TRANSATLANTIC CONSUMER DIALOGUE (TACD) 2008 RECOMMENDATIONS REPORT

<u>AND</u>

EUROPEAN COMMISSION SERVICES' RESPONSES

[Month] 2009



TRANS ATLANTIC DIALOGUE TRANSATLANTIQUE CONSUMER DIALOGUE DES CONSOMMATEURS

TACD 2008 RECOMMENDATIONS REPORT

As part of its role as a consultative forum to the EU and U.S., TACD makes policy recommendations on issues of concern to its European and American members.

This report brings together TACD recommendations made in 2008 to allow the US government and the European Commission to respond formally. TACD's last recommendations report included recommendations from 2006 and 2007. This report is the fourth of an annual collection of TACD's recommendations in a year-end report to governments and the public.

TACD represents the demand side of the two biggest economic blocks in the world - the 735 million U.S. and EU consumers. Its network of EU and U.S. national consumer organisations has a direct paid-up membership of some 20 million consumers.

On both sides of the Atlantic, these groups have long track records of achievement in the consumer protection and safety fields. Many have successful publishing, research and product testing operations as well as advocacy and policy activities and are self-financed; others, according to their cultural traditions, are financed from public or foundation funds. All are independent.

More information can be found at <u>www.tacd.org</u>.

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Recommendations to the 2008 U.S.-EU Summit June 6, 2008

TACD calls on the EU and U.S. to stop "playing chicken" with public health and work together to reduce the level of dangerous pathogens in poultry

TACD strongly opposes the current Commission proposal to open the EU market to U.S. poultry products treated with chemical washes and is pleased that following a vote in the Standing Committee on Food Chain and Animal Health on 2 June 26 EU members state experts were also opposed. Such a proposal would frustrate efforts to reduce bacterial infection rates in Europe and signal the prioritisation of trade per se over measures to ensure consumer protection.

Infection rates in chickens offered for sale are too high on both sides of the Atlantic, but are lower in the EU than in the U.S. A January 2006 report by the Consumers Union¹ found an 80% contamination rate of campylobacter in chicken purchased in supermarkets in the U.S. Rates in Europe vary between member states but are not nearly as high.

There are ongoing efforts to reduce these rates in Europe by trying to improve standards at all stages of the production chain. These efforts will be jeopardized if the current ban on American poultry is lifted. The rate of infection in Europe would be likely to go up, especially as European producers would switch to the U.S. system for economic reasons.

EU-U.S. cooperation should be about the raising not lowering of standards. TACD has called repeatedly on the US and EU to work together to improve and upgrade safety on both sides of the Atlantic and to reduce contamination rates in poultry for consumers.

TACD calls upon both governments to undertake urgent action to assess and manage the risks posed to public health and the environment by products containing manufactured nanoparticles

Manufactured nanoparticles are already present in a large number of consumer products including food, clothing and cosmetics. Tiny nanoparticles give consumer products new properties. For instance, they turn white sunscreens into clear sunscreens. It is possible that some nanoparticles could enter the bloodstream and cross the brain blood barrier, yet they are inadequately regulated and their safety has not yet been demonstrated.

The U.S. and EU governments have so far failed to respond to the research, risk assessment and regulatory gaps that some uses of nanotechnologies raise for consumers. There is currently no regulation within the EU or U.S. dealing specifically with the issues posed by nanotechnologies either in terms of an over-arching framework or within specific regulations dealing with products that are now being developed using nanotechnologies. This is particularly alarming in view of recent research published in

¹ http://www.consumerreports.org/cro/food/food-safety/chicken-safety/chicken-safety-1 07/overview/0107_chick_ov.htm

the journal *Nature Nanotechnology*² that found health risks posed by long carbon nanotubes are comparable to those posed by asbestos.

TACD urges the EU and U.S. to develop a regulatory framework that will protect consumers on both sides of the Atlantic. This should include appropriate environmental and risk assessment and pre-market safety review of all products containing manufactured free nanoparticles.

TACD calls on the EU and U.S. to eliminate their opposition to work at WIPO to provide better access to copyrighted material for the blind

TACD calls for the EU and the U.S. to engage constructively in the discussions at the World Intellectual Property Organization (WIPO) Standing Committee on Copyright and Related Rights (SCCR), on the topic of minimum copyright limitations and exceptions for the protection of consumer and public interests. TACD urges the SCCR to engage in analysis and consider norm setting in this area. In particular we stress the importance of addressing the concerns and needs of the most vulnerable or social prioritized sectors of society, and ask that the EU and U.S. take urgent action to solve the well-documented problems of the visually impaired as regards access to information and knowledge.

TACD calls on the EU and U.S. to abandon their efforts to prioritize trade impacts over consumer protection in the development of regulations

TACD sees no justification for the sweeping regulatory process changes proposed in the recent Review of the Application of EU and U.S. Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment, which would result in the placing of disproportionate emphasis on trade and investment at the expense of consumer protection. We are deeply troubled by the headlong rush to impose yet more burdens on the regulatory process without any prospective assessment of the very real tradeoffs involved. At stake is nothing less than the capacity of government programs to get things done to protect the public from health, safety, environmental, financial, and other harms that individuals cannot surmount on their own. "Paralysis by analysis" is not merely a rhyme: it is a real threat, which will have real consequences in the lives of real people. Instead we call for the EU and U.S. to reject trade impact statements and other devices which unnecessarily burden the regulatory process and pursue a balanced approach to regulatory impact assessment which places consumer, environmental and social needs at its heart.

* * *

² http://www.nature.com/nnano/journal/vaop/ncurrent/abs/nnano.2008.111.html

Improving Toy Safety May 2008, PSAFETY 01-08

(This is limited to the recommendations – read the full resolution).

Recommendations

To effectively remedy the imported product safety crisis, the US and the EU must:

1) Strengthen regulatory approaches.

In Europe, the toy safety legislation includes essential safety requirements which are by their nature more or less vague principles, which cannot be directly enforced. The more detailed requirements are then left to standardization bodies. This is problematic as standardization bodies are industry driven and consumer interests are rarely taken into account.

The current EU toy safety directive contains many loopholes. Many requirements related to e.g. physical or chemical properties do not adequately address the risks posed by toys. In our view, we need stricter regulatory requirements for the safety of toys i.e. more detailed specifications/limits are needed in the legislation. The establishment of noise limits was a good example where standardization processes were not suitable to quickly address newly identified risks.³

Similarly in the US, the industry's voluntary toy safety standards should be made mandatory – and therefore would ensure that all toys are tested to comprehensive criteria, including requiring that strong magnets do not fall out of toys. The Senate version of the CPSC reform legislation includes a provision giving the CPSC authority over, and requiring third party testing of, toys now covered by the voluntary ASTM F-963 toy standard. This standard, and all industry standards, should be reviewed and updated in an appropriate regulatory fashion before being made mandatory.

2) Expand and develop programs for mandatory 3rd party testing of toys and durable children's products such as cribs by independent laboratories. Pre-market testing of key children's products is critical to identifying dangers before they harm children.

In the EU, toys must bear the CE marking to be placed on the market. The CE Marking is a self-declaration by manufacturers that their products comply with EU legislation. However, it is wrongly interpreted by most consumers to mean that a product has been tested or approved by a third party, perhaps even by an official body, and/or that that the product was made in Europe. Consumer organisations have long been calling for the CE

³ Within the EU standardization body CEN, it was not possible to establish a safe limit for impulsive noise emitted by toy cap pistols after years of debate involving an enormous amount of resources. Even after Germany and Austria had triggered the safeguard clause, CEN's Toys Committee refused to establish safe limits. Such limits were finally established after strong political pressure from the Commission. The lesson to be drawn is therefore that the regulators should be responsible for defining the necessary level of detail, where needed, by establishing specifications (e.g. ban or limit values for dangerous chemicals). A specific procedure (so-called 'comitology' in the EU) should be foreseen in order to allow for a quick adaptation of these specifications to e.g. emerging risks without having to transfer the tasks to the standards bodies.

Of course, some of these tasks (e.g. development of test methods) may be allocated to the Standards Bodies. But it should be based on a case by case basis, decision and efficient measures to take corrective action must be available.

marking not to appear on or with consumer products any more – although the underlying requirements regarding liability and technical documentation should remain.

The EU has currently 3rd party testing of toys only on a limited number of toys if there are no harmonized standards available. As the current EU system of CE marking (displayed by producers without any third party controls) on toys is not a guarantee of safety, the system of third party testing should be reviewed and expanded to certain categories of toys and children's products that have been identified as problems.⁴

The House and the Senate version of CPSC reform legislation expected to pass into law this year includes such 3rd party testing program for toys and durable children's products. The provisions in both bills which allow in-house proprietary labs to be certified should be removed.

