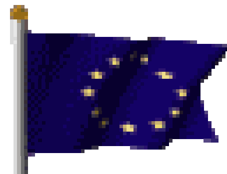
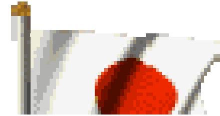
(Provisional Translation)

Japan's Proposals For Regulatory Reform Dialogue





December, 2008

(Final version).

Japan's Proposal
For Regulatory Reform Dialogue
— List of Proposals—

December 2008

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Introduction

[EC, M.S.]

(1) The value of the regulatory reform dialogue and the responsibility of Japan and the EU

The Japan-EU Regulatory Reform Dialogue marks its 15th year in FY2008, after its launch in 1994 as a framework for dialogue designed to enhance trade and investment relations between the two sides through the improvement of the business environment. Today, Japan and the EU account for about 40% of world gross domestic product (GDP), about 40% of global trade and about 50% of direct investment, and together constitute one of the cores of the world economy. As such, Japan and the EU are responsible for contributing to the development of the world economy and the creation of global-scale standards, through advancing their commitments to regulatory reform and further expanding two-way trade and investment.

At the Summit on Financial Markets and the World Economy on 14 and 15 November 2008, the G20 leaders shared the understanding that inconsistent and insufficiently coordinated macroeconomic policies and inadequate structural reforms were among the major underlying factors that led to unsustainable global macroeconomic outcomes. The leaders stressed the importance of continuing their commitment to an open global economy, while rejecting protectionism and not turning inward in times of financial uncertainty. As drivers of sustained growth of the world economy, Japan and the EU share the responsibility of contributing to the development of an open and competitive world economy by respectively promoting regulatory reforms.

Regulation in the EU which is adequate but not excessive for maintaining a competitive environment, and simple, consistent and transparent is a source for the growth in the Single Market which will certainly allow foreign as well as EU firms to flourish. It will also benefit the EU itself which can remain competitive through healthy rivalry with foreign investment, and hence will benefit the world economy as a whole. The GOJ is in full support of the EU in bringing forward these principles in its regulatory policy, and hopes for continued work in this area.

The EU commissioners will change in 2009. The GOJ appreciates the efforts of the current EU leaders, beginning with President Barroso, who has stood at the forefront of recent EU reforms. It wishes to see these results inherited seamlessly by the next president and commissioners inaugurated in November 2009 and strengthened further. The GOJ is paying careful attention to the revised Lisbon Strategy that aims to create the world's most competitive market by 2010, as well as "better regulation" as one of its specific measures. The GOJ sincerely hopes that the incumbent president and commissioners can achieve even further concrete reforms in the remainder of their terms until October 2009, beginning with the aforementioned areas.

(2) GOJ proposals based on the voice of Japanese businesses

For effective and efficient dialogue, the GOJ proposals for FY2008 have been drawn up, based on the results of an extensive and timely inquiry carried out in the autumn of 2008 on around 3,000 Japanese companies active in the EU, industry professionals with interest in EU regulatory trends, business organisations, and related government ministries and agencies. The GOJ requests that the EU will further advance reform efforts, paying careful attention to the opinions of the Japanese parties referred to in the proposals, and appropriately reflect these requests in current and future policies.

(3) Reform in modality of this dialogue

In view of effective and efficient dialogue, the GOJ proposal documents have been made after careful selection of the priority items to be requested of the EU. Accordingly, the GOJ requests that the EU address Japanese proposals appropriately both in its written replies and on the occasion of a meeting in Brussels. As for the general management of Brussels and Tokyo meetings hereafter, the GOJ emphasises the importance of in-depth and substantial discussions. From that perspective, the GOJ proposes that the EU and Japan set the order of priority to their respective proposal documents when holding High Level Meetings, Directors Meetings, and Expert Meetings

A. Cross-sectoral Issues

1. Investment Environment within the EU (Overview)

(1)Introduction [EC]

The GOJ supports the EU's initiatives in regulatory harmonisation in the process of deepening integration. While these commitments may include creative regulatory instruments, they should be based upon the principle of better regulations, through review of excessive or unnecessary regulations, reduction in regulatory costs and enhancement of legal predictability. The GOJ endorses those efforts as good instruments to facilitate economic activities of both internal and external corporations, thereby making the EU as a single market even more attractive and competitive.

In this connection, EU regulations should be (i) adequate to maintain competitive environment but least excessive, and (ii) simple, consistent and transparent. In our view, those two elements constitute essential sources for the dynamism of the EU as the single market and innovation, thereby contributing to secure benefits of EU economies as a whole including foreign businesses.

(2) General review of the regulatory environment within the EU [EC, M.S.]

In "The European Competitiveness Report 2007" issued by the European Commission in November of that year, an assessment of the microeconomic policies which serve as the pillars of the Lisbon Strategy was conducted. Announced in the report was the importance of reforms for improving the environment for research and innovation, which has a significant effect on the competitiveness of the EU, and promoting structural reform. It goes on to explain the necessity of improving economic efficiency in the form of harmonisation and promotion of competition at EU level, by strengthening free trade, and the single market in the service sector in particular, and enhancing further liberalisation in the networking industry and manufacturing market.

In the Economic Review of the European Union by the OECD in September 2007, it was shown that structural reform within the EU has led to results, in particular in countries which embarked on tackling reform early. However, it also points out the disparity within the EU in the achievement of growth and employment, and the difficulty in dealing with the challenges of technological innovation, globalisation and aging populations.

On that basis, the report (i) proposes, in addition to the full implementation of the Services Directive, the removal of barriers to the establishment of companies which transcend national borders, the abolition of vertical market division in the financial services, forceful implementation of better regulations and competition rules, and a reduction of government subsidies and allocation to effective areas, as forms of further market integration within the EU. (ii) It points out the necessity of further competition in the networking industry, and the areas of electric, gas, telecommunications, transportation, harbours and postal services in particular. Integration of the markets of each country is shown to be necessary, most notably for creating a pan-European energy market structure. (iii) Since it is vital to further increase the mobility of labour in order to raise productivity and promote innovation, it proposes the portability of social security services such as pensions, and the simplification of qualification approval. (iv) It proposes also, the effective distribution of regional policy funding into fields that invest in sustainable growth.

Regarding the barriers to foreign direct investment, the GOJ would like to point out that according to the "FDI Regulatory Restrictive Index" in the OECD's "Economic Policy Reform – Going for Growth 2007"(as referred to on the last page of this section), in February of that year, while the regulations in

countries such as the United Kingdom, Germany, Belgium, Ireland, Italy and the Netherlands, are weaker than those of Japan, the average figures for the EU's 19 Member States (OECD members), although lower than the OECD average, are higher than those of Japan and the United States. For that reason, while the GOJ praises the efforts of the EU countries as a whole to attract direct foreign investment, it hopes that further reforms are promoted, with a focus on those EU Member States that have not achieved the international standards of organisations such as the OECD.

Based on the aforementioned Competitiveness Report and OECD Report, the GOJ requests that the EU further advance its regulatory reforms based on the proposals pertaining to various sectors raised in this year's Japanese proposals, beginning with services (movement of people, commercial laws and practices, employment, financial services), harmonisation of standards (standards and certification, environmental regulations, taxation), and networking (ICT).

(3) Review of FY2007 RRD and the outlook for FY2008 RRD

In FY2007, regarding the internal investment environment as a whole, the GOJ made specific proposals on (i)the review of inward investment regulations in Germany, (ii) the consideration of common EU regulations on inward investment, and made a general comment on (iii) "Better Regulations." This fiscal year the GOJ will make assessments on (i) and (ii) as below, and make a concrete proposal relating to (iii).

(a) Regulations on incoming investment by Germany [Germany]
Last fiscal year regarding this issue, Germany responded that a transparent and fair verification process regarding the investigation into foreign investment is ensured through amendment to the Foreign Trade and Payments Act (AWG) and Foreign Trade Regulation (AWV), because such processes are in line with the essential verification criteria as laid down by the EU Treaty and as interpreted in European Court of Justice case law, that is to say the public order and security. After the law and regulation received Cabinet approval on 20 August 2008, the German Federal Ministry of Economics and Technology made an announcement to the effect that Germany would continue to be open to direct investment from abroad and that setting conditions for business acquisition or refusal would be restricted to exceptional circumstances from the standpoint of public order and safety.

The GOJ supports such general policy direction by the German government. Meanwhile, it will continue to bear in mind the fact that the target of this regulation is limited to circumstances involving acquisition of 25% or more of the voting rights of a company. Nevertheless, it is interested in the element that the regulation is applied to investment from outside the EU and EFTA, from the standpoint of ensuring non-discriminatory treatment between inside and outside the EU. The GOJ will thus pay close attention to the application of this regulation in the future, from the perspective of its call for the guarantee of maximum transparency and fairness from the German government, in the investigation process for cases of individual inward investment.

(b) Consideration of a common EU regulation on inward investment [EC]
In FY2007 regarding this issue, the EU replied that any legislative proposal on corporate takeovers by investing entities owned by foreign governments was not being considered by the European Commission. However, it also stated that discussion regarding sovereign wealth funds (SWFs) was in progress and that the establishment of common EU guidelines for governance and transparency in particular was being aimed for.

The GOJ requests that discussions at the OECD and IMF are appropriately reflected in the EU's

establishment of SWF guidelines, and that opportunities for the opinions of stakeholders, including ones of concerned governmental and private parties from Japan, are granted appropriately. As discussed in the G7 and IMF, it is important for SWFs to increase their transparency and demonstrate sound management. At the same time, the GOJ views that it is important for countries which receive investment from SWFs, Japan and the EU included, to establish best practices on investment policy through discussions in organisations such as the OECD and thereby create international standards to ensure progress in opening investment. Therefore, the GOJ would like to continue cooperation with the EU in this area.

(4) FY2008 proposal: Accelerated implementation of "Better Regulations" [EC, M.S.]
In FY2007 regarding this issue, the EU responded that the highest priority is given for improving and simplifying the regulatory environment in the EU as it is an important tool to realise the full potential of the internal market and to promote growth and employment. The GOJ considers that while the regulations in the EU need to be sufficient to maintain the competitive environment, they should not be excessive, and they need to be simple, consistent and transparent, in order to be the source of the EU's vitality as a single market. As such, such regulations are of benefit to both foreign companies and those of the EU. The GOJ continues to support the EU in adopting regulatory policies based on the aforementioned principles.

The GOJ appreciates the sound implementation of policies for better regulations. It welcomes the fact that according to the communication pertaining to the Second Strategic Review of Better Regulation in the European Union (COM(2008) 32 final), the simplification of regulations in the fields of agriculture, packaging, pharmaceuticals, automobiles, settlement and insurance has been advanced through simplification of existing legislation. The GOJ also heeds the fact that there has been forward-looking development in the area of company law, regarding the reduction of administrative expenses through the swift transposition of EU directives into domestic law.

On the other hand, in order to achieve the ambitious target set in January 2007, namely a 25% reduction of administrative costs for business across the whole EU by 2012, it is necessary from here on for the EU to further accelerate the implementation of policies for better regulations. As such, the aforementioned communication presents the following problems which exist as of January 2008.

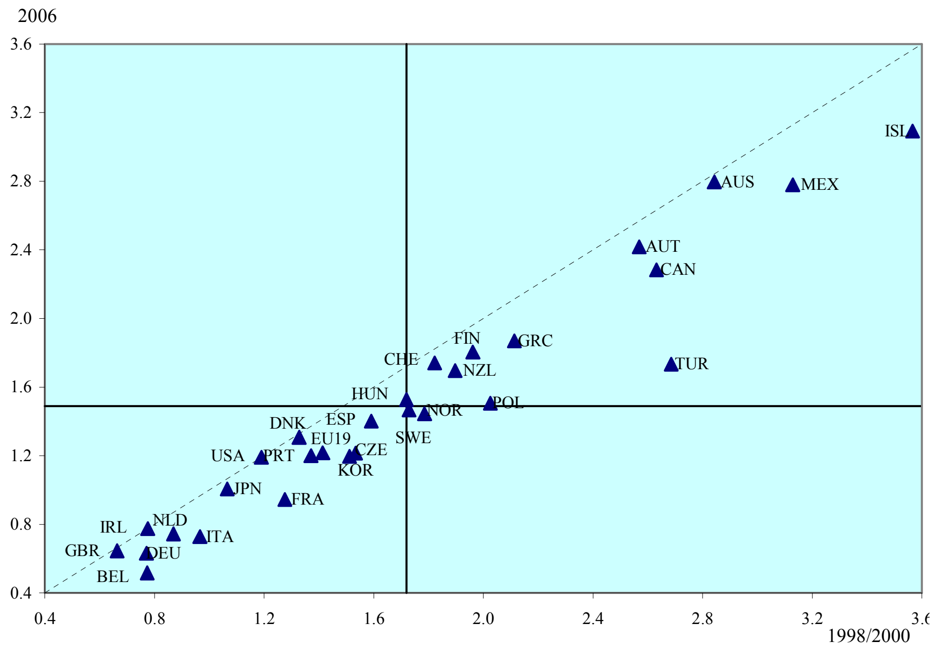
(i) Of the 400 measures that should have been adopted between 2005 and 2009 in the "Simplification Rolling Programme" a mere 16 have received European Council and European Parliament approvals (p8).
(ii) Only 12 countries have submitted national targets relating to the reduction of administrative expenses, in accordance with the March 2007 Action Programme (COM (2007)23) (p4).
(iii) In general, the Regulatory Impact Assessment is functioning, but there are cases where the evaluation start time is delayed, or where there is a lack of clarity in the priority criteria for deciding in which area evaluation will take place. As for these cases, improvement is also necessary. (p5, p6).

<u>Therefore, the GOJ requests that the European Commission reports on the recent situation regarding efforts relating to the abovementioned points, while at the same time it requests that the Commission strives for further acceleration of efforts for better regulations, by working to coordinate with Member States in the European Council and European Parliament. In addition, while the GOJ is paying due attention to the relation in terms of competence between the European Commission and the Member States, it requests forward-looking cooperation in implementation of the Simplification Rolling Programme in the European Council, in order to show political commitment to accomplishing better</u>

regulations, which serve as the main pillars in the revised Lisbon Strategy. Meanwhile, in the event that national targets relating to the reduction of administrative expenses have not yet been submitted, the GOJ asks relevant Member States to make a contribution to the Commission policies, through taking swift action.

Figure A.14. **Barriers to foreign direct investment**[1]

Indicator scale of 0-10 from least to most restrictive



1. Please note that the index is still under discussion by the Working Party No.1 of the Economic Policy Committee and the Investment Committee Working Party.

Source: Koyama, T. and S. S. Golub (2006), "OECD's FDI regulatory restrictiveness index: revision and extension to more economies", *OECD Economics Department Working Papers*, No. 525.

2. Investment Environment within the EU (Commercial Laws and Business Practice)

(1) Integrated EU policy for commercial laws and business practices (including Statute for a European Company) [EC, M.S. (in particular France, holding the EU Presidency)

The harmonisation and integration of the commercial laws and business practices in the EU will greatly benefit not only the EU companies but also third country corporations that operate in the EU, including Japanese ones. The GOJ appreciates that under the initiative of France, which currently holds the presidency of the EU Council, the European Commission recognises the central role of small and medium-sized enterprises in the EU and advances the establishment of the Small Business Act for Europe as the first comprehensive framework in the EU. We understand that the Act was adopted in the Commission on June 25, 2008 and is now under review at the European Council and the European Parliament. We expect that the EU will further demonstrate political initiative toward the enactment of the Small Business Act for Europe by the end of 2008.

