EUROPEAN COMMISSION SERVICES' RESPONSES TO TACD'S APRIL 1999 RECOMMENDATIONS ON TRADE

RECOMMENDATIONS ON TRADE

1. Economic Regulation

2. Fair Trade

3. Pharmaceuticals

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Economic Regulation

TACD RECOMMENDATION

1. International competition rules and an effective code of practice for multinationals are the priority for the TACD rather than an investment regime. Consumer organisations recognise that foreign direct investment can stimulate economic growth which may, in turn lead to more jobs, higher purchasing power, a wider range of products and improved value and quality of goods and services. A predictable and safer environment achieved through investment rules can therefore be a positive development.

2. However, the Transatlantic Consumer Dialogue affirms the rights of governments to regulate business to protect consumers, workers, the environment, and public health. We therefore oppose the MAI and other investment terms based on the MAI model, which would threaten the ability of governments to fulfil this protective role. We will also oppose any efforts to complete the MAI and-or shift MAI negotiations to the TEP or the WTO.

3. The TACD supports investment rules, but not the MAI model because:

• We reject the creation of new corporate rights to sue governments directly in closed trade tribunals.

• The rights of investors should be subordinated to the rights of democratically elected governments to regulate business in the public interest, and not vice versa, as proposed with MAI.

4. Instead of a MAI, the U.S. and the E.U. should affirm the following in the TEP:

• The national treatment principle of a future investment agreement must provide for the establishment of and maintenance of exceptions or qualifications.

• Any new agreement on investment must set binding terms of conduct for TNCs and on competition policy.

• Multinational corporations must be held accountable to universally recognised human rights, labour and environmental standards.

· Countries must be free to develop investment policies that promote creation of jobs and generally raise living standards.

• In any investment rules specific obligations such as the promotion by foreign investors of the economic and social development of the host country and the protection of consumers and the environment must be included, and best practice in such matters as job creation and the promotion of innovation and transfer of technology should be encouraged. Terms should include best practice in the area of consumer information, to prevent recurrence of the serious issues raised by the non-segregation and labelling of GMOs. Cases of abuse could be referred to the Courts in the investing country, which could compare behaviour with the Code. The European Parliament has suggested setting up a Monitoring body, to examine any breaches.

EUROPEAN COMMISSION SERVICES' RESPONSE

Economic Regulation

1. In the first sentence, the Recommendation states that an investment regime is not a priority for the TACD. However, this appears to contradict the rest of paragraph 1, which lists the benefits of FDI and rightly explains that a predictable and safer environment achieved through investment rules would therefore be helpful.

2. The European Commission services' view is that a possible framework of investment rules to be negotiated in the WTO should preserve the ability of host countries to regulate the activity of investors (whether foreign or domestic) on their respective territory. The European Commission does not support the negotiation of any MAI style agreement in any forum, such as the WTO or the TEP. The objective of an investment framework in the WTO should be to secure a stable and predictable climate for investment worldwide.

3. The European Commission services believe that such framework of multilateral rules on investment should be part of the WTO system and therefore linked to the existing WTO Dispute Settlement mechanism.

4. We believe that a bottom-up approach to the question of admission of investors, based on commitments undertaken by each Member, is the way to allow for the flexibility that many WTO Members require.

It is doubtful whether multilateral rules can, in themselves, play a role in ensuring the good corporate citizenship of all companies in host countries. Nevertheless, WTO Members could set out the kind of behaviour, which they expect and encourage their international investors to achieve, building, inter alia, on the corporate or industry codes of "good corporate citizenship" that have developed substantially in recent years. The European Commission services support a constructive review of the OECD Guidelines for Multinational Enterprises with the aim of strengthening them.

Fair Trade

TACD RECOMMENDATION

The recent US-EU banana controversy raises the following issues of principle of concern to the TACD:

• The TACD supports the principle of application of international social, environmental, health, safety and consumer protection rules to companies operating internationally. These rules should provide for judicial enforceability that sufficiently protects the right of injured parties.

• The TACD welcomes the development of voluntary fair trade labelling. Whilst avoiding protectionism, such labelling should be treated as permitted under the WTO/TBT Agreement.

• The TACD supports the right of countries to negotiate the setting of priorities as between overlapping international obligations, such as the Lomé Convention, and to have such negotiated exceptions respected.

