3. Reducing the Burden of Regulation for Companies

In order to stimulate the growth of new businesses, particularly SMEs, the compliance burden and costs attendant on the current level of regulation need to be addressed. Moving to an optimal level of regulation and further advancing towards international standards will not only reduce compliance costs for domestic and foreign companies, but enable both the Japanese corporate and public sectors (e.g. medical services) to source at lower cost from domestic and foreign suppliers. The European Union's proposals, many of which have been put forward for some time already, are thus highly relevant in this regard.

3.1. Healthcare and Cosmetic Market Regulation

A good case in point is medical services where the current Government policy is geared to providing a high quality service, while seeking to improve cost efficiency.

3.1.1. Pharmaceuticals

The European Union 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 European Union therefore applauds the progress made towards reducing the approval time for New Drug Applications (NDA) to twelve months, and notes with satisfaction that NDA approval times have consistently been coming down over recent years. The *kiko* (Organisation for Pharmaceutical Safety and Research - OPSR) consultation system in the NDA (New Drug Application) process within MHLW has existed for over four years, and the importance of these consultations in speeding up the drug approval process and realising a consistent approach right through from the development to the review stage is increasing. The EU considers MHLW's openness to unifying the Evaluation Centre/*kiko* functions to be positive, but would like to emphasise the importance of ensuring that the new agency – to be transformed into an independent administrative agency under the revised Pharmaceutical Affairs Law of July 2002 – will actually streamline the drug evaluation and approval process and increase the quality of the review system. The new agency also aims to centralise the system for handling drug safety, and the EU supports the pharmaceutical industry in its desire to see that this process does in practice achieve an improved, proactive and consolidated system for drug safety. Furthermore, the new agency should provide improved service reflecting the fees which will be requested of pharmaceutical companies for drug approval applications. One notable positive point is that, in line with EU and US practice, minor changes in drug applications will be accepted without review.

The EU also 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. Concerns have been voiced by industry about inconsistent implementation of the ICH E5 Guidelines (guidance aimed at facilitating the registration of medicines among ICH regions by

recommending a framework for evaluating the impact of ethnical factors upon a medicine's effect), and scientifically questionable arguments made by some OPSR officials, particularly since several years have passed since the ICH E5 Guidelines were introduced, and there have been several successful examples of the use of bridging studies. Discussions on bridging studies between the industry and the Japanese authorities are necessary in order to develop the use of the Guidelines, and to ensure that Japan too can play its part in the global development of new pharmaceuticals.

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

Priority reform proposals:

a. Further improve the quality and efficiency of the review and consultations process for NDAs by finalising the merger of the Evaluation Centre (PMDEC review) and kiko (OPSR - consultation) functions in order to create a single independent agency able to realise a fully consistent approach right through from the development to the review stage.

b. Ensure consistent and scientifically well-founded implementation of the ICH E5 Guidelines.

3.1.2. In-vitro Diagnostics (IVDs)

This issue has been consistently raised by the EU with Japan over the last ten years or more. Welcome, if belated, progress has come with the European Business Community's (EBC) recent case before the Office of the Trade Ombudsman (OTO). Whereas a mere 12% of applications for the approval of IVD products were formerly processed within the six-month period promised as far back as 1985 by MHW, predecessor to MHLW, recent MHLW surveys show that 87.6% of all applications are now being approved within the six-month period.

However, residual problems remain and are largely attributable to the fact that IVDs are classified in Japan as pharmaceuticals under the Pharmaceutical Affairs Law and not, as in the EU and the US, as medical devices. Strict examination 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, and improving patients' quality of life. International harmonisation of regulations on IVDs is in keeping with the objectives of the reforms currently underway in Japan's healthcare system.

In this respect, the EU welcomes the MHLW's proposals, in the context of the newly revised Pharmaceutical Affairs Law (PAL), to introduce a product approval process for IVDs based on risk classifications, namely: (i) Low Risk with Standard Substances available (self-notification), (ii) Low Risk (3rd party approval), and (iii) High Risk

(ministry approval). In order for these positive changes in notification and approval procedures to have the intended effect of simplifying regulatory requirements while ensuring maximum levels of safety and quality, it is vital that they be based on global standards for GMP and for data requirements in the case of approval applications. When the new independent administrative agency is created to take over the ministerial approval function under the revised PAL, the EU urges that this should charge reasonable fees and build on the increased allocation of resources allocated to IVD approvals which has allowed the recent improvements in approval times.

