors to

examine a modality of an effective service system based on measures such as comparison of various media's characteristics. The conference also examines the specifics of filed tests.

As part of efforts to share information with other countries, the GOJ actively presents its achievements and challenges ahead at opportunities such as the ITS World Congress.

Future outlook

(1), (4) Based on the New IT Reform Strategy and prioritized plans, the GOJ is further committed to steadily realizing “a healthy and reassuring society,” in which everyone can feel qualitative wealth.

(2) (Improvement of the ICT environment)

The GOJ intends to achieve the targets laid out in the New IT Reform Strategy to actively promote measures that contribute to the use of ICT in education. For improving the environment for children's reassured and safe use of the Internet, the GOJ will continue to coordinate with relevant organizations to enhance the initiatives.

(Development of digital archives for cultural assets)

The GOJ seeks to expand the number of participant museums and other organizations, as well as the volume of information available for searches. The GOJ is also creating an English test version of the site, from the perspective of presenting Japan's quality and diverse cultural heritage not only at home but also abroad. The English version will undergo adequate reviews from time to time for further improvements, targeting a full-fledged operation for international viewers.

(3) A flexible multi-lingual speech recognition engine is scheduled to be developed in FY2008. This achievement is expected to be applied to digital consumer electronics such as car navigation systems by relevant manufacturers.

Also on schedule is the targeted launch in or around 2010 of a speech translation service using mobile phones, for travel conversations in Japanese, English and Chinese.

Furthermore by 2015, basic technology is expected to be developed for multi-lingual translation for general conversation levels without limiting any specific purpose of conversations.

(4) The GOJ will continue to steadily endeavour for realizing practical application and spread of ITS based on the New IT Reform Strategy.

26. Security (including e-government) issues

BDRT recommendation

- (1) Both governments should implement e-Government services whereby citizens and businesses can experience the convenience and improvements of service quality by making the most of ICT. Specifically, both governments should strengthen their cooperation concerning the compatibility of e-Passports for prevention of falsification and for safe and speedy airport procedure, cost reduction and improvement of service quality of ports and harbours, information sharing about the development of port information system to improve assuredness of shipping and so on.
- (2) Security and reliability of systems such as communication networks and financial information systems are global issues, especially when major accidents or catastrophes with a wide-ranging impact occur. Therefore, international cooperation is essential and both governments should exchange their current policies to foster effective revision or implementation of common policies. Both the EU and Japan should raise awareness among citizens about information security by promoting industry-government-academia cooperation to develop specific curricula on information security.
- (3) Protection of private information can be assisted by security technologies such as biometrics technologies. Both governments should promote the deployment of such technologies to enhance consumer confidence by further utilization of ICT.
- (4) Nowadays, businesses must address information security issues and if adequate measures are not taken, they must face significant risk to pay high compensation for damages caused by leaks of private information. However, some businesses are disclosing the assessment of the risks and measures taken for information security. Therefore, both governments should promote disclosure of information security correspondence by businesses, and discussion about of the need to standardize items to be disclosed.

State of the measures taken thus far

Since formulating the e-Japan Strategy, the GOJ has been promoting IT strategy in combination with its structural reform. In January 2006, the IT Strategic Headquarters compiled the New IT Reform Strategy to address social challenges faced by 21st-century Japanese society (declining birth rate and aging society; measures for

environmental issues; the realization of a safe and reassured society, etc.) in order to take advantage of IT solution capabilities to progress reform of the Japanese society. The new strategy further presented the following promotion measures to realize ubiquitous and universal network society where everyone can enjoy the benefits of IT.

- Concerning the compatibility of e-Passports, since November 2005 the GOJ has been operating an e-Passport Depository as a centre for investigating compatibility within the New Media Development Association upon approval by member countries of the International Civil Aviation Organization (ICAO).

Among EU countries, thus far the UK and the Netherlands have offered their sample passports to the Depository. It is our earnest wish to obtain active commitment from other EU countries as well.

Homepage of the e-Passport Depository:

<http://www.epassport-depository.org/>

- Japan has ratified the Convention on Facilitation for International Maritime Traffic (FAL Convention) to provide simplified procedures and documents required of incoming and outgoing ocean transport vessels. Concerning the development of a port information system, the GOJ is working on a reconstruction of the systems which aims not only at the interconnection among existing systems, but also at thorough reviews of procedures employed at relevant offices and ministries that will involve aspects such as simplification of procedures and compliance with international standards.

The GOJ seeks to enhance the reliability and safety of social systems through the compilation of mid-to-long-term plans for comprehensive issues on information security “The First National Strategy on Information Security” (February 2, 2006) and through annual plans in “Secure Japan 2006” (June 15, 2006).

Fully aware of the need for international collaboration, the GOJ identifies the promotion of international collaboration and harmonization as one of the key areas in the above mentioned plans. Japan and EU agreed to join hands in enhancing the safety, etc. of information systems and networks, as set forth in their Joint Statement on Cooperation on Information and Communication Technology, compiled at their regular Summit in June 2004. Japan and EU have hitherto been intensively sharing information on occasions such as the Japan-EU policy discussions.

The GOJ furthermore designated February 2 the Day of Information Security, effective in 2007. On this occasion, efforts are made by alliances of industry, the

academe and administration to enhance the awareness of the entire people for the importance of information security.

