



EUROPEAN COMMISSION

EU Priority Proposals
for Regulatory Reform in Japan

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INDEX

Introduction	2
1. Investment	4
2. Competition policy	6
3. Telecommunications	8
4. Financial Services	10
4.1. Insurance Sector	10
4.2. Banking	13
4.3. Asset Management	13
5. Legal Services	14
5.1. Joint Enterprise, Employment and Partnerships	15
5.2. Qualifying experience needed to be licensed in Japan	16
6. Transport	16
6.1. Air transport	16
6.2. Sea transport (International Shipping)	18
7. Testing and Certification	19
7.1. Recognition of foreign testing/inspection bodies	19
7.2. Inspection and certification of tank containers	20
8. Recognition of International Standards	21
8.1. Engines for fishery vessels	21
8.2. Tank containers	22
8.3. Electrical equipment	23
8.4. Motor Vehicles	23
9. Sectoral Concerns	26
9.1. Cosmetics	26
9.2. In-vitro Diagnostics (IVDs)	27
9.3. Sanitary and phytosanitary issues	28
Annex 1	Issues where the EU will continue to monitor progress
Annex 2	EU Supplementary Proposals for Regulatory Reform in Japan

Introduction

The European Union welcomes the recent announcement by the Government of Japan that it will continue the regulatory reform process with a new Three-Year Regulatory Reform Programme from the beginning of financial year 2001. The EU continues strongly to support this reform process. It is also committed to the dialogue between the EU and Japan on regulatory reform: in this two-way dialogue, each side can draw inspiration from the experience and concerns of the other.

The EU is therefore pleased to submit today, in the framework of this dialogue, revised proposals for regulatory reform in Japan. Special care has again been taken to identify priority areas for reform, and the EU proposals are once more presented in two sets (priority and supplementary).

Experience shows that as reform progresses, governments are increasingly faced with difficult decisions. However, it is important to realise that as the economic environment is constantly changing, the regulatory environment must be constantly updated to keep pace with these changes. While concerns about job security and social stability are inevitable, it is necessary to recall the benefits of regulatory reform to the population at large and the economy as a whole in terms of creating better conditions for business and new employment opportunities. Strong political leadership is essential to promote reform, and to deal with vested interests. It is equally important to have a high-level body such as the Regulatory Reform Committee (RRC) to keep reform at the top of the policy agenda.

Over the next year, there are important issues to be addressed when seeking to create an information society in which entrepreneurship and innovation become economic reality. Of key importance - as the EU has learnt for itself in the creation of its Single Market - is the adoption of cross-sectoral approaches to regulatory reform. Comprehensive approaches are required in order to ensure that the benefits acquired in one sector are not diluted by continued inflexibility in another. Inspiration can be drawn from the co-ordinated approaches which, with explicit political backing, the RRC has brought to IT and environment issues in its "Opinion" of July 2000.

Sweeping reform in the areas of competition, telecommunications, financial and legal services, transport, testing/certification and standards, as suggested in this submission, would go a long way towards lowering costs for all economic operators and stimulating investment, to the benefit of both business and the consumer. However, as requested by the EU-Japan Business Dialogue Roundtable, much also remains to be done to improve the overall investment environment in Japan. The introductory section on investment highlights major cross-cutting issues such as the need to enhance the transparency, accountability, predictability and independence of the regulatory process, as issues to be addressed as a matter of priority.

The EU welcomes progress made in the course of the past year on a number of issues addressed in its 1999 submission. In relation to two priority proposals submitted last year, sea transport (port services) and pharmaceuticals, new legislative and regulatory measures have come into force or are about to do so. The EU welcomes the measures taken and will continue to follow the implementation of the new rules (see Annex 1). In the telecommunications sector, the EU welcomes as a first step in the right

direction the fact that Japan has committed itself to reduce interconnection rates to some degree, but notes that important structural and regulatory issues remain to be tackled.

The EU looks forward to working with the Government of Japan on the basis of these proposals throughout the year to come, in particular with regard to the preparation of Japan's new Regulatory Reform Programme, due to be adopted on 31 March 2001.

As always, the EU stands ready to supply any additional information the Government of Japan may request in relation to its proposals.

1. Investment

Context

Despite significant recent increases in the level of Foreign Direct Investment (FDI) in Japan, the flow of Japanese direct investment abroad was still around 3.1 times higher in Japanese FY 1999 than direct foreign investment in Japan. The inflow of Japanese direct investment in the EU in FY 1999 was double the level of EU investment in Japan, and the disparity in accumulated stock of investment remains huge. The sudden but welcome improvement in its performance in attracting FDI in FY 1998 continued in FY 1999. However, as in FY 1998, the pattern in FY 1999 was of a small number of very large take-overs and capital tie-ups with Japanese firms. This effectively means that the benefits which accrue to the economy as whole through higher levels of investment, domestic and foreign (including greater employment opportunities and access to new technological and managerial know-how), are not permeating as widely through all layers of the Japanese economy as they should.

There is no guarantee that FY 1999's level of FDI will be reached again in FY 2000. It remains the case that foreign investment in Japan tends to be greatest in those sectors that have benefited, or are in the process of benefiting from significant deregulation.

Despite these recent improvements in investment levels, EU (and indeed Japanese) businesses continue to bring to the attention of the European Commission numerous factors which make Japan less attractive as an investment destination for potential investors. In a nutshell, it is significantly more time-consuming and costly to set up a business or get new products or services approved in Japan than is the norm in other modern, industrialised economies. EU businesses operating in Japan raise in particular concerns about the cost of doing business, the transparency of the regulatory system and the implementation of competition policy, and the friendliness of the business environment. It should be noted that these remarks apply more specifically to specialised and often high-tech EU SMEs – as much the backbone of the European economy as larger companies – which often give up their plans to trade or invest in Japan. Some such SMEs are even discouraged after having made a first approach to the Japanese market on their own or under programmes financed either by the EU or by Japan.

Foremost amongst disincentives for potential investors is the high cost of the basic infrastructure for doing business. This comes on top of the already generally higher costs of running a business operation in Japan. Telecommunications interconnection rates (see section 3), harbour fees (see section 6.2), landing fees at Japan's international airports (see section 6.1), domestic transport costs and electricity charges remain persistently at or near the top end of international comparisons. The EU has made concrete regulatory reform proposals in most of these areas, which would significantly lower such costs for both domestic and foreign businesses.

A second area of continuing concern is the **transparency, accountability, predictability and independence of the regulatory process**. The following are amongst the most important concerns regularly voiced by businesses operating in Japan:

- It is difficult to obtain from regulatory authorities written, binding clarification of how they will handle specific regulatory situations. A case in point is Article 65 of the Securities and Exchange Law (which forbids banks from doing securities business and vice-versa). This **lack of transparency** directly affects European securities firms operating in Japan, and the FSA has still not issued any written clarification of its stance.
- When regulatory decisions are made, they are rarely easily available to interested parties in a suitable written form. A case in point is decision-making by Japan's tax authorities, which do not make their guidance available to the public. The consequent lack of a reliable and easily accessible body of precedent creates a **lack of predictability and accountability**, causing businesses unnecessary difficulties in making their way through the regulatory process, with a considerable penalty in time and money.
- **Regulators in many areas of economic activity in Japan lack independence.** For example, Japan's telecommunications sector lacks an independent regulatory authority (see section 3). In harbour transport, for instance, the Ministry of Transport delegates certain regulatory functions, including many with a bearing on free competition, to the Japan Harbour Transport Authority (see section 6.2). This body represents all the major waterfront businesses except the shipping lines, but operates a "prior consultation" process for changes in shipping operations which effectively binds the shipping lines.
- Fundamental conflicts of interest such as the above, coupled with **weak overall competition policy enforcement** by the JFTC (see section 2) contribute to a business environment which all too often unfairly favours incumbent operators over new entrants.