Furthermore, the Japanese authorities are recommended to align risk classifications for IVDs with global practice, notably by introducing a notification type approval system for most 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 is mainly because IVDs are in principal not applied directly to the human body.

In the longer term, the EU strongly invites the Japanese legislator to follow the example of regulatory practices in other advanced countries, i.e. to remove medical diagnostics from the category of pharmaceuticals under the Pharmaceutical Affairs Law. This is also in line with trends in the Global Harmonisation Taskforce (GHTF), in which Japan actively participates.

Priority reform proposals:

a. Introduce risk classifications for IVDs which are in line with global practice and based on global standards for GMP and approval data.

b. In the longer term, treat IVDs as medical devices, rather than as pharmaceuticals under the PAL, in order to reduce the approval procedure to that which is necessary to protect public health.

3.1.3 Blood plasma

A stable and plentiful supply of blood plasma is essential for any medical care system. Large volumes of plasma are required for manufacture of medicinal products, especially immunoglobulin. Although techniques such as plasmapheresis can yield large amounts of plasma from a smaller number of donors, in order to satisfy the demand for plasma in their healthcare systems both Europe and Japan need to take plasma, including imported plasma, from a large number of both non-remunerated and remunerated donors. Legislation applicable to blood products in Japan has recently been undergoing extensive revision. In the 2002 ordinary session of the Diet, amendments to both the Blood Collection and Donation Arrangement Control Law ("the Blood Law") and the Pharmaceutical Affairs Law were passed. Although the Blood Law in fact bans the use of paid donors in Japan, imported products are made up mostly of plasma from paid donors.

The Blood Law in particular contains two elements of concern to the EU:

(i) It contains a supply and demand plan under which companies are obliged to provide specific information about future supply, in order to allow this information to be compared with estimated demand. If discrepancies occur, the government has the power to force companies, on pain of penalties which may extend to termination of their operations in Japan, to change their forecasted supply. The premise of this plan is to promote blood self-sufficiency.

(ii) It contains a new labelling requirement whereby the label must state the country of origin of the plasma and whether it is form a *kenketsu* or *hi-kenketsu* donor. These terms are ill-defined, but correspond approximately to "paid" and "unpaid" donorship.

Point (ii) above raises especial concerns since, as in Europe, a substantial proportion of the plasma-derived medicinal products used in Japan originate from paid donors. Legal provisions which tend to discriminate between sources of donorship, or unfairly to imply – without scientific basis – that products derived from unpaid domestic donors are safer than imported products derived from paid donors, are unwelcome. They are also likely, contrary to the Blood Law, to create supply problems by in effect favouring domestic over imported products when in fact it is known that imports are often essential to satisfy overall demand. Such provisions may also result in technology-led new products not being made available to Japanese patients.

The basic safety of all plasma-derived medicinal products needs to be ensured by the application of a large number of complementary measures, including inspections of collection and manufacturing facilities, selection of donors, screening of individual donations, testing of pooled plasma units for markers of infection, and the application of validated production processes which are capable of inactivating and/or removing a range of viruses. This is the system operated in the EU, and may be supplemented in individual Member States by further release testing of plasma pools and finished plasma-derived medicinal products by Official Medicines Control Laboratories. Applied in combination, such measures minimise the risk of transmission of infective agents, although no system can reduce the level of risk to zero.

Like Japan, the EU applies the strictest standards for the safety of blood plasma. Only products which meet these criteria, regardless of whether they derive from paid or unpaid donations, receive marketing authorisation from the European Agency for the Evaluation of Medical Products (EMEA). There is, therefore, no scientific justification for a labelling system which makes a distinction between those two categories.

Regulatory reform proposals:

(i) Blood plasma self-sufficiency is questionable as an aim in itself, since over-reliance on any one source of supply may lead to serious supply problems if the safety of any one source, be it domestic or foreign, is brought into question. The EU invites Japan to reconsider the presumption in favour of domestic blood plasma on which the supply/demand provisions of the new Blood Law are based, and to formulate provisions on reliability of supply which are not based on making questionable distinctions between domestic and foreign sources.