- Companies are responsible for actively engaging in measures to protect information security from the perspective of the social responsibility they bear as members of IT society, besides striving to minimize damage they could possibly suffer in terms of information security and to comply with the relevant law. To these ends, there needs to be a system to allow companies to promote information security measures autonomously and continuously. However at present, companies' efforts to ensure information security fail to be linked to enhancing their corporate value. This points to problems such as companies actively committed to information security falling short of reasonable evaluation by their stakeholders.
- In recognition of these events, the GOJ has been promoting a Study Group on a Modality of Companies' Information Security Governance since September 2004 in order to deliberate on concrete measures to incorporate a new concept of "information security governance" into company management.
- A result of this study group is an information security reporting model.
- The information security report is designed to help stakeholders such as clients and investors to fairly evaluate companies of their interest, as the report discloses those types of efforts for information security that draw high social interest, such as the companies' policies on information security, the companies' internal structures to realize such policies and any third-party assessments.
- The GOJ is currently promoting the use of the information security reporting model in a bid to encourage companies to disclose their information security measures.

Future outlook

In order to accelerate the realization of the New IT Reform Strategy, the GOJ plans to compile the Priority Policy Program 2007 by the targeted period of June 2007. In this way the GOJ intends to continuously secure reliability and safety of IT and further upgrade security while paying heed to the enhancement convenience for users, with the aim of realizing a society in which people can feel the benefits of IT.

- Concerning the inspection of e-Passports, the operation period of the e-Passport Depository will last until the end of FY2008.

The GOJ further seeks to enhance the reliability and safety of social systems and promote international collaboration pursuant to the First National Strategy on Information Security.

On and around the Day of Information Security of February 2, 2007, the GOJ promoted related events in tie-ups of the government and industry with the aim of enhancing all people's awareness of information security.

The GOJ intends to moderate the information security reporting model upon necessity. It also intends to promote the use of this model and take other relevant means to advance the corporate disclosure on information security measures.

27. R&D Cooperation with particular focus on international standardization initiatives

BDRT recommendations

- (1) Both governments should deepen their cooperation concerning R&D and the resulting standardization in international organisations in order to facilitate the uptake of next-generation networks that provide security, safety, and simplicity of use.
- (2) Integrated infrastructures and seamless services in the future “digital home” are combining entertainment and new appliances for household control and management as a new value for consumers. The successful development of these services depends highly on interoperable solutions. Both governments should ensure that standardisation bodies address the need for standards in this area.
- (3) Both governments and relevant EU and Japanese institutions which handle standardization should combine efforts so as to create international standards that satisfy global requirements by ensuring their relevance in a worldwide context. The EU and Japan should take a leadership role in formulating such International Standards by means of a proactive partnership that aims to limit regional and national options in standards to an absolute minimum.

State of the measures taken thus far

Aiming to maintain and enhance international competitiveness, the GOJ intends to prioritize those areas of ICT in which Japan leads the world, such as optic network and home information appliances and also those that provide the basis of other industrial segments, as set forth in the “New IT Reform Strategy” formulated in January 2006. The GOJ thus seeks to take the lead in establishing global standards in those technological areas which Japan has developed ahead of the world. To this end, the GOJ intends to promote government-industry tie-up activities at the International Telecommunication Union (ITU) and other international standardization bodies.

A specific instance is next generation network (NGN) technology, which serves as the infrastructure for the ubiquitous network society (UNS); the GOJ sees the realization of this technology as a primary pillar for its UNS Strategic Programs, designed to contribute to promoting future ICT R&D and realizing a UNS. Also at the Council for Science and Technology Policy, NGN technology is identified as one of the strategically emphasized scientific technologies that should receive intensive investment

in the next five years. An alliance of the government and private sector has thus been working on intensive R&D for NGN technology. Also, with the aim of promoting the dissemination of home information appliances, the GOJ is working to establish R&D and a common basis for these appliances.

Concerning international standardization of NGN and home network technologies, a government-private alliance is underway between the ITU-T Sectional Meeting of the Information and Communications Council and the Telecommunication Technology Committee (TTC), a private standardization organization.

TTC also concluded a memorandum of understanding (MOU) with the European Telecommunications Standards Institute (ETSI) to seek an alliance for creating international standards. GOJ supports these efforts to enhance ties between standardization organizations of Japan and EU.

Future outlook

NGN is expected to play a significant role as the network infrastructure in view of realizing a future ubiquitous network society (UNS). In the concept of the digital home, the realization of a home network is hoped for as a means to enable everyone to use home appliances conveniently regardless of the type of appliance and as a critical link between users and the ubiquitous network.

Currently, the International Telecommunication Union (ITU) is enhancing its commitment to international standardization, considering the importance of NGN and home networks. International standardization also draws strong interest from the viewpoints of users and vendors. In this light, the GOJ intends to further progress its coordination and alliances with EU and countries in other areas regarding international standardization.

In Japan, the development of a next-of-next IP network has just begun in an alliance between the industrial, academic and government sectors. This network would allow free switching among the Internet, telephone lines and PHS depending on transmission conditions to realize constant high-quality communication and a definite assurance of communication safety. The alliance plans to complete the basic designs by around 2010. The GOJ intends to promote cooperation with the EU to aim at an international standardization regarding this technology.