A third area of concern is that the local business environment is still not sufficiently friendly and open for potential investors. Major concerns brought to light in this area by businesses operating in Japan include the following:

- Japan as yet has **no consolidated taxation system** for taxing company groups, and although plans for such a system are in the offing, it is not known when they might be introduced. Thus companies either have to pay more tax, or to maintain sub-optimal and more costly structures in order to avoid paying more tax. They can, for example, neither offset profits and losses between members of the company group, nor set acquisition financing costs against the profits of acquisition targets. The taxation system is thus also an unnecessary hindrance to both corporate restructuring and M&A.
- Businesses still find that **Japan's commercial code lacks clarity**. In M&A cases it is often difficult to know what the applicable rules are, which body enforces them, and how to obtain recourse if investor rights are breached.
- **Access to high-quality legal advice on multi-jurisdictional questions is artificially restricted** by the fact that Japanese and foreign lawyers are still prohibited from practising together in Japan in a single integrated law firm. This is out of step with practice in the majority of industrialised countries (see section 5.1).

The EU fully recognises that Japan has taken a number of measures to facilitate foreign investment, including steps to simplify and rationalise M&A procedures, and the gradual introduction of accounting standards which are in line with international norms. However, structural problems in the business environment persist for domestic

and foreign firms alike, and the continuing imbalance in inflows and outflows of direct investment is anomalous. This has been highlighted in the Joint Recommendation of the EU-Japan Business Dialogue Round Table Meeting of 17-18 July 2000.

Priority reform proposals:

- a. *The Government of Japan should take a broad cross-sectoral approach to investment in the revised Three-Year Regulatory Reform Programme due for March 2001. The EU urges the Government of Japan to introduce a heading into the revised programme entitled “improving the environment for business and investment”, along the lines of the special cross-sectoral approaches proposed for the IT and environment sectors by the RRC in its “Opinion” of July 2000. This would include focusing as a priority on a set of reforms to improve market entry conditions and reduce establishment and basic operation costs (see also relevant EU proposals in specific sectors).*
- b. *The EU urges the Government of Japan to:*
 - (i) *introduce a formal rulings process in cases where a company wishes to have written clarification regarding a planned business situation or a particular regulatory situation;*
 - (ii) *publish regulatory decisions, including official guidance to individual companies, so as to provide a reliable body of administrative precedent;*
 - (iii) *take advantage of the ongoing revision of the commercial code to improve further its clarity, especially with regard to the rules applicable to M&A.*
- c. *The EU urges the Government of Japan to include as many as possible of the Joint Recommendations of Working Group 1 (Trade and Investment) of the EJBDR meeting of 17-18 July 2000, as they apply to Japan, in its revised Regulatory Reform Programme.*
- d. *The EU urges Japan to remove its few remaining non-security related restrictions on foreign investment.*

2. Competition policy

Context

The European Commission fully supports the Japan Fair Trade Commission’s (JFTC) objective strictly to enforce competition rules, and welcomes the JFTC’s positive ongoing efforts to eliminate exceptions and exemptions from the Anti-Monopoly Act, as well as the forthcoming civil litigation system for those who are harmed by anti-competitive practices. A more vigorous implementation of competition policy is an essential step to achieving an open, balanced and modern economy. It not only vital in order to create conditions which ensure that investment decisions are made on a rational and efficient basis, but also for improving the domestic and international competitiveness of Japanese companies and removing barriers for new entrants to the

market, be they domestic or foreign. This commitment needs to be backed up by bold action.

The EU considers that it is essential pro-actively to target core violations and arrangements that keep prices at higher than competitive levels. Violators should not feel safe from prosecution in the absence of a specific complaint against them. It must be noted that in the case of hard core violations evidence is difficult to uncover. Often it becomes available during investigations of other, seemingly unrelated violations. For reasons of deterrence the prescription period needs to be extended. Very short prescriptions convey the message that it is enough to cease (or suspend) the infringement for a while in order to be immune from prosecution. The level of sanctions is also important. In hard core cartel cases, the firms involved often succeed in maintaining considerably higher price levels (sometimes considerably more than 20-30%). A relatively modest overall level of fines or a statutory cap on the amount of pecuniary fines makes it easy for firms to calculate the cost of the highest fine possible if they were caught and factor this into their budget plans. This diminishes significantly the deterrent effect of fines.

The European Commission welcomes the progress towards limiting exceptions and exemptions from the Japanese competition rules. A recent English-language publication by the JFTC (September 2000), entitled “How the Japan Fair Trade Commission ensures a robust economy”, stated that “... *it is crucial to pursue deregulation and conduct a sweeping review of cartel exemptions and other exemptions from the application of the Anti-Monopoly Act ...*”. However, it is not always easy to distinguish between systems which are entirely abolished, systems which are reformed and continue under different conditions and scope, and systems embedded in other laws or administrative regulations which have in practice the effect of making certain anti-competitive practices impervious to the application of the AMA. It would be useful now to focus on exemptions or exceptions that remain in force and provide a clear list of what is still excluded from the AMA.

The new civil remedy system which will come into force in 2001 as a result of the amendment of the AMA in May 2000 is welcome. However, both as regards core infringements by private firms as well as administrative guidance which may encourage or tolerate such practices, civil litigation is in itself not sufficient to replace a tough enforcement policy by relevant government agencies. Essential complements to vigorous enforcement policies are both competition advocacy at all government levels and a review of all administrative guidance currently in force with the aim of eliminating guidance which has anti-competitive effects.

Under the reform of the central government ministries and agencies due to come into force in 2001, the JFTC will become part of the Ministry of General Affairs. It is to be hoped that the independence of the JFTC will not only be maintained, but that steps will be taken if necessary to enhance its independent powers in the context of this reorganisation. The example of the Financial Reconstruction Commission, which established quickly for itself a reputation for robustness under a Minister with Cabinet status, points the way to what could be achieved with the requisite political will.

Priority reform proposals:

- a. *Violations of the Anti-monopoly Act (AMA), in particular in the field of*

distribution and in cases of exclusive and/or discriminatory practices by Trade Associations, should be vigorously pursued and eliminated. The prescription period for such violations should be extended to 5 years from the discontinuation of the violations.

- b. *Sanctions and penalties should be increased and fully applied in order to deter anti-competitive behaviour. The investigating powers and the operational capacities of the JFTC should be further strengthened.*
- c. *Some clarification is needed regarding exemptions and exceptions that remain in force under specific laws and the AMA (for example, in the form of a list indicating the exact nature and scope of each system).*
- d. *The JFTC should review all administrative guidance currently in force in order to verify its conformity with anti-monopoly guidelines. Results of the review should be published. Private parties negatively affected by anti-competitive administrative guidance should have the right to challenge it before the courts.*

3. Telecommunications

Context

The conclusion of the GATS/WTO Agreement showed a consensus among Member countries that liberalisation and the promotion of competition are the most effective instruments to ensure the rapid development of the telecommunications sector and the dissemination of its benefits to the overall economy. It is therefore important not only for the telecommunications sector, but for the IT sector as whole, including the broadcasting and information industries, to develop in Japan an adequate regulatory framework which promotes a competitive environment.

The EU welcomes the Government of Japan's recent deliberations concerning the further liberalisation of the telecommunications market, and the initiative to launch a study on the necessary reforms to Japan's telecommunications legislation. The services of the European Commission submitted extensive comments on MPT's outline of the "Advisory Report on the Ideal Policy for Competition in the Telecommunications Industry" and on the first recommendations by the Subcommittee of MITI's Industrial Structure Council.

The EU's main recommendations are as follows:

In a rapidly changing world, the process of defining the markets by reference to which the market dominance of an undertaking is assessed has to be a dynamic and responsive process. We would urge Japan **to reconsider the designated carrier definition** to reflect effectively the dominance of the NTT Group and of NTT DoCoMo in the market in Japan, while NTT West and East should continue to be subject to dominant carrier rules. The European Commission remains convinced that fair trading conditions should apply to NTT restructuring, and **competition** should also be promoted in the local market in Japan in order to pass on the expected benefits

of deregulation to consumers and industry.

