

**TACD
TRANSATLANTIC CONSUMER DIALOGUE**

BRUSSELS MEETING, 23-24 APRIL 1999

**TACD RECOMMENDATIONS ON
FOOD, ELECTRONIC COMMERCE AND TRADE
AND
EUROPEAN COMMISSION SERVICES' RESPONSES**

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Foreword

The TransAtlantic Consumer Dialogue met for the second time in Brussels on 23 - 24 April 1999. On that occasion it adopted unanimously 21 recommendations on three main topics: food safety, e-commerce and other trade issues.

The European Commission services committed themselves to respond to all the Recommendations.

The following responses represent the view of the European Commission services. The responses will be circulated to the Member States, to the committees of the European Parliament dealing with consumer affairs and health, legal affairs, agriculture and external relations and to the Economic and Social Committee.

Generally speaking, the European Commission services support the views of the TACD on the issues raised. Although the Commission services cannot guarantee that they will implement all of them, they will nonetheless take account of the Recommendations when developing their policies in the areas targeted by the TACD.

The responses are also available on the Internet site of DG XXIV: <http://europa.eu.int/comm/dg24/>.

I. RECOMMENDATIONS ON FOOD:

- **Genetically Modified Organisms**
- **Antibiotics in Animal and Food Production**
- **BST (bovine growth hormone)**
- **Dietary Supplements**
- **Consumer Participation**
- **Inspection**
- **Microbial Safety**
- **Nutrition Labelling**
- **Precautionary Principle**

Genetically Modified Organisms

TACD RECOMMENDATION

Since consumers are concerned about risks, the environment, socio-economic factors, ethical issues and the lack of benefit for consumers, the TACD calls upon the governments of the US and the EU to establish effective and mandatory government approval systems of human health, safety and environmental protection.

Genetically modified foods should provide a clear showing of consumer benefits and present no harm to human or animal health or the environment.

In order to ensure consumers' right to choose and to be informed, governments must require mandatory labelling of all genetically engineered foods and ingredients based on complete traceability of GMOs throughout the entire production, processing and distribution chain.

EUROPEAN COMMISSION SERVICES' RESPONSE

Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMOs) establishes Community-wide provisions for a human health and environmental safety evaluation of releases of GMOs. No product containing GMOs has been or can be placed on the market without an evaluation under Directive 90/220/EEC or under sector-based legislation, which covers the specific evaluation, foreseen by Directive 90/220/EEC.

The European Commission has now proposed to amend this Directive in order to increase the efficiency, and the transparency of the decision-making process whilst ensuring a high level of protection for human health and the environment. With regard to the latter, time limited authorisations linked to monitoring have been introduced and long term effects must be considered in the safety evaluation.

Specifically in the food sector, Council Regulation (EC) No 258/97 on Novel Foods covers inter alia food and food ingredients containing, consisting of, or produced from GMOs and sets out a mandatory pre-marketing safety assessment for such products. The Regulation clearly states that Novel Foods must not present a danger to the consumer.

The mandatory evaluation implies that foods or food containing, or consisting of, or produced from a GMO cannot be placed on the market unless their safety has been determined through the appropriate procedures foreseen by the Regulation either at Member State or European Commission level. Furthermore, the Scientific Committee for Food is consulted on any matter likely to have an effect on public health.

Consumer concerns have also been addressed in the general labelling framework laid down in the Novel Foods Regulation, which ensures that the final consumer is informed of the following:

- the presence of a genetically modified organism;
- any characteristic (including the method by which it was obtained) which renders the food or food ingredient no longer equivalent to an existing food or food ingredient because of its composition, nutritional value or effects or intended use. This non-equivalence must be based on a scientific assessment taking into account a comparison of the GMO-derived product with other similar conventional products;
- the presence of material not normally present in equivalent foodstuffs and which may have implications for the health of certain parts of the population (e.g. allergies);
- the presence of material not normally present in existing equivalent foodstuffs and which gives rise to ethical concerns.

The European Commission is now developing further detailed implementation rules on labelling.

The European Commission is currently considering the development of a legislative framework for a GMO-free production line in order to enable the consumers to have a clear choice between GMO products and non-GMO products. A GMO-free production line would be based on producers' voluntary adherence to the scheme, as it happens in the case of the organic farming regime.

The European Commission has also co-ordinated and/or financed studies in order to develop and validate qualitative and quantitative methods for the detection of GMOs.

Furthermore, the European Commission's independent adviser group, the "European Group on Ethical Questions relating to New Technologies", delivers opinions upon request from the European Commission, European Parliament or Council, or on its own initiative. This group has presented a series of opinions on key biotechnology issues over the last 7 years.

It should also be noted that, within the Fifth Framework Programme of Research and Technological development, the thematic programme "Quality of Life and Management of living Resources" includes the Key Action "Food, Nutrition and Health" which has the objectives to improve the understanding of consumer requirements and providing a healthy, safe and high quality food supply. In particular, research areas such as *"development of food raw materials better adapted to consumer requirements; detection of specific GMOs in food including development and standardisation of methods to enable and assure traceability throughout the food chain and food network; rapid detection test for hormones along the food chain, development of new methodologies for assessing microbial, chemical and allergies risk and exposure; identification of beneficial effects of foods containing physiologically active components for defined target functions"*, are addressed by this Key action.

Antibiotics in Animal and Food Production

TACD RECOMMENDATION

Antibiotic resistance is a growing health problem. Because of the potential risks to human and animal health, the TACD calls on the governments of the US and the EU to institute a total ban on the non medical use (including use as growth promoters) of antibiotics in animal and food production, and a ban on the prophylactic use of antibiotics, except where disease has been identified in an animal or within a group of animals.

EUROPEAN COMMISSION SERVICES' RESPONSE

Being adopted by the working group on food, the recommendation only deals with the use of antibiotics in animals and food production.

However, the growing problem of antimicrobial resistance has been recognised in various ways within the EU.

Following discussions in several of the specialised Scientific Committees, the European Commission asked the Scientific Steering Committee (SSC) to establish a multidisciplinary working group to examine all aspects related to the use of antimicrobials and the development of resistance. The working group includes experts designated by the Scientific Committees having competence on the issue, as well as external experts.

The mandate of the group implies a multidisciplinary assessment of all aspects of the use of antimicrobials in human, animals and plants. On 28 May 1999 the SSC adopted its opinion on the matter "Opinion of the Scientific Steering Committee on Antimicrobial Resistance"¹.

The opinion proposes four important areas of action:

- Prudent Use of Antimicrobials;
- Prevention of Infection and Containment of Resistant Organisms;
- New modalities of Prevention and Treatment for Infections;
- Monitoring the Effects of Interventions.

In September 1998 - on the initiative of the Health authorities of the European Union - an EU conference was held in Copenhagen on the "Microbial Threat", that is human health implications of the increasing resistance to antimicrobial agents.

The conference adopted a Recommendation on inter alia the need for surveillance, for collection of data, for encouraging good practice and for co-ordinated research.

The Council (Agriculture) endorsed these recommendations at its meeting on 17 May 1999 and the Council (Health) at its meeting on 8 June 1999 adopted a resolution encouraging the European Commission to continue its work on reducing the emergence and spread of anti-micro-organisms.

¹ Available on the DG XXIV web site : http://europa.eu.int/comm/dg24/health/sc/ssc/out50_en.html

Specifically concerning surveillance including the use of antimicrobials can be mentioned: The Community Network for the Epidemiological Surveillance and Control of Communicable Diseases, and The European Antimicrobial Resistance Surveillance System (EARSS).