(ii) All blood plasma authorised for marketing in the EU complies with the strictest safety criteria, regardless of source of donation. The EU proposes to rectify the implicit discrimination in the Blood Law by a more precise definition of the term kenketsu*, as follows:*

"A product made from plasma from donors who have donated their plasma of their own free will in a well-regulated environment, and which meets all quality and safety requirements as defined by the Ministry of Health, Labour and Welfare".

3.1.4. Cosmetics

At almost ¥ 1.5 trillion in value, Japan is the world's second largest market for cosmetics. EU manufacturers have established brands in a market which nevertheless remains dominated by domestic manufacturers. Legislation dating from 2001, and warmly welcomed by the EU, has shifted the responsibility for product safety towards manufacturers, and largely resembles the European model of a negative ingredient list, limited positive ingredient lists and full ingredient labelling.

However, the new positive lists still contain many differences from those in Europe, and no mechanism has been established yet to bring about their harmonisation. Certain conservation agents, sun filters and coal/tar pigments appear on the EU's positive lists, but are forbidden in Japan . Many companies find that continuing requirements for lengthy safety and innocuity data put them off even attempting to add new ingredients to the positive lists. Such requirements often duplicate tests already performed in the European Union, frequently involve products which have a proven record of safe use in the EU in large volumes over several years, and results in extensive and costly reformulation of products for the Japanese market.

The European Union welcomes Japan's intention to consult further with foreign countries for the purpose of international harmonisation. The EU also emphasises the need for transparency in the application of the new domestic regime with respect to the qualification of ingredients and the implementation of full ingredient labelling.

The "quasi-drug" category used by Japan consists of products ranging from deodorants, hair dyes, hair growers and depilatories, medicated cosmetics (notably whitening agents) and medicated toothpaste to sanitary napkins and over-the-counter health drinks. In practice, the criteria for classification as a quasi-drug are not clear, and it has proved almost impossible to get new ingredients in the quasi-drug category approved (including some ingredients already accepted when incorporated in cosmetics). Pending fundamental reform of this category, a further problem 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 reclassify a number of quasi-drugs as cosmetics, as is the case for those products in the EU and the US, and in accordance with its announcement in the Deregulation Programme of March 1999.

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.

Finally, the number of accepted marketing claims should be expanded on the basis that the burden of proof of any such claims lies with the manufacturer, with a view to harmonisation with EU standards.

Priority reform proposals:

a. The EU requests that common products such as deodorants, hair dyes, etc. should be regulated as cosmetics. In the meantime, the EU requests a clear statement of which active ingredients qualify a product as a "quasi-drug", and why, and a clarification of the criteria for approval of new ingredients in this category. Useful first steps would include the publication of a nomenclature list, specifications, doses, product categories, and related claims, allowing easier registration of new active ingredients and the use of new cosmetics ingredients, and a move to full labelling analogous to that applied to 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 and provide official English versions of these lists in order to make them easily accessible to foreign makers.

c. The EU requests Japan to provide information concerning the conditions for acceptance of non-animal testing data on cosmetic products.

d. Allow manufacturers to make legitimate marketing claims on the basis of their responsibility to be able to back those claims with proof, in accordance with standards harmonised with EU norms.

3.2. Promoting International Standards

For some time now, the European Union has advocated that Japan should move more decisively in promoting international standards in order to reduce costs for importers and supply high quality goods for Japanese consumers at competitive prices. Moreover, residual problems in such areas as construction components (see supplementary proposals) underline the need for further progress in establishing internationally based performance norms.

3.2.1. Recognition of foreign testing/inspection bodies

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 and if

conformity is required with regulations under more than one law and under more than one ministry's responsibility. 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.

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 European Union 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 and Building Standards 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 new Regulatory Reform Programme of harmonisation with international standards wherever possible. 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. The "Progress Report on Reviewing the System of Standards Certification, etc." published in April 2001 in accordance with the Regulatory Reform Programme contains useful data. In particular, the EU welcomes the information provided by METI (in the annexes to Point 5-2) on the criteria for accrediting conformity assessment body by legislation making reference to the corresponding provisions for Guide 65 or ISO 17020.