As part of the package of the initiatives mentioned above, the GOJ supports the efforts of the EU, particularly those concerning the Statute for a European Private Company, on which Japan in the past has consistently made requests to the EU and expressed its opinions in the course of public consultations. Now the EU is working to adopt the Statute by the end of December 2008 and implement it by July 2010. The GOJ would like to evaluate this case as a good example in which Japan and the EU worked together based on the shared recognition of the needs of the industrial sectors.

The GOJ further hopes that the EU will complete the adoption and approval procedures of the Statue at the European Council and the European Parliament; that each Member State will complete the designated domestic procedures under the EC's initiative during the transition time frame through July 1, 2010; that the EC monitors periodically and assumes responsibilities in order to ensure harmonisation of the operation and interpretation among Member States; and that the EC shares the results of the monitoring transparently with related countries including Japan.

On the other hand, the business community of Japan points out discrepancies that it claims still exist among the EU Member States. They include varied commercial practices concerning the costs for the cancellation of an agent contract and incorporation procedures. The business community sees these differences as additional burdens on Japanese companies developing business activities within the EU. In light of this, the GOJ continuously requests that the EC will take further initiatives for the harmonisation and integration of commercial practices within its internal markets.

In addition, concerning the cross-border offset of profits and losses, about which the GOJ has made requests in the area of commercial laws and business practices, the GOJ will this time make requests separately in the area of taxation, for the convenience of the EU, as it categorized this in the area of taxation in its written response.

(2) Directive on cross-border mergers [EC, related M.S.]

In its FY2007 proposal, the GOJ requested steady progress in the establishment of the Directive on cross-border mergers as domestic law in Member States (deadline December 15, 2007), as this directive, which was adopted by the European Council in October 2005 and entered into force in December of the same year, will make cross-border mergers easier for limited liability companies.

In response, the EU provided notification that at the Brussels Meeting of October 15, 2008, 24 of its Member States reported that they have already implemented the Directive, while the remaining three Member States reported that smooth progress was underway toward its establishment as domestic law. The GOJ appreciates these moves. Moreover, according to the Press Releases (IP/08/872) dated June 5, 2008 on the European Commission website, the EU said it was considering legal actions against those 11 Member States (Belgium, Greece, Spain, France, Italy, Lithuania, Latvia, the Netherlands, Portugal, Sweden, and Slovenia) which by that time had not implemented the directive in question. The GOJ recognises the strong initiative demonstrated by the European Commission.

The GOJ furthermore requests: that those Member States which have not made the Directive their domestic law promptly complete the necessary procedure; that the EC monitors on a regular basis that the Directive is operated in a unified manner among its Member States; and that the EC discloses the monitoring results in a proper manner to related parties including Japan.

3. Investment Environment within the EU (Movement of People)

(1) Work and residence permits

(a) Overview [EC, M.S.]

In the comprehensive immigration policy tackled by the EU as a priority issue, the GOJ notes the point that the EU is advancing the policy to promote the integration of legal immigrants from the viewpoint of having immigrants as a driving force for development. The intra-corporate transferees (ICTs) of Japanese companies operating in the EU represent resources to promote investment and employment in the EU. On these grounds, the GOJ reiterates that ICTs should be clearly distinguished from the group of people the EU defines as economic migrants. As part of its policies on legal immigration, the EU should ease the complicated and time-consuming procedures for ICTs to move into and within the EU. The EU should further take active measures to facilitate such movements. In this connection, the EU should strive toward the realisation of the common visa policy presented in the communication on the common immigration policy, which the European Commission announced in June 2008. The GOJ appreciates that the communication identifies the need for the EU and its Member States to strive for a common visa policy that allows flexible responses to movements of ICTs.

Improving procedures for obtaining work and residence permits continues to be the most prominent issue of concern in the movement of people for the management of Japanese companies in Europe, their employees, and the employees' families. The GOJ also attaches great importance to this area from the viewpoint of improving the infrastructure of the investment environment. In particular, prominent measures are necessary for those ICTs who are unable to establish their living base in the places to which they are posted and who are unable to bring their families with them, both of which cases represent grave issues from a humanitarian viewpoint.

With regard to the Policy Plan on Legal Migration, the GOJ appreciates that the European Commission gave consideration to the GOJ's opinions presented in various ways such as the comments about the Green Paper on an EU Approach to Managing Economic Migration (April 2005). The GOJ also appreciates that those Member States on which the GOJ called for further improvements have been striving to make such improvements with their respective authorities holding consultations with the Japanese embassies in their countries. Among the countries on which the GOJ called for improvements in their jurisdictions in FY2007, Portugal has enacted a new law for foreigners, which designates certain periods for deciding on issuance of permits. In addition, Portugal has exempted part of the obligation to post recruiting advertisements targeting EU citizens as part of the procedures. The country has also abolished the requirement to submit a health certificate. Romania has simplified the procedures to acquire permits. The United Kingdom has significantly relaxed the level of the English Language requirement in Tier 2 of the country's new immigration rules. The UK has also decided to exempt ICTs from the English Language requirement for the first three years of their stay in the UK so as to prevent the new rules from imposing an excessive burden on them. The GOJ appreciates the forward-looking measures taken by these countries.

The GOJ sees some more points to be further improved by Portugal and Romania and the UK, Member States mentioned above, as well as by Greece, Ireland, Spain, and France, Member States identified by the GOJ in FY2007 as amongst those that the GOJ appreciated for the improvements of their systems though continued to observe their operation of the systems. The GOJ will make no specific request exclusive to each of those Member States in the FY2008 Dialogue, on the grounds that those countries have improved their systems and for the purpose of narrowing down the number of Member States to which priority requests are made. On the other hand, as for Hungary, which was also among the

Member States that the GOJ appreciated in FY2007 for the improvements to their systems though continued to observe their operation of the systems, the GOJ will make an individual request to the country because the GOJ wishes to ask the country to seek improvements in a new area.

Based on the above matters, the GOJ sets forth the issues of priority in FY2008 RRD as follows: As for (d) below that refers to specific requests for individual Member States, the requests focus exclusively on those countries that have yet to show improvements and those the GOJ asks for new improvements. In this regard, the GOJ requests that these countries provide specific answers to its proposals for improvements and that they make utmost efforts to send their government representatives to the FY2008 RRD Meeting in Brussels.

(b) Policy Plan on Legal Migration [EC]

Under the Policy Plan on Legal Migration published in 2005, the European Commission is to submit a draft directive on procedures regulating the entry into, temporary stay and residence of ICTs (hereinafter: the "draft directive") in 2009. In this connection, the GOJ appreciates being given an opportunity to present its opinions by means of answering a questionnaire on the occasion of the Impact Assessment on Community Instruments on ICT in March 2008. The end of this section covers main points of the opinions the GOJ presented in April 2008. The GOJ hopes to have these opinions reflected in the draft directive.

During the RRD High Level Meeting in October 2008, the EU side explained the draft directive is scheduled to be submitted in or around March 2009, after a delay in the initial schedule of submitting it in the autumn of 2008. Moreover, with regard to the draft directive, the EU side explained that to ease the burdens imposed on ICTs, the EU was planning rules including that work permit and residence permit should be united into one permit and that issuance of permits should be made within 30 days in principle and within 90 days for exceptional cases. Consideration for ICTs' families would also be in place, such as enabling family members to work.

The GOJ welcomes the prospect that forward-looking factors will likely be incorporated in the draft directive. The GOJ at the same time requests that the exceptional longer period for the issuance be implemented in limited cases. The GOJ has also been requesting that through the adoption of the draft directive, the application process will be unified across all Member States. In this regard we would like to know whether or not exemption or relaxation will be applied to the procedure of acquiring the permit a second time in cases in which an ICT who has acquired the permit in one Member State is then posted to another office of the same organization that is located in another Member State. The GOJ continues to request that the European Commission ensures an early submission of the draft directive; further opportunities to present opinions on the draft directive; and provision of information at suitable times.

【Overview of the opinions presented by the GOJ in April 2008 about the Impact Assessment on Community Instruments on ICTs】

- ICTs of Japanese companies operating in the EU should be clearly distinguished from the group of people defined by the EU as economic migrants;
- Issuance procedures for work/residence permits and visas should be accelerated and simplified;
- Renewal procedures for work/residence permits should be accelerated and renewal frequency should be reduced;
- The initial term of validity for work/residence permits should be at least three years;

- All Member States should allow both ICTs and their families to apply for residence permits at the same time;
- ICTs should be exempted from the rules of the labor market test (the need to post recruitment ads targeting EU citizens);
- Imposing language proficiency requirements on ICTs applying for residence permits should be avoided; and
- Situations in which different regions and application desks demand different application papers and procedures should be avoided.

(c) Preservation of the agreements/arrangements on mutual visa exemption between Japan and the states to which the Schengen Agreement applies [EC]

In the Directors' Meeting (March 2008) and the High Level Meeting (October 2008) of the Japan-EU Regulatory Reform Dialogue FY2007, the EU side said that the bilateral agreements/arrangements on mutual visa exemption between Japan and the states to which the Schengen Agreement applies remain valid, while they must conform with the Lisbon Treaty. In addition, in written response to the Japan's Proposals For Regulatory Reform Dialogue dated December 18, 2007, the Commission said that the problem of the conformity of the bilateral agreements/arrangements on mutual visa exemption could disappear as no specific – 3-month – limitation of the duration of the short stay would be provided pursuant to the regulation concerning travel of third country nationals within the Schengen area under Article 77, paragraph 2 of the Lisbon Treaty.

The GOJ pays great attention to this response. The GOJ thus requests that in light of the importance of human exchanges between Japanese and European citizens, conformity will be ensured between specific measures to be formulated under Article 77, paragraph 2 of the Lisbon Treaty and the agreements/arrangements on mutual visa exemption. The GOJ also requests that the Commission spares ample time to offer sufficient information to third countries including Japan, during its course of deciding on specific measures pursuant to Article 77, paragraph 2 of the Lisbon Treaty. The GOJ also requests that the Commission provides related countries with opportunities to express their opinions and seeks to reflect these opinions in its specific measures. In this connection, the GOJ asks for replies as to: how the Commission will decide on specific measures pursuant to Article 77, paragraph 2 of the Treaty; and how the Commission will receive opinions from third countries including Japan and reflect them in the process. Furthermore, the GOJ asks the Commission to clearly specify in its written response that in the current situation before the Lisbon Treaty comes into effect, the agreements/arrangements on bilateral mutual visa exemption prevail.

(d) Specific proposals to respective Member States on work and residence permits [M.S. set forth below]

In view of the progress since the FY2007 Dialogue, the GOJ has classified a number of Member States into three categories listed below: countries in need of prompt improvement; countries in need of prompt improvement due to new, unsolved problems; and countries facing new areas of improvement even though their institutional improvement has been appreciated.

Countries in need of prompt improvement	Czech Republic, Italy, Poland, Slovakia
Countries in need of prompt improvement due to new, unsolved problems	Belgium, Slovenia

Countries facing new areas of improvement even though their institutional improvement has been appreciated	Hungary

(i) Countries in need of prompt improvement (acceleration and simplification of work and residence permit procedures)【Czech Republic, Italy, Poland and Slovakia】

Japanese companies operating in these countries call in unison for improvements of the procedures, or more specifically, acceleration of the issuance of permits; simplification of documents to be submitted; and unification of the handling modality at the application counters. <u>The GOJ asks each of the governments for their utmost efforts for improvements.</u>

In the case of Italy, there have been fewer cases in which the issuance of work permit and visas requires an excessively long time. The GOJ appreciates efforts by relevant authorities. At the same time, however, there are many cases in which issuance of residence permits requires six months to one year, causing trouble for applicants' daily living. Government authorities are asked for immediate measures, including reviews of procedures, for the further acceleration of the issuance of work and residence permits. As for Italy, which gave no written answers in FY2007, the GOJ asks it for particularly clear answers this time around.

As for the Czech Republic and Poland, Japanese companies operating in these countries voice in common that issuance of work and residence permits has taken a longer period since the two countries joined the Schengen area in December 2007. These companies also ask the two countries to extend the initial term of validity of permits, which is currently one year. In the Czech Republic, the issuance of long-term visas, in many cases, takes the legally maximum duration of 120 days. The country is strongly asked to speed up the issuance, and efforts should include the cutback of the legally maximum duration. Moreover, in its written response for FY2007, the country said, “there is a bill under discussion in the Parliament, according to which the excerpt of criminal register will not be required to present anymore.” Now the country is asked to report the results of this discussion. Poland is asked to exempt the one-month obligation to post recruitment advertisements for EU citizens, which is imposed upon the application of work permits for ICTs.

As for Slovakia, its written responses for FY2007 were limited to explaining about its existing systems. The country is asked to present specific responses to the GOJ's requests for improvements.

(ii) LIMOSA system and work and residence permits in Belgium【Belgium】

With the introduction of the LIMOSA system in April 2007, persons going from Japan to Belgium on business for a period of five days or longer (21 days or longer when the persons attend meetings in closed circles in Belgium) are now required to declare their activities in Belgium to the authorities in advance. As this poses an added burden for Japanese companies with business interests in Belgium, the GOJ urges the Government of Belgium to extend the period of exemption of LIMOSA to 90 days to coincide with the period of exemption for business visas between Japan and Belgium.

In its responses for FY2007, the Government of Belgium explained that it was reviewing the registration system. Officials of the Government also explained about the system at the seminar for Japanese companies held by the Japanese Embassy in Belgium in April 2008. The GOJ saw these

efforts as sincere responses by the Government of Belgium. However, as no specific progress has been seen thus far, the GOJ renews its request to extend the period of exemption of LIMOSA to 90 days. The GOJ also asks the Government of Belgium to disclose information about the current status of the review undertaken by the Belgian government authorities. Thirdly, the GOJ once again asks for Belgium's response to the GOJ's request to which Belgium did not respond in FY2007: to simplify documents required for submission, related to health certificates and police certificates.

As Europe's base, housing the EU headquarters, Belgium is chosen by many Japanese companies as a place in which to locate their general control offices for operations in Europe. In light of this, the GOJ asks for prompt responses to its requests mentioned above from the Belgian side, for the purpose of promoting smooth economic exchange, not only between Japan and Belgium, but also between Japan and the EU as a whole.

(iii) Residence permits for families of business workers in Slovenia【Slovenia】

In Slovenia, according to provisions of Article 36 of the Aliens Act, which was amended in October 2006 following EC directive 2003/86/EC, resident employees of foreign companies from non-EU countries cannot apply for residence permits for their families unless they have been resident in the country for at least one year. Many Japanese companies conducting business in Slovenia have expressed strong dissatisfaction regarding this regulation. The GOJ appreciates the efforts by the Slovenian government authorities to improve this issue by using an escape clause that applies when "the interest of the Republic of Slovenia" is identified. On the other hand, no improvement has been made to the situation that forces ICTs to wait for several months after they are posted to Slovenia until their families can join them in the country. The GOJ strongly requests that Slovenia takes improvement measures including legal amendments to allow ICTs and their families to simultaneously apply for their stay permits, given the humanitarian basis and taking the perspectives of enhancing the investment environment.

In its FY2007 responses, the Slovenian side said that the GOJ's position that the EU directive does not apply to ICTs should not be understood as a basis to give to ICTs more rights than other third-country nationals. However it is not the GOJ's position that the EU directive 2003/86/EC does not apply to ICTs; it is a view of the European Commission that it expressed in its written responses of FY2006. Furthermore, the GOJ is not urging more rights to be given to ICTs than other third-country nationals; rather, the GOJ is requesting that a distinction be drawn between ICTs and economic migrants. The GOJ believes that this request is understood by the European Commission. The GOJ would like to point out once again that Article 36 of Slovenia's Aliens Act contradicts the position of the European Commission and that this Article risks posing unfair discrimination against third-country nationals. The GOJ thus requests clear explanation on these points from the Slovenian side.