3) Establish meaningful civil penalties that will deter wrongdoing. The fines that can be applied to toy companies that manufacture or import dangerous toys should be increased to act as an effective deterrent. In the US, Congress has proposed increasing civil penalties from a maximum \$1.8 million to \$10 million, with the Senate allowing \$20 million in some circumstances. U.S. TACD members had recommended even stronger penalties, or at least \$100 million as a compromise, which would take into account the number of violations and force companies to treat penalty threats seriously, not as a mere cost of business.

In Europe, penalties imposed by member states should be reviewed and revised upward. It is crucial that penalties act as a meaningful deterrent in all member states. Penalties should increase according to the number of infringements committed by the economic operator.

4) Review and expedite systems to stop unsafe imports from getting to children. In the US, in many instances the CPSC cannot issue a recall or stop unsafe imports at the border without having a formal hearing first. The CPSC needs authority similar to that of the FDA to stop unsafe imports at the border immediately and issue an Import Alert to all ports and U.S. inspection personnel.

In the EU, we consider it crucial to develop harmonised control standards amongst Member States. This only will ensure that products, which have been refused in one EU country, cannot get access to the EU market by approaching another country.

The Commission can issue a RAPEX alert, but it is up to member states to act upon the alert to intercept unsafe products at the border and issue recalls. We need to require Member States to monitor and follow up notifications. Moreover Member States should

⁴ In the EU, the following types of toys (and children's products) should undergo a mandatory EC-type examination:

⁻ toys intended for children under three years (e.g. rattles);

⁻ toys which, for functional reasons, cannot be designed to eliminate all risks (e.g. toys with high accessible surface temperature, magnetic toys);

⁻ toys which, in case of a failure, can lead to severe health impacts of a child (e.g. toy containing a laser);

⁻ toys which have caused severe accidents in the past (cf Rapex notifications);

⁻ toys which have raised considerable concern in enforcement activities

monitor and verify that economic operators fulfill their legal obligations arising from product recalls.

For both, the EU and the US the overall number of controls has to be increased and provisions as to how controls should be performed must be developed. In particular, dangerous chemicals contained in toys should be detected through comprehensive laboratory checks, before the products can be placed on the market. As these analyses are time consuming and rather expensive, market surveillance authorities need better equipment as well as human, technical and financial resources in order to carry out their tasks.

5) Ensure rapid transatlantic communication about dangerous products. Unlike other U.S. agencies such as the FDA which have negotiated Memoranda of Understanding with their European counterparts to allow for the rapid exchange of information regarding dangerous products, the CPSC has failed to do so. In many cases, the agency delayed nearly seven months after learning of dangerous, defective products before telling the public and European regulators. This problem must be solved so that both transatlantic regulators and consumers on both sides of the Atlantic have quick access to information regarding dangerous products and products under investigation. Both the U.S. House and Senate versions of the CSPC reform legislation should remove any remaining barriers to CPSC sharing information promptly with their European counterparts. Upon passage, CPSC and the EU should take immediate action to set up effective and timely information sharing systems.

6) Alter various provisions of trade agreements, whose rules limit product safety standards and border inspection. For instance, the WTO's Technical Barrier to Trade Agreement (TBT), with very limited exceptions, discourages countries from taking a leadership role in safety regulation by stating that standards shall be based on existing international standards. The TBT agreement's "national treatment" rule requires that member nations treat foreign produced goods the same as domestically produced goods, thus imported goods may not be inspected at a greater rate than similar domestic goods or a trade challenge could be brought. Also needed is a long term strategy to improve production and processing methods (PPMs). Dangerous products and unacceptable environmental and societal production methods often go hand in hand. In the long term, we need to develop strategies to address the issue of production methods of goods in the countries of origin. This is a complex problem that will require a range of strategies, including a review of relevant international trading rules that may impede the appropriate application of PPMs.

7) Establish public databases of consumer complaints about products so that consumers can learn if others have had a problem with a product they are using. Legislation put forward by the U.S. Senate establishes a new public right to know database of injury reports and consumer complaints reported to the CPSC based upon a longstanding database at the National Highway Traffic Safety Administration (NHTSA). This mechanism will be most useful if dissatisfied consumers are able to post a complaint to the data base and all the information regarding that complaint is immediately available to the public, without screening or delays. Such data bases could lead to the more immediate identification of global problems and quicker action on the part of government officials.

8) Review and ban unsafe ingredients in toys that can be put into children's mouths.

- The US should examine the work of the EU and the state of California to ban phthalates in children's toys. The Senate proposal incorporates an improved version of California's ban on toxic phthalates. The EU should strengthen it guidance document to ensure that all toys that can be put in children's mouths or chewed upon are covered by the 2005 directive on phthalates.
- The use of chemicals in toys should be more strictly regulated, including a ban on allergenic fragrances and carcinogenic, mutagenic and toxic for reproduction (CMR) substances. CMRs 1, 2 and 3, should be banned in all toys in the EU. The U.S. should study and emulate this action.

Both governments should introduce a complete zero tolerance ban on all lead in toys and children's products.

European Commission Services' Response

1) Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys⁵ is based on the New Approach principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards.⁶ Thus, the Directive sets out only the essential safety requirements with regard to toys, including the particular safety requirements regarding physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity. Technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services.⁷ Conformity with harmonised standards so set, the reference number of which is published in the Official Journal of the European Union, provides a presumption of conformity with the requirements of Directive 88/378/EEC. Experience has shown that these basic principles have worked well in the toys sector and should be maintained.

Technological developments in the toys market have, however, raised new issues with respect to the safety of toys and have given rise to increased consumer concerns. In order to take account of those developments and to provide clarification in relation to the framework within which toys may be marketed, a review of Directive 88/378/EEC was therefore undertaken based on a legislative proposal submitted by the European Commission on 25 January 2008⁸. Following a first reading agreement, the European Parliament and the Council are expected to formally adopt the new Toy Safety Directive

⁵ OJ L 187, 16.7.1988, p. 1, as amended Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p.1).

⁶ OJ C 136, 4.6.1985, p. 1

⁷ OJ L 24, 21.7.1998, p. 37,as last amended by Council Directive 2006/96/EC of 20 November 2006 (OJEU L 363, 20.12.2006, p. 81).

⁸ COM (2008) 9 final of 25.1.2008.

in June 2009. The finally adopted text will then forthwith be published in the Official Journal of the European Union and entry into force 20 days later.

EU Member States will have 18 months after the date of entry into force of the Directive to transpose the new Toy Safety Directive into national law. The national implementing provisions will then start applying two years after the entry into force of the Directive. Hence, the likely application date is currently estimated at July 2011. The new Toy Safety Directive foresees a 2-year transitional period for all requirements which apply to toys except for the chemical requirements for which a 4-year transitional period is foreseen. The transitional period means that toys complying with the current Toy Safety Directive 88/378/EEC can be made available on the market if they have been placed on the market during a period of 2 years from the entry into force of the Directive (4 years as regards the chemical requirements).

The new Directive is the first sectoral Directive to incorporate and be aligned to the general framework for the marketing of products in the EU, the so called "goods package"(namely, *Regulation No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, and repealing Regulation (EEC) no 339/93⁹ (hereafter, "Regulation No 765/2008") and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing decision 93/465/EEC (hereafter, "Decision No 768/2008/EC")¹⁰).*

The European Commission is financially supporting consumer organisations to participate in standardization activities. It should also be noted that the Toy Safety Directive foresees a safeguard clause procedure to allow the possibility of contesting the conformity of a toy, *inter alia* on the basis of failures or shortcomings of the relevant harmonised standards. When the latter is ascertained, the harmonised standards in question cease to give presumption of conformity and an expedite review aimed to remedy such failures or shortcomings is then undertaken by CEN or CENELEC. Consumer organisations have traditionally played a key role in denouncing potential or actual problems with the application of harmonised standards

2) Experience has shown that the current rules on conformity assessment are adequate for the toys field. The new Directive maintains the principle that the manufacturer can certify the conformity without a mandatory involvement of an independent third party if he has followed the harmonised standards covering all the safety aspects for the toy. The new Directive contains rules for cases where a toy has to be subject of third-party certification (EC type-examination), i.e.:

- When harmonised standards do not exist;

⁹ OJEU L 218, 13.8.2008, p. 30.

¹⁰ OJEU L218, 13.8.2008, p. 82.

