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TACD Comments on Regulatory Cooperation between the United States and the European Union

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1. Introduction

The Transatlantic Consumer Dialogue (TACD) is a forum of 80 US and EU consumer organizations which develops and agrees on joint consumer policy recommendations to the US government and the European Union to promote the consumer interest in EU and US policy making.

TACD welcomes this opportunity to respond to the request for public comments concerning regulatory cooperation between the United States and the European Union. We are supportive of close EU-US cooperation as a means to deliver a fairer, safer and more vibrant marketplace for consumers.

2. Process and mechanisms

TACD is keen to play a constructive role in EU-U.S. regulatory cooperation and we appreciate the efforts being made to ensure an open, transparent and inclusive process.

The stakeholder sessions that take place alongside the meetings of the High-Level Regulatory Cooperation Forum are certainly an interesting mechanism for briefing stakeholders on the discussions that have taken place. However, we believe that additional measures are required to ensure on-going discussion and engagement with a broad spectrum of stakeholder groups in between meetings. This is fundamental as many of the issues under discussion are technical in nature, and it's important that the appropriate experts have the opportunity to participate and comment on these. We welcome the decision taken to combine the TEC and HLRCF physical meetings with regular video conferences in order to maintain a sufficient level of ongoing dialogue and consider it essential for all stakeholder groups to be associated to these conferences.

Of course, it is essential to the process that work plans with clear objectives are made available, indicating key contact points on both sides of the Atlantic. We must also reiterate the importance of ensuring parity with other stakeholder groups as regards the distribution of materials and consultation more broadly.

TACD believes that an effective involvement of stakeholders in EU-US cooperation calls for an expansion of this process beyond TEC and towards the bilateral sectoral dialogues. From the consumer perspective, it is indeed crucial to be consulted on all consumer relevant transatlantic issues, irrespective of whether they fall under the TEC or with another intergovernmental dialogue.

3. Background on regulatory cooperation

We approach the issue of regulatory cooperation with a core principle in mind: that it is the responsibility of government to protect consumers. We agree that it's desirable to avoid unnecessary barriers and regulatory divergences between the EU and US, however this goal should not impede or delay the formulation and implementation of important and necessary consumer protection regulations on either side of the Atlantic. The TACD is adamant that the threats from unregulated hazards greatly outweigh those presented by regulatory divergences. Furthermore, we stress that consumer and other public interest protections should not be viewed as analogous to barriers to trade and investment.

Ensuring rigorous and effective regulation must be a primary objective of EU-US regulatory cooperation, with clear commitments from both sides to learning from best practices as well as regulatory failures.

TACD also reaffirms its support for the precautionary principle, and calls on the US and the EU to incorporate the precautionary principle in regulatory decisions involved in consumer health and safety and the environment. International work on risk analysis should be further developed which ensures openness and transparency. Consumers should be effectively involved throughout the process, beginning with the initial development of a risk assessment policy by risk managers.

4. Sectoral regulatory cooperation

4.1 Nanotechnologies

Nanotechnologies is an emerging technology that poses a number of potential benefits but also concerns to consumers. We urge the EU and US to convene intensive consultations among the relevant regulatory bodies on both sides of the Atlantic to exchange data and establish sound approaches to assessing and preventing risks associated with nanotechnologies. Regulatory systems regarding consumer and environmental protection must be updated in order to address the special characteristics of nanomaterials.

As there are no agreed definitions on nanomaterials and nanotechnologies available at international level, this leads to differences in interpretation and to legal uncertainties. We see a need for further exchange and cooperation regarding definitions for nanomaterials.

More transparency is urgently needed concerning what foods and other products containing nanoparticles are available on the market. Voluntary reporting has not been effective on either

side of the Atlantic and TACD emphasizes once again that mandatory solutions should be developed. The EU and US should address this issue as part of the broader regulatory dialogue in the area of nanotechnologies that is taking place in the High Level Regulatory Cooperation Forum.

TACD has recently issued a resolution on the need for a mandatory reporting scheme and inventory for nanomaterials contained in consumer products, which presents recommendations for EU and US government. This is included in annex 1.

4.2 Product safety

A formal agreement between the US Consumer Product Safety Commission (CPSC) and the European Commission's Directorate General for Health and Consumer Policy (DG SANCO) to improve the exchange of confidential information relating to unsafe products has the potential to deliver real benefits to consumers. The ability of competent authorities to cooperate freely on a reciprocal basis in exchanging information, detecting and investigating infringements and taking action to bring about their cessation or prohibition is essential to guaranteeing the protection of consumers on both sides of the Atlantic.

We strongly urge the EU and US to overcome the hurdles that have prevented the conclusion of a formal agreement.

4.3 Smart Grids

The deployment of the Smart Grid and intelligent power meters warrants close attention by policymakers in order to ensure that promises of consumer protection, privacy controls, cost savings and social benefits are fully realized.

While industry and some government entities promise that a smart electrical grid will save energy, protect consumers, safeguard the environment and ultimately save money for all stakeholders, consumer advocates on both sides of the Atlantic call for independent study of these anticipated benefits.

TACD has recently issued two resolutions on smart grids. Both resolutions recommend standards and regulatory requirements as critical to consumer protection against risks ranging from inadequately designed and implemented Smart Grid technology to unforeseen consequences of new technology rollouts. The resolutions are included as annex 2 and 3.

4.4 Food

4.4.1 Food safety

The recent *E. coli* outbreak in Germany and France provided a stark reminder of the challenge of food safety and the complexity of food supply chains. Late last year, the U.S. Congress passed new legislation, the Food Safety Modernization Act that will mandate process control systems for all food processors, requiring facilities to anticipate problems before they occur and

utilize controls that will prevent them. It is our hope that this new law will significantly reduce the numbers of outbreaks and illnesses that are experienced each year by U.S. consumers. The implementation of this law will require international cooperation and we believe that strong collaboration between the EU and US, for example in the area of inspections and traceability, will lead to better results for consumers in addition to ensuring the most efficient use of government resources.

This new law is important, with its emphasis on prevention. However, more remains to be done. The meat inspection program in the United States is based on a model developed in 1906. The European Union is currently implementing a new review of its meat hygiene legislation. TACD members and consumer organizations hope to participate in this review and also encourage the United States to develop strong and harmonized practices in this area. We believe that this is also a potentially fruitful area for regulatory cooperation.

TACD has also recently adopted a resolution on the use of antimicrobials in animal and food production, urging both the EU and US governments to develop policies to protect and preserve the use of important antibiotics for human medicine, as recommended by the World Health Organization. On World Health Day in April 2011, the WHO called for governments to reduce the need for antimicrobial use on the farm through better policies and animal husbandry practices. Their call has been joined by FAO and OIE. TACD supports this call and urges the governments in the EU and the US to adopt more sustainable policies that will protect the use of critically important antimicrobials in human medicine. TACD's recent resolution is attached as annex 4.

Given our experiences with food safety, it is clear that events such as the recent *E. coli* outbreak s highlight the need for governments to take an aggressive approach to anticipating hazards and emerging risks before they occur. Strong EU and US regulatory cooperation is extremely important in this respect.

1.4.2 Tackling obesity and diet-related disease

It is essential that efforts to tackle obesity and diet-related disease remain a priority for both the EU and U.S. governments. Several policy initiatives are underway, but rates remain at unacceptable levels. There is a real opportunity to share experiences, best practice and collaborate on key policy initiatives. In particular, we would like to highlight the importance of co-operation in the following areas:

- Providing clear information to consumers about the nutritional quality of their food, both at retail level and out of home: The US has had mandatory back of pack nutrition information for a number of years and there is currently interesting research being conducted regarding the introduction of front of pack labeling schemes. The EU has recently agreed new Food Information Regulations, which yielded good progress through the introduction of country of origin labeling and mandatory back of pack nutritional labeling, however to the regret of TACD members it has not introduced mandatory front of pack labeling. Food companies in the EU and US have developed

various voluntary labelling initiatives in addition to legislative requirements, including front of pack nutrition labelling. TACD supports mandatory back of pack nutrition information as well as mandatory front of pack to highlight key nutrients and help consumers interpret government guidance. The proliferation of different approaches is however counter-productive. It is important to move forwards based very clearly on research assessing what works best for consumers. Based on the independent research conducted, this requires traffic light colour coding to be included on food packaging. TACD has issued a resolution on simplified nutritional labeling. This is included in annex 5.

TACD also welcomes the recent enacted US law that requires calorie labelling in chain restaurants with 20 or more outlets across the US. We hope that companies who have to provide this information for consumers in the US will do this for EU consumers - but also hope that the EU and its Member States can take a similar approach. TACD has issued a resolution on nutrition disclosure for restaurant foods – see annex 6.

- Responsible marketing of foods: The U.S. has committed to developing nutrition principles for responsible marketing of foods to children in order to ensure that marketing promotes more positive health messages. As part of this, the US is looking at nutrient profiling models to underpin any guidance. TACD recently submitted comments to the US Interagency Working Group on Food Marketed to Children's preliminary proposed nutrition principles to guide industry self-regulatory efforts. These are included in annex 7. The EU has had some discussions on this issue, but has made little progress, relying on voluntary commitments through the EU Platform on Diet, Physical Activity and Health rather than providing direction on the issues to be addressed. TACD sees this as an important area for collaboration, particularly as many marketing tactics, such as marketing on the internet, go beyond national boundaries. The adoption of WHO recommendations on this issue at the World Health Assembly in May 2010 should also provide a basis for further work. We also consider that there is an opportunity for collaboration in relation to controls over health and nutrition claims in order to ensure that robust nutrition criteria are in place so that health claims cannot be made on "unhealthy foods" ie. those high in fat, sugar and salt.

4.4.3 Tackling divergent approaches

Over the years, there have been a number of instances where the EU and US have taken divergent approaches to regulating new technologies used in food production, whether regarding the approval and labelling of genetically engineered foods, the use of growth hormones for food production or the treatment of poultry carcasses. Similar divergences can be expected concerning technologies such as cloning (see TACD resolution in annex 8) and the use of nanotechnologies in food production (see section on nanotechnologies above).

TACD stresses the importance of informing regulation on such issues both through sufficient scientific research but also importantly, social and ethical considerations. It is fundamental that governments ensure mechanisms that enable effective consumer choice.

4.5 Protecting consumer privacy in the digital age

Advances in technology and the increasingly global marketplace have raised concerns about privacy to a new level. It is now a priority in both Europe and the United States. Consumers' lack of confidence that the privacy or security of their personal information is adequately protected by government or business is a barrier to cross-border trade. A common approach to privacy issues is essential for consumers and for businesses.

The European Commission is evaluating the Data Protection Framework Directive in the light of developments over the past 15 years. New privacy legislation has been proposed in the US Congress to address behavioural advertising and other privacy issues. The Federal Communications Commission is also examining privacy issues related to communications. The Federal Trade Commission recently asked for comments about updating its rules concerning children's online privacy and is expected to release a major report about privacy soon based on a series of Privacy Roundtables that it has held. In addition, the 10th anniversary of the Safe Harbor agreement has raised questions about its effectiveness in protecting the data of European consumers when it is transferred to the US.

There are already well-established TACD policy recommendations for government and industry on digital privacy, children's privacy, the Safe Harbor, and other privacy issues. We believe that it would be useful to explore the role that regulatory cooperation could play in helping to improve protection for consumers' privacy on both sides of the Atlantic.

TACD has developed three new resolutions which address the issues of behavioral advertising (see annex 9), cloud computing (annex 10) and privacy issues relating to smart meters (annex 2). TACD is also currently developing a patient bill of rights for e-health records, which will soon be available.

4.6 Intellectual Property

TACD has long expressed concerns regarding the impact of EU and US intellectual property policy and enforcement on innovation, access to knowledge and access to medicines. TACD calls for a forward looking agenda on intellectual property that works both to the benefit of business and consumers.

4.6.1 Intellectual property enforcement

The enforcement of any particular intellectual property right, whether copyright, trademark, patent or others, is a complex and important area of public policy that touches on personal privacy, civil rights, freedom, social and economic development, and plethora of other issues.

According to the WTO TRIPS Agreement, the enforcement of intellectual property rights should be consistent with the promotion of technological innovation and the transfer and dissemination of technology. The policies should be to the mutual advantage of producers and users of knowledge, in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Governments have responsibilities in formulating or amending their laws and regulations to adopt measures necessary to protect public health and nutrition, to promote the public interest in sectors of vital importance to their socio-economic and technological development, and to include appropriate measures that may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The European Union and the United States are engaged in extensive efforts to shape global norms for the enforcement of copyright, trademarks, patents and other intellectual property rights. These discussions and norm setting activities are taking place in multilateral, plurilateral, bilateral fora and through unilateral actions. The proposals that are under consideration would in important areas be significant departures from the norms of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While trademark, copyright, and patents are private rights that enable the right holders to seek remedies for infringements through legal proceedings, some initiatives create public responsibilities to monitor, prevent and penalize infringing activities, creating burdens on state resources. The extent to which this is appropriate will depend upon the specific initiative, and the competing priorities regarding scarce resources. This is a special concern in developing countries, where the public enforcement of private intellectual property rights may not be a high priority.

TACD has developed resolutions on intellectual property enforcement (see annex 11) and specifically on the Anti-Counterfeiting Trade Agreement (see annex 12) which outline detailed recommendations to the EU and US.

4.6.2 A positive agenda on intellectual property, innovation and access

Copyright limitations and exceptions

TACD believes that the EU and US should lend their support to the Treaty proposal by the World Blind Union, as presented at the World Intellectual Property Organization, to introduce minimum copyright limitations and exceptions for works for the visually impaired. This is needed to end the present "book famine" that affects millions of blind people around the world who often do not have access to accessible versions of books due to copyright law that does not permit their import and export. TACD's resolution addressing this issue is included in annex 13.

Unlocking access to orphan works

Taking note of TACD resolutions on copyright adopted in July 2008¹ and in July 2009², TACD strongly urges US and EU authorities to overcome legal barriers to access to orphaned copyrighted works.

¹ http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=34&Itemid=40

With copyright terms of life plus 70 years, and automatic copyright under national laws, there exist countless books, articles, pamphlets, letters, photographs, audio and visual recordings, software, architectural and other copyrighted works that are not being commercially exploited, and for which it is difficult or impossible to identify and or locate the owner of the copyright protecting the work. These works are largely inaccessible to the public, because copyright laws create large financial risks for acts of infringement associated with the copying, distribution and use of such works. Orphan works are potentially valuable to historians, documentary film makers, scholars, persons engaged in genealogical research, and artists. Solutions to the Orphan Works problem will require changes in copyright laws.

TACD points out that the lack of a legal solution that permits wide access to orphan works undermines the social credibility and legitimacy of international and national copyright law and its enforcement.

TACD's resolution on orphan works is included in Annex 15.

Competition and copyright

Creative individuals, communities and industries increasingly depend on innovation in the digital technology industry. Creative and digital technology industries are both characterized by dominant players, network effects and use of copyright. Copyright law and licensing should support innovative and competitive markets, driving and financially rewarding technological and creative innovation. However, copyright systems cannot always be assumed to do this, and the practices of copyright owners do not always support innovative and competitive markets. Therefore competition law and policy has a key role to play in maintaining competitive creative and digital technology markets as they seek to prevent abuse of dominant position and anti-competitive agreements.

The Transatlantic Consumer Dialogue (TACD) wants to see a digital economy characterized by competitive, dynamic and innovative markets to which consumers have meaningful access to a wide range of knowledge, information and cultural products on fair terms. We want to see a copyright culture that supports this by striking a fair balance between the rights of creators, investors and consumers. Consumers are also creators, such as when they use copyrighted works as part of their own political or cultural expression. Unfortunately the reality is that there are many barriers to innovation and competition in these markets. These barriers raise prices, reduce consumer choice, hinder market entry by small new innovative companies offering new business models and hamper the development of a competitive and innovative digital economy.

TACD has issued a resolution on copyright and competition, which is included as annex 14.

Innovation and access to medicines

² http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=34&Itemid=40

The question of access to medicines is of global concern. For many citizens in the South, access to essential medicines is often a question of life or death while in the European Union and in the US, the cost of medicines is creating a growing financial burden for national health systems.

Equitable access to medicines requires sustainable responses to medical needs that go far beyond the current efforts of charity or international aid. It requires policies that allow for and promote the full participation and economic development of the South. The cost of research and development of new medical technologies can be substantial and requires investment by both the public & private sectors. Innovation in medical technologies also requires access to knowledge, materials & technology. The mechanisms to finance the cost of R&D for new medical technologies should be transparent, economically efficient and avoid conflicts of interest and anti-competitive practices, and be consistent with human rights, including the right to development.

Official EU and US inquiries in to the pharmaceutical sector have revealed a number of systematic anti competitive practices that lead to the delay of market access for more affordable generic medicines with the EU and the US. This raises major concerns about the incentives in the current system of innovation.

Monopolies over medical knowledge exclude many from the benefits of the development of medical technologies, while these are considered public goods. It is imperative to find an appropriate balance between protecting the interests of IP rights holders; incentives for innovation; the right to access to knowledge; and the protection of public health. Furthermore, it is essential to explore and establish new models for biomedical innovation that promote knowledge sharing and address critical barriers to access and innovation.

The EU and the US should also prioritise policies that ensure the rational use of medicines and curb malpractice driven by commercial interests, leading to irrational use and putting patients in danger.

TACD has developed a resolution which presents recommendations on innovation and access to medicines. This is included in annex 16.

4.7 Financial services

Financial services, their governance and their development, are particularly important to consumers in the EU and US, who rely on financial products and services to facilitate purchases, for savings and investments and to insure against risk. Over the years, however, financial products, such as mortgages, investments, credit cards, small loans and other payment products, have become more complex and potentially risky for consumers. The rapid pace of innovation in the market and the long term nature of many transactions mean that consumers need protection at every level in order to avoid the considerable risks that these services pose.

The financial system also needs those protections to insure its own stability. The financial crisis of the last several years dramatically illustrates that weak consumer protections pose a

significant risk to the wider economy. In the words of Sheila Bair, the former Chair of the US Federal Deposit Insurance Corporation, *“There can no longer be any doubt about the link between protecting consumers from abusive products and practices and the safety and soundness of the financial system.”*³ Similarly, the January 27, 2011 final report released by the Congressionally mandated Financial Crisis Inquiry Commission (FCIC) concluded that the financial crisis was an “avoidable” disaster caused by widespread failures in government regulation, excessive risk taking by Wall Street and corporate mismanagement.⁴

TACD has previously expressed its concern at the slow effort of both governments and the financial industry to correct the continuing market failures and recognized the urgent need for them to take action on financial consumer protection, notably in its resolution of June 2009⁵ and through the subsequent 2010 Ljubljana declaration on consumers and financial services,⁶ to which it is a signatory.

TACD has recently issued a new resolution calling on the governments of the US and EU to work with the FSB and OECD to implement the commitment made in the G20 Seoul Action Plan to “report on options to enhance consumer protection” in financial services. Specifically, the TACD urges the US and EU governments to collaborate with the FSB and OECD to develop a strong set of recommendations drawing on those listed in TACD’s resolution⁷ (included in annex 17); support their adoption at national and where appropriate international levels, and establish suitable processes to review their implementation.

³ Statement of Sheila C. Bair, Chairman of the Federal Deposit Insurance Corporation, on Modernizing Bank Supervision and Regulation before the US Senate Committee on Banking, Housing and Urban Affairs, March 19, 2009

⁴ FIN. CRISIS INQUIRY COMM’N, THE FINANCIAL CRISIS INQUIRY REPORT: FINAL REPORT OF THE NATIONAL COMMISSION ON THE CAUSES OF THE FINANCIAL AND ECONOMIC CRISIS IN THE UNITED STATES xvii-xxv (2011), *available at* http://c0182732.cdn1.cloudfiles.rackspacecloud.com/fcic_final_report_full.pdf.

⁵ TACD resolution on financial services regulation June 2009
http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=214&Itemid=40

⁶ Ljubljana declaration on consumers and financial services, May 2010
http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=291&Itemid=40

⁷ These recommendations draw on those developed by Consumers International, which are outlined in their publication “Safe, fair and competitive markets in financial services: recommendations for the G20 on the enhancement of consumer protection in financial services”, March 2011.

<http://www.consumersinternational.org/media/669348/cifinancialreport2011.pdf>

Annex 1.

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Resolution on the need for a mandatory reporting scheme and inventory for nanomaterials contained in consumer products

Background

In its 2009 Resolution on Consumer Products Containing Nanoparticles⁸, the TACD called for establishing mandatory reporting schemes⁹ in the EU and the US as there is an urgent need to identify which kind of nanomaterials are used in which consumer products. Moreover, the TACD called for establishing a publicly available inventory¹⁰ of consumer products containing nanomaterials¹¹.

The TACD emphasized the call for more transparency concerning what foods and other products containing nanoparticles are available on the market in its submission to the Transatlantic Economic Council (TEC) in September 2010¹².