Among European Commission initiatives with special reference to the recommendation from the TACD working group, as quoted above, can be mentioned the suspension - as a precautionary measure - as from 1 July 1999 (at the latest) of the use of 4 antibiotics (bacitracin zinc, spiramycin, virginamycin and tylosin phosphate) as feed additives. Carbadox and oliquinox for growth promotion purposes in pigs have been banned as from 1 September 1999.

BST (bovine growth hormone)

TACD RECOMMENDATION

The TACD recommends that the government of the US follows the lead of Canada (which has prohibited the use of BST (also called bGH or bovine growth hormone) on the basis of animal health and welfare) and that the EU institutes a permanent ban on BST. In the interim, the US and EU should promptly require mandatory labelling of all milk and dairy products from cows treated with BST.

EUROPEAN COMMISSION SERVICES' RESPONSE

The moratorium prohibiting the use of BST in the European Community will end on 31st of December 1999. On the basis of the conclusions of the reports of the two Scientific Committees², the European Commission is studying the follow up to give to these scientific opinions. A prolongation of the moratorium may be proposed to the Council and the European Parliament.

The moratorium would apply to use of BST within the EU. No mandatory labelling is currently foreseen, in particular because such an option would be enforceable only if analysis of residues can be performed and can demonstrate that the milk comes from cows treated with BST. For the moment it is not clear whether it is possible.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, decided to hold the MRLs for BST at step 8.

² Report of the Scientific Committee on Animal Health and Animal Welfare on Animal Welfare Aspects of the Use of Bovine Somatotrophin (Adopted 10 March 1999).
Report of the Scientific Committee on Veterinary Measures relating to Public Health on Public Health Aspects of the Use of Bovine Somatotrophin (15-16 March 1999).

Dietary Supplements

TACD RECOMMENDATION

The TACD calls upon the governments of the European Union and the United States to require that dietary supplement ingredients be subjected to a government safety and efficacy review which shall include the establishment of safe upper limits.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission is preparing a preliminary draft directive to cover supplements marketed as foodstuffs. This draft is one of the measures to deal with the presence of certain nutrients in foodstuffs (a draft directive on the addition of nutrients to foods is also planned). As a first stage the draft will cover vitamin and mineral supplements.

Primary consideration will be given to:

- the definition of the products;
- ensuring correct and appropriate information of consumers (prohibition of making claims as to prevention, treatment or cure of a disease or of misleading statements);
- fixing upper limits for vitamins and minerals that will take into account scientific risk assessment (the Scientific Committee for Food is currently working on the establishment of upper safe limits for vitamins and minerals), intakes of these nutrients from all sources, and where necessary, recommended intakes;
- providing for a notification system of marketed products to the competent authorities in order to facilitate monitoring.

Consumer Participation

TACD RECOMMENDATION

The TACD recommends that the government of the US and the EU guarantee that consumers can fully participate in the setting of international food standards at the Codex Alimentarius and the World Trade Organisation (WTO). Furthermore, the decision-making process must be transparent, with full disclosure of documents. These requirements must also apply to decisions on equivalency by the US and the EU.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission Services welcome the request for participation, openness and transparency in the international fora.

The EU has sent to the Codex Commission its position on consumers' involvement in the work of the Codex Commission³. The EU welcomes the document, which was drawn up by the Secretariat of the Codex in co-operation with Consumers International and considers that it is a good document. As regards access to Codex documents, it should be the subject of close attention of the Secretariat that the consumer associations are allowed full participation in the work.

The EU supports a large part of the recommendations, but would underline that each Codex Member must keep freedom to organise the consumers' participation at national activities. The legal means and the methods by which governments improve the effective participation of consumer organisations in food standards and controls are matters for the Members. In the EU, Article 153 of the Amsterdam Treaty gives to the Community and its Member States shared responsibility in the protection of the consumers' interests and health.

The European Commission Services also note the request for full participation and disclosure of documents on equivalency decisions. The European Commission will continue to apply its policy of largest possible access to documents, based on the European Commission Decision of 8/2/1994⁴, on the Access to Documents and will involve the stakeholders to the larger extent, according to the existing rules.

³ The Codex Alimentarius Commission, during its session from 28 June till 3 July, has adopted a series of recommendations.

⁴ OJ L 46 of 18/2/1994

These rules are currently being reviewed, with a view to adopt the necessary Rules of Procedure to comply with art 255 of the Amsterdam Treaty, saying:

"1. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to European Parliament, Council and Commission documents, subject to the principles and the conditions to be defined in accordance with paragraphs 2 and 3.

2. General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the Council, acting in accordance with the procedure referred to in Article 251 within two years of the entry into force of the Treaty of Amsterdam.

3. Each institution referred to above shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents."

The European Commission Services will keep the TACD abreast of further developments in this respect.

Inspections

TACD RECOMMENDATION

There is a need for a coherent, hazard-based inspection program which covers food production from farm to table, consisting of the following items :

A general food inspection which follows and assesses the content of undesirable micro-organisms, chemicals and physical hazards in various foods—both presently and in the long term. This would provide a basis for both national and international decision making.

A system of industry self control in all stages of production from farm to table, based on HACCP (Hazard Analysis Critical Control Point System adopted by Codex) principles. The control system should be approved and regularly reviewed by authorities

Frequent and unannounced inspection by the authorities responsible for inspection of manufacturers and their control program to including sampling of manufactured goods; intensive control campaigns in susceptible areas; and screening tests.

EUROPEAN COMMISSION SERVICES' RESPONSE

At Community level, the European Commission has reviewed the manner in which it carries out its statutory control and inspection responsibilities in the food, veterinary and phytosanitary sectors.

The Food and Veterinary Office (FVO) was established within DG XXIV (Consumer Policy and Consumer Health Protection) on 2 April 1997 to undertake these responsibilities. It is governed by the three principles of transparency, independence and excellence, which have guided its progress in the last two years. In reviewing working practices and procedures within the FVO, certain key elements have been introduced:

- the use of audit techniques to focus control and inspection effort on the performance of competent authorities. This not only allows the best use of resources by the FVO, but also emphasises the central role of national authorities in ensuring adequate levels of consumer health protection.
- the development of a structured mission prioritisation system. This was intended to ensure that the FVO could identify and target production sectors and countries where particular risks to consumer health were considered to exist.
- the application of a "plough-to-plate" approach to the planning and performance of inspections, such that all parts of a production sector could be adequately assessed.

Responsibility for the implementation and operation of food safety controls rests with the national authorities. For this reason, the FVO's inspection effort is increasingly focussing upon the performance of the relevant competent authority, in particular the manner in which it organises, performs and responds to the results of food safety controls. This is supported by visits to individual farms, markets, processing establishments ("reality checks"). These are important both in providing a balanced picture of the health situation, and in reassuring consumers of the production standards being achieved. During these visits, the manner in which the competent authority implements and enforces EC (or equivalent) legislation is checked. This includes the operation and control of auto-control and HACCP systems within processing establishments.

The FVO will carry out audits of control systems in third countries with which agreements on sanitary measures applicable to trade have entered into force, following the operational procedures laid down in those agreements.

Reports of missions, which are published on the DG XXIV internet site⁵, provide information on the findings and conclusions of the inspectors, as well as making recommendations as to the action required to improve standards.

At national level, the European Commission supports the principle that the "day-to-day" responsibility for the production of safe food rests with the food business and that this must be underpinned with effective official controls undertaken by competent and well-trained officials.

The European Commission Services welcome the recommendation of the TACD for the use of HACCP systems. It supports the principle that HACCP systems should be developed by food businesses to identify potential food safety hazards and apply controls at the most effective step in the production of the food to ensure that the food is safe and wholesome when it reaches the consumer. HACCP systems cannot be applied in isolation and the European Commission Services support the principle that businesses must ensure that good hygiene practices are in place in addition to HACCP.