28. Regulatory environment allowing a dynamic development of the ICT-World

BDRT recommendations

- (1) Both the EU and Japan should work towards a regulatory environment that facilitates digital convergence at all levels. Digital convergence developments provide an excellent opportunity for adjusting existing regulations, and foster liberalization initiatives; therefore governments should adopt a regulatory approach which leaves as much as possible and appropriate to market forces.
- (2) Digital convergence will depend on different elements. First of all, governments should support the ability of service providers to offer integrated services. For consumers, regulation should encourage open access to all services any time and any place. The EU and Japan should also foster a competitive level playing field that does not inhibit open access to their respective markets for ICT equipment vendors.
- (3) Consumers will in the future be able to choose between an even larger number of different platforms using different technologies. New services, e.g. video conferencing for residential costumers, three dimensional internet shopping or interactive classrooms are applications requiring networks with a large bandwidth to be available in the mass market. Therefore governments should ensure a competitive development of the ICT sector, not prohibiting through regulation the development of new and alternative networks.
- (4) The precondition for the development of new technologies, new products and new markets is that companies bearing commercial risks also have the possibility to gain profits. It is undisputed that both regulation and regulatory uncertainty can have a negative impact on innovation and investment activities. Consequently, governments should set clear incentives for innovation and investment when shaping the regulatory framework for the ICT industry.
- (5) Governments should develop public procurement policies that promote interoperability, in particular by purchasing solutions compliant with open standards developed and supported by industry and thereby ensuring that government installations contribute to interoperability. Public administrations should aim to employ highly flexible, vendor independent, and interoperable ICT architectures, which are responsive, open to new technological developments and value-driven. Any procurement decisions should be made on solid business rationale such as degree of interoperability, cost, functionality, security, innovation, support for open standards and adaptability to future technologies.

State of the measures taken thus far

(1), (2) Recently expanding events include the sharing of terminals by communication, broadcasting services and networks, etc. and cross entry into each other's fields by communication and broadcasting providers. These events have been triggered by the progress of digitization in communication and broadcasting services and the drastic improvement of transmission capabilities based on technological renovations. The resultant integration of communication and broadcasting represents a typical phenomenon of digital convergence.

In line with these moves of integration by communication and broadcasting, the GOJ has been promptly taking necessary measures in every aspect of institution, technologies and business.

In terms of technologies, the GOJ actively supports technological development associated with the integration of terminals and that of transmission channels pursuant to the Law Concerning Promotion of Development of Technologies for Communications and Broadcasting Convergence.

In terms of institution, the GOJ institutionalized broadcasting by the use of telecommunications services when it enacted in January 2001 the Law Concerning Broadcast on Telecommunications Service. These moves are in response to the progress of integration of transmission channels, such as broadcasting services using optic-fiber-to-the-user networks provided by telecommunications carriers. The GOJ also responded to the progress of content integration, such as broadcast contents being supplied through the Internet; based on the principle of promoting contents distribution without dividing communication and broadcasting terrains, the GOJ has been working to smoothen licensing processes for rights such as copyrights, by establishing relevant systems and improving the business environment. December 2006 saw the passage of the Bill to Revise Part of the Copyright Law and thus a legal improvement concerning the handling, etc. of IP multicast services under the Copyright Law. Also in progress is the retransmission of IP multicast services by the high definition method of terrestrial digital television broadcasting services, as the preparation for such retransmission has now reached the final stage.

Concerning the legislative improvement encompassing a modality of regulation conforming to the integration of communication and broadcasting, comprehensive

deliberations were presented in the Agreement between the Government and Ruling Parties on a Framework for Communications and Broadcasting (July 2006), as a result of the coordination between the government and the ruling parties. This agreement was reflected in the government's Basic Policy 2006 concerning Economic and Fiscal Management and Structural Reform, which set a course for the government to promote reform in communication and broadcasting sectors to realize infrastructure and services able to cater to the world's most advanced communication and broadcasting.

Based on these moves, the Ministry of Internal Affairs and Communications established a Study Group on Comprehensive Legal System Governing Communications and Broadcasting in August 2006, with the aim of putting into shape the direction of deliberations on a legal system that responds to the integration and coordination of communication and broadcasting. While referring to the state of deliberations overseas such as the EU's draft Audiovisual Media Service Directive, the Study Group has been advancing deliberations on modalities for the regulation for contents, protecting service users and ensuring fair competition in a scope that exceeds the existing frameworks of communication and broadcasting. Concerning the legal institution for communication and broadcasting, the GOJ has up until now been conducting reviews when possible and as needed, regardless of the progress of integration and coordination between the two media and taking adequate reliance on the autonomy of the market into due consideration.

- (3), (4) Concerning the competitive development in the area of information transmission, the government and the ruling parties sought coordination, which led to the Agreement between the Government and Ruling Parties on a Framework for Communications and Broadcasting in July 2006. Pursuant to the Agreement and with a view to realizing advanced yet low-cost ICT services, it was decided to promote the establishment of necessary rules for fair competition, with regards to issues such as the opening of networks. Also pursuant to the Agreement, the government's Basic Policy 2006 designated the promotion of reform in communication and broadcasting sectors with the aim of realizing the world's most advanced communication and broadcasting infrastructure and services.

Based on these moves, the Ministry of Internal Affairs and Communications compiled and announced the "New Competition Promotion Program 2010" in

September 2006 as a roadmap to establishing fair competition rules to be implemented in the early 2010s in the telecommunications sector.

Currently, pursuant to this Program, discussions are underway concerning the establishment of rules to ensure fair competition, in the hope that fair competition will facilitate the innovation and investment recommended by the BDRT.