EUROPEAN COMMISSION SERVICES' RESPONSE

The "Fair trade" question covers not only bananas but also a wide range of products, principally primary products, but also handicrafts and small transformation products. In practical terms, the breadth of the concept can sometimes lead to problems in the implementation of standards and for this reason some have attempted to distinguish between "ethical" and "fair" trade.

The European Commission services support judicial enforceability of measures to protect the rights of producers, and note that national legislation already provides a legal framework for international companies. It acknowledges that there are grey areas and limitations in the international regulatory framework. The European Commission services see considerable

potential for progress in voluntary standards, which are increasingly being adopted by private actors.

The European Commission services also support transparent voluntary fair trade labelling and would draw the TACD's attention to discussions on the issue which have taken place in the WTO/TBT framework.

The question of overlapping international obligations is a very broad one and covers not only fair trade issues, nor only consumer issues. In general terms, there is already the possibility of negotiated exceptions to multilateral trade rules, but third trading partners then have to be compensated for any negative effect on them of the exception. Meeting the cost of such compensation is primarily a political decision on the part of trading partners.

Pharmaceuticals

TACD RECOMMENDATION

The TACD recommends that the governments of the US and the EU should consider the following:

1. Regarding World Health Assembly and the World Trade Organization:

Require that a country engaged in WTO dispute resolution proceedings be permitted to request a report from the WHO on the public health aspects of the policies that are subject to review by the WTO.

2. Regarding Patents and Exemptions for Exports:

Agree that a country may provide exemptions to patent rights to companies who are exporting the product to another country where patent rights have expired or where patent rights have been licensed under compulsory licensing and the legitimate interests of the patent owner has been protected under Article 31 of the WTO TRIPS agreement.

3. Regarding Parallel Imports of Pharmaceuticals:

Not bring trade sanctions against poor countries that seek to use parallel imports to obtain cheaper access to pharmaceuticals.

4. Regarding developing countries and medical patents

Not use trade pressures against developing countries over access to essential medicines if those countries have satisfied WTO/TRIPS requirements for the protection of patents. Developing counties should not be prevented from using compulsory licensing to expand access to medicines, if the compulsory licenses are issued in compliance with Article 31 of the TRIPS agreement.

5. Regarding compulsory licensing:

Agree that governments, the World Health Organisation (WHO) and the World Intellectual Property Organisation (WIPO) should consult with the academic community, consumer groups and a wide range of industry groups to determine where compulsory licensing of medical technologies is needed to overcome market failures, such as those that are related to complex inventions, follow on inventions, or for providing access to inventions on reasonable terms.

EUROPEAN COMMISSION SERVICES' RESPONSE

1. Regarding World Health Assembly and the World Trade Organisation

Cases which concern the lack of correct implementation of the relevant WTO agreements e.g. such as the TRIPs Agreement are subject to WTO's Dispute Settlement mechanism. However, the procedure for conducting Dispute Settlement cases is in the hands of the parties involved, including their rights (and obligations) to submit relevant evidence for their complaints, e.g. such as WHO conclusions and reports. The Panel can also make use of all relevant documentation to support its report.

WHO papers, however, often do not reflect the official WHO points of view, but are only financially supported by the WHO.

The effectiveness (for all parties) of the Dispute Settlement mechanism could be significantly damaged if the parties had to await the delivery of WHO reports before a Panel would be in a position to conclude. The Dispute Settlement procedure includes several fixed deadlines for interventions, written submissions etc.

2. Regarding Patents and Exemptions for Exports

Article 28 of the TRIPs Agreement states that a patent shall confer on its owner the following exclusive rights: where the subject matter of a patent is a product or a process making, using offering for sale, selling or importing for these purposes that product of this process.

Article 30 of the TRIPs Agreement provides for exceptions to the rights conferred by a patent. Members may provide for limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.

Domestic production for export only, in a country where a product or a process is covered by a patent, falls under the exclusive rights conferred by a patent. Whilst the European Commission services would not support a general exception from the rights conferred by a patent as proposed in the TACD recommendation, it should be noted that a country may provide for exclusions to the exclusive rights conferred by a patent in accordance with Article 28 of the TRIPs Agreement within the limited exceptions as provided for in Article 30 of the TRIPs Agreement.

3. Regarding Parallel Imports of Pharmaceuticals

It is not clear what this recommendation means as notions such as "trade sanctions", "poor countries" and "cheaper access to pharmaceuticals" are not well defined.