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 performance norms, 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 would be grateful for comprehensive information on all legislation that permits the designation of foreign conformity assessment bodies. Such information should take a user-friendly form in order make clearly understandable additional requirements to ISO/IEC standards/guidelines by listing 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.*

3.2.2. Motor Vehicles

3.2.2.1 Compliance with UN-ECE Agreement

On 5-8 June 1995 the European Union and Japan reached an understanding regarding automobiles and components. 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 European Union believes that the international harmonisation of automobile regulations is in the fundamental interest of all producing nations, especially as the auto industry in every aspect is a truly global industry. The European Union appreciates greatly Japan's full participation under the revised 1958 UN-ECE Agreement, but, trusts that the Japanese side will sign up quickly to a significant number of the annexed regulations as agreed on 5-8 June 1995. 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 European Union 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.

The EU and Japan co-operate very well in the framework of UN-ECE and have a common view that, when possible and practical, world harmonisation should be an ultimate goal for new vehicle regulations. In the case of Japanese recent draft proposal on "Driver Visibility Standards for Passenger Cars, etc." the EU had hoped that this work could have been held back in anticipation of UN-ECE efforts to establish an internationally harmonised requirement. The EU has stated that it wishes Japan to bring the relevant WG of the UN-ECE up to date following the Japanese public comments procedure. If further details are known at the time of the next European Commission-MLIT expert meeting, this item might usefully be discussed.

Priority reform proposals:

a. The EU has a long standing request for Japan to speed up its adoption of UN-ECE regulations. EU notes that Japan aims for the adoption of 30 UN-ECE regulations by 2003. The EU request that beyond 2003 the number of regulations adopted per year could be considerably more than in the past .

b. The EU has stated that it wishes Japan to bring the relevant WG of the UN-ECE up to date following the Japanese public comments procedure on "Driver Visibility Standards for Passenger Cars, etc".

3.2.2.2. Engine Type Stamping by the Official Importer

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. Dealers cannot respond quickly to consumer requirements and must bear the cost of transportation to and from the Land Transport Office.

On 5 July 2001 MLIT revised the relevant regulations to allow official importers to stamp cylinder blocks imported for engine repair. But the significance of this amendment is limited by the fact that this concession only applies when the cylinder block forms part of a complete engine. This means that an importer cannot stamp a cylinder block and then supply it to his dealer for incorporation in a repaired engine. Either the dealer must deliver the engine to the importer for repair and stamping or the dealer must return the engine after repair to the importer for stamping.

Priority reform proposal:

The EU requests that official importers be allowed to supply their dealers for repair purposes with stamped cylinder blocks that do not form part of a complete engine. Japan was also to consider whether an authorised employee of the official importer could stamp the complete engine at the place of the repairer or dealer.

3.2.2.3. Number Plate Attachment and Dimensions

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, MLIT has offered no immediate prospect of changing the legislation on the grounds that traffic control and criminal investigations require easily legible number plates.

MLIT has confirmed its viewpoint that the work should be undertaken within the (UN-ECE) WP29 framework and that they are proceeding on this track.

Priority reform proposal:

MLIT stresses the importance of an international standardisation. The EU would be very interested to discuss with Japan the scope for such a solution and invites Japan to come forward with a proposal on this line. As an international solution may take considerable time, the EU requests Japan to explore an interim solution which could accept normal EU number plate size and attachment. This could also have the benefit of solving related issues concerning the illumination of the number plate.

3.2.2.4. Specification Table Form 1 for TDS Passenger Cars

Technical progress advances quickly in the motor industry, and the names of components used in the specification table quickly become out of date. Furthermore, it is necessary to fill in details of items even where they are not subject to inspection for compliance with safety standards, or which do not lead to enquiries from users or maintenance workshops. Applicants are required to waste time and effort in producing specification data which, in practice, are not used. Furthermore, when these unused specifications change, it is necessary to obtain approval for the change by submitting a new application.