The Commission in its review of hygiene legislation will be focussing on measures that require food businesses to apply good hygiene practices and overlay these with HACCP systems. Official controls are required at a frequency reflecting the risk in the food business and these should include frequent and where necessary unannounced visits.

The European Commission Services support the use of sampling of foods as an adjunct only to the assessment of compliance with food legislation as it is inherently unreliable as a tool for detecting contaminated foods. The European Commission through its Co-ordinated Control Programmes identifies annually areas of concern for more focussed controls. These may include sampling of foods for contaminants, for example, pesticide residues in fruit and vegetables and an assessment of other control activities in relation to ensuring compliance with Community legislation.

⁵ <http://europa.eu.int/comm/dg24/>

Microbial Safety

TACD RECOMMENDATION

The TACD calls upon the governments of the US and the EU to take the following steps to reduce food-borne illness caused by pathogen contamination of food products:

- **Establish high performance standards to be implemented through HACCP (Hazard Analysis Critical Control Point System adopted by Codex) systems extending from farm to table;**
- **Collect and publish data on contamination levels;**
- **Expand sampling of products to include a wider range of pathogens;**
- **Encourage programs to minimise human pathogens in animal populations by eliminating infected flocks and other steps.**

EUROPEAN COMMISSION SERVICES' RESPONSE

The development of legislative and operational controls designed to ensure the microbial safety of foodstuffs intended for human consumption has a high priority within the European Commission and in Member States.

In line with the Codex Alimentarius Commission General Principles of Food Hygiene the European Commission supports the application of good hygiene practices in food establishments and in some sectors there are already Community requirements for the application of HACCP systems. The European Commission is committed to the extension of HACCP to other sectors. In its review of the community hygiene legislation the European Commission is considering the role of targets and performance standards for HACCP systems in ensuring the microbiological safety of foods.

This is reflected within Community legislation and in the approach adopted by the Food and Veterinary Office in its control and inspection activities. The development of auto-controls within food processing establishments, including HACCP systems, was emphasised in the European Commission's recent Green Paper on Food Safety. These principles form an integral part of the food safety controls in place in Member States, and will increasingly form the basis for Community legislation in this sector.

Member States have, in conformity with Community provisions, to collect and evaluate data on zoonotic diseases and zoonotic agents in animals and they have to report to the European Commission the trends and sources of these diseases and agents recorded. The European Commission evaluates these data and reports yearly to the Standing Veterinary Committee. Furthermore, EU legislation provides for monitoring data of human cases of zoonoses

As regards the zoonoses legislation, preparatory work is currently in hand to amend the existing Directive for the following reasons:

- the actual legislation is not adequately implemented in different Member States and the trends in food borne infections show that the current situation seems to be worsening ("new" pathogens are emerging and infections by "traditional" pathogens remain constantly high);
- the stable to table approach creates a new environment, which necessitates redefining the scope of the Directive as regards the responsibility of the primary producer;
- a clear policy should be created as regards placing on the market rules including imports and trade negotiations with third countries.

Taking into account the subsidiarity principle, future rules would allow a flexible, step by step, approach, based on monitoring and surveillance results and focussing on an effective reduction in the prevalence of certain pathogens in livestock in the Member States.

Other actions undertaken include official checks at border inspection posts on imported foodstuffs, according to pre-set sampling frequencies, which reflect the perceived risk associated with the product and country concerned. Where certain pathogens are found, immediate action is taken to remove the product concerned from the human food chain.

A Rapid Alert System exists, which allows Member States and the European Commission quickly to notify all Member States of incidents where food-borne pathogens are identified, and for the appropriate control action to be initiated.

In respect of a number of zoonoses, including brucellosis, tuberculosis and rabies, Community-funded eradication programmes have been in operation for several years. In some Member States this applies for salmonellosis.

In most of the Member States, these have achieved considerable success in reducing the incidence of these diseases in the susceptible animal populations. Such programmes are subject of regular inspections by the Food and Veterinary Office, to ensure that their rules are being respected, and that the objectives are being achieved.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, adopted principles and guidelines for the conduct of microbiological Risk Assessment.

Nutrition Labelling

TACD RECOMMENDATION

The TACD calls upon the governments of the EU to require mandatory nutrition labelling for food products, disclosed in a meaningful, consistent and easy to read format, regardless of whether nutrition claims are made. Both the EU and US should support mandatory nutrition labelling requirements at Codex Alimentarius.

EUROPEAN COMMISSION SERVICES' RESPONSE

A draft European Commission Communication on the follow-up to the "Green Paper on the General Principles of Food-Law in the European Union", adopted in 1997, is being drafted.

Among the tasks to be undertaken, the Communication mentions the revision of Directive 90/496/CEE on nutritional labelling of foodstuffs. Among the options envisaged by the European Commission is to make such labelling compulsory

Currently, the EU is supporting in the Codex Alimentarius an enlargement of the number of nutritional elements that must appear on the label when a nutritional claim is made about them.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, returned the proposed amendment on Nutrition Labelling to step 3 for further consideration.

Precautionary Principle

TACD RECOMMENDATION

The precautionary principle should apply in cases when the scientific evidence is not conclusive enough to determine a level of protection but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment.

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.

In this perspective, the TACD calls on the Codex Alimentarius Commission to set a clear policy that includes the precautionary principle, along with science, social and ethical factors, animal welfare and environmental protection within the decision making process.

We urge deletion of the word « provisional » in the first sentence of Article 5.7 of the SPS agreement. We call on the US and EU to seek to strengthen this article. In addition, we urge reconsideration of the current rules relating to the burden of proof to demonstrate that a product is safe.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services welcome the TACD recommendation calling for the incorporation of the precautionary principle in regulatory decision.

In essence, it is the European Commission view that the Precautionary Principle may be invoked in order to determine appropriate protective action in those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary assessment, that the possible effects on health, safety or the environment may be inconsistent with the chosen level of protection. In these cases all efforts must be made to obtain more comprehensive information concerning the risk in order to review the basis and necessity for the measures taken.

Concerning the environmental protection, the European Commission applies the provisions of the Amsterdam treaty amended Article 130r(2) as follows:

“Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community: it shall be based on the precautionary principle and on the principles that preventive action should be taken that environmental damage should as a priority be rectified at source and that the polluter should pay”.

The European Commission services also support the recommendation of TACD to consider the Precautionary Principle in its proposals for consumer health protection. In this respect the European Commission has already stated in its Communication of 30 April 1997 on consumer Health and Food Safety that:

“The Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists.”

The European Commission makes this point again in its Green Paper on “The General Principles of Food Law in the European Union”, reiterating the obligation imposed by the Treaty to take a high level of protection as a basis for action. The European Parliament has endorsed this approach.

In addition, the European Court of Justice has upheld the European Commission’s decision banning the exportation of beef from the United Kingdom on the basis of the precautionary principle. The Court stated: “Where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality and seriousness of those risks become apparent.”

Finally on 13 April 1999, the Council adopted a resolution calling on the European Commission “to be, in the future, even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle”.

The institutions of the European Community therefore agree that application of the precautionary principle should not be restricted to the environment but should, on the contrary, be extended to all instances where there is an obvious need to protect the health of the public, animals or plants, without waiting for scientific uncertainty to be clarified.

The European Community will continue to support reference to the precautionary principle in the Working Principles for Risk Analysis in the Codex Alimentarius Commission Procedural Manual, and to the development of guidelines for the application of this principle in the Codex Alimentarius decision making process.