(iv) Work permit in Hungary【Hungary】

As stated in its proposals for FY2007, the GOJ appreciates efforts by the Hungarian government authorities for extending the initial term of validity of work permits to two years. On the other hand, the GOJ has received improvement requests from Japanese companies operating in Hungary on the point that a work permit is demanded for the heads of branch and representative offices of non-EU companies, while it is exempted for the heads and executives of local judicial persons of non-EU companies. The GOJ thus requests, from the perspective of further enhancing the investment environment, that Hungary abolishes the work permit requirement for the heads of branch and representative offices of non-EU companies, given that these people do represent their companies in Hungary.

(2) Driving licenses

(a) Overview [EC, M.S.]
The EU requires through the Directive on Driving Licenses (91/439/EEC, 2006/126/EC) that Japanese nationals living in the EU Member States surrender their Japanese driving licenses when exchanging them for driving licenses issued by EU Member States. If Japanese nationals temporarily return home to Japan having surrendered their Japanese driving licenses, they cannot drive in Japan, which hampers their smooth economic and social activities.

The European Commission made a proposal in February 2004 that when any Member State issues driving licenses to Japanese nationals in exchange for the surrender of their Japanese driving licenses, the authorities of the EU Member State concerned will then return the surrendered licenses to the Japanese Embassy in that State. The GOJ accepted this proposal and the return of driving licenses has taken place in many countries. The GOJ appreciates the ongoing contribution of the relevant Member States and the European Commission in this matter.

The GOJ is paying attention to Slovakia's move for realizing an exchange of Japanese driving licenses not through bilateral agreements, but through amendment of its domestic law. The GOJ expects the early realization of an exchange.

In its FY2007 Proposals, the GOJ requested that Japanese licenses in Belgium and Spain be returned to the Japanese Embassy. A positive answer was received from Spain. However, no response was made by Belgium. For FY2008, the GOJ requests that the European Commission relay the following requests to Belgium and Spain.

(b) Belgium [Belgium]
The GOJ requests that Japanese driving licenses be promptly returned to their owners or at the very least to the Japanese Embassy. It was disappointing for Japan not to receive any form of response from Belgium in FY2007. Belgium hosts numerous EU-based Japanese companies. From the viewpoint of improving the investment environment, Japan requests that this issue be addressed in a sincere manner and that a clear response be provided in FY2008.

(c) Spain [Spain]
In FY2007, Spain provided Japan with a positive response to the effect that the Spanish Traffic Authorities would send the driving licenses to the Japanese Embassy if it is the wish of Japan. Japan recognises and appreciates this response. In order to see that the driving licenses are promptly returned, the GOJ requests that Spanish Traffic Authorities continue to offer their active cooperation in discussions progressed by the Japanese Embassy in Spain.

(3) Tourism
(a) Overview [EC]
In the Action Plan for Japan-EU Cooperation agreed in 2001, Japan and the EU stated their commitment to the promotion of human and cultural exchanges as an objective. Tourism is the most accessible means of exchange for people in general.

From that perspective, it is favorable for both the EU and the GOJ that around two million Japanese

visit Europe every year and eliminating unreasonable impediments in tourism is in the interests of both sides.

(b) Nationality requirement for tour guide license and obligation to engage an accompanying local guide in Spain [Spain]

Tour guides operating in Spain are required to hold nationalities of EU countries (including Spain), the EEA countries, or signatory countries of a reciprocity agreement in this field. Japan has repeatedly urged the abolition of the above nationality requirement on the grounds that it compelled Japanese tour companies to hire local guides who usually do not speak Japanese and consequently placed an unnecessary burden on those tour companies.

As a result, Spain responded by abolishing the nationality requirement in the city of Madrid. However, there are many attractive places in Spain other than Madrid, and many of the over 200,000 Japanese visitors to Spain visit areas other than Madrid. The nationality requirement prevents capable Japanese from becoming guides in all areas of Spain excluding Madrid without just reason. A great number of Japanese are required to pay unnecessary costs, particularly in the following areas.

Andalucia: Seville, Cordoba, Granada, Malaga, Mijas, Ronda

In addition, in some regions in Spain, at present, a local tour guide is required to accompany tourists, even, in extreme cases, when tourists wish to take a stroll in the town. The GOJ views that the imposition of this obligation to engage an accompanying local guide is an excessive restriction on tourists. Furthermore, in view of the fact that most of the local guides do not understand any Japanese, this regulation is simply an inconvenience placed on a large number of Japanese tourists. This problem is especially serious in the following areas.

Andalucia: Seville, Cordoba, Granada, Malaga, Mijas, Ronda

With the understanding that the above issues are problems which pertain to local government authorities, Japan urges the Government of Spain to continue to make an appeal to local government authorities to refrain from unnecessarily restricting the employment opportunities of capable Japanese tour guides and at the same time to refrain from imposing an unnecessary burden on travelers and travel companies by abolishing the nationality requirement for tour guides and the requirement to have an accompanying guide.

(For reference purposes, Japanese nationality and residence are not requirements for acquiring a tour guide license in Japan.)

4. Investment Environment within the EU (Employment and Social Security)

(1) Overview
[EC, M.S.]
The GOJ is aware of the EU position that existing EU legislation in the employment and social field lays down only the minimum requirements, and that many of the issues raised in Japan's list of proposals fall within the exclusive competency of the Member States. The GOJ is also aware that employment has a sensitive aspect stemming from the historical background of labour practices and labour law that are unique to each Member State.

Nonetheless, the employment systems and customs in many EU Member States are rigid, thus productivity commensurate with the quality of the workforce has not been reached. To be specific, there is a noticeable lack of flexibility in areas such as dismissal from employment, working hours, and salary, and these factors are obstacles in the launch and operation of enterprises. Furthermore, the GOJ understands that similar points have been raised not only by Japanese and non-EU enterprises, but also by enterprises of EU Member States. Therefore, the GOJ is convinced that listening to the voices of these enterprises and addressing the problems will promote labour productivity in the EU and investment to the EU by other countries including Japan. Furthermore, in light of the goals advocated by the Lisbon Strategy to achieve growth and job creation through economic revitalization and the strengthening of competitiveness, the GOJ believes that there is significant importance in the EU's careful consideration of the requests of both EU and non-EU enterprises, including Japanese enterprises.

Therefore, the GOJ requests the EU side to make efforts towards improvement of the employment market at both the EU and Member State levels, from the viewpoint of improving the business and investment environment. Furthermore, it requests the European Commission continues to indicate the direction of how the latter intends to balance between flexibility in the labour market and security of employment (Flexicurity).

Moreover, the duplicate payment burden of social insurance is a major problem for Japanese companies operating in the EU or considering such an expansion. The GOJ hopes that Japan and the EU can continue to work together on this issue. As for social security agreements, the GOJ recognizes that Japan-EU cooperation is progressing in this field. The GOJ hopes that both Japan and the EU will continue to make their efforts to address this issue. With regard to social security agreements with EU Member States, the GOJ intends to proceed with the exchange of information with a view to commencing negotiations in accordance with priority, taking into account, in a comprehensive manner, the size of social insurance contributions, the number of people of Japanese nationality as well as number of Japanese companies, requests from the business sector, the status of bilateral relations, differences between the social security system of Japan and the social security system of each EU Member State.

Also, making adjustments to social security systems within the EU would be beneficial not only to citizens of EU Member States, but also to Japanese companies, thus, Japan welcomes efforts by the EU toward establishing a social security system that does not hinder the mobility of employment including the mutual application of public health insurance and pensions in the EU.

(2) Ensuring flexibility in the labour market [Czech Republic, Hungary] (♦)
[Czech Republic]
Reducing the percentage of workers on sick leave

The GOJ has until now been making requests to the Czech Government to make efforts for improvement in this issue, pointing out to the Czech Government that a high sick-leave rate is a serious problem for Japanese companies, that health insurance benefits are a significant burden for companies, that the sick-leave rate in the Czech Republic is extremely high among European countries including Central and Eastern European countries, and that if the high sick-leave rate continues there is a likelihood that it will have an adverse effect on companies seeking to enter the Czech market in the future.

In connection with this, the GOJ is aware of the problems related to structural amendments created by a new law that took effect in January 2008 (an unconstitutional judgment for three days without compensation and the recovery of said compensation), as well as the fact that the Czech Republic Government has made it an objective of their policy to recover the three days of no compensation. The GOJ, however, looks forward to seeing improvements in this issue next year, as the problem remains to be solved.

[Hungary]
Improvement to the abuse of sick-leave system

For the reasons that Japanese companies operating in Hungary continue to point out that employees often seek to use all of their annual 15-day sick-leave grant, while doctors tend to easily issue medical certificates allowing for employees to make sickness claims and that, since sick leaves are designed to be used for medical treatment when employees are sick or injured, using sick leaves as if they were part of ordinary paid leaves is a problematic practice, the GOJ continues to request that the Hungarian Government continues to make improvements to address this problem.

On this, Hungary explains that the Government Decree regulates the medical assessment of incapacity/capacity to work and related supervision, and sick leave can be demanded on the basis of the medical assessment carried out according to professional guidance. Therefore, Hungary maintains that a legal framework is in place for preventing the abuse of the sick leave system by employees through rigid guidance and a strong supervision mechanism by local authorities. While the GOJ recognises Hungary's efforts, it points out that as there have been no major improvements on this issue for Japanese companies, there is concern that, unless the situation changes, this will have a negative impact on businesses that are considering entering the Hungarian market in the future. The GOJ also requests that the Hungarian Government take concrete action so that the sick leave system can function properly.

Alleviating restrictions on overtime hours (♦)
Hungary has traditionally imposed a 200-hour annual limit on hours of overtime. An amendment made to the labour law in July 2007 now allows for up to 10% of employees who have technical or special skills based on individual contracts with their company such as Japanese ones which do not have any in-house unions to extend the annual limit to 300 hours; however, some Japanese companies are facing difficulty keeping to the 10% limit as more personnel are required to maintain their facilities. There are many instances where overtime is necessary, depending on region or type of job, and thus restriction on overtime in Hungary is a significant problem common to Japanese companies. Therefore, the GOJ requests that the Hungarian Government alleviate restrictions on overtime hours in order to improve Hungary's investment environment and enhance economic competitiveness, specifically that the annual 300-hour overtime limit apply not only to employees with technical and special skills, but also to all employees including general employees.

(3) Social Security: Improving social security systems in the EU [EC] (♦)

The EU is addressing employment mobility in the EU. In this context, it is tremendously important and beneficial also for Japanese companies, whose employees often transfer to or visit other EU countries on business, that free movement within the EU be ensured while social security rights such as medical treatment and pension payment in particular, are maintained. Therefore, the GOJ welcomes efforts by the European Commission to solve this issue through establishing public health insurance and a pension system which are coordinated to address the movement of people within the EU, and requests that the European Committee continues efforts to solve the problem.

5. Standards and Certification

(1) Overview [EC]

The EU's New Approach and Global Approach aimed at the free movement of goods in the EU through technical harmonisation in the area of manufacturing have played an important role in reducing trade barriers in the EU in various ways such as the issuance of directives defining merely essential requirements to be met in each product area, the framing of a conformity assessment system into modules, and the introduction of CE marking. However, these approaches result in an excessive burden on manufacturers both inside and outside the EU. Since directives are issued one by one, each covering a different product area, a single product may be subject to multiple directives. Also, frequent revisions of harmonised standards make it necessary to reassess conformity and issue a declaration of conformity each time.

In its FY2007 reply, the EU stated that the whole New and Global Approach is currently under review, notably to restrict the number of modules of conformity assessment. In FY2008, the GOJ requests the supply of concrete information from the European Commission regarding the review in progress within the EU, and expresses its desire to participate in the review process.

6. Trade and Customs

(1) Overview [EC]

The GOJ believes that cooperation between Japan and the EU is essential in striking a balance between the security of international trade and its facilitation. From this perspective, the GOJ's priorities in 2008 are to secure the mutual recognition of the AEO system and to clarify the technical requirement concerning the advance notice system for international maritime containerized cargo information.

Regarding the EU's tariff treatment of certain IT products raised in FY2007 RRD, Japan, together with the US and Taiwan, requested at the Dispute Settlement Body meeting in September 2008 that the WTO establish a panel, which was established as a result. The GOJ intends to carry out the remaining steps necessary to secure an appropriate resolution, following the WTO's rules.

(2) Mutual recognition of the AEO programs [EC]

The Authorised Economic Operator (AEO) program allows customs authorities to identify businesses involved in the international supply chain who have excellent freight security compliance records, who then reap benefits such as simplification of customs procedures. The program thus helps strike a balance between the security of international trade and its facilitation. Japan and the EU continue to work together towards the mutual recognition of their respective AEO programs. In order to make mutual recognition a reality, the GOJ intends to cooperate closely with the EU. Such cooperative measures could alleviate the impact of the EU's 24-hour advance notice system for the submission of maritime containerized cargo information, which will be applied after July 2009, on the efficiency of distribution of Japanese freight into the EU.

(3) Clarification of technical requirement concerning the advance notice system for international maritime containerized cargo information [EC]

The EU plans to implement a 24-hour advance notice system for the submission of maritime containerized cargo information after July 2009. As it has not yet made clear the technical requirements for the process of providing cargo information to customs and for the IT systems, shipping companies cannot complete provisions necessary to implement the system from their side.

Consequently, the GOJ requests that the European Commission move quickly to clarify the technical requirements for the process of providing cargo information to customs and for the IT systems, and to report this to the GOJ. In the event that such clarification is not possible at the time of making the written reply, the GOJ requests detailed explanation on the current preparation status, an outlook as to when such clarification will be possible, and provisions for the delayed introduction of the system.

7. Intellectual Property Rights

(1) Overview [EC, M.S.]

As advanced knowledge-based economies, Japan and the EU share an interest in the global protection of intellectual property rights (IPR). The protection of IPR such as patents is of particular importance for the maintenance of competitive strength and the advancement of innovation. The GOJ expects the EU, by implementing the Lisbon Strategy launched in 2000, to become the most competitive market in the world by 2010.

To that end, the GOJ strongly requests on patent issues that the EU (i) continue its efforts to speed up discussion on international harmonisation of patent systems; (ii) establish an EU-wide single patent system; and (iii) ensure efficient, cost-effective and high-quality patent examination and implementation. Furthermore, in view of securing a copyright protection system consistent with the advancement of digitisation, it requests that the EU (iv) continue its efforts to harmonise copyright levy systems for private copying in the EU.

As for maintaining the design protection for spare parts that it requested in FY2007, the GOJ continues to monitor the situation regarding the progress made since the European Parliament adopted the Commission's amendment proposal in December 2007, and it will consider making another proposal in line with future developments.

(2) Reform of European and global patent systems

(a) Overview (including the international harmonisation of patent systems) [EC, M.S.]

In FY2007, the GOJ made a request relating to the international harmonisation of patent systems, early establishment of the Community Patent, a reduction of patent translation costs, and improvement in the patent judicial system in Europe.