- When standards exist but the manufacturer has not applied them or has applied them only in part;
- When the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

Introduction of an EC type-examination in other cases is neither necessary nor proportionate in terms of expected benefits and costs. The reasons are the following:

- Rules on verification of safety of toys as foreseen in the new Directive are sufficient; they are complemented by the provisions of the recently adopted New Legislative Framework which provide for a very strict regulation of market surveillance
- Third party testing does not guarantee *per se* safety and does not avoid the need to have strong market surveillance.

Systematic mandatory third party intervention (testing and/or certification) is adequate for high risk equipment where manufacturers may have limited capacity to undergo testing, due to lack of knowledge, complicated technologies involved or test equipment. Toys do not belong to those categories; their technology is low and the level of risks manageable by manufacturers.

The CE marking indicates conformity of a product with the applicable requirements of the relevant EU harmonisation legislation providing for its affixing. The CE marking is common to all the EU legislation based on the New Approach principles, not only toys. The horizontal "goods package" provides general rules on the CE marking. The new Toy Safety Directive provides for specific rules for the affixing of the CE marking for toys to enhance its visibility in order to facilitate market surveillance operations. The "goods package" contains provisions aiming to *inter alia* clarify the meaning of CE marking and lays down the general rules for its affixing. In particular, it is made clear that the manufacturer, by affixing the CE marking, assumes the full responsibility for the compliance of his product. The general rules on CE marking are contained in Regulation (EC) No 765/2008, while the model provisions to be used in sectoral harmonisation legislation are included in Decision No 768/2008/EC.

3) Pursuant to the new Toy Safety Directive Member States shall lay down the rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to the Directive, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the Directive.

4) The Directive foresees a procedure for dealing with toys presenting a risk at national level (other than a RAPEX notification under the General Product Safety

Directive (GPSD: 2001/95/EC) which covers products posing a serious risk the effects of which go beyond the national territory (i.e. because they are placed on the market in more than one Member State).

Where, within three months of receipt of the information notified by the market surveillance authorities who took appropriate provisional measures to prohibit or restrict the toy being made available on their national market, no objection has been raised by either a Member State or the European Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified. Member States other than the Member State initiating the procedure shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned, and, in the event of disagreement with the notified national measure, of their objections.

When Member States take measures against toys representing a serious risk and which are placed on the market in more Member States, they inform the European Commission of these measures through the RAPEX system under the GPSD. Once such a notification is validated by the European Commission, it is send to all other Member States (and EEA members), which are obliged to follow up the notification by verifying the presence of the notified product on their market and, if the product is indeed found, taking appropriate action.

When products are recalled, the Member States' market surveillance authorities typically closely follow up such recalls and engage with the economic operators if the recall is not undertaken satisfactorily. In a related development, the Dutch Food and Product Safety Authority has recently undertaken a study into recall effectiveness which came out with several improvement recommendations that have been shared with the other Member States.

For the purpose of ensuring the equivalent and consistent enforcement of EU harmonisation legislation, a Community Market Surveillance Framework, defining minimum requirements against the background of the objectives to be achieved by Member States in their enforcement activities, has been adopted by Regulation (EC) 765/2008. Consequently Member States shall from 1.1.2010 organise and carry out market surveillance on a common basis. Cooperation at EU and international levels will also be organised. The relevant provisions of Regulation No 765/2008 are referred to in the new Toy Safety Directive.

Moreover, the European Commission provides financial support to the Member States for undertaking cross-border market surveillance actions, thereby allowing the development of best practices and shared surveillance procedures which has already resulted in a significant improvement of the cooperation between Member States in this area. A good example of the development of such best practices is the so-called "best practice techniques in market surveillance" handbook which was developed under one of the joint actions (for more information please see: <u>www.emars.eu</u>). 5) Europe and the United States face many similar challenges concerning the safety of products. As many products are common to both markets, a strong transatlantic relationship in this area is of key importance. Both sides agree that the exchange of information and best practice is vital to keep consumers on both sides of the Atlantic safe from dangerous products. In the course of 2008, a closer and more frequent dialogue was established between European and US regulators. The most notable development was the adoption of the US Consumer Product Safety Improvement Act. The new law enables the Consumer Product Safety Commission (CPSC) to share confidential product safety information with foreign governments and agencies. The European Commission is currently in discussions with the CPSC on how these new provisions can be implemented in practice between both jurisdictions.

6) With respect to TACD's remarks on the WTO Agreement on Technical Barriers to Trade (TBT), the European Commission observes that the protection of human health and safety is listed in Article 2.2 of the TBT Agreement as one of the legitimate objectives WTO Members may pursue through technical regulations. The TBT Agreements does not therefore prevent Members from aiming at a high level of protection of children's safety – which is the fundamental objective pursued both in the EU and the US by our respective toy safety legislations.

Article 2.4 of the TBT Agreement provides that international standards, when they exist or their completion is imminent, should be taken as a basis by WTO Members for their technical regulations, except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

As the TACD notes, the national treatment principle enshrined in Article 2.1 of the TBT Agreement requires that imported products should not be treated less favourably than like domestic products as regards the conditions for market access. In the context of post-market enforcement and preventive market surveillance actions, the intensity and frequency of checks on any product made available on the market should be based on a proper risk assessment taking into account all relevant factors including e.g. the product characteristics and the hazards associated with it, the likelihood and severity of an injury scenario, previous accidents caused by identical or similar products, the track record of the manufacturer(s)/importer(s) concerned, etc.

7) The GPSD specifically provides for Member States to ensure that consumers and other interested parties are given the opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. Whether such consumer complaints (which may also cover quality rather than safety problems) are public depends on the actual implementation of this provision in the individual Member States. At this point in time, the European Commission has no intention to establish such databases at EU level.

8) The new Toy Safety Directive enhances the requirements on the use of chemicals in toys. A prohibition of CMR chemicals (Carcinogenic, Mutagenic or Toxic for Reproduction) in accessible parts of toys with limited exemptions is foreseen, besides a reduction in the limits of certain substances (mainly heavy metals as e.g. lead, mercury) and limit values for certain new substances as well as the replacement of bioavailability limits by migration limits. In addition, the new Directive prohibits the use of the most potent allergenic fragrances and provides for a labelling requirement for fragrances that are potentially allergenic for some consumers.

Everyone seems to accept that a full ban of all CMRs without any possibility for exemptions would not be proportionate or workable, and therefore exemptions have to be granted in some cases. The new Directive therefore relies in the first place on the accessibility criterion to allow the use of CMRs inside the toy when there is no possibility of exposure to it. It would indeed be disproportionate to ban the substances in this case or to oblige producers to undergo a heavy exemption procedure. In addition, a full ban of CMRs in relation to accessible parts without limit values was considered not be possible in practice. Allowing unavoidable traces instead of setting a fixed safe limit is a solution that would be very difficult to apply in practice in a coherent way.

The European Commission considers that exemptions from the CMR ban should be granted following a specific procedure which involves a scientific evaluation of the safety of the substance to be used. For these reasons, it was considered that the inclusion of an exhaustive list of exemptions in the new Directive itself was not feasible. The list would probably be too vague, and subject to different interpretations by economic operators and authorities. However, already at the present stage, it has been possible to foresee an exemption for nickel in stainless steel, because it has proven to be safe. If proven safe, other substances and their allowed use could be later added to the new Directive. Furthermore, it is important to note that the new Directive foresees a possibility for the European Commission to set specific limit values by the so-called comitology procedure (i.e. the Commission is assisted in this task by a Committee composed of Member State experts which issues an opinion on the draft proposed measures) for toys intended for children under 36 months and other toys intended to be put in the mouth in order to ensure adequate protection in the case of these toys that involve a high degree of exposure.

Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and should therefore not be intentionally used in those parts of toys that are accessible to children, are set at levels that are half of those considered safe according to the criteria of the relevant EU Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.

Country of Origin Labelling

March 2008, FOOD 29-08

(This is limited to the recommendations - read the full resolution).

Recommendations

Mandatory Program

TACD supports a mandatory country of origin labeling program to assure that consumers are provided necessary information about the origin of the food they purchase and consume. Voluntary labeling programs do not offer the same benefit as a mandatory labeling program since, by definition, voluntary programs do not require all foods in a particular category to be labeled.

Proper Labeling

TACD supports mandatory country of origin labeling notification for commodities including, but not limited to, meat (including beef, lamb, pork, and goat), poultry, farmraised and wild fish and seafood, fruits, vegetables, dairy products and nuts. All food products in these categories should be identified through the use of a label, stamp, mark, or sign that is on or near the food product. If the food product is prepackaged, the country of origin should be identified on the label. This should include information about the origin of the main ingredients as well as information about where the food was processed. Labeling should include all variations of the food product, whether it is fresh, frozen, canned or otherwise minimally processed.