There is an urgent need to improve the traceability of nanomaterials in products and to enhance transparency for consumers as more and more products containing nanomaterials or claiming to contain nanomaterials are available to consumers in the EU and the US. In October 2010, ANEC and BEUC released their updated inventory of products claiming to contain nanomaterials. Compared to 2009, many more products (475 across the categories of appliances, cross cutting, electronics, food & drink, products for children, health & fitness and home & garden) were found to be claiming to use nanomaterials. Only 4% of products present in the inventory of 2009 were missing from the purported market in 2010. Worryingly, some manufacturers do not use a nanoclaim when advertising the product on their homepage. However, the same products often have a nanoclaim when sold/ advertised on other websites such as internet shops. As was the case in 2009 BEUC and ANEC did not test the products but looked for the claims about nanotechnologies and nanomaterials that consumers can find while shopping¹³. The updated inventory was presented to the Health and Consumers Commissioner John Dalli at a high-level workshop on Friday 22 October 2010.

⁸ TACD Resolution on Consumer Products Containing Nanoparticles, June 2009.

⁹ We use the term "mandatory reporting scheme" for a system under which manufacturers have to report to a public body which nanomaterials are used in which products and in which quantities before placing the products on the market.

¹⁰ We use the term "inventory" for a public accessible database which lists all consumer relevant products which contain nanomaterials. Ideally such a database should have different search options for the general public such as a search per manufacturer, per product and per nanomaterial.

¹¹ In this paper we use the term "nanomaterial" for engineered/ manufactured nanomaterials. In our understanding this includes soluble and non-soluble nanomaterials. Moreover, the term comprises manufactured nanomaterials if they are present in products due to by-products from a manufacturing process which involves the bulk form.

¹² TACD Recommendations to the Transatlantic Economic Council, September 2010, http://tacd.org/index.php?option=com_docman&task=cat_view&gid=57&Itemid=40

¹³ <http://www.anec.eu/attachments/ANEC-PT-2010-Nano-017.xls>

In Denmark a similar inventory has been compiled by the Danish Environmental Protection Agency. In 2007, the inventory¹⁴ contained 243 products, and a soon to be published¹⁵ update will show that there are now more than 600 products on the Danish market.

In the US, the Woodrow Wilson Center¹⁶ established an inventory of nanotechnology-based consumer products which, as of March 2011, had more than 1,300 entries. The Project on Emerging Nanotechnologies Director David Rejeski stated, "When we launched the inventory in March 2006, it contained 212 products. If the current trend continues, the number of products could reach 3,400 by 2020."¹⁷ PEN believes this to be a very conservative number. Rejeski testified in 2009, "These products are available in shopping malls or over the Internet, and we have purchased many of them online. Thanks to business-to-consumer (B2C) e-commerce, nanotechnology products easily flow across international borders, raising control, trade, and oversight issues."¹⁸ In the absence of mandatory government reporting schemes this list and another list kept by the International Center for Technology Assessment on silver products have been compiled relying primarily on product claims made on the Internet.¹⁹

Following significant pressure for a reporting scheme from Parliament, NGOs and consumer groups, in 2010, the European Commission asked the consultancy "Milieu" to analyse the current status of information reporting on nanomaterials in the context of the EU chemical legislation (REACH and CLP) and to assess the need for additional information reporting. Although the initial aim of the study²⁰ was to explore the feasibility of setting up a voluntary reporting scheme, the consultants felt that the chemicals legislation has serious gaps²¹ with regards to nanomaterials and recommended setting up a mandatory reporting system. The study recommended keeping such a mandatory reporting system within the REACH framework.

1. Why is there a need for a mandatory reporting scheme?

No one (person, organisation, company or authority) has a complete overview of the usage of nanomaterials and nanoparticles in consumer products. It is essential that governments and regulators are able to assess exposure of consumers and the environment coming from nanomaterials to enable them to take an appropriate approach to the management of risk. This need becomes all the more important when there is significant uncertainty over the potential impact of the materials in question. This is certainly the case for nanomaterials for which there

¹⁴ <http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-468-1/html/default.htm>

¹⁵ The Technical University of Denmark has announced that it will publish the inventory in June 2011

¹⁶ Woodrow Wilson International Center for Scholars, <http://www.nanotechproject.org/inventories/consumer/>

¹⁷ Cited in "Nano-enabled Consumer Products Continue to Rise," Project on Emerging Nanotechnologies, March 11, 2011. <http://www.nanotechproject.org/news/archive/9231/>

¹⁸ David Rejeski, "Comments submitted to the Consumer Products Safety Commission," Project on Emerging Nanotechnologies, August 18, 2009, http://www.nanotechproject.org/process/assets/files/8278/pen_submission_cpssc.pdf

¹⁹ See 'nano silver product list' available at: <http://www.nanoaction.org/nanoaction/page.cfm?id=239>

²⁰ Milieu/RPA (2010): Information from Industry on Applied Nanomaterials and their Safety: Final Report. Proposal for an EU Reporting System for Nanomaterials, p. ii.

²¹ Among the gaps identified are the following: 1) substances placed on the market of less than 1t p.a. will not be registered under REACH, 2) in case a specific use will not be reported in the registration dossier, there may be an information gap in the communication between different economic operators 3) significant time lags in REACH and CLP implementation.

are well reported gaps in the knowledge of environmental toxicology, toxicokinetics, and human toxicity²²

Voluntary reporting schemes have been experimented with in various EU countries and around the world, with very limited reporting of nanomaterial product data²³. Consequently, national compulsory declaration measures are being taken in France²⁴ and are being examined in Italy, Belgium and the Netherlands²⁵.

In the US, since December 2008 the voluntary Nanoscale Materials Stewardship Programme (NMSP) has received submissions on only a small fraction of the number of products which are available to US consumers. In order to address the remaining environmental health and safety data gaps, the US EPA is considering launching a mandatory reporting scheme²⁶. In addition, the US EPA uses the regulation on pesticides to require reporting on health effects related to nanomaterials used in pesticides.

While there may be benefits of reporting schemes at national level, there is a risk of market fragmentation. Thus, harmonization is needed at EU and international level. The TEC provides an excellent forum to share the experiences about the development of harmonised reporting schemes in the EU and US and to work to ensure that such schemes are harmonised.

2. Official calls for a reporting scheme

The role of the Belgian EU Presidency (July – December 2010)

The Belgian EU Presidency organised a workshop "Towards a regulatory framework for the traceability of nanomaterials", held on 14th of September 2010. In the conclusions from the workshop, the Belgian Presidency calls for:

- developing harmonized compulsory databases of nanomaterials and products containing nanomaterials;
- using such databases as the base for traceability, market surveillance, gaining knowledge for better risk prevention and for the improvement of the legislative framework;

²² Emergnano: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology. March 2009.

²³ The UK scheme received only 12 submissions in 2 years.

²⁴ Outcome of Grenelle (French initiative on environmental policy): Commitment n°159 about manufacturing of nanomaterials (organization of public debates, mandatory system of reporting, cost/benefits analysis, information and protection of workers), Mandatory reporting scheme, which aim is traceability, risk management and workers protection, to be in place in two years time (obligation for manufacturers, importers and distributors about identity of nanomaterials and downstream users, unique database). It will anticipate and complement REACH as it will also cover substances under 1 t/y. Enforcement decree to be drafted soon.

²⁵ Regulering van onzekere risico's van nanomaterialen mogelijkheden en knelpunten in de regelgeving op het gebied van milieu, consumentenbescherming en arbeidsomstandigheden, STEM, 2010; Legal feasibility study on the introduction of a nanoproduct register, Öko-Institut e.V., Produced with the support of the Federal Environment Agency, and with funding from the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Germany, 2010.

²⁶ Milieu/RPA (2010): Information from Industry on Applied Nanomaterials and their Safety: Final Report. Proposal for an EU Reporting System for Nanomaterials, p. ii.

- o taking into account in the design of such databases the need for providing information to the citizens, workers and consumers regarding nanomaterials and products containing nanomaterials as well as the industry's need for data protection²⁷.

EU Council Conclusions on environmental & Health action plan on 20 Dec 2010

On December 20th 2010, the European Environmental Council adopted some conclusions on nanomaterials and nanotechnologies, as part of its recommendations to the European Commission about the preparation of a second Environment and Health Action Plan (EHAP). The Council "invites the Commission to" (...) evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials (...)"²⁸.

The European Parliament on nanotechnologies

In 2009, the European Parliament (EP) had shown in its resolution on nanotechnologies²⁹ disagreement with the Commission's view³⁰ that present legislation is sufficient to cover nanotechnologies. The EP had been calling on the Commission "(...) to review existing legislation and to compile an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available (...)"³¹. Moreover, the EP reiterated "calls on the Commission for the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labeling of the product (...)"³².

The European Parliament called on the Commission to compile such an inventory before June 2011.

4th annual nanotechnology Safety for Success Dialogue

On 29-30 March 2011, the EU Commission organised the 4th nanotechnology Safety for Success Dialogue, a workshop which brings together regulators and stakeholders. At this occasion, a call for a mandatory database was made and a joint project (from Belgium, France, Italy, NL and Germany as observer) was presented³³.

US EPA approach on pesticides

The US EPA has proposed regulations that require reporting of an active ingredient as a "new" pesticide if it is a nanoscale form of a pesticide (FIFRA - *Federal Insecticide, Fungicide, and Rodenticide Act* or PRIA – Pesticide Registration Improvement Act)." This would apply even

²⁷ http://docushare.anec.org/docushare/dsweb/Get/Document-65461/CONCLUSIONS%20OF%20THE%20HLE%20100914_FINAL.pdf

²⁸ http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/envir/118646.pdf

²⁹ European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)), <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2009-0328+0+DOC+PDF+V0//EN>

³⁰ Expressed in the Commission Communication of 17 June 2008 on „Regulatory aspects of nanomaterials“ (COM(2008)0366).

³¹ European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)), point 16.

³² Ibidem, point 17.

³³ Report to plenary from break-out group 1 (INTELLIGENCE).

when a non-nanoscale form of that same active or inert is already in a registered product³⁴. Unfortunately, this new regulation is being held up at the White House Office of Management and Budget after complaints from nano-silver and other pesticide industry lobbyists.

3. What should a mandatory reporting scheme look like?

3.1 What information has to be reported to the authorities?

All nanomaterials which are used in products - whatever the nature of the product – should be notified before the products can be placed on the market. Independently of the intended user group and product the minimum statement should take the following form³⁵:

- identification of the substance to include:
 - CAS number and name of the substance
 - Size range
 - Specific surface area
 - Aspect ratio
- the quantity in which the substance is used;
- the toxicological profile of the substance and relevant safety data;
- information about the test methodologies used and reasonably foreseeable exposure conditions;
- A full risk assessment for the use of the nanomaterial in the specific product.

Current annual production estimates of nanomaterials are very uncertain. The degree of uncertainty about production levels was a key finding of a study that estimated annual U.S. production of nano- titanium dioxide at somewhere between 7800 and 38,000 tons per year.³⁶ Nanomaterial manufacturers should be required to submit to competent authorities an annual report on the production level of each kind of Engineered Nanoscale Materials the manufacturer produces to assist in pre-market safety assessment and post-market surveillance programs. The per firm production levels would be maintained as confidential business information while overall levels would be published as part of the competent authority's annual reporting on nanotechnology regulation and oversight.

In addition, for all products including food, the presence of nanomaterials should be indicated in the product technical files and/or the safety data sheets. Any definition of nanomaterials for such a purpose must have an upper size limit of at least 300nm³⁷. These requirements would allow governments and competent bodies to assess those products which are most likely to be of greatest concern and would allow for proper exposure assessments to be carried out.

³⁴ See comments of Bill Jordan, Office of Pesticide Programs, US EPA

http://www.nanotechproject.org/process/assets/files/8309/epa_newpolicy_nanomaterials.pdf

³⁵ [ANEC comments on prCEN ISO/TS 13830 "Manufactured nanoparticles - Guidance on labelling", May 10](#) (ANEC-PT-2010-Nano-006).

³⁶ Christine Ogilvie Hendren et al., "Estimating Production Data for Five Engineered Nanomaterials As a Basis for Exposure Assessment," *Environmental Science and Technology*, March 10, 2011, 2564 and Table 2, 2566.

<http://pubs.acs.org/doi/pdfplus/10.1021/es103300g>.

³⁷ For drugs, the upper size limit should be 1000nm.

For products containing nanomaterials already available to consumers, industry should provide the above information to the authorities without delay or remove the product from market until which time they can provide the required information.

A harmonised mandatory reporting scheme will anticipate and be complementary to the REACH requirements as it would apply to all nanomaterials irrespective of tonnage threshold, etc. The mandatory reporting scheme should be harmonised at the EU level, but should be divided to show country and sector specific data. As a lot of the products are marketed in many EU countries, resources can be saved if the inventory is set up at EU level. Based on the EU inventory, national inventories can be made available in the Member States.

As a prerequisite for an EU harmonised reporting scheme, the adoption of a regulatory definition of nanomaterial is essential. As European and American consumers, we support the principles adopted in the definition proposed by the European Commission in the draft Recommendation of October 2010, although we believe the upper size limit should be of at least 300nm.

The development of mandatory reporting schemes in the US and EU should be harmonised and the TEC would provide a suitable arena for this to take place.

In the US, the Environmental Protection Agency has proposed mandatory reporting for nano-pesticides³⁸. No other US agency has proposed mandatory reporting of nano-materials, although the FDA has used guidance documents relative to nano-drugs and says that it will consider “size” as an aspect of food contact substance approvals.

3.2 Who should provide the information on nanomaterials?

Economic operators (manufacturers, importers and retailers³⁹) should nominate a responsible person who is required to collate and report the information detailed above to the authorities in charge of administering the mandatory register.

3.3 Who should have access to the information?

The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 25 June 1998, the “Åarhus Convention” establishes, inter alia, the right of the public to receive environmental information that is held by public authorities. For this reason, the information of the reporting scheme should be publicly available, whilst respecting justified commercial secrets.

3.4 How would the reporting scheme be used?

The mandatory reporting scheme would be used by national authorities to monitor exposure and ensure traceability as it provides information along the supply chain of substances and products containing nanomaterials. Main users could be:

- Regulators;

³⁸ Bill Jordan, Office of Pesticide Programs, US EPA

http://www.nanotechproject.org/process/assets/files/8309/epa_newpolicy_nanomaterials.pdf p.16

³⁹ Retailers would only be required to feed-in data into a mandatory register and product inventory for own-brand products which contain nanomaterials. However, we point out the need for retailers to be informed about the products they sell and to be able to give meaningful information to consumers about nanomaterials.

- Market Surveillance Authorities;
- Agencies working on occupational health and safety;
- Toxicologists;
- Poison emergency centers.

4. How to inform consumers about nanomaterials in consumer products?

4.1 Inventory of products containing nanomaterials and nanoparticles

A product inventory should provide members of the public with clear and easily understood information on what products sold to them use nanomaterials, why they use nanomaterials, and what the uncertainties surrounding their use may be. This information should be required of manufacturers and should respect justifiable commercial secrets.

The public inventory would be used to inform the public of where nanomaterials are used and to highlight the benefits and uncertainties of the nanomaterials to allow consumers to make informed purchasing decisions. Main users could be:

- Consumer organisations;
- Environmental NGOs;
- Trade unions;
- Individual consumers.

In order to effectively inform consumers, the inventory of products containing nanomaterials should allow for unambiguous product identification. As a minimum, the following information should be provided: product brand, type, article number, batch number, and picture. It is also important to specify in which part of the product/component the nanomaterial is used. For example, in case of food, it should be specified whether the nanomaterial is present in the food itself or in the packaging (food-contact material).

4.2 Labelling

Products which contain a list of ingredients on the label should indicate the presence of the nano form by adding the word 'nano' in brackets after the ingredient in the ingredients' list. This will soon be required for cosmetics under EU law. We ask for this to be introduced in particular for nanomaterials used in food including food packaging.

For products that do not contain a list of ingredients, the need for labelling should be evaluated on a case-by-case basis taking into account the level of consumer exposure. The format of the labelling would also have to be decided on a case-by-case basis.

However, labelling requirements for products should not at all be considered sufficient or be regarded as an acceptable substitute for pre-market safety assessment systems. Regulatory measures ought to be initiated to prevent exposure of consumers and the environment to potentially dangerous nanomaterials and to ensure that consumer products are safe. Requiring only labelling requirements for products shifts the responsibility onto consumers to decide

whether to be exposed or not and is thus not acceptable. Moreover, labelling requirements need to be backed up with broader consumer information about nanotechnologies and nanomaterials. Labelling of materials as 'nano' must be accompanied by clear information on that nanomaterial to enable consumers to make an informed purchasing decision. This information could be supplied by the manufacturer to the public inventory.

National authorities, such as the Environment Protection Agencies, should be able to give more information to consumers. And we call for such bodies to be required to develop sources of clear consumer information on the use, benefits and uncertainties of nanomaterials.

4.3 Claims

All claims which are made about health, safety and/or environmental aspects of products containing nanomaterials should be scientifically substantiated and supported by publicly available information of the methods used to substantiate the claim. Claims made for the efficacy of a product should be backed up by rigorous evidence.

5. TACD Recommendations to the EU and US governments

Today there is a serious lack of information on which products using nanotechnologies are already on the market, in the pipeline or at the research stage. More transparency regarding the uses and applications of nanomaterials is needed⁴⁰.

Mandatory Reporting Scheme

We urge the US and EU, with the help of Member States, to set up an extensive mandatory reporting scheme of all nanomaterials used in all products available on the market. At EU level we advocate for one single EU-wide inventory and that all economic operators (producers, importers, and retailers of own branded products) marketing products containing nanomaterials in the EU should be required to register.

Inventory

In addition, we call for a publicly available inventory of products containing nanomaterials with which consumers come in direct, close or regular contact, and products which lead to discharges into the environment. Such an inventory would not only be in line with the public's right to know what they are being exposed to but would also ensure a proper evaluation of exposure of humans and the environment to nanomaterials. For example, in Europe, the inventory should be based on an EU inventory but should also show which products are available in which EU country and the annual production level of each nanomaterial that enters the market.

Labelling

⁴⁰ [Small is beautiful but is it safe? ANEC/BEUC joint position paper on Nanotechnology - June 2009](#) (ANEC-PT-2009-Nano-002final).

The requirements to inform the consumer of the presence of nanomaterials in consumer products by labelling must be clearly defined in regulations.

Claims

Claims made on labels of products containing nanomaterials must be substantiated and meet regulatory requirements. Compulsory information to the public about the presence of nanomaterials in products is a way to regulate false claims and avoid unfair commercial practices⁴¹.

⁴¹ For more information see TACD resolution on Consumer Products Containing Nanoparticles, June 2009.

Annex 2.

DOC No. INFOSOC 44-11

DATE ISSUED: JUNE 2011

Resolution on Privacy and Security Related to Smart Meters⁴²

For decades, water, gas, and electric utility service providers have used meters to record household energy (gas and electricity) consumption for billing and management purposes. Typically these meters require utility companies to send personnel to physically collect data, which could be at intervals as long as two years. Next-generation “smart meters” are being installed in homes in great numbers in the US and parts of the EU, replacing old meters as the means by which consumer electricity usage data is recorded and collected. These smart meters include new features, which can provide an end to estimated billing and enable households to monitor their energy use over a period of time — thus, it is argued, providing a tool to assist in the public policy goals of affordable energy and carbon reduction. Consumer organizations stress that if smart meters are deployed they must provide improved social assistance to vulnerable⁴³ and low-income households.

However, TACD members also have grave concerns related to the privacy, data protection and security implications of smart meters. The dramatic increase in the granularity of data available and frequency of collection of household energy consumption means that the smallest detail of household life can be revealed, with potential risks for consumers including identity theft, augmenting private and data broker consumer profiles (US), real-time surveillance, and unwanted publicity. In addition to these smart meter privacy risks there may also be security risks — e.g., software or firmware, programming or installation, interoperability conflicts with other smart-grid-enabled technologies, and the threat of cyber attack.

Smart meters must be reliable, secure and enable all customers to better manage their energy use. They must also maximize meaningful consumer choice, drive down prices and enable consumers to make well-informed and effective purchasing decisions — all without sacrificing essential consumer and human rights to privacy and data protection.

Recommendations

TACD resolves that EU and US government should:

1. Enact or revise data protection and privacy legislation to:

⁴² To be read in conjunction with the TACD Resolution on Smart Grids CC 04-11, June 2011

⁴³ Those who for reasons of age, health or disability are at greater risk if disconnected from the power supply.