Regarding the realisation of the international harmonisation of patent systems, the GOJ recognises it will bring significant merits for both Japanese and the EU businesses by improving predictability and legal stability of patent acquisition for users, thereby contributing to reducing costs pertaining to the establishment of rights. In addition, the realisation is also essential for companies with global operations to gain infrastructure which helps promote a smooth acquisition of rights. Against these backdrops, the importance of this issue was confirmed at various summit-level meeting such as Japan-France summit meeting in April 2008, the EU-US summit meeting in June 2008, as well as G8 Hokkaido Toyako Summit Meeting in July 2008. Furthermore, there have been strong calls for the realisation of this international harmonisation from global business leaders, including Japanese ones, through channels such as the G8 Business Summit in April 2008, and the Japan-EU Business Dialogue Round Table (BDRT) in June 2008.

In this light, we must take note of the recent discussion in September 2008 at the meeting of developed countries on international patent harmonisation, hosted by the European Patent Organisation, which confirmed to continue deliberations on the international patent system harmonisation, also bearing mind the issue of strengthened cooperation among patent authorities in practical areas such as a patent prosecution highway.

Therefore, the GOJ strongly requests that the Commission should continue to be proactively committed to the discussion on international patent harmonisation and in particular play a leading role in coordinating the Member States.

Regarding the Community Patent, the GOJ is concerned about the stagnation of discussions within the EU since the political agreement reached at the 2003 European Council meeting. The fact that the EU has still not established an integrated patent system is considerably reducing the attractiveness of the EU as a single market, and for this reason it is necessary for the EU to swiftly tackle this issue.

According to the Annual Report 2007 of the European Patent Office (EPO), Japan submits the third highest number of applications to the EPO (16.3%), behind the US (25.3%) and Germany (17.9%). Further, Japanese companies account for seven of the top 25 companies by number of applications made. These two figures clearly show the level of contribution the Japanese business world is making to R&D and innovation in Europe, and the close link that exists between Japan and Europe in the area of patents. For that reason, it must be stressed that patent reform in the EU is as vital to Japanese companies as it is to EU companies. As an important stakeholder in EU patent policy, the GOJ has a great deal of interest in the question of how the EU market will retain its attractiveness and competitive edge in relation to the markets of emerging economies such as China and India, which have been coming to the fore in recent years. Urgent patent reforms by the EU are therefore necessary from this perspective, too.

Based on recognition of the above, and taking the short- to medium-term perspective, the GOJ continues to call for the realisation of international harmonisation of patent systems and the Community Patent. Meanwhile, from the perspective of responding quickly to the voices of the Japanese and EU business worlds, the GOJ has established the reduction of patent translation costs and unification of the patent judicial system as its priorities for this fiscal year, as detailed below.

Speeding up the process of patent examination and acquisition is important as a practical and immediate issue, and unfortunately the EU is also lagging behind Japan and the US in this area. For this reason, while the GOJ welcomes the significant developments in relation to the Patent Prosecution Highway between Japan and the EU Member States, it wishes for the Patent Prosecution Highway between the EPO and the Japan Patent Office (JPO) to commence as early as possible.

Based on the above, the GOJ considers the Patent Prosecution Highway, a reduction of patent translation costs, and the unification of the patent judicial system as specific issues, and hopes that the EU will act accordingly in order to usher in concrete development in these areas within a one year period from now (i.e., from December 2008 to December 2009).

(b) Patent Prosecution Highway [EC, M.S.]

With the Patent Prosecution Highway, applications judged to be patentable at the First Office in accordance with the choice of the applicant may receive early examination at the Second Office due to simpler procedures that make use of the search and examination results carried out at the former. The Patent Prosecution Highway aims to (i) provide support for early rights acquisition abroad by patent applicants, and (ii) reduce the examination burden on each country's patent office and raise the quality of examinations. The Patent Prosecution Highway has great significance for the promotion of international R&D and innovation.

As of the end of September 2008, Patent Prosecution Highways have been implemented in earnest between Japan and the US, and between Japan and the ROK, while trial implementation is underway between Japan and each of the countries of the UK, Germany and Denmark. The efforts are evaluated highly by the business worlds of each nation, including Japan and those in Europe, as they make it possible to speed up the acquisition of patent rights and reduce costs. Based on the aforementioned

progress and the strong demand from Japanese and EU industries, discussion pertaining to the Patent Prosecution Highway is now underway between the EPO and the JPO. The GOJ welcomes the ongoing discussion.

A new development in Europe that is of interest to the GOJ is the commencement in September 2008 of the Patent Prosecution Highway between the EPO and the United States Patent and Trademark Office (USPTO). The GOJ furthermore welcomes the fact that the EPO explained at the Trilateral Conference held in September 2008 that it will begin to consider, in a forward-looking manner, starting a Patent Prosecution Highway with the JPO.

In this connection, the JPO notes that the Commission acknowledged the importance of mutual use of examination results, as stated in the Communication (COM(2007)165 final, p12, "3.1. Quality, costs and efficiency of the Patent system") published in April 2007. It goes that "(w)ith the increasing demand for patents, an increasing burden on examiners as well as the advances in technological developments, it is important that patent offices in Europe work together, for example, on the mutual exploitation of examination results and that they strive to maintain a high quality of granted patents"). In this light, the GOJ anticipates a greater role for the EU in this area. Furthermore, the GOJ wishes to add high expectations expressed by Japanese users on reduction in cost associated with examination procedures, renewal fee and others through the realisation of the Patent Prosecution Highway between the JPO and the EPO.

Based on the above, the GOJ wishes for timely progress in the coordination of opinions within the EU, by all of its Member States (all Member States are signatories of the European Patent Convention (EPC)) and the European Commission, which is responsible for coordinating patent policies between Member States, in order that the Patent Prosecution Highway can be realised between the EPO and the JPO within one year from now (i.e., the period between December 2008 and December 2009).

(c) Reduction of patent translation costs [EC, M.S.]
(The universalisation of the London Agreement designed to reduce the burden of translation required concerning a European Patent)
[EC, non-ratified countries (Ireland, Italy, Estonia, Austria, Cyprus, Greece, Spain, Slovakia, the Czech Republic, Hungary, Finland, Bulgaria, Belgium, Poland, Portugal, Malta, Lithuania and Romania), in particular, those that did not respond last fiscal year (Ireland, Italy, Cyprus, Belgium, Poland, Portugal and Lithuania)]

Under Article 65-1 of the current European Patent Convention (EPC), when the EPO judges to grant a patent and the applicant for the patent wishes the patent protection to apply in EPC member countries, the EPC member countries may prescribe that the applicant for the said patent shall supply a translation of the description of the aforementioned patent in official languages of the countries. Such translation obligations incur extensive costs that heavily strain patent applicants including Japanese companies. This system, which complicates and delays the procedure for a European Patent, is discouraging the international utilisation of the said patent.

With a goal of breaking away from this situation, on 17 October 2000, the London Agreement (the Agreement dated 17 October 2000 on the application of Article 65 of EPC) was adopted by several member countries of the EPC, namely, the UK, France, Germany, and seven other countries (the Netherlands, Monaco, Luxemburg, Switzerland, Sweden, Denmark, and Lithuania), aiming to reduce the burden of submitting translations concerning a European Patent. The GOJ welcomes the fact that this agreement came into effect on 1 May 2008, thanks to the forward-looking efforts of the European

countries, France in particular. It appreciates that as of September 2008, nine of the EU Member States, namely Denmark, France, Germany, Latvia, Luxemburg, Slovenia, Sweden, the Netherlands and the UK, have joined the London Agreement.

On the other hand, Japan wishes to indicate that 18 EU Member States including Italy and Spain have not yet ratified the agreement. In order to advance unified EU patent policies, it is important for the European countries to solve the patent translation problem via the universality of the London Agreement, and for this reason the GOJ hopes for further efforts by the aforementioned 18 countries that have not ratified.

The number of submissions made in response to the Japanese proposals in FY2007 can be deemed high, at 11 signatory countries. Of these, the GOJ was particularly impressed by the fact that Greece was positive on ratification and that Malta has the obligation to make an English translation stipulated under its domestic law, while Estonia was heeding the requests of Japan and Hungary was considering ratification as a task for the future. Meanwhile, the GOJ is following the efforts of Austria, Slovakia, Finland, Bulgaria and Romania, which are still engaged in domestic investigation into the feasibility and effects of ratification. Regarding Spain, which is cautious about ratification due to the language issue in the EU, and the Czech Republic, which is similarly cautious from the perspective of the provisions of its constitution, the GOJ calls for progress in forward-looking consideration, from a broader perspective of establishing common EU patent policies.

Of the nine Member States that did not respond in FY2007, the hope of the GOJ is that those non-ratified countries (Ireland, Italy, Cyprus, Belgium, Poland, Portugal and Lithuania) submit a response in FY2008.

The GOJ understands as per the FY2007 reply of the Commission that the London Agreement itself is not a community issue. However, the same reply noted that support was announced for the London Agreement at the April 2006 EC Public Consultation. This fact, coupled with the proactive position of the European Commission in advancing the agreement, is rated highly by the GOJ. In the Communication made by the Commission in April 2007, the patent translation problem was considered an issue of the highest priority, along with the judicial standardisation problem. Therefore, it is clear that the universality of the London Agreement is intimately related to the solution of the translation problem in the Community Patent.

For this reason, the GOJ requests that the EU should continue to pay due attention to the universality of the London Agreement, and that it should make a concerted effort to ensure coordination among the EU Member States, in order that those which have not yet ratified the London Agreement show positive progress in the patent translation issue.

The patent translation problem was also discussed at the Conference on Industrial Property Rights in the Internal Market, which was held in October 2008 at the European Parliament, co-hosted by the European Commission and France, holder of the EU Presidency. Participants, including Internal Market Commissioner McCreevy, expressed their hopes for a practical solution to the problem, by using machine translation on the wording of the descriptions. The GOJ would like to add that it is paying close attention to this as a new technical breakthrough.

(d) Reform in the judicial system - early establishment of the European Union Patent Court [EC, M.S.]

The European Patent Litigation Agreement (EPLA) has been under discussion since 1999, with the goal of unifying the European patent litigation systems. In recent years, discussion on the EPLA has been converging on the founding of a European Union Patent Court, which will control both the existing European Patent and the future Community Patent, aimed at realising a unified judicial system for Europe. The GOJ welcomes this move, along with the intensive way in which discussion is proceeding under the leadership of France, holder of the EU Presidency.

The establishment of a European Union Patent Court is expected to provide a higher level of legal stability to European patents and the Community Patent and to bring about a simplification of litigation procedures and cost reduction. As such, it is a major priority for the GOJ, and Japanese business has high expectations. These reforms will therefore further enhance the attractiveness of the EU as a single market, through the development of a more legally stable and cost-effective environment for research and innovation. Since this will be of great benefit not only to EU companies, but also to businesses outside the region, including those of Japan, it must be made a greater political priority within the EU.

The GOJ recognises that the current priorities for the EU lie in the concrete proposal for a European Union Patent Court to control both the European Patents and Community Patents, and the announcement of a schedule with specific deadlines. Some progress was seen with the presentation of the general concept for a European Union Patent Court, based on stakeholder opinions, in the April 2006 Public Consultation on future European patent policies and the April 2007 Communication by the Commission. Presentation at European political level in the form of a specific bill will be the next step, and discussion of the said bill must commence at the European Council and the European Parliament once the bill has been submitted.

While the GOJ sufficiently acknowledges the significance of prudent, democratic decision-making processes within the EU on the one hand, it strongly recognises the necessity for policy decisions to be made in a timely manner, in order to promote the attractiveness of the EU as a single market, in the area of patent policy wherein it is important to respond appropriately to economic globalisation and rapid technological innovation. The GOJ recognises that the necessary opinions have been gathered and adequate time has been taken for examination for the European Commission to be able to make policy proposals. As such the GOJ believes that it is now time for a concrete policy proposal to be made.

Therefore, the GOJ requests that the European Commission should offer the specifics of the bill relating to a European Union Patent Court and a concrete work schedule, while the EU Member States go to lengths to contribute more positively to EU efforts led by the European Commission.

(3) Reform of the private copying levy system in the EU
[EC, relevant M.S. (Italy, Estonia, Austria, the Netherlands, Greece, Sweden, Spain, Slovakia, Slovenia, the Czech Republic, Denmark, Germany, Hungary, Finland, France, Bulgaria, Belgium, Poland, Portugal, Latvia, Lithuania, Romania)

The private copying levy system was introduced as a means of charging compensation fees for reproductions of copyrighted works for private use at a time when analogue equipment was commonly used to make copies. With the prevalence of digital technology today, however, digital equipment and media account for the majority of items covered by private copying levies. To respond appropriately to progress in technology of this nature, deliberation is currently underway in countries all over the world, the EU included, which includes a review of the private copying levy system.

In addition, the GOJ would like to point out some cases where sufficient agreements are not in place between stakeholders in terms of their decisions on the ratio as well as scopes of private copying levy systems pertaining to photocopying of copyrighted works. As a result, it is pointed out that in such cases levies are charged to those equipments with an extremely small possibility of being used to reproduce copyrighted works, and unreasonably expensive private copying levies are charged to those instruments whose prices have already been lowered due to technological progress.

The GOJ is concerned that since (i) there have been no common EU-wide policies established regarding the compensation methods for the private copying of works, and (ii) there is no provision in Article 5-2(b) of the EC Directive (2001/29) pertaining to the modality of systems to secure "fair compensation," the EU Directive does not possess sufficient efficacy to achieve harmonisation within the EU.

Taking into consideration such an environment, the European Commission formulated, in 2006, a road map (2006/MARKT/008) for the harmonisation of the levy system in the EU relating to reproduction for private use. The European Commission is proposing to the Member States a future policy option of indicating guidance on the usability of digital rights management (DRM) technology as an alternative method of protection, as well as guidance for ensuring transparency with respect to the application, collection and distribution of private copying levies.

In 2006, the European Commission implemented an impact survey of the influence of the private copying levy system on the free movement of electronics within the EU, along with its first consultations. This survey also dealt with areas such as (i) the question of how charges are being administered and (ii) the question of what kind of "grey market" issues are appearing due to problems in administration.

In February 2008, the European Commission carried out its second consultation. At that time, Internal Market Commissioner McCreevy stated, "There can be no question of calling into doubt the entitlement of rightsholders to compensation for private copying. At the same time there is a need to look at how the levies are applied in practice. It should be possible to envisage some workable solution that assures the rightholders of their due compensation and at the same time applying the levies in a way that is commensurate to the loss caused by private copying." The GOJ supports such efforts by the European Commission.

The GOJ understands that items of great interest to Japan were discussed at a public hearing held by the European Commission in May 2008, including (i) the question of what would be the fairest method to determine the private copying levy rate that applies to digital equipment and blank media, (ii) the

question of what is the most suitable party to pay private copying levies, and (iii) the question of how private copying levy schemes should evolve to take into account convergence in consumer electronics.

The GOJ recognises that the time has come for new policy directions to be launched by the European Commission, based on the impact survey and public consultations and hearings held between 2006 and 2008. There are demands for the EU to establish common policies to realise a fair and transparent private copying levy system as quickly as possible in order to respond to the rapid technological advances being made in the area of digital equipments and media.

As previously mentioned, the legal hurdles impeding harmonisation are understood to lie in the deficiency of the current EC Directive (2001/29), and for that reason the GOJ requests that the European Commission should take appropriate steps in its future political initiatives, including reform of the aforementioned directive.

The European Commission Internal Market Directorate-General website says that the European Commission will publicise the results of the consultations made with the Member States since October 2004 on the scope of the private copying exception and existing systems of remuneration, starting January 2006. However, the said results have not yet been made public. While the GOJ appreciates the efforts by the European Commission to coordinate opinions of the Member States, it requests that these results are made public as soon as possible in order to ensure transparency for stakeholders outside the EU, including Japan.