- (5) To further improve the government procurement associated with information systems, the GOJ intends to compile a “Basic Policy for the Public Procurement of Computer Systems,” based on the Priority Program 2006 (IT Strategic Headquarters decision, July 26, 2006) and the “Program for Promoting e-Government” (Chief Information Officers (CIOs) Council Decision, August 31, 2006). A draft of the Basic Policy has been made, to which the GOJ has asked for public comment (http://www.soumu.go.jp/s-news/2006/061222_8.html (in Japanese)). The draft indicates that it is important to operate strategic procurement that would designate the contents of procurement orders in adequate scopes and enable with minimum costs flexible combinations of hardware and software and smooth interoperations among information systems. Based on this policy, the GOJ intends to take the following measures:
- (a) Preparation of procurement plans and procurement specifications upon consideration for procurement methods that encompass the viewpoints of expanding competition and of ensuring the expandability of information systems.
 - (b) Prohibition in principle of designating brands, etc as part of requests to be filled in the procurement specifics, so that such requests should be based on open standards without reliance on any specific technology.

Future outlook

- (1), (2) The GOJ believes that it should continue to actively promote digital convergence, in which regard, the GOJ shares the position presented in the BDRT recommendations. Targeting 2011, when broadband is expected to cover the entire Internet communication and broadcasting is scheduled to be fully digitized, the GOJ will continue deliberations at the Study Group on Comprehensive Legal System Governing Communications and Broadcasting and plans to compile a report, targeted for December 2007. Subsequently, after the consultation and reporting by

the Telecommunications Council, the GOJ intends to submit a relevant bill at the ordinary session of the Diet in 2010.

- (3), (4) In consideration of the rapid changes of the market structure due to the progress and spread of IP technology, the GOJ is promoting a review on comprehensive competition rules for the entire broadband market based on the New Competition Promotion Program 2010. The GOJ will then implement as needed whatever results of such a review are applicable as concrete measures. Concerning this Program, the GOJ plans to compile a report of its progress targeted for July of each year, submit it to the Telecommunications Council and publicly disclose it. The GOJ intends to review the Program as necessary while ensuring the transparency of procedures, such as those for soliciting opinions.

Based on the degree of progress of this Program, the GOJ plans a comprehensive inspection of the entire legislation associated with communication in 2010.

- (5) The above-mentioned Basic Policy (draft) is scheduled to be put to a decision at the CIO Council, based on which ministries will steadily advance their endeavours.

29. IPR-Policy

BDRT recommendation

- (1) Both governments are collaborating to address counterfeit goods and pirated production issues in the Asian region in recent years. Although countries in Asia are making efforts to protect intellectual property rights, violations of the rights are still taking place. Both governments should increase their collaborative efforts to ensure an effective enforcement of intellectual property rights. Regarding countries where violations are too much to ignore, both governments should collaborate and propose a framework facilitating the sharing of information between the private and public sectors on actual infringements to effectively enforce their IPRs.
- (2) It is noted that both governments are focusing on the issues of content protection, private copying and fair compensation. Both governments should share the underlined issues and ideas for solutions in order to promptly issue directions or recommendations in the area of content protection, private copying and fair compensation which strikes a good balance between content protection and usage. It should facilitate distribution and consumption of content in protected and user-friendly digital platforms, e.g. by DRM's.

State of the measures taken thus far

- (1) Based on agreements at the Japan-EU Summit in 2003, Japan and the EU have held the meetings of the Japan-EU Dialogue on Intellectual Property Rights (director-level) in Tokyo and Brussels in turn. At each meeting, the both sides have exchanged views on a wide range of issues concerning IPRs including patents, copyrights, trademark, measures against counterfeits and pirated goods, geographical indications and protection of pharmaceutical data. After the latest meeting held in Tokyo in February 2006, the next one is scheduled in February 2007 in Brussels, where the both sides will discuss such issues as a proposed international legal framework on preventing proliferation of counterfeits and pirated goods.

Concerning Japan-EU cooperation on IPR fields, the Japan-EU Summit in 2006 concluded that “Japan and the EU expressed satisfaction with the discussions held in the framework of their dialogue on Intellectual Property. They will continue their close dialogue on intellectual property-related matters including in the area of the international patent agenda, geographical indications and counterfeits and pirated goods, such as dialogue on the proposed international legal

framework on preventing proliferation of those goods.” The both sides also agreed to identify the continuation of their dialogue on IPRs as one of the priority actions to be taken by the EU-Japan Summit of 2007.

Japan has also extended its cooperation to the EU in other forum including the WTO’s Trade-related Aspects of Intellectual Property Rights (TRIPS) Council, where in October 2006 Japan co-sponsored, together with the U.S. and Switzerland, the proposal submitted by the European Commission (EC) on the enforcement of IPRs.

- (2) Based on the Intellectual Property Strategic Programs, GOJ has worked for establishment of IPR systems that can respond to the digital era. GOJ has also implemented various measures to promote the use of contents with Japanese origins.

Future outlook

- (1) In line with the current cooperation framework mentioned above, GOJ will further strengthen its cooperation with the EU through bilateral channels including the Japan-EU Dialogue on Intellectual Property Rights and multilateral ones including the TRIPS Council.
- (2) The Task Force on Contents of the Intellectual Property Strategy Headquarters is scheduled in March to compile specific measures to make Japan the world’s leading nation in contents creation. The measures are expected to refer to the adoption of a protection system with a due consideration for a balance between contents protection and users’ convenience. Furthermore, based on these proposals, the GOJ plans to compile the Intellectual Property Strategic Program 2007. Against these backdrops, GOJ intends to promote its IPRs policies such as the enhancement of Japan’s contents business with due reference to cases from the EU and other areas overseas.

WP4: WTO

30. Policy Statement concerning the World Trade Organisation

BDRT recommendations

- (1) The BDRT has repeatedly and consistently expressed its strong support for the strengthening of the multilateral free trade system and the Doha Development Agenda (DDA), and has requested the European Commission and the Government of Japan to promote the conclusion of the agenda.