International experience indicates that the local access network usually remains one of the least competitive segments of a liberalised telecommunications market, and the EU urges MPT and its Telecommunications Council to pay greater attention to this area. Providing **unbundled local loops** to all new entrants will increase the level of competition and technological innovation in the local access network, which in turn would stimulate the competitive provision of a full range of telecommunication services, from voice telephony to broadband multimedia and high-speed internet services. This will also facilitate the growth of e-commerce and e-business in Japan.

Regulation of both **interconnection and end user tariffs** must meet the key criterion of creating a truly competitive market, and must secure real possibilities for “arbitrage” by market players so that competition can develop. End user tariff regulation through the establishment of a notification system (instead of an approval system) and a price cap are not of themselves sufficient to detect anti-competitive practices by NTT East and West in Japan. Adequate safeguards and appropriate instruments should be developed to prevent predatory pricing practices. MPT has announced the review of NTT’s interconnection rates for 2002 using a new rate calculation model. This should produce additional rate reductions for 2002. Nevertheless, comments made by the European Commission and industry on several occasions regarding the introduction of LRIC do not seem to have been taken into account by MPT and the Telecommunications Council.

Under the NTT Law only NTT West and NTT East have **universal service obligations**. Other operators are prevented from providing universal service, despite the important benefits that can be derived from such provision. The EU urges Japan to review and clarify its rules regarding the provision of universal service. Moreover, the EU requests that particular attention be paid to the costing methodology, in view of the benefits derived by NTT West and East through being universal service providers, and asks that service suppliers other than NTT also be granted the right to provide universal service according to the “pay or play” principle.

The EU considers that the current regulatory framework regarding access to **rights of way** in Japan still has certain weaknesses, notably the absence of mandatory requirements to grant access to ducts and poles owned by designated carriers or other utilities operating telecommunications services, and the transparency of rules and procedures. Any new legislation in Japan concerning rights of way should provide for a single agency to have over-riding authority to implement a clear, detailed and unified set of rules for the use of rights of way. If this is not possible, a co-ordination mechanism should be established between the Ministries having jurisdiction so that the granting of rights of way can be both simplified and accelerated.

The establishment of **procedures to benchmark and evaluate policy and regulatory activities** is a challenge that all countries with liberalised, competitive markets must face. Such evaluations are needed in order to assess the extent of competition in a given market, for instance when deciding whether to either impose, maintain or withdraw obligations on specific undertakings.

Priority reform proposals:

- a. *Particular emphasis should be put on the prevention of anti-competitive*

practices such as predatory pricing, cross-subsidies from monopolies or quasi-monopolies to competitive market activities, and discriminatory practices or misuse of proprietary customer information. The EU takes the position that an effective dominant carrier regulation (see above) should replace the current NTT law, and firewalls against anti-competitive practices by the NTT Group should be improved.

- b. The telecommunications regulatory authority should be fully independent, impartial, and devoted to the promotion of competition in the Japanese market*
- c. The local loop should be unbundled, and new rules enacted in order to enable new entrants to compete in the market for high-speed advanced data services.*
- d. Further action is required to bring NTT interconnection rates down to levels comparable with other advanced industrialised countries. Adequate instruments and safeguarding regulations are necessary for both interconnection and end user tariffs if the market is to become truly competitive.*
- e. Universal service: the EU recommends (i) that NTT West and NTT East should not be the only operators with universal service obligations and (ii) that measures be taken to ensure that universal service can be provided in a competitively neutral manner.*
- f. Rights of Way: the EU recommends that regulations be rapidly adopted in order to provide mandatory access to ducts, poles and conduits owned by designated carriers operating telecommunications services, and thereby secure effective access for new entrants to rights of way.*
- g. Policy and regulatory impact analysis: The EU recommends that evaluation should be conducted on a regular basis, be open to the public for comment, and be subject to a peer review by other relevant Agencies and Ministries interested in Information Society issues and the promotion of competition in Japan.*

4. Financial Services

4.1. Insurance Sector

Context

The financial Big Bang programme of the Japanese Government - due to be completed in March 2001 - has contributed considerably over the last 3 years to improving the regulatory framework of the Japanese insurance market. For instance, the recent revision of the Insurance Business Law constitutes a step in the right direction. However, a number of hindrances to the creation of a truly dynamic, innovative and sound insurance market remain.

Market share figures indicate that foreign firms still hold a meagre share of the total risk premium, with European insurers' share being a minor proportion, in spite of recent acquisitions by foreign companies in the life sector. Recently announced mergers and alliances between Japanese insurers tend to consolidate more premiums

in fewer groups to the detriment of genuine competition. The EU is therefore seeking further genuine and effective deregulation of the Japanese insurance market.

As from July 1998, the obligation for non-life insurance companies to use rates calculated by the rating organisations has been abolished. But as long as individual product and rate approval is maintained, competition will be stifled and the level of economic regulation will be administratively burdensome for insurers, with delayed delivery of innovative products to consumers.

Despite the progress that has taken place, the scope of liberalisation of the non-life market is not yet significant and should be expanded. In the context of an overall move away from the concept of product approval, all commercial lines products should now be fully deregulated.

The expansion of the product notification system (so-called “file and use”) in 1997 - with respect to rates and riders for insurance products - represents a positive step, but it is limited to some commercial lines. It should be extended to cover all commercial lines, and subsequently personal lines. In addition, the current 90-day processing period should be streamlined down to 30 days.

The EU appreciates the Government of Japan’s aim to ensure a fair degree of consumer protection in the insurance market. However, meeting consumer concerns does not require an approval-in-principle system. Consumer protection and soundness of the insurance market can be adequately guaranteed by a notification system, which is much less cumbersome. A notification system also offers the necessary flexibility to business, allowing for innovation and the placement of new products on the market, thus addressing consumer needs better, and enhancing economic growth. Consumer protection can be ensured through specific “transparency” measures, such as publication of the terms and conditions for the products, including rates and details of the liable person, as well as anti-trust safeguards. In any case, it would be worth considering applying the file and use system to all insurance products that are sold to sophisticated commercial buyers, as these policyholders do not need such far reaching consumer protection measures as individuals do.

Japan’s current supervisory methods hinder competition. In order to introduce genuine and transparent regulatory reform, the process of micro level individual product and rate approvals should be abolished and replaced with macro supervision of the solvency margins and capital adequacy of insurance companies. Japan should apply here its announced principle of transforming its administrative approach from *a priori* regulation and supervision to *ex post facto* checking and scrutiny. In a sector where there is demand for new products tailored more closely to customers’ needs, it is not in the interests of any of the participants in Japan’s insurance market that regulations should continue to act as a brake on competition and innovation.

For new market entries the procedure to obtain an insurance license in Japan should be streamlined and simplified in a transparent way. The information needed and procedure to be followed should be defined objectively and be available publicly. The application should be processed, according to the Administrative Procedures Law, within a period of up to 90 days in accordance with Japan's commitment to the principle of speeding up regulatory procedures.

Provisions governing insurance schemes that apply to public entities, such as the Housing Loan Corporation (HLC) and Post Office (*kampo*), need to be rendered more transparent in order to ensure a non-discriminatory basis for all participants in the insurance market. In principle, public sector entities should not be engaged in the creation of any new products that could be provided by the private sector, especially when they are not subject to the same regulatory oversight as the private insurance sector. Regarding the HLC, there is no open tender process for business and therefore no transparency in the allocation of the markets for non-life products by the HLC Committee. Regarding *kampo* funds, MPT should not be involved in any new underwriting activities. In addition, distribution of and/or participation in existing product offerings should be available equally to all private sector companies, be they domestic or foreign.