8. Maritime Policy [EC]

(1) Overview

A package of seven directives on maritime safety (Erika III) was proposed by the European Commission in November 2005 and is currently subject to legislative procedures within the European Parliament and European Council. In June 2006, the European Commission presented its "Green Paper for Maritime Policy (SEC(2006)689)," in which it made clear its intention to formulate a comprehensive EU maritime policy that horizontally covers many fields such as maritime transportation, the marine industry, coastal areas, energy, fisheries and the marine environment. In October 2007, the European Commission released the so-called Blue Paper (COM(2007)575) in which it set out specific plans regarding the direction of EU maritime policy integration and a working plan for its realisation.

Ensuring maritime issues such as maritime safety is a matter of interest for Japan, which is also a maritime state. In Japan, the Basic Act on Ocean Policy came into force in July 2007, which clarifies Japan's basic position on maritime policy, and the Headquarters for Ocean Policy was established in the Cabinet in order to promote measures with regard to the oceans in an intensive and comprehensive manner. In view of progress in this area, Japan has been paying attention to trends in the integration of maritime policies in the EU.

The GOJ understands that, in aiming to integrate EU maritime policy, the European Commission is conducting research and studies in various areas including coastal management, navigational safety, and fisheries based on the action plan projected in the Blue Paper. The GOJ continues to request that the EU pay adequate consideration to the following position of the GOJ and that these conditions are ensured when working on specific regulations and directives. In addition, the GOJ requests that information be provided as necessary on progress made in developing integration policy.

- Ensure that integration of EU maritime policy does not conflict with the international maritime legal order through an excessive increase in coastal control, given that the international maritime legal order where the UN Convention on the Law of the Sea (UNCLOS) is at the core is established in a delicate balance to meet various requirements such as ensuring the use of the seas and freedom of navigation as well as protection of the marine environment and preservation of marine living resources.
- Ensure that the EU maritime policy is not intended to serve as any new discriminatory legal control over commercial vessels of non-EU countries including Japanese ones, in terms of the maritime navigation of vessels in territorial waters and EEZs of EU Member States and access to ports of EU Member States.

Furthermore, the GOJ continues to request that the European Commission pay consideration to Japan's position, particularly in regard to the following issues that are of significant concern to Japan. The GOJ further requests that a proper explanation and information be provided on maritime policy through regular bilateral dialogue between Japan and the EU on maritime affairs, when appropriate. It is also requested that opportunities for consultation be secured as necessary for the GOJ and other Japanese stakeholders on issues that could impact third parties including Japan.

(2) Directive packages relating to maritime safety

The GOJ continues to request that the European Commission present its views on possibility that, regarding the system under Article 8 and 9 of "Regulation on common rules and standards for ship

inspection and survey organizations" which is under consideration upon the packages whereby the Community's inspectors have the access to the ships as a means to verify that the recognised organizations (RO) meet the obligations under the regulation and fulfill the minimum criteria, such inspections could be regarded as extraterritorial application of executive jurisdiction, if EC inspectors go on board and inspect in areas or vessels which are under the jurisdiction of non-EU countries.

Also, on Article 10 of the regulation which states that the ROs shall agree on the technical and procedural conditions under which they will mutually recognise their respective classification certificates, particularly taking into account marine equipment bearing the mark of conformity. However as the GOJ has expressed its concern repeatedly in meetings such as the Japan-EU bilateral regular dialogue on maritime affairs, it believes that this regulation would infringe the jurisdiction of Japan as a flag state for ensuring the safety of its flag ships, in case this mutual recognition is applied to the certification for safety of equipment of Japan's flag ships, unless Japan accepts the mutual recognition. Therefore, the mutual recognition of the classification certificate issued by ROs of EU Member States shall not apply to the equipment loaded in flag ships of Japan. The GOJ requests strongly that the European Commission clearly indicate its views on this issue.

(3) Proposal for Implementing Agreement of the UN Convention on the Law of the Sea (UNCLOS) on marine biodiversity in areas beyond national jurisdiction

The GOJ understands that the EU emphasises creating standards for marine areas subject to protection, stating that the EU proposal is in a position to provide rules and mechanisms to allow for ensuring marine protection in areas beyond national jurisdiction which includes the possibility of marine protected areas.

Meanwhile, Japan's position is that the issue should be solved through implementation and observation of the existing legal framework, strengthening of the existing organisation and mechanism, and the concerted action and cooperation of these organisations. Thus Japan is against enforcing it in the framework of UNCLOS that ensures free use of oceans and free marine navigation. In that regard, with a view to establishing Marine Protected Areas (MPA) beyond national jurisdiction, scientific criteria were adopted for identifying marine areas of ecological and biological importance and in need of protection at the Convention on Biological Diversity's Ninth Meeting of the Conference of the Parties in May 2008. However, the GOJ recognises that there is still unfinished debate over the handling of the MPA.

Japan believes that this issue must be considered from the viewpoints of the scientific grounds and consistency with international law, and also emphasises the perspectives of sustainable use in addition to preserving marine resources when making these considerations. Therefore, the GOJ requests the European Commission to discuss this issue at relevant specialised agencies, such as the Food and Agriculture Organization (FAO) and Regional Fishery Management Organizations (RFMOs).

(4) Reduction of pollution and greenhouse gas emissions from ships

Japan recognizes that discussion on these issues is progressing in the International Maritime Organization (IMO). Japan also understands the importance of making efforts in this area, but at the same time believes that regional measures in this area could damage the international marine transportation balance (the nature of the world single market of international marine transportation). The GOJ thus requests that the European Commission continues efforts to resolve these issues, through adequate discussion at various international forums such as the IMO. However, in the event that the EU does not wait for the establishment of an IMO treaty and the implementation of provisional measures is unavoidable, the GOJ continues to request that the provisional measures are consistent with the

proposed IMO treaty and that consideration be paid to not bring about any unnecessary confusion or burden on the shipping industry.

(5) Fair administrative procedures for maritime transport and simplification of customs and port-related procedures

The GOJ appreciates the explanation by the European Commission that it is not intending, when drafting a new ports policy, to introduce discrimination or complicate procedures for foreign vessels. The GOJ continues to request that the European Commission takes care not to introduce discriminatory legal regulations or complicate procedures for commercial vessels of non-EU countries including Japan.

FAO is now working on the draft agreement for port state measures. The current draft includes even cargo ships and replenishment ships; the GOJ, however, takes the position that it is indispensable to consult and coordinate with the IMO sufficiently, in cases when a port state measure, which could have an impact on usual commercial vessels, will be created. The GOJ will thus cooperate with the EU in order to ensure systematic coordination for the work and systems of both organizations.

(6) Environmental problems accompanying the dismantling (recycling) of ships

The IMO is currently preparing the relevant convention (Ship Recycle Convention), which is planned for adoption in May 2009. To put the convention into force at an early date, the GOJ recognises the importance of concordant cooperation among IMO member countries. At the same time, just as with the issues of reducing pollution and greenhouse gas emissions from ships, the GOJ believes that also regional measures in this area could damage the international marine transportation balance (the nature of the world single market of international marine transportation), and thus maintains that early enforcement of this convention is the best way to solve the problem. The GOJ will thus continue to cooperate with the EU in the context of deliberations at the IMO.

9. Environment

(1) Overview
[EC, M.S.]

The GOJ appreciates the EU's efforts for taking the lead in tackling environmental issues, and with regard to many challenges in this field, such as the recycling issue, Japan shares common awareness with the EU. On the other hand, regulations implemented by the EU in the field of the environment would not only have significant impact on non-EU companies including Japanese ones, but also have an effect which is not negligible on the EU's efforts to strengthen European economic competitiveness based on the Lisbon Agenda. Therefore, the GOJ believes it is necessary to give due consideration to striking an appropriate balance between the environmental goals and their effect on corporate economic activities, international trade and investments.

Based on these ideas, the GOJ continues to request that the EU make sure that environmental regulations do not impose an excessive burden on enterprises, impede sound economic activities or create trade barriers.

Furthermore, concerning particularly new regulations implemented in recent years, problematic aspects are sporadically observed, such as vagueness in definitions and scope of application, as well as delays in preparing detailed operational rules and guidelines. For the reason that these problems remain unresolved or unclear, as well as due to the lack of time to prepare for changes in the regulation, many Japanese companies find it difficult to comply with these regulations even after they are officially put into effect. In addition, some Japanese companies still experience confusion caused by vagueness of legal interpretation and operation, the inability to acquire a concise and official response regarding said vagueness, as well as inconsistency among EU Member States or among related organizations within a state.

To sweep away these obstacles, the GOJ requests the European Commission to make every effort to ensure that operation instructions are drafted well before the regulations are made effective and enforced, and if necessary to make them public along with guidelines that are clear and easy-to-understand for related corporations. In addition, the GOJ requests that particular efforts be made to secure unified enforcement and application of regulations within the EU and a support system for companies, such as through responding to inquiries, regarding all regulations.

Furthermore, regarding the legislation of Europe's fuel consumption standards, for which the GOJ submitted its requests in 2007, the GOJ is expecting that an impact study on the issues such as the long-term target (the long-term scenario) of the legislation is well implemented before any political discussions and that the legislation becomes a fair and effective system designed through an integrated approach that includes not only the introduction of fuel consumption standards, but also measures related to fuel and traffic and the introduction of incentives as the GOJ has requested for years. The GOJ is taking notice of discussions in the European Parliament and Ministers Councils, and would consider its requests anew, depending on status of the discussions in the future.

(2) Specific Issues

[EC, M.S.]

(a) REACH (chemical regulations)

REACH regulations are envisioned to be enforced in a unified manner within the EU as a matter of course. However, based on the actual past experience of Japanese companies, there is concern that the operation will differ for imports by EU Member States, initially, following the pre-registration period that ended on 1 December. Therefore, the GOJ requests that the European Commission operate said regulations in a clear and unified manner within the EU so as not to cause any confusion or trouble for Japanese industries, and also make efforts to resolve the following specific issues.

- In this connection, the "Guidance on requirements for substances in articles (RIP3.8)" was issued. However, the fact that six Member States noted their disagreement over the 0.1wt% denominator in the guidance undermines the basis on which the regulations will be observed and may confuse Japanese companies. Therefore, the GOJ requests that the regulations are implemented in a unified manner in the EU as guidance which is established under the responsibility of the European Commission and European Chemicals Agency.

- The GOJ requests that regulations be fairly implemented through clarification and harmonization of inspection criteria so that Japanese corporations that observe regulations do not suffer from any unfair prejudice, and so that there is no operational discrepancy among EU Member States regarding penalties and inspection methods for clearing national customs.

- The European Commission's 2008 reply states that the helpdesk of ECHA as well as the helpdesk of the Member States' Competent Authorities are already actively providing responses to questions raised by industry. However, while the helpdesks are quite a useful service, Japan remains aware that there are cases where clear responses have not been received and where responses differed between Member States. Thus Japanese companies are experiencing confusion. The GOJ therefore requests to the European Commission to clarify the responsible administrative organizations and departments that possess the final official interpretative authority in the event of doubt. In particular, the GOJ requests that a prompt response that is consistent among EU Member States be provided for inquiries made to related authorities of EU Member States regarding the discrimination of preparation and article.

- Concerning Article 8 of the REACH regulation for "Only representatives (OR) of non-Community manufacturers," the European Commission clarified in its 2008 reply that the only-representative system was introduced in response to concerns by non-EU manufacturers relating to the company information being disclosed to importers and that it is the choice of the non-EU manufacturer whether they wish to adopt the system. Further, the Commission noted that adopting the system is not mandatory and the European Commission and European Chemicals Agency cannot be involved in the decision. Nevertheless, many Japanese companies (especially small- and medium-sized enterprises) that do not have overseas subsidiaries in the EU should rely on an only representative for registration and other requirements. For this reason, the possibility that the economic activities of Japanese companies will be inhibited due to the inability to secure adequate and reliable only representatives cannot be eliminated. Therefore, the GOJ continues to request that the European Commission proactively work to establish a support system (e.g. establishing a list of "only representatives" that pass a certain screening officially recognised by the EU governments) for securing only representatives of qualitative and quantitative sufficiency in order to avoid adverse effects for non-EU companies and thereby ensure fair competition.

- Subsidiaries of non-EU companies located in the EU and "only representatives" are stipulated to participate in the Substance Information Exchange Fora (SIEF) after the pre-registration (REACH

regulation Article 29). However, Japan is aware that a substantial exchange of information is already taking place in optional consortiums centered on EU companies. The GOJ requests that the European Commission sufficiently oversee and direct activities so that the views of non-EU companies, too, are taken into account, when the SIEF commences activities following December 2008, and so that non-EU companies are not treated in a unfair and disadvantageous manner.

- According to Article 33 of the REACH regulation “Duty to communicate information on substances in articles,” suppliers of articles shall provide a consumer with information including the names of substances of very high concern (SVHC), upon request by the consumer, within 45 days of receipt of the request. In the European Commission’s 2008 reply, it was noted that comments by third parties are permitted in working on a draft SVHC list, and that related parties can acquire advanced information on substances being placed on the draft list. However, it is not easy for non-EU companies to reconfirm whether upstream suppliers include said substance, particularly when the supply chain is complicated. Even when taking into consideration the time frame for working on the draft SVHC list, there are cases where it is realistically difficult for information to be provided within the prescribed time frame. Therefore, given that work is currently underway on identifying SVHC and that the overall details of SVHC are still unclear, the GOJ requests that a grace period be established so that said requirement will be applied after the notification (REACH regulation Article 7.2) deadline to the European Chemicals Agency of candidate substances in articles subject to the deadline (end of May 2011 or after). In addition, the GOJ requests that considerations are made for flexible operation of the regulation, such as permitting a necessary extension as an exception to the 45-day rule in accordance with actual circumstances if a special application has been made. Furthermore, the GOJ requests that EU companies are familiarised with the obligation within the supply chain of downstream users to relay information to upstream companies (REACH regulation Article 34) and the obligation of downstream users to make reports to the European Chemicals Agency (Article 38), so that Japanese upstream companies can follow the regulations.

- The European Chemicals Agency proposed 16 substances as SVHC at the end of June 2008 and 15 of those were identified as SVHC at the end of October 2008. Japan also understands that more SVHCs are to be added to the list as necessary in the future. In this case, this requires companies to conduct a content inspection each time substances are added, which is an enormous burden for the companies. Frequently adding target substances will also cause great confusion within the global supply chain. Therefore, the GOJ requests that the release of SVHC be limited to around once every two years, and that a long-term timetable be made public regarding the decision-making process in order to increase predictability.

- REACH regulation Article 6, “General obligation to register substances on their own or in preparations,” requires polymer manufacturers to register monomer substances contained in polymers under certain conditions. In the process for drafting the REACH regulation, Japan continued to express doubts about registering monomer substances contained in polymers because, firstly, polymerized monomers do not negatively impact the environment, and, secondly, mandating the registration of polymerized monomers is inappropriate given the possibility that problems will arise in the consistency with Article 2 of the TBT Agreement, which prohibits regulations restricting trade more than necessary. As there is no change in Japan’s position on this issue, the GOJ requests that sufficient consideration be paid to new scientific knowledge such as OECD undertakings for the international standardization of Polymers of Low Concern (PLC), and that the merits of registering monomer substances contained in polymers are reconsidered.

