

**TRANSATLANTIC CONSUMER DIALOGUE**  
**WASHINGTON DC MEETING, 29-30 OCTOBER 2002**

**TACD 2002 REPORT CARD,**  
**TACD RESOLUTION ON**  
**CHILDREN AND E-COMMERCE**  
**AND**  
**EUROPEAN COMMISSION SERVICES' RESPONSES**

**April 2003**

## **1) Objective Review of WTO before a New Round**

### **Boxed wording taken from 2001 Priorities document**

*TACD reiterates its call for an objective review of the WTO agreements based on common data sets for each agreement, and their impact on consumers and the environment before any new round of WTO negotiations is launched. We call upon our governments to support this review, and include substantive participation from all quarters of civil society.*

#### **EU - SLIGHT PROGRESS:**

We are unaware of any European Commission support for independent and objective reviews of the consumer impacts of WTO agreements, or of trade liberalization more generally. However, the European Commission is carrying out sustainability impact assessments of WTO agreements and we await the completion of this development with interest.

#### **US - NO PROGRESS:**

We are unaware of any U.S. government support for independent and objective reviews of the consumer and environmental impacts of WTO agreements or of trade liberalization more generally.

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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In the context of mainstreaming sustainable development into trade policy, the two main objectives of the Commission are:

- To develop and implement an impact assessment methodology to ensure that trade agreements are sustainable and to make proposals aimed at enhancing the positive effects of such agreements on sustainable development and to mitigate their negative ones.
- To promote the consistency of international trade rules with sustainability objectives (precaution, labelling, consistency between WTO rules and MEAs)

The Commission awarded a contract for carrying out a Sustainability Impact Assessment (SIA) in June 1999 to a team of independent experts from the University of Manchester.

The consumer aspects are not directly included as one of the key objectives selected for the SIA, but are indirectly included as a part of the assessment of the social and economic impact of the Doha Development Agenda. As the SIA process is seen as a policy dialogue tool, TACD comments are welcomed and should be directed to the consultants responsible for the SIA (whose contact details are on DG Trade's web site, mentioned page 3).

The SIA is conducted with the following timetable:

- 2002-2003 : overall preliminary SIA and 3 sector studies
- 2003-2004 : other sector studies
- 2005 : Overall full SIA

Sectoral studies:

The three first sectors are:

1. Environmental services (with a special emphasis on water and waste treatment)
2. Market Access (with a special emphasis on pharmaceuticals, Non-Ferrous Metals, Textiles)
3. Competition

Overall Preliminary Assessment:

This qualified preliminary assessment will cover both Doha Development Agenda (DDA) negotiation mandate and sectors which could be included in the negotiation mandate after the 5<sup>th</sup> WTO Ministerial meeting in Cancun (in particular implementation and Singapore issues). It should provide an overview of the potential major impacts on sustainability of *all* of the proposed sectoral measures. This is intended to assist in determining the more detailed sectoral assessments to be undertaken in the further stages of the study (2003-2004).

Outside the scope of the WTO SIA other studies are being conducted in conjunction with each negotiation process (EU-Mercosur, EU-ACP, EU-GCC, Euro-Mediterranean Free Trade Area, EU-Chile).

A major event was organised by the Commission on 6-7 February to take stock of previous methodological/process improvements and to identify major challenges for future work. More than 200 participants (country representatives, NGOs, experts) attended this seminar.

For further information please use the following internet links:  
<http://europa.eu.int/comm/trade/sia/background.htm> for general information on SIA and  
[http://europa.eu.int/comm/trade/sia/seminar/index\\_en.htm](http://europa.eu.int/comm/trade/sia/seminar/index_en.htm) for information on the SIA seminar organised in Brussels on 6-7 February 2003.

## 2) Trade in Services

### Boxed wording taken from 2001 Priorities document

*The GATS negotiations must consider modification to GATS Article XIV (General Exceptions) to take account of measures to protect the environment and recommendations must be developed on the relationship between services, trade, and the environment, including the issue of sustainable consumption.*

#### **EU - NO PROGRESS:**

(in the context of the GATS negotiations)

#### **US - NO PROGRESS**

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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In addressing environmental concerns, GATS Article XIV(b) allows WTO Members to adopt exceptional policy measures if this is 'necessary to protect human, animal or plant life or health'. This provision allows members to take measures even in violation of the provisions of the agreement if necessary. Apart from this provision of Article XIV, which addresses exceptional circumstances, nothing in the agreement hinders governments from protecting the environment through environmental regulation. In fact, the EC and its Member States successfully implement very high environmental standards which are in no way contradictory to its obligations under the GATS.

There have been suggestions that Article XIV GATS could be modified to bring it in line with Article XX GATT which also refers to 'conservation of exhaustible natural resources'. The EC supported the suggestion that the WTO secretariat continued its analysis of the issue on the relationship between services trade and the environment. On the basis of such an analysis, WTO members can consider whether it is necessary to amend Article XIV GATS.

The EC is entirely committed to the suggestion of studying the link between services, trade and the environment. Within the framework of the sustainability impact assessments in all of the EC's current trade negotiations, trade in services is one of the sectors being studied. This should provide an opportunity to identify the potential environmental, social and economic impacts of trade liberalisation in advance. This helps all parties in a negotiation to develop policies that can mitigate any potential negative effects that might be identified in a given country, while maximising the benefits of integration.

*A provision must be added exempting domestic subsidies from the obligation of national treatment for developing countries.*

**EU - NO PROGRESS**

**US - NO PROGRESS**

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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At present the GATS contains no specific rules on subsidies. In those services where a WTO Member has made market access commitments, nothing prevents that country from limiting access to domestic subsidies to domestic service suppliers, but it must, in such instances, list this restriction in the schedule of commitments as a national treatment limitation.

It is up to every WTO Member to decide whether, and to what extent, it wants to extend domestic subsidies to foreign service suppliers and to undertake GATS commitments accordingly. Any WTO Member, whether a developing country or not, wishing to grant national treatment to foreign service suppliers with regard to subsidies (e.g. to attract foreign direct investment) should not be deprived of its sovereign right to do so.

## **Boxed wording taken from Resolution Trade-11-01**

*The right of governments to provide and regulate basic services in the consumer interest should be broadly asserted in a new article included in the body of the agreement.*

### **EU - NO PROGRESS:**

We are unaware of any effort to amend the GATS with a new article ensuring the right to regulate.

The EC letter of 24 June does not directly address the TACD proposal for a binding 'right to regulate' article in the GATS. The letter does state that "the objective [of GATS 2000] is certainly not to seek derogations from domestic legislation based on health reasons of public order." TACD believes, however, that such derogations might occur as a result of trade dispute management or even in bilateral request-offer negotiations.

### **US - NO PROGRESS:**

We are unaware of any effort to amend the GATS with a new article ensuring the right to regulate.

## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The EC does not see a need to amend the text of the GATS in order to introduce a new article which would ensure the right to regulate. Any sovereign government has the right to regulate in any area of policy, and the GATS does not override this fundamental right. In fact, the GATS preamble recognises the '*right of Members to regulate, and to introduce new regulations, on the supply of services within their territories in order to meet national policy objectives.*'

This means that, subject to the obligations set out in the agreement, any member of WTO can introduce or change regulation of services sectors as it sees fit. The GATS neither prohibits nor reduces a Member State's ability to introduce new, or change existing regulation, or to provide and regulate 'basic services'. The Community will make sure that such rights are not altered as a result of the negotiations on domestic regulations.

*The right of governments to assure the provision of critical services – health, education, telecommunications, water and energy utilities – should be protected by revising the governmental exemption in the agreement to make it self-defining. The rights of governments to provide universal access and affordability should be assured.*

**EU NO PROGRESS:**

The EU rejected the self-defining approach at the TACD meeting in December 2001.

**US NO PROGRESS**

**EUROPEAN COMMISSION SERVICES' RESPONSE**

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Public services are an essential feature of the European model of society and the EC fully shares the importance citizens in Europe and elsewhere attach to maintaining and developing public services.

Nothing in the GATS obliges Members to deregulate public services or prevent them from designing policies that safeguard the provision of such services. WTO Members maintain the sovereign right to regulate economic and non-economic activities within their territory in pursuance of public policy objectives. The GATS does not seek to influence these objectives. The EC has no intention of changing these rules.

First, many public services are not subject to the GATS, thereby excluded from the general obligations and disciplines set out in the Agreement. This exclusion, by virtue of Article I:3 (c) in the GATS, covers services that are neither provided on a commercial nor on a competitive basis.

No single model exists across countries for what constitutes public services and there are, today, a variety of ways in which the public and the private sectors interact to provide such services. How much the public versus the private sector is involved depends on the national traditions and legal conditions prevailing in the countries concerned. The GATS leaves it entirely to its Members to decide whether they provide public services themselves, directly or indirectly (through public undertakings), whether they entrust their provision to a third party, or finally whether they rely entirely on private markets. Thus public services can and are carried out either by the state, or by public or private undertakings and experience has shown that competition can, in certain cases, be a tool in improving performance. Given the absence of a common notion of what constitutes public services, it would be very difficult to arrive at a common definition of Article I:3 and launching such an unpredictable exercise would be fraught with risks.

Second, even for services that fall outside the carve-out contained in Article 1:3, Members still retain, under the Agreement, the right to determine the list of activities for which it is prepared to offer market access and national treatment to foreign service providers (“bottom-up approach”). Each country can therefore exclude from its commitments those activities that it considers politically sensitive. Monopoly suppliers, whether public or private can, for example, be maintained and limitations of

any other kind can be imposed on foreign supply if that is deemed necessary to safeguard a public service.