In view of the recent DDA negotiations, however, we are concerned about the slow progress, which could undermine the talks. Time is running out. The BDRT therefore reiterates its strong request to the European Union and the Government of Japan for their maximum efforts in the negotiations to reach an agreement by the end of 2006.

- (2) There is an increasing trend towards regional free trade agreements (FTAs). If the DDA negotiations fail to achieve a substantial success, it may become difficult to ensure consistency between various FTAs and the multilateral free trade system. A successful and ambitious DDA result would reduce the risks of creating many confusing bilateral agreements.
- (3) The BDRT has a strong interest in the ambitious reduction and where possible elimination of tariff and non-tariff barriers against industrial products trade. With regard to the non-agricultural market access (NAMA), the BDRT supports the Swiss formula to eliminate tariff peaks and to harmonise tariff structures downwards among OECD and emerging countries. The BDRT welcomes the possibility for sectoral initiatives among willing industries that can further promote free trade while reducing or eliminating tariffs. While believing that special and differential treatment for developing countries is an integral part of the modalities, we are concerned that excessive flexibility for the emerging countries might undermine the goal of achieving real market opening and south-south trade.
- (4) Services trade is one of the main pillars of the DDA. At the Hong Kong Ministerial Summit held in December 2005, WTO members agreed to pursue multilateral sector negotiations with a view to vastly improving GATS offers. More progress is needed in this field to achieve the BDRT's objective of real market openings for the service trade among OECD and emerging countries. The services trade negotiations should aim towards a level of ambition equivalent to those of other negotiating areas. All WTO members hold an important stake in the

negotiation of the Doha Round, and should provide substantial offers for the liberalisation of the service trade. In view of the significance of the sector in industrialised economies, increasing access to the service market will provide new prospects to emerging economies, developing countries and developed countries alike.

- (5) Agriculture is a key to the successful conclusion of the DDA. Although significant progress has been made in the elimination of export subsidies, considerable differences in views between countries remain in the fields of market access and domestic support policies. The BDRT strongly requests further progress in the agriculture negotiations by all the major players.
- (6) The BDRT supports the progress made in the development of ambitious and specified rules on trade facilitation. Other rules on issues such as anti-dumping are an integral and important part of the DDA negotiation and need to be effectively addressed. While the BDRT recognises that Singapore Issues (investment, competition, and transparency in government procurement) are not in the DDA talks, it underlines the importance of the WTO addressing these issues in the future.
- (7) The BDRT has stressed that, in order to reduce concerns of developing countries, developed countries must continue to make efforts to address capacity building in developing countries, to deliver results in various aspects including market access, and to facilitate the active participation of least developed countries in the DDA talks. We therefore repeat that it is of utmost importance that all member countries continue to seriously address the issue.
- (8) The BDRT has high expectations of Mr. Pascal Lamy, WTO Director-General, as an individual of outstanding qualifications with a strong trade background, and hopes that he will exercise his excellent leadership for the successful negotiation of the DDA. However, it recognises that WTO members hold the ultimate responsibility for achieving an ambitious and balanced compromise on all negotiating issues.
- (9) The current Round negotiation is extremely important as it is to establish a new set of trade rules that conforms to the new era of the 21st century. The next six months are the last and the most critical period for a successful conclusion of the DDA. The BDRT encourages the EU and Japan to maintain strong contacts with each other and take true initiatives for the success of the DDA.

State of the measures taken thus far

- (1) Following the Doha Ministerial Declaration in 2001, Japan has been actively engaged in the Doha Development Agenda (DDA) (the Doha Round) negotiations, which include negotiations on the issues of agriculture, non-agricultural market access (NAMA), services and rules such as anti-dumping rules, trade facilitation and trade and development. The GOJ has been keenly participating in the negotiations to obtain balanced agreements, focusing not only on market access, but also on the areas of establishing and enhancing rules.
- (2) Major WTO members held a ministerial meeting in July 2006, which failed to break through the triangular deadlock (agricultural market access; agricultural subsidies; and NAMA), resulting in a suspension of negotiations. Japan however strove for the resumption of the negotiations while taking part in various related ministerial meetings and exchanging opinions with related countries, as well as by working on private economic organizations.
- (3) November 2006 saw a resumption of negotiations at a working level by the negotiation groups for agriculture, NAMA, services, rules and trade facilitation respectively, based on the proposal by WTO Director-General Pascal Lamy. Also at the APEC Summit of the same month, a stand-alone statement was issued to back the resumption of the Doha Round negotiations, based partly on Japan's initiatives. As exchanges of opinions have become more active among major players such as the US and EU since the start of 2007, Japan too has been calling on these countries for their cooperation toward an early conclusion of the Round negotiations during tours by Japan's top and senior government officials (the UK, Germany, Belgium and France by Prime Minister Shinzo Abe; France and the US by Minister Toshikatsu Matsuoka of Agriculture, Forestry and Fisheries; and the US and Belgium by Minister Akira Amari of Economy, Trade and Industry).
- (4) In the area of NAMA, discussions have been underway since the resumption of working level negotiations in November 2006 on an agenda covering sectoral initiatives; reduction of tariffs; and the treatment of developing countries. Japan, as a strong competitor in industry sectors, has been seeking achievements that help to improve substantial market access in its continuous efforts for an early agreement on the modality.
- (5) In the area of services, momentum was increasing among member countries including developing countries in order to attain high quality second revised offers scheduled to be submitted by the end of July 2006. Since the soft-resumption in November 2006, member countries have agreed to accelerate negotiations in order to realize full-fledged resumption. Japan, as a promoter of the services trade

liberalization, continues its efforts to realize early submission of high quality second offers.