- a. Forbid utilities from installing smart meters without consumers' informed consent
 - b. Prohibit use of utility consumer consumption data for marketing, selling, sharing, or reuse without the customer's specific and unambiguous consent
 - c. Establish data retention rules regarding utility usage data
 - d. Define utility consumption data as personally identifiable information (PII)
 - e. Ascertain that consumers have control over their data in terms of what PII data is exported out of the smart meter, who collects and processes that data, how that data is used, and how long it will be retained
 - f. Encourage privacy and security by design, including data minimization, anonymisation and aggregation, and models that focus on consumers' maintaining control of their utility consumption data
 - g. Ensure that customers have access to their transfer log files in order to see which data was transmitted to whom at what time
 - h. Carry out privacy and security impact assessments on all aspects of smart meters and grids before they are developed
 - i. Require utility companies to establish a balanced and effective social marketing strategy to engage and educate consumers on new smart meter functionality and benefits
 - j. Require utility companies to develop a strategy for monitoring and enforcing data privacy rules including:
 - Creating effective complaints and redress mechanisms
 - Collecting and making available data on consumer privacy and security complaints and their resolution
 - Taking timely action to address the causes of those complaints
 - k. Require that additional (such as energy management) services by utility companies or third parties only be provided with the express authority of the consumer
 - l. Require third party energy management service providers to protect consumer personal information, utility service provider information, and utility usage data from access by non-authorized persons, abuse, or misuse through effective processes and established encryption technologies
 - m. Require utilities to develop a secure transport protocol for utility usage data that does not only rely on anonymisation, but also on use of effective encryption technologies
 - n. Mandate independent internal audits of energy suppliers' security and privacy processes to evaluate risks around their practices
 - o. Develop upgradeable technical standards and systems to safeguard future-proved, end-to-end security
 - p. Ensure that all customers have free access to their energy consumption information in a format that enables them to better manage their energy use and compare all energy deals available in the market.
 - q. Establish clear roles and responsibilities around data security and privacy, and strong enforcement mechanisms for failure to deliver the appropriate standards or service.
2. Initiate pro-active cooperation between relevant EU and US agencies to achieve better harmonization of utility privacy protection practices. This is particularly important as smart meter technology and utility service delivery may involve large geographic areas across physical national borders. Differing national data protection and privacy regulatory practices may create confusion for users and reduce the potential benefits of improved utility infrastructure.
 3. Raise utility provider and public awareness regarding the benefits and potential risks of smart meters on privacy and consumer rights.

4. Harmonize privacy protective statutes and regulations through universal ratification of Convention 108⁴⁴.

TACD resolves that EU and US smart meter operators should:

1. Integrate privacy and security by design. This means that the default settings and usability features for smart meters should ensure maximum privacy for users' energy consumption data.
2. Enable consumers to remain "masters of their data" by allowing them to:
 - a. Manage their own utility usage
 - b. Change technology for utility usage management or third party service providers (e.g., when moving house, or requesting assistance in their management of energy usage)
 - c. Port or delete data free of charge
 - d. Request that service providers or user management systems delete their information after they have changed technology or management assistance entities. There should be statutory deleting periods.
3. Develop common binding ethical codes for the design, deployment and provision of utility smart meter management services, including data protection and security.

Background

Smart meters and related technology will create opportunities for consumers to better manage electricity usage, while also creating new privacy risks. We are outlining in this section areas for additional attention by policy makers as they move to regulate the deployment of smart meters as they relate to electricity service provision.

Privacy and security challenges posed by smart meters

Smart meters are one piece of a larger effort to integrate computing technology and networking capacity into the end-to-end infrastructure of electricity generation and delivery. Utility companies' stated goals are a just-in-time provision of electricity service, and enhanced accuracy in the calculation of customer billing.⁴⁵ These objectives will be reached via features such as:

- Real-time statistics on energy consumption available to the consumer
- Remote delivery of that data, as frequently as every 15 minutes or less
- Remote instruction and reconfiguration
- Remote changes of tariffs changes or payment methods
- Remote disablement/enablement

⁴⁴ See: <http://www.conventions.coe.int/Treaty/en/Treaties/Html/108.htm>

⁴⁵ <http://www.ferc.gov/industries/electric/indus-act/smart-grid/gao-report.pdf>

Using more advanced metering systems, utilities may also communicate directly with customers via an in-home display unit. Smart meter communications may take place via existing mobile (cell-phone) operator networks, fixed telephony networks or electricity grids.

The power generation and delivery system melded with a high capacity communication infrastructure is referred to as a “smart grid.” It is estimated that it will be 100 to 1000 times larger than the Internet.⁴⁶

Privacy concerns about smart meter and grid technology center on the collection, retention, sharing or reuse of energy consumption information on individual households or offices. Such energy data processing could provide insight into personal behavior patterns, (when someone watches TV, plays video games or goes to bed); occupation of premises, household composition, consumer appliances in the home, home security, etc. Over time these technologies will mature, providing details about consumers that may not be immediately apparent.

In the near future, smart meters will also be able to collect more specific personally identifiable information when paired with Home Area Network (HAN) enabled appliances. Currently, smart meters cannot differentiate energy consumption between two different appliances. Like a GPS tracking device attached to a car recording its every move, a HAN-enabled appliance transmits specific information related to the use of that individual appliance. A HAN-enabled clothes washing machine can transmit the time of day a consumer washes his or her clothes as well as the wash cycle and water temperature settings. While utility companies or third party energy manage service providers can collect this information under the guise of energy efficiency management, this information can also reveal very private, personal consumer habits. For example, data that would become available could include when someone is or is not at home; the time of arrival indicated by a change in electricity consumption may reveal the age or health situation of the occupants; as well as other information that would otherwise not be available outside of the home.

This scale of data storage and collection is vulnerable to both commercial and criminal interests – for example consumer profiling and targeting for marketing purposes, identity theft, real-time surveillance, targeted home invasions or unwanted publicity or embarrassment.

There is increasing recognition in the EU and US that privacy and security are issues that must be taken seriously; the episodes in the Netherlands and in California, in which privacy concerns contributed towards the halting of smart metering rollouts and subsequent legislative/regulatory efforts to manage future deployments, are stark reminders of the importance of tackling consumer concern about a “spy in the home.”⁴⁷ Such awareness not only to protects

⁴⁶ http://news.cnet.com/8301-11128_3-10241102-54.html

⁴⁷ <http://www.bigbrotherwatch.org.uk/home/2010/01/privacy-concerns-scotch-smart-meters-plan-in-holland.html>, <http://www.dailyfinance.com/2010/07/19/the-california-smart-meter-revolt/>

consumers, but also strengthens consumer engagement. It is essential that privacy risks be addressed as a matter of urgency, as millions of consumers already have smart meters.

Smart meter data collection should be limited to data that is consumer-consumption-specific, operational and critical to utilities in providing the correct amount of electricity to end users. Smart meter data reporting should be based on the use and purpose of the data collection. Operational data may be stripped of identifying information and communicated securely and more frequently, while consumer data may be communicated less frequently, but more securely than operational data.

Actions taken by the EU

In the EU, the gas and electricity directives of the third Energy Package, adopted in 2009, require member countries to prepare a timetable for the introduction of intelligent metering systems. In the case of electricity, at least 80% of consumers should be equipped with smart meters by 2020, subject to an economic assessment analyzing the reasonability and cost-effectiveness of intelligent metering. Additionally, the EU Directive on energy performance of buildings also requires countries to encourage introduction of smart meters in new or renovated buildings. Many EU countries have set up regulatory frameworks to roll out smart meters; Sweden was the first to install smart meters for all its consumers, by end of June 2009. Netherlands' initial regulation mandating universal use of smart meters with quarter-hourly meter readings was blocked by Parliament due to privacy concerns (now replaced with more privacy-friendly rules and the right to refuse the smart meter); Italy, Ireland, Norway, France, Spain, Finland and the UK are all implementing regulated smart meter roll-out programs.

The data protection and privacy aspects of smart meters in the EU are subject to existing data protection legislation, in particular the Data Protection Directive of 1995 (currently under revision), and the ePrivacy Directive (reviewed 2009). Member countries implement both of these directives with various degrees of strictness. However, the legal bases for processing smart meter/grid data are not as yet properly defined on the European level and interpretation may vary from country to country, with resulting gaps in the available protections.

A taskforce set up by the European Commission is currently looking at issues specifically related to smart-grid data handling, security and consumer protection. This review includes an overview of legislation on data protection, and whether or not further protective measures should be put in place, including through standardization⁴⁸. Similar work is ongoing on national levels; for example, in the UK the government has an ongoing program of consultation with stakeholders prior to finalizing policy, including privacy and data protection.

⁴⁸ The European Commission issued Standardisation Mandate M/490 to the European Standards Organisation in March 2011, which includes *inter alia* requirements to address privacy and security.

Actions Taken by US Government

In September 2007, the Department of Energy's Research and Development Division's Office of Electricity Delivery and Energy Reliability published its "Transforming Electricity Delivery Strategic Plan,"⁴⁹ and in December 2007, the Energy Independence and Security Act of 2007 was enacted as Public Law 110-140. The law, among other things, directed that smart grid technology be studied for its potential "to maintain a reliable and secure electricity infrastructure that can meet future demand growth."⁵⁰

In 2009, the Obama Administration began its first term with a strong commitment to global climate change policy, which began with funding in an economic stimulus bill for \$3.4 billion in funding for smart grid deployment.⁵¹ This level of policy and regulatory activity around the issue of climate change was a dramatic and a marked departure from previous administrations.

As directed by Public Law 110-140, the National Institute of Standards and Technology (NIST) in the Department of Commerce conducted an open process that engaged the utility industry, civil society and federal agencies in the development of recommendations regarding smart grid deployment.⁵² In June 2010, NIST published "Guidelines for Smart Grid Cyber Security: Privacy and the Smart Grid."⁵³ These guidelines address critical security concerns and make sound recommendations on ways to address them; such as conducting privacy impact assessments; and development of formal documented privacy policies that establish a set of fair information practices for smart meter PII. The document also includes a comprehensive review of privacy concerns that arise from the "many new data collection, communication, and information sharing capabilities related to energy usage." Over 23 civil society organizations participated in the public commenting opportunity regarding the deployment of smart grid.⁵⁴

In October 2010, the Federal Energy Regulatory Commission (FERC) began rulemaking proceedings on the NIST recommendations as required by Section 1305 of the Energy Independence and Security Act of 2007.⁵⁵ However, FERC has not identified a means of monitoring whether companies will be in compliance with the standards once they are developed and issued by the agency.⁵⁶

In addition to the federal government's efforts, each of the 50 states has oversight of utility service generation and provision; for example, the State of California has drafted regulations

⁴⁹ http://www.oe.energy.gov/DocumentsandMedia/RD_Strategic_Plan_Final07.pdf

⁵⁰ http://epic.org/PL110-140-Smartgrid_section.pdf

⁵¹ <http://online.wsj.com/article/SB125663945180609871.html>

⁵² http://csrc.nist.gov/publications/nistir/ir7628/nistir-7628_vol2.pdf

⁵³ http://csrc.nist.gov/publications/nistir/ir7628/nistir-7628_vol2.pdf

⁵⁴ http://epic.org/privacy/smartgrid/EPIC_Smart_Grid-Cybersecurity_12-01-09.2.pdf

⁵⁵ <http://www.ferc.gov/media/news-releases/2010/2010-4/10-07-10.pdf>

⁵⁶ <http://www.ferc.gov/industries/electric/indus-act/smart-grid/gao-report.pdf>

regarding the deployment of smart meters in that state.⁵⁷ Which government entity will have regulatory authority over smart meters is unclear, but the interest of many state and federal government agencies highlights its importance to policy and decision makers at this point in time.

For these reasons, US actions on energy issues to date are marked by their lack of coordination.

Conclusion

Privacy and personal security protections are essential to consumer trust and acceptance of smart meters in their homes and businesses. Failure of the US and EU governments to develop effective security and privacy policies for smart meter deployment may hinder adoption of these new devices and their related applications and services.

It is both imperative and timely for consumer advocacy organizations to open a dialogue with decision makers on the development of consumer security and privacy standards guiding the design and implementation of smart meters.

⁵⁷ <http://www.cpuc.ca.gov/PUC/energy/smartgrid.htm>

Annex 3.

DOC No. CC 04-11

DATE ISSUED: JUNE 2011

Resolution on Smart Grids⁵⁸

With the development of more flexible energy supply and demand (smart grids) come new opportunities for EU and U.S. citizens, but as with any new technology, increasingly sophisticated functionality can result in unintended consequences.

In the context of the rollout of smart meters in parts of the EU and US, TACD calls on EU and US governments to consider the following recommendations, which are important for ensuring that consumers' interests are well-served by the implementation of smart grids:

- The cost-benefit assessment should cover potential risks to consumers of the new technology in addition to social, environmental, and consumer benefits.
- A strategy should be developed and implemented which identifies and delivers the maximum benefits to consumers and tax payers
- The costs and benefits of rollouts to consumers and tax payers should be publically reported on a regular basis to ensure value, efficiency, and accountability.
- Deployment of smart meters should be particularly carefully considered, as these are being rolled out before many questions relating to standards, regulatory requirements and data privacy and security and their relationship to smart grids as well as consumer benefit have been answered;
- Social equity should be closely scrutinized, especially if consumers need smart appliances, broadband access or micro-generation to realize expected benefits
- Consumers' expectations of the functionalities of smart grids should be well-understood and fulfilled.
- Consumers should not bear the risk that energy savings do not materialize as the utility predicts nor the cost of meter replacement due to premature obsolescence.

THE NEED FOR A COMPREHENSIVE ASSESSMENT OF THE BENEFITS AND RISKS FOR CONSUMERS

Much of the debate to date on smart meters and smart grids has been industry-driven, focused on technical requirements and functionality. But little consideration has been given to risks of the technology, the cost to consumers and tax payers and the impact of smart metering on the consumer experience of the energy market. Included in these risks is the failure to realize the potential benefits that would in fact motivate consumers' uptake of the new products and services, including enticing consumers to actively engage with their energy consumption. In this

⁵⁸ To be read in conjunction with the TACD resolution on privacy and security related to smart meters, INFOSOC 44-11, June 2011

context it is important to consider the ability of different customer groups to engage in these new opportunities.

The investment risks of meter obsolescence, poor performance, or inadequate energy savings should not be borne solely by consumers. Safeguards are also needed to ensure that consumers are protected from any detrimental impact from new functionality. In this context it is important to consider:

- The ability of different customer groups to engage in these new opportunities (e.g. vulnerable consumers picking up costs, but not sharing in benefits because they cannot invest in smart appliances or home interfaces that require broadband)
- The creation of opportunities (e.g. new tele-care services) for vulnerable consumers, including better targeting of social assistance.
- Safeguards necessary to ensure that consumers are protected from any detrimental impact from new functionality (e.g. data protection and privacy issues, remote disconnection)
- Is the cost of the functionality worth the social and environmental benefits?
- Who should pay where the benefit of the function is for society not the individual?
- What steps will be taken to help consumers navigate what will become an increasingly complex energy retail market?
- Social equity of smart grid and meter investments should also be closely examined. Key questions include the following:
 - Who will be the winners and losers from smart meter investment and pricing options?
 - Do all consumers have discretionary load that they can shift to lower cost off peak rates?
 - Do some customers live in property types or parts of the country where it won't be possible to install a smart meter but they will still be expected to pay for rollout?
 - What choices and rights do these consumers have?

Consumer backlash in the Netherlands and in California highlights that consumer engagement and acceptance of smart meters is essential for the success of any rollout and that consumer views need to be at the heart of the decision making process. If consumers do not feel the added value of smart meters or if they feel the demand management as envisaged as intrusive or too costly, they will rightly resist the rollout.

SMART GRIDS VERSUS SMART METERS

The term “smart grid” has been used as a catch-all for a variety of concepts and solutions. We would like to see a smart grid developed as defined by European Regulator's Group for Electricity and Gas (ERREG) in its recent consultation paper: “an electricity network that can cost efficiently integrate the behaviour and actions of **all users** connected to it—generators and consumers and those that do both— in order to ensure economically efficient, sustainable power systems with low losses and high levels of quality and security of supply and safety.” Smart meters, on the other hand, are digital devices that monitor electric or gas usage and can transmit this information to the utility and the consumer at regular intervals. Some smart meters can also be used for demand-side management initiated from remote locations.

MAIN DRIVERS FOR THE SUCCESS OF SMART GRIDS AND SMART METERS

The main drivers for the successful uptake of smart meters are consumer confidence, satisfaction and engagement with the new technology, cost-effectiveness, and ease of use by all. Broken down into more detail, examples of the issues now being raised by national consumer organizations include:

1. Security of personal data and information privacy
2. Security of meters
3. Accuracy of billing and flexibility of payment methods
4. Potential social benefits for low-income and vulnerable consumers
5. Transparent and consumer-friendly pricing
6. Preservation of consumer choices and ease of switching
7. Long term downward pressure on energy costs for consumers
8. Consumer-focused remote management of meters and appliances
9. Potential improvements to reliability and service

1. Security of personal data and information privacy

Privacy should be designed into smart meter systems right from the start as part of the whole compliance life-cycle. Therefore, the principle of privacy by design should be made mandatory, including the principles of data minimization and data deleting when using privacy-enhancing technologies. Moreover, appropriate technical standards should be in place to ensure end-to-end security of the system. Research undertaken by the Information Commissioner's Office in the United Kingdom indicates that 94 per cent of the population thought that 'protecting people's personal information was the most important social concern along with preventing crime' highlighting the importance of this issue. Fear over 'a spy in the home' was a contributory factor in smart meter roll out being halted in the Netherlands.

In addition, customers should have control and choice over how their own energy consumption information is used and by whom. Beyond information necessary for standard operations and customer communications, the incumbent energy company should not have default access to customer's detailed consumption data as this will have a negative impact on competition in the energy services market, result in unsolicited sales and marketing, and may serve to limit consumers' choices as they are profiled by companies to manage their own risk.

2. Security of meters

Consumers should have confidence that their meter will not be tampered with or hacked into. Smart meters and grids must be safe from infection with viruses and malware. This is to ensure both security of supply and the protection of personal data. The smart meter worm demonstrated by IO Active at the Black Hat annual security conference in July 2009 managed to hack into and take control of about 15,000 out of 22,000 homes in just 24 hours. IO Active reports that substantial numbers of existing smart meters on the international market have poor authentication, lack of encryption and inadequate authentication processes making them accessible to hacking. These experts suggest that addressing security concerns once devices are installed would be cost prohibitive. We therefore urge decision makers to get this right before rollout and that decisions on meter design, functionality, operation, management and technology are taken following key decisions on security.

3. Accuracy of billing and flexibility of payment methods

Billing is a major source of consumer complaints. Estimated and inaccurate billing is a considerable problem in the utility market and can often have the added effect where people fall into debt and are then put onto more expensive payment methods. Having access to real-time information on energy usage as well as historic data on one's energy consumption is a key for

consumers to be able to change their consumption behaviour and lower their energy bills. This should be free of charge at any time.

The current investigation into the accuracy of new smart meters in Bakersfield, California, is a reminder to give consumers peace of mind that new functionality will deliver accurate billing. It is also important that smart meters deliver flexibility of payment methods for customers – that consumers can continue to choose to pay a fixed sum monthly to help them budget over the more expensive winter months and do not have to pay a variable direct debit. In addition, in countries with prepayment meters, smart meters should facilitate flexibility of top up methods, over the phone, internet, via an ATM providing greater convenience and control for customers. Care must be taken though to ensure that customers are not forced to prepay. This is particularly a risk where the customer has a poor credit rating and therefore advanced payment is used to manage the company's debt risk.

4. Potential social benefits for low-income and vulnerable consumers

Opportunities around delivering tele-care services to vulnerable consumers also need to be explored to ensure that they are not missed. For example, warnings if the temperature in the home falls below a certain level or an elderly person has not turned on the kettle in the morning could send an alarm to care providers. In addition, the smart meter installation visit may provide an opportunity to identify and target help and assistance to hard to reach groups that may be struggling to afford to heat their homes. In countries with prepayment meters, smart metering could be used to help identify customers who are not regularly topping up their meters and could be struggling to afford their energy bills. In countries such as Tasmania, energy companies are obliged to monitor customers vending and target them with support should they suspect they are in financial difficulties.

5. Transparent and consumer-friendly pricing

New utility pricing must deliver demonstrable benefits to consumers and society. For example, higher cost critical peak pricing may be justifiable on a voluntary basis if consumers are able to switch to cheaper off peak deals and results in better load management that keeps electricity flowing for all consumers during high demand periods. But new fees must not be used as an excuse to increase revenues across the board or impose peak rates on vulnerable ratepayers who cannot shift their use safely. This will result in a loss of trust. For example, Victoria in Australia is currently considering a moratorium on new tariffs because of bill hikes. Regulators should ensure there are protections in place limit consumers' financial exposure in transitioning to new programs

In addition, research is needed into the distributional impact of time of use tariffs, and new "smart deals" on different social groups needs to be considered. Work carried out by the GB regulator Ofgem has identified that some low income working households may be particularly adversely affected by new pricing practices as they have little flexibility over when they use energy often forced to use it at peak times. AARP in the U.S. has found that many elderly customers do not have the ability to shift load off-peak and or may make unhealthy choices to reduce energy use when faced with steep prices. More generally, empirical evidence from North America suggests that, faced with a choice, many consumers prefer direct load control to price response programmes. Clear rules around remote demand management tariffs will need to be developed.

6. Preservation of consumer choices and ease of switching

Smart meters should make it easier for consumers to switch to the best deal for them. Smart meters are likely to be coupled with a range of new pricing options – critical peak pricing, time of use tariffs, single energy tariffs, seasonal options, energy services packages, which include displays and energy efficiency measures, remote management fees among them. Consumers should have choices among these programs and be able to pick a plan that is best suited to their needs and budget. Customers must also have the choice to reject a smart meter. Emphasis should be on winning hearts and minds, not forcing customers to accept meters, especially in the early stages of rollout.