Multi-ingredient products

TACD supports mandatory country of origin labeling of the main ingredients in a multiingredient food product. The product should be labeled with the country of origin of the main ingredients as well as the place of processing. TACD encourages manufacturers and retailers to label additional ingredients where possible. Identification of country of origin should be listed prominently on the food label.

The U.S. government should implement the country of origin labeling law as outlined in the 2002 Farm Bill and further clarified in the House and Senate versions of the 2007 Farm Bill. The U.S. Department of Agriculture should promulgate regulations in this regard so that mandatory COOL is implemented in the U.S. by September 30, 2008. Existing exemptions for butcher shops, fish markets and uncovered processed foods should be eliminated. The USDA should conduct periodic surveillance of the consumer marketplace to assure that COOL is being implemented properly and consumers are afforded this information. Repeated and willful violations of the law should be assessed penalties.

With its draft regulation on the provision of food information to consumers, the E.U. commission has gone a step forward in improved country of origin labeling, as it has clarified that there is a difference between the place of processing and the origin of a food product. We welcome this proposed clarification in language as it will provide consumers with appropriate information about the true origin of the main ingredients of a multi-ingredient food and not just where that food product was processed. The E.U. proposal, however, is a voluntary one. The E.U. commission should, instead of leaving mandatory COOL to the member states, introduce mandatory country of origin labeling on the E.U. level. Leaving COOL to the member states will lead to different rules and schemes in different member states which may cause confusion among consumers. A

mandatory European country of origin labeling regulation should then provide consumers across the E.U. with information on the origin of the main ingredients of food products as well as the place of processing. Furthermore, TACD does not support a "made in the E.U." label as it is too broad for consumers who want to know the particular country in which a food product has been produced.

* * *

European Commission Services' Response

Information about the country of origin of a food is important but it is not considered as such to determine consumers' choices in all cases. One of the aims of the general food labelling legislation¹¹ is that consumers should not be misled by the presentation of products and, therefore, the Commission supports the idea that information on origin must be given if there is a risk for consumers to be misled if such information was not provided.

To strengthen this principle the Commission proposed¹² clarification for country of origin or place of provenance labelling of food products under the general food labelling legislation which indicate that the country of origin should be determined in accordance with the Community Customs Code¹³. In addition, the country of origin or place of provenance of the primary ingredients must be declared if those ingredients originate from a different place than the finished product. The Commission's proposal is currently under discussion in the European Parliament and the Council and the Commission will consider amendments that might be finally proposed on this point.

There are cases for specific foods where indications of origin that are technically correct in that they show the place a product was prepared or produced, may not correspond to the consumer's understanding that the place of origin is where the raw materials were farmed. That is why the Commission has adopted specific rules in some sectors to require the place of harvest to be indicated for certain crop products (e.g. fruit and vegetables, wine, olive oil, etc.). For beef and veal, the place of farming (birth and raising of the animal) must be shown as well as the place of slaughter.

Consumers are more and more interested in the origin of the food they buy, and in certain cases it might be a legitimate matter for consumer labelling. However, the Commission is concerned that origin should not be exploited for unjustified ends, such as to present certain foodstuffs as meeting inferior hygiene and safety standards than others. In the EU, hygiene and safety rules ensure that all food placed on the market, whatever its source, meets the EU's high standards of hygiene and safety.

¹¹ Directive 2000/13/EC of the European Palriamnet and of the Council of 20 march 2000 on the approximation of the laws of the member States relating to the labelling, presentation and advertising of foodstuffs

¹² Commission Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers (COM(2008) 40)

¹³ Council Regulation (EEC) No. 2913/92 of 12 October 1992 establishing the Community Customs Code and its implementing provisions in Commission Regulation (EEC) No. 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No. 2913/92 establishing the Community Customs Code.

On the specific issue of place-of-farming labelling, on 28 May the Commission adopted a Communication on Agricultural product quality policy¹⁴ that addresses how to improve communication from farmers of information about the farming attributes of product, including production method and place of farming. This Communication builds on the Commission's Green Paper¹⁵ on agricultural product quality policy that consulted stakeholders on these questions at the end of 2008, and on the conclusions to the Czech Presidency High Level Conference on agricultural product quality policy held in Prague on 12-13 March 2009. The Green Paper responses showed that while consumers and farmers' representatives support increased place-of-farming labelling, there were concerns from the processing sectors and retailers about the costs and potential for confusion of such labelling on processed foods where raw materials from different sources are used. The Commission confirms in the Communication that it will consider further use of place-of-farming labelling within marketing standards for agricultural products, while taking into account the specificities of some sectors, in particular concerning processed agricultural products.

¹⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Agricultural Product Quality Policy (COM (2009 234 final)

¹⁵ Green Paper on agricultural product quality: product standards, farming requirements and quality schemes (COM(2008)641 final)

Nutrition disclosure for restaurant foods May 2008, FOOD 30-08

(This is limited to the recommendations – read the <u>full resolution</u>).

Recommendations

The Transatlantic Consumer Dialogue calls upon the governments of the United States and the European Union to require fast-food and other chain restaurants with 10 or more establishments to provide information about nutritional quality on menu boards or menus for standardized menu items.

Requirements for nutrition disclosures may vary from nation to nation, due to nutritional health priorities, cultural traditions, results of consumer research studies, and consumer expectations. In general, such requirements should be based on the following principles:

- Nutrition disclosures requirements for chain restaurants with 10 or more outlets should be mandatory for each standardized menu item.
- Nutrition disclosures should be made at the point of purchase, in a uniform location on menu boards or menus next to the name and price of each standard menu option, and should be easy to comprehend by consumers, including children.
- Current practices by some companies of disclosing nutrient levels and GDA's for particular items on the Internet, in brochures, and/or on posters, or trayliners are difficult to comprehend, confusing, and do not sufficiently inform consumers at the point of sale.
- National authorities should determine the most useful form of nutrition disclosure. This may include use of universal symbols indicating calorie content and/or saturated fat, sodium and sugar levels. Simple signposting should clearly indicate healthier and less healthy options consistent with national dietary guidelines based on public heath priorities.

* * *

European Commission Services' Response

In the European Community, it is considered that in the case of non-prepacked foods Member States are in the best position to determine the information that should be provided and the means of communicating such information to consumers. As highlighted in the TACD position, this means that the information can be adapted to the local circumstances.

The existing Community rules in Article 8 of the Council Directive of 24 September 1990¹⁶ on nutrition labelling of foodstuffs provides that, in the case of non-prepacked foods, the nutrition information and the manner of its communication may be determined by national provisions.

¹⁶ OJ L 276, 6.10.1990, p. 40

In the Commission proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers,¹⁷ it is proposed that the nutrition declaration should be mandatory. With respect to non-prepacked food, the Commission proposal provides is the possibility for the Member States to decide, except in the case of substances causing allergies or intolerances listed in the proposal, whether the mandatory information should be provided. In practical terms because the proposal is in the form of a Regulation it would be directly applicable to food businesses, therefore, in the absence of national rules that derogate, there would an obligation on food business operators to provide the nutrition information on non-prepacked food, including food sold through restaurants and other catering establishments.

With respect to simplified means of presenting nutrition information, the Commission proposal includes the possibility for other forms of presentation, symbols or graphics to be endorsed at national level through the system of national schemes. The Commission believes that this mechanism allows for innovation in the presentation of nutrition related information taking into account the consumer understanding and use of the information.

¹⁷ COM(2008) 40

Food products from cloned animals

November 2008, FOOD 31-08

(This is limited to the recommendations - read the <u>full resolution</u>).