Third, even where Members decide to make commitments they are free to tailor the sector coverage and substantive content of such commitments in a way that is consistent with other legitimate policy objectives. They can exclude from commitments any activity where foreign competition is unwanted and can schedule limitations on the level of market access and national treatment committed. The commitments thus tend to reflect national policy objectives and constraints, overall and in individual sectors. For this reason, the GATS is respectful of the diversity of economic and social situations among its member countries.

Fourth, GATS does not undermine the ability of governments to enact domestic regulations, legislation and other measures to safeguard the public interest. For example, designing and implementing policies aimed at ensuring the availability, quality and affordability of essential public services, such as universal service obligations, is not restrained by the GATS.

*The imposition through the GATS of "necessity tests" or requirements to only implement measures that are "the least trade restrictive" should be rejected. Existing WTO regulatory disciplines are sufficient. The EU principle of proportionality may not be appropriate in the WTO context.*

**EU NO PROGRESS:**

The EU is continuing to pursue disciplines under Article 6.4 contrary to TACD recommendation.

**US SOME PROGRESS:**

The US government told TACD in December 2001, that new disciplines under Article 6.4 may not be necessary. The US should make its position consistent and oppose a necessity test in the draft disciplines on accounting.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The EC does indeed remain committed to the development of disciplines under GATS Article VI:4. The EC objective is that GATS disciplines on certain domestic regulation measures (i.e. measures related to qualification requirements and procedures, technical standards and licensing requirements - not all regulations) should ensure that those measures are based on objective and transparent criteria and that they do not unnecessarily hamper trade in services.

Discussions in WTO have looked at different aspects of such possible disciplines. In particular, the two concepts of transparency and necessity have been discussed in some detail, based on the existing provisions in GATS Article III (transparency) and VI:4 (Domestic regulation).

The latter sets out, as one of the principles to be taken into account, that disciplines should aim to ensure that licensing and qualification requirements are '*not more burdensome than necessary to ensure the quality of the service*'. The EC thinks that this principle should indeed be reflected in GATS disciplines, but also that the term 'necessity' for this principle might be imperfect: Rather, we should be talking about proportionality of a measure - this means that it is not questioned whether a measure is necessary at all, but if the measure is proportionate to the objective it is supposed to achieve. Also, the validity of the policy objective itself should not come into question. This remains up to governments and parliaments. We have no intention to establish rules in the GATS that 'all domestic regulation had to be the least restrictive to trade', and nothing in the GATS actually stipulates such a requirement.

With regard to transparency, discussions have essentially centered around the publication of services measures, provision of information to other Members and notification obligations to the WTO, as well as the merit of establishing a 'prior consultation + comment' obligation for WTO members which would allow all interested parties to comment on proposed services regulations of other Members.

This has been one of the priorities for the US. We agree with the US that prior consultation mechanisms can be a useful way to consult all interested stakeholders in the process of policy formulation. However, we are reluctant about a WTO obligation for all governments to establish such consultation mechanisms, regardless of the legislative and administrative traditions and procedures in place.

*The GATS articles on market access and national treatment should be amended to clearly state that they do not apply to non-discriminatory domestic regulations.*

**EU - NO PROGRESS**

**US - NO PROGRESS**

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The EC does not see a need to amend GATS Articles XVI (market access) and XVII (national treatment), in order to state that they do not apply to non-discriminatory domestic regulations. Both with regard to market access and national treatment, both discriminatory and non-discriminatory regulation determine the conditions under which services can be supplied. Listing limitations to both market access and national treatment in the schedules of commitments provides for transparency, predictability and legal certainty for service suppliers wishing to enter a market.

Article XVI stipulates that a member should set out in its schedule the 'terms, limitations and conditions' with respect to market access in a given sector. In addition, there is a list of measures (mainly of a quantitative nature, such as limitations on the number of services suppliers, number of service operations, number of natural persons that may be employed, limitations on participation of foreign capital) which a member must clearly list in their schedule of commitments if they wish to maintain them, even though they have taken a market access commitment.

While some of these measures might be of a non-discriminatory nature, i.e. they would apply to both domestic and foreign service suppliers (e.g. limitations on the number of service suppliers in a given sector regardless of their nationality), they nevertheless are part of the conditions determining market access. In fact, the GATS only requires members to list them, not to eliminate them, in order to provide transparency and predictability for foreign service suppliers wishing to enter a particular market.

Article XVII stipulates that in principle, a member should accord national treatment in sectors where commitments are undertaken, but at the same time allows for limitations to such treatment, if inscribed in the schedule of commitments.

This provision would first of all apply to discriminatory regulation. However, full national treatment in a given sector and mode of supply is defined as providing that the conditions of competition are no less favourable to services or service suppliers of other Members than those accorded to domestic-like services and service suppliers. As formulated, this language takes account of the fact that regulation, although non-discriminatory at face value, can affect foreign suppliers much more, and in a different way, than domestic suppliers, and thus can lead to discrimination. As an example, if a government requires 'prior residency' in the country by a service supplier in order to be allowed to apply for a licence, it is clearly much easier for a domestic service supplier to fulfil this requirement than for a foreign company.

*Key GATS documents should be made public. Consumer groups and other civil society groups need to be consulted on a regular basis on the GATS, particularly in regards to the negotiations on domestic regulation and professional standards.*

**EU - NO PROGRESS:**

The draft EU requests were leaked to the public, but the EU has no plans to make further negotiating documents public. However, the European Ombudsman has required the EC to make public the briefing notes of meetings with the TransAtlantic Business Dialogue (TABD). Publication of these briefing notes and other communications with TABD would improve transparency in the services and other trade-related areas.

**US - NO PROGRESS:**

The US continues to state that it will not release GATS negotiating documents.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission aims to be as transparent as possible with all stakeholders, but an appropriate balance must be struck between transparency and our ability to negotiate in an atmosphere conducive to frank and open discussions. The Commission believes that an appropriate balance has been struck and that there are ample opportunities for all interested parties to provide meaningful input if they so desire. It recalls that the EC's general objectives for the GATS negotiations as well as its objectives for most of the sectors covered by the GATS have been publicly available for some time through, for example, the EU<sup>1</sup> and WTO<sup>2</sup> web sites. It has furthermore made public comprehensive documents summarizing its own initial requests but also the requests addressed to it from third countries.

As far as negotiating documents are concerned the Commission refers to its reply of July 2002, to an open letter from a number of NGOs (available at: <http://europa.eu.int/comm/trade/services/plreply.htm>) and which explains its efforts at providing transparency in the negotiations and the rationale for not making such documents public.

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<sup>1</sup> <http://europa.eu.int/comm/trade/>

<sup>2</sup> [http://docsonline.wto.org/gen\\_search.asp](http://docsonline.wto.org/gen_search.asp)

*The “bottom up” architecture of the GATS (i.e. the negotiation of specific commitments rather than the negotiation of exceptions to very broad commitments) should be maintained and the needs of developing countries should be given special consideration in the negotiations. For example, the US and EU should provide funding for capacity building.*

**EU - NO PROGRESS:**

To the contrary, the EU is still pursuing disciplines on domestic regulations that could be applied across the board.

**US - NO PROGRESS:**

TACD is unaware of any affirmative commitment to keep the structure of the GATS bottom up.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The GATS architecture has an 'in-built' mechanism which has the same, if not more, effect as 'traditional' SDT, by providing total flexibility in making commitments. In fact, Article XIX.2 spells this out by recognising the right of developing countries to open fewer sectors, liberalising fewer types of transactions, progressively extending market access in line with their development situation. Most developing countries have made ample use of this flexibility during previous rounds of negotiation. In view of this, the EU have taken a balanced and measured approach to service liberalisation during the GATS negotiations. The EU has, for example, modulated its requests so as to take account of, inter alia, the level of development of individual members and their ability to adopt and implement an appropriate regulatory framework. As a result the EU is seeking commitments in a more limited number of sectors and for fewer modes of supply in the case of developing countries.

The EC is also putting a great emphasis on trade related technical assistance and capacity building (TRTA/CB). The EC and the 15 Member States are already the largest provider of bilateral development assistance, including trade-related assistance. As part of their implementation of the Doha commitments, the EC has agreed to further increase funding for trade related technical assistance and capacity building.

*US and EU governments should support a full, complete and independent assessment of the impacts of the current GATS regime and the implications of the proposed GATS 2000 rules on domestic social, environmental and economic laws, policies and programs drawing on the expertise of citizens groups in member countries.*

**EU - NO PROGRESS:**

The EU has failed to honor their commitment under GATS Article XIX.3, which calls for overall and sectoral assessment of trade liberalization of services impacts.

**US - NO PROGRESS:**

The U.S. government has failed to honor their commitment under GATS Article XIX.3, which calls for overall and sectoral assessment of trade liberalization of services impacts.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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As regards requests for a full evaluation and impact assessment of the current or proposed GATS obligations, the European Commission decided in 1999 to initiate a sustainability impact assessment (SIA) of the proposed WTO new round of multilateral trade negotiations. Consequently we have launched a Sustainability Impact Assessment of the EU position on a new round of negotiations, which will guide our negotiators in their preparation of policy and negotiating proposals. This will also allow to identify flanking measures that would mitigate any negative impacts and enhance the positive impacts, of trade measures agreed under a negotiation. We have included some service sectors (waste and water management) in the first raft of sector-specific studies now underway, and the services field as a whole will be dealt with in the more detailed sectoral assessment to be undertaken in further stages of the SIA. In addition, the EC's SIA methodology is available for all players who wish to engage in their own work on sectors not yet under the microscope.