Concerning the deletion of the word “provisional” in the first sentence of Article 5.7 of the SPS Agreement, the European Commission services believe that the provisional nature of measures taken on the basis of precaution pending further scientific data is desirable. The Article 5.7 does not specify how much time a provisional measure can be maintained in force. In fact, this duration depends on the acquisition of new scientific evidences and re-assessment of the risk. It could be years; in other words, the provisional nature of measures taken on the basis of the precautionary principle is not bound up with a time factor but with the development of scientific knowledge. The provisional nature of the measure is also linked to the obligation of searching new scientific data.

The European Commission services think that Article 5.7 needs clarification and explanation. With this objective in mind, the European Commission has proposed to the Council and the European Parliament, in the context of the new round of multilateral trade negotiations "to clarify and strengthen the existing WTO framework for the use of the precautionary principle in the area of food safety, in particular with a view to finding an agreed methodology for the scope of action under that principle".

2. RECOMMENDATIONS ON ELECTRONIC COMMERCE

- **Consumer Protection in Electronic Commerce**
- **Safe Harbour Proposal and International Convention on Privacy Protection**
- **Children and Electronic Commerce**
- **Minimum disclosure standards for suppliers in electronic commerce transactions**
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- **Participation in Policy Making**

Consumer Protection in Electronic Commerce

TACD RECOMMENDATION

Consumers must have effective consumer protections when shopping on the Internet. Advertisements should be truthful and provide complete information necessary to make an informed choice. Purchase decisions should be deliberate and documented. Products and services should be required to be as represented. Payment should be secure and consumers' risk of financial loss limited. If anything goes wrong, consumers should have recourse and opportunity for redress. The goals for a consumer protection framework in global electronic commerce should be to foster justified consumer confidence, fair competition, and economic development around the world. Consumers expect at least the same level of protections in the virtual marketplace as they currently have in the real marketplace.

Resolved:

The EU and the US should support the establishment of minimum standards in electronic commerce, including the simplification of contracts, means for cancellation, effective complaint mechanisms, limits on consumer liability, non-enforceability of unreasonable contract provisions, recourse at least to the laws and courts of their home country, and co-operation among governments in support of legal redress. Such minimal standards should provide a functional equivalence to current safeguards offering at least the same levels of protection that would be afforded in the off-line world.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission notes the concerns expressed by the TACD and agrees that support should be given for the establishment of minimum consumer protection standards in electronic commerce. We believe that for business-to-consumer electronic commerce to develop its full potential, a concerted effort must be made to enhance consumer confidence. It is unlikely that a single party or factor will determine the level of consumer confidence. Such confidence is more likely to rest on a combination of factors including consumer education and awareness, good marketing and business practices, transparency measures, codes of conduct, self-regulatory initiatives, including effective out-of-court dispute-settlement and arbitration schemes, and government regulation.

On the specific issues covered by the Resolution, the European Commission services would like to make reference to the existing framework of regulation that is in place at the EU level. This in general terms aims at the establishment of minimum standards and covers in particular:

Means of cancellation, as foreseen in Directive 85/577/EC on contracts negotiated away from business premises, Directive 94/47/EC on purchase of the right to use immovable property on a time-share basis, Directive 97/7/EC on distance selling and the proposal for Directive on distance marketing of consumer financial services (Com(98) 468 final).

Effective complaint mechanisms, as foreseen or referred to inter alia in Directive 97/7/EC on distance selling, Commission Recommendation 98/257/EC on the principles applicable for bodies responsible for the out-of-court settlement of consumer disputes and the proposal for Directive on certain legal aspects of electronic commerce in the internal market (Com(98)586 final).

Limits on consumer liability as recommended in Commission Recommendation 97/489 concerning transactions by electronic payment instruments and in particular the relationship between issuer and holder.

Non-enforceability of unreasonable contract provisions as foreseen by Directive 93/13/EC on unfair terms in consumer contracts.

In respect of jurisdictional issues, the European Commission hopes for a successful outcome of The Hague Conference aiming at drafting a global convention on jurisdiction and the enforcement of judgements in civil and commercial matters.

The European Commission services take note of the recommendation on the need to simplify contracts and co-operation among governments in support of legal redress, and observes that to a certain degree these issues are addressed in the context of specific measures.

Governments around the world are faced with the dilemma that while the law operates on a territorial basis, electronic commerce and the Internet operate on a global basis. As indicated in its Communication COM/98/50 on "Globalisation and the Information Society", it is against this background that the European Commission attaches priority to international co-operation and co-ordination both in private sector (e.g. Global Business Dialogue on electronic commerce) and inter-governmental fora and between governments and stakeholders.

With regard to the specific issues referred to above, the European Commission is committed to meeting the deadline set by the OECD Ministers at the Ottawa in October 1998 to agree guidelines for effective consumer protection in electronic commerce among OECD countries by the end of 1999. The European Commission welcomes the input of the business and consumer communities in this respect. The TACD may wish to take note of a similar commitment on the part of the EU Member States as set out in the Council Resolution of 19 January 1999 on the Consumer Dimension of the Information Society.

The European Commission services observe that they are currently engaged in examining existing consumer-related legislation in the new circumstances arising from electronic commerce, to identify possible loopholes in this legislation concerning specific problems in the context of the information society and to identify possible areas where additional measures may be required.

The European Commission services would also like to refer the TACD to the comments they submitted to the US Federal Trade Commission in the context of its workshop in consumer protection in the global electronic marketplace⁶. As the EU Member States have done in their Council Resolution on the Consumer Dimension of the Information Society, the European Commission emphasises that consumers making use of electronic commerce should not be less well protected than they are when using traditional forms of commerce and that the level of protection afforded in electronic commerce must, in its effect, be equivalent to the level of protection afforded in off-line commerce.

The European Commission services invite the TACD to elaborate further on its Resolution and would welcome practical suggestions on how the issues could be addressed and what the core characteristics are that should feature in the requested standards. The European Commission services encourage the TACD to analyse the European Union's policy initiatives and present further recommendations and suggestions as appropriate. The European Commission services would welcome any initiatives the TACD and its members may take to work with the business community with a view to establish a better mutual understanding and common recommendations.

⁶ Available on the Internet, at the following address :
http://europa.eu.int/comm/dg24/policy/developments/e_comm/index_en.html

Safe Harbour Proposal and International Convention on Privacy Protection

TACD RECOMMENDATION

The Safe Harbour proposal now under consideration by the United States and the European Union fails to provide adequate privacy protection for consumers in the United States and Europe. It lacks an effective means of enforcement and redress for privacy violations. It places unreasonable burdens on consumers and unfairly requires European citizens to sacrifice their legal right to pursue privacy complaints through their national authorities. The proposal also fails to ensure that individual consumers will be able to access personal information obtained by businesses.