The EU requests that those specifications containing information which are not necessary for demonstrating compliance with the Safety Standards, or which are not needed by users or maintenance workshops, should be removed from the specification table. The MLIT circular of 10 May 1999 informed us of the revision of the Specification Table to delete/simplify 9 items on the basis of the conclusion of the study undertaken by the end of March 1999. However, the deletion is not sufficient, since more than half of the items which the EU has proposed for removal remain untouched. The EU supports the work by the Japan Automobile Importers Association (JAIA), in co-operation with the major automobile manufacturers, in setting out proposals for the further modification of the Specification Table. The EU has been provided with a copy of the JAIA proposal, which has been presented to MLIT for examination.

Priority reform proposal:

The EU calls for MLIT to study seriously the proposal made by the Japan Automobile Importers Association, in co-operation with the major automobile manufacturers, in setting out proposals for the further modification of the Specification Table.

3.3. Food safety and agricultural products

3.3.1 Food additives and flavourings

Recent scandals involving the use of food additives, including flavourings, have revealed major problems in the way food additives are approved for use in Japan. Many substances in common use around the world and recognized as being safe by international food safety bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are not allowed in Japan. Conversely, numerous substances have been approved in Japan that have not been reviewed and approved by the international scientific community.

While food safety must remain a priority, the manner in which Japan's MHLW has responded to recent scandals is a matter of serious concern to the European Union. A large number of food recalls ordered recently by MHLW have, as indeed publicly stated by the ministry, been made despite there being no human health concerns at stake. These recalls have involved products containing flavourings and additives manufactured in Japan (in some cases for over 30 years), as well as products in common use around the world – many of them imported from the European Union's 15 Member States. The EU deeply regrets the negative effects on Japanese consumers, many of whom have wrongly been led to believe that food they have found on the shelves for the past 30 years is potentially unsafe, European Union food producers and their Japanese partners are intent on respecting the Japanese law and providing safe food products to Japanese consumers.

The European Union follows closely the work of the CODEX Alimentarius on determination of the safety of ingredients and additives, according to internationally accepted scientific methods. Further, the EU urges Japan to move towards international standards and bring its list of additives in line with the work of CODEX Alimentarius, an organization to which Japan adheres and provides support. In particular, research to determine a "positive list" of acceptable substances and residue levels has already been done by the international community and has been accepted, after serious consideration, by CODEX Alimentarius. Japan should act on this issue without delay to avoid the unnecessary problems now being experienced, and to help ensure a high level of consumer protection.

The attached **Annex** contains some additional information on the EU guidelines for handling food additives, including the definition of food additives, and additional information on the use of iodine in salt in the EU which may be of help in revising the Food Sanitation Law.

Priority reform proposal:

The EU urges the Japanese government to modernize Japan's list of accepted food additives in line with the applicable international standards – the CODEX. Alimentarius – and to accept flavourings recognized as being safe by food safety evaluation bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the EC Scientific Committee on Food or the European Food Safety Authority.

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

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 then 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, which were promised in early 2001, are not yet available to the European Commission. Much as the Commission appreciates the efforts made by the Japanese phytosanitary experts to produce a proposal for tolerance levels for these organisms with regard to cut flowers for the other items, such as fruit and vegetables, no further progress has been made, and no indications on tolerance levels have been presented by the Japanese side.

Priority reform proposal:

The EU requests that the Japanese list of non-quarantine organisms be extended to include all non-harmful organisms found in, fruit and vegetables, cut flowers, pot plants in approved growing media. 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.

3.3.3. "Regionalisation" – recognition of the EU's single market as regards animal and plant products

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 European Commission is now engaged in further elaborating this proposal.

Priority reform proposal:

The EU requests recognition 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).

3.3.4. 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. The US and Japan have recently reached agreement on the implementation of this report.

Import authorisation has been granted by Japan for Spanish navel oranges and French golden apples. The European Union 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. The duration of SPS approval in Japan is in any case far too long – it has taken up to 20 years for the approval of some citrus fruits. While the Japanese government has replied with respect to Spanish Salustiana and Clementina oranges that a public hearing will be held, the EU notes with regret that, owing to postponement by MAFF, no such hearing has yet taken place.

Priority reform proposal:

In the light of the report of the WTO Appellate Body on the US-Japan varietals case, the EU requests Japan 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 Salustiana oranges, French apples, and Italian fruits and vegetables (notably the orange variety Tarocco*). SPS approvals should in future be processed quickly and without delay.*