Finally, the brokerage system has not been liberalised. Currently, under Ministry of Finance rules, brokers are not allowed to work with agents and nor are they allowed to collect premiums on behalf of the company or the client. In other major insurance markets, collecting such premiums is a normal part of the broker's professional activities. Japan should align its practice to conform with international standards. Ministry of Finance should commit to creating a modern brokerage system under which brokers are allowed to sell insurance products directly to customers, and to collect premiums from both insurance companies and policy holders. Brokers should have the right to submit their tailor-made policies directly to FSA, and not via an insurance company. There are a number of other requirements which hinder the development of the insurance brokerage sector in Japan. A combination of stringent financial requirements and various administrative and processing issues discriminate against brokers and encourage intermediaries to remain as agents. These issues should be addressed so as to encourage the development of brokers and so give customers access to professional independent advice.

Priority reform proposals:

- a. *Abolish product and rate approval for insurance products by a gradual move to a notification system. This is crucial in order to allow services suppliers to operate on a commercial basis. A first positive step could consist in extending the file and use system to commercial lines, and subsequently to personal lines. In addition, the processing period should be reduced to 30 days.*
- b. *The EU urges Japan to move over time to a system of regulation based on solvency ratios and overall financial stability comparable with international standards in the insurance industry. (See also “banking sector”).*
- c. *Streamline and simplify licensing procedures for new entrants to the insurance market, including ensuring that regulatory authorities have the requisite staff to handle applications expeditiously.*
- d. *As regards some government-related undertakings, parity of access for private sector insurers is not guaranteed. We request that insurances arranged through government-related undertakings such as the HLC and Kampo and other similar entities be made subject to the same business rules that are applied to private sector enterprises, including, in the spirit of transparency and non-discrimination, opportunities for foreign companies to participate and compete.*

- e. *Allow brokers to sell insurance products directly to the customers and to engage in the collection of premiums, from both insurance companies and policy holders, as a normal part of their remunerative activities. Allow brokers to submit their tailor-made policies directly to FSA, and not via an insurance company, bearing in mind that brokers are representing industrial and sophisticated commercial clients rather than private individuals.*

4.2. Banking¹

Context

On 1 July 2000, the Financial Supervisory Agency (established in June 1999) was recreated as the Financial Services Agency (FSA) and given increased powers, including taking over the Financial Planning Bureau of the Ministry of Finance. The EU would like to stress the need, at the current stage in the restructuring of the banking sector and its supervisory regime, for the FSA's new policy to make transparency a prime objective. Most importantly, Japanese banks should be encouraged to adopt and enforce prudent principles as regards valuation, capital requirements and disclosure of impaired assets. It would be preferable, whenever possible, for all banks to be subject to G-10 principles. Furthermore, it appears important, in view in particular of FSA's enhanced regulatory status, to improve the transparency of its new regulatory regime. Such a policy would improve both market discipline and market confidence.

Priority reform proposal:

Japan should be encouraged to strive for improved standards of transparency and prudent valuation of assets, striving to apply G-10 principles of disclosure and capital requirements on all Japanese banks.

4.3. Asset Management

Context

In the past, much has been achieved in terms of opening the Japanese pension funds market to Investment Advisory Companies (IACs). However, some limited restrictions remain and should be eliminated in order to offer IACs access to the management of pension funds assets on the same footing as for life insurance companies and trust banks. Also, the EU welcomes the discussions currently going on within the Japanese government on a defined contribution pension system, intended to supplement the current defined benefit system. The EU hopes that IACs will be granted unrestricted access to the management of the related assets.

Access to Japanese pension fund and mutual fund markets by IACs began in 1990 and has been substantially improved. Access to Tax Qualified Pension Plans, a private pension system built on tax exemptions and supplementary to the public pension

¹ See also supplementary proposal on securities requesting the abolition of Article 65 of the Securities and Exchange Law.

system (value approximately ¥ 20 trillion) by IACs has been granted since October 1997. From April 2001, IACs will be granted direct access to the management of both Employee's Pension insurance and National Pension funds (value approximately ¥ 178 trillion).

However, some restrictions still prevent a part of Japanese public assets from being managed by IACs. Ministry of Health and Welfare reports that currently a piece of legislation which aims to grant direct access for IACs to the management of these pension funds, through the use of "specified trust schemes" to a Pension Fund Management Fund (*nenkin shikin unyoh kikin*), is being discussed in the Diet.

Mutual Aid Associations, public pension schemes for civil servants, with funds valued at ¥ 50 trillion, allow limited access for management by IACs. Rules applicable are prescribed by the relevant ministry and vary considerably.

Access to the management of funds administered by the Ministry of Posts and Telecommunications (MPT), including the assets of savings (*yucho*) and life insurance funds (*kampo*) should be fully opened up in order to eliminate the current lack of transparency with regard to the level of access of IACs. . The major difficulty appears to be lack of agreement on the question of the opportunities for management offered to IACs between Ministry of Finance and MPT, both of which are responsible for oversight. In addition, with regard to *kanpo*, the applicable rules for access by IACs are highly complex and allow advisory services only. The EU welcomes the reform undertaken by MPT scheduled for the year 2003 and requests that full direct access will be granted to IACs, a regards both advisory and discretionary investment services.

For Mutual Aid Associations, the 5:3:3:2 rule (bonds, equity, property and foreign assets) on asset allocation continues to apply and gives rise to inefficient portfolio management. Only two associations have so far abolished it.

Priority reform proposals:

- a. *All remaining restrictions on access to pension and mutual aid association funds by Investment Advisory Companies (IACs) should be abolished forthwith regarding both advisory and discretionary investment services.*
- b. *Regarding access to management of yucho and kampo funds IACs should be included in the scheduled reform for the year 2003 and should cover advisory and discretionary investment services. Operational rules should be made transparent*
- c. *The 5:3:3:2 rule on allocation of assets under management by Mutual Aid Association funds should be abolished.*

5. Legal Services

Foreign lawyers in Japan are subject to a regulatory system which imposes upon them restrictions which impede them from offering the highest-quality, seamless and global legal services to their clients. The EU seeks the abolition of the prohibition imposed

on foreign lawyers becoming partners with or employing Japanese lawyers, and of the obligation, imposed on foreign lawyers alone, to meet post-qualification experience requirements before they can obtain a licence to practice in Japan.

5.1. Joint Enterprise, Employment and Partnerships

Context

The opportunities for foreign lawyers to practice in Japan are limited due to a restrictive regulatory regime. While this is a clear problem for foreign, including European, law firms, it also severely restricts the opportunities for young Japanese lawyers to gain experience of supplying international legal services in what is an increasingly global market place. The legal regime regulating the opportunities for foreign lawyers to practice in Japan is based on the revised Foreign Lawyers Law, which entered into force on 13 August 1998.

Current rules prohibit a *bengoshi* from being in a true partnership with or employed by a licensed foreign lawyer (*gaikoku-ho jimushita bengoshi* – “GJB”) who is licensed in Japan. Partnership or employment relationships do not affect the independence and professional responsibility of individual lawyers. In other jurisdictions, which permit such relationships between lawyers qualified in different jurisdictions, neither the independence of individual lawyers nor the quality of the professional service rendered to clients has been adversely affected.

The compromise reached in 1995 by creating the so-called “joint enterprise scheme”, and further amended in 1998, does allow joint work on specific cases by a Japanese lawyer and a GJB. However, it does not allow them to enter into relationships of partnership or employment. The suggestion by the Ministry of Justice (MOJ) and *Nichibenren* that such a prohibition is needed in order to avoid Japanese lawyers engaging in illegal acts is unjustified. It has no basis in experience, is capable of being addressed by the legal system itself, and is protectionist in nature. It also has the effect of creating professional legal environments which are not in the interests of clients by preventing the provision of a seamless service.

Further improvements are therefore needed, mainly in order to introduce the possibility of concluding a full partnership with Japanese lawyers (*bengoshi*) (since without this foreign lawyers do not have access to Japanese law), and also to allow employment of *bengoshi* by foreign legal consultants.