Therefore,

- 1. The TACD urges the European Commission and the Ministers of the European Council to reject the Safe Harbour proposal. The proposal will undermine the purpose of the EU Data Directive and compromise the privacy interests of European citizens.**
- 2. The TACD recommends the development and adoption of an International Convention on Privacy Protection that will help safeguard the privacy interests of consumers and citizens in the twenty-first century.**
- 3. The TACD further urges national governments to ensure that consumer organisations are given a more central role in the future development of international privacy policies and practices that affect consumer interests.**

EUROPEAN COMMISSION SERVICES' RESPONSE

- 1. The TACD urges the European Commission and the Council to “*reject*” the Safe Harbour proposal. The European Commission services attach the greatest importance to the protection of individuals with regard to the processing of personal data and (“privacy interests”) and privacy and consider that the best way to serve these interests is persuading the US side to improve their proposal, rather than “rejecting” it. The TACD assessment is based on a version of the “Safe Harbour Principles” which is being significantly improved as a result of the EU-US dialogue on Data Protection. The two sides plan to finalise these discussions in the Autumn. The results will be submitted to both the Data protection Authorities (the Art. 29 Working Party) and the Member States. Due to the evolving nature of this exercise, drawing conclusions at this stage would be premature.**

2. The TACD “*recommends the development and adoption of an International Convention on Privacy Protection that will help safeguard the privacy interests of consumers and citizens in the twenty-first century*”. The European Commission services share entirely this objective. The OECD Guidelines of 1980 prove that building consensus on the basic privacy principles is possible and other International Instruments (e.g.: Article XIV of the GATS, European Convention on Human Rights) confirm that Privacy and Data protection are regarded as a fundamental right. However, reaching an agreement on a legally binding and enforceable instrument, such as an International Convention is likely to take a long time. This objective at the multilateral level, which may be proposed in the framework of the WTO, does not exclude (and would indeed be facilitated by) the achievements that are deliverable in the shorter term via the EU-US dialogue. It should be further noted that the European Commission’s Communication on “Globalisation and the Information Society: the need for strengthened international coordination” COM/98/50 recommends developing an “International Charter” on global electronic commerce issues, such as the protection of personal data.

Children and Electronic Commerce

TACD RECOMMENDATION

Electronic commerce will have an enormous impact on children's lives. The Internet will provide children with many new opportunities for learning, civic engagement, community building, and new forms of creativity. New forms of electronic media may also have potentially negative effects on children's lives. For example, the Internet, Digital Television, and other forms of electronic media allow for the "one-to-one" targeted marketing.

Children, particularly younger children, are more vulnerable to advertising and commercial messages. Small children also have difficulties distinguishing between advertising and programming. Other studies suggest negative effects of food, alcohol and tobacco advertising to children on public health. Further, many parents and consumer groups are concerned with the impact of advertising on the development of children's values, particularly materialism.

Resolved:

Children must be able to take advantage of the benefits of new digital media in a safe environment. TACD recommends that appropriate safeguards are put in place by governments of the US and EU based upon the following principles.

- 1. Data collectors should not collect personal information from children unless it is relevant, necessary and lawful.**
- 2. Parents should be involved when data are collected from young children. Therefore, data collectors must be required to obtain parental consent prior to data collection from young children.**
- 3. Advertising and promotions targeted at children should be clearly identifiable as such and separated from content.**
- 4. There should be limitations on advertising to children, for example with regard to the products or the manner in which they are sold or promoted. Business should not take advantage of children's credulity and lack of experience.**
- 5. Every child should have affordable access to high quality educational and cultural information and services. There should be non-commercial spaces and electronic commons akin to public playgrounds, where children can safely explore, play, create, learn, and participate in civic life.**

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services support the five principles on which the TACD Recommendation on "Children and Electronic Commerce" adopted in Brussels last 23-24 April 1999, is based.

On 23 October 1996 the European Commission adopted a Communication⁷ on illegal and harmful content on the Internet and a Green Paper on the protection of minors and human dignity in audiovisual and information services. Both documents advocate closer co-operation between the EU Member States and on an international level, the use of filtering software and rating systems, and an encouragement to self-regulation of access providers. On 25 January 1999 the European Parliament and the Council adopted a multi-annual Community Action Plan on promoting safer use of the Internet by combating illegal and harmful content on global networks.

European Community provisions have already been adopted for the protection of minors in the field of television programmes (Directive 97/36/EC of the European Parliament and of the Council of 30 June 1997 amending Council Directive 89/552/EEC on the co-ordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities⁸). In September 1998, the European Community went further with the adoption of a Recommendation on the protection of minors and human dignity in audio-visual and on-line services.⁹ The Recommendation invites the parties concerned to draw up codes of conduct and lays down guidelines for these, with the aim, inter alia, of restricting access by minors to content which may impair their physical, mental or moral development. As far as the subject "Children and Electronic Commerce" is concerned, the European Commission wishes to further explore any potential problems and verify whether there is a need to take legislative or voluntary measures; the European Commission has launched a number of initiatives on this issue including organising a dialogue between representatives of the industry and of the consumer organisations.

Such a dialogue could lead to the adoption of a Code of Conduct, similar to that concluded with the consumers' organisations on the Euro.

The European Commission would consider, following the outcome of this dialogue, whether it was necessary to propose other measures.

Therefore, both the industry and the consumers' organisations, have been contacted in order to know their views about the European Commission's plans as well as about the subjects they want to be included in the dialogue.

⁷ COM(96)0487

⁸ See in particular Chapters IV and V (as amended) in respect of both advertising and programming.

⁹ Council Recommendation 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. (Official Journal L 270 of 07.10.1998, p.48).

Concerning the consumers' side, the discussion is being held within the Consumers' Committee, an advisory council supported by DG XXIV, in which the European Consumers' Organisations are represented.

On the industry side, the contacts include the European Advertising Tripartite, the European Alliance for Ethics in Advertising, and the World Federation of Advertisers. The European Commission expects that the first conclusions of the dialogue can be reached within 1999.

In addition, the European Commission recently published a Call for tender¹⁰ to carry out a study on advertising and teleshopping to children to cover all media throughout the European Union and the European Economic Area States.

The study will consider specifically the issues raised by the identification of advertising/teleshopping, provisions concerning violence, provisions relating to social and ethical values, provisions relating to safety, and provisions relating to the presentation (i.e. Truthfulness, clear indication of price etc.). The study is expected to be completed within six months following the award of the study contract, and will be of major importance in respect of any regulatory or voluntary initiatives to be taken in respect of this issue.

¹⁰ Official Journal S 139 of 21.7.99

Minimum disclosure standards for suppliers in electronic commerce transactions

TACD RECOMMENDATION

The EU and the US should determine the necessary minimum of information that businesses have to provide to achieve sufficient market transparency in electronic transactions. For transaction involving the purchase of goods and services over the Internet, consideration should be given to the following items:

[Editors note: This is not a resolution on the issue of jurisdiction, and takes no position on what jurisdiction should be. However, the resolution does address the relevant information about jurisdiction that sellers must disclose to consumers].

1. Information on the supplier

From the consumer's point of view it's necessary to know who the partner of the contract is and where the supplier is located. According to the national laws in many countries it is often necessary to publish the name of a person who is allowed to represent the company. In some countries this is a necessary pre-condition to file claims in legal proceedings. Apart from this specific problem the following details about the supplier are important:

- i) name of the company**
- ii) geographic address of the company**
- iii) phone, fax and e-mail numbers of the company**
- iv) any relevant registration or license number and the name and address of the body by which the business is registered or authorised.**

2. Information on the offer

To make the use of electronic offers as convenient as possible and to provide consumers a basis for purchase decisions, they must know, at least, the following:

- i) geographic targeting, length and validity of the offer**
- ii) price and currency of the purchase including all relevant costs, including, for example, such items as actual costs of delivery, postage and handling, insurance and customer taxes and duties**
- iii) any safety or care warnings required by relevant national laws as well as instructions for proper use, where necessary**
- iv) for offers targeted to other than the suppliers' home country, additional duties and taxes or an easy accessible source where the consumer can get these information.**

3. *Information on the terms and conditions*

Before buying consumers should be informed about the terms and conditions of the transaction, including such items as:

- i) the main characteristics of the goods or services,**
- ii) terms of payment including a clear description of the procedure,**
- iii) information on the liability of the supplier for fraudulent use of consumers' personal data provided by them online**
- iv) terms of delivery including the time period of delivery**
- v) guarantees, warranties or other provisions relating to after-sales service**
- vi) details of any cooling-off period**
- vii) information on the complaint procedure**
- viii) conditions related to return, exchange, cancellation, refund policy.**
- ix) privacy policy**

4. *Information on the applicable law and jurisdiction*

For cases of any dispute related to the contract the consumers must be informed about the applicable law and jurisdiction and procedures for redress.