Consumers should also be able to access their consumption data free of charge in a user-friendly format so that they can easily compare options. An investigation into the energy retail market in Great Britain by Ofgem revealed that around a third of consumers switch to a worse deal. It is important smart meters do not add complexity hindering effective switching decisions. In deregulated markets, particular safeguards will be needed around sales and marketing practices and new contracts to avoid problems encountered in other sectors such as telecom. In theory, same day switching should be possible in a smart world, but regulatory changes may be needed to incentivize this. It is important that customers have the tools they need and there is appropriate regulation so they can engage in this market with confidence. Consumers need pricing and meter choices that will help them reduce their usage and energy bills.

7. Long term downward pressure on energy costs for consumers

Smart grids offer the potential to reduce energy costs through greater operational and other efficiencies across the supply chain, which in turn, should lead to a downward pressure on energy retail prices. Regulators need to ensure accountability that the benefits of cost savings for distributors and generators are passed through to ratepayers or customers. This is likely to require changes to regulatory frameworks, market rules, charging methodologies and industry codes. Accordingly, costs must be transparent and functionality must provide value for the money. Regarding the financial costs of smart meters for consumers, national regulators and Member States should ensure that costs are justified, transparent and fair.

The DECC 2011 impact assessment into smart metering identifies that the majority of consumer benefits come from customers changing behavior and reducing their energy use. Such results have not yet been consistently shown in smart meter rollouts in the U.S., but if smart meters are going to provide consumers real-time information, the rollout must at the very least include the option for consumers to have an in-home display. Social marketing strategies need to be developed to ensure that behavior change is delivered and customers need the tools, whether information via in home displays, one to one support and advice, or financial assistance to buy energy efficiency measures to ensure that they benefit from new technology. As there is no “one-size-fits-all”, it is important to bear in mind that different consumer groups should be approached in an appropriate manner. In addition, most smart meter benefits will not materialize without smart grid upgrades to lay the foundation for efficiency and savings. “Smart meters first” is likely a poor policy choice in smart grid development.

Closer analysis is needed for certain industry assumptions, such as, “Smart grids will be more reliable and save consumers money,” or “Higher prices at peak times will incentivise lower energy usage.” These assertions need to be verified based on large-scale, empirical evidence. It should also be noted that there will be winners and losers from new time of use tariffs, and where customers are hard hit by rising prices, this may cause a backlash against smart meters.

8. Consumer-focused remote management of meters and appliances

Remote management of meters and monitoring of energy use is expected to bring cost- savings such as an end to the need for visits from meter readers. It is important that the functionality chosen minimises the need for additional expenses, e.g. the need for regular upgrades. Safeguards are, however, needed around remote management of appliances - consumers must have the choice whether they opt in to remote management of appliances in their home. Clear consumer complaints procedures and redress must be in place in case things go wrong, such as a freezer is accidentally switched off for longer than it should be resulting in the defrosting of food. Consumers should have the capability to override remote load management if necessary. Finally, and most importantly, consideration must be given as to how to prevent abuse by suppliers of the new remote-disconnection functionality and load limiting capabilities. Consumers must be assured basic safeguards, such as an in-home visit and temperature-based limits for health and welfare before meters are turned off for non-payment.

9. *Potential improvements in reliability and service*

Utilities often tout smart grids' reliability and service benefits. Such benefits should be reasonably demonstrated, and risk should be shared between the utility and ratepayers in the event these benefits do not come to fruition as predicted. Utilities often promise improved response time on outages and fewer outages, and these promised benefits should be monitored for compliance. Functionality standards must also include security and privacy by design. Technology chosen must be safe and communications limit any health risks and address concerns such as electromagnetic sensitivity.

Regulators should also monitor the utility's performance on customer service and hold utilities accountable for inadequate service. The utility should institute effective policies to handle complaints with smart meters or grid upgrades and provide support and advice in how to use their smart meter and energy display to help them save money on their energy bills. As part of the installation visit, customer displays must be set up and left operational, consumers should be taught how to use them, and given advice and support on how to cut their energy bills. Low income and vulnerable consumers should be given extra support as appropriate. Smart grids will provide utilities with more information, and this benefit should be shared with consumers. Consumers should be provided up-to-date account balance information to help them budget their expenses more readily.

Conclusion

It is too early to completely identify the drivers for consumer engagement on the potential objectives of smart grids. There will be different drivers for the rollout of smart grids in different countries and different segments of consumers will have very different motivations even within the same area. However, it is imperative that there be a clear consumer value proposition so that customers are aware of the potential benefits. It is also essential that adequate protections are put in place to help ensure consumer confidence. The experience of the early recipients of smart meters will have critical impact of the acceptance of smart grid more widely and consumer acceptance is best served by consumer-friendly policies and protections.

Annex 4.

DOC No. FOOD 32-11

DATE ISSUED: June 2011

Resolution on Antimicrobials in Animal and Food Production

The World Health Organization has said that the “routine use of antimicrobials in vast numbers of healthy animals is likely to result in the emergence and spread of antimicrobial resistant bacteria, and cause resistant infections in animals and humans.”

The more antimicrobials are used, the more rapidly resistance develops. When resistance develops, bacterial growth cannot be effectively stopped by the antimicrobial, and, thus, the antimicrobial is no longer useful for treating or curing the infection. Antimicrobial resistance can transform easy-to-treat infections to severe illnesses that require prolonged treatment, necessitate lengthy hospitalization or cause death.

Since the 1950s, farmers have been using antimicrobials as a production tool in raising livestock. They add antimicrobials to livestock feed and/or water to counteract the effects of crowded living conditions, poor hygiene, and to promote enhanced body weight of the animal and prevent illnesses. Such use causes the development of antimicrobial resistance among foodborne pathogens that can infect people who consume tainted foods or are in contact with infected animals. It can also result in antimicrobial resistance in non-pathogenic bacteria. Resistant-bacteria can transfer their resistance genes to disease-causing bacteria, resulting in antimicrobial resistant infections in people.

Antimicrobials are used in animals in three ways: therapeutic use (antimicrobial administered to treat animals suffering from a bacterial infection), prophylactic use (antimicrobial used to prevent bacterial infection and disease), and growth promotion (non-therapeutic antimicrobial used to improve the efficiency of animal feed digestion or absorption).

Several countries have banned or restricted antimicrobial feed additives. The United Kingdom banned the use of penicillin and tetracycline for growth promotion. Sweden then banned the use of antimicrobial feed additives in 1986, making the use of antimicrobials illegal without a veterinary prescription. The results of the Swedish ban demonstrated that it is possible to achieve competitive production results without the continuous use of antimicrobial growth promoters. The Danish decision to terminate the non-therapeutic use of antimicrobials in 1999 was also an important illustration of the successful phasing out of antimicrobials. Denmark is a major food producer in Europe and the world's largest exporter of pork. Denmark's antimicrobial use has significantly declined, and so have the incidences of antimicrobial resistance, despite its industrial scale meat production. Finally, in 2006, the European Union banned the use of most antimicrobials as feed additives for growth promotion, though some antibiotics are still allowed in broiler production to prevent coccidiosis. The U.S. and other European countries have not adopted this broad policy, but have withdrawn approval for some categories of drugs for use in food-producing animals.

Consumer concerns:

Today, antimicrobial resistance is a growing public health threat. There is a grave worldwide concern among health authorities, physicians and researchers working in the field of infectious diseases that rapidly emerging antimicrobial resistance will significantly reduce possibilities of treating common infectious diseases in humans, with increased fatal consequences.

Consumers recognize that antimicrobials have a vital role to play in human and animal medicine. However, considering that new antimicrobials are not likely to become available in the near future, TACD believes action is urgently needed to control the emergence of resistant strains of zoonotic bacteria like *Salmonella*, *Campylobacter* and *E.coli*. These pathogens have developed resistance to multiple antimicrobials, and caused illnesses through the transmission of pathogens from animals to humans through the food supply. In the U.S., reports of foodborne outbreaks linked to antimicrobial strains of these common human pathogens have grown over the last 30 years. In the European Union, 25,000 people die each year because of problems related to resistant bacteria.

The major factors contributing to the problem are: excessive use of antimicrobials in animal husbandry, overuse of antimicrobials in human medicine, and use of antimicrobials in plants and for crop protection. With regard to animal farming, antimicrobials are not just used to cure infections, but are also routinely added to livestock feed and/or water to prevent infections in healthy animals and as growth promoters.

Resistance to one antimicrobial can lead to resistance to other related antimicrobials. For example, bacteria resistant to Avoparcin, an antimicrobial used in animal feed, may also be resistant to Vancomycin, the most powerful antimicrobial used against *Staphylococcus aureus*. Sweden stopped the use Avoparcin in the beginning of the 1980s and it was banned in the EU in 1997. The use of antimicrobial growth promoters encourages the colonization of resistant bacteria like *Salmonella*, *E.coli*, etc. in the gut of animals.

In conclusion, TACD urges governments in both regions to consider the recommendations of the World Health Organization to reduce the use of antimicrobials in food-producing animals.

Recommendations:

- TACD calls for a total ban on the non-therapeutic use (including use as growth promoters) of antimicrobials in animal and food production, and a ban on the prophylactic use of antimicrobials, except where disease has been identified in an animal or within a group of animals.
- TACD urges governments to create and fund national systems to monitor antimicrobial usage in food-producing animals, and to share the findings of the surveillance promptly. Antimicrobial resistance surveillance systems should encompass a farm-to-table approach, and integrate the findings of public health, veterinary and food safety laboratories.
- TACD calls for all antimicrobial usage in animals to be subject to veterinary prescription. TACD urges the restriction or elimination of the use of antimicrobials identified as critically important in human medicine in food-producing animals, especially the use of floriquinolones, and third- and fourth-generation cephalosporins.
- TACD emphasizes the need to improve hygiene and health management on farms and improve animal housing by implementing new concepts for feed and animal management, which could reduce substantially the need to use antimicrobials. A

coherent strategy should be developed, as well as research on alternative production methods.

- TACD calls for a total ban on the use of antimicrobials in plant/crop protection.
- TACD requests that the national health authorities implement a strategy to limit any unnecessary and uncontrolled consumption of antimicrobials, including the introduction of prescription only antimicrobials and a limitation of the consumption of broad-spectrum antimicrobials.

Resolution

Antimicrobial resistance is a worldwide public health threat. Because of the potential risk to both human and animal health, the TACD calls on the U.S. and the EU to develop a common approach to addressing antimicrobial resistance, and adopt the recommendations of the World Health Organization. Specifically, TACD requests that all antimicrobial usage in animals be subject to veterinary prescription and that the use of critically important drugs to human medicine in animals be significantly reduced or eliminated.

ANNEX 5.

DOC No. FOOD-27-07

DATE ISSUED: FEBRUARY 2007

Resolution on Simplified Nutrition Labelling

The issue

With the rising incidence of obesity and diet-related diseases across Europe and the United States (U.S.), discussions have recently been taking place in several fora, including the European Platform for Diet, Physical Activity and Health, about the need for a simplified labelling scheme.

TACD has strongly supported full nutrition information on the back of pack⁵⁹, which already exists in the U.S., and which we believe should be made mandatory as part of the European Union's review of the nutrition labelling directive.

TACD now believes that it is also necessary to consider a more simplified system of nutrition labeling that will act as a simpler 'sign-post' for those consumers who are less likely to read the full nutrition information and as an initial guide to the levels of nutrients that are of current public health concern.

The aim of front of pack simplified labelling would be to enable consumers to quickly and easily identify which foods are high in fat, sugar or salt, and which ones are healthier options but also to provide an incentive for food manufacturers to reduce the levels of fat, sugar and salt in their products⁶⁰.

Recommendations

TACD believes that a simplified labelling scheme should be based on the following principles:

1. It should be based on scientific criteria developed by experts while also taking into account the need for effective, simple communication and consumer research as to what is the most useful and easy to understand approach;
2. It should be prominent, on the front of pack, and complement the nutrition information on the back of the pack;

⁵⁹ Resolution Food-08-99 on Nutrition Labelling (www.tacd.org/docs/?id=8) and Resolution Food-14-00 on Misleading Food Labelling, (www.tacd.org/docs/?id=13)

⁶⁰ See also TACD position papers on Nutrition, Obesity and Diet-related Disease (www.tacd.org/docs/?id=299); Trans Fatty Acids (www.tacd.org/docs/?id=277) and Nutrition Labelling (www.tacd.org/docs/?id=8).

3. It should enable consumers to easily make comparisons between different products within a food category, as well as across food categories;
4. No product groups should be excluded *a priori* from a simplified labelling scheme, although the consumer is likely to find it more beneficial for processed foods;
5. It should be mandatory, because a proliferation of supposedly 'simple' corporate labelling schemes in the U.S. and Europe, or nationally developed schemes will only add to consumer confusion;
6. The underlying criteria of such a scheme should be endorsed by an independent body (e.g. EFSA or the U.S. National Academy of Sciences) and a harmonised format should be developed by DG SANCO or the U.S. FDA in consultation with key stakeholders including consumers, industry, public health and communication experts;
7. It should put the nutrition information into context by indicating whether or not a product is high, medium or low in key nutrients as established by scientific research;
8. It should include an interpretative element (i.e. traffic light system indicating the levels of nutrients or the overall nutritional value of food products), in addition to factual information to enable consumers to have an 'at-a-glance' assessment of the nutritional value of the food and a preliminary comparison of products.
9. It should be based on the nutrients that are of most public health significance and, in order to keep the information clear and immediate, it should include a limited number of nutrients including fat, saturated fat, sugar and salt.
10. It should be backed up by clear government advice on what to eat for a healthy diet and how to use the labelling scheme;
11. While ultimately developed for pre-packaged food, the scheme should be extended to catering outlets serving standardized menu offerings and its use in other catering outlets should be explored.

Annex 6.

DOC No. FOOD 30-08

DATE ISSUED: MAY 2008

Resolution on Nutrition Disclosure for Restaurant Foods

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.

Introduction

The United States

Americans are increasingly relying on restaurants to feed themselves and their families. Almost half of the typical American's food budget is spent on food consumed away from home and Americans consume about one-third of their calories from restaurants and other food-service establishments.^{61, 62, 63}

Foods that Americans eat from restaurants are generally higher in calories and saturated fat and lower in nutrients, such as calcium and fiber, than home-prepared foods.⁶⁴

Studies link eating out with obesity and higher caloric intakes. American children eat almost twice as many calories when they eat a meal at a restaurant (770 calories) compared to at home (420 calories).⁶⁵ The average American eats out almost six times a week; enough to exceed calorie requirements over the course of an entire week.⁶⁶

⁶¹ US Department of Labor. Bureau of Labor. « Consumer Expenditures in 2005 » Accessed at <<http://www.bls.gov/cex/csxann05.pdf>> on March 3, 2008.

⁶² Lin B, Guthrie J, Frazao E. *Away-From-Home Foods Increasingly Important to Quality of American Diet*. Washington, DC: U.S. Department of Agriculture, Economic Research Service, 1999. Agriculture Information Bulletin No. 749.

⁶³ Lin B, Guthrie J, Frazao E. « Nutrient Contribution of Food Away From Home. » *America's Eating Habits: Changes and Consequences*. Washington, DC: U.S. Department of Agriculture, Economic Research Service, 1999b. Agriculture Information Bulletin No. 750, pp. 213-242.

⁶⁴ Lin, *et al.* *Ibid.*

⁶⁵ Zoumas-Morse C, Rock CL, Sobo EJ, Neuhouser ML. « Children's Patterns of Macronutrient Intake and Associations with Restaurant and Home Eating. » *Journal of the American Dietetic Association* 2001, vol. 101, p. 923-925.

Without nutrition information, it is difficult to compare options and make informed decisions. For example, a large chocolate shake at McDonalds has 400 more calories than a whole meal of a hamburger, small fries, and a small Coke. A Burger King Tendercrisp Chicken Sandwich (780 calories) has about the same number of calories as a Burger King Whopper hamburger (700 calories).⁶⁷

Three-quarters of adults report using labels on packaged food, and using labels is associated with eating more healthful diets.^{68, 69} Studies also show that the provision of nutrition information at restaurants helps people make lower calorie choices.

Nutrition disclosure also leads to reformulation of existing products and the introduction of new nutritionally improved products. For example, trans fat labeling in the U.S. on packaged food has lead many companies to reformulate their products and use healthier fats and oils. In a similar fashion, nutrition labeling on menus and menu boards is likely to spur nutritional improvements in restaurant foods.⁷⁰

The U.S. National Academies' Institute of Medicine recommends that restaurant chains "provide calorie content and other key nutrition information, as possible, on menus and packaging that is

⁶⁶ National Restaurant Industry. « 2008 Restaurant Industry Forecast. » Quoted in « Restaurant Industry to Continue to Be Major Driver in Nation's Economy Through Sales,... » Reuters Online. Accessed at < <http://www.reuters.com/article/pressRelease/idUS138203+12-Dec-2007+PRN20071212> > on March 3, 2008.

⁶⁷ Wootan, Margo. *Anyone's Guess: The Need for Nutrition Labeling at Fast-Food and Other Chain Restaurants*. Washington,. DC: Center for Science in the Public Interest, November 2003.

⁶⁸ U.S. Department of Health and Human Services (US DHHS). *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General, 2001. U.S. Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention, National Center for Health Statistics. *Healthy People 2000 Final Review*. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 2001b. DHHS Publication No. 01-0256.

⁶⁹ Kim SY, Nayga RM, Capps O. « The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis. » *Journal of Agricultural and Resource Economics* 2000, vol. 25, pp. 215-231. Kreuter MW, Brennan LK, Scharff DP, Lukwago SN. « Do Nutrition Label Readers Eat Healthier Diets? Behavioral Correlates of Adults' Use of Food Labels. » *American Journal of Preventive Medicine* 1997, vol. 13, pp. 277-283. Neuhouser ML, Kristal AR, Patterson RE.

« Use of Food Nutrition Labels Is Associated with Lower Fat Intake. » *Journal of the American Dietetic Association* 1999, vol. 99, pp. 45-50, 53.

⁷⁰ Silverglade, Bruce. « Food Labeling: Rules You Can Live By. » *Legal Times*, July 17, 1995, pp. 21-24.

prominently visible at point of choice and use" (2006).⁷¹ The Food and Drug Administration, Surgeon General, and U.S. Department of Health and Human Services also recommend that restaurants provide nutrition information.⁷²

However, half of the largest chain restaurants in the U.S. do not provide any nutrition information about their foods.⁷³ Those that do provide information usually do so in hard to use formats. Brochures and posters are often hard to find and provide nutrition data tables that are hard to read. Nutrition information on company websites requires people to access computers. Information on tray liners or fast-food packages is not accessible to customers until after they order.

Recently, two American cities/counties, New York and King County (Seattle, Washington), passed laws requiring calorie disclosure on menu boards. Some chain restaurants, such as Subway, have already begun to comply with the New York City menu labeling law, demonstrating that such requirements are practical for the industry to follow and practical for regulatory authorities to implement.

The European Union

Europeans are increasingly shifting their diets towards greater fast food consumption and larger portion sizes. McDonald's is now the largest food service provider in Europe with sales of €12.7 Billion in 2006;⁷⁴ sales growth for McDonald's in Europe (11.2% in 2007), has been more than enough to offset declining sales in the US.

Out-of-home eating grew from 24.4% of eating occasions to 27% throughout Europe between the years 2002 and 2007. In some European countries, rates are even higher; in the United Kingdom, 35.5% of eating occasions were out-of-home in 2007.⁷⁵ Britons spend an average of 25 minutes eating in cafes and restaurants every day for a cost of £11.41 each week.⁷⁶

⁷¹ Committee on Food Marketing and the Diets of Children and Youth, J. Michael McGinnis, Jennifer Appleton Gootman, Vivica I. Kraak, Editors. *Food Marketing to Children and Youth: Threat or Opportunity?* Washington, DC: The National Academies Press, 2006, p. 382.

⁷² U.S. Department of Health and Human Services (US DHHS). *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General, 2001.

⁷³ Wootan, Margo, D.Sc., and Melissa Osborn. « Availability of Nutrition Information from Chain Restaurants in the United States. » *American Journal of Preventive Medicine*. Volume 30, Issue 3, March 2006, pp. 266-268.

⁷⁴ Horizons (Market Research), 2006.

⁷⁵ Datamonitor Report. Quoted in « Habit of a lifetime. » *Bakery and snacks.com*. July 21, 2003. Accessed at < <http://www.bakeryandsnacks.com/news/ng.asp?id=13909-habit-of-a> > on March 3, 2008.

⁷⁶ « Britons spending ever more time and money on out-of-home dining. » *The Leisure Report*. February 2008.

A leading study of European eating habits away from home, “Eating out of home and its correlates in 10 European countries...”, considered survey data from 36,894 individuals, and found that out-of-home eating “is associated with increased energy intake” and corresponds with the increasing prevalence of obesity in Europe.⁷⁷ When eating out, Europeans tend to consume more sweets (23.7% of all out-of-home calories), cereals (16.8%), and dairies (11.2%), and fewer fruits (7.3%) and vegetables (1.6%)⁷⁸ than when eating at home. Little difference in nutritional quality between fast food items in the US and Europe also suggest that these statistics correlate with higher caloric intake and a corresponding rise in obesity rates.