In its report of December 1999, the Regulatory Reform Committee recommended that the Government of Japan should examine how to revise the joint enterprise system so as to make available on the Japanese market legal services “based on comprehensive, general co-operative relationships between foreign legal consultants and *bengoshi*”. For that purpose, MOJ has launched a study into why the joint enterprise system is failing to deliver high-quality, integrated, multi-jurisdictional legal services. This study is most welcome as a first step towards the eventual abolition of all restrictions on partnership and employment.

Priority reform proposal:

Take action to abolish restrictions on partnership and employment between Japanese lawyers (bengoshi) and foreign legal consultants (gaikoku-ho jimusho).

5.2. Qualifying experience needed to be licensed in Japan

Context:

Experience in the country of principal qualification is a requirement for a GJB license. This condition is not imposed on Japanese lawyers. This is a disincentive to set up in Japan, and an unnecessary regulatory barrier to those with less than five years of experience. Such a requirement is to be distinguished from continuing education requirements which exist in some jurisdictions, but which are imposed by the supervisory authorities of the home country, and not by supervisors of the host country.

Progress was made in 1998 in that the experience required to be registered as a GJB was reduced from 5 to 3 years, while at the same time reducing the amount of time spent in Japan that would count toward meeting that requirement from 2 years to 1 year. Also, the place of experience, which used to be limited to the home country, was expanded to include periods during which legal services relating to the licence applicant's home country law were provided in other countries.

Priority reform proposal:

Full abolition of the post-qualification experience requirement before a licence can be granted as a designated foreign lawyer authorised to practice in Japan.

6. Transport

6.1. Air transport

Context

The demand for additional flight services to and from, in particular, Tokyo's international airport, Narita, is great and the provision of such services is vital to the economies of both Japan and Europe. There is a need to increase capacity and reduce unit costs for all users of Japan's airports while further improving slot allocation.

At Narita airport, the number of slots available from the existing single runway could be further increased through changes in both air traffic control procedures and the management of runway capacity. This could be done within internationally recognised noise limits, without compromising safety and before the completion of the second runway. This latter is, in any case, unlikely to be of use to European airlines unless diversion of movements from the existing runway opens up new possibilities there. In

this context the European Commission continues to be willing to sponsor exchanges of information and experience between Japanese and European air traffic control experts.

Improvements appear to have been made to the transparency of slot allocation. However, certain rules specific to Japan's Ministry of Transport (MOT) i.e. the hourly, 3-hourly and daily limits on slot numbers continue to limit the freedom of the slot co-ordinator to meet demand. Furthermore, the allocation criteria to which he works should explain clearly the extent to which IATA guidelines are not applied and the reasons why. Since the two runways at Narita will be operated as separate airports and every slot is a valuable commodity, it is unlikely that anyone will surrender slots at the existing runway in exchange for slots at the new runway. It is essential therefore that non-discriminatory allocation of slots be implemented at both.

Overall, in line with the Government of Japan's commitments, as set out in the revised Deregulation Programme of 31 March 1999, there is considerable potential to simplify and enhance the transparency of regulations and to modify regulations to conform to international standards (IATA guidelines). The EU disagrees with the contention of the Ministry of Transport that these are not deregulation issues. The EU remains convinced that the Regulatory Reform Committee has been right in considering these issues to be of a regulatory nature, and should therefore be dealt with in the context of regulatory reform.

Recent statements by Japanese airlines as well as foreign airlines operating in Japan have shown that issues relating to capacity and costs are beginning to impinge unduly on sound business decision-making. Landing charges in Japan are amongst the highest, if not the highest, in the world. The pricing of international air fares in Japan and the ways in which they may be publicised and settled in that country are all matters of deep concern to the airline industry as a whole. The same applies to the setting of fees for navigation in Japanese airspace and the setting of charges applied for the use of communal spaces at Japanese international airports..

Priority reform proposals:

- a. *In order to meet market demand for landing and takeoff slots at Tokyo's Narita Airport the current regulations which limit their numbers should be revised so as to permit a substantial increase in the total available for general allocation.*
- b. *A transparent, fair and equitable slot allocation system in full accordance with IATA guidelines should be established and operated at all international airports in Japan.*
- c. *Slot allocation procedures at Japanese international airports should be subject to critical regulatory reform in order to give the slot co-ordinator the freedom to respond more readily to market demand*
- d. *By making optimum use of all facilities and reforming the systems currently applied in Japan, which result in de facto command economics, landing charges at Japanese international airports, fees for navigation in Japanese airspace, and charges applied for the use of communal spaces at Japanese international airports should be able to be decreased to levels matching more closely those*

applied in major countries of the world and which are in accordance with ICAO principles.

- e. Arrangements for the setting of official prices in Japan for international air fares should be liberalised so as to reflect the reality of the market. The ways in which these fares may be publicised should permit airlines to quote real market prices directly to the consumer. Arrangements for the settlement of bills in Japan for international air fares should be simplified into a single operation if that is what the parties involved desire.*

6.2. Sea transport (International Shipping)

Context

The main problems faced by the European shipping industry in Japan arise from restrictive working practices on the waterfront. These practices limit competition and operational flexibility and raise the costs of doing business. Charges at ports in Japan, among the highest in the world, undermine the competitive position of Japanese ports *vis-à-vis* other ports in East Asia. They form part of a broader picture of high costs for all those doing business with Japan and in Japan.

Under the current Prior Consultation System the Japan Harbour Transportation Association (JHTA) has an agreement with relevant parties to hold consultations with shipping lines prior to any changes that might reduce employment or adversely affect working conditions. Shipping lines are therefore required to consult the JHTA for approval of certain changes to their operations. This situation remains unimproved despite the best efforts of Japan's Ministry of Transport. Consequently, the Three-Party and Four-Party Agreements of October 1997, concluded with a view to improving the system, have yet to be fully implemented.

It must be acknowledged that at the moment no particular difficulties are experienced. However, this situation is based solely on good will, and good will may be ephemeral. There remains considerable potential to rationalise and simplify regulations as well as to accelerate reform of regulatory procedures in the area of prior consultation.

Priority reform proposals:

- a. Establish a prior consultation procedure which is transparent, equitable and swift.*
- b. Implement fully the agreement on improving the prior consultation system.*
- c. Ensure the proper functioning, transparency, equity and rapidity of operation of the alternative prior consultation system.*

7. Testing and Certification

7.1. Recognition of foreign testing/inspection bodies

Context

Conformity assessment plays an important role in ensuring public policy objectives such as ensuring product safety, consumer protection and workplace safety. It can, however, place a substantial procedural/regulatory burden on manufacturers and/or importers, particularly if requirements for local and foreign products differ.

One of the means to reduce this burden - without lowering the protection level that conformity assessment helps to ensure - is to recognise the results of certification activities carried out by approved conformity assessment bodies that can be located locally or abroad. The establishment of clear, even and non-discriminatory criteria facilitates the appointment of competent conformity assessment bodies. International procedures and standards can assist in this respect.

The EU welcomes the fact that moving towards an increased reference to international principles and standards in the Japanese regulatory system is a priority of the current Deregulation Programme and hopes to see this reflected in the new Programme due for March 2001 as well. Recognition of foreign testing bodies and the disciplines imposed by the ongoing process of switching to international standards not only has the capacity to increase foreign products' penetration of the Japanese market, but also to improve the performance of Japanese products in overseas markets.

To this end, it is important to have clear criteria for appointing competent conformity assessment bodies, especially where Japanese product standards differ from international ones. The rules, standards and procedures that determine the operation of conformity assessment bodies in the context of Japanese laws, should be transparent, non-discriminatory and aligned with international standards, especially with the criteria enshrined in ISO/IEC guidelines. This would ensure that all competent third parties that have demonstrated their technical competence in accordance with and against international standards and practices could be recognised under the relevant Japanese laws.

The EU welcomes the different schemes that have come into existence over the past years in different laws (such as the recently amended Electrical Appliances Safety Law) that allow competent foreign testing, inspection and certification bodies to perform conformity assessment functions under these laws. This move towards internationalisation is an important step towards meeting the overall objective of the Japanese government and the recommendations in the "Opinion" of the Regulatory Reform Committee.