- (6) In the area of agriculture, Japan is actively working on negotiations to seek a balanced final conclusion based on the idea of attacking what should be attacked; protecting what should be protected; and conceding what should be conceded. In these negotiations, Japan, as in the past, takes into consideration issues other than trade, such as the multi-dimensional functions of agriculture and food security.
- (7) In the area of trade facilitation, Japan is actively committed to negotiations with the recognition that all stakeholders of trade will enjoy various merits by the establishment of rules that effectively enhance transparency, predictability and fairness.
- (8) Japan seeks to enhance the development of developing countries through the Round negotiations so that those countries can further benefit from the free trade system. To this end, at the opportunity of the Hong Kong Ministerial Conference in 2005, Japan presented the “Development Initiative for Trade,” a comprehensive package focusing on “Aid for Trade”, which includes not only border measures but also means to empower the supply side. As part of efforts to steadily realize this initiative, the GOJ is scheduled to submit a bill for necessary revisions of law to expand the duty-free and quota-free measures for LDCs in the current Diet session.

Future outlook

- (1) An informal WTO ministerial meeting is scheduled to begin on January 27, 2007 in Davos. The meeting is expected to boost the momentum for a resumption of full-fledged negotiations, while adding to the negotiation process in Geneva further bilateral and multilateral movements among members to push forward ongoing efforts to break the deadlock of negotiations. Japan, as one of the key players, will actively participate in the negotiations to achieve a balanced agreement as a whole.
- (2) A successful conclusion of the Doha Round negotiations will only be made possible by close coordination among member countries including EU members. Japan wishes to exchange opinions thoroughly not only with developed but also developing countries as an effective contribution to the negotiation process.
- (3) The GOJ has made frequent contacts with the private sector, including an exchange of opinions with, among others, the business community. The GOJ will continue to deepen its cooperation with the private sector.

WP 5: Life Sciences & Biotechnology (LS&BT)

31. General Recommendations

BDRT recommendations

- (1) Continue to implement the Action Plans issued by the EU in 2002 and by Japan in 2002 through the strong initiatives by both Governments. Continuous review of these Action Plans is recommended to ensure that they keep pace with advances in LS&BT and the changes of society. Proper allocation of resources has to be carried out by the strengthened function of pre- and post-evaluation of projects in cooperation with industries. Further, governments and industries should work together to consider ways to increase the mobility of human resources within/between the regions, especially of post-doctoral fellows.
- (2) No recognizable progress has been seen in the promotion of LS&BT public understanding, both in the EU and Japan, regarding recommendation 5-EJ-2 in 2005.

Governments should urgently establish “National LS&BT Understanding Promotion Plans” through a strong governmental initiative in cooperation with industrial and academic sectors, and establish a cross-ministerial head office for the accelerated and efficient promotion of public understanding of biotechnology. Information exchange between the EU and Japan will be valuable during the process. For example, mutual introduction of experiences such as best practices will elucidate critical issues on this matter and be helpful for the promotion. Also, academic research through the social scientific approach should be encouraged to evaluate the risks and benefits of cutting-edge technologies.

- (3) Make research for LS&BT a priority in public research funding schemes.
 - ① The Japanese government should invest continuously in the LS&BT fields according to the 3rd Science and Technology Basic Plan adopted in 2006.
 - ② Continuous funding in basic research of LS&BT is important because its R&D usually takes a long period of time before launch. Also, much more funding in the social/regulatory science field is essential to promote public acceptance of LS&BT stagnating in the EU and Japan.

State of the measures taken thus far

- (1) The Council for Science and Technology Policy compiled a Promotion Strategy of the GOJ for Life Sciences in March 2006 based on the principles set forth in the Japanese Biotechnology Strategic Plan, established by the Biotechnology Strategy Council in December 2002. Under this Promotion Strategy, the whole government is committed to promoting LS&BT.

The Third Science and Technology Basic Plan, decided by the Cabinet in March 2006, calls for the enhancement of liquidity of human resources, as part of the reform for science and technology. The Plan also proposes the construction of a sustainable and developable coordination system among the government, academic and business sectors. Both ideas are being deliberated under the initiative of the Council for Science and Technology Policy to realize specific measures to carry out each of them

- (2) With regard to the promotion of public understanding, emphasis is put on the concept of “science technology that is supported by the society and public” in the Third Science and Technology Basic Plan. Likewise, the promotion of public understanding for achievements of life science R&D is regarded as one of the promotion measures in the Promotion Strategy of the GOJ for Life Sciences. Furthermore, specifically concerning life ethics in terms of human cloning technology and other relevant issues, the reinforcement of an inter-office/ministerial coordination is being sought under the initiative of the Research Committee on Life Ethics within the Council for Science and Technology Policy.

(3)

- ① The GOJ has decided to invest intensively and continuously into the life science field through 2011, as one of the four key fields pursuant to the Third Science and Technology Basic Plan.
- ② The Third Science and Technology Basic Plan indicates that in order to overcome various issues faced by the modern society including those in the LS&BT fields, human science and social science play significant roles. The Plan thus notes clearly that the GOJ will engage in comprehensive actions in combination of these two science fields.

Future outlook

The whole government is committed to promoting measures to develop the LS&BT fields, with steady follow-up being made regarding the Third Science and Technology

Basic Plan and the Promotion Strategy of the GOJ for Life Sciences, under the initiative of the Council for Science and Technology Policy.