In relation to the issue of parallel import of pharmaceuticals, Article 6 of the TRIPs Agreement provides that "for the purpose of dispute settlement under this Agreement...nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights". Nevertheless, the rights conferred by a patent (Article 28 of the TRIPs Agreement) may not be contravened, these rights include the right to prevent importation of patented products.

The European Commission services believe that further evidence would be valuable about whether parallel importation of pharmaceutical products affects the prices of pharmaceuticals and in particular, whether, parallel importation will increase the prices of pharmaceuticals on the global market and if it has an influence on the consumer safety.

4. Regarding developing countries and medical patents and,

5. Regarding compulsory licensing

The first sentence of this recommendation is unclear as the notion "trade pressure" is not defined. If developing countries comply with the minimum requirements of the TRIPs Agreement, they will clearly not be faced with an EU request to bring their legislation into compliance with the TRIPs Agreement. Most of the essential drugs on the WHO's "essential drug list" are anyway products whose patent has expired.

In setting up national legislation for granting compulsory licenses the minimum requirements

of Article 31 of the TRIPs Agreement should be met. In particular, it must be ensured that the rights conferred by a patent are not affected.

However, the European Commission services believe that developing countries may implement national legislation on compulsory licenses so long as, in doing so, the minimum requirements of Article 31 of the TRIPs Agreement are taken into account.

Auto Safety standards

TACD RECOMMENDATION

1. Purpose of Harmonization. The primary purposes of national motor vehicle safety and environment standards are to reduce deaths and injuries as well as the adverse environmental effects related to the use of motor vehicles. TACD opposes any harmonization that would merely integrate existing national standards or reduce the level of protection provided by any existing national standard and wishes to emphasise that it is the right of sovereign nations to adopt standards higher than prevailing international standards. Industry goals of achieving economic efficiency and cutting costs in the design and production of vehicles and in the facilitation of standards compliance are secondary considerations. Consequently, international harmonization of these standards must first and foremost further enhance such public protections through upward harmonization. Upward harmonization means individual national standards to a higher level with a newly developed standard based on best available technology. The new Global Agreement contains a commitment to continuous improvement in public protection. TACD calls upon both the US and EU governments to affirm and honour this commitment in order to avoid the need to deharmonise. TACD is concerned that the additional levels of complexity in establishing global regulations suggests that the process may be even slower than the ones with which we are already familiar.

2. Protection or Establishment of Democratic National Procedures. TACD condemns any negotiations between business and industry for standards setting that take place behind closed doors. Consumers are concerned that the Global Agreement could be used to supplant in fact, if not in law, national procedures that assure transparency and citizen participation in the process of developing new standards and amending existing ones. The TACD calls upon the governments of the US and the EU to develop national policies and procedures that assure full transparency, consultation with citizen organisations and public participation in standards processes under the Agreement. These arrangements should respect all existing national obligations for citizen participation. The policy statements should fully confirm the application of all existing national requirements governing vehicular standards requirements. TACD considers openness and transparency in the standards-setting procedure to be a pre-requisite for the acceptability of the resulting standards and will address this issue again in the future.

3. Openness and Transparency of work under the 1998 Global Agreement The TACD is most concerned that, in the interests of transparency, the substantive discussions within the Executive Committee should be capable of being observed by the NGOs. The procedural rules designed to apply to the existing as well as the proposed WP.29 framework will serve as the practical interpretation of the openness and transparency principles outlined in the agreement. It is important that these rules are clear and unambiguous. TACD seeks the inclusion of NGO participation in the activities of the working parties; which includes the receipt of documents from the Executive Committee. The TACD is however concerned that the relationship between the Executive Committee and the working parties should be similar to that between AC.1 and WP.29 under the 1958 agreement. The proposed Executive Committee under the draft global agreement is composed exclusively of delegations from contracting parties. There is only a guarantee for participation of nongovernmental organisations in the working party under the Executive Committee. Stronger provisions for NGO participation in substantive policy-making discussions are needed.

4. Harmonization Priorities. Business and governments are already identifying their priorities

for global harmonisation. TACD will go on to consider this in the near future. TACD has already considered the business proposals for tyre regulations and makes the following comments. The Transatlantic Business Dialogue, in its Charlotte Conference report, recommends that the US and the EU "review existing passenger tyre regulations to identify testing and labelling criteria that can become part of a new tyre standard which will improve safety, free trade, and the environment, on a global basis." The recommendation identifies for consideration as the new standard a proposed "Global Tyre Standard (GTS-2000)". It urges adoption of this proposal by WP-29.