5. *Information after placing an order*

Confirmation concerning the details of an order should contain such items as:

- i) the date and the number of the order**
- ii) the shipping address**
- iii) the number of items and name of the product**
- iv) the price the consumer has to pay as a whole.**

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services welcome the TACD Recommendation on minimum disclosure standards for suppliers in electronic commerce transactions and are encouraged to find in it strong support for the policy they have been pursuing with regard to market transparency and information in general and electronic commerce specifically. Community legislation and proposals already cover many of the information elements referred to in the Recommendation for legislation.

With regard to general information such as the identity of the seller, information on the terms and conditions and information after placing the order this is addressed by generally applicable measures such as Directive 97/7/EC on distance selling, Directive 98/6/EC on the indication of the prices of products offered to consumers or the proposal for Directive on certain legal aspects of electronic commerce in the Internal Market.

With regard to specific information on for example the offer and the terms and conditions this is approached in a range of sector specific measures governing product or service categories such as for example financial services.

As electronic commerce allows consumers to transact directly with businesses in other countries, there is obvious value in international co-ordination and co-operation to avoid that businesses will be confronted with disclosure requirements and consumer expectations with which they are unfamiliar and to ensure that consumers receive the information they expect and rely on to make informed decisions.

The European Commission services see a close link between the TACD Recommendation and the ongoing OECD discussion with a view to agree on guidelines on consumer protection in electronic commerce. Within this context the European Union Member States and the European Commission are endeavouring for clear guidelines to governments, business and consumers as to the meaning of full and fair disclosure of information.

The European Commission services note that the concept of full and fair disclosure is a dynamic one and that the value and usefulness of information should be assessed under the circumstances. It is against this background that we are of the opinion that certain elements of information have an absolute value and should always be provided, whereas others should be provided where this is useful and relevant under the circumstances.

On the issue of information on applicable law and jurisdiction, the European Commission services draw the attention of the TACD that this kind of information could be misleading to the consumers. In fact, applicable law and competent jurisdiction are determined by legal rules of each country, which are not harmonised at international level. The business could thus only indicate to the consumer what law it would like to be applicable and what courts it would like to be competent, but the lawfulness of this choice would always be submitted to review of any judge of any country to whom the dispute would be submitted.

The European Commission services encourage the TACD and its members to monitor the ongoing OECD discussions and to continue to provide input where it is felt that the expectations of the consumer community are not being met. In this respect the European Commission services would like to also encourage the TACD and its members to continue to pursue efforts to come to an understanding with the business community as to what information elements should be given as well as the way in which they should be presented.

Unfair Contracts

TACD RECOMMENDATION

Disputes over jurisdiction in cyberspace have led to increased interest in the role of contracts to define rights in transactions involving sellers and consumers. However, policy makers should be wary of measures that permit sellers to enforce unreasonable contract terms. Various "click on" type contracts used in web pages today are often one-sided measures that unfairly would limit consumer rights in a wide range of areas, including the rights to benefit from exceptions and limitations of copyright, the right to criticise products, the right to offer competing products, the right to seek redress for defective products or service, and many other important consumer rights.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services invite the TACD to refer to their response to the Recommendation on **Consumer Protection in Electronic Commerce**, particularly where it refers to Non-enforceability of unreasonable contract provisions as foreseen by Directive 93/13/EC on unfair terms in consumer contracts.

Anticompetitive Practices

TACD RECOMMENDATION

In the area of data networks, it is essential that policy makers protect consumers against monopolistic and anticompetitive practices. Increasing returns and network effects lead to problems when dominant firms use market power to exclude rivals or limit the ability of rivals to develop products that are interoperable. Practices of bundling products, technological tying of products, or other techniques can reduce competition and lead to high prices, reduced consumer choice or lower quality. There are particular concerns for those elements of networks that provide user interfaces for consumers, including default menus for electronic commerce and selection of editorial content. Policy makers should use appropriate competition policy and regulatory remedies to ensure that consumers have open platforms for network access, and that private control over network bottlenecks are not used to exercise control over essential network navigation tools or content.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services agree with the objective of preventing anticompetitive practices regarding electronic commerce.

While it may be true that certain aspects of Internet trading are subject to economies of scale of demand, it is nevertheless only where price distortion is deemed to be occurring that competition law at European level is generally applicable.

Such price distortion could, indeed, result from practices such as unwarranted bundling of products or technological "lock-in".

Clearly consumers will benefit from the judicious application of competition law and sectoral regulation aimed at preventing abuse of dominant party ownership of network bottlenecks. Whether the essential facilities doctrine could be applied in such cases remains to be seen.

When promoting electronic commerce throughout Europe's industrial sectors the European Commission places emphasis on the online marketplace to be as open and competitive as the offline marketplace. Europe's industry has a strong tradition in sectoral consensus building and networking. To this end, and in addition to the safeguard provided by European Community competition rules, the European Commission services will invite comments on the preparation of guidelines on how to establish industrial consensus –by consortia, for instance- in sectors whilst keeping the market open.

The European Commission has started to analyse the role of open standards and common interfaces in the network economy. For this purpose, a study on the role of standards in the network economy has been finalised. It will be widely discussed in the second half of 1999 in order to collect comments on its findings and recommendations such as the establishment of guidance documents in this domain.

Intellectual property and electronic commerce

The Internet and new information technologies present a number of complex issues regarding intellectual property rights. Authors and creators have an interest in protecting unauthorised commercial exploitation of their own works, but also in obtaining access to the works of others. Firms that sell computing equipment and software may seek protection for those works, but also may need the right to reverse engineer or develop products that are interoperable with works owned by others. Citizens benefit from the economic incentives of copyright laws, but also from fair ("innocent") use exemptions in several national copyright systems. The free flow of information is essential for a variety of purposes, including the exercise of free speech and the ability of innovate and create. Education use presents special issues, including those involved in distance learning.

For these reasons, governments in the US and the EU should embrace an intellectual property framework that includes the following elements:

- 1. Distance Education.** Mechanisms to protect copyrighted works on the Internet should not unduly restrict the ability of educators to share information with students in ways that are equivalent to current practices involving more conventional teaching methods.
- 2. Privacy.** There are important conflicts between privacy and certain technologies that protect copyrighted materials. Privacy is a social good. Society should avoid mechanisms to protect copyright that are unreasonable intrusions on personal privacy, particularly when less intrusive mechanisms are technologically feasible.
- 3. Copyright exceptions.** Governments should provide copyright exceptions that address such issues as fair or innocent use, private copying, library uses, research and private study, and exceptions that are essential for reverse engineering and other techniques needed for the development of interoperable products. Consumer rights in the digital world should not be less than traditional rights in older publishing and other information technologies. Consumer rights for fair uses of copyrighted materials should not be alienated by coercive or unfair contracts. Legislation to implement WIPO treaties should address these concerns.
- 4. TRIPS Article 13.** Governments should ask the WTO to expand Article 13 of the TRIPS regarding exceptions to copyrights. The language is currently too narrow, and does not even include the language in Article 30 concerning patents, that permits governments to consider the legitimate interests of third parties.