The conclusion of the EU-Japan Mutual Recognition Agreement will facilitate the market access to Japan for EU exporters for the sectors covered by this agreement. Also, it will certainly facilitate confidence building and exchange of information between regulators and operators in the conformity assessment field.

Fuller deregulation leading to greater self-certification, however, would significantly further facilitate trade even in these sectors. More importantly, there are many sectors where an MRA is not possible or not envisaged for the time being, and which would greatly benefit from the above-mentioned proposals.

Priority reform proposals:

- a. *The EU requests the Japanese authorities concerned to streamline their regulatory procedures, make greater reference to international standards, and align their criteria for the recognition of conformity assessment bodies – including the non-discrimination of foreign testing and inspection bodies - with ISO/IEC standards and practices.*
- b. *The EU reiterates its request to recognise, by means of accreditation or otherwise, foreign bodies that can demonstrate compliance with relevant ISO/IEC standards and criteria, to adapt regulatory procedures where necessary, and to inform it of such steps where taken.*
- c. *The EU would be grateful to be informed about the correspondence that exists between, on the one hand, standards and criteria for recognition and designation, and, on the other hand, the comparable ISO/IEC standards and criteria. One means of ensuring that such important information is publicised would be for the Japanese government to create a single database which lists (i) the law or enforcement order which allows the relevant minister to accredit a foreign conformity assessment body, (ii) the criteria applicable to such accreditation, and (iii) the degree of compatibility of these criteria with ISO/IEC standards/guidelines.*

7.2. Inspection and certification of tank containers

Context

Most tank containers admitted into Japan, and intended for the carriage of dangerous goods, have to be subjected to a physical inspection by Japanese authorities. Responsibility for various categories of dangerous goods is divided between (1) Fire and Disaster Management Agency (FDMA) - flammable liquids, (2) Ministry of International Trade and Industry (MITI) – high pressure gases and (3) Ministry for Health and Welfare (MHW) - toxic materials.

All tank containers intended for the carriage of flammable liquids have to undergo inspection on importation and to have a plate attached to verify that the tank container is suitable for the transport of dangerous goods. This time-consuming activity takes place at the port where the tank container first enters Japan and, according to FDMA, municipalities collect fees of about US\$250 per inspection of flammable liquids tanks. However, industry reports that there are several other costs which have to be born beyond the fee levied for FDMA inspection and that real costs can be as high as US\$ 1000. Following representations by the EU, FDMA are seeking ways to reduce the time taken for the inspections together with their associated costs. Although these moves are most welcome they are, nonetheless, seen as insufficient.

FDMA is still engaged in investigating international rules, procedures and practices.

Given that tank containers entering Japan have been previously inspected and certified in line with the UN Recommendations on the Transport of Dangerous Goods, there is no need for a national administration to query the approvals already granted. The design, construction, initial inspection and testing of tank containers is authenticated and witnessed by agencies, such as Lloyds Register, Bureau Veritas and Germanischer Lloyd, which are appointed by the competent authorities. The principle behind these approvals is that, having met the design and construction requirements, the necessary level of safety and health have been assured and the tank container should be admitted for use by the appropriate modes of transport.

There is also a need to extend the recognition of international standards to all tank containers used for the transportation of dangerous goods.

Since three separate ministries share responsibilities for regulations in respect of different categories of dangerous goods this is clearly a domain in which the regulatory arrangements are in need of rationalisation.

Priority reform proposals:

- a. Recognition by all appropriate Japanese authorities of the validity of the physical inspection and certification of tank containers for the carriage of dangerous goods admitted into Japan when this is authenticated and witnessed by agencies, including, but not limited to, Lloyds Register, Bureau Veritas and Germanischer Lloyd, which are appointed by competent authorities*
- b. Abolition of all supplementary inspections of tank containers for the carriage of dangerous goods which have been inspected and certified in line with the UN Recommendations on the Transport of Dangerous Goods.*
- c. Unification into a single agency of the expertise and regulatory authority relating to dangerous goods which is currently held in a variety of ministries (currently in the hands of at least three: FDMA, MITI, MHW). Industry has indicated that it would find it more efficient to deal with only one ministry.*

8. Recognition of International Standards

8.1. Engines for fishery vessels

Context

MAFF has acknowledged that Japan's regulation, relating to the power of engines to be installed in a fishing boat in relation to the size of the vessel, needs to be revised. This regulation, the *gyosen-ho-bariki* (Engine Performance Index - EPI) measures engine output on the basis of engine displacement. Such an approach to measuring the performance of an engine is unique to Japan and is not in line with international (ISO) standards, which are based on actual engine output (in terms of horsepower or kW). As a result, imports of engines are unnecessarily restricted.

The control of the engine power of fishing boats is an instrument of fisheries policy. However, as a consequence of the progress in engine technology, the relation that

once existed between the EPI and engine output no longer holds, thus undermining the legitimate policy aims of MAFF and the Fisheries Agency.

At the beginning of 2000, MAFF established a Study Group, consisting not only of Japanese experts and industrialists, but also representatives of foreign engine manufacturers. The mandate of this Study Group was to advise MAFF on how engine output for fishing boats should be regulated. Although the Group reached a common understanding that actual engine output (in horsepower) was the best method of regulation, not all members supported this solution for the current legal revision, planned to enter into force from October 2001, and proposed the formula “multiplying engine displacement by engine revolutions”. The EU believes that this will not resolve the problem as it is not compatible with international standards. Such a revision also raises questions of WTO compatibility.

Priority reform proposal:

The Commission requests that the regulation be revised in line with international standards so that the power of engines to be installed in a fishing boat is regulated in terms of actual engine output expressed through an internationally accepted unit of measurement (horsepower/kW).

8.2. Tank containers

Context

Following EU representations, the international standard of 30.48 tonnes is now admitted by Ministry of Construction, Ministry of Transport, Fire and Disaster Management Agency and Ministry of International Trade and Industry for the transport of tank containers by road. However, under the Ministry of Health and Welfare’s primary legislation, the Poisonous Substances Control Law, the amount of toxic substance which may be moved in a single tank container remains limited to 10 000 litres. This volume will normally represent a weight less than 30.48 tonnes. Regulations should be modified to conform with international standards.

Overall, there is scope for a simplification of regulations and broader adoption of international standards in the area of design and construction parameters for vehicles to be used for inland transport of heavyweight tank containers built to international standards. Following some recent liberalisation by Japan, clarification is being provided on the precise amendments introduced. Adoption of international standards is a basic principle in the current Deregulation Programme. The EU seeks adoption or recognition of international standards for tank containers by all authorities involved.

Priority reform proposal:

Adopt or recognise international standards for tank containers, in particular containers complying with ISO standards and the IMDG Code.

8.3. Electrical equipment

Context

The EU has expressed its appreciation of the ongoing harmonisation process of technical requirements in the context of the Electrical Appliances and Material Safety Law (*denan-ho*), especially the commitment of Japan to harmonise its standards with IEC standards.

However, the Commission remains concerned about transparency issues, especially:

1. The type of standards that apply to products: many standards are harmonised with IEC standards, but some are not; some standards are technical specifications, and others are performance oriented (functional) standards. This applies to both the new standards which will be applicable under the revised *denan-ho*, and to JIS standards.
2. The applicable regime in the transitional period: the new law is due to come into force on 1 April 2001. It is not clear at the moment which standards and conformity assessment procedures are applicable before and after that period. By the same token, will it be necessary for currently approved foreign testing and inspection bodies to apply again for accreditation?