With regard to the use of animal clones and their progeny in the food supply, the TACD makes the following recommendations to the EU and US Governments:

- 1. We consider it is premature to permit the use of cloning and the offspring of clones for food production while there are unresolved issues around food safety, animal health and how an effective consumer choice could be maintained.
- 2. Prior to any cloning for commercial purposes, TACD calls for the EU and US governments to sponsor an open and transparent public discourse on the economic, ethical and social impacts and issues associated with the use of such technologies. Such discourse should fully analyze the risks and any purported benefits of animal cloning, should inform the governments and the public about whether and why cloning should be allowed and, if so, how it should be used.
- 3. TACD calls for the EU and US governments to reassess the safety of all foods produced or derived from cloned animals and/or their offspring, and to insist on studies designed specifically to assess safety of clones that look at animals over their entire lifetime and include sufficiently large study populations to draw valid conclusions. Such a pre-market assessment process should be transparent and allow for public input before any safety determination is made. Until a particular species of cloned animal and its progeny has been evaluated under such a regulatory process, products from those cloned animals and their progeny should not be allowed into the food supply. As well as a safety assessment, the approval process should utilize the precautionary principle and include an analysis of other legitimate factors, such as social and ethical considerations (see TACD resolution <u>Food-16-00</u>) TACD reiterates that the precautionary principle applies in cases where the scientific evidence is not conclusive to determine the level of protection but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment. (See TACD position paper <u>Food 9PP-99</u>).
- 4. TACD currently believes that there is a paucity of publicly available scientific evidence concerning the safety of cloning on the welfare of animals, food products derived from those animals and their progeny, and the impact on agricultural management practices. Furthermore, appropriate regulatory agencies should conduct a thorough assessment, including a cost/benefit assessment as well as an assessment concerning the impact on sustainable agriculture. It must be guaranteed that this assessment be conducted in a transparent and participatory manner, and publicly available information must be used.
- 5. Consistent with existing principles, regulations and practices, the governments of the EU and US should maintain prohibitions on the use of cloned animals and their progeny in organic production.
- 6. If cloned animals or their offspring are used for food production, TACD calls upon the EU and US governments to establish mandatory labelling and traceability of such products. Such information should allow consumers to exercise their choice to eat or not eat food made from this technology.

European Commission Services' Response

The European Commission requested European Food Safety Authority (EFSA) to provide an opinion on food safety, animal health, animal welfare and environmental implications on the use of animal clones. The final opinion was published in July 2008.

The EFSA opinion notes that reduced welfare of clones can be assumed as a consequence of adverse health outcomes. In addition, surrogate dams suffer from reduced welfare conditions due to low efficiency of the cloning process. As regards the progeny of clones, EFSA noted that there is no indication of abnormal effects in the species it examined, namely cattle and pigs. At the same time they underline that data is missing on the full life span of these progenies. The opinion also concludes that there is no indication that differences exist in terms of food safety for meat and milk of clones and their progeny, compared with those from conventionally bred animals.

The European Commission asked the European Group on Ethics (EGE) to give their opinion on the issue's ethical considerations. They delivered their opinion in January 2008. EGE advocates that at the moment there are no convincing arguments to justify the production of food from clones and their offspring.

Moreover, the Commission launched a Eurobarometer seeking European's attitudes towards animal cloning. The findings of the Eurobarometer, covering all 27 EU Member States, are available on the Europa website. A majority of European citizens is concerned about the lack of knowledge on the long-term effects on animal cloning and they think it is morally wrong. Also 63% of citizens would not or would probably not buy food from cloned animas while 35% were likely or somewhat likely to do so. However, an overwhelming majority (83%) considers that special labelling of food production from clones is important. On the other hand, it is worth mentioning that the majority of citizens could accept cloning when specific benefits were mentioned. For example, 65% could fully or partly accept cloning to preserve rare animal breeds.

With the above mentioned information at hand, the Commission discussed the issue in January 2009 and concluded that there is a need to collect more detailed information on the state of play on cloning of farm animals for food production in particular on scientific data and statistics. A mandate has been forwarded to the European Food Safety Authority, asking for more data on the mortality observed in clones during the gestational and postnatal periods and the health and welfare of clones during their productive life and natural life span. More detailed information from EFSA is expected by the end of June 2009.

The Commission noted also that there was a need to launch international consultation on this issue, in particular with the US, Canada and Japan. The Commission is committed to pursue the discussion with the main trade partners.

The Commission is also in continuous contact with stakeholders; farmers, breeders and consumers.

Currently, foods from cloned animals are covered by the Novel Food Regulation¹⁸ and therefore they need a pre-market assessment and authorisation. The proposal for the revision of the Novel Food Regulation will be subject to the second reading when the new Parliament is set in September.

The Commission would re-examine the need for action and the various options in due course, in particular when further information would be available.

¹⁸ OJ L 43, 14.2.1997, p. 1–6

<u>Net Neutrality</u> March 2008, INFOSOC 36-08

(This is limited to the recommendations - read the <u>full resolution</u>).

Recommendations

1. TACD calls upon the US and EU governments to recognize, promote, and encourage the above-defined principles of net neutrality.

2. TACD calls upon regulators to assess the level of competition in broadband Internet access, and take steps to ensure that consumers have continued access to a neutral network.

3. TACD urges regulators to prevent ISPs and network providers from engaging in unfair discrimination against content, services, applications, or devices.

4. TACD calls upon telecommunications and competition regulators in the US and EU to require that ISPs provide fair and accurate information regarding Internet service plans, including average estimated speeds and any existing caps on bandwidth. ISPs and network providers should also detail their compliance with net neutrality principles and regulations; where any content, services, applications, or devices have been blocked or degraded on their networks, ISPs and network providers must be able to justify to the regulators how these actions fall within the scope of legitimate network management.

5. TACD urges ISPs to provide consumers with more information about limitations on Internet service plans, as well as any network management occurring on their networks and how that management affects access to particular content, services, applications, or devices. Such management should be limited to legitimate purposes.

6. TACD calls upon regulators and lawmakers to ensure that consumers have recourse to an effective complaint and enforcement mechanism if providers fail to provide service plan information or discriminate unfairly against content, services, applications, or devices.

7. TACD calls upon regulators to periodically assess the extent to which ISPs and network providers discriminate against content, services, applications, or devices on their network; whether such discrimination falls outside the scope of legitimate network management; and take action against unfair discrimination.

European Commission Services' Response

The debate on the need for regulatory intervention to safeguard the "neutral" character of networks, in particular the Internet, has been stronger in the US than in Europe. Nevertheless, the issue has been raised during the debate on the reform of the EU Telecoms Framework¹⁹.

¹⁹ <u>http://ec.europa.eu/information_society/policy/ecomm/tomorrow/reform/index_en.htm</u>

The Commission services consider that a robust and competitive marketplace is the best method of delivering to consumers the benefits of choice, innovation and affordability. Unlike in the United States, where the concentration of network ownership has provoked real concerns that there could be foreclosure of the Internet, consumers and service providers in Europe seem in a good position overall with regard to "Net Neutrality". This is because European consumers generally have a greater choice of competing broadband service providers available to them. The EU regulatory framework for electronic communications (the EU Telecoms Framework)²⁰ as well as EC competition rules (Articles 81 and 82 EC) have proved their effectiveness in ensuring that the market remains open, that consumer offers are transparent and that competition is effective.

The Commission services believe that the regulatory framework should continue to allow the market forces to play out while allowing companies to experiment with different business models and innovative offers. In line with this approach, the Commission has proposed in the context of the on-going reform of the EU telecom package, that where competitive forces alone are not enough to safeguard the openness of the Internet, national regulators should be able to intervene by setting minimum quality of service requirements for network transmission services (Article 22§3 of the Universal Service Directive²¹). Consumers will be better informed about possible limitations to access and use of lawful services or applications, if any, as well as about traffic management policies and their impact on service quality (Articles 20 and 21 of the Universal Service Directive). In addition, EC competition rules (Articles 81 and 82 of the EC Treaty) will continue to play a crucial role in addressing anti-competitive conduct, including abusive practices by dominant network operators.

The Commission services will continue reflecting on the questions of the users' right to use the services of their choice and the related broader discussion about "Net Neutrality", in particular with a view to safeguarding the end-to-end connectivity principle. The recommendations made by the TACD will be considered as part of this reflection.

²⁰ <u>http://ec.europa.eu/information_society/policy/ecomm/current/index_en.htm</u>

²¹ OJ L 108, 24.4.2002, p. 33–50

Consumer Rights in the Digital World

March 2008, INFOSOC 37-08

(This is limited to the recommendations - read the <u>full resolution</u>).

Recommendations

1. Right to access neutral networks²²

The TACD calls upon:

- Governments to recognise, promote and encourage principles of net neutrality.
- Regulators to assess the level of competition in broadband Internet access, and to take steps to ensure that consumers have continued access to a neutral network.
- Regulators to prevent ISPs and network providers from engaging in unfair discrimination against content, services, applications, or devices.
- Telecommunications and competition regulators to require that ISPs and network providers provide fair and accurate information regarding Internet service plans, including average estimated speeds, any existing caps on bandwidth, and regarding content, services, applications or devices that may be blocked or degraded on their networks. ISPs and network providers should also detail their compliance with net neutrality principles and regulations.
- ISPs to provide consumers with information about limitations on Internet service plans, as well as any network management occurring on their networks and how that management affects access to particular content, service, application, or devise. Such management should fall within the scope of legitimate network management.