### 3) Precautionary Principle

#### **Boxed wording taken from 2001 Priorities document**

*The TACD calls on the governments of the US and the EU to incorporate the precautionary principle in regulatory decisions involved in consumer health and safety and the environment. The precautionary principle is generally understood to mean that in cases where scientific evidence points to a risk to health, safety or the environment, but the available data are insufficient to accurately quantify or assess that risk, that regulators have a right and a responsibility to err on the side of safety. Open, transparent and inclusive regulatory processes are an essential part of precautionary decision-making.*

#### **EU - SOME PROGRESS:**

Following the publication of the Commission's Communication on the Precautionary Principle, the EU has continued to support the use of the Principle, for example, within its Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety. This has generally been positive, although further steps are still needed to ensure that decision-making on food issues are truly open, transparent and inclusive. The European Food Safety Authority will be important in this respect.

#### **US - NO PROGRESS:**

The U.S. government has failed to support a consistent use of precaution in domestic regulation.

#### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission services are committed using the Article 7 of the Food Law in the decision-making process when, following a risk assessment, scientific uncertainty is identified but a provisional risk management measure is necessary to ensure the high level of protection of consumers.

However, the measures taken shall be proportionate and no more restrictive of trade than is required to achieve this objective. These measures will be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

The EC regrets that the Codex Alimentarius Commission refused to apply the precautionary principle to Codex Standards, but welcomes the decision to elaborate guidelines addressed to the governments for risk analysis policies, including the precautionary principle.

*We call upon the governments to work with TACD to develop within the Codex Alimentarius definitions and guidelines for the application of the precautionary principle. We urge the EU and US to make efforts to develop a mutual framework and seek acceptance for such a framework by the WTO for utilizing the precautionary principle in a non-discriminatory manner that preserves a nation's right to take action to protect its citizens and that allows for consideration of social, ethical, animal welfare and other factors in decision making.*

**EU – GOOD PROGRESS:**

The EU has also continued to be a strong advocate for recognition of the precautionary principle within Codex work on principles for risk analysis and we hope that this issue can be resolved at the next meeting of the Codex Committee on General Principles.

**US - NO PROGRESS:**

The US government has argued against use of even the word “precaution” in Codex documents and has argued that Codex should not give national governments guidance – in general standards for risk analysis – on when a precautionary approach should be employed in risk management decisions.

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**EUROPEAN COMMISSION SERVICES’ RESPONSE**

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As a management tool, the precautionary principle must be enshrined in the risk analysis process. The Commission services believe that Codex Alimentarius should develop definition and guidelines for the application of the precautionary principle and welcome the decision taken by the Codex Alimentarius Commission to elaborate a code of practice when there is evidence that a risk to human health exists but scientific data is insufficient or incomplete. The EC strongly supports this Codex work on risk analysis principles.

*TACD also calls upon the governments to seek changes in the SPS agreement to ensure that the burden of proof is on proponents of a potentially risky product or technology, not upon nations taking a protective action, and to delete the word 'provisional' in the first sentence of SPS Article 5.7, as it suggests that precautionary decisions are always temporary.*

**EU - SOME PROGRESS:**

The EU tabled SPS reform language in the WTO agriculture negotiations.

**US - NO PROGRESS:**

The US opposes any clarifications or modifications to the SPS agreement.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission services believe that the principle of a pre-authorisation marketing list of potentially risky substances or technology, putting the burden of proof on the proponents, is not inconsistent with the provisions of the SPS Agreement. This is already the case in the European legislation for food additives, GMOs etc.

The Commission services consider that the provisional character of measures taken in application of the SPS 5.7 does not mean that there is *a priori* a specific time limit and refers to the obligation to seek for more scientific information. Accordingly, there is no need to delete the word "provisional".

## 4) Access to Medicines

### Boxed wording taken from 2001 Priorities document and Trade-10-01

*TACD supports changes in US and EU policy to improve access to medicines in developing countries. TACD again calls on the EU and US governments to provide a communication to the WTO in support of mechanisms, such as patent exceptions permitted under Article 30 of the TRIPS, that would permit the production of essential medicines for export when this is needed to meet public health needs in other countries and where the legitimate rights of patent owners are protected in the markets where the products are used. The US and the EU should not insist that countries adopt protections under Article 39.3 of the TRIPS that would be anticompetitive or undermine compulsory licensing.*

#### **EU – SOME PROGRESS:**

TACD welcomes the steps taken in recognition of the importance of the access to medicines issue. We note that the EU has supported the World Trade Organization's recent Doha Declaration on TRIPS and Public Health, and that the EU has made a number of positive contributions in the ongoing discussions over paragraph 6 of the Doha Declaration on TRIPS and public health, on the important issue of exports of medicines without the permission of the patent owner. However, there are aspects of the EU position that harm consumers in both developing and developed economies. In particular, the EU is asking that developing countries not be permitted to export medicines to developed economies without the permission of the patent owner, even when the legitimate interests of the patent owner are protected in the market where the product is consumed. Also, the EU is objecting to a European (or other developed-economy) generic producer supplying the developing country. This could lead to a situation where a European country issues a compulsory license for an abuse of the patent right (such as for charging prices that are too high), and the generic producer would be barred from exporting the generic version of the product to a poor country. It could also lead to a case where a European country could not import a generic drug from a qualified developing country producer, even if the developing country producer was the best option in terms of product quality and / or price. This would appear to prevent European countries with small domestic markets from being able to obtain efficient suppliers in the event that they need to issue a compulsory license, creating an unequal status among different European countries, and also marginalizing developing country producers by excluding the largest markets for products.

#### **US – SOME PROGRESS:**

TACD welcomes the steps taken in recognition of the importance of the access to medicines issue, and note that the US has supported the World Trade Organization's recent Doha Declaration on TRIPS and Public Health, and that the US has supported clarifications on issues such as the ability of least developed countries to exclude pharmaceutical products from patent protection. However, the TACD is disappointed that the US government has taken a restrictive and anti-consumer position on current

WTO negotiations over the ability of countries to export medicines without the permission of patent owners, even when the legitimate interests of patent owners are clearly protected in the countries where medicines are consumed. We note that during the recent Anthrax attacks, the United States considered importing ciprofloxacin from generic firms that relied upon Asian suppliers, a scenario that would be barred under US government proposals to the WTO TRIPS council. We also note that it would be immoral, and indeed unthinkable, for the US to withhold exports to medicines to treat a public health emergency, such as the spread of smallpox, and that the US proposals to the TRIPS council would not permit this, even in emergency circumstances such as those referenced in HR 3235, the Public Health Emergencies Act. We note that the US has a large number of trade actions against developing countries on issues regarding Article 39.3 of TRIPS and has taken positions that would undermine compulsory licensing, contrary to the position stated in the TACD Priorities document.

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### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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In 2002, the EU continued to play a key role in the WTO proceedings on the TRIPs Agreement and Public Health. The EU submitted two Communications to the TRIPs Council on the issue of compulsory licences for countries without manufacturing capacities in the pharmaceutical sector (paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health). These communications were tabled, respectively, on 4 March 2002 (IP/C/W/339) and on 20 June 2002 (IP/C/W/352).

The first paper explored possible options for a legal solution, either on the basis of Article 30 or on the basis of Article 31 of the TRIPs Agreement. The second paper advocated an amendment to the TRIPs Agreement that would facilitate the export of pharmaceutical products manufactured under a compulsory licence. It proposed to add a new paragraph to Article 31 that would carve out an exception to the restriction imposed by Article 31(f). The basic idea behind this proposal was that inserting a textual provision into the TRIPs Agreement itself would provide for a clear, legally secure, effective and permanent solution within an existing legal framework, *i.e.* Article 31 of the TRIPs Agreement. So there would be a clear ground, in the TRIPs Agreement itself, for countries without manufacturing capacities to rely on another country to grant compulsory license for export.

These contributions were welcomed by all other Members as constructive contributions to the debate, and several suggestions contained therein have contributed to shape the 16 December 2002 draft decision on paragraph 6 of the Doha Declaration.

The EU fully endorsed this draft decision, as did all other WTO Members, except one. The Commission regrets that this draft decision was not adopted and deplores the current deadlock in the paragraph 6 process. The Commission remains convinced that a multilateral solution must be found as soon as possible. In this spirit, the Commission launched, on 7 January 2003, a compromise proposal in order to put multilateral talks back on track. The main element of this proposal is to add a confidence-building element to the process by involving the World Health Organisation (WHO) in order to give its advice on the occurrence of serious public

health problems. (See EU Trade Commissioner Lamy's letter of 7 January 2003 to the WTO Members' trade ministers: <http://europa.eu.int/comm/trade/csc/plletter.pdf>)

In this context, the Commission services want to make the point that, in the EC, compulsory licences are, generally speaking, not used as a means to facilitate access to medicines. Compulsory licences can play a role as price regulator in developing economies, but this is not the case in Europe, where access to health care is guaranteed by elaborate social security systems. Member States do not appear to have the intention of increasing recourse to compulsory licensing in the future. It should be noted that, as proposed by several WTO Members, including the EU, the 16 December draft decision on paragraph 6 of the Doha Declaration foresees the possibility of developed country producers to manufacture under a compulsory licence for export to developing countries.