Thus, the case for nutrition disclosure for standardized restaurant foods can and should be made for the European Union as well as for the U.S. As in the U.S., nutrition disclosure would assist Europeans in making healthier eating choices, spur product reformulations, and help reduce the incidence of obesity and diet-related disease.

Legislative and Regulatory options

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 health priorities.

⁷⁷ P Orfanos et al. « Eating out of home and its correlates in 10 European countries. The European Prospective Investigation into Cancer and Nutrition (EPIC) Study. » *Public Health Nutrition* : 10(12), 1515-1525. 21 June 2007. Accessed online.

⁷⁸ P Ofanos et al. *Ibid.*

Annex 7.

TACD Comments on the Interagency Working Group on Food Marketed to Children's Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts

July 14, 2011

Introduction

The Transatlantic Consumer Dialogue (TACD) is a forum of US and EU consumer organisations which develops and agrees on joint consumer policy recommendations to the US government and European Union to promote the consumer interest in EU and US policy making. We welcome this opportunity to submit comments on the Interagency Working Group on Food Marketed to Children's Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts.

The TACD has long called for action by the United States (US) and European Union (EU) Governments to ensure a more responsible approach to the way that foods are marketed to children, particularly given the rates of obesity and diet-related disease on both sides of the Atlantic. We have called for rules to ensure that food marketing does not undermine progress towards improving diets, for example, by encouraging excessive consumption of foods that are high in fat, sugar and/or salt.

Last year, the World Health Organisation (WHO) also adopted a set of recommendations on the marketing of foods and non-alcoholic beverages to children. These state that the overall policy objective should be to reduce both the exposure of children to, and power of, marketing of foods high in saturated fats, *trans*-fatty acids, free sugars, or salt and that it is the responsibility of governments to set clear definitions for the key components of the policy, in order to allow for a standard implementation process.

We therefore very much welcome this initiative by the US Interagency Working Group which is designed to encourage children, through advertising and marketing, to choose foods that make a meaningful contribution to a healthful diet and minimise consumption of foods with significant amounts of nutrients that could have a negative impact on health or weight.

General comments on the proposed approach

TACD recognises that there have been several industry initiatives relating to food marketing in the EU and US in recent years. However, we are concerned that although these Pledges cover some aspects of the way that foods are marketed to children, they are limited in several respects:

- > the age of children covered – they only cover younger children;
- > the channels that are covered – very few of the channels used to market food to children identified by the Federal Trade Commission are covered in the policies;
- > the foods that are covered - food companies have developed different approaches to limiting foods that can be marketed to children according to the nature of their portfolios;
- > the way that marketing to children is defined – various child-appealing techniques are still permitted, such as use of brand equity characters; and
- > the breadth of companies covered – as the initiatives are self regulatory, only a limited number of companies have signed up to the pledges.

We consider that a more comprehensive approach is needed to tackling food marketing to children that addresses these weaknesses, as part of broader strategies to tackle obesity and diet-related disease. We, therefore, have the following general comments on the approach proposed by the Interagency Group:

Age of children

TACD supports the Working Group's recognition that older as well as younger children should be protected, by proposing that the principles should apply to marketing of children up to 17. We do consider that the prevalence of obesity in both children and adolescents warrants the same approach to limits on food marketing for both age groups (question 1). The rationale for the restrictions should be public health protection. It is important not to confuse this with issues around children's understanding and response to specific marketing techniques. We do not, therefore, consider it appropriate to narrowly define the scope of marketing to which the nutrition principles should apply to for adolescents.

Definitions of marketing to children

It is important that the nutrition principles are supported by clear definitions of what is considered to be marketing of foods to children so that there is no ambiguity. Foods are marketed to children through a range of complex, integrated and increasingly sophisticated techniques, many of which may not be immediately obvious, and so it is important that a comprehensive approach is included in order to ensure that the principles achieve their overall objective.

When determining the specific definitions for whether a marketing technique is targeted to children, including adolescents, it is also important to ensure that the number of children as well as the proportion of children watching is taken into account in order to have a meaningful impact on their exposure. Children may make up a relatively small proportion of viewers of TV programmes or users of web-sites, despite the programme or site having the largest number of children watching compared to any others. Percentage audience share is therefore not a sufficient basis for restrictions in isolation and needs to be combined with other methods for ensuring that children are not targeted during very popular evening programmes for example, including use of scheduling restrictions and clear definitions for the techniques used to target children through different channels.

Brand marketing

It is important that the principles take account of brand advertising by ensuring that brands that are predominantly associated with less healthy foods do not circumvent the recommended principles.

Specific comments on the Principles

Implementation period up until 2016

We recognise that it is proposed that the principles are voluntary, but we are concerned that given the urgent need to take action to address the causes of obesity and diet-related disease, an implementation period up until 2016 is too long and instead suggest that this is reduced to two years.

Food categories

We agree that it is useful to focus on the food categories currently most heavily marketed to children (breakfast cereals, snack foods, candy, dairy products, baked goods, carbonated beverages, fruit juice and non-carbonated beverages, prepared foods and meals, frozen and chilled deserts and restaurant foods), but think that the principles should apply across the board.

Nutrition criteria

We support the overall approach of specifying which foods make a meaningful contribution to a healthful diet, combined with criteria for nutrients to limit. The nutrition principles should help drive reformulation so that a wider range of healthier products are made available. However, we do not think that feasibility of reformulation should be confused with whether or not it is appropriate to market certain food products to children, or be a reason to delay action in this area.

Annex 8.

DOC No. FOOD 31-08

DATE ISSUED: NOVEMBER 2008

TACD Revised Resolution on Food Products from Cloned Animals

Introduction

Animal cloning came to the public's attention in 1996 with the birth of the first mammal clone, Dolly, a sheep. Since then, a number of companies have continued to use cloning to asexually produce a wide array of animal clones, and the commercial sale of meat and milk derived from cloned livestock and their offspring appears imminent.

Cloning is a relatively new technology and its impacts are still not well understood. According to a number of scientific studies the vast majority of cloning attempts fail. Even "successful" clones can have severe health problems, such as metabolic or cardiopulmonary abnormalities, that can result in death or the need for euthanasia. There are concerns that food safety and animal health could be impacted if cloned animals or animal products derived from them are used for food.

In 2003, the U.S. Food and Drug Administration (FDA) requested a voluntary moratorium on the sale of food products from animal clones and their offspring, essentially asking companies not to market or sell cloned food but without any legally enforceable restrictions. However, in January 2008 the FDA published a final risk assessment which concluded that the products from cattle, goat and pig clones posed no additional risk relative to their conventional counterparts⁷⁹.

In the European Union there is currently no specific binding legislation dealing with animal cloning. The Novel Foods Regulation, which is currently under review, requires that the products of clones have to be approved before they can go onto the market. However, products from the offspring of clones are not covered and so can legally enter the European market without prior assessment and approval. The European Food Safety Authority (EFSA) and the European Group on Ethics (EGE) have, however, recently issued Opinions on the use of cloned animals for food production. EFSA looked at the food safety, animal health and welfare and environmental impact, whereas the EGE looked at the ethical implications. EFSA⁸⁰ highlighted animal health issues for the surrogate dams and the clones. Based on the currently available knowledge, which is limited, it felt that there is no indication that there would be differences in food safety between food products from healthy clones and their offspring compared with healthy conventionally bred animals. The EGE⁸¹ questioned the ethical justification of cloning animals for food considering the current level of suffering and health problems of surrogate dams and animal clones. It highlighted a number of considerations, including the need to ensure traceability if clones did enter the market. These Opinions will inform the approach that is taken by the European Union, along with a European Commission Eurobarometer survey to gauge public opinion in the 27 Member States.

It is already clear that many consumers, in both the U.S. and EU, have significant concerns and

⁷⁹ Animal Cloning: A Risk Assessment, US Food and Drug Administration, January 2008.

⁸⁰ Food Safety, Animal Health and Welfare and Environmental Impact of Animals Derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals, Scientific Opinion of the Scientific Committee, 15 July 2008, EFSA Journal (2008) 767, 1-49.

⁸¹ Ethical aspects of animal cloning for food supply, Opinion No 23, the European Group on Ethics in Science and New Technologies to the European Commission, 16 January 2008.

objections to the use of clones in animal agriculture and the sale of milk and meat derived from such clones and their progeny. Recent polls show that most Americans would refuse to buy food from animal clones, and that Americans have serious concerns about the ethics of animal cloning. A recent independent poll found that 79% of Americans are unsure about the safety of cloned food, including 43% who believe that cloned food would be unsafe. A food industry-sponsored poll last year similarly found that 63% of Americans would not buy cloned food, even if the FDA deemed the products safe.

A recent Eurobarometer survey commissioned by the European Commission in 2008⁸² found that the vast majority of EU citizens (84%) thought that the long-term effects of animal cloning were unknown. It also found that people were significantly less willing to accept animal cloning for food production purposes with 58 per cent saying that such cloning should never be justified. A majority said that it was unlikely that they would buy meat or milk from cloned animals, even if a trusted source said that such products were safe with 20% saying that it was somewhat unlikely and 43% saying that it was not at all likely. Eight out of 10 (83%) said that special labelling should be required if food products from the offspring of cloned animals became available in shops. A survey conducted by Which? the UK consumer organisation, in February 2008 found that 81 per cent of people were concerned about eating meat from cloned animals and the same percentage for meat from the offspring of cloned animals. Eighty per cent of respondents preferred to buy foods that were not produced using cloned animals and 80 per cent thought that food produced using cloned animals should be clearly labelled⁸³.

TACD believes that, if the US and EU governments fail to adequately regulate the use of cloned animals and their progeny for food, it could compromise human health and undermine consumers' fundamental right to know and to choose what they are eating.

Cloning – The Process

Cloning or Somatic Cell Nucleus Transfer (SCNT) involves replacing an egg's nucleus with the nucleus from the adult cell or from an embryo or foetus to be cloned using cell fusion or direct injection. The egg is then manipulated so that it develops without fertilisation and the embryo clone is implanted into a surrogate female animal.

There is interest in cloning because it allows more offspring to be produced from animals that have particularly desirable traits than would be possible through other methods of reproduction. It is likely, for this reason, that cloning will be used in combination with genetic modification (GM), although the recent Opinions do not address this. Clones are also more likely to be used for breeding. It is, therefore, the offspring of clones that are most likely to be used for food production.

Reasons for Concern:

1. Food Safety Concerns

There are limited studies assessing the safety of cloned animal products. Both EFSA and the FDA have taken the view that the indications are that food products from healthy clones are unlikely to raise different concerns to conventionally bred healthy animals. They regard the issues for the offspring of clones as being no different to conventional animals.

However, EFSA is clear that uncertainties arise from the limited number of studies available, the small sample sizes investigated and the absence of a uniform approach to allow all of the relevant issues to be

⁸² Europeans' attitudes towards animal cloning, Analytical Report, Flash Eurobarometer 238, European Commission, October 2008.

⁸³ 2061 people representative of the general population of the UK were interviewed by telephone in February 2008.

addressed. They felt that the data on cloned sheep was too limited and they therefore could not include them within the Opinion.

Both opinions acknowledge the adverse animal health effects that result from cloning, but take the view that these should be identified and affected animals removed from the food chain. Unusually, the risk assessment is predicated on assumptions about the effectiveness of food safety controls, including ante- and post-mortem inspection.

A. Potential Pathogen Issues

The US National Academy of Sciences' report, *Animal Biotechnology: Science Based Concerns*, stated that:

'A number of data sets suggest that the health and well-being of neonatal and young somatic cell clones often are impaired relative to those of normal individuals. Direct effects of any abnormalities in patterns of gene expression on food safety are unknown. However, because stress from these developmental problems might result in shedding of pathogens in fecal material, resulting in a higher load of undesirable microbes on the carcass, the food safety of products, especially such as veal, from young somatic cell cloned animals might indirectly present a food safety concern'.

EFSA also recommends that there should be further investigation into the immunocompetence and susceptibility of clones and their offspring to diseases and transmissible agents when reared and kept under conventional husbandry conditions. It advises that: *'Should evidence become available of reduced immunocompetence of clones, it should be investigated whether, and if so, to what extent, consumption of meat and milk derived from clones or their offspring may lead to increased human exposure to transmissible agents'.*

B. Intervention such as antibiotics

The questionable health of some clones could raise significant new herd management issues that may affect the quality and state of animal products for consumers. Significantly reduced genetic diversity combined with confined industrial farming practices could make herds more susceptible to widespread disease issues. Sicker herds, in turn, might result in more interventionist approaches to herd management including new and increased subtherapeutic and therapeutic uses of antibiotics.

2. Animal Health Concerns

Use of cloning techniques raises animal health concerns. Because of the high failure rate of cloning, surrogate animals can be subjected to repeated surgical operations to implant cloned embryos and extract cloned foetuses. Most cloned animals exhibit a condition known as "large-offspring syndrome," which results in overly stressful deliveries for surrogates and newborns. For the few cloning attempts that result in a live birth, the cloned animal's health is often so poor that many die within 24 hours due to respiratory distress, increased birth weight and major cardiovascular abnormalities. Even apparently "healthy" clones often suffer unexpected health consequences and will require a lot of husbandry care. As well as any food safety implications arising from sick animals, many consumers do not wish to use food products derived from techniques that cause such problems to farm animals.

3. Unresolved Ethical Considerations

There are significant ethical issues associated with cloning that are of varying degrees of concern to consumers and reinforce the need to trace clones, their offspring and enable choice. Some consumers believe that asexual production such as cloning fundamentally alters the natural status of the animal and raises serious concerns as to the extent to which society should allow humans to further objectify and

commodify animals. Consumer research conducted by the Food Standards Agency in the UK⁸⁴, for example, found that most participants saw animal cloning as a quantum leap 'from giving mother nature a helping hand to interfering with mother nature' and people struggled to identify convincing benefits. There is also a fear by some that animal cloning is merely a stepping stone in the path to human cloning and eugenics. Leading scientists acknowledge that cloning procedures developed on mammalian animals would remain essentially the same if utilized to produce human clones. Many citizens feel that the continued cloning of animals represents a scientific "transgression" and is a dangerous precedent which will be cited widely by proponents of human cloning as they push for acceptance of the technology.

The EGE raised concerns that the use of cloning in the food supply raises a number of specific ethical concerns relating to clones and their offspring, humans, the environment and society more broadly. The first relates to the moral status of animals and the recognised principles as defined by the World Organisation for Animal Health (OIE): freedom from hunger, thirst and malnutrition; fear and distress; physical and thermal discomfort; pain, injury and disease and to express normal patterns of behaviour. Other considerations include: the importance of considering issues around sustainable agriculture; the potential that use of cloning in animal production will open the door for possible human uses, what they call the 'slippery slope argument'; religious considerations as the relationship between humans and animals will vary according to religious beliefs; public perception and the consumer's right to know, free choice and labelling and concern that patents might be extended to specific genes or to animals leading to a concentration of resources that are important for breeding.

4. Consumer Right to Know

Consumers have a fundamental right to know what they are eating and to make informed choices about what they eat. For the reasons outlined above, and based on the available consumer research, it is likely that many consumers will wish to avoid the products of clones and their offspring. Traceability is, therefore, fundamental to ensuring that consumers can make this choice, but also that the effects of cloning – whether in terms of food safety, animal health or environmental impact – can be monitored.

However, in the United States, the FDA has suggested that milk and meat derived from cloned animals will be permitted to be sold without labelling. The EU is currently considering what approach to take to cloning.

Once clones and their offspring are introduced on to the market in one country, traceability will be challenging – particularly as many clones will be used for breeding and so the available products will come from their offspring. It is already the case that the semen from clones is being traded and some breeders have planned to export embryos from cloned livestock.

Conclusions and Recommendations

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

⁸⁴ Animal Cloning and Implications for the Food Chain, Findings of Research Among the General Public, Food Standards Agency, May 2008.

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 Food-16-00, www.tacd.org/docs/?id=18). 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 Food 9PP-99, www.tacd.org/docs/?=15).
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.

Annex 9.

DOC No. INFOSOC 45-11

DATE ISSUED: JUNE 2011

Resolution on Behavioral advertising

Introduction

New forms of advertising are emerging online and they are overtaking traditional media as a consequence of the digital shift. With the advent of the Internet and the growth in computer processing and storage capacity, advertisers have the tools to collect and analyse unprecedented loads of data to help target their ads. When surfing the Internet, consumers' data are being collected at different layers, by Internet Service Providers, web browsers, email scanning, publishers, affiliation companies, social network platforms, ad-serving agencies and data aggregator companies. All these layers are increasingly interconnected, thus raising concerns as regards consumers' privacy and protection of their personal data.

Recommendations

TACD resolves that EU and US governments should:

1. Investigate and take regulatory action as needed to address new threats to consumer privacy from the growth of real-time tracking and sales of information about individuals' online activities on ad exchanges and other similar platforms.
2. Commit to developing a global common standard for protecting privacy and consumer welfare in the digital marketplace that reflects the highest possible standards for human rights.
3. Ensure a coherent implementation and proper enforcement of existing personal data protection and privacy legislation rules, including the principles of data minimisation, necessity, purpose limitation, limitation of storage period and data security.
4. Address the constantly evolving techniques used by advertisers for the profiling of online users and adopt measures that go beyond the standard third party cookies that have been the focus of regulators to date.
5. Clarify the rules on informed, specific, revocable and limited consent required to lawfully store information or to gain access to information stored in the user's terminal equipment. There should be specific and rigorous rules on the consent for the processing of sensitive personal data.
6. Carry out a legal gap analysis to assess how the current legislation and regulations on unfair and misleading or deceptive commercial practices applies to profiling and behavioural advertising and adapt new measures if needed.
7. Consider clarifying that matching identifiers and contact data fall under the scope of personal data. Matching identifiers may allow for the cross matching of data from different sources, while contact data are increasingly being used to send location-specific advertisements to mobile phones' users.
8. Adopt privacy by default as a regulatory principle to ensure that any technology developed is designed with the highest privacy and security requirements and consider the development and implementation of browser control tools to give consumers more control over their data.

9. Improve transparency and fairness of privacy notices through several means including prominent ad tracking disclosure, development of standard and multi-layered privacy notices, use of privacy seals and use of Transparency Enhancing Technologies.
10. Ban the use of Deep Packet Inspection and email scanning technology for the purpose of collecting user information to deliver targeted ads.
11. Develop solutions to enable consumers to receive information about the companies that have had access to his data and to exercise this right to access his personal data.
12. Encourage the development of international standards for behavioural advertising through cooperation within the Organisation for Economic Cooperation and Development (OECD).
13. Adopt specific rules for the protection of children and young people. Online marketing practices that have a negative impact on children and young people's cognitive and emotional development should be prohibited.
14. Monitor closely the merger of online advertising networks and the blurring of boundaries between content and advertising providers and carefully assess the impact on competition and on consumer welfare.
15. Ensure that self-regulation and voluntary codes of conduct fully comply with the principles of independent governance, added value for consumers, effective monitoring, robust sanctions, effective redress and significant market coverage.
16. Set up joint and multi-layered liability rules to ensure that users can claim compensation for any damage suffered from any of the parties involved in the processing of their personal data.
17. Improve the enforcement of existing legislation by Data Protection Authorities and consider the adoption of an instrument of judicial collective redress that would provide for compensation of the damages suffered, together with specific guidelines of the quantification of the damages suffered, which are often moral and of low value.
18. Investigate the emergence of ad exchanges, demand side platforms, data trading desks that buy and sell individual users in real-time, where they are online—including mobile devices.

Background

Introduction

Profiling has expanded enormously since the arrival of Web 2.0. A number of new business models have emerged that are based on harvesting data from data subjects, and subsequently converting these massive streams of data into profiles. These profiles can then be used to make suggestions or recommendations to users, to improve services, to learn more about customers, or to generate personalised advertising on the Internet. Today, companies are able, via the enhanced possibilities of profiling consumers, to discriminate against consumers i.e. by offering the same products at different prices based on individual users' online profile. Such practices already happen on the Internet. Interactive advertising techniques incorporate some of the latest developments in such fields as semantics, artificial intelligence, auction theory, social network analysis, data mining, and neuroscience.

Consumers and many policymakers are largely unaware about how online advertising operates, let alone its impact. This data collection and targeting apparatus has already been purposely migrated into the core business models shaping social media, mobile devices, gaming platforms, virtual worlds, and online video. Advanced techniques for the buying and selling of

individuals online for targeted advertising are found in EU countries, the US, and many other countries.

Targeting and profiling techniques are not as such harmful for consumers; they can even bring forward consumer benefits, if adequately designed. However, many existing practices lack the necessary transparency and accountability.

Consumers should not be expected to understand the privacy dimensions of a “custom targeting” system that uses wide-ranging data sets to determine “the absolute value of each impression” for an advertiser. And even if they did, it is currently impossible for consumers to exercise control over how their data is collected and used. The global growth of real-time digital ad exchanges depends on the ability of advertisers to seamlessly access both online and offline consumer information. To better serve the 21st century digital marketing industry, behavioral targeting warehouses and “co-ops” have been formed. Such services are a kind of data-mining “one-stop-shopping” for online targeting. Across the world, both established companies and new entrants are now part of a consumer data outsourcing supply chain. So-called “third parties” collect and sell information that can be used by ad networks, audience buying platforms, and other data buyers.