2. Right to access digital media and information ²³

DRMs should only be used under the following – cumulatively effective – conditions:

- The practical use of DRMs on the Internet must not generate unnecessary vulnerabilities with regard to consumers' equipment or personal information.
- User profiles must not be created. The anonymity of users of digital media must be protected.
- Copyright owners must not hinder consumers' use of digital media within the framework of prevailing legal prescriptions. This particularly applies to the right to make copies for private use and the right to transform content for private use.
- Because the relevant legal situation is often complicated, copyright infringements for non-commercial reasons must not be criminalized.
- The impact of DRMs on functionality should be limited to what is necessary to protect copyright and should not otherwise affect a consumers' use of content.
- The format of the storage medium must not be used for protectionist barriers that prevent consumers from exercising free choice and their legal rights. Consumers should be allowed to decide for themselves what player or platform they will use, and to move any content they have bought to any medium of their choice.

²² See also: Resolution on Net Neutrality (Infosoc-36-08) and Resolution on The role of Internet Service Providers (ISPs) in mediating online content and communications (IP-04-08)

²³ See also: Resolution and Background Paper on Digital Rights Management, The Sequel (IP-03-07): and Resolution on Digital Rights Management (IP-01.05):

- Consumers should be allowed to circumvent DRMs if any of their usage rights are not respected.
- Copyright holders and providers of digital media must provide users at an early stage with comprehensive information regarding the scope of use permitted for digitalized and copyright-protected content. Enterprises must also provide fair, clear and comprehensible contractual conditions. These measures are required to ensure that consumer behaviour is legal and in line with market requirements and to avoid civil proceedings against copyright infringements.
- Consumers should have clear and "fair" rights to use digital material and not be penalized for simply moving with the times. The industry should develop new business options that are consistent with consumption patterns and meet consumers' needs.

3. Right to secure networks and services²⁴

The TACD calls for businesses to observe the following fundamental principles to provide secure networks and services:

- When choosing a security system, providers of Internet-based services must ensure that the risks to consumers are minimized as much as possible.
- Security must be integrated into the technology. That means that security should be the default setting.
- Internet access providers must ensure that access to online services and offerings is free of manipulation. This presupposes a high standard for the security and reliability of networks and services.
- The providers of Internet-based services must provide consumers of particularly sensitive online services such as online banking and online auctions with regular and timely information regarding current security risks and effective protective measures.
- Providers of digital products and services should be made legally accountable for losses as a result of damage caused by non-observance of appropriate security measures.

4. Right to privacy and data protection

The TACD calls for:

- Business and governments to be subjected to enforceable Fair Information Practices that give rights to consumers and impose responsibilities on organizations that collect and use personal data.
- Business and governments to use effective and updated technology to protect confidential personal data against unauthorized use.
- Business and governments to inform consumers of the measures they can take to protect their own data. Important in this context is information about the form, collection, processing and use of the relevant data.
- Business and governments to refrain from making the use of services or the claim to special offers contingent on agreement by the consumer to the use of his or her data for other purposes.

²⁴ See also: Resolution on Internet Security (Infosoc-34-07): and Resolution on Identity Theft, Phishing and Consumer Confidence (Infosoc-33-07):

- Businesses to ensure that data about consumers is collected, processed and used only with their expressed and voluntary permission – acquired through an opt-in procedure – in so far as the use of this data is not obligatory for the direct settlement of a contract.
- Governments to ensure that programs to combat terrorism and organised crime do not undermine self-determination in terms of personal information and the protection of individuals' privacy.
- Providers of broadcast and media services as well as governments to preserve the preconditions for free and anonymous use of media in the future.

5. Right to software interoperability²⁵

The TACD therefore calls on governments to:

- Analyse with a clearly defined consumer welfare perspective efficiency, cost, flexibility of all tools available to achieve interoperability.
- Close gaps in the legal framework that hinder the promotion of interoperability.
- Promote the creation and adoption of non-proprietary hardware and software interfaces through a combination of policy, legislation, regulation and procurement policies in addition to voluntary standards development activities.
- Adopt and make use of traditional ex-ante regulatory approaches. Apply effectively, enforce vigorously and adapt where necessary traditional consumer protection laws to the digital environment by amending information requirements (for example through clear/simple warning labels on products to signal lack of interoperability), adapting unfair commercial practices laws, clarifying unfair contract terms and sales guarantees legislation.
- Promote open standards through procurement.

6. Right to barrier free access and equality

TACD calls on businesses and governments to ensure barrier-free access and equality by:

- National governments and European institutions to carefully stimulate the provision of barrier free services by strengthening existing legislation (such as public procurement rules and accessibility requirements in public tendering) and to introduce a horizontal legislative framework addressing the accessibility of ICT products and services not covered by sectoral legislation.
- Making digital products and services accessible for use by people with disabilities based on national, regional or international standards and other specifications.
- Creating websites that comply with the accessibility guidelines of the World Wide Web Consortium (W3C).
- Creating digital products and services that are easy to use by people of all ages, levels of education, and social status, and providing easy to understand instructions and tutorials for their use.

7. Right to Pluralistic Media

TACD calls upon governments to:

²⁵ See also: Resolution on Software Interoperability and Open Standards (Infosoc- IP-35-08)

- Assess the impact that the growing concentration of Internet firms will have on the growth of the Internet and the future of the Internet economy.
- Ensure that competition law is enforced paying particular attention to the increasing vertical integration in this sector.
- Establish privacy and consumer safeguards as a central requirement in the context of merger review for Internet firms.

* * *

European Commission Services' Response

1. Right to access neutral networks

(Please, refer also to the Commission Services' Response on the section on Net Neutrality)

The Commission Services support net neutrality as an essential principle for the Internet of Services aimed at maintaining an easy access to Internet and a level playing field for companies developing and offering services, especially SME's.

However, the text of the recommendation could, in some cases, appear confusing. Particularly, the phrasing "network management" is probably intended to mean network traffic management and this could be specified.

2. Right to access digital media and information

In the Communication on creative content online of 2008, the European Commission expressed the need to adopt more interoperable and transparent Digital Rights Management systems (DRMs). TACD's recommendations are in principle consistent with the European approach.

This is also reflected in the EU Directive 2001/29/EC (Directive on copyright in the information society)²⁶, which requires Member States to accord legal protection to technological protection measures against all acts of circumvention by ensuring in the same time that technological protection measures do not hinder lawful uses by the beneficiary of exceptions or limitations provided by national laws.

However, the prohibition on circumvention suffers no exceptions. Instead, exceptions are considered under article 6(4), which privileges voluntary measures on the part of right holders, such as exceptions built-in the TPM technology, and subsidiary intervention by Member States. The underlying assumption is that the adequate and effective level of protection is better achieved with an absolute prohibition on circumvention and trafficking in circumvention devices.

²⁶ OJ L 167, 22.6.2001, p. 10

Article 6 of the Directive 2001/29/EC provides for legal protection against the circumvention of technology measures. From a copyright perspective, all "effective" technological measures benefit from this legal protection. Certainly, applicable consumer protection law and privacy law should be respected by the parties which apply technological measures/digital rights management.

From the right to privacy and data protection point of view, and in line with European legislation, any individual has the fundamental human right to protection of personal data and the right to enjoy private life and communications. Any system, based on digital rights deployment, should be therefore designed in a way that complies with given data protection and privacy principles.

One of the ways for better implementation of the data protection principles announced already in the Commission's First Report on the Implementation of the Data Protection Directive²⁷ and in the Commission's Communication on Promoting Data Protection by Privacy Enhancing Technologies (PETs)²⁸ is to involve privacy enhancing technologies that will improve the current state of play by making infringements to privacy and data protection not only illegal but technically impossible, or at least much more difficult. The Commission has launched a study to assess the economic impacts and benefits of PETs for both public and private sectors and with a focus primarily on SMEs. It should also explore to what extent the deployment of PETs could be economically beneficial.

The call in the TACD document is upon industry and addresses an area of uncertainty in the law. In fact, European consumers have no consistent right to fair use but there are exceptions and limitations to copyright provisions. Thus, consumers should be aware of these exceptions in order to avoid infringing the rules in their country. Generally, current EU law does not make distinctions between copyright infringements for commercial or non-commercial reasons, which, at national level, might make consumers subject to criminal sanctions notwithstanding whether or not their infringement is of noncommercial nature.