Priority reform proposals:

- a. *The EU requests the Japanese authorities to continue the process of harmonising all standards relating to electrical appliances to the maximum extent possible with IEC standards.*
- b. *The EU reiterates its request to change the conformity assessment procedure for products classified as “designated electric appliances” under the new *denan-ho* to self-certification (‘self-confirmation’).*

8.4. Motor Vehicles

General remark concerning adoption of UN-ECE regulations

The EU expects that all the understandings reached on 5-8 June 1995 regarding automobiles and components will be fully implemented in accordance with the timetable for implementation as set out in the letter of MOT to the Commission of 21 June 1995. These understandings include Japan's decision to adopt a significant number of the technical annexes to the 1958 UN-ECE Agreement on motor vehicle regulations. The EU believes that the international harmonisation of automobile regulations is in the fundamental interest of all producing nations. The EU welcomes Japan's accession to 1958 UN-ECE Agreement and trusts that the Japanese side will sign up quickly to a significant number of the annexed regulations as previously agreed. The Japanese government has lately announced an adoption rate of about 30 regulations, out of over 100 regulations, by the end of FY 2003, or about 5 to 6 regulations per year. The EU is of the firm opinion that this adoption rate should be speeded up. The EU also believes that Japan should concentrate on the adoption of regulations in areas where the absence of harmonisation with the international standards is the most disruptive to trade. Early adoption of the maximum number of UN-ECE regulations will help to build on and consolidate the improvements which

have already been made in reducing the time needed for type approval of motor vehicles in Japan.

Evidence of compliance with UN-ECE Proposals

Context

The UN-ECE Revised 1958 Agreement, to which Japan has acceded, provides for the mutual recognition of approvals granted in accordance with UN-ECE Regulations among signatory countries having adhered to the relevant UN-ECE regulation.

MOT accepts lighting components, which comply with UN-ECE Regulation without detailed inspection. But in the case of brakes, the horn, and side-impact, MOT inspects the vehicle or components as well as the data/specifications in the ECE approval documents. This invalidates the principle of mutual recognition.

Priority reform proposal:

The EU requests that MOT should accept the UN-ECE Approval Number or a manufacturer's certificate as evidence of compliance with a UN-ECE regulation, without the need for submission of detailed documentation and physical inspection of the vehicle/component in question.

PHP for incomplete trucks

Context

In 1996 the Ministry of Transport (MOT) extended the application of the Preferential Handling Procedure (PHP) for vehicles imported in limited quantities to cover trucks and buses. However, MOT has indicated that this should only apply to vehicles which are completed in the exporting country. Since the majority of large trucks imported into Japan are customised by local bodyworkers, MOT's interpretation excludes large numbers of large truck imports from the PHP. This is not in accordance with the spirit of the MOT letter to the Commission of June 1995.

The Commission welcomes the study on this subject announced by MOT on 18 February 1999. The EU further understands that EU truck manufacturers are in direct discussions with MOT on this issue in order to find a common solution.

Priority reform proposal:

The EU requests MOT to extend the application of the PHP to cover imported trucks and buses which are completed in Japan. The trucks in question are only modified insofar as bodywork specifically tailored to the Japanese market is added to the otherwise completed truck. The inspection data required under PHP can be supplied for these imports.

Engine Type Stamping by the Official Importer

Context

When an engine cylinder block is imported for repair purposes, it is imported as a component and not as an assembled engine. As a result, the cylinder block has not been stamped. In these circumstances, the cylinder block can only be stamped by a Land Transport Office. There is a risk that engine cylinder blocks stamped in this manner will depreciate substantially in value. Dealers cannot respond quickly to consumer requirements and must bear the cost of transportation to and from the Land Transport Office.

MOT has agreed to consider in FY 2000 giving the official importer the right to stamp cylinder blocks.

Priority reform proposal:

The right to stamp cylinder blocks should be granted to official importers by widening the interpretation of "those who make it their business to manufacture motor vehicles" to include applicants for type designation, type notification and PHP.

Number plate attachment and dimensions

Context

The Japanese requirements for number plate attachment and dimensions are unique.

These special Japanese requirements affect the rear part and the styling of the car and require in some cases specific additional parts for the Japanese market. While recognising the problem for European cars, and undertaking to study it further, the Ministry of Transport (MOT) has offered no immediate prospect of changing the law on the grounds that traffic control and criminal investigations require easily legible number plates.

The Commission understands that MOT will bring this matter up for discussion within the (UN-ECE) WP29 framework, and seeks confirmation that MOT is indeed preparing such a request.

Priority reform proposal:

Acceptance of normal EU number plate size and attachment. This could also have the benefit of solving relating issues concerning the illumination of the number plate

9. Sectoral Concerns

9.1. Cosmetics

Context

At almost ¥1.5 trillion in value, Japan is the world's second largest market for cosmetics. Although many foreign manufacturers have established brands in the market, it remains dominated by domestic manufacturers. The EU therefore welcomes the fact that draft legislation has been developed which aims to bring Japan's hitherto cumbersome system for regulating new ingredients and products into line with international practice. The proposed new system will shift the responsibility for product safety towards manufacturers, and will largely resemble the European model of a negative list, limited positive lists and full ingredient labelling.

However, it must be underlined that this new system will only be a first step in the regulatory reform process. The new positive lists, for instance, will still be different from those in Europe and no mechanism has been established yet to bring about their harmonisation. The EU therefore especially welcomes Japan's intention to consult further with foreign countries for the purpose of international harmonisation. The EU also looks forward to a transparent new domestic regime with respect to the qualification of ingredients and the implementation of full ingredient labelling. Another very important issue is to overcome the gap between product categories, i.e. products categorised as cosmetics in the EU (and indeed the US), but as "quasi-drugs" in Japan. Japan has yet to proceed to the reclassification as quasi-drugs of products classified in both the EU and the US as cosmetics, as it announced in the Deregulation Programme of March 1999.

The EU has already welcomed the shift in responsibility for product safety to manufacturers and importers, and would be grateful for further information, when available, about the relevant guidelines and guidance. In view of the ongoing process of making some abusive animal tests illegal in favour of alternative methods, the EU also welcomes Japan's confirmation that in principle recognition of safety data generated from non-animal alternative testing methods is possible and would welcome information on the applicable guidelines. Mutual acceptance of testing methods would of course be a major benefit of greater international harmonisation.

Priority reform proposals:

- a. *The EU urges Japan to fulfil its announced intention to reclassify a number of "quasi-drugs" as cosmetics in order to comply with the most commonly accepted international standards, so that common products such as deodorants, hair dyes and cosmetics containing greater than 3% of vitamin C are regulated as cosmetics.*
- b. *The EU invites Japan to consult with EU regulatory agencies with the aim of internationally harmonising positive and negative lists, and establishing mutually recognised testing and acceptance criteria for adding new ingredients to these lists. Finally, the EU encourages Japan to work towards an early adoption of the*

International Nomenclature for Cosmetic Ingredients (INCI) for full ingredient labelling.

- c. As responsibility for product safety is shifted to manufacturers and importers, MHW should provide them with clear guidelines for ensuring product safety and should monitor their implementation. The EU requests that it be kept informed about such guidelines as they are developed.*
- d. The EU requests Japan to provide information concerning the conditions for acceptance of non-animal testing data on cosmetic products.*

9.2. In-vitro Diagnostics (IVDs)

Context

The EU continues to be concerned about the slow progress in reforming the approval system for medical diagnostics in Japan. Although some procedures in the new product approval process have been simplified, the main problems have not been solved. These problems are attributable to the fact that IVDs are classified as pharmaceuticals under the Pharmaceutical Affairs Law and not, as in the EU and the US, as medical devices. Strict testing and approval procedures delay patients' access to new IVDs. This situation is detrimental for Japanese citizens, since IVDs are essential components of any health system, indispensable in preventing sickness, detecting and diagnosing diseases, and monitoring treatment. The economic benefit of medical devices is well documented, as they allow costs to be saved by reducing hospitalisation and pharmaceutical consumption. Improving the availability of IVDs is in keeping with the objectives of the reforms currently underway in Japan's healthcare system.