Specifically, the category “Translational and Clinical Research” is identified as one of the key categories of strategic science technologies into which the government should invest intensively. The government further identifies “Translational and Clinical Research” as an “Inter-Ministry Coordination Program,” which the government plans to progress actively as a comprehensive program across Ministries, combined with the viewpoint of the coordination among the industry, academic and government sectors.

In FY2007, the GOJ intends to appropriate about 300-billion yen as the budget for life science, which accounts for almost 10 percent of the entire science and technology budget.

32. LS&BT for Health

BDRT recommendations

- (1) Ensure the communication mechanisms between industry and government regarding the pricing system of medicines in order to address the barrier to innovation. Consistency between industry promotion measures and pricing policy is the key to the increased competitiveness of the healthcare industry.
 - ① Establish in Japan an official committee for dialogue between government and industry in order to discuss consistent promotion measures for the industry.
 - ② Enhance dialogues to realize “pricing systems reflecting innovation of medicines” which is believed to be essential for medical advancements.
- (2) Enhance funding to clinical research and facilitate development of infrastructures for clinical trials/research. The government should make clinical research a priority area for funding in research programmes. Intensive support to translational research is also important for practical application of basic findings.
- (3) Continue to facilitate regulatory harmonization with respect to increasing demand for simultaneous global development of medicines. International common rules on the handling of clinical data should be applied, especially on the handling of adverse event data. Regarding the approval review of biosimilars, authorities must be careful to ensure patient safety as the first priority. The Japanese government should encourage PMDA to strengthen its capabilities in terms of both quality and quantity.

State of the measures taken thus far

(1) ① The Ministry of Health, Labour and Welfare believes it is important to have opportunities for dialogue with industrial circles, and therefore constantly listens openly to opinions of relevant companies regardless of their nationality. The Ministry established a Working Group (WG) to Create Visions for New Pharmaceutical Industry in 2006. The WG has so far held three sessions with industry to listen to its opinions and exchange information on themes related to the pharmaceutical industry such as R&D, the pharmaceutical system, and the drug pricing system.

The Ministry has also decided that its Minister will host dialogue among the industry, academic, and government sectors combined with inter-office/ministry accessibility. The dialogue is aimed at sharing recognition among the leaders of the three sectors concerning the directions of various measures associated with the enhancement of innovation in Japan’s pharmaceutical segment and strengthening the

industry's international competitiveness. The first session of such dialogue was held on January 31, 2007.

In promoting the dialogue, the Ministry asks representatives of EFPIA (European Federation of Pharmaceutical Industry and Association) Japan to take part, in order to secure opportunities for them to present their views.

② While the research and development (R&D) of new medicines requires tremendous amounts of time and financial resources, it is not necessarily the case that the success rate for the R&D will be particularly high. It is, therefore, essential that future R&D resources be secured to ensure that people will be able to receive the benefits of new drugs in the future.

A new measure has come into effect based on the Amendment of the Drug Pricing System in FY2006 compiled by the Central Social Insurance Medical Council that convened on December 16, 2005: MHLW began to officially provide those pharmaceutical pricing applicants who seek an adjustment premium with opportunities to directly express their views at Drug Pricing Organization (DPO) meetings before the reimbursement prices of pharmaceuticals are decided by the DPO.

(2) Based on the Three Year Plan for National Clinical Trial Vitalization which was jointly formulated by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare in 2003, efforts have continuously been made to enhance the infrastructure and environment for clinical trials. Specifically, in addition to engaging in educational activities for raising awareness of the significance of clinical trials among the people, as a measure to develop the infrastructure and improve the environment for clinical trials in medical institutions, the GOJ is making efforts to enhance the implementation system for clinical trials, advancing the cultivation of clinical trial coordinators, who are to provide on-site support, etc., for doctors and other personnel giving treatment.

In order to promote clinical research as a whole, including clinical trials, the GOJ has been implementing Clinical Research Infrastructure Promotion Programs since FY2006, which aim to nurture human resources such as young doctors who will be responsible for clinical research in the future and also biostatisticians through Health and Labour Science Research Grants. In addition, an Ad hoc Expert Committee for Formulating Plans to Vitalize New Clinical Trials was established in June 2005. The Committee has been deliberating on issues such as securing a system to promote clinical trials; human resource development; enhancement of efficiency; and awareness raising campaigns. Furthermore the Committee is now preparing a New Five-Year Plan for National Clinical Trial Vitalization.

In the FY2007 Guidelines on Budgetary/Personnel Resources Allocation in Science and Technology, the Council for Science and Technology Policy highlights the prioritisation of studies bridging basic research and clinical cases, as well as clinical research including clinical trials as measures that the government should promote.

The report of the Council for Science and Technology Policy, which forms the basis for the Third Science and Technology Basic Plan, states as one of its basic stances to “promote science and technology to be supported by the public and to benefit society.” Under the Basic Plan, the Council for Science and Technology Policy formulated a promotion strategy of the GOJ for life sciences in March 2006. The strategy encompasses measures to promote clinical studies and studies bridging to clinical cases.

(3) Since the establishment of the International Conference on Harmonisation (ICH), the Ministry of Health, Labour and Welfare has been promoting harmonisation of pharmaceutical regulations related to new drug products among Japan, the EU, and the United States through the activities of the ICH. The ministry compiles with the ICH guidelines concerning the treatment of clinical data, such as those on side effects.

Regarding the approval review of biosimilars, the Ministry carries out procedures from the perspectives of safety, effectiveness and product quality. In order to strengthen the review system, the Ministry is seeking to increase the number of inspectors at PMDA. The Ministry also seeks to enhance the competency of inspectors through stricter progress management of review tasks, etc., and by making use of external training opportunities.