3. Right to secure networks and services

The European Commission has proposed, as part of the reform of the EU Telecoms Framework, to clarify and strengthen the obligations of providers of public electronic communications networks and services, including providers of Internet access, with respect to security of networks and services. Taking account of the state of the art and the cost of the measures, these providers are obliged to take measures which ensure a level of security appropriate to the risks posed to network security, in particular to minimise the impact of security incidents on users and connected networks. However, while the implementation of these provisions shall lead to a high standard of security for communications services and networks, even the most advanced measures taken by providers of communications networks and services cannot guarantee that internet access

²⁷ Directive 95/46/EC, OJ L 281, 23.11.1995

²⁸ COM (2007) 228 final

is 100% free of security risks. All parties involved, including consumers, have to be aware of the security risks and take the appropriate measures in their domain of responsibility.

In the context of the reform of the EU telecom package, the Commission proposed to introduce an obligation to notify personal data breaches (e.g. breaches of security which have affected personal data of subscribers or users) the ePrivacy Directive²⁹ as an additional means to enhance the protection of individuals' privacy and personal data in the electronic communications sector.

In addition, Article 17 of the Data Protection Directive³⁰ lays down the data controller's obligation to implement appropriate technical and organisational measures and to ensure a level of security appropriate to the nature of the data and the risks of processing it. It is clear that without implementing appropriate security measures, there is no efficient way to protect privacy and personal data.

4. Right to privacy and data protection

The Commission services stress that the EU data protection Directive³¹ defines the conditions under which the processing of personal data is legitimate, such as the consent of the individual concerned, the necessity in order to perform a contract or to fulfil a legal obligation. It defines the responsibilities of the entities processing personal data, including the obligation to take appropriate security measures, as well as liabilities and sanctions in cases of non-compliance, and the rights of the individuals, including remedies for breaches of these rights.

The Directive has been transposed into 27 Member States national laws and is enforceable by independent national data protection authorities. The Directive imposes several obligations on data controllers and provides rights to data subjects. It applies to natural persons, whatever their nationality or place of residence as well as both to private and public sectors and is technology neutral. Therefore, any processing of personal data has to respect basic data protection principles such as proportionality, rule of privacy by design, data minimization, etc. Furthermore, data should be kept in a form which permits identification for no longer than necessary.

The date of January 28 has been proclaimed as "Data Protection Day". On this occasion, several awareness raising activities have been undertaken by the European Commission as well as by individual Member States' Data Protection Authorities. These activities should contribute to a better recognition of the right to protection of personal data as a fundamental right in the EU.

²⁹ http://ec.europa.eu/information_society/policy/ecomm/library/proposals/index_en.htm

³⁰ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, O.J. L. 281, 22(11/1005 m 21)

^{281 23/11/1995} p. 31 ³¹ Directive 95/46/EC, O.J. L. 281 23/11/1995 p. 31

Article 17 of the Data Protection Directive lays down the data controller's obligation to implement appropriate technical and organisational measures and to ensure a level of security appropriate to the nature of the data and the risks of processing it. It is clear that without implementing appropriate security measures, there is no efficient way of protection privacy and personal data.

The EU rules for electronic communications sector oblige Member States to ensure that communications and related traffic data are kept confidential, unless the users concerned have freely given specific consent to any interception or surveillance after having been informed about the measures. Concerning the specific rules for the processing of personal data in the electronic communications sector, the European Commission has proposed to strengthen and clarify several provisions, e.g. on cookies and spam. In particular, in addition to the obligation to inform consumers about risks of security breaches and possible protection measures they can take, providers of electronic communications services will be obliged to notify security breaches that affect personal data.

The European Commission has also launched an assessment of the impact of online data collection, targeting and profiling of consumers with an Experts discussion held on 31 March 2009. The aim was to establish whether the additional knowledge of advertisers and sellers about consumers put consumers at a disadvantage; whether profiling leads to discriminatory practices, e.g. by individualised prices or reduced consumer choice; and whether contracts, terms of use or privacy notices are frequently unfair.

The collection of information and positions on the topic will continue, amongst others by setting up a public forum on the internet.

The European Commission will also liaise with consumer organisations and regulators in the US, and will raise this topic in multilateral fora (such as the Organisation for Economic Co-operation and Development) in order to evaluate the need and possibilities for an international response.

5. Right to software interoperability

(Please, refer to the Commission Services' Response on the section on Software Interoperability and Open Standards).

Article 6(1) of Directive $91/250/\text{EEC}^{32}$ on the legal protection of computer programs provides for the so-called "decompilation" exception. The decompilation of a computer program (reproduction of the code and translation of its form) with the aim of achieving the interoperability of an independently created computer program with other programs is authorised under certain limited conditions.

³² OJ L 122 , 17/05/1991 p. 42 - 46

6. Right to barrier free access and equality

The Commission services acknowledge TACD Recommendations.

7. Right to Pluralistic Media

The Commission services acknowledge TACD Recommendations.

Software Interoperability and Open Standards

July 2008, IP 04-08

(This is limited to the recommendations - read the full resolution).

Recommendations

TACD resolves that EU and US governments should:

1. Analyse with a clearly defined consumer welfare perspective the efficiency, cost, and flexibility of all tools available to achieve interoperability.

2. Promote the creation and adoption of nonproprietary hardware and software interfaces through a combination of policy, legislation, regulation and procurement policies in addition to voluntary standards development activities.

3. Adopt concrete definitions of interoperability and open standards in different areas that take into account the context of the problem being addressed, and which promote economic and social development goals. These should clearly have the consumer and enduser interest as their focus. When possible and appropriate, such definitions should be explicit in addressing policy objectives of competition and functionality on different technology platforms, including those involving free software.

4. Adopt and make use of traditional exante regulatory approaches. Apply effectively, enforce vigorously and adapt where necessary traditional consumer protection laws to the digital environment; for example, by requiring clear and trustworthy warning 5 labels on products to signal lack of interoperability, adapting unfair commercial practices laws, and prohibiting unfair contract terms and sales.

5. Promote open standards through procurement and ensure the use of software and services based on open standards in public procurement policies through for example legal mechanisms such as mandatory eGovernment Interoperability Frameworks. Ensure that public services and information/data are based on open standards.

6. Government procurement of software should include requirements that word processing and presentation graphics programs can read and write to open standards compliant document formats that are not effectively controlled by one company, and which realistically facilitate competition in the market for such programs, and which can be implemented effectively on at least the three leading operating system platforms. Government procurement of computer printers should include requirements that manufactures provide the drivers and interface information necessary to make such printers work with at least the three leading operating system platforms. By 2010, the US and the EU should make efforts to ensure government procurement of audiovisual software and services that use open standards compliant formats that work on at least the three leading operating operating system platforms. By 2010, the US and the EU should make efforts to ensure government procurement of software should include requirements that saving data into an Open Standard should be the default setting of the program. Every two years, the US and EC should solicit public comment on additional areas where government procurement policy can be used to promote interoperability and open standards.

7. Where appropriate, mandate open standards for file formats, open intercommunication protocols, and interoperability for consumer software and services

8. Ensure disclosure of interoperability information that is essential to create interoperable applications and services.

9. Require data portability between systems and applications, as well as longterm access to personal and public electronic records

10. Vigorously apply antitrust legislation and investigate and expeditiously pursue anticompetitive practices that affect interoperability.

11. Proactively investigate and pursue any infringements of data protection and privacy regulations resulting from the development of new interoperability based systems and services.

12. Establish a level playing field upon which Open Source or proprietary software can compete with each other fairly. This should be based on both the technical merits of the software and the merits of non-software features: for example the potential for software to be redistributed or modified because of permissible copyright licensing, the availability of multiple service vendors, and the viability of the development community or company producing the software.

13. Ensure consumer organisations participation in standards, which is crucial to ensure best protection for consumers, and better acceptance of products and services in the market place. This will require increased public resources and greater openness in the standardisation system.

* * *

European Commission Services' Response

The EU approach to interoperability has for many years been considered to be an area that should be market led. Only in areas where there are failures of competition, has the Commission sought to intervene. In this context, the TACD recommendations are considerably more interventionist than current EU policy could accept. Nevertheless, the recommendations are a valuable input for the development of future policies (as for example in the case for the post-i2010 strategy³³) which are being developed with an increased emphasis on the user's perspective.

There are also some sectors where Software interoperability and open standards have already been singled out as key issues, such as ICT applications for healthcare ("eHealth"). The Commission has recently issued a specific recommendation on interoperability of electronic health record systems³⁴, and further analysed semantic interoperability in this sector.

³³ <u>http://ec.europa.eu/information_society/eeurope/i2010/index_en.htm</u>

³⁴ Commission Recommendation on cross-border interoperability of electronic health record systems, 2008/594/EC

Furthermore, EU legislation requires companies to provide adequate information to consumers on their products and services. Under the Unfair Commercial Practices Directive³⁵, omission to provide upfront clear indications of important characteristics of a product, such as its interoperability (and/or significant limitations thereof), may be considered illegal by national authorities, based on the specific facts and circumstances of real cases.