- According to remarks by the European Chemicals Agency (6 October 2008 edition of *News Alert*), the Agency recommends that a "pre-registration" of monomers contained in polymers be made by downstream polymer manufacturers if it is unclear whether the monomers will be "registered" by an upstream monomer manufacturer or importer by the pre-registration deadline of 1 December 2008. Furthermore, the same recommendation is made for three additional cases (REACH regulation Article 2. 7c "re-imported substances," Article 2.7d "recovered substances," and Article 7.6 "substances which are intended to be released from articles").
  If these are in fact recommendations to make pre-registrations, it means that the manufacturers and importers who are primarily exempted from the registration in these cases must make a pre-registration on all relevant substances at this time unless the substances are "Non Phase in Substances," which is obliged to be registered from the first in order to be brought to the market. This serves to increase the burden on manufacturers and importers in the EU.
  In addition, it is unclear whether the aforementioned monomer "registration" by upstream monomer manufacturers and importers by 1 December includes "being pre-registered," which is causing confusion for Japanese companies. Therefore, the GOJ requests that a clear definition of the term of "registration" that was used in the *News Alert* be presented promptly (specifically, whether "registration" includes a pre-registration).

- As the REACH regulation commenced operations while there were still issues such as ambivalence and confusion over the regulation's content and operation, the GOJ has taken note that the prompt resolution and clarification of these issues is of pressing importance for Japanese companies. In addition, the GOJ is placing emphasis on learning about new information and trends in a timely manner that are produced by the official operation of REACH. Therefore, the GOJ would like to have a forum for discussion (or liaison meeting) between Japanese and EU officials in charge and specialists (including related parties from the industrial sector as necessary) to be held once every two to three months, and requests that the European Commission consider having such a forum.

(b) RoHS Directive (Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment)

- The REACH regulation already makes decisions on the hazardousness of chemical substances, and also regulates and manages said substances including for articles. This means that the RoHS Directive imposes a secondary obligation on electrical and electronic equipment alone, doubling the burden on companies. The GOJ wants to hear the views of the European Commission regarding the necessity of the RoHS regulations within this context. In addition, the GOJ does not believe it to be appropriate for additional substances to be included as applicable targets in the future, at least within the context of the RoHS Directive, and would like to know the position of the European Commission on this issue.

- In countries without a recycling system for electrical and electronic equipment, the need for the RoHS Directive can be recognised to preserve soil and water quality. However, the electrical and electronic equipment subject to the RoHS Directive will ultimately just be recovered through the WEEE Directive, which regulates the recycling of these equipments. From this perspective, and in consideration of the 25 October 2005 message from the European Commission "Strategy for Streamlining the Regulatory Environment," steady and thorough implementation of the WEEE Directive will allow the legislative purpose of the RoHS Directive to be achieved by itself. In that sense, the GOJ believes that the RoHS Directive should be abolished once a thorough implementation of the WEEE Directive is achieved so as to streamline regulations, and would like

to hear the views of the European Commission.

- For companies, the termination of exemptions requires responses such as changing the manufacturing process in order to introduce alternative technologies and confirming the credibility of alternative technologies, just as in the case of adding new regulations. The GOJ thus requests that an adequate transitional period be established. For example, in April 2008, Deca-BDE was eliminated as an exemption as a result of the judgment by the Court of Justice of the European Communities. In this instance, the grace period was only three months, and Japan did not receive a notification on the decision. Responding to this decision is impossible for Japanese companies, which require a few months to handle activities such as shipping, thus making the regulation exclusionary. The GOJ understands that the termination of exemptions and adding of regulated substances is expected for the RoHS Directive, which is currently under review. The GOJ requests that the European Commission makes sure to notify Japan well in advance when making terminations or additions and provides an adequate grace period.

- Related to the above, Japan understands that the reason that the Court of Justice of the European Communities ruled to nullify the Deca-BDE exemption was due to a deficiency in official procedures despite the fact that there was not adequate scientific data to show hazardousness in the substances. As this is not a termination based on scientific assessment, and as the European Commission stated in its FY2007 reply that the exemption will meet the principle of transparency and is grounded on scientific arguments, the GOJ requests that the European Commission recover the exemption on Deca-BDE through the proper procedures.

- The GOJ continues to request that the European Commission provide clear rules on RoHS Directive exemptions and exemption terminations while taking into consideration the following points.
  - Applications for exemption should not be granted if an EU company files the application because a substitutable application could not be made for some reason.
  - In the event that regulations prevent the use of conventional technologies, alternative technologies can be developed and implemented if there is any incentive such as increased market share, even if the cost for implementing an alternate technology is very high. On the other hand, there is the possibility that sufficient investments will not be made for developing alternative technologies if there are no clear rules.
  - It is also necessary to create and present clear rules concerning the screening of exemptions for new products so that incentives will not be lost for developing products and manufacturing methods with remarkable energy conservation and recycling effects.

- The GOJ continues to request that the European Commission continue to exempt the spare parts of related items even after exemptions are terminated by such actions as revising the RoHS Directive. Specifically, in regards to the scope of spare part exemptions, the GOJ requests that "products congruent with requirements of the RoHS Directive when placed on the market" be added to "products which were placed on the market before the RoHS Direct was put into effect".

- Japanese companies report that the Directive is still not being strictly enforced in many EU Member States, and that there are many non-Japanese companies that do not observe the rule and do not suffer penalties. Thus, there is a concern that the competitiveness of Japanese companies that observe the regulation is being damaged because of unfair competition. Therefore, the GOJ requests that the European Commission operate this Directive within the EU in a just and fair

manner.

(c) WEEE Directive (Directive on waste electrical and electronic equipment)

- The GOJ requests that the European Commission make improvements in the following.
  - The current system is inappropriate as it inflicts collection and disposal costs on products exported to non-EU countries as used goods, etc. Several high-quality and long-life products produced in Japan are exported as used goods to non-EU countries. However, these products are beyond the scope of this Directive and as a result related companies face the burden of paying costs that would normally be unnecessary. Therefore, the recovery and disposal cost burden on related companies should be determined by the amount of products disposed in the EU and not the amount of product sales.
  - Related companies face unnecessary cost burdens as the WEEE Directive's national registry (registration procedures, reports, etc.) vary by EU Member State. Therefore, a mechanism should be established in the EU with unified registration procedures and reporting.

- Japanese companies report that the Directive is still not being strictly enforced in many EU Member States, and that there are many non-Japanese companies that do not observe the rule without penalty. Thus, there is a concern that the competitiveness of Japanese companies that observe the regulation is being damaged because of unfair competition. Therefore, the GOJ requests that the European Commission operate this Directive within the EU in a just and fair manner.

(d) Nickel Hydroxide (♦)

The usefulness of nickel hydroxide as a material in nickel hydride batteries is widely acknowledged. Japan is thus concerned that this substance will be subject to the Dangerous Substances Directive in the EU. In this regard, nickel compounds, including nickel hydroxide, are candidates for regulation under the ATP-31 (Adaptation to Technical Progress 31). However, there are doubts about targeting nickel hydroxide because tests required by OECD guidelines are not being conducted.

Numerous countries including Japan expressed objection to this proposed regulation at the 5 November 2008 WTO/TBT Committee meeting due to problems related to grounds for the regulation and decision-making procedures, and 12 countries including Japan presented a letter to the European Commission expressing their concern.

Therefore, Japan believes it proper to avoid adopting the classification proposal for ATP-31 until a sufficient explanation is provided in response to concerns, and requests that the European Commission reconsider the merits of adopting said proposal.

(e) Battery Directive (♦)

The Battery Directive mandates the labeling of battery capacity beginning from 26 September 2009. However, there is a problem as measuring methods for capacity have yet to be made public. Furthermore, regarding the enforcement of this requirement, unlike EU companies which face no problem as long as the placement of batteries makes into market is in time for the enactment of the directive, it is impossible for non-EU companies to comply with this requirement in the roughly half-year grace period, taking into consideration handling batteries that are bundled with other exported products. Therefore, the GOJ requests that the European Commission institute a grace period of at least one year between the Directives's promulgation and enactment so that non-EU companies are not subject to any disadvantage.

Furthermore, Article 11 of this Directive, "Removal of waste batteries," requires that manufacturers design equipment so that batteries can easily be removed, and that instruction manuals include safe methods for removing batteries and battery types for consumers. The GOJ believes that this requirement has the following two problems: (i) regulations for exempted batteries are unclear, and (ii) persons who can remove batteries have not been specified. The GOJ therefore requests that the European Commission clarify these two issues.

(f) EuP Directive (Directive on a framework for the setting of Eco-design Requirements for Energy-using Products)

- The GOJ requests the following points of the European Commission.
  - The GOJ requests that Japanese industry groups be permitted to participate in consultation forums in sectors in which Japanese companies have an important position in terms of share of sales in the EU, such as Lot 4 (imaging equipment), Lot 5 (television), and Lot 10 (residential air-conditioner).
  - Ecological profiles impact the overall supply chain. Thus, the GOJ requests that the European Commission aim to consider a unified method that is both realistic and of minimum cost with a basic stance of creating profiles in a scope where manufacturers can manage data of target products.
  - There is concern that confusion will be brought to the overall supply chain when dealing with each Lot individually, where the requirements are operated without consistency with each other. The GOJ therefore requests that considerations are made to 1) hold studies on adequate methods as part of product design tools applied cross-sectionally for each Lot, or 2) authorize CEN/CENELEC, etc., to promote the development of unified regulations by evaluating considerations within IEC TC111 or existing industry standards, or otherwise.
  - In the event that the EuP Directive will refer to energy labeling upon implementation, the GOJ requests that an organised interpretation be provided on the relationship between handling CE marking as a minimum performance rating and energy labeling as an energy efficiency rating.
  - Lot 6 (standby and off-mode losses) is different from other lots of every product category in that it regulates "standby and off-mode losses" in a cross-categorical manner. The GOJ requests that EU regulatory authorities prepare an FAQ at least to the degree of that of the WEEE Directive and RoHS Directive, so that the industries of various countries are not confused about the lot's applicable scope, content, etc.
  - Revisions are currently being made to IEC 62301 for a method to measure power consumption. The GOJ asks that also regulatory authorities make proactive efforts to adopt international standards, in addition to that the CEN/CENELEC be requested to harmonize it with international standards.
  - As it is difficult to regulate Lot 26 (networked standby) in a cross-categorical manner, the GOJ requests that considerations be made under the premise that the requirements be made consistent with the International Energy Star Program, etc., when appropriate for relevant products in each lot.

- Regarding targeted products for the following term (2009-2011), there are many business-to-business (B2B) product categories. However, most B2B equipment and devices are designed to meet the conditions and specifications of users, and there are no established methods for measuring energy-saving capabilities. Therefore, regulations for manufacturers alone will not reduce the actual environmental burden and bolster energy-saving effects. Top runner standards on transformers were introduced in Japan as well, but because in many cases transformers are used

well beyond depreciation as they have a long working lifetime, Japan has worked to provide aid for users of equipment to comply with regulations based on energy conservation law or top runner standards, so as to increase the effectiveness of regulations. Accordingly, the GOJ is ready to provide the European Commission with case studies, knowledge, etc., based on Japan's experience in order to support the EU's work on this issue.

B. Sectoral Issues

1. Information and Communication Technologies (ICT) and Audiovisual Media Services

(1) Overview [EC]

In its FY2007 proposal, the GOJ made requests regarding mobile telephone services, as follows: (i) facilitation of international roaming, and (ii) adequate application of the upper limit regulation on international roaming rates for mobile phones; requests relating to regulations for new telecommunication services; (iii) application of unbundling regulation to fibre-optic networks and (iv) application of competition safeguard measures to the provision of fixed-mobile conversion (FMC) services; and requests regarding (v) the importance of non-discrimination in media services (relaxation of the majority proportion provision for Europe-made programmes).

Regarding the (i) facilitation of international roaming, the EU explained in its FY2007 reply that there is no prohibition preventing connection of non-CE marked products, provided that the product meets the technical requirements of the Radio and Telecommunications Terminal Equipment Directive (R&TTE Directive). As the EU's response has resolved Japan's doubts, the GOJ appreciates the explanation.

Meanwhile, the EU's response regarding (ii) adequate application of the upper limit regulation of international roaming rates for mobile phones was not sufficient to address concerns held by Japan. The GOJ thus continues to make the following requests for FY2008.

In the FY2007 response, the EU noted that it shares the same position as Japan on the necessity of (iii) the application of unbundling regulation to fibre-optic networks based on the technical neutrality principle in the R&TTE Directive. Japan appreciates the EU's position and, considering that this is an important field of cooperation for Japanese and EU authorities to share policy direction, the GOJ would like to continue its request thereof in FY2008.

In the FY2007 reply, the EU noted that it agrees in general terms with Japan's position on the necessity of (iv) the application of competition safeguard measures to the provision of FMC services. The GOJ appreciates the EU's response and it will continue to observe the progress of discussion in the EU regarding this issue.

Regarding (v) the relaxation of the majority proportion provision for Europe-made programmes, the GOJ remains concerned as past replies by the Commission have not adequately answered Japan's concern about the possibility of the international distribution of quality contents being hindered by a substantial quota system that regulates European-made programme ratios. The GOJ continues to request sufficient answers from the EU on this issue and will continue to pay attention to it.

(2) Specific Issues [EC]

(a) Adequate application of the upper limit regulation of international roaming rates for mobile phones [EC]

(i) Background until FY2007

In its FY2007 proposal, the GOJ requested that the Commission take appropriate measures, including competition safeguards, in order to prohibit or control unfair and discriminatory price setting by EU companies on non-EU companies upon implementing its regulation (Regulation (EC) No 717/2007) on international roaming rates for mobile telephones. The regulation defines upper limits on retail and wholesale prices for calls made while roaming between EU Member States.

In its FY2007 reply, the EU said that, firstly, this regulation targets intra-Community roaming and not international roaming, and therefore does not give rise to discrimination between EU and non-EU countries, and, secondly, the EU recommends negotiations between the EU and third country operators.

(ii) Recent developments
As part of a review of this regulation, the Commission held in 7 May 2008 the public consultation, "Review of the functioning of Regulation (EC) No 717/2007 (the "Roaming Regulation") and its possible extension to SMS and data roaming services."

According to the above document (p3), between April and September 2007 wholesale rates sank from 1.10 euros to 0.49 euros per minute, and retail prices sank from 0.58 euros to 0.24 euros per minute. Generally speaking, the GOJ welcomes these price decreases in the EU, the favorable impact it has on competition as well as the increase in consumer convenience. However, such major price decreases in short time frames may place excessive cost burden on EU business. Japan is concerned that these burdens may cause EU operators to set higher prices for third country operators.

According to the document, the Commission still takes the position that this regulation will not be applied to international roaming agreements between EU operators and third country operators. Nevertheless, the GOJ remains concerned that under the circumstances of high cost pressures in the EU, the regulation can have substantial impact on price setting in international roaming contracts between Community operators and third country operators.

In a recent development, on 23 September 2008 the European Commission submitted a proposal to the European Parliament and European Council to extend the applicable period of this regulation and expand this regulation to SMS and data communication. The GOJ would like to register a similar concern about SMS and data communications.

Meanwhile, as a forthcoming remark with regard to Japanese concerns, the GOJ is taking note of the public consultation document's comment that, "The Commission will continue to monitor whether market players seek to compensate for the effects of the Regulation by increasing the prices for other services," (p4). Furthermore, the GOJ appreciates that in the same document (p8) the Commission discusses the impact of this regulation on roaming agreements between EU operators and their counterparts in third countries (Q15) and whether or not EU operators have negotiated agreements with third country operators concerning a reduction of roaming tariffs comparable to those set in the regulation (Q16).