As regards Article 39.3, this provision has not been discussed in the TRIPs Council in 2002. In this context, in the EC non-paper of 20 September 2001 (Draft Declaration on TRIPs and access to affordable medicines), the EU stated that "the obligation under Article 39.3 of the TRIPs Agreement to protect test data against unfair commercial use and against disclosure should not be interpreted in such a way as to weaken or nullify Members' rights under other Articles of the TRIPs Agreement, such as the possibility foreseen under Article 31(b) of the TRIPs Agreement to grant compulsory licenses without making prior efforts to obtain authorisation from the right holder in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". This position, which applies, *inter alia*, to compulsory licensing as provided by Article 31 TRIPs, has not changed.

*TACD asks that the EU and US agree to provide the World Health Organisation with the right to use patents from publicly funded research and development in poor countries. The United States and the European Union and its member countries should enter into agreements with the World Health Organization, UNAIDS, UNICEF and other global public health organizations, to enable these organizations to use patents that were developed with public support, to expand access to health care in poor countries.*

**EU - NO PROGRESS:**

The EU has not reported to the TACD that it has entered into agreements with the WHO, UN, UNICEF and others to enable these organizations to use patents that were developed with public funding.

**US - NO PROGRESS:**

The US has not reported to the TACD that it has entered into agreements with the WHO, UN, UNICEF and others to enable these organizations to use patents that were developed with public funding.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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Over the past two years a series of activities has been undertaken to foster stronger partnerships with EU Member States, civil society, the private sector, UN agencies, funds and programmes and the World Bank.

The World Bank is a strong partner in different global fora for capacity building and specific activities such as research for an AIDS vaccine.

Work with UNAIDS and the WHO has been reinforced at different levels and in different fora, with the shared key priority for forthcoming years of better partnership at the country level. Dialogue with civil society has been institutionalised through the 'trade and public health' debate but is, as yet, less strong in the other areas of the EC Programme for Action on Communicable Diseases.

Pharmaceutical companies are increasingly involved as partners in policy and implementation, in particular in areas such as tiered-pricing and research and development. Other private sector partners are also increasingly committed and ready to work with the EU on fighting communicable diseases in developing countries. Partnerships with the developing countries are likely to grow in significance, once these are brought together in a Stakeholder Forum on Communicable Diseases in the Context of Poverty Reduction which the Commission intends to establish.

*TACD asks the EU and US governments to make specific commitments regarding funding of research and development for neglected diseases, and to explicitly discuss how the intellectual property rights from that research will be managed, so as to ensure broad access to the resulting inventions. The US and the EU should support the NGO call for a global convention on supporting Research and Development (R&D), including support for AIDS and malaria vaccines, low cost diagnostic technologies and other appropriate technologies, new drugs for tuberculosis, malaria and other neglected diseases, as well as other global R&D efforts, such as basic research, development of drugs for severe illnesses, and other research that benefits public health. Such a convention should include agreements to provide public funding for such research and development, as is appropriate given the immense suffering and economic costs of these diseases. Also, the inventions from such funding should be licensed in a manner consistent with the greatest global public health benefit. The US and the EU should ask WIPO, WHO and the WTO to propose alternative methods of burden sharing for R&D for poor countries that cannot effectively manage a European and US patent system.*

**EU - SLIGHT PROGRESS:**

The EU has participated in discussions in the G8 on R&D on drugs for neglected diseases but has not agreed to discuss the need for a formal treaty on health care related R&D, as outlined in the TACD resolution Trade-10-01. The EU has not explored alternative methods of sharing the burdens of R&D that are more appropriate for developing countries.

**US - SLIGHT PROGRESS:**

The US has participated in discussions in the G8 on R&D on drugs for neglected diseases but has not agreed to discuss the need for a formal treaty on health care related R&D, as outlined in the TACD resolution Trade-10-01. The US has not explored alternative methods of sharing the burdens of R&D that are more appropriate for developing countries.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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Poverty related diseases have become one of the priorities of the Sixth Framework Programme of Research, Technological Development and Demonstration Activities (FP6, 2002-2006). FP6 was adopted in July 2002 and a substantial budget increase of € 400 million has been allocated to HIV/AIDS, malaria and TB research.

The overall research strategy for R&D in FP6 is built on two components:

- The support for large research consortia which integrate different disciplines and approaches and which generate new partnerships between the different players involved. Different phases of the R&D development process from discovery to safety testing in humans shall be covered. Roughly € 200 million is earmarked for such activities.

- The establishment of a clinical trials programme to unite and support Europe's clinical trial activities specifically targeted at interventions for use in developing countries (EDCTP). The Commission earmarked € 200 million for this initiative.

## **Boxed wording taken from Trade-10-01**

*The US and the EU should ask the World Health Organization to report on the capacity of poor countries to evaluate patent claims on medical inventions, the costs of doing so, the costs of patent litigation in poor countries, and the policy implications of the capacity of poor countries to examine and litigate patent claims.*

### **EU - NO PROGRESS:**

The EU has not asked the WHO to evaluate the costs of patent examination and litigation in developing countries or to examine the capacity of developing countries to manage a patent system.

### **US - NO PROGRESS:**

The US has not asked the WHO to evaluate the costs of patent examination and litigation in developing countries or to examine the capacity of developing countries to manage a patent system.

## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission is also developing a work plan for reinforced technical assistance in the areas of trade and development, which includes support for the efforts of developing countries to participate in trade negotiations, support for building developing countries' capacity to implement trade agreements and support for the necessary policy reforms and investments<sup>3</sup>.

Several countries, such as Mauritius, requested specific studies on IP and a general study on TRIPs implementation in Sub-Saharan Africa is being contracted. Less progress has been made on work with the World Intellectual Property Organisation (WIPO), but partnerships with key civil society groups, such as Oxfam and MSF, and with the pharmaceutical industry (in particular with regard to tiered pricing) have been further developed.

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<sup>3</sup> Trade and Development Communication COM (2002) 513 final.

*The US and the EU should ask the G7 countries to support sufficient levels of donor support for health care needs in poor countries, and that this donor support not be tied to country policies on patents or other intellectual property concerns.*

**EU - SLIGHT PROGRESS:**

The EU member countries have not adequately responded to the request to support the Global Fund at \$7 to \$10 billion per year in donor funds.

**US - SLIGHT PROGRESS:**

The EU member countries have not adequately responded to the request to support the Global Fund at \$7 to \$10 billion per year in donor funds.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission services are very much aware of the need to support the Global Fund. The Commission services are working towards a sustainable financing strategy with all donor partners, including the G7 countries.

*The US and the EU should report to the TACD on the efforts that are being undertaken to improve the quality of generic drugs in poor countries.*

**EU - NO PROGRESS:**

The EU has not reported to TACD on efforts being undertaken to improve the quality of generic drugs in poor countries.

**US - NO PROGRESS:**

The US has not reported to TACD on efforts being undertaken to improve the quality of generic drugs in poor countries.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The EC is programming support to initiatives on technology transfer and local production of generic essential medicines against HIV/AIDS, malaria and tuberculosis. This initiative will focus in several countries in Sub-Saharan Africa (most needed region and lacking anti-retroviral generic production initiatives). It is supposed to be embedded in national strategies and with regional (eg SADC, NEPAD...) support. It will not only focus on technology transfer but also on training, capacity building, particularly oriented towards women, and previously disadvantaged populations. Likewise, it will ensure affordability and creation of enabling conditions for effective delivery to the neediest. Overall, these initiatives can also act as a catalytic process for science and technology in the generic pharmaceutical sector in the countries.

Within the strategic partnership being developed with WHO, the EC is also supporting the strengthening of pharmaceutical policies at country level. Some of its components aim at improving the capacities to ensure the quality of generic essential medicines.

## 5) Genetically Modified Organisms

### Boxed wording taken from 2001 Priorities document

*TACD continues to urge the governments of the EU and the US to adopt comprehensive mandatory labelling, including labelling of derivatives.*

#### **EU - GOOD PROGRESS:**

The EU has published a proposal on labelling and traceability of GMOs and on GM food and feed which, in line with the TACD recommendation, would require traceability of GMOs throughout the food chain and labelling of all GM derivatives. GM derivatives used in animal feed would also have to be labelled. This is a very positive step forward, which TACD fully supports. These proposals were supported by the European Parliament at first reading and are now being discussed within the Council.

#### **US - NO PROGRESS:**

The US has failed to establish a mandatory labelling system for genetically modified plants. Further, the US has blocked consensus at the Codex Committee on Food Labelling on compromise draft guidelines. The US, while considering approval of a genetically modified fish, also has also given no indication that it will require labelling of genetically engineered animals.

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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In November and December, the Council reached a political agreement on the Commission Proposals on traceability and GM food/feed, introducing comprehensive labelling and traceability requirements. The Council formally adopted its Common Positions on 17 March 2003. The Common Positions and the Commission Communications on the Common Positions were, following their submission, acknowledged by the European Parliament on 26 March 2003, signalling the onset of second reading.

*TACD urges adoption of mandatory pre-market safety testing and approval systems for genetically modified food.*

**EU - SOME PROGRESS:**

The preliminary proposal for a regulation on GM food and feed would also strengthen the approval process, including the removal of the simplified notification procedure based on the principle of substantial equivalence. One outstanding issue of concern however is the possibility that a threshold may be allowed for adventitious contamination with unapproved varieties provided that they have undergone an EU risk assessment, rather than full approval. The European Parliament did not support this proposal at first reading.

There will be a greater role for the European Food Safety Authority for centralised approval of GMO food and feed. However there are still some omissions, for example GM processing aids are not included.

The EU supported sound safety assessment guidelines in Codex.