Future outlook

- (1) ① The GOJ intends to actively promote exchanges of opinions.
② The GOJ will continue to ensure adequate operation of the system and also engage in the operation in accordance with the Amendment of the Drug Pricing System in FY2006.
- (2) Through efforts within such frameworks as the Ad-hoc Expert Committee for Clinical Trials, the GOJ will continue to work to develop the clinical trials environment in Japan and provide translational research (TR) with intensive support
- (3) The GOJ will continue to actively address the relevant issues.

33. LS&BT for Industrial/Environmental Uses

BDRT recommendations

- (1) Provide more incentives to enable industries to switch to more sustainable production processes utilizing biotechnologies.
 - ① Consider tax abatements and investment tax credits as incentives and speed up the implementation of sustainable production technologies.
 - ② Provide financial support to improve infrastructures for the utilization of biomass and production of bioethanol fuels.
- (2) Some progress has been made in Japan to promote such biotechnology demonstration projects as biorefinery, bioethanol and bioplastics. Encourage these activities and provide further support to promote the commercialisation of these projects.

State of the measures taken thus far

- (1) The Ministry of Economy, Trade and Industry (METI) and New Energy and Industrial Technology Development Organization (NEDO) are implementing research and development programs (Green Biotechnology Program) aimed at creating a cyclical industrial system in harmony with the environment. These programs, by promoting the use of biotechnology in the industrial process and environment-related areas, aid the establishment of an advanced manufacturing society that utilises bioprocesses, and advance biodegradation and disposal technologies for waste and pollutants, etc.

For all aspects of the tax reform, see the attached appendix.

- (2) As one project within the Green Biotechnology Program described in (1) above, METI and NEDO are implementing the development of biorefinery technologies, such as production technology for useful, biomass-derived materials utilising bioprocesses.

Future outlook

- (1) The Green Biotechnology Program aims, by the end of FY2010, to build a technological foundation that can contribute to establishing a cyclical industrial system and apply it to practical uses, under which useful substances are produced through bioprocesses and waste and pollutants are either disposed of or converted to renewable resources by microorganisms, while ensuring safety and preserving

ecosystems.

- (2) The program described in (1) above aims to construct a bioprocessing system (biorefinery technology) whereby by FY2010 it will be possible to convert biomass to sugar with a high level of efficiency, from which the building block chemicals for a variety of commodity chemicals can be produced with a high level of efficiency.

34. LS&BT for Plants

BDRT recommendations

Further implement and enforce existing regulatory frameworks of EU and Japanese central government on GMO crops.

- ① We urge the Japanese central government to take effective actions to discourage local governments from delaying and/or restricting by local laws and/or guidelines the cultivation and use of the GMO crops that are approved by the central government for cultivation and use in Japan based on safety evaluation.
- ② We would like the Japanese government to organize nationwide discussion of the importance of GMO crops in sustainable growth of the economy in the near future, and to encourage every stakeholder to actively participate in the discussion.

State of the measures taken thus far

The Ministry of Agriculture, Forestry and Fisheries seeks to deepen understanding by providing easily comprehensible information and promoting dialogue with the public, based on “Towards the Promotion of Public Understanding on Biotechnology,” prepared by various liaison committees from the relevant ministries and agencies. Efforts to this end include the promotion of a Planning Conference for Biotechnology Communication made up of experts as part of an entrusted project for surveys on attitudes toward GMO crops, as well as a Local Community Communication Conference held at eight locations nationwide participated by consumers, both of which Conferences started in FY2006.

The Third Science and Technology Basic Plan, decided by the Cabinet in March 2006, indicates that in order to gain public understanding for GMO crops, it is necessary to disseminate among the people the right recognition for safety, as well as both sides of the risks and benefits, and a sense of reassurance regarding GMO technology. The Plan suggests that this goal should be attained by actions such as disclosing information on risk management and safety, decent explanations based on scientific evidence about benefits and safety.

Future outlook

The GOJ is further working in the dissemination of understanding by providing easily-comprehensive information and promoting dialogue with the public, based on the Third Science and Technology Basic Plan.

(Appendix)

Proposals relating to the Tax System

In the annual tax reform process, the contents of the reform were decided based on requests and opinions submitted to the tax authorities by related ministries and agencies, taking into account various factors including economic circumstances, the financial situation and discussions by the Government Tax Commission and the Tax Commission of the ruling parties. Related ministries and agencies refer to opinions from various levels, including proposals raised by the BDRT, when compiling their tax reform requests. These opinions have been reflected in past annual tax reforms.

Proposals relating to the tax system have been made for the following items in the recommendations from the 8th Japan-EU BDRT meeting.

- WP 1: Trade and Investment
- 2. The optimisation of returns on investment
- 4. Facilitating reorganisation from a legal and tax point of view
- 9. Modernising legal and tax systems to support foreign investment
- 22. CFC rules
- WP 2: Accounting and Taxation
- 24. Tax Issues
- WP 5: Biotechnology(LS/BT)
- 33. LS&BT for industrial/environmental uses

The GOJ will refer to these proposals when they seem appropriate, from the standpoint of improving the business environment.

Among the proposals raised by BDRT, with regard to the item 24.(4), GOJ was asked that, before taxes are assessed, it reaches a common understanding with the tax administration of the second jurisdiction in which an associated enterprise operates, in order for taxpayers in Japan to avoid the excessive burden of transfer price taxation. In light of this, the GOJ, in its FY2007 tax reform, intends to create a tax postponement system for transfer price taxation, applied during the relevant mutual consultation with any of the countries with which Japan maintains tax conventions.