Therefore, the GOJ expects that the above monitoring (on whether Community operators seek to compensate for the effects of the Regulation by increasing the prices for other services) by the Commission will bring about effect as safeguard measures to prohibit unfair and discriminatory price setting by Community operators on third country operators that may be caused by the regulation in question through price reduction for intra-EU mobile telephone roaming.

(iii) GOJ's proposals
Based on the above observation, the GOJ continues to request that the European Commission adequately acknowledge Japan's concern regarding the impact of the regulation on roaming agreements between EU and non-EU operators, and implement appropriate measures including competition safeguards to prohibit or control unfair and discriminatory price setting which can be imposed by EU operators on non-EU operators.

As for specific measures, the GOJ requests that the Commission conduct regular monitoring on the implementation of the said directive by Member States and make an assessment on whether the current upper limit is set at an appropriate level from the viewpoint of preventing Community operators from compensating for the effects of the said regulation by increasing the prices for other services, including roaming services for third country operators. Furthermore, the GOJ requests the Commission make public the result of such monitoring, and in cases when the Commission identifies such acts of compensation, the GOJ requests the Commission should take necessary measures to rectify such situations in a swift and accurate manner and report them to Japanese government.

(b) Application of unbundling regulation to fibre-optic networks

In its FY2007 proposal, from the perspective that it is important to develop a fair competition environment through applying strict regulations when dominant operators in the telecommunications market make new investments in new-generation networks, the GOJ requested that the European Commission confirm whether the text of the Commission's Recommendation on Relevant Markets, "wholesale (physical) network infrastructure access (including shared or fully unbundled access) at a fixed location," includes the obligation to ensure fibre-optic network access.

A reply by the EU explained that:(i) the transmission media (copper wire or fibre-optic) is irrelevant when considering the necessity for regulations based on the principle of technological neutrality of the 2002 Telecommunications Regulatory Framework Directive; (ii) this stance is the same for new-generation networks; and (iii) it is important to ensure appropriate access and a level playing field in the future if third-party network access is a premise for effective competition. The GOJ recognises that Japan and the EU share a common direction regarding regulatory policy for new-generation networks such as fibre-optic networks. The GOJ appreciates the EU's response.

In recent developments, on 18 September 2008 the European Commission released a recommendation on regulations for Next-Generation Access broadband networks. The GOJ takes note of the fact that the recommendation dictates that regulatory authorities of EU Member States must allow access to dominant operators' networks at the lowest level, and, particularly in regard to the path of dominant operators, that authorities must allow for competitive operators to use the path when developing fibre-optic networks.

The EU's maintaining an adequate competitive environment in the ICT market is of significant interest to the EU as well as other major world economies, including Japan. The GOJ notes that the EU and Japan share a common direction regarding the necessity of appropriate competition safeguard measures including unbundling regulations on new-generation networks such as for fibre-optics.

Just as the EU recognises in its recommendation, the EU is still in its transitional phase of developing new-generation networks. It is therefore important for Japan, which has developed new-generation networks ahead of the EU, to support reform efforts in the EU by sharing its knowledge and experience.

(c) Cooperation in countermeasures against illegal and harmful information

In advanced countries such as Japan and those of the EU, the rapid development and spread of the Internet has brought great convenience for its users. At the same time, however, circulation of information that is illegal, harmful to certain individuals, that offends public order and morals, or jeopardises the lives of individuals is becoming a significant social problem.

In response, the GOJ is proactively working to coordinate existing efforts relating to countermeasures against illegal and harmful information in consideration of the 2008 Act on the Development of an Environment that Provides Safe and Secure Internet Use for Young People and the Amended Act on Regulation of Transmission of Specific Electronic Mails. Moreover, the GOJ is planning to formulate a "Japan Safer Internet Program" by the end of 2008 as a comprehensive policy package clarifying the future direction of countermeasures for illegal and harmful information on the Internet. Japan acknowledges that the European Commission also implements measures such as the Safer Internet Plus Programme and is working to promote self-imposed regulations in the private sector and raise awareness of users.

In addition, Japan and the EU agreed to enhance cooperation in "security of networks and ICT usages" in Japan-EU Cooperation on Consumer Safety and Protection, the joint press statement annex from the 17th Japan-EU Summit.

In consideration of the increased global need for countermeasures against illegal and harmful information and the individual efforts of Japan and the EU, Japan sees value in enhancing cooperation between Japan and the EU by sharing best practices of countermeasures. For that purpose, the GOJ wishes to continue exchanges of views with the EU by taking up this issue within the existing framework of Japan-EU Policy Dialogue and others.

2. Financial Services

(1) Overview [EC, M.S.]

In the field of financial services, the world has witnessed a variety of both immediate and unprecedented measures take to address the global financial crises. On 15 November 2008, the Summit on Financial Markets and the World Economy was convened in Washington, D.C., in the United States, where the leaders agreed the Common Principles for reform of financial markets and also decided an action plan to implement the said principles.

In line with the above principles and action plan, it is essential that Japan and the EU continue to implement necessary and appropriate measures in a swift manner. On the part of the Japanese government, while paying close attention to the regulatory policies of the Commission and countries in Europe, we wish to ensure good coordination with European partners in addressing the issue. From this perspective, the GOJ desires to have discussions on the issue with the EU also in the framework of the Japan-EU Regulatory Reform Dialogue when necessary and appropriate.

As for FY2008 Japanese proposals, the GOJ wishes to present two new items, one of which is related to the issue of regulations on credit rating agencies, whose introduction is currently under consideration in the policy of the European Commission and is of particular concern to the GOJ.

Concerning the equivalence between the Japanese Generally Accepted Accounting Principles (GAAPs) and the International Financial Reporting Standard, which the GOJ has requested in its proposals since FY2004, the GOJ welcomes the Commission’s announcement on December 12, 2008, that the Japanese GAAPs were found to be equivalent to IFRS as adopted by the EU. The decision enables Japanese companies listed on EU market to continue to file their financial statements prepared in accordance with the Japanese GAAPs, and it ensures the openness of both Japanese and EU financial markets. The decision in itself is a solid achievement founded by cooperation between Japanese and the EU authorities toward the convergence between the Japanese GAAP and IFRS. In this light, the GOJ highly appreciates efforts made by the EU side. It also rightly values the EU’s decision as a proof of confidence and high quality placed in the Japanese GAAPs.

(2) Regulation of credit rating agencies [EC] (♦)

On 12 November 2008, the European Commission announced proposed regulations that included the introduction of a registration system for credit rating agencies. In this proposal, there is a requirement for the registration of credit rating agencies with the Committee of European Securities Regulators in order that the ratings granted by such agencies be used for regulatory purposes within the EU. The establishment of corporations within the EU is also a requirement to gain this registration.

In light of the fact that the application of ratings from credit rating agencies transcends national borders, it is clear that the regulation of such agencies, as confirmed in the G20 Declaration announced at the Summit on Financial Markets and World Economy held on 15 November 2008, should be tackled with the international cooperation of authorities from each country, and be consistent with the internationally agreed “IOSCO Code of Conduct Fundamentals for Credit Rating Agencies”.

However, the obligation to establish a corporation within the EU is not consistent with the IOSCO code. Also, as it does not rely on supervision by the regulating authorities of the home country, it also contradicts the approach of strengthening international cooperation.

While some of the large-scale non-EU credit rating agencies will be able to set up a legal entity within the EU and act accordingly if such an obligation is introduced, the small- to medium-scale ones from outside the EU, including those of Japan, may be forced out of the EU market, finding their competitive condition unjustly strained.

In addition, obliging non-EU CRAs to establish a legal person in the EU might breach the GATS-WTO obligation of a certain EU Member State to not restrict the provision of service by maintaining or adopting measures that require the establishment of specific types of legal entities.

Therefore, the GOJ strongly requests that the European Commission remove from the draft regulations relating to credit rating agencies the obligation to establish a legal entity within the region.

(3) Equivalence of auditing [EC] (♦)

A notification system concerning foreign auditing firms has been introduced into Japan's Revised Certified Public Accountant Law, which was established in June 2007. In the event that European auditing firms and the like, which have given notification to the Financial Services Agency, provide necessary information based on Japan's Certified Public Accountant Law, the GOJ requests that the European Commission and the authorities in the EU Member States show support.

Furthermore, the GOJ calls for the European Commission and EU Member State authorities to provide Japanese auditing firms, which have registered with those authorities or had interim measures applied, with an efficient supervisory framework wherein inspection by the Japanese Financial Services Agency is accepted, and inspection by the EU Member State authorities is not required.

(4) Financial standards to be used for individual financial statements [EC, M.S.]

The GOJ understands that the European Commission encourages the Member States to permit the use of statutory financial statements which apply IFRSs, but there are some cases in which Member States apply their own accounting standards to the individual financial statements of non-listed companies and do not recognise IFRSs. While it is relatively easy to identify differences between IFRSs and Japanese GAAP, it is not always easy to identify differences between the unique accounting standards of each Member State and Japanese GAAP. Therefore, the handling of accounting in this way cannot be considered efficient for subsidiaries of Japanese companies that wish to prepare their financial statements in accordance with IFRSs for the parent company.

Therefore, the GOJ requests that each Member State permit the use of IFRSs and Japanese GAAP in the preparation of non-consolidated financial statements in the EU Member States for improving the business environment for foreign subsidiaries in the EU.

In its FY2007 reply to the GOJ, the European Commission stated that since the accounting standards of each country serve as the basis of profit and loss calculations which play an important role in taxation and distribution of dividends, it could not force its Member States to accept the impact of introducing IFRS. It also explained that discussion regarding the effect that IFRS would have on the profit and loss calculations is ongoing, and that the information obtained in this area would be used in future consideration into the adoption of IFRS for individual financial statements. The GOJ would like to know how the discussion has progressed since then, and also requests that the European Commission recommend that each country permit the use of IFRS and Japanese GAAP in the creation of individual financial statements.

3. Health Care and Pharmaceuticals

(1) Overview [EC, Germany and France]

The GOJ would like to focus on two subjects as priority issues in the area of health care and pharmaceuticals in FY2008. The first subject is the reinforcement of measures to prevent intrusions of counterfeit drugs accompanying parallel importation, which has been continuously addressed in the framework of this Dialogue since 2004. The second subject covers regulation concerning the registration system of medical equipment.

The GOJ continues to have interests and concerns regarding the abolition of Germany's jumbo groups and the issue of France's target growth of medical expenses, both taken up in the Dialogue in FY2006. The GOJ hopes for further efforts on the part of both countries in promoting regulatory reforms in these respective areas.

On the other hand, concerning the review of the classification of medical X-ray film for direct radiography ("X-ray film, medical screen" and "X-ray film, medical, non-screen") addressed in FY2007, the GOJ presented opinions at the public consultation on the "Recast of the Medical Devices Directives" (MDDs), held from May 9 through July 2, 2008. There the GOJ renewed its call on the EU to adopt the GHTF risk-based classification rule in a new legal framework. The GOJ also requested that when the EU formulates the new legal framework, it undertake review to avoid any possible excessive regulation, giving due consideration to stakeholders, and that as soon as a draft of the new legal framework has been formulated, the EU present the draft in a new round of public consultation. The GOJ hopes that these opinions will be duly reflected in the future; otherwise, the GOJ would consider taking up the subject again in the next Dialogue.

(2) Reinforcement of measures to prevent intrusions of counterfeit drugs accompanying parallel importation [EC, M.S.]

In the framework of this Dialogue, the GOJ has been continuously taking up the question of intrusions of counterfeit drugs accompanying parallel importation from the viewpoints such as patients' health and safety and avoidance of possible shift of blame to the manufactures of original products.

This is against the background that complicated distribution channels of parallel importation are prone to induce intrusions of counterfeit drugs, besides practices such as repackaging often accompanying unpredictable shortcomings or defects. Therefore, the GOJ considers that parallel importation of drugs requires thorough supervision and control that include punitive measures against malpractices and defects that can accompany such trade. Moreover, the GOJ would like to point out that if any serious situations occur in which manufacturers voluntarily have to recall their products because of counterfeit drugs intrusion, the manufacturers would incur not only recall costs, but also a loss of sales that would otherwise be materialised in the future, as well as imputative legal responsibilities and the setback of social credibility.

Based on such recognition, the GOJ requests the following two points:

(A) Tougher and thorough supervision and control over counterfeit drugs
Recognising that the EU authorities also are strongly interested in this issue, the GOJ highly evaluates the European Commission's proposed resolute actions announced on March 11, 2008, in the document entitled "Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines"

(hereinafter referred to as “Key Ideas”).

In particular, the GOJ supports the Commission’s concrete proposals to prevent the distribution of counterfeit drugs by means such as having pharmaceutical regulations target all related parties including parallel importers, brokers and traders and reinforcing regulations on repackaging, those proposals being framed based on the Commission’s recognition of the current situations and problems of the distribution channels apt to induce counterfeit drugs. The GOJ hopes that such measures in the “Key Ideas” will be implemented at an early stage.

(B) Avoidance of the manufactures’ assuming imputative responsibility
It remains difficult to wipe away concerns about the malpractices and defects accompanying repackaging and other problems, such as failure to insert proper attached documents. Nevertheless, as no reference was made in the “Key Ideas” regarding the location of the responsibility of recalling products when cases such as medical accidents occur, the GOJ submitted an opinion in the public consultation with regards to the “Key Ideas” that it is absolutely necessary to clarify the location of the responsibility of recalling products in the forthcoming legal proposal in order to avoid such a situation as manufactures having to assume imputative responsibility. The GOJ hereby reiterate the request, while at the same time requesting that new legal proposals and draft texts on this area be duly presented for public consultation and sufficiently reflect opinions of non-EU manufactures as well, including those from Japanese industry.

<Reference 1>
As for pharmaceuticals, the EU is not a single market; rather each Member State has a market that considerably differs from the others due to the different levels of consumption prices and the particular medical system created by each Member State. This environment allows for large drug price differences within the EU, giving grounds for active parallel importation of drugs and further expansion of such trade. In fact, while drug sales have grown by 4.7% in the EU, sales of parallel import drugs have grown by as much as 14.1%. Moreover, the amount of parallel import drugs has reached US$4.6 billion, with losses incurred by pharmaceutical companies being estimated at between US$1 billion and US$1.5 billion. (See the IMS (International Medical Service) report.)

<Reference 2>
In response to the public consultation on the above-mentioned “Key Ideas,” the GOJ has made requests concerning the following points in its comments as well, besides the request for avoidance of the manufacturers assuming imputative responsibility.

1. Regarding obligation of a specific record (pedigree) and traceability (pp.8-9), it is not clear the extent to which the requirements on the outer packaging may become complicated. The GOJ hopes that due consideration will be paid so that additional costs for manufactures are kept to be minimum.
2. Regarding a mandatory notification of the manufacturing/import of active ingredients (pp.11-12), it is not clear as to which manufacturing stage of active ingredients is subject to this obligation. The GOJ requests the EC that the mandatory notification be not applied excessively and unnecessarily.
3. Regarding requirement of regular audits of active substance suppliers on GMP compliance by manufactures and importers of medicinal products and requirement of control of active substances via sufficiently discriminating analytical techniques as a mandatory method for identification by the manufacturer of the medicinal products (pp.12-13), the GOJ hopes that due consideration will be paid so that the additional costs and time will be kept to the

minimum necessity and not cause an excessive burden on manufacturers.