**US - SOME PROGRESS:**

The US has failed to establish a system of mandatory safety reviews for genetically modified plants. In 2001, the US appeared to be making one small step forward when it proposed a regulation that would require mandatory pre-market notification to the FDA, and submission of certain safety data. However, the US has failed to finalize this proposed regulation, and thus has only a system of voluntary consultations. However, at Codex the US supported agreement on sound international guidelines for safety assessment. These have been forwarded to the Codex Commission for final approval.

The FDA is currently reviewing an application for approval of a genetically modified salmon, under its mandatory procedures for insuring safety of new animal drugs. This is a positive step. However, the FDA has failed to issue an overall policy on how it intends to regulate genetically engineered animals. Thus, the FDA still does not require mandatory pre-market human and environmental safety review, even though it seems to be carrying out such a policy in one case. Because the approval is being considered under the new animal drug provisions, the process is being conducted in complete secrecy with no public participation.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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It is correct that the Commission has proposed that small traces of GM material, not yet authorised in the EU, can be accepted in products for food, feed or for processing. It should be stressed, however, that this is accepted only on the condition that the GM material has undergone a scientific risk assessment by the EU Scientific Committees or the European Food Safety Agency and concluded to be without risk for its placing on the market in the Community. Therefore, the proposal is fully in line with the basic EU requirement of conducting a pre-market safety assessment. In November 2002, the

Council endorsed the Commission proposal on this point, but it was agreed to lower the threshold to 0.5 % and to limit the application of the threshold to three years. It was also agreed that a method for the detection of such GM material should be publicly available.

At the current time, the EU does not have any mandatory pre-market safety requirements concerning processing aids in general. However, the Commission is currently considering the regulatory status of enzymes used as processing aids, including GM enzymes.

*We are pleased that thus far the EU and US have managed to avoid any WTO challenges in this area.*

**EU - SOME PROGRESS:**

There has been no trade challenge so far.

**US - SOME PROGRESS:**

While the US has on numerous occasions threatened a WTO trade challenge against the EU on its pro-consumer labelling, traceability and pre-market approval policies, such a challenge has not been launched.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission considers that the current EU legislation concerning GMOs and GM food/feed, as well as its proposals on traceability and GM food/feed, are compatible with WTO rules.

*We urge the governments to seriously explore recent EU proposals on establishing systems of traceability.*

**EU - SOME PROGRESS:**

Proposals that would make traceability of GMOs a legal requirement have been proposed by the European Commission and are being discussed by the Council and Parliament.

**US - NO PROGRESS:**

The US has not established a system of product tracing for genetically modified food. However recent bioterrorism legislation may require much more record-keeping on food products in the future.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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Traceability of GMOs is already a legislative requirement in the EU. Article 4 (6) of Directive 2001/18/EC provides that Member States shall ensure traceability at all stages of the placing on the market of GMOs.

In December 2002, the Council reached a political agreement on the Commission Proposal on traceability and labelling of GMOs and traceability of food and feed produced from GMOs, establishing comprehensive and harmonised traceability requirements in the EU. The Council formally adopted its Common Position on 17 March 2003. The Common Position and the Commission Communication on the Common Position were, following their submission, acknowledged by the European Parliament on 26 March 2003, signalling the onset of the second reading.

## 6) Antibiotics in animal and food production

### Boxed wording taken from 2001 Priorities document

*The TACD is concerned about over-use of antibiotics in human medicine, animal husbandry and in plants for crop protection, which contribute to antibiotic resistance. The TACD urges the EU and US governments to adopt a total ban on the non-medical use of antibiotics in animal and food production and on prophylactic use of antibiotics except where disease has been identified in an animal or within a specific herd or flock. We welcome the steps that the EU has already taken in relation to antibiotic growth promoters and hope that the US can take the same approach.*

#### **EU – SOME PROGRESS:**

In February 2002 the European Commission proposed a regulation on additives for use in animal nutrition, which is intended to phase out the use of the remaining four antibiotics for growth promotion by January 2006. Although yet to be adopted by the Council and Parliament, this proposal would also amend the approval process for feed additives with the European Food Safety Authority (EFSA) evaluating them first.

Authorisations of new feed additives would be limited to 10 years and provide for maximum residue limits (MRLs) to be set, unless an applicant can show that they are unnecessary. Companies would have to apply for re-evaluation and re-authorisation of existing additives within 7 years. The proposals would provide for MRLs for coccidiostats of antibiotic origin to be set. The Danish Presidency has given a high priority to animal feed safety and is expected to maintain a "strict line" on antibiotic growth promoters. In the Codex Alimentarius Task Force on Animal Feeding, the European Community proposed that antibiotics should not be used in feed for growth promoting purposes.

#### **US - NO PROGRESS:**

The US has not banned any antibiotics for growth promotion. However the FDA has proposed guidance indicating that it may take potential increases in antibiotic resistance into consideration in the future when making decisions about new animal drugs.

The USTR continues to oppose the EU ban on the non-medical use of four antibiotics in animal feed.

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### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The European Commission services hope that the legal basis will be adopted definitively by the end of 2003 and that the ban on the use of antibiotics for growth promotion purposes can enter into force at the proposed date, i.e. 1 January 2006.

## **Boxed wording taken from Food-18pp-01**

*TACD calls for a total ban on the use of fluoroquinolone antibiotics in poultry unless the drug is administered by injection.*

### **EU - NO PROGRESS:**

Fluoroquinolones are not dealt with in the above proposals as they are considered medicines.

### **US - SOME PROGRESS:**

US FDA has proposed to ban fluoroquinolones in poultry. Bayer requested a formal hearing on the FDA proposed ban, to which the FDA has agreed.

## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The European Commission has addressed a question on this subject to its Scientific Committee on Veterinary Matters relating to Public Health. The Committee was asked to advise the Commission on the risk to human health caused by fluoroquinolone resistant Salmonella and Campylobacter strains derived from animals and foodstuffs and on possible measures to control the risk. After receiving the opinion from the Committee, the Commission services intend to consider the matter and, if necessary, to propose measures for adoption.

## 7) Consumer Protection in Electronic commerce

### Boxed wording taken from 2001 Priorities document

**7.1.** *TACD urges the US and EU governments to undertake measures to address cross border e-commerce issues in ways that reflect democratic values and ensures public accountability. Specifically, the US and EU are asked to:*

*Establish international minimum standards to promote trust and confidence in electronic commerce*

#### **EU - SOME PROGRESS:**

**In the context of the European Commission's e-confidence initiative, BEUC and UNICE reached an agreement on a European framework for e-commerce trustmarks schemes. The proposal comprises a set of requirements for trustmark schemes complemented by a detailed system for approval and monitoring based on the assessment by an independent third party. The proposed scheme should enable consumers to identify more easily which websites they can trust. The funding necessary to put this scheme into practice is still lacking.**

**TACD is waiting for the Commission to present a Communication on how to improve consumer confidence in e-commerce which should consider the work done by BEUC and UNICE. This agreement should be part of a legal framework establishing requirements for trustmarks. A section of industry has, for the moment, only agreed a declaration of intention. To become a real standard, applicable to all online trading, this agreement should be included in a sufficiently restricting legal framework.**

#### **US - SOME PROGRESS:**

In September 2002, the FTC launched a new Internet security initiative to promote good Internet security practices and provide resources for consumers and businesses.

In 2001, the FTC brought over 60 cases targeting fraudulent or deceptive marketing practices on the Internet.

At the intergovernmental level the US worked within the Asia Pacific Economic Cooperation (APEC) Electronic Commerce Steering Group (ECSG) to develop guidelines for consumer protection. These guidelines will be released in late October 2002 following endorsement at the Ministerial level. Alike other APEC initiatives these guidelines are voluntary and non-binding.

At the OECD the US participated in the development of the new Guidelines for the Security of Information Systems and Networks that were released in August 2002. Again, these guidelines are voluntary and non-binding.

The US also participates in the International Marketing Supervision Network (IMSN) and, in *econsumer.gov*, a pilot project run by the IMSN. *Econsumer.gov* focuses on cross-border e-commerce B2C transactions, and provides an online portal for consumers to obtain information about the approaches to enforcement of consumer

protection law within the participating countries, and on how to make a complaint online.

## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The Commission Services intend to introduce a Recommendation on e-confidence in 2003. This will clearly set out general principles for codes of good practice designed to ensure a high level of consumer protection. It should establish a standard to which Trustmark Scheme owners (whether in Europe, the USA, or elsewhere in the world) should aspire. These general principles would be based on the BEUC-UNICE proposals.

The Commission has also endeavoured to convince third countries to adopt, and implement where necessary, regulations to protect consumers in electronic commerce. In October 2002, the Commission convinced ASEM partners to agree to a number of objectives for e-commerce regulation, including consumer protection (see: <http://www.ktm.fi/eng/news/asem2002ecom/Recommendations.htm>). The Commission has also launched a number of dialogues on e-commerce regulation with third countries (Chile, Mercosur) to explain to them the benefits of consumer protection in e-commerce and will launch further dialogues in 2003 with other Latin American countries and with the Gulf Cooperation Council.

7.2. *Establish minimum standards to ensure that methods for resolving disputes are fair, effective, and do not deny consumers the right to seek legal redress*

**EU - SOME PROGRESS:**

The Commission issued a recommendation on the principles for mediation services. This Recommendation complements the 1998 recommendation which mainly apply to arbitration.

The Commission set up the EEJ-Network which is based on a system of "clearing houses", i.e. national contact points, which should help consumers with information and support in making a claim to the out-of-court dispute settlement systems in the country where the business is located.

Measuring this project by this aim as well as demands of fairness will not be able to take place until it has been in place for several years. Progress is still necessary on on-line where ADR systems are developing with no specific framework and no visibility for consumers.