5. **Public Domain and non-commercial software.** The public domain and non-commercial software plays an important role in public and commercial life. The Internet is built upon public and open protocols and uses a wide range of free software programs. Free software operating systems such as Linux and xBSD are important alternatives to more monopolistic server technologies. Databases of government information provide an important new foundation for civic democracy in the information society.
6. **Database rights.** National legislation to protect investments in databases should avoid overly broad protections, creating rights in facts, or rights that lead to anticompetitive or monopolistic acts.
7. **Business Practice Patents.** The US and EU governments should ask competition authorities to solicit public comments and hold public hearings on the policy issues associated with issuing patents on business practices, including those associated with electronic commerce, to determine if these patents are needed, or if they are unnecessary, anticompetitive and socially wasteful.
8. **Parallel Imports.** Electronic commerce raises profound and fundamental challenges to national policies that seek to restrict parallel imports of goods. Government should provide for international exhaustion of rights for copyrights, patents and trademarks, as is permitted under Article 6 of the WTO/TRIPS agreement, so that consumers can benefit from the free flow of goods. Governments can require that goods be labelled or identified as parallel imports, if such requirements benefit consumers and do not present unreasonable restrictions on trade in parallel goods.

Appendix

TRIPS Articles 6, 13 and 30

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 13

Limitations and Exceptions

(copyright)

Members shall confine limitations or exceptions to exclusive rights to certain special cases, which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

Article 30
Exceptions to Rights Conferred
(patents)

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services take note of the Recommendations made by the TACD on matters relating to the protection of intellectual property rights in the framework of electronic commerce. The emerging Information Society will bring new challenges to the protection of intellectual property rights. A number of these challenges resulting from the digital environment have already been addressed in two international treaties adopted in December 1996 under the auspices of the World Intellectual Property Organisation (WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty). They represent a major step forward in providing for adequate protection of authors, performers and phonogram producers in the digital environment. The Draft Directive on Copyright and Related Rights in the Information Society¹¹ plays a crucial role in this context. The aim of this proposal is to adjust and complement the existing EU framework on copyright and related rights to provide for a Community-wide level playing field in the digital environment, which ensures public acceptance of the new services and fosters creativity and investment in them. At the same time, the draft Directive serves to implement the main obligations of the two WIPO treaties signed by the European Community and Member States in the course of 1997. The European Community and the Member States are currently in the process of ratifying and implementing these treaties. Citizens will benefit from a harmonised legal framework on copyright and related rights, including appropriate exceptions to these rights, as well as the conditions of their application. Such a harmonisation is crucial in order to facilitate cross-border exploitation of copyright protected goods and services, including their dissemination to users. The TABD has already stressed the need for swift ratification and implementation of the two treaties by the U.S., the EU and other third countries.

The TRIPs Council has just begun to look into matters related to the impact of electronic commerce on the protection of intellectual property rights. Further discussions will be held in the near future to examine the current provisions of the TRIPs Agreement and the possible need to adapt them to the new developments.

On the general introduction to the Recommendations, it should be noted that authors and related right holders have an interest not only to receive protection against commercial exploitation of their works and other subject matter, but also against their illegal exploitation by private users. Access to works is, naturally, facilitated through publication. As regards reverse engineering, Article 6 Council Directive No. 91/250/EEC on the Legal Protection of Computer Programs already provides for this

¹¹ Reference : COM(97)0628 – C4-0079/98-97/0359(COD)

facility in order to achieve the interoperability of computer programs with other programs.

The need for limitations and exceptions to copyright and related rights for certain uses, such as for educational use (Recommendation No. 1), private copying, library use and research (Recommendation No. 3) has always been recognised, in the international conventions as well as in the EC "acquis communautaire" on copyright and related rights, including proposed legislation which explicitly allows for exceptions for specific uses. However, the economic impact of any such exception in the new technological environment may be different compared to the traditional environment. The scope of certain exceptions may therefore need to be re-assessed in the light of the new environment, in order to avoid economic damage to the market of protected works and other subject matter.

In general, conflicts between privacy and copyright protection should not arise (Recommendation No. 2). As far as personal data are concerned, Directive No. 95/46/EC on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data, also applies to the area of copyright and related rights, thereby ensuring adequate mechanisms to respect privacy.

Article 13 of TRIPs Agreement (Recommendation No. 4) provides for the possibility to allow limitations and exceptions to copyright and related rights based on the corresponding Article 9, paragraph 2 of Berne Convention. Given the different nature of industrial property, the corresponding provisions in the patent area (Article 30 of TRIPs Agreement) also requires account to be taken of the "legitimate interests of third parties".

The creation of works, notably software, often requires considerable creativity and deployment of skill and labour (Recommendation No. 5). Authors are vested with intellectual property rights. It is, therefore, up to the author to decide if and when to allow third parties to use his works against the payment of a fee or not. While it is true that public domain and non-commercial software play an important role in public and commercial life, this must not undermine the author's legitimate interest in receiving adequate compensation for exploitation of his property.

On the protection of databases (Recommendation No. 6), Directive No. 96/9/EC on the Legal Protection of Databases allows Member States to provide for a number of exceptions to the rights of authors and makers of databases conferred under the Directive, including for private purposes, teaching and scientific research, etc. It, therefore, strikes a careful balance between the interests of authors and makers of databases and of users. With regard to possible anti-competitive practices in the area of databases, it has to be recalled that the exercise of intellectual property rights is subject to the provisions of competition law. Moreover, the Directive provides for rights in databases or in substantial parts of databases, but not in facts.

With regard to patents on so-called "business practice patents" (Recommendation No. 7), currently Article 52 of the European Patent Convention excludes from the scope of patentable inventions "schemes, rules and methods...for doing business". Therefore, the request by the TACD to solicit public comments and hold public hearings in this respect would not be of any additional value at the moment.

The question of parallel imports, i.e. the exhaustion of exclusive rights (Recommendation No. 8), remains very sensitive. The TRIPs Agreement leaves it up to the WTO Members whether or not to allow parallel importation. The European Commission has commissioned, in the area of trademarks, a study on the impact of parallel imports which was discussed with the interested parties in April 1999. The European Commission is currently evaluating the outcome of the study and the comments received in order to review the current system of regional exhaustion in the Community. In this respect it has to be noted that the TABD expressed its opposition to the international exhaustion of intellectual property rights.

Global Institutions and Consumer Protection

TACD RECOMMENDATION

The TACD Working Group on Electronic Commerce recommends that governments of the US and EU should:

- 1. Recognise that the creation of the WTO, the rise of electronic commerce and other aspects of the globalisation of commerce require citizens to confront difficult problems associated with the development of global norms and enforcement mechanisms for the protection of consumers.**
- 2. Acknowledge that the WTO's role in consumer protection measures is currently a negative one, eliminating regulatory measures that are judged to be barriers to trade. In contrast, the WTO lifts global standards for the protection of intellectual property.**
- 3. Begin a dialogue with consumer groups and governments on the issues related to the development or reform of international organisations that can or should play a role in elevating global consumer protection.**
- 4. 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.**

EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services have taken note of the proposal made by the TACD to create a global Consumer Protection Organisation. The European Commission has already been officially addressed a similar idea on 19-20 March 1999, on the occasion of the Forum "Political Institutions and Democracy in the Information Society".

It is evident that consumer policy is becoming increasingly important and that international organisations are increasingly tackling consumer issues. The work of these organisations should therefore be better co-ordinated.

The European Commission services find the idea of a World Consumer Organisation a novel one and will reflect further on it. However, it is premature to discuss in detail the possible role and structure of such organisation. It is clear that the creation of such a body would require international support.

In any event, it would not seem appropriate to limit the mandate of such a body to e-commerce related issues. The remit would be too narrow and would not cover a vast range of consumer concerns.

On the question of the WTO and the impact of e-commerce, the European Commission has on several occasions acknowledged that the appearance of new technologies and in particular the rise of electronic commerce, while creating new and interesting business and cultural opportunities for consumers, creates new and difficult challenges.

The market globalisation, while enlarging the choice for consumers and sometimes decreasing the prices of products, has some drawbacks, namely in terms of guaranteeing an adequate balance between market access and consumer protection.