The combination of all this data used for real-time targeting should be a central focus for the privacy policy debate. Given the consolidation within the online marketing industry, advances in advertising technologies, the growth of new online ad markets and the dizzying data-chain of partnerships and alliances, it is vital for regulators to develop appropriate rules that reflect today’s challenges to privacy.

Many of the same consumer data collection techniques that have raised privacy concerns on the Internet have also been brought into the mobile marketplace. Mobile devices, which know users’ locations, are being turned into portable behavioral tracking and real time tracking tools. Consumers are increasingly tracked “across platforms,” including when on the Web, using mobile devices, playing online games, or soon when watching television.

The commercial digital media system is largely designed to promote data collection through “360-degree” online marketing strategies. Advertisers are now able to track, buy, and sell an individual in real time, through what’s known as digital ad exchanges. In just milliseconds, a user is subject to an invisible auction process, where advertisers—armed with copious amounts of information on that person—compete in a bidding process for the ability to serve them an ad. Real-time bidding is available for consumer targeting whether they are visiting a website, watching an online video, or using their mobile phone. A complex array of data is used for consumer profiling, tracking, and targeting on these “exchange” and “demand-side” platforms. Data collected on an individual, including via behavioral tracking, “intent” data warehouses, and outside databases, are used to determine the value of an individual targeting “impression.”

Online marketers, including Google, Microsoft, and Facebook, have proposed that the U.S. engage in negotiations with the EU on consumer privacy that will lead to a revamped “safe harbor” regime. What U.S. online marketers hope to achieve is a new treaty that creates a “separate, but equal” privacy regime, enabling them to conduct business in the EU as unfettered as possible by rules on data controllers. This approach argues that if the U.S. enacts a federal privacy law—even a weak one relying on self-regulation—it should be treated as the equivalent of the civil liberties-based EU system.

Research evidence

Consumer organisations in the EU and the US have carried out significant qualitative and quantitative research which clearly demonstrates that awareness of online behavioural advertising is low while a significant proportion of consumers currently feel uncomfortable with the idea of being tracked online.

- Research by Which? in the UK found that over 74% of over a thousand respondents had not heard of the term online behavioural advertising and only 50% claimed to understand what cookies are.
- The results of an omnibus study by Consumer Focus (February 2010) have shown that overall 47% of respondents were unsure/did not know/never heard of cookies
- These figures are confirmed by a recent scientific report “Young People and Emerging Digital Services (2009), according to which 82% of young people are concerned that personal information is used without their knowledge, 75% that their identity is reconstructed using personal data from various sources and 69% that their views and behaviours may be misinterpreted based on their online behaviour.

The privacy policies include complex and legal terms which fail to comply with the principles of transparency and fairness, aiming exclusively at complying with legal requirements rather than informing consumers. They are often obscure on issues where clear explanations matter the most, as for instance the question of whether data is shared with or sold to third parties, who these third parties are and what they intend to do with the data, the use of cookies and other data collecting technologies and data retention limits. As a result, consumers rarely read and even more rarely understand privacy notices.

- According to the Eurobarometer survey, 64% of users feel that information on the processing of their data is not yet satisfactory.
- According to a study by the Norwegian Consumer Council, 73% of users aged 15-30 years seldom read Terms of Service,
- The research carried out by Which? in March 2010 found that only 6% adults aged 16+ with internet access questioned have read the privacy policies of websites.

These surveys demonstrate that although consumers are concerned about their privacy, they do not view the privacy policy as a suitable way to understand and answer their privacy concerns. Consumer organisations are also concerned with recent efforts by the advertising industry to develop self-regulatory proposals. These proposals, despite their value in terms of information disclosure about profiling practices, fail to meet the higher standards of governance, independent monitoring, effective sanction, redress and significant market coverage that are needed for self-regulatory schemes to be effective.

- The recent icon-based proposal by the European Advertising Standards Alliance is unlikely to enhance consumers’ empowerment. A recent TRUSTe study in the US of a comparable icon showed that out of approximately 20 million consumers, it was accessed 56,000 times with 44,000 unique views. If calculations are just made on the unique visitors and unique views, this means that only 0.6% of consumers clicked through to the ad info page. This, in no way, signifies informed consent.
- It is also highly questionable whether all industry players will adhere to such self-regulation. The recent example in the UK, where the Code of Conduct by IAB is only applied by 9 out of the 540 members is clear example of the low take-up. Similarly, ad networks do not have to comply with the code if the web publisher is within the same corporate group.

- Even if consumers click on the icon and got to the control page to opt-out, they will only stop receiving ads based on tracking, but their data will continue to be tracked.
- Research conducted by consumer groups in the U.S., including World Privacy Forum, documents the failure of online ad industry self-regulation.
- The Center for Digital Democracy and U.S.PIRG have documented the failure of the new icon-based self-regulatory system, and also demonstrated that sensitive data—including on a consumer's finances and health interests—is a risk.

Annex 10.

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DATE ISSUED: JUNE 2011

Resolution on Consumer Protection in Cloud Computing

Consumers, businesses and governments are increasingly using cloud computing services to store and share data. These services can offer users many benefits such as a large storage capacity, convenient access from any computer, and a high level of security. Use of cloud computing services by governments and businesses can reduce their expenditures for hardware and software, and the resulting savings may be passed along to taxpayers and consumers. However, the use of cloud computing services for data pertaining to consumers also raises many concerns. These concerns center mainly on control of the data: Who has access to it? How can it be used? How easy is it to move one's data from one cloud service to another? How secure is the data? Who is responsible if the data is lost or abused? Unresolved, these concerns are likely to prevent the widespread adoption of these valuable and efficient services. Therefore, governments and businesses must adopt policies that protect consumers with regard to law enforcement access to their data in the cloud, secondary uses of their data, portability and interoperability, data security, data deletion, transparency, and terms of use.

Recommendations

The Trans Atlantic Consumer Dialogue resolves that the governments in the United States and Europe should require these protections for business-to-consumer cloud computing services:

1. Data that consumers store in the clouds should have the same legal protections with regard to access by governments and others as it would if it was stored on their own computers. To the extent appropriate, consumers should receive notice of criminal and civil requests for data that is stored with cloud computing services before such requests are fulfilled.
2. Cloud computing services should not use or allow others to use consumers' data for secondary purposes without first clearly explaining to consumers how it will be used and by whom and obtaining their express affirmative consent. Secondary use should be limited to those purposes for which consumers have provided such consent.
3. Cloud computing services should not be allowed to exploit the physical locations of their servers in order to limit consumers' rights concerning the privacy and security of their data.
4. Cloud computing services should not interfere with consumers' ability to move their data to another service or to use their data in an interoperable manner with other services.
5. Cloud computing services should be required to meet and demonstrate that they maintain adequate security standards to protect consumers' data. Compliance with security measures should be monitored through independent auditing. Consumers should be provided with information about the security of their data and given the means to safeguard their data through tools such as encryption for which only the consumers themselves have the keys.

6. Consumers should have the right to delete the data that they had provided to cloud computing services for storage.
7. Cloud computing services should be required to be transparent about how they operate, what legal protections apply to consumers' data, and whom to contact to ask questions or make complaints.
8. Cloud computing services should be prohibited from using unfair contract terms such as requiring consumers who use free services to agree to a lower level of protection than those who pay or requiring that consumers give up the right to take legal action to resolve disputes.
9. Cloud computing services should be required to provide consumers with clear information on redress and compensation in the event that their data is lost, shared or stolen and with easy- to- use methods for making such claims.

The Trans Atlantic Consumer Dialogue also urges businesses and governments that outsource individuals' data to the cloud to consider these issues and ensure that their contracts for cloud computing services provide for adequate protection. In these instances, businesses and governments should be fully accountable to those individuals for the privacy and security of their data.

Background

Cloud computing has been defined as “the sharing and storage by users of their own information on remote servers owned and operated by others and accessed through the Internet or other connections.”⁸⁵ There are many popular cloud-based consumer services available in the U.S. and the EU, including webmail (such as Gmail and Hotmail), photo sharing websites (such as Flickr), and social networking sites (such as Facebook, MySpace and Badoo). Convenience is a major reason why consumers use cloud computing; it enables them to access their data from any computer and share it with others easily.⁸⁶ Cloud computing services can also protect consumers from loss of data if their computers fail and may offer better data security than they have on their own computers.

While the use of cloud computing services can benefit consumers, it also raises many concerns. These concerns focus mainly on control of the data. Once consumers' data is entrusted to a cloud computing service, it may be accessed and used by the cloud service provider or third parties for a variety of purposes unrelated to fulfilling the services that the consumers have requested. Consumers may have no idea, however, that their data may be accessible to parties to whom they have not specifically provided it, for uses beyond the purposes for which it was originally given. For instance, the data may be sought by the government or others for criminal

⁸⁵ See World Privacy Forum, *Cloud Computing and Privacy*, www.worldprivacyforum.org/cloudprivacy.html.

⁸⁶ John Horrigan, *Use of Cloud Computing Applications and Services*, Pew Research Center's Internet & American Life Project, www.pewinternet.org/Reports/2008/Use-of-Cloud-Computing-Applications-and-Services.aspx.

or civil litigation, or cloud service providers may want to access consumers' data for their own commercial use or to sell it to others.⁸⁷

In the U.S., federal law does not provide adequate protection for the privacy of data in the cloud. While data stored in a consumer's own hard drive is protected from government access by Fourth Amendment rights, requiring a judge's permission in most cases, the same data may lose that protection when transferred to a third party such as a cloud computing service. In a report for the World Privacy Forum, Bob Gellman describes the confusing legal landscape under the Electronic Communications Privacy Act of 1986 as it applies to current Internet activities.⁸⁸ He also points out that since the U.S. lacks an overarching legal privacy framework and relies on a narrow sectoral approach, consumers may have no rights concerning the secondary use and sharing of the data that they place in the cloud. While in Europe the [EU Data Protection Directive](#)⁸⁹ and the [Directive on privacy and electronic communications](#)⁹⁰ provide a comprehensive privacy framework, the [European Network and Information Security Agency \(ENISA\)](#) recommended in its recent cloud computing risk assessment that European officials should determine how the data protection laws apply to cloud computing services.⁹¹

Consumers are clearly concerned about the privacy of their data in the cloud. According to one survey,⁹² 90 percent of respondents said that they would be very concerned if cloud providers sold their files to others, and 80 percent said they would be very concerned if the service used their photos and other information for marketing. Sixty-eight percent said they would be very concerned if the data was used to tailor advertisements to them.

Data that consumers store in the clouds should have the same legal protections with regard to access by government and others as it would if it was stored on consumers' own computers. To the extent appropriate, consumers should receive notice of criminal and civil requests for data that they have stored with cloud computing services before such requests are fulfilled. Furthermore, consumers' data should not be used by cloud computing services or others for secondary purposes without first explaining those uses and obtaining consumers' express affirmative consent.

Portability is also an important consumer concern. While there may be no contractual barrier to switching from one cloud computing service to another, providers could use proprietary formats or employ technical obstacles to make it difficult to do so. For instance, a consumer might be required to select each file individually to download. For consumers who have spent years uploading data, this could effectively make the service non-portable, locking them in and

⁸⁷ See Alan Weissberger, *ACLU Northern CA: Cloud Computing – Storm Warnings for Privacy?* Viodi View, <http://viodi.com/2009/02/13/aclu-northern-ca-cloud-computing-storm-warning-for-privacy>.

⁸⁸ Bob Gellman, *Privacy in the Clouds: Risks to Privacy and Confidentiality from Cloud Computing*, 2009, www.worldprivacyforum.org/pdf/WPF_Cloud_Privacy_Report.pdf.

⁸⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:NOT>

⁹⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:337:0011:0036:En:PDF>

⁹¹ See www.enisa.europa.eu/act/it/oar/cloud-computing/

⁹² See fn 2 supra.

threatening competition. Interoperability is a related issue; unless standardized data formats are used, it might be hard for consumers to use data that they have customized on one service with another service. Cloud computing services should not interfere with consumers' ability to move their data to another service or to use their data in an interoperable manner with other services. Once consumers entrust their data to the cloud, they must rely on the cloud service provider to keep it secure. One potential benefit to consumers is that the security that the cloud service provider employs may be even stronger than they have on their own computers. Consumers can have no confidence about the security of cloud services, however, unless those services are required to meet adequate security standards and to be independently audited on a regular basis to ensure compliance. Cloud computing services should provide consumers with information about their security. In addition, cloud computing services should provide consumers with the means to safeguard their data through tools such as encryption for which only the consumers themselves have the keys. While the location of the servers that cloud computing services use can actually enhance the protection of consumers' data, cloud computing services should not be allowed to exploit the physical locations of their servers in order to limit consumers' rights concerning the privacy and security of their data.

Consumers should have the right to delete data that they upload to the cloud. To address the fact that sometimes consumers regret deleting data, the Norwegian Consumer Council's best practices standard for cloud storage of photographs may serve as a good model: it recommends that customer files and metadata be quarantined for a period before actually being deleted.⁹³

Transparency is a guiding principle for all consumer transactions: consumers cannot make informed choices without understanding exactly what is being offered and on what terms. Many cloud services' terms of service, however, are unclear and missing important information.⁹⁴ Information about cloud services' business models is also important; if services are based primarily on monetizing the secondary use of consumers' data that should be made clear. Other key information that should be provided includes what countries' laws apply, who the primary regulatory agencies are, what the termination policy is, and whom to contact if consumers have questions or complaints.⁹⁵ This information should be prominently disclosed in clear, easy to understand language.

Another concern is the fairness of terms of service. Many consumer contracts, including those for cloud computing, are one-sided agreements in which the providers disclaim any liability if things go wrong, reserve the right to change terms unilaterally, and require that disputes be resolved through privately-operated arbitration that is binding on consumers.⁹⁶ Unfair contract

⁹³ See http://forbrukerportalen.no/Artikler/2010/standard_for_secure_online_photo_storage.

⁹⁴ Simon Bradshaw, Christopher Millard, and Ian Walden, *Contracts for Clouds: Comparison and Analysis of the Terms and Conditions of Cloud Computing Services*, Queen Mary School of Law Studies Research Paper No. 63/2010, <http://ssrn.com/abstract=1662374>.

⁹⁵ See model disclosure form in Appendix B, *Consumer Protection in Cloud Computing Services: Recommendations for Best Practices from a Consumer Federation of America Retreat on Cloud Computing*, November 2010, www.consumerfed.org/pdfs/Cloud-report-2010.pdf.

⁹⁶ See fn 7 supra.

terms for cloud computing services should be prohibited. For instance, cloud service providers should not be allowed to disclaim responsibility if they lose consumers' data, or to suddenly terminate services without notice and giving consumers sufficient time to retrieve their data. Furthermore, terms of service should not require consumers who use free services to agree to a lower level of protection than those who pay or require that consumers give up the right to take legal action to resolve disputes. Cloud computing services should provide consumers with clear information on redress and compensation in the event that their data is lost, shared or stolen and with easy- to- use methods for making such claims.

Annex 11.

DOC No. IP 09-09

DATE ISSUED: June 18, 2009

Resolution on enforcement of copyright, trademarks, patents and other intellectual property rights

Introduction

The enforcement of any particular intellectual property right, whether copyright, trademark, patent or others, is a complex and important area of public policy that touches on personal privacy, civil rights, freedom, social and economic development, and plethora of other issues.

According to the WTO TRIPS Agreement, the enforcement of intellectual property rights should be consistent with the promotion of technological innovation and the transfer and dissemination of technology. The policies should be to the mutual advantage of producers and users of knowledge, in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁹⁷ Governments have responsibilities in formulating or amending their laws and regulations to adopt measures necessary to protect public health and nutrition, to promote the public interest in sectors of vital importance to their socio-economic and technological development, and to include appropriate measures that may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.⁹⁸

The European Union and the United States are engaged in extensive efforts to shape global norms for the enforcement of copyright, trademarks, patents and other intellectual property rights. These discussions and norm setting activities are taking place in multilateral, plurilateral, bilateral fora and through unilateral actions. The proposals that are under consideration would in important areas be significant departures from the norms of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

While trademark, copyright, and patents are private rights that enable the right holders to seek remedies for infringements through legal proceedings, some initiatives create public responsibilities to monitor, prevent and penalize infringing activities, creating burdens on state resources. The extent to which this is appropriate will depend upon the specific initiative, and the competing priorities regarding scarce resources.⁹⁹ This is a special concern in developing

⁹⁷ See, for example, Article 7 of the TRIPS.

⁹⁸ See Article 8 of the TRIPS, and paragraph 4 of the 2001 Doha Declaration on TRIPS and Public Health.

⁹⁹ See TRIPS Part III, Enforcement Of Intellectual Property Rights. Section 1: General Obligations. Article 41.5. "It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any

countries, where the public enforcement of private intellectual property rights may not be a high priority.

The members of the Trans Atlantic Consumer Dialogue (TACD) agree to the following concerning the enforcement of intellectual property rights:

Recommendations

1. General Principles and Concerns

- a. **Transparency and Openness.** Negotiations concerning norms for the enforcement of intellectual property rights should be transparent.
 - i. Governments should explain the rationale and evidence in support of proposed policies, and invite public comment and questions regarding both.
 - ii. Governments should disclose the date and location of meetings, the names of negotiators, and the rules of negotiations.
 - iii. Documents that are distributed to all countries in a negotiation should be public, and not withheld on grounds of secrecy.
 - iv. Governments should disclose negotiation-relevant contacts and communications with representatives of right owners and other stakeholders.
 - v. Consumers should be allowed to attend negotiations as accredited observers.
- b. **Human Rights.** The enforcement of intellectual property rights should not undermine essential human rights, particularly as regards to:
 - i. The **freedom** of thought, speech, or expression, or the right to communicate,
 - ii. The **civil rights** of individuals,
 - iii. The **rights to health, education** and to **freely participate in the cultural life of the community**, and
 - iv. The enforcement of intellectual property rights should be consistent with the 1986 UN Declaration on the **Right to Development** as a human right.
- c. **Privacy**
 - i. National implementation of enforcement measures should be least restrictive of consumer **privacy**.

obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general."

- ii. An IP address is personally identifiable information subject to legal protection.
- iii. Any monitoring of consumer activity should be undertaken in accordance with the principle of proportionality.

d. Competition.

- i. **Free movement of goods.** Legitimate goods in transit should not be subject to enforcement measures that are based upon territorial patent rights or other inappropriate measures.
- ii. **Anti-Competitive Practices.** The enforcement of intellectual property rights should not undermine competition or limit the ability of governments to control or prevent anticompetitive practices.¹⁰⁰
- iii. **Exhaustion of Rights.** Enforcement measures should not eliminate the flexibility now available to countries under the WTO TRIPS Agreement to protect consumers by policies that embrace the national, regional or international exhaustion of intellectual property rights.

e. Consumer Protection. Enforcement measures should not undermine appropriate measures to protect consumers.

- i. **Unfair contracts.** In recent years, publishers have sought to limit consumer rights to use copyrighted works through non-negotiated contacts. Enforcement rules should not automatically enforce such contracts, when they are unfair or contrary to other public policy concerns.
 - ii. **Interoperability.** Many manufacturers or publishers attempt to restrict the use of copyrighted works to particular devices, software programs or services. Consumers want the right to modify, translate or otherwise transform data or software to extend the functionality or expand the choices for devices, software or services.
 - iii. **Defective products.** Consumers should have the right to refunds if digital goods area defective.
 - iv. **Excessive pricing.** Governments should act to protect consumers in cases of excessive pricing.
- f. **Access to Knowledge.** Personal, social, and economic empowerment and development depend in part upon access to knowledge. Measures to enforce intellectual property rights should not themselves become barriers to access to knowledge.
- g. **Preservation of culture and cultural diversity.** The preservation of culture requires overcoming technical and legal barriers to making copies of works, adapting works to

¹⁰⁰ See Article 8 and 40 of the TRIPS Agreement.

new formats, and preserving the integrity and accessibility of works. Enforcement measures should recognize the social value and importance of such activities.

2. **Evidence and Analysis.** Public policy on the enforcement of intellectual property rights should be informed by credible evidence, transparent and realistic assumptions and objective peer reviewed analysis. Multiple approaches to addressing the legitimate concerns of right owners and consumers should be considered.

- a. Statistics on counterfeiting and or infringement must be objective, accurate, and presented in the appropriate context.
- b. Statistics on counterfeit and substandard medicines should not be combined when this misleads policy makers about the extent of either problem. The solutions to counterfeit and substandard products are often quite different.
- c. Estimates of losses from infringements of intellectual property rights should be based upon realistic demand and usage parameters.
- d. Governments should collect and analyze statistics on the relationship between infringement and affordability of products.
- e. Counterfeiting is one part of broader public health concerns regarding drug quality. Addressing the problem of counterfeiting will not eliminate the range of public health concerns about drug quality. Governments should evaluate whether or not improving drug registration frameworks of quality, safety and efficacy regulation and its enforcement and/or policies that facilitate access to quality assured medicines and their rational use is a more cost effective solution than policies that are excessively focused on intellectual property enforcement measures.
- f. Confusion in terminology should be avoided and not encouraged. 'Counterfeit' should not be used as a generic term to designate all infringements, or to indicate the lack of quality of certain products. Policy makers should not allow public health terminology to be appropriated by intellectual property rights holders, in order to use public health terms and concerns to defend their own interests in areas where the terms confuse and mislead policy makers and the public.

3. **Specific Concerns.** In light on these general principles and concerns, TACD offers the following specific recommendations:

a. Enforcement of Internet Related Intellectual Property Rights.

- i. The EU and US should implement the recommendations set out in the TACD July 2008 Resolution on the Role of Internet Service Providers (ISPs) in Mediating Online Content and Communications (TACD Doc No. IP 06-08).
- ii. Digital Rights Management (DRM) schemes and Technological Protection Measures (TPMs) can and often do harm consumers directly and indirectly. The legal protection of DRM and TPMs should be limited, and subject to safeguards.

- iii. Hypertext linking to protected works on the Internet should not be subject to criminal sanctions.
 - iv. Any proposals for online enforcement of IPRs, such as monitoring the use of digital content, should be accompanied by a review of alternative systems of remuneration for creative communities, in order to foster the development of innovative business models and, more broadly, the development of the digital economy.
 - v. Governments should take due account of the distinction between the intentional or unintentional character of acts, and between the commercial or non-commercial nature of infringement. Criminal provisions must be limited to cases of commercial infringement with direct motivation of financial gains, excluding acts carried out by those acting in good faith.
 - vi. For any online enforcement efforts, careful assessment on the sanction and the crime targeted should be conducted, pursuant to the principles of effectiveness and of dissuasiveness.
 - vii. Governments should not cut off access to communications systems or the Internet as a sanction for infringement of copyrighted works.
- b. **ACTA.** The proposed Anti-Counterfeiting Trade Agreement (ACTA) negotiation lacks transparency and legitimacy, and needs safeguards for consumers.
- i. There should be no further meetings on the Anti-Counterfeiting Treaty until the EU and the US publish the full text of all negotiating documents, and agree to additional transparency measures, including the accreditation of consumers and/or their representatives as observers.
 - ii. The term "counterfeit" should not be used to describe activities relating to the mere infringement of copyrights or trademarks where there is no intent to deceive or any likelihood of confusion as to the authorized manufacturer, distributor or provider of the service. Possible patent infringements should not be referred to as counterfeits.
 - iii. EU and US negotiators have acknowledged that ACTA is designed to be expanded to apply to developing countries. Developing countries should therefore be allowed to participate in the ACTA negotiation, as either as full parties or as observers.
 - iv. ACTA should not reduce the flexibilities regarding injunctions that currently exist in Article 44.2 of the TRIPS.
 - v. ACTA should not require governments to impose inappropriate damages on consumers. Damages should not be excessive. In appropriate cases, governments should be able to tailor damages to public purposes.
 - vi. ACTA should not foreclose the ability of governments to create reasonable liability rules for the use of protected works or inventions, such as to facilitate access to orphaned copyrighted works, to address infringement of

architectural plans for building under construction, to allow governments to use or authorize uses of patents, copyrights or other intellectual property rights (such as 28 USC 1498), or to facilitate access to biomedical inventions or inventions necessary to implement standards involving complex technologies.

- vii. ACTA should not interfere with legitimate parallel trade, or goods in transit. For example, legitimate medicines in transit should not be subject to enforcement of patent rights in countries where goods are only in transit.
- viii. ACTA should not incorporate enforcement measures against individuals that undermine privacy, civil rights, or other human rights.
- ix. Patent infringement should not be subject to criminal penalties.
- x. Customs officials should not be required to devote excessive resources to the overzealous enforcement of possible intellectual property violations, at the expense of other pressing needs, such as those presenting other threats to public health and safety, or constituting other more serious illegal activities.

Annex 12.

DOC No. IP 11-11

DATE ISSUED: JUNE 2011

Resolution on the Anti-Counterfeiting Trade Agreement

The TransAtlantic Consumer Dialogue (TACD) believes that the Anti-Counterfeiting Trade Agreement has failed to strike an appropriate balance between the enforcement of intellectual property rights and the fundamental rights of users, citizens and consumers such as the right to information, education and culture, the freedom of expression, the right to accessible health care, the right to privacy and protection of personal data, the right to due process as well as other human rights and good governance in general.

TACD reaffirms the 19th of June, 2009 TACD "Resolution on enforcement of copyright, trademarks, patents and other intellectual property rights," with special regard to the general principles and concerns: transparency and openness, human rights, privacy, competition, consumer protection, access to knowledge and the protection of culture and cultural diversity.

TACD takes note of the December 3, 2010 "Opinion of European Academics on the Anti-Counterfeiting Trade Agreement" and the submission by legal academics to the Obama Administration on "ACTA's Constitutional Problem", in response to a request for public comment.

TACD has evaluated the December 3, 2010 version of the ACTA text, the final text, and finds the desired equilibrium between intellectual property rights, innovation and citizens' rights has not been achieved. TACD deplores ACTA's sole focus on greater civil and criminal enforcement measures without seriously considering necessary copyright reform and flexibilities that would favour greater access to knowledge and the blossoming of new innovative business models.

TACD offers the following specific comments regarding the negotiating process and the status and substance of the agreement.

Negotiating process

1. TACD regrets the lack of transparency and democratic accountability that has shrouded the whole process of the ACTA negotiations that has seriously impaired public and consumer participation in the ACTA negotiating process.
2. TACD notes that ACTA has bypassed multilateral institutions such as WIPO and the WTO, and that this appears to have been a deliberate attempt to avoid broader international participation, transparency and public scrutiny.
3. TACD objects to any new international norms for IP enforcement that are introduced through the back-door of opaque, secret negotiations.
4. TACD points out that these important decisions on intellectual property enforcement have not enjoyed full parliamentary scrutiny by any of the participating parties, including the US, the EU and its member states.

5. TACD does not deem acceptable the creation of new global IP enforcement norms that could constitute serious barriers to the access to knowledge by and the transfer of technology to developing countries, when the ACTA negotiating process was designed to exclude the participation by most countries from the global South.

Status and substance of the agreement

6. ACTA establishes new IP enforcement norms that go beyond existing EU, US and international norms and that taken together, these new rules will weaken innovation, consumer rights and threaten fundamental freedoms. TACD notes that ACTA's sole focus on greater civil and criminal enforcement measures could be counterproductive in its attempt to stop online piracy. The threat of disproportionately high damages and criminal measures in ACTA could chill innovation by making new digital and other industrial initiatives less attractive due to the fear of back-breaking financial penalties and criminal measures. Innovation could be inhibited by discouraging economic and time-consuming risk-taking in new creative ventures. This approach could be detrimental for consumer rights and interests by limiting competition and consumer choice.
7. TACD questions the possible incoherence and unfairness of a Treaty in which the two principal parties to the treaty have very differing views on the implications of ACTA. The European Union considers ACTA a binding treaty to be interpreted literally, while the United States apparently sees ACTA as an "understanding" that provides guidelines but not obligations to enforce the literal provisions.
8. There is a contradiction between ACTA and existing laws in several countries regarding criminal measures of IP enforcement, and also with regard to damages, injunctions and other remedies (Articles 8.1, 9.1 and 10).
9. TACD notes that ACTA does not make a clear distinction between the intentional and unintentional character of acts, and between the intentional or unintentional nature of possible IP infringements (art. 23. 1 and 23. 3). TACD points out the calculated ambiguity of ACTA's definition of "commercial scale" could lead to the victimization of non-commercial sharing of digital content, placing outside the law millions of people. TACD noted ACTA does not limit criminal provisions to cases with direct motivation of financial gains nor does it exclude actions carried out by those acting in good faith.
10. ACTA will create new global barriers to access to the vast cultural legacy of historic works for which the owners of works are difficult or impossible to identify or locate. ACTA would eliminate the flexibility to limit remedies for infringement in cases involving millions of orphaned copyrighted works, and requires ACTA parties to increase the penalties and criminal risks for using these works (Art. 8.1,9.1 and 10).
11. In some areas, ACTA proposes bypassing important procedural protections by courts in the application of IP enforcement. Article 12 could unreasonably limit the right of a defendant to be heard and Article 26 and Article 27.3 do not rule out the creation of extra-judicial IP enforcement bodies, and ACTA creates troubling new norms promoting ex officio judicial and IP enforcement in cooperation with right owners.

12. ACTA's provisions on trademarks are poorly drafted and could result in inappropriate seizures of products, including legal generic medicines and other products.
13. The ACTA provisions that impose obligations on third parties such as Internet Service Providers "to prevent goods that violate an intellectual property right from entering channels of commerce...where appropriate" encourage non-government actors to censor and monitor Internet content, without provisions to protect the public's rights in the area of express or uses of copyrighted materials, or the right to privacy.
14. TACD is concerned that ACTA creates a new institution out of a secret and non-transparent process, without any guarantees at all that the new institution will operate in an open, transparent and inclusive manner. TACD also notes the new institution has the power to amend the ACTA agreement.

TACD calls on:

- The US Government to clarify the possible contradictions of ACTA with US law, as well as the Constitutionality of the US ratification of ACTA as an "executive order".
- The US Government to clarify whether it expects other parties to interpret the provisions of ACTA as binding notwithstanding that the US itself does not interpret ACTA in this way.
- The European Commission and EU Council to clarify what EU member states' rules on criminal measures and other issues would need to be changed by ACTA.
- The European Parliament, without further satisfactory assurances and clarifications from the European Commission, to vote "no" on ACTA in the upcoming "consent" procedure.

Annex 13.

DOC No. IP 05-08

DATE ISSUED: JULY 2008

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

Resolution

TACD strongly supports the proposal to the WIPO Standing Committee on Copyright and Related Rights (SCCR) by Chile on November 22, 2005 (SCCR/15/5) and elaborated in March 2008 by Brazil, Chile, Nicaragua and Uruguay, for a working program on limitations and exceptions (L&E) for copyright. This proposal focuses on the concerns of and will be of benefit to consumers. The Brazil/Chile/Nicaragua/Uruguay proposal could be paraphrased as having three main elements:

1. To have the SCCR identify and share information on state practices in the area of L&E in the area of copyright,
2. To undertake research and to analyze the L&E needed to promote creative and innovative activity, and for the dissemination of creative and innovative works and services,
3. To establish agreements (including one or more treaties) to ensure member states adopt the minimum L&E needed to protect the public interest, especially as concerns the needs of the most vulnerable or social prioritized sectors of society.

TACD was deeply disappointed that during a March 2008 WIPO SCCR meeting, the EC and the US limited their support for a WIPO program on L&E to the sharing of information on state practices, and opposed activities relating to further analysis and norm setting.

TACD requests the EC and the US eliminate their opposition to the elements of the proposed L&E work program that relate to analysis and norm setting.

Needs of Visually Impaired Persons

A particularly compelling aspect of the Brazil/Chile/Nicaragua/Uruguay proposal is the opportunity to address concerns of visually impaired persons. The World Blind Union (WBU) has on several occasions petitioned and provided comments to WIPO asking the SCCR to address the need for norm setting in the area of minimum L&E, in order to improve their access to protected works. As detailed in their several submissions and comments to the SCCR, and discussed at length in WIPO's February 2007, 227 page "Study on Copyright Limitations and Exceptions for the Visually Impaired" (SCCR/15/17), the products and services that are needed by the visually impaired are most effectively provided globally, across national borders. As WIPO's 2007 study noted, "copyright legislation is territorial in nature... Where activity is undertaken across jurisdictions, it is usually, therefore, extremely difficult to determine with

certainty what parts of that activity are lawful and what parts are not.” The World Blind Union reports and WIPO confirms the extreme complexity and legal uncertainty of navigating different national copyright regimes, in order to publish works and services for the visually impaired in one country that are used in another country. The WBU has called for global norm setting to create the type of harmonization and legal certainty needed in the area of *minimum* L&E, in order to facilitate investment in services that are essential for expanded access to protected works for visually impaired persons.

Given the extensive documentation and the several years of petitioning WIPO for action, TACD is concerned that the EC and the US have not been sufficiently supportive of efforts to solve the problems of visually impaired persons. In this regard, we are particularly grateful for the delegations from Brazil, Chile, Nicaragua and Uruguay for their initiative.

What is true for the visually impaired is true for others groups and industries – namely that there are areas where cross-border publishing and innovative services cannot fully develop without greater harmonization and legal certainty regarding *minimum* L&E. However, the case for early action for the visually impaired is particularly clear, given the extensive research already undertaken in this sector, and the fact that it involves a highly vulnerable population.

An agreement on minimum L&E for visually impaired persons will present challenges, but with a modicum of good will by the EC and the US, it should be achievable. One benefit of early action to address the concerns of the visually impaired is that it may provide a concrete model for addressing other areas where there are compelling benefits of harmonization of minimum L&E. But in any event, it should move forward now.

TACD specifically calls upon the EC and US to meet with representative of TACD and World Blind Union to discuss this issue, and to propose, by the WIPO General Assembly in September 2008, a concrete proposal for addressing norm setting for the minimum L&E needed to expand investments in publishing and services for visually impaired persons. This proposal should anticipate a draft treaty on minimum L&E for the visually impaired be presented in the November 2008 SCCR meeting, and discussed further in the 2009 SCCR meetings, with a goal of scheduling a diplomatic conference in early 2010.

Access to Orphan Works

TACD supports work on the problem of access to orphan works, not as a separate agenda item in the SCCR, as proposed by the members of the European Union in the March 2008 SCCR meeting, but as part of the larger SCCR work program on L&E, within the framework set out by Brazil/Chile/Nicaragua/Uruguay.

In terms of the solutions to the problem of access to orphaned works, state practice is quite limited at this point, and it may be fruitful to focus on research and analysis as much as sharing of experiences. 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.

Relationship between term extensions and orphan works

TACD also calls attention to the relationship between the problem of access to orphaned works, and the extension of copyright terms. Many of the problems of access to older orphaned works are caused by the extension of copyright terms beyond that required by the Berne, Rome or WCT treaties or the TRIPS agreement. The older the work, the more difficult to locate “owners,” as records become lost or difficult to access, companies change addresses, go bankrupt or change names, and there is no recent history of exploiting the works commercially.

TACD members oppose such extensions of the terms for protected works. While reiterating our opposition to term extensions, TACD notes that in cases where governments do in fact extend terms, the harm to consumers can be limited somewhat by the introduction of limitations and conditions on the works that benefit from such term extensions. In particular, to the extent that any works benefit from term extensions, 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.

Summary of Action Items for EU and US

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,
5. 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.

Annex 14.

DOC No. IP 13-11

DATE ISSUED: JUNE 2011

Resolution on Competition and Copyright

Introduction and Motivation

Creative individuals, communities and industries increasingly depend on innovation in the digital technology industry. Creative and digital technology industries are both characterised by dominant players, network effects and use of copyright. Copyright law and licensing should support innovative and competitive markets, driving and financially rewarding technological and creative innovation. However, copyright systems cannot always be assumed to do this, and the practices of copyright owners do not always support innovative and competitive markets. Therefore competition law and policy has a key role to play in maintaining competitive creative and digital technology markets as they seek to prevent abuse of dominant position and anti-competitive agreements.

The Transatlantic Consumer Dialogue (TACD) wants to see a digital economy characterised by competitive, dynamic and innovative markets to which consumers have meaningful access to a wide range of knowledge, information and cultural products on fair terms. We want to see a copyright culture that supports this by striking a fair balance between the rights of creators, investors and consumers. Consumers are also creators, such as when they use copyrighted works as part of their own political or cultural expression. Unfortunately the reality is that there are many barriers to innovation and competition in these markets including:

- Market dominance by a few very large companies with large market shares
- Lock-ins and high switching costs for consumers through proprietary standards, Digital Rights Management (DRM) and onerous contract terms
- Excessively restrictive copyright law provisions and excessively expansive enforcement provisions
- Restrictive and excessively costly copyright licensing processes by collecting societies

These barriers raise prices, reduce consumer choice, hinder market entry by small new innovative companies offering new business models and hamper the development of a competitive and innovative digital economy.

TACD calls upon the US and EU governments to:

- Actively enforce and ensure compliance with competition law in creative and digital technology markets
- Encourage the use of open standards through public procurement, standards development and regulation
- Ensure adequate and workable fair use exceptions and immunise them from DRM and contractual over-rides
- Create sufficient disincentives to the misuse of copyright enforcement procedures
- Introduce competition impact assessments for all proposed amendments to copyright law

- Require efficient licensing models including extended collective licensing and cross-border licensing
- Introduce effective supervision, governance, transparency and accountability of collecting societies

Background

Market structure and characteristics

The creative and the digital technology industries are characterised by dominant companies with large market shares and monopolies, and a complex ecosystem of entrepreneurs, micro-businesses and small and medium sized enterprises (SMEs). Markets for digital products and services demonstrate network effects where a single standard emerges as dominant once sufficient numbers of consumers have adopted it. As a result, one producer tends to dominate the market and their products become the “standard” or the “gatekeeper” for complementary products. Despite the dominance of some players, such markets can experience a high degree of competition if there is rapid innovation and paradigm shift. Competition is on innovation, not price, and companies will invest in innovation and development to dislodge the incumbent with new technology.

However, the ability to dislodge the incumbent is reduced if the dominant company can prevent network effects by, for example, constraining consumer choice through lock-ins and high switching costs, such as proprietary standards, DRMs and onerous contract terms, or by preventing other companies from producing complementary interoperable products. For example, while most digital music is sold in MP3 format, a common format for hardware and software, some companies sell digital music in proprietary formats. Proprietary formats are commonly only supported by the hardware and software of the relevant company, for example Amazon’s e-books and Kindle hardware. This effectively prevents consumers switching hardware and software which stifles competition and the ability of companies to challenge the dominance of incumbents.

Failure by competition authorities to rigorously enforce competition law in the creative and digital technology industries will be to the detriment of SMEs who want to develop new innovative products, consumers who will face higher prices and restricted choice, and the development of the digital economy.

Copyright law and enforcement

Copyright law confers exclusive rights, such as the right to copy, adapt and distribute a work. These temporary monopoly rights effectively regulate the markets in knowledge goods and facilitate the financial reward of creativity and innovation. However, like any monopoly copyright risks stifling economic development and innovation as creators and innovators, including consumers, are prevented from building on past innovation. The exclusive rights conferred by copyright should be no more than is necessary to ensure a fair return to investors and creators, sufficient to reward and therefore incentivise creativity and innovation. Over the last few decades there has been an extension of both the scope and term of copyright, while fair access through copyright exceptions has been eroded. This over-extension of the monopoly rights has frequently been based on economic evidence provided by the industries seeking increased protection rather than a thorough independent assessment of the cost and benefits of such extensions to society as a whole. A recent proposal by the European Commission to extend the period of protection for sound recordings from 50 to 95 years has been heavily criticised and its passage through the legislative process delayed by the Council.

Copyright exceptions have an important role to play in allowing fair access to copyrighted work and encouraging social and commercial innovation. For example, the exceptions for fair use in the US and private copying in the EU make it possible for consumer electronics companies to develop technologies such as DVR. The fair dealing/fair use provisions and other exceptions in national laws as regards to criticism, review and news reporting are central to the functioning of the news and publishing media in a democratic society. The exceptions for the benefit of visually impaired people allow for the creation of assessable formats which would otherwise not be provided by the market. Copyright exceptions that allow consumers to format-shift the digital content they have purchased allow them to overcome lock-ins through propriety formats.

In the EU law copyrights are mandatory for Member States whereas most exceptions are merely permitted and Member States have implemented them in different, and sometimes very limited, ways. The US has a broad fair use defence which has provided welcome flexibility if a little uncertainty about what is permissible in practice. In addition, the exceptions designed to benefit consumers, public institutions and businesses can be denied through contract law and restricted through licensing provisions and DRMs. DRMs are protected through anti-circumvention provisions in most copyright laws regardless of their intention and effect. Copyright enforcement procedures can also have a significant impact. Expedited enforcement procedures and enhanced remedies, particularly when directed at internet intermediaries instead of the actual alleged infringer, can encourage the premature cut-off of fair or authorised uses.

Limited exceptions, which have not kept pace with technological development, and legal uncertainty cause a chilling effect discouraging innovation as companies seek to develop new products and services for consumers within the limits of existing copyright law. The role of exceptions in encouraging competition and innovation deserves recognition and support from policy makers.

Copyright licensing

Innovation and mass use of copyrighted content in the digital market requires appropriate licensing solutions by collecting societies. Consumer access to copyrighted content is in most cases not directly provided for by the copyright owner, but by licensees, such as leisure and hospitality businesses, radio and TV broadcasters, online retailers and platforms. While the internet has opened up a global market, allowing the cost effective sale and consumption of copyrighted content across national borders, collecting societies and copyright owners still insist that the exclusive rights conferred by copyright, and related rights, are licensed on a country-by-country basis.

When potential licensees are unreasonably refused a licence, or have unreasonable licence terms or rates imposed on them, it stifles competition and prevents the development of new products and services. Similarly, the high costs associated with obtaining licenses, including negotiating time, act as a barrier to the development of new digital business models. In 2005, the European Commission, quoting the European Digital Media Association (Edima) which represents online music providers, said that “the direct cost of negotiating one single licence amounts to €9,500 As mechanical rights and public performance rights in most Member States require separate clearance, the overall cost of the two requisite licences per Member State would amount to almost €19,000.”¹⁰¹ Licensing complexities are also a problem for

¹⁰¹ Commission staff working document: Study on a Community Initiative on the Cross-Border Collective Management of Copyright, Commission of the European Communities, Brussels, 7 July 2005 p47-48

audiovisual content. In the absence of functioning copyright licensing solutions consumers are denied access to their cultural heritage and innovative new products, while creators miss out on financial rewards resulting from the continuous use of their works.

Extended collective licensing provides access to creative works, ensuring that creators and copyright owners receive remuneration and allows licences to respond quickly to consumer demand. It facilitates smooth rights clearance and reduces instances where the licensing transaction costs make the use of works financially unviable. Such licensing schemes were designed to facilitate the cost effective mass use of copyrighted content in Nordic countries in the 1960s as market based alternatives to compulsory licensing. In the past 40 years extended collective licensing has been successfully implemented for radio and TV broadcast, and a number of education and research uses. Collecting societies, which are deemed sufficiently representative, can represent all copyright and related rights owners in a specific category of works on a non-exclusive basis. It allows collecting societies to issue “extended licences” covering the works of creators who are not members and ensures that non-members have the right to be remunerated by the collecting society, just as members are. Creators and copyright owners can opt-out of the extended collective licence.

There may be areas where innovative licensing solutions such as extended collective licensing allow collecting societies to overcome market failure and offer a viable alternative to compulsory licensing. Including in particular, markets for works where transaction costs for negotiating individual licences constitute a barrier to the development of new business models, services, and uses, particularly with regards to multi-media content and mass use of works in the online and broadcast environment.

The international **cross-border licensing** of copyrighted content has continuously been frustrated by collecting societies. Reciprocal representation agreements, negotiated by national collecting societies to facilitate cross border licensing, have repeatedly been found to be anti-competitive by competition authorities because they seek to maintain the territorial monopoly of collecting societies by imposing un-competitive terms on members and licenses. Yet International Confederation of Societies of Authors and Composers (CISAC) members have refused to amend their model contract, the Santiago Agreement. The European Commission has identified a number of anti-competitive practices by collecting societies which prevent cross-border licensing of music including territorial restrictions, discrimination in cross-border distribution of royalties, and membership rules which restrict cross-border licensing. In 2005 the European Commission concluded that “if left entirely to the market, innovative and dynamic structures at EU level for cross-border collective management of legitimate online music services would not emerge. This applies to cross-border licensing and cross-border distribution of royalties.”¹⁰²

The internet provides consumers and businesses with a global platform to exchange knowledge, goods and services. But by not offering the creative and digital technology industries the appropriate licences, collecting societies are limiting the emergence of new products, markets and technical development to the prejudice of consumers. Yet reciprocal representation agreements and cross border licensing are rarely within the scope of existing collecting society supervision arrangements.

Supervision of collecting societies

¹⁰² As above p23

Typically creators cannot choose which collecting society should administer their rights, and potential licensees cannot choose which collecting society to buy a licence from. Because collecting societies are monopolies they are subject to some regulation and supervision in most countries to ensure they comply with competition law. The majority of EU Member States impose transparency and accountability requirements on collecting societies through supervision by a designated body or the competition authorities. Countries such as Germany require prior authorisation for collective rights management and once established collecting societies are under permanent supervision. In the US the Department of Justice has imposed anti-trust consent decrees to target anti-competitive licensing practices by collecting societies which harm creator members and licensees.

Ongoing issues in relation to the way collecting societies operate and treat both their creator members and licensees who provide products and services to consumers demonstrate that more robust supervision of collecting societies is needed. The European Commission intends to bring forward a framework Directive to enhance governance, transparency and multi-territory licensing for online rights management in 2011. The recent Hargreaves review in the UK has recommended that collecting societies should be required by law to adopt codes of practice, approved by the Intellectual Property Office and the UK competition authorities, to ensure that they operate in a way that is consistent with the further development of efficient, open markets.

¹⁰³

All collecting societies should meet minimum standards on transparency, accounting, the publication of tariffs, distribution keys, annual accounts and management costs. To ensure that they effectively serve the interest of their members and licensees, and support competitive and innovative markets for copyrighted content, minimum standards on the treatment of licensees, members and reciprocal representation agreements with other collecting societies should be set and actively enforced.

¹⁰³ <http://www.ipo.gov.uk/ipreview.htm>

Annex 15.

DOC NO: IP 12-11

DATE ISSUED: June 2011

Resolution on Unlocking Access to Orphaned Works

Taking note of TACD resolutions on copyright adopted in July 2008¹⁰⁴ and in July 2009¹⁰⁵, TACD strongly urges US and EU authorities to overcome legal barriers to access to orphaned copyrighted works.

With copyright terms of life plus 70 years, and automatic copyright under national laws, there exist countless books, articles, pamphlets, letters, photographs, audio and visual recordings, software, architectural and other copyrighted works that are not being commercially exploited, and for which it is difficult or impossible to identify and or locate the owner of the copyright protecting the work. These works are largely inaccessible to the public, because copyright laws create large financial risks for acts of infringement associated with the copying, distribution and use of such works. Orphan works are potentially valuable to historians, documentary film makers, scholars, persons engaged in genealogical research, and artists. Solutions to the Orphan Works problem will require changes in copyright laws.

TACD points out that the lack of a legal solution that permits wide access to orphan works undermines the social credibility and legitimacy of international and national copyright law and its enforcement.

Among the measures that will expand access to orphan works are the following:

- Exceptions for uses of orphaned works.
- Limitations on damages for good faith infringement of orphaned works.
- Restrictions on the use of injunctions for new works that recast, transform, adapt or integrate an infringed orphaned work with a significant amount of original expression,
- Compulsory licensing of works
- Obligations to actively make protected works available, within the flexibility available under the WTO TRIPS Agreement

In considering mechanisms to expand access to orphaned copyrighted works, TACD notes that limitation on remedies for infringement are not subject to the “three-step” tests in the Berne Convention or the TRIPS that are applicable for certain exceptions to exclusive rights. For this

¹⁰⁴ http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=34&Itemid=40

¹⁰⁵ http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=34&Itemid=40

reason, it is quite important to avoid creating new global norms on remedies for infringement that reduce the flexibility to expand access to orphaned copyrighted works.

1. TACD supports wide and accessible registration of copyrighted works to facilitate the identification of the owners of protected works.

2. TACD calls for flexible and economically sustainable proposals that promote and permit the massive public and private digitalization of our common historical cultural heritage. To prevent a digital "black hole of the 20th century".

3. TACD requests the creation of an exception in copyright law for Orphan Works that can give the cultural sector, public bodies and citizens as a whole, legal certainty when digitalizing historical material. TACD also recognizes the need for creating incentives for rightsholders to digitise their works independently, or in collaboration with the cultural sector or public authorities. TACD calls upon orphan works to be digitized both in private and public programs, like the EU project Europeana.

4. TACD believes that legally guaranteed digital preservation, and digital access to the content of "orphan works" for educational, scientific and research purposes, should be a pillar of International, European and US Copyright laws.

5. TACD supports the use of (i) copyright exceptions, (ii) limitations on remedies for infringement, or (iii) the issuance of non-exclusive compulsory licenses, in cases where reasonable efforts to locate a copyright owner have been unsuccessful.

6. TACD objects to IPR enforcement regimes, such as ACTA, or the enforcement measures proposed by the U.S. in the Trans Pacific Partnership Agreement, that would increase damages and mandate injunctions and other remedies for infringement of orphaned copyrighted works.

7. TACD calls for the establishment of flexible and fair EU and US regulations to address the rights, compensation and obligations when a work ceases to be an orphan work, taking into account the interests of the right holders and the persons who have invested in making the work available, and the public interest in expanding access to orphan works.

8. These recommendations also apply, *mutatis mutandis*, for related or neighboring rights.

Annex 16.

DOC No. IP 14-11

DATE ISSUED: JUNE 2011

Resolution on Innovation and Access to Medical Technologies

The question of access to medicines is of global concern. For many citizens in the South, access to essential medicines is often a question of life or death while in the European Union and in the US, the cost of medicines is creating a growing financial burden for national health systems.

Equitable access to medicines requires sustainable responses to medical needs that go far beyond the current efforts of charity or international aid. It requires policies that allow for and promote the full participation and economic development of the South. The cost of research and development of new medical technologies can be substantial and requires investment by both the public & private sectors. Innovation in medical technologies also requires access to knowledge, materials & technology. The mechanisms to finance the cost of R&D for new medical technologies should be transparent, economically efficient and avoid conflicts of interest and anti-competitive practices, and be consistent with human rights, including the right to development.

Official EU and US inquiries in to the pharmaceutical sector have revealed a number of systematic anti competitive practices that lead to the delay of market access for more affordable generic medicines with the EU and the US. This raises major concerns about the incentives in the current system of innovation.

Monopolies over medical knowledge exclude many from the benefits of the development of medical technologies, while these are considered public goods. It is imperative to find an appropriate balance between protecting the interests of IP rights holders; incentives for innovation; the right to access to knowledge; and the protection of public health. Furthermore, it is essential to explore and establish new models for biomedical innovation that promote knowledge sharing and address critical barriers to access and innovation.

The EU and the US should also prioritise policies that ensure the rational use of medicines and curb malpractice driven by commercial interests, leading to irrational use and putting patients in danger.

1. General Principles

1 Consumers benefit from the development of new medicines but only when they are accessible, when they have a well established safety profile and when they have an added therapeutic value. Innovation and research should target public health and health results-driven

consumers' and patients' needs.

1.2 The costs of research and development of new medical technologies can be substantial, and require investments by both the public and private sectors. Innovation in the medical sector also requires access to knowledge, materials and technology.

1.3 The mechanisms to finance the costs of R&D for new medical technologies should be transparent, economically efficient and avoid conflicts of interest, fraud and anticompetitive practices, and be consistent with human rights and economic development.

2. Previous TACD Resolutions

2.1 TACD recalls and reiterates its support for the following resolutions relating to medical technologies:

- a) Pharmaceuticals. Doc No. HEALTH-1-99 Date Issued: April, 1999
- b) Access to Medicines in Developing Countries. Doc No. HEALTH-2-00 Date Issued: February 2000
- c) Data Exclusivity and Health Registration Data. Doc No. HEALTH-3-00 Date Issued: February, 2000
- d) Early Working of Patents and Research Exceptions. Doc No. HEALTH-4-00 Date Issued: February, 2000
- e) Patents on Genetic Diagnosis. Doc No. HEALTH-5-00 Date Issued: February, 2000
- f) Transparency of Pharmaceutical Economics. Doc No. HEALTH-6-00 Date Issued: February, 2000
- g) Global Access to Health Care, Doc No. TRADE-10-01 Date Issued: May, 2001
- h) Resolution on Intellectual Property Aspects of Pandemics. Doc No. IP 07-09 Date Issued: May 2009
- i) Enforcement of Copyright, Trademarks, Patents and Other Intellectual Property Rights. Doc No. IP 09-09 Date Issued: June 18, 2009

3. Control of Anti-Competitive Practices.

3.1 TACD calls upon the EU Member States and the US government to use competition legislation to address TACD concerns over barriers to generic competition, including measures such as "pay to delay" and fraudulent patent claims. In this respect TACD takes note of the results of EU Commission's Pharmaceutical sector inquiry and calls for the strict compliance with EU competition law.

3.2 TACD calls upon the EU Member States, the EU Parliament, the EU Council, and the EU Commission and the US to take stock of competition laws to address anticompetitive uses of patents to block follow-on innovation, including restrictive licensing of biomedical patents. In this regard, TACD calls upon the EC to take legal action to follow up its pharmaceutical inquiry into anti-competitive practices that was concluded in 2009.

3.3 TACD calls upon the US and the EU to investigate the restrictive licensing of patents on ritonavir, and important NIH funded drug discovery that is used in co-formulated protease inhibitor regimes for the treatment of HIV/AIDS.

4. Protection of Test Data and Medical Ethics

4.1 TACD expresses its concerns that the granting of exclusive rights in pharmaceutical test data is economically inefficient, subject to abuses and violates medical ethics.

4.2 TACD calls upon the US and EU to ensure that intellectual property rights for pharmaceutical test data are subject to safeguards against abuses, as are patents on medical inventions.

4.3 TACD notes it is economically wasteful to require generic manufacturers to replicate clinical trials on new medicines.

4.4 TACD notes that requirements for generic manufacturers to replicate clinical trials on new medicines violates Article 20 of the "Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects," which states the following:

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

4.5 TACD notes that the 2008 World Health Assembly called upon governments to:

promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines.

4.6 TACD asks the EU and the US to evaluate alternatives to exclusive rights for the protection of pharmaceutical test data, such as cost sharing models. In this regard, TACD encourages the US and the EU to consider the proposed language in Article 11 of the intellectual property chapter of the proposed Canada - EU Comprehensive Economic Trade Agreement (CETA), concerning steps taken to avoid "duplicative testing on vertebrate animals," which states:

7. Rules to avoid duplicative testing on vertebrate animals will be laid down by the Parties. Any applicant intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

8. The new applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

9. Where the new applicant and the holder or holders of the relevant authorisations of plant protection products cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the new applicant shall inform the Party.

10. The failure to reach agreement shall not prevent the Party from using the test and study reports involving vertebrate animals for the purpose of the application of the new applicant.]

10. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The Party may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law.

4.7 TACD opposes the inclusion of data exclusivity requirements in trade negotiations which will delay generic competition and limit access to medicines in developing countries.

5. Developing Country Trade Policies

5.1 TACD condemns the seizures in EU ports of legitimate generic medicines in transit destined for developing countries and calls upon the EU to amend its customs regulation EC1383/2003 to remove the threat of further seizures.

5.2 With respect to trade agreements and medical technologies, the TACD reiterates its opposition to trade agreement obligations on developing countries that exceed obligations already contained in the WTO TRIPS agreement.

5.3 TACD notes in particular its opposition to demands that developing countries adopt exclusive rights for pharmaceutical test data, patents on new uses of existing medicines, patent extensions, or linkages between private patent rights and the government regulatory approval of medical technologies.

5.4 TACD condemns EU and the US bilateral trade pressure on developing countries for using the flexibilities in the TRIPS Agreement to expand access to medicines, pursuant to important global norms on public health, including paragraph 4 of the 2001 Doha Declaration on TRIPS and Public Health, or the 2008 WHO Global Strategy on Public Health, Innovation and Intellectual Property (WHA61.21). TACD condemns the use of “name and shame” lists such as the US “Special 301 Watchlist” to discourage countries from making use of legitimate public health safeguards to secure access to medicines for their citizens.

6. Research and Development

6.1 When feasible and efficient, consumers support the de-linking of research and development costs from the price of medical technologies. In this regard, we support implementation of the following recommendation in WHA61.21, the WHO Global strategy on public health, innovation and intellectual property:

Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product.

6.2 TACD supports exploration of alternative models for innovation and pricing, including but not limited to prize funds to reward innovations, product development partnerships for affordable new products, open source dividends to reward openness and sharing of knowledge, materials and technologies, and increased public sector funding of R&D, including clinical trials for product development and to establish comparative effectiveness.

6.3 TACD calls upon the US and the EU to support an alternative global framework of R&D, that recognizes the importance of both public and private sector investments, access to medical technologies, human rights, development, and promotes greater access to scientific knowledge. Possible elements for such a framework have been described in the 2009 submission to the WHO Expert groups on R&D Financing:

PROPOSAL by Bangladesh, Barbados, Bolivia and Suriname for WHO Discussions on a Biomedical R&D Treaty, April 15, 2009.

Possible Elements of a WHO Biomedical R&D Treaty

Discussions on a biomedical R&D treaty should focus on a wide range of issues that would benefit from global coordination, collaboration and norm setting, including, but not limited to, creation of a framework for sustainable funding support for priority medical R&D. A comprehensive biomedical R&D treaty should address, at a minimum, the following elements:

1. Coordination and facilitation of periodic global priority assessments—including estimates of funding needs—for R&D to address public health needs.
2. Norms and mechanisms to ensure sustainable financing for R&D, including funding for:
 - (a) the development and delivery of health products and medical devices to address the special health needs of developing countries;
 - (b) the development of new antibiotics, vaccines, and other global priority health products and medical devices;
 - (c) funding of basic health-related science, open libraries for materials, open databases, open access medical publishing, and other initiatives to enhance and expand access to medical knowledge;
 - (d) the global sharing of costs for clinical trials associated with the development and independent evaluation of new medical products; and
 - (e) other relevant matters.

3. Measures to facilitate, encourage, and otherwise stimulate new incentive schemes for R&D (such as medical innovation inducement prizes, advanced market commitments, openness dividends, and other new innovative approaches), with special attention to measures that de-link R&D incentives from product prices, and reward innovations that improve health outcomes.
4. Possible governmental agreement to contribute to the global cost of R&D, considering each nation's level of development, size of economy and capacity to pay, in order to establish global norms for R&D contributions. Contributions should be allowed through multiple means.
5. Global norms and best practices to facilitate access to government funded research.
6. Norms and measures regarding the transparency of global medical innovation, including but not limited to:
 - (a) Agreements on the required disclosures of clinical trials, including results, in publicly accessible registries;
 - (b) Requirements for greater disclosure of the costs of R&D inputs, such as the costs of clinical trials;
 - (c) Standards for reporting and sharing information on resource flows used to support R&D; and
 - (d) Greater transparency of the terms under which intellectual property rights are licensed, including, for government funded research, disclosures of licensing provisions regarding access to inventions.
7. Mechanisms to develop and improve innovative capacity for research and development, particularly in developing countries.
8. Measures to facilitate encourage or otherwise stimulate the transfer of technology between developed and developing countries as well as among developing countries.
9. Norms promoting the management of intellectual property rights in a manner that reconciles the public interest in access to knowledge and health-related innovation, including prioritizes the R&D needs of developing countries, and that protects public health and promotes access to medicines.
10. Relevant measures to improve the delivery of and access to health products and medical devices.
11. Mechanisms to monitor and evaluate both the performance of global R&D efforts and the implementation of the treaty, including appropriate reporting systems.

12. Measures to more effectively achieve compliance with appropriate ethical standards for medical research.

6.4 TACD calls for the EU to incorporate into its financial commitments concrete proposals to de-link R&D costs from the price of medicines through the promotion of biomedical innovation prizes and the reversion of public investments into medical research into shared public knowledge and goods within the context of the 8th Framework for Research and other EU innovation programs.

7. Counterfeits and Pharmaceutical Fraud

7.1 Consumers face a number of serious risks in developed and developing countries as regards pharmaceutical fraud:

- a. Counterfeit drugs: the practice of falsely claiming to be an authorized product of another firm, including but not limited to the use of another firm's mark to deceive the public.
- b. Deliberately manufacturing and marketing falsified products that do not contain the required active ingredients or not contain the right amount of active ingredient.
- c. Packaging and labeling of drugs that make false claims regarding medical properties, including but not limited to the active medical ingredients, the date of expiration of products, or the methods of storage.
- d. Marketing of products using false claims regarding the efficacy of the product which will lead to its irrational use or deliberately failing to provide information about safety concerns of the product.
- e. Deliberate suppression of data, including evidence from clinical trials that reveal adverse secondary effects of the medicine.

7.2 Not all types of fraudulent practices concerning pharmaceutical drugs can be usefully addressed through the enforcement of intellectual property rights. For example, remedies to certain types of fraud are best addressed by improving the capacity and resources of government authorities with responsibility for the regulation of medicines manufacturing, distribution and marketing authorisation.

7.3 TACD urges the EU and the US to support a new resolution at the WHO on pharmaceutical fraud.

Annex 17.

DOC No: FINANCE 02-11

DATE ISSUED: June 2011

Resolution on G20 Action on Financial Consumer Protection

Background

Financial services, their governance and their development, are particularly important to consumers in the EU and US, who rely on financial products and services to facilitate purchases, for savings and investments and to insure against risk. Over the years, however, financial products, such as mortgages, investments, credit cards, small loans and other payment products, have become more complex and potentially risky for consumers. The rapid pace of innovation in the market and the long term nature of many transactions mean that consumers need protection at every level in order to avoid the considerable risks that these services pose.

The financial system also needs those protections to insure its own stability. The financial crisis of the last several years dramatically illustrates that weak consumer protections pose a significant risk to the wider economy. In the words of Sheila Bair, the Chair of the US Federal Deposit Insurance Corporation, *"There can no longer be any doubt about the link between protecting consumers from abusive products and practices and the safety and soundness of the financial system."*¹⁰⁶ Similarly, the January 27, 2011 final report released by the Congressionally mandated Financial Crisis Inquiry Commission (FCIC) concluded that the financial crisis was an "avoidable" disaster caused by widespread failures in government regulation, excessive risk taking by Wall Street and corporate mismanagement.¹⁰⁷

TACD has previously expressed its concern at the slow effort of