At the international level the draft Hague Convention on jurisdiction and enforcement of judgements has yet to address our biggest concerns in the field of traditional court procedures.

**US - SLIGHT PROGRESS:**

In February 2002 the FTC held an informal roundtable to how to use the consumer.gov forum to promote ADR services, educate consumers about the features of ADR and help link them with ADR providers, but has not taken further steps to implement even minimal standards.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The EEJ-Net was launched as a one-year pilot phase on 16 October 2001. The network now comprises of 17 Clearing Houses (15 Member States as well as Norway and Iceland) which provide information and practical assistance to consumers in accessing an appropriate alternative dispute resolution ('ADR') scheme.

Over 1,100 complaints have been dealt with by the network during the pilot phase (between October 2001 and October 2002). All Clearing Houses have received further Commission funding for 2003 to consolidate this initiative and improve co-ordination and implement some common technical tools. A thorough review will take place during 2003 involving a conference (10-11 June), comprehensive statistical data and a report from the Commission.

In addition to the 1998 Commission Recommendation, a further Recommendation (2001/310/EC) was adopted in 2001 to provide a similar set of principles tailored to promote best practice for less formal ADR schemes such as mediation. Information about these ADR schemes is available through a database on the Commission's

website. It contains nearly 400 ADR schemes which have been notified by Member States as applying either the 1998 or 2001 Recommendation principles.

In parallel, the Commission services have also been looking at the relationship generally of ADR methods with the Court system. A Green Paper on ADR was produced in 2002 covering a number of different areas including family, employment and consumer issues to consult on the broad legal issues that the use of ADR raises.

The TACD also referred to the draft Hague convention. The Commission on General Affairs and Policy of the Hague Conference, at its meeting from April 2002, set up an “Informal Working Group on the Judgements Project” to explore whether a text could be presented to a Special Commission, to be held in mid-2003, with sufficient prospects of reaching an agreement. The working group, in which the European Commission participated, drew up a draft convention at the end of March 2003. This text could not be discussed at the Special Commission on General Affairs and Policy of the Hague Conference, which met in The Hague at the beginning of April 2003. It was decided at this meeting that the text will be circulated for comments to the member states of The Hague Conference. Depending on these comments, a Special Commission may be held in December 2003.

The attention of the TACD may be drawn to the fact that the draft convention excludes, from its scope, consumer contracts, and is limited to the choice of court clauses in business-to-business cases.

*7.3. Review the effectiveness of the Safe Harbor arrangement to determine whether further steps should be taken, including the adoption of national law and the development of an international convention, to ensure adequate protection for electronic commerce; the US Department of Commerce should instruct private companies on how to comply with either Safe Harbor or the EU Data Protection Directive in order to facilitate their legal obligations to protect personal information transferred from the EU.*

**EU - NO PROGRESS:**

The Safe Harbor agreement entered into force on 1 November 2000. The European Parliament's resolution of 5 July 2000 called on the Commission to ensure that the operation of the Safe Harbor was closely monitored and to make periodic reports. As a response to that undertaking, the Commission presented a working document at the end of 2001. This report was not an evaluation of the functioning of the Safe Harbor agreement, but only a presentation of developments. A full assessment report is necessary and we are expecting it to be done by 2003.

**US - SLIGHT PROGRESS:**

In October 2001, the Chairman of the FTC announced his intention to improve FTC action on privacy issues, including Internet privacy issues. He promised a 50% increase in resources and staff; increased enforcement of privacy policies and laws; improved collection, use, and public reporting of privacy complaints received from the public; and priority for complaints under the Safe Harbor Arrangement.

The Department of Commerce has put in place an outreach and education program. Since November 2000, they have held approximately 25 workshops and seminars around the country. In March 2002, representatives from a number of US government agencies met with the European Data Protection Commissioners to discuss, among other issues, the functioning of the Safe Harbor agreement. It is unclear whether any further steps have been taken regarding Safe Harbor or the protection of European consumer privacy interests.

The FTC has increased enforcement actions for deceptive spam, identity theft and other privacy violations occurring online. In August 2002, the FTC settled a privacy enforcement action against Microsoft for violations associated with the Passport identification and authentication system.

There has been no effort to adopt a comprehensive national law or international convention on online privacy. The Asia Pacific Economic Cooperation (APEC) Electronic Commerce Steering Group has begun work on privacy issues and is considering the development of new guidelines in this area. These would be voluntary and non-binding.

## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The European Commission will, as announced in the EC decision of 26 July 2000 on the adequacy of the safe harbor, prepare a report on the implementation of this scheme after 3 years of operation. In the meantime, frequent contacts with the American authorities involved take place at working level.

The Commission issued a staff working paper concerning the application of the safe harbour decision in February 2002. The main conclusions of the report were that all elements of the arrangement are in place but that there are a number of points that require attention, in particular the transparency of privacy policies of the organisations that have self-certified adherence and of the dispute resolution mechanisms. This paper was discussed in the Committee on Citizens' Freedoms and Rights, Justice and Home Affairs of the European Parliament in March without reviving the opposition to the Safe Harbour voiced in the Parliament's Resolution of July 2000.

The above mentioned staff working paper is an additional step taken by the Commission in order to keep all interested parties informed about the progress made but it is in no way meant to replace the obligation to produce an implementation report in 2003.

The Commission wishes to encourage the American counterparts to make renewed efforts to promote the safe harbor arrangement within the American companies.

The services of the European Commission, taking into account articles 7 and 8 of the Charter of Fundamental Rights, encourage the TACD to work towards a set of common rules based on the 1980 OECD guidelines for transborder data flows that would govern the way in which personal data is processed and shared world-wide.

7.4. *Support open access to the Internet, particularly in the broadband and digital television arenas.*

#### **EU - NO PROGRESS**

#### **US - NO PROGRESS:**

In the past year, the Federal Communications Commission has initiated significant actions threatening open access to the Internet. Specifically, by classifying broadband Internet service delivered over cable facilities as an "information service," the Commission is moving to eliminate open access and content non-discrimination requirements for the dominant means of accessing the high-speed Internet. It has proposed to do the same for broadband Internet service delivered over wireline (DSL) facilities. Also, in February 2002 the U.S. House of Representatives passed the Internet Freedom and Broadband Deployment, a bill that would threaten the ability of competing ISPs to reasonably interconnect with the high-speed facilities of Regional Bell Operating Companies. This has not passed the Senate however.

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#### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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- The European Summits of Barcelona and Seville held in March and June 2002 recognised that digital television and third-generation mobile communication (3G) will play a key role in providing widespread access to interactive services. They called upon the Commission and the Member States to foster the use of open platforms to provide freedom of choice to citizens for access to applications and services of the information society.
- The Commission is committed to ensuring widespread access to services through multiple platforms.
- Taking account of all platforms for the provision of access to high-speed internet services, including in particular cable modems, in October 2002, there were 10.8 million retail broadband customers in the EU, of which 4.5 million (41%) are served by new entrants and 6.3 million by incumbents. The figures combine broadband access via all types of providers.
- Access to the incumbents' unbundled local loops has been required since January 2001 by Regulation 2887/2000/EC. The objective is to facilitate market entry and to develop services competition for high-speed internet access. Incumbent operators that are subject to this Regulation must offer two services: (1) fully unbundled access, where the entire twisted metallic pair is rented to a new entrant for him to install his own broadband equipment, as well as (2) shared access to the twisted metallic pair, where the new entrant only rents the high frequency part suitable for high-speed internet.

- A new regulatory framework will be applied in the EU from July 2003. The new framework is designed to stimulate the growth of new services, in particular broadband customer access<sup>4</sup>. The EU regulates on basis of dominance.
- The eEurope 2005 Action Plan will try to stimulate a synergy between infrastructure upgrading, both broadband and multi-platform, and service developments<sup>5</sup>. Some important features of the Action Plan are: (1) Member States should aim to have broadband connections for all public administrations by 2005. (2) Public services should be interactive by 2004. (3) By the end of 2003, the Commission will issue an interoperability framework to support the delivery of pan-European e-government services. These measures of the Action Plan, and others, seek to ensure infrastructure upgrades that will drive the development of on-line services and new applications.

Investment in broadband will come mostly from the private sector, and public policy should focus on issues where competition is not effective or where political objectives, such as territorial coverage need to be ensured. Among other actions, public authorities and the private sector should offer their content on different technological platforms, such as interactive TV and 3G, to improve public services and ultimately, to increase productivity and growth. The Commission issued, on 12 February 2003, a Communication to this effect. The Commission also recently launched a public consultation on a report on the remaining "Barriers to widespread access to new services and applications of the information society through open platforms in digital television and third generation mobile communications". The Commission plans to adopt a Communication on this issue this coming spring.

- Digital TV
- Despite modest overall development, digital TV penetration has grown rather strongly during the past year in those Member States which are at an early stage of digital take-up. The divergent development in different Member States has evened out the market bias of previous years. In 2001, 90% of the market was represented by five Member States (Germany, France, Spain, Italy and United Kingdom), whereas by July 2002 their share of the total market (in terms of digital television households) has decreased to 84%.
- The figures regarding development of different delivery platforms indicate that digital satellite TV represents 64% of the overall satellite TV market and digital cable TV represents 16% of the overall cable TV market. Terrestrial digital TV represents only around 4% of terrestrial TV services. The latest developments in the market suggest that future terrestrial services will rely more on the free-to-air concept than on pay TV in the short term.