As regards public services, interoperability has been an EU policy priority for several years. The ministerial declaration approved unanimously in Lisbon, Portugal on 19 September 2007 has paved the way for a concrete agenda on software interoperability and open sources for eGovernment. The Commission is therefore now working with the Member States on defining a five year plan to achieve interoperability of public services: the European Interoperability Strategy (EIS)³⁶. In parallel the European Interoperability Framework³⁷ is being formalised for political adoption at EU level. This document will give detailed guidance to public administrations on cross border and cross sector interoperability for public services delivery. On a practical level, the ICT Policy Support Programme³⁸ focuses on large scale pilots for efficient and interoperable eGovernment services.

³⁵ Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC and 2002/65 of the European Parliament and of the Council and Regulation (EC) no 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive).

³⁶ <u>http://ec.europa.eu/idabc/en/document/7772</u>

³⁷ http://ec.europa.eu/idabc/en/document/7728

³⁸ http://ec.europa.eu/information_society/activities/ict_psp/index_en.htm

The role of Internet Service Providers in Mediating Online Content and Communications July 2008, IP 06-08

(This is limited to the recommendations - read the full resolution).

Recommendations

TACD resolves that EU and US governments should:

1. Require a thorough and critical review of the risks to consumers and an assessment of the unintended consequences of any proposals regarding the monitoring of consumers' communications and use of online content.

2. Consider whether such proposals would erode consumer and civil rights, such as the rights of privacy, due process, defense and access to information and knowledge. A full range of consumer protection safeguards should be provided for these rights.

3. Ensure that any monitoring of the Internet and use of collected electronic data is done under judicial control and in compliance with all laws on the protection of personal data, and with the understanding that an IP address is personally identifiable information subject to legal protection

4. Ensure that any monitoring of consumer activity is undertaken in accordance with the principle of proportionality.

5. For any online enforcement efforts, assess the sanction and the crime targeted pursuant to the principles of effectiveness and of dissuasiveness. Under these principles, the termination of Internet access is an extreme solution, legally and economically disproportionate as a response to alleged infringement.

6. Ensure that any proposals to monitor online content are accompanied by a review of alternative solutions that focus on systems of remuneration for creative communities, thus fostering the development of innovative business models and, more broadly, the development of the digital economy.

7. Analyze all the legal consequences of any monitoring or ISP liability approach in order to avoid conflicts with existing laws as well as potential conflicts of norms or other legal uncertainties that could be caused by the proposed system.

European Commission Services' Response

Commission Services support the TACD Recommendations of 2008 on the role of Internet service providers in mediating online content and communications. The recommended approach aims at striking the right balance between content users' rights and civil liberties and the need for adapted copyright enforcement measures.

As for point 3, EU law already (Directives 2000/31/EC and 2002/58/EC) does not allow Member States to impose general monitoring obligations. In the current framework, only national judicial authority may impose such a monitoring to internet service providers.

The EU rules for the electronic communications sector oblige Member States to ensure that communications and related traffic data are kept confidential, unless the users concerned have freely given specific consent to any interception or surveillance, after having been informed about the measures. These rights may only be restricted through national legislation where such restriction constitutes a necessary, appropriate and proportionate measure within a democratic society to safeguard *inter alia* national security or the prevention, investigation, detection of prosecution of criminal offences.

Concerning recent activities of some intellectual property rights groups related to monitoring use and dissemination of copyrighted works and profiling activities of individuals (in this case consumers), the European Commission has to point out that any deployer of a monitoring system, such as for example Digital Rights Management (DRM), is required to comply with data protection and privacy laws. Such systems should therefore be designed as to comply with given data protection and privacy principles. For instance, one of these principles is that data collected via DRM shall be used only for the purpose they have been collected. In any case, the acquis communautaire requires unambiguous i.e. informed, specific and freely given consent of the data subject. Such consent should not be conditional.

The Commission Services would however refrain to endorse point 5 of the recommendation to the extent that, while in most cases termination of internet access could be considered a disproportionate measure, this would not be the case for certain cyber crimes. In the way in which point 5 is drafted, it could be inferred that termination should be considered as an absolute disproportionate measure.

WIPO Negotiations on Copyright Limitations and Exceptions, with Special Reference to the Needs of Visually Impaired Persons and Access to Orphan Works

July 2008, IP 05-08

(This is limited to the recommendations - read the full resolution).

Recommendations

- 1. The EC and the US should eliminate their opposition to the elements of the proposed WIPO SCCR L&E work program that relate to analysis and norm setting.
- 2. The EC and US are requested to meet with representative of TACD and World Blind Union to discuss a treaty for *minimum* L&E for the visually impaired.
- 3. The EC and US should submit to the WIPO General Assembly in September 2008, a concrete proposal for or addressing norm setting for the minimum L&E needed to expand investments in publishing and services for visually impaired persons.
- 4. The EC and the US should propose a draft treaty on minimum L&E for the visually impaired at the November 2008 WIPO SCCR meeting,
- The EC and the US should ask WIPO to prepare an experts report on the areas where flexibilities in the enforcement sections of the TRIPS can be used to address the orphan works problem, including in particular, the flexibilities in Article 44.2 of the TRIPS.
- 6. The EC and the US should not extend the term of copyright or related rights beyond that required by Berne, Rome or WCT treaties or the TRIPS agreement. In cases where such term extensions are used, the extended term should only be given in those cases where the owners of the rights register the works, and pay at least nominal fees, in order to ensure that the works for which right owners are not actively exploiting commercially enter the public domain, and become freely available, without a requirement to obtain a license or pay royalties.

* * *

European Commission Services' Response

The Commission Services are participating in a constructive manner in the World Intellectual Property Organization (WIPO) discussions on exceptions and limitations and support the continuing analysis and information gathering currently being considered in the Standing Committee on Copyright and Related Rights (SCCR). The Commission Services believe that it is too early to go forward with norm setting on an international scale and supports rather a stakeholder dialogue proposed by the SCCR. The EC already caters for exceptions for persons with disabilities (including therefore the visually impaired) and all EU Member States have an exception in place in their national laws to this effect.

The European Commission services have met with representatives of the World Blind Union (WBU) in May 2009. Previous meetings with EU-based organisations representing the disabled have revealed that 'access to knowledge' is an essential demand for all people with a disability and that speedy and practical solutions are at the forefront of their concerns. The Commission's services are working to set up practical arrangements to guarantee access 'here and now'.

The European Commission published a Green paper in July 2008 which addressed the issues of exceptions and limitations for libraries and archives, teaching and research and the persons with a disability and orphan works. Nearly 400 responses were received and the Commission is preparing a Communication outlining the main findings. This Communication will be published by autumn of 2009. Moreover, the European Commission was also instrumental in the preparation of a Memorandum of Understanding on Diligent Search Guidelines for Orphan Works signed on 4 June 2008 by the representatives of libraries, archives and right holders in the framework of the European Digital Libraries Initiative.

In July 2008, the European Commission proposed to extend the term of protection for performers and sound recordings. The main impetus behind this proposal was to increase income levels for musicians and, in particular, session players. The latter have to relinquish their copyright when signing a recording contract. No jurisdiction in the world has made copyright terms contingent on a revenue sharing model whereby session musicians are entitled to 20% of a sound recordings' gross sales revenue in the extended term. In order to guarantee benefits, the 20% will be calculated on a track-by-track basis.

The proposal also contains accompanying measures to ensure extra revenue to session musicians and the lesser known featured artists (the clean slate) and the retrieval of rights by performers so that they may make their music available themselves or find another producer who will sell their music (the use-it-or-lose-it clause).

As part of the co-decision procedure, the European Parliament voted an extension of 70 years in its plenary session of 23 April 2009 and supported the accompanying measures. The negotiations with EU Member States indicate that their position is very close to that adopted by the Parliament. A formal adoption of this proposal is hoped for in the near future.

Making the benefits of term extension and the session players fund contingent on prior registration by performers would essentially hurt the weakest performers who might not benefit from the term extension and the accompanying measures due to a failure to register or a failure to pay a 'nominal fee'. Often these performers are not legally advised as to the proper registration procedures. Furthermore, a registration requirement is alien to the European management of performers' copyright where the management of remuneration rights is entrusted to independent collecting societies. The proposal therefore does not impose registration requirements, but instead relies on existing databases already operated by performers' collecting societies to enjoy maximum distribution to performers.