It is clear that if the WTO is to continue to be respected as the international arbiter of trade disputes, it has to take consumer concerns into account in making its rulings.

The European Commission services are indeed always ready and willing to dialogue with the consumer representatives to analyse the best possible solution to take into account consumers' interests on the international scene. The European Commission has already offered to the European consumer associations a number of opportunities to express their views on this matter. The European Commission will continue to inform and brief the European consumer associations on the developments taking place in the WTO. Furthermore, the European Commission has created a WTO Working Group in the framework of its advisory body for consumer affairs, the Consumer Committee (CC). The WTO Working group of the CC is invited to express the consumers' concerns with respect to the general question of world trade liberalisation; more precisely, the group should identify specific issues of concern in view of the new "Millennium Round".

Participation in Policy Making

TACD RECOMMENDATION

EU and US negotiations on standards for the electronic marketplace should develop means for consulting consumers as an integral part of the negotiating process. TACD groups are encouraged to participate in the FTC workshops on consumer protection in global electronic marketplace in the US and to actively consult with European governments.

EUROPEAN COMMISSION SERVICES' RESPONSE

Technological development has created an Information Society, which is changing rapidly. Standards are being created both to regularise activities in specific areas and to provide consistency of product and operation. The inclusion of consumers into this process at all levels is to be encouraged if consumer requirements are adequately to be taken into account in the development of standards via their input before, during and at the end of the standards specification process.

The European Commission services take note of the message addressed to the TACD Members. The European Commission services agree with this idea and encourage the TACD Members to follow the Recommendation, while confirming their openness to the Dialogue.

3. RECOMMENDATIONS ON TRADE

- 1. Economic Regulation**
- 2. Fair Trade**
- 3. Pharmaceuticals**
- 4. Auto Safety standards**

Economic Regulation

TACD RECOMMENDATION

1. **International competition rules and an effective code of practice for multinationals are the priority for the TACD rather than an investment regime. Consumer organisations recognise that foreign direct investment can stimulate economic growth which may, in turn lead to more jobs, higher purchasing power, a wider range of products and improved value and quality of goods and services. A predictable and safer environment achieved through investment rules can therefore be a positive development.**
2. **However, the Transatlantic Consumer Dialogue affirms the rights of governments to regulate business to protect consumers, workers, the environment, and public health. We therefore oppose the MAI and other investment terms based on the MAI model, which would threaten the ability of governments to fulfil this protective role. We will also oppose any efforts to complete the MAI and-or shift MAI negotiations to the TEP or the WTO.**
3. **The TACD supports investment rules, but not the MAI model because:**
 - **We reject the creation of new corporate rights to sue governments directly in closed trade tribunals.**
 - **The rights of investors should be subordinated to the rights of democratically elected governments to regulate business in the public interest, and not vice versa, as proposed with MAI.**
4. **Instead of a MAI, the U.S. and the E.U. should affirm the following in the TEP:**
 - **The national treatment principle of a future investment agreement must provide for the establishment of and maintenance of exceptions or qualifications.**
 - **Any new agreement on investment must set binding terms of conduct for TNCs and on competition policy.**
 - **Multinational corporations must be held accountable to universally recognised human rights, labour and environmental standards.**
 - **Countries must be free to develop investment policies that promote creation of jobs and generally raise living standards.**
 - **In any investment rules specific obligations such as the promotion by foreign investors of the economic and social development of the host country and the protection of consumers and the environment must be included, and best practice in such matters as job creation and the promotion of innovation and transfer of technology should be encouraged. Terms should include best practice in the area of consumer information, to prevent recurrence of the serious issues raised by the non-segregation and labelling of GMOs. Cases of abuse could be referred to the Courts in the investing country, which could compare behaviour with the Code. The European Parliament has suggested setting up a Monitoring body, to examine any breaches.**

EUROPEAN COMMISSION SERVICES' RESPONSE

Economic Regulation

1. In the first sentence, the Recommendation states that an investment regime is not a priority for the TACD. However, this appears to contradict the rest of paragraph 1, which lists the benefits of FDI and rightly explains that a predictable and safer environment achieved through investment rules would therefore be helpful.
2. The European Commission services' view is that a possible framework of investment rules to be negotiated in the WTO should preserve the ability of host countries to regulate the activity of investors (whether foreign or domestic) on their respective territory. The European Commission does not support the negotiation of any MAI style agreement in any forum, such as the WTO or the TEP. The objective of an investment framework in the WTO should be to secure a stable and predictable climate for investment worldwide.
3. The European Commission services believe that such framework of multilateral rules on investment should be part of the WTO system and therefore linked to the existing WTO Dispute Settlement mechanism.
4. We believe that a bottom-up approach to the question of admission of investors, based on commitments undertaken by each Member, is the way to allow for the flexibility that many WTO Members require.

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

Fair Trade

TACD RECOMMENDATION

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

- **The TACD supports the principle of application of international social, environmental, health, safety and consumer protection rules to companies operating internationally. These rules should provide for judicial enforceability that sufficiently protects the right of injured parties.**
- **The TACD welcomes the development of voluntary fair trade labelling. Whilst avoiding protectionism, such labelling should be treated as permitted under the WTO/TBT Agreement.**
- **The TACD supports the right of countries to negotiate the setting of priorities as between overlapping international obligations, such as the Lomé Convention, and to have such negotiated exceptions respected.**

EUROPEAN COMMISSION SERVICES' RESPONSE

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

The European Commission services support judicial enforceability of measures to protect the rights of producers, and note that national legislation already provides a legal framework for international companies. It acknowledges that there are grey areas and limitations in the international regulatory framework. The European Commission services see considerable potential for progress in voluntary standards, which are increasingly being adopted by private actors.

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

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

Pharmaceuticals

TACD RECOMMENDATION

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

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

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

2. Regarding Patents and Exemptions for Exports:

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

3. Regarding Parallel Imports of Pharmaceuticals:

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

4. Regarding developing countries and medical patents

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

5. Regarding compulsory licensing:

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

EUROPEAN COMMISSION SERVICES' RESPONSE

1. Regarding World Health Assembly and the World Trade Organisation

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

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

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

2. Regarding Patents and Exemptions for Exports

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

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

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

3. Regarding Parallel Imports of Pharmaceuticals

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

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

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

4. Regarding developing countries and medical patents and,

5. Regarding compulsory licensing

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

In setting up national legislation for granting compulsory licenses the minimum requirements of Article 31 of the TRIPs Agreement should be met. In particular, it must be ensured that the rights conferred by a patent are not affected.

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

Auto Safety standards

TACD RECOMMENDATION

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

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

3. Openness and Transparency of work under the 1998 Global Agreement

The TACD is most concerned that, in the interests of transparency, the substantive discussions within the Executive Committee should be capable of being observed by the NGOs. The procedural rules designed to apply to the existing as well as the proposed WP.29 framework will serve as the practical interpretation of the openness and transparency principles outlined in the agreement. It is important that these rules are clear and unambiguous. TACD seeks the inclusion of NGO participation in the activities of the working parties; which includes the receipt of documents from the Executive Committee. The TACD is however concerned that the relationship between the Executive

Committee and the working parties should be similar to that between AC.1 and WP.29 under the 1958 agreement. The proposed Executive Committee under the draft global agreement is composed exclusively of delegations from contracting parties. There is only a guarantee for participation of non-governmental organisations in the working party under the Executive Committee. Stronger provisions for NGO participation in substantive policy-making discussions are needed.

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

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

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

EUROPEAN COMMISSION SERVICES’ RESPONSE

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

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

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

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

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

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

(Priorities and GTS 2000 – tyre standard)

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

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