4. Regarding equivalency of GMP (pp.13-14), the GOJ proposes that a legal proposal which follows this communication should clarify the definition of "equivalency," and that it should be consistent with the standards that have won relevant consensus from the international community (ICH, WHO, etc.).

(3) Unification of the medical equipment registration system in the EU [EC, Italy] (♦)

Italy's Health Ministry specified that, save for certain exceptions, no medical equipment sold in Italy should be purchased, used or distributed in domestic medical services, unless such equipment is registered in the domestic database by December 31, 2008 and included in the designated lists. This rule appears in Article 5 of the Health Ministerial Ordinance dated February 20, 2007 (featured in the official gazette No. 63 dated March 16, 2007). (This rule also applies to such medical equipment sold in Italy on and after January 1, 2009, when the ministerial ordinance in question comes into effect.) Currently, however, the Government of Italy is examining the possibility to postpone the enforcement of this new registration system and sales regulation. Japan's concern is that this sort of compulsory registration system of medical equipment by a single Member State would undermine the smooth distribution of medical equipment within the EU and impose massive costs on manufacturers.

For this reason, the GOJ requests that the Government of Italy review the above-mentioned ordinance and rethink the necessity of such an ordinance. At the same time, the GOJ requests that the EU set up a unified database registration system within the EU, in order to fully exploit the merits of the EU's single market and to facilitate both internal and external companies selling their products in the EU market.

To establish a single and common registration system within the EU, the GOJ thinks that the existing EUDAMED (European Database for Medical Devices), currently used by five to six governmental authorities of the Member States, could be able to be applied, if renovated so as to be perfectly equipped with a completely functional system for medical equipment, including unified certification system for products. The GOJ requests that the EU establish such system so that respective Member States will no longer need to introduce or maintain their particular domestic registration systems.

<Reference>
Currently, with regards to medical equipment in the EU's internal market, each Member State provides domestic regulations and ordinances in accordance with the EU's plural medical devices directives. In the public consultation held from May to July 2008 for the purpose of the recasting of the medical devices directives and eventual strengthening of the whole legal framework, the document entitled "Recast of the Medical Devices Directives" suggests the implementation of "a Regulation" to ensure uniformity as to definition of a medical device and the rules for classification and the registration procedures (p.15), and also the establishment of a "central European registration system for devices" (p.12).
(see http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm)

4. Food safety, agricultural and fishery products

(1) Overview [EC]

Concern for the safety of food is steadily growing both in Japan and Europe, and it is important to further develop cooperation between the EU and Japan in this area. The GOJ therefore welcomes the fact that the work in creating a memorandum of cooperation between Japan's Food Safety Commission and the European Food Safety Authority (EFSA) is now in its final stages.

The GOJ appreciates the EU's efforts in promoting the harmonisation of food safety standards at the Community level with the aim of protecting health and safety and maintaining a high standard of consumer protection through the Regulation EC/178/2002. In the area of food safety, Japan has also been implementing appropriate regulations founded on reasonable and scientific grounds in view of the strong concerns of its citizens in this area.

At the same time, the GOJ believes that the appropriate export of food products must not be hampered by the excessive and unreasonable implementation of measures in the name of securing food safety standards.

The prolonged period taken for safety and equivalence inspections, which in no way reflects the original purposes of the food safety standards, and uniform regulations, which do not appropriately take into consideration the characteristics of the food products, are restricting export opportunities and imposing an excessive burden at the time of export. For this reason, the GOJ took up three proposals as priorities in the FY2007 Regulatory Reform Dialogue. Of these, the GOJ would like to give the EU credit for its forward-looking response to the proposals pertaining to the export of meat and meat products and equivalency approval for the organic JAS Standard. However, no satisfactory response was received in the written reply to the proposal concerning new regulations on the export of fish oil, and the fact that a sufficient explanation was not given at either the Experts Meeting in March or the High Level meeting in October is of some concern.

The same proposals will be raised in the FY2008 Regulatory Reform Dialogue as in the previous year. Therefore the GOJ would like the European Commission to continue its prompt, forward-looking responses with regard to the export of meat and meat products and equivalency approval for the organic JAS Standard, as well as to make a serious response to Japan's reform proposal concerning new regulations on the export of fish oil. These proposals are important for Japan to meet the needs of consumers in Europe for high quality agricultural and fishery products and food.

(2) Request for lifting the suspension on the export of Japanese meat and meat products to EU Member States [EC]

Countries authorised to export beef, pork, horse meat, lamb, goat meat and meat products to the EU and the requirements of exports are set forth under EU directives. A country which wishes to export meat and meat products to the EU needs to be included in the list of authorised countries (third countries). In March 2006, the GOJ submitted its answers to the questionnaire from the European Commission with the aim of having Japan listed on the list of authorised countries (third countries) for meat and meat product exports. In particular, Japanese beef, collagen casing and gelatine are of significant interest to Japan. Therefore, the GOJ has requested the European Commission to give special consideration to these items.

Regarding Japanese beef, at the start of 2008 the European Commission proposed making on-site inspections, which were conducted in meat processing facilities, and other sites, between October 22

and 30, by an investigation team from the Food and Veterinary Office (FVO) of the European Commission.

On the other hand, in the October 2008 on-site inspections, collagen casing and gelatine processing facilities were not investigated, so the GOJ requests that these facilities also be inspected.

(3) Equivalency approval of the organic JAS Standard with the EU organic product certification standard [EC]

In March 2001, Japan recognised the equivalence of the European Council Regulation No. 2092/91 (hereafter "the EC Regulation") with the Japanese Agricultural Standards for organic crops and organic crop products (hereafter "the organic JAS Standards"). As a result, it became possible for Japanese importers certified by a registered Japanese certifying body under the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law) to attach the organic JAS logo on organic crops and organic crop products produced or manufactured in the EU-15 countries in compliance with the EC Regulation, and to distribute them in Japan.

On the other hand, because the equivalence of the organic JAS Standards with the EC Regulation has not yet been received, organic products which are exported from Japan to EU Member States must receive direct approval from an EU certifying body and this requirement results in additional administrative procedures and costs relating to organic certification. The GOJ made a request to the European Commission to make an equivalence determination between the organic JAS Standards and the EC Regulation in August 2000 and completed submitted required materials and responded to questions in February 2006.

The additional points which were raised in a letter from the European Commission on 7 March 2008 were discussed between Japan and the EU at an Experts Meeting held in Brussels on 11 March, and an official document was sent to the European Commission on 8 July. Subsequently, in the letter from the European Commission on 25 September, the EU reported that all points except one technical point (the use of forms of DL-tartrates in foodstuffs) have confirmed the organic JAS Standard equivalency, and that therefore it would be possible to move on to conducting on-the-spot inspections in Japan.

The GOJ requests that the European Commission promptly execute the on-site inspection in Japan, and quickly addresses the remaining technological challenge in order that the equivalence between the organic JAS Standard and the EU organic product certification standard can be recognised through cooperation between Japan and the EU as soon as possible.

(4) New regulations relating to the export of fish oil [EC]

Due to the November 2006 revision of EU regulations for fishery products, in order to export fish oil to EU countries, exporters are required to attach health certificates to the fish oil, as other fishery products, following the certification or registration of facilities involved in the production of the product in accordance with EU regulations (transitional period for implementing this measure until the end of October 2007 was extended twice, once until the end of October 2008, and then until the end of April 2009). Therefore, an exporter is required to have all relevant facilities in the supply chain (i.e. the fishing vessel that catches the bonito (the raw material), the fishing market for landing, the refrigerated storage used, the primary plant where the fish are processed (bonito processing plant), the fish mill, and the final production plants) certified or registered anew in order to export fish oil to EU countries.

In the preparation of fish oil at final production plants where it is refined, the product undergoes heating, deacidification, bleaching, and molecular distillation processes where any potential threat to

food hygiene is completely eradicated, and therefore the GOJ believes that the new measure is an excessive regulation. Furthermore, fish oil from Japan has been exported to EU countries for almost 10 years and during that period there have been no problems regarding food hygiene. Therefore, the GOJ repeats its FY2007 request for the European Commission to ease these regulations to make possible the export of fish oil to EU countries on the basis of certification of the final production facility alone by a competent authority in Japan.

The FY2007 reply of the EU to this proposal was limited to an explanation of the amended rules that serve as the basis for new regulations. It did not address the proposal to ease the regulations. Furthermore, there was no European Commission specialist among the attendees at the FY2007 Experts Meeting which dealt with this proposal. Subsequently, on 2 October 2008, a relevant authority of the European Commission insisted, as a scientific basis for demanding certification and registration of facilities in all supply chains, that there were reports to the effect that fish oil refined from deteriorated fish poses a significant danger to food hygiene.

Pointing to the fact that no WTO/SPS notifications were made upon the introduction of these regulations by the European Commission, the GOJ would like to request in its FY2008 proposals that the European Commission gives a clear response to the questions of what steps it will take in the future, and whether or not it will consider special relaxation measures for Japan, taking into account its compliance record so far (in the event that there will be no further extension of the transitional period and no amendment to the regulations). The GOJ also calls for the European Commission to present the scientific basis behind the necessity of ensuring the safety of fish oil from the raw materials stage, and strongly urges it to secure specialists' attendance at the FY2008 Experts Meeting. To aid the European Commission in its consideration of special steps for relaxing these regulations, the GOJ is prepared to explain at the meeting, in concrete terms, that all hazards in food hygiene are completely eliminated at the final production facility and that as yet there have been no food hygiene problems in Japanese exports of fish oil to EU countries.

5. Taxation

(1) Overview [EC, M.S.]

While the EU continues to look into the harmonisation of corporate tax systems, there has been no great improvement in the issue of discrepancies among the tax systems of EU Member States with regard to, among others, transactions across national borders within the EU. Under such circumstances, companies operating in the EU are still facing the problem of additional tax and administrative burdens. The GOJ recognises that the harmonisation and unification of company tax systems in the EU will be beneficial not only for Japanese companies operating in the EU but also for EU companies. Therefore, the GOJ continues to urge the European Commission and each EU Member State to work towards an early realization of such policies of harmonisation.

(2) Cross-border offset of profits and losses [EC]

The GOJ has repeatedly stressed that the cross-border offset of profits and losses in the EU should be seen not only as a means to reinforce the EU Internal Market, but also as a matter of great importance for companies of non-EU countries operating in the EU.

According to the December 2006 communication to Member States on the "Tax Treatment of Losses in Cross-border Situations," the Commission recognises the necessity of automatically and directly factoring into loss calculations those branch offices and permanent establishments established in other Member States. It also states that subsidiaries established in other Member States should also be considered as part of profit-loss calculations. The GOJ highly appreciates such a position of the Commission. However, as regards the proposal for a directive resulting from this communication, the Commission maintains in its reply to the GOJ that direct taxation in the EU is subject to unanimous voting and since there is no expectation of such a unanimous vote, it has at present no plan to present a proposal of the directive. Nonetheless, the GOJ hopes that the European Commission will seek a speedy resolution of the issue, striving to improve the political environment within the EU with a view to formulating the directive and securing its unanimous approval.

(3) Harmonisation of taxation

(a) Transfer Pricing Taxation [EC]

The GOJ shares the European Commission's recognition that, from the perspective of increasing the international competitiveness of both the Japanese and EU businesses operating in the EU, it is essential to bring about a reduction of compliance costs of transfer pricing through the unification, simplification and rationalisation of transfer pricing regimes. The GOJ requests further efforts be made through the work of the "EU Joint Transfer Pricing Forum" (JTPF) to secure a resolution to the issue. The GOJ understands that the European Commission is currently engaged in establishing a common understanding within the EU on the issue of transfer pricing within groups, and continues to express hope for prompt progress on the aforementioned work and the early establishment of a policy to reduce compliance costs of transfer pricing.

(b) VAT [EC]

The efforts of the European Commission in this area are highly appreciated. At the same time, as differences in the practical application among EU Member States constitute obstacles for Japanese companies operating within the Internal Market, it is continuously requested that the application of the VAT system be unified. The political agreement reached over the amendment to the VAT Directive made by the Economic and Financial Committee in December 2007 is an important step in achieving this. The GOJ continues to expect that harmonisation of the VAT rate and items subject to VAT, as well as the simplification and expedition of registration and refund procedures, will be promptly realised.

(c) Passenger car tax system [EC, M.S.]
The GOJ understands that the directive proposal for the harmonisation of the passenger car tax system, including proposals for (i) the gradual abolition of car registration tax within the EU and (ii) tax refunds to prevent dual taxation accompanying a change of address or the resale of a car after registration, did not gain consensus at the Economic and Financial Council in December 2007, and further that the moratorium period for the gradual abolition of car registration tax has been extended to the latter half of 2010. The GOJ continues to call for the harmonisation, or otherwise convergence, of the EU region passenger car tax system through the enactment of the above draft proposal, both from the perspective of non-EU manufacturers' sales promotion and for the benefit of EU consumers in general. Further, the GOJ requests that, pending the adoption of the draft directive, the European Commission will advise Member States to use national legislation to reduce the burden to the greatest possible degree.

(4) The Merger Directive – Deferred taxation on unrealised gains on goodwill [EC, M.S.]
The Merger Directive (2005/19/EC) provides for the deferred taxation on capital gains arising from cross-border business restructuring carried out in the form of mergers, divisions, transfers of assets or exchange of shares within the EU. However, unrealised gains on the cross-border transfer of goodwill are not included in the scope of deferred taxation. Japanese companies operating within the EU are restructuring their business groups in order to remain competitive in the Internal Market. In such cross-border restructuring, they often transfer goodwill within the group, resulting in substantial tax imposition. This constitutes an obstacle to reorganisation, and some companies have in fact given up reorganisation.

The European Commission's FY2007 reply says that the goodwill arising due to the restructuring operation may be taxed since no deferral rules are provided for in the Merger Directive. Meanwhile, the GOJ requests that the EU continue to make efforts to realise uniform implementation of the Merger Directive in the EU with the aim of extending the scope of deferred taxation and preventing dual taxation.

(5) The Merger Directive – Shareholding requirements [EC, M.S.]
The different application of the Directive in each EU Member State constitutes obstacles, in terms of work and cost, for Japanese companies considering restructuring of their groups in the EU. In addition, due to provisions under Japanese tax law relating to the scope of foreign tax credit, it increases the risk of dual taxation, and the obligation of long-term shareholding is a significant burden to companies conducting activities in the EU.

While the amended Merger Directive has not received unanimous approval from EU Member States, and regulation on long-term shareholding was not included, the European Commission has made clear its intention to make positive efforts to tackle this issue. The GOJ pays attention to this and continues to ask the European Commission to realise unified implementation of the Merger Directive throughout the EU and ask EU Member States not to impose long-term shareholding requirements which may pose substantial obstacles to corporate restructuring.

(6) Common consolidated corporate tax base [EC]
It is desirable that Japanese companies operating within the EU compute the taxable income of the entire group in the EU according to one set of accounting standards such as IFRS. However, under the current situation, companies need to create multiple sets of financial statements based on multiple

accounting standards and are thus bearing a significant burden, such as legal and accounting costs.

The GOJ understands that, while the European Commission has confirmed the importance of the common consolidated corporate tax base (CCCTB) and is moving forward in its consideration through various actions such as establishing a working group composed of experts from governments of the Member States and conducting analyses on the degree of its impact, the Commission at the same time has explained that the CCCTB is not a regulation and that a voluntary instrument is preferred in this case. However, the GOJ believes that a common consolidated corporate tax base would herald a great improvement in the business environment of the EU. Therefore the GOJ continues to request that the Commission maintain the option of putting this instrument into law and make progress toward a speedy resolution of the issue.