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<sup>4</sup> In its "Recommendation on Relevant Markets Susceptible of ex ante Regulation" of 11 February 2003, the Commission identifies the relevant markets that may justify for ex ante regulation under the new framework. This includes a "wholesale broadband access" market, which includes "bitstream" services provided by telcos and equivalent wholesale services provided over other infrastructures if they exist

<sup>5</sup> See:

[http://europa.eu.int/information\\_society/eeurope/news\\_library/documents/eeurope2005/eeurope2005\\_en.pdf](http://europa.eu.int/information_society/eeurope/news_library/documents/eeurope2005/eeurope2005_en.pdf)

**7.5.** *Work with the TACD to discuss the feasibility of proposals to create one or more permanent institutions that have as the central mission the protection of consumers in the global economy.*

**EU - NO PROGRESS**

**US - NO PROGRESS**

### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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As the Commission services indicated in the 1999 response, there is always the willingness to participate in open, constructive dialogue. It also said that the restriction to e-commerce issues is somewhat artificial.

However, the Commission services believe that, so far, there has been insufficient evidence and analysis of “system failure” to justify the creation of an entirely new institution dedicated to consumer issues. Consumer issues may cover a very wide range of subjects and certain overlapping with other areas, such as environment. A new institution might not contribute to the coherence of the international system and to understanding the consumer perspective, considering also the scarcity of resources and expertise.

We agree, however, that the consumer interest and input into international work should be more clearly advocated and taken into consideration – this might be a more effective way of promoting consumer concerns than creating a new institution. We suggest therefore that consumer organisations within the TACD should prepare a discussion paper, identifying priority areas of work, for wider consideration.

The Commission services also wish to highlight the fact that it is part of EU Consumer Policy to better integrate consumer considerations into other policy areas. The Commission services would welcome observations on how successful or not this has been and comments on priority concerns.

## **Boxed wording taken from Ecom-24-01**

***7.6.** TACD calls upon the US to develop legal means to safeguard the privacy of US consumers based on Fair Information Practices as articulated in the 1980 OECD Guidelines on the Protection of Privacy and Trans-border Flows of Personal Data. TACD calls upon the EU to report annually on the implementation of the EU Data Protection Directive, the various means undertaken within the EU to safeguard privacy, and the level of oversight on trans-border data flow. TACD calls upon the European Parliament to hold hearings on the operation of the Safe Harbor arrangement.*

### **EU - NO PROGRESS:**

The EU has not taken action to implement the OECD Guidelines. The EU has failed to report on implementation of the Data Protection Directive. Further, the European Parliament has not held hearing on operation of the Safe Harbor arrangement.

### **US - SOME PROGRESS:**

In January 2002, the FTC issued proposed changes to the Telemarketing Sales Rule (TSR) that would create a national Do-Not-Call (DNC).

Similarly, in September 2002, the FCC issued a Notice of Proposed Rulemaking (NPRM) seeking comment on whether to revise the current rules regulating the Telephone Consumer Protection Act (TCPA) and whether to exercise its authority to establish a national do-not-call list.

On the other hand, there have been negative developments in the area of medical privacy. In August 2002 U.S. Department of Health and Human Services (HHS) released final modifications to the HIPAA medical privacy regulation of 2000. The changes eliminate the patient consent requirement and allow for the use of individual's medical records for marketing purposes without notice or consent.

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## **EUROPEAN COMMISSION SERVICES' RESPONSE**

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Data protection is already ensured in the EU by Directive 95/46/EC. This Directive provides a level of protection that guarantees the protection afforded by the OECD guidelines and even goes further.

The European Commission services are actively working on the report on implementation of the Data Protection Directive. In this context, the European Commission services work on the basis of different sources. One of them is an external study made by an expert. Others are the submissions provided by interested parties, the answers received to the on-line questionnaire addressed last summer to citizens and business, answers to the detailed questionnaires sent to the data protection authorities and the national governments. The Commission organised, at the end of September 2002, a large conference with all interested parties in order to

discuss the implementation of the Directive. All these interesting and numerous materials are being carefully analysed by the Commission services. The report should be ready within the coming months.

## 8) Regulatory Cooperation and Transparency

### Boxed wording taken from 2001 Priorities document

*TACD members support the effort by United States to encourage the EU to develop a notice and comment rulemaking system parallel to the US system. US consumers have benefited greatly from this open and on the record process for promulgating domestic regulations. European consumers would surely benefit from such a system. As a general rule for transatlantic cooperation, TACD recommends that comments by foreign regulatory officials about each other's rules and technical standards be made on the record via formal comments to the appropriate agency, which are then made available to the public, and via some similar system in the EU. This would allow all interested parties to engage in an open exchange of ideas.*

#### **EU – SLIGHT PROGRESS:**

TACD submitted comments on the Draft Guidelines for Regulatory Cooperation in December 2000. Were they adopted, these Guidelines would have become an effective tool to promote transparency for all members of the public. However TACD was never again consulted by the governments. The final document does very little to increase transparency or public participation, but rather puts its main emphasis on harmonization.

#### **US – SLIGHT PROGRESS:**

TACD submitted its comments on the Guidelines for Regulatory Cooperation in December 2000. Were they adopted, these Guidelines would have become an effective tool to promote transparency for all members of the public. However TACD was never again consulted by the governments, despite a request to the US Government for a revised draft. The final document does very little to increase transparency or public participation, but rather puts its main emphasis on harmonization.

TACD's request for officials' comments to be made on record happens on occasion with specific regulatory proposals.

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### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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#### **Guidelines for Regulatory Cooperation and Transparency**

##### ***1. The Guidelines for Regulatory Cooperation and Transparency***

The TACD was consulted at the beginning of the process, along with other Dialogues, in the preparation of the Guidelines, and TACD comments on the draft Guidelines, in particular concerning transparency, were widely appreciated and taken on board in the final text.

We believe the Guidelines represent an important political commitment to encourage regulators on both sides to cooperate. Doing so would allow experiences and resources of both to be taken into account, which will result in better regulations and, at the same time, reduce the risk for trade frictions.

The Guidelines are voluntary, and will be implemented informally between regulators. There will not, therefore, be a formal procedure for this. We encourage the TACD to continue to come up with ideas for pilot projects, i.e. areas where new or amended regulations are being made and where, in your view, cooperation between the relevant regulators in the EU and US would be beneficial.

## ***2. On transparency***

Transparency in the regulatory procedure is governed by specific rules and principles. The Commission services do not agree that only "slight progress" has been achieved in this area.

The Commission has taken major initiatives in 2002 to strengthen transparency in its rulemaking procedures. Specifically, a "better regulation package" was approved by the Commission, comprising:

- (i) an *action plan to simplify and improve the regulatory environment* ;
- (ii) *general principles and minimum standards for consultation* ; and
- (iii) an integrated *impact assessment system*.

The *action plan* sets out detailed measures that cover the whole lawmaking process, from preparation of proposals by the Commission to transposition into national law by Member States. For example, requirements to be introduced progressively from 2003 for draft laws include minimum standards for stakeholder consultations, an analysis of the law's expected impact, and justifications of the degree of legal constraint at EU level (subsidiarity and proportionality).

The *minimum standards for consultation* include making available all relevant information to all interested parties, publishing widely (e.g. by using the recently established single access point on the Europa web-site), allowing for sufficient time for responses (minimum 8 weeks) and acknowledging receipt of contributions. They also cover making contributions to consultations open to public scrutiny on the single access point. The explanatory memoranda accompanying the Commission's final legislative proposals will also include the results of the consultations and an explanation of how these were conducted and how the results were taken into account.

The new *impact assessment system* integrates and replaces the various impact assessment procedures traditionally used by the Commission. Assessment findings should provide legislators and the public with more accurate and better-structured information about positive and negative impacts of Commission proposals on the economy, society and the environment.

### ***3. On pilot projects***

The Commission services welcome the TACD recommendation to have nutritional labelling as a pilot project under the Guidelines. The issue has been discussed with the U.S. FDA, and it has been agreed that possible areas for cooperation shall be examined.

*Similar rules should apply to the governments' 'early warning' system. A list of the early warning items being discussed by the governments should be posted on an ongoing basis on the governments' websites, and the public should be consulted as to whether or not these are appropriate items for early warning of potential trade disputes.*

**EU – NO PROGRESS:**

The list of early warning items is not apparent on the European Commission's DG Trade website, despite a written promise to do this in January 2002.

**US - SOME PROGRESS:**

A list of early warning items was posted by the US Government. However, there is no explanation of the items, no contact names and no provision for updates, severely limiting the usefulness of the posting.

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**EUROPEAN COMMISSION SERVICES' RESPONSE**

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The **Early Warning Mechanism (EWM)** is the Administrations' commitment to ensuring appropriate flow of information on potentially problematic EU-US trade issues. Through the continuous use of this mechanism, many potential disputes have either not escalated or have been solved.

In an effort to promote transparency, an illustrative list of recent Early Warning items, which provides an insight on what is being discussed under this heading, has been published on the European Commission's DG Trade Website (<http://europa.eu.int/comm/trade/bilateral/usa/usa.htm>). Given the ever changing and evolving nature of those items, this cannot be an exhaustive or fixed list.

Regarding the request for public consultation, it is important to keep in mind that the EWM is an intergovernmental tool and a mutual commitment for ensuring appropriate flow of information between both Administrations on potentially problematic EU-US trade issues. Its role and purpose is not to establish a consultation process between business, consumers and government. Nevertheless, input on EWM items may come from many different sources including business and consumer organisations. The role of the Dialogues in the EWM is therefore mainly that of identifying and indicating possible problematic issues to the administrations, but not to participate in the inter-governmental discussions.