The cumbersome approval procedure is exacerbated by excessive workloads at testing agencies, leading to lengthy product approval delays. This also leads to higher costs for the products once they reach the market.

The EU welcomes the "further measures" which MHW has announced it is studying, and strongly invites the Japanese legislator to follow the example of regulatory practices in other advanced countries, i.e. to remove medical diagnostics from the Pharmaceutical Affairs Law. This is also in line with trends in the Global Harmonisation Taskforce, in which Japan actively participates.

Furthermore, the Japanese authorities are recommended to change the approval system by introducing a notification type approval system for most, if not all IVDs, taking into consideration that the typical health risks which justify the stringent approval procedures for pharmaceutical products, largely do not exist for IVDs. This mainly because IVDs are in principle not applied directly to the human body. IVDs represent a further test case for Japan's commitment to simplify regulatory procedures.

Priority reform proposal:

The EU reiterates its recommendation that IVDs be treated as medical devices, reducing the approval procedure to that which is necessary to protect public health, and looks forward to the announcement of measures to simplify legislative procedures.

9.3. Sanitary and phytosanitary issues

Import of cut flowers, pot plants in approved growing media, fruit, vegetables - Japanese list of non-quarantine organisms

Context

Japan's Plant Quarantine Law was partially revised and passed by the Diet in June 1996, but so far this revised law has had a limited effect on imports of plant products because in practice it does not make a scientifically justifiable, practical distinction between harmful ("quarantine") and non-harmful ("non-quarantine") organisms.

Japan's list of non-quarantine organisms is incomplete and many common organisms which are present both in Europe and Japan, such as aphids and mites, are not included on this list. Any plant products which have such non-harmful organisms on them are treated by Japan in the same way as if they were infested by harmful organisms and must be fumigated or rejected for import. The regulations are not in line with international standards and norms. In line with the Government of Japan's commitment set out in the deregulation package of 31 March 1998, regulations should be modified to conform to the principles of the WTO SPS Agreement.

In February 1999 the European Commission requested the addition of 9 priority organisms to the Japanese list of non-quarantine organisms, and this was repeated in a letter dated 28 July from Director-General Legras to Vice-Minister Kumazawa. In his reply of 24 January 2000, Mr Kumazawa refused to add the 9 organisms to the non-quarantine list, but indicated that Japan is studying the possibility of introducing tolerance levels and alternative methods of disinfection. The results of this study appear to be delayed and are now unfortunately only expected in early 2001.

Priority reform proposal:

The Japanese list of non-quarantine organisms should be extended to include all non-harmful organisms found in cut flowers, pot plants in approved growing media, fruit and vegetables. As a first step the 9 organisms specifically requested by the EU should be added to the list. In parallel tolerance levels should be established for quality viruses which are not on the non-quarantine list.

“Regionalisation” – recognition of the EU’s single market as regards animal and plant products

Context

Japan has not yet recognised that a single market for animal and plant products exists in the EU and has not yet implemented the provisions of the Sanitary and Phytosanitary Standards (SPS) agreement of the World Trade Organisation (WTO) on regionalisation with respect to this single market. Each EU Member State must therefore negotiate bilaterally and pass through lengthy approval procedures for each new variety or type of animal or plant product which it wishes to export to Japan.

As a result of ongoing discussions on this point, in July 2000 Japan accepted a proposal from the EU to serve as an informal case study to examine the feasibility of applying regionalisation in the way requested by the EU. The Commission is now engaged in further elaborating this proposal.

Priority reform proposal:

Recognition of the EU as a single market for animal and plant products, with application of the principle of regionalisation in the determination of disease status, thus eliminating the need for 15 separate approvals (one for each Member State).

Regulatory Procedures for Acceptance of Varieties of Fresh Fruit and Vegetables

On 22 February 1999 the Appellate Body of the WTO, acting on a complaint from the US, found that Japan’s policy of “varietals testing” (i.e. insisting on tests for every single variety of a fruit or vegetable before granting import authorisation) was not consistent with the requirements of the SPS agreement.

Import authorisation has been granted by Japan for Spanish navel oranges and French golden apples. EU is asking for an application of the Appellate Body ruling to its own exports to Japan, particularly in relation to other varieties of Spanish oranges and French apples.

Priority reform proposal:

In the light of the report of the WTO Appellate Body on the US-Japan varietals case, Japan is requested to apply the rulings of the report to imports of EU fruit and vegetables and, in particular to grant import authorisation for Spanish Clementina and Salustina oranges and French apples.

Issues where the EU will continue to monitor progress

Progress has been made over the past year on a number of issues addressed in the EU's 1999 Priority Proposals for Regulatory Reform in Japan. On two issues in particular, sea transport (port services) and pharmaceuticals, new legislative or regulatory measures have come into force or will do so shortly. These changes have the potential to bring considerable improvements to the regulatory environment in these sectors. The EU welcomes the measures already taken and will continue to monitor the implementation of the new rules.

1. Licensing and other arrangements for the provision of port services

The new Harbour Transportation Business Law is due to enter into force on 1 November 2000. This will introduce an approval system in place of a licensing system, and change the tariff system from an approval system to a notification system. The final report adopted by the Port Transport Sub-Committee of MOT's Council for Transport Policy on 10 June 1999 failed to provide details on how the permit system will operate in practice. This reinforced the EU's preoccupation that the permit system might be in practice be implemented in a similar way to the license system.

In addition, the EU remains unconvinced that the provisions of the new Law (and associated regulations and guidance) mentioned below will bring about the improvements they aim at. However, the EU is prepared to suspend judgement and to monitor the situation.

- Additional employment provisions providing for a 150% increase in the current minimum number of workers that operators are required to employ.
- The proposal to retain Article 16 of the old Harbour Transportation Business Law, which restricts general port transport operators very heavily in the sub-contracting out of work.
- The replacement of the rate approval system by a tariff-filing requirement, despite the fact that tariff filing in the maritime and port industries is generally recognised as imposing undue and unnecessary burdens on the operators concerned.
- The system for ordering fee changes under which MOT can *de facto* veto notified port service charges, and the emergency audit scheme with the objective of avoiding destabilisation in labour relations pursuant to any increase in competitive conditions arising through deregulation.
- Measures for securing contributions to port labour pension funds and better welfare for port workers by maintenance and development of on-site facilities and housing, with the aim of ensuring the ongoing financing of these funds and activities (which form part of the current rate approval system).

The EU expects that the Government of Japan will ensure the implementation of the new arrangements in a transparent, non-discriminatory and predictable manner, so that deregulation achieves the desired effect of introducing free competition in the provision of port services.

2. Pharmaceuticals

The EU acknowledges that the Japanese healthcare system is currently experiencing a period of fundamental change. The availability of affordable, state-of-the-art drugs will benefit the population at large, not only by offering a wider choice at better prices, but also by opening up new ways to cope with present and future health care challenges, such as those inherent to an ageing population.

The EU applauds the progress made towards reducing the approval time for New Drug Applications (NDA) to twelve months, and considers that the main thrust of its regulatory reform request has been met.

However, the EU will remain vigilant as to the evolution of the inspection and approval system, the deliberations in the Central Pharmaceutical Council, and - in general - the total time taken for the approval process. Furthermore, the EU stresses once more the importance of transparent guidelines determining the conditions that cause the clock to be stopped on an application for approval of a drug. The EU appreciates the Japanese authorities' greater degree of acceptance of global clinical trial data in approval applications, and hopes that such data will be even more widely accepted by the Japanese authorities in future.

The *kiko* (Organisation for Pharmaceutical Safety and Research) consultation system in the NDA (New Drug Application) process within MHW has existed for over three years, and the importance of these consultations in speeding up the drug approval process is increasing. Industry indicates that it would greatly appreciate a strengthening of this consultation system, including reinforcing the *kiko* with additional expert staff and maximising consistency between the *kiko* consultation and the Evaluation Centre review after the NDA submission.

Finally, a note of concern remains also with regard to the manner in which intellectual property rights are protected in Japan.