The TACD agrees with the TABD on the principle of improving standards. We believe that certain outcomes of tyre standards harmonization can improve safety. However, as we understand GTS-2000, it would simply compare US and EU standards and for each performance element of the standards choose the higher requirement to be an element of the new, harmonised standard. This new standard would, in the view of the TACD, be inadequate for safety purposes.

Both US and EU tyre standards are based on outdated tyre technology. Harmonisation to achieve the goal of reducing death and injury related to motor vehicle use requires a "ground up" revision of standards based on best available tyre technology and safety needs. TACD recommends that the EU and US undertake to develop new tyre standards that will achieve this goal.

EUROPEAN COMMISSION SERVICES' RESPONSE

The TACD adopted recommendations in the field of technical safety regulations for motor vehicles, pointing to upward harmonisation, for democratic national procedures, transparency of work under the 1998 Parallel Agreement, and indicating harmonisation priorities.

The European Commission services welcome the contribution from the TACD with regard to technical safety regulations for motor vehicles. Both the EU and its Member States have always been at the forefront of international harmonisation. Whereas nearly all the EU Member States have been since long Contracting Parties to the UN/ECE 1958 Agreement in the Automotive sector, the European Community itself could only adhere to the Agreement after its revision in 1995, opening the way for regional economic integration organisations to also become Contracting Parties to the Agreement. Since its accession the EC is actively participating in the works undertaken within the Geneva forum.

Due to the ever increasing globalisation of the automobile industry, international harmonisation in the field of motor vehicles regulations, procedures and certification requirements, is becoming ever more important. The EC's accession to the 1958 Agreement in March 1998 is helping to avoid parallel regulatory costs therefore benefiting both industry and the consumers alike. In addition, and since article 95 of the EC Treaty (ex article 100 A) is requiring in the EC decision making a high level of protection concerning health, safety, environment and consumer protection, the EC is committed to ensure that such a high level is also respected with regard to the regulations to be adopted under the revised 1958 Agreement as well as under the 1998 Parallel Agreement, the latter having been signed by the US that is not a Contracting Party to the 1958 Agreement.

(Democratic national procedures + openness and transparency within 1998 Global Agreement)

The decision process within the EU is such that democratic procedures are followed throughout the legislative process, and in particular with regard to the automobile safety and environment legislation. In summary, the decision-making process starts from the drawing of a Commission services draft proposal, discussed with Member States representatives and experts at an early stage. Then the draft proposal will have to be endorsed by the European Commission, the Council of Ministers and the Parliament before it is adopted. All these steps are made in full transparency, therefore allowing all interested parties, including consumer representatives, to voice their concerns at both technical level and political level.

Within WP 29, the procedure is also open and transparent. Working groups and WP 29 sessions are attended not only by Contracting Parties representatives, but also by interested NGOs, including consumer representatives that are contributing positively to the discussion. It is the European Commission's firm intention that both transparency and openness be maintained within the 1998 Parallel Agreement, and these principles will be laid down in the Terms of Reference and rules of procedure for WP 29.

(Priorities and GTS 2000 - tyre standard)

It is evident that harmonisation under the Parallel Agreement will not embrace at once a complete set of technical regulations in the automobile sector with respect to safety and environment issues. It is, however, to be noted that more than 100 regulations have already been adopted under the revised 1958 Agreement to which the EC and Japan became Contracting Parties in 1998. Priorities for global technical regulations under the Parallel Agreement will have to be established. The choice of these priorities is important since they will constitute test cases of the new framework.

The TABD already recommended to the EU and the US to consider the new passenger car tyre draft standard GTS 2000. The UN/ECE WP29 Working Party on Brakes and Running Gear (the GRRF) had a first discussion in February 1999 on the proposal on global technical regulation for passenger car tyres, presented by the European Tyre and Rim Technical Organisation (ETRTO). In order to ensure that adequate attention be given to this proposal, the GRRF requested, and in view of the importance of the proposal the WP29 agreed to, the creation of an informal working group to define a short and medium term strategy for the planned regulation so that a strategic decision on the way to proceed to establish a global tyre regulation could be made at the next meeting of the WP29. It was also agreed that the principles of the Parallel Agreement should be observed, both in cases of harmonisation of existing or creation of a new regulation.