Private interested groups are normally aware of such contacts and exchanges and the Commission is always willing to keep interested parties, including the Dialogues, fully informed about developments on issues of interest to them which have been raised as early warning items. This takes place in the framework of the regular contacts between Administrations and the Dialogues.

*While much can be done to facilitate regulatory cooperation and common approaches to common problems, we do not think that harmonization, mutual recognition or equivalency should be promoted in the proposed Guidelines for Regulatory Cooperation now under discussion. The TACD paper entitled “Principles of Harmonization” articulates our concerns about the lack of transparency and industry domination in international harmonization negotiations. Finally, we do not support “trade impact statements”.*

**EU – NO PROGRESS:**

Harmonisation, mutual recognition and equivalency were all promoted in the Guidelines, contrary to TACD recommendation.

The European Commission, Commissioner Erkki Liikanen is pushing for trade impact assessments which TACD opposed in principle.

**US – NO PROGRESS:**

Harmonisation, mutual recognition and equivalency were all promoted in the Guidelines, contrary to TACD recommendation.

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**EUROPEAN COMMISSION SERVICES’ RESPONSE**

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We want to stress that regulatory cooperation provided in these guidelines takes place on a voluntary basis and in ways that:

- (a) Contribute to achieving high levels of protection for health, safety, consumers and environment;
- (b) Are fully consistent with any applicable domestic legal requirements, and preserve the integrity of the domestic regulations development process;
- (c) Are fully consistent with any applicable international rights and obligations.

From 2003, the Commission will gradually introduce a new impact assessment tool to assess the social, economic and environmental impact of all major EU initiatives. This method integrates all sectoral assessments into one global instrument. This means that the trade impact of major EU initiatives will have to be assessed as other impacts, such as the impacts on health, safety and consumer rights.

## Children and E-commerce

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### INTRODUCTION

The TACD has already adopted two important resolutions on children and electronic commerce. These resolutions focus mainly on the problems and dangers facing children commercially, namely the problems of increasingly targeted advertising and the lack of distinction between advertising and content, privacy and data protection, and the need for children to have access to high quality non-commercial educational material. The TACD reiterates the problems highlighted and the calls for action made in the two previous resolutions. The purpose of this resolution is to provide a framework for further actions to protect children.

Consumer organisations on both sides of the Atlantic are very concerned about activities that some parents may consider inappropriate for, or harmful to, their children. These include:

- a) Inappropriate marketing to children of merchandise or services,
- b) Access to information technologies that allow children to either intentionally or unwittingly access sites with content which their parents believe is likely to disturb or harm them, including access to material which incites violence, racial hatred, encourages gambling, smoking or drinking, sexually explicit material or other material that might conflict with the values of the parent.
- c) Problems such as paedophiles posing as children.

In order to address these concerns, TACD proposes the following actions:

### FORA FOR ADDRESSING ISSUES

1. The US and EU should consider and discuss the feasibility of proposals to create one or more permanent institutions that have as the central mission the protection of consumers in the global economy, where issues concerning the protection of children can be discussed.

### MARKETING PRACTICES AND PRIVACY

2. The EU and the US should request that UNICEF and the World Health Organization report on the status of harmful marketing commercial practices to children.
3. The EU should introduce legislation to limit and regulate the marketing of potentially harmful content to children, including tobacco, alcohol and gambling sites.
4. The EU should undertake new measures to protect children's privacy, taking as a starting point the requirements of the US Children's Online Privacy Protection Act (COPPA). COPPA requires parental consent before personal information can be gathered from children, as well as requiring web sites to post a detailed and easy-to-find privacy policy on their home pages.
5. Violent games and adult material should only be made available on a verifiable order from an adult and should require a credit card, rather than automatically being added to the consumer's phone bill.
6. Authentication systems for credit cards are urgently needed, in order to address the problem of children using their parents' credit card unauthorised for purchasing on-line. One

possible solution could be to require a personal identification (PIN) for use of credit cards on-line.

#### ACCESS TO ADULT MATERIALS

7. Voluntary rating systems for web pages have floundered. The most pressing issues for rating are to make it easier for parents to protect young children from having access to what the parent considers to be adult material, including materials that are overly violent, incite hatred, or are sexually explicit.

8. There also exists a market for software that attempts to screen web sites for adult material. These filtering systems are used by many parents, but have also been criticized for false identification of sites that should not be blocked and for not blocking sites that parents may consider harmful to their children.

9. The EU and US should adopt rules for filtering software that is marketed to protect children in a manner consistent with the wishes of the parent. These rules should include criteria to ensure that filters effectively block undesired materials, and include mechanisms to determine if a specific web site is blocked by the filtering software, and to unblock sites that are incorrectly blocked.

#### PROTECTION AGAINST ADULTS PREYING ON CHILDREN

10. Many parents are concerned that children can be harmed by contact with adults who engage children through internet chat services.

11. The EU and US should encourage those in a position to do so, notably the Internet Service Providers, web sites targeted at children, and others, to give more priority to protecting children and alerting them to potential dangers. On their home pages ISPs should advise children not to arrange to meet someone or give personal details.

12. Parents, guardians and children should have effective mechanisms to report complaints about practices that are harmful to children.

#### CREATION OF WHOLESOME INTERNET CONTENT FOR CHILDREN

13. The EU and the US should support public funding for the development of digital libraries, distance education tools and other wholesome internet content for children.

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### **EUROPEAN COMMISSION SERVICES' RESPONSE**

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The European Commission attaches great importance to the effective protection of children and welcomes the attention the TACD has given to this issue.

#### FORA FOR ADDRESSING ISSUES

##### Recommendation 1

European Commission services are planning to set up a Forum under the Safer Internet programme, as a platform to allow discussion on issues related to Internet and new technologies, in particular related to protection of children. The Forum will be open to participation from third countries including the USA.

#### MARKETING PRACTICES AND PRIVACY

##### Recommendation 3

Protection of children is a matter of utmost importance. However, it is the firm view of the European Commission services that TACD should address its Recommendations jointly to the EU and the USA, since to do otherwise would incorrectly imply that such marketing is totally unregulated in the EU. Moreover, any such Recommendation should be carefully formulated, so as to specify the types of advertising and other marketing practices which, in the view of the TACD, give particular cause for concern in protecting minors.

The European Commission services would like to note that the EU is seeking to introduce a ban on Internet advertising of tobacco. However, it should also be noted that many EU Member States already ban the sale of tobacco and alcohol to minors and limit their access to gambling activities. Since all such general restrictions are non media specific, they apply equally to Internet site operators established within the EU.

Moreover, the EU is currently seeking to ban free gifts of alcoholic beverages to minors and adolescents, whether online or offline, in the proposed regulation on sales promotion.<sup>6</sup> The TACD could also consider issue given the recognised problem of binge drinking.

The forthcoming framework directive on unfair commercial practices will establish rules for determining whether commercial practices are misleading or otherwise unfair. Where a trader has directed its activities at groups of consumers, such as children, the impact of the practice will be assessed from the perspective of the average member of that group so they will need to take extra care to ensure that their practices do not mislead these consumers or otherwise infringe the directive. Apart from this initiative, the European Commission services consider that at this stage the existing rules in the EU regarding minors offer adequate protection.

#### Recommendation 4

Whilst recognising the importance of the issue of the protection of the privacy of children on the Internet, the European Commission services would like to note that in the EU children are already protected by the EU legislation on data protection in place and for the time being there are no elements that would motivate deciding on the adoption in the EU of a COPPA-type regime, though the European Commission services certainly keep following the developments. Should the EU decide in the future to consider this question, it will be necessary first to assess whether it is necessary to do so through legislation as the existing legislation already covers children and, if so, whether such legislation should follow a similar line as the US COPPA Act. The European Commission services agree with the importance of the issue and of the necessity of following this question in the future, but considers that Recommendation 4 is premature.

#### Recommendation 5

The European Commission services would like to point out that in the EU this is a matter for the authorities in Member States under national provisions relating to protection of minors.

#### Recommendation 6

The European Commission services would like to point out that this is a matter for the authorities in Member States under national provisions relating to consumer protection and protection of minors.

### ACCESS TO ADULT MATERIALS

#### Recommendation 7

The European Commission services do not agree with the statement that voluntary self-rating has “floundered”. There is considerable scope for further use of self-rating by the main content

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<sup>6</sup> Proposal for a Regulation of the European Parliament and the Council concerning sales promotions in the Internal Market, Com (2001) 546 final, 2.10.2001.

providers in Europe, but even if content is not rated, a system such as the new ICRA filter allows parents to deal with it appropriately by downloadable or user-configured stop lists or white lists.

#### Recommendation 9

The European Commission services are planning to support benchmarking to increase the information available to parents about the performance of filtering software.

#### PROTECTION AGAINST ADULTS PREYING ON CHILDREN

##### Recommendation 11

The European Commission services will continue to provide support for awareness-raising to educate both children and adults, which is best achieved as a combined effort. Various channels need to be used in order to reach the various target audiences and industry should play its part in this.

#### Recommendation 12

This point is covered by the Recommendation on protection of minors and Human Dignity<sup>7</sup>.

#### CREATION OF WHOLESOME INTERNET CONTENT FOR CHILDREN

#### Recommendation 13

If funding is made available for production of digital content, the European Commission services consider that it is appropriate for part of this to be aimed at quality content for children, who are part of the target audience and who also represent the future.

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<sup>7</sup> Council Recommendation 98/560/EC of 24 September 1998 on the development of the competitiveness of the European audiovisual and information services industry by promoting national frameworks aimed at achieving a comparable and effective level of protection of minors and human dignity OJ L270 07/10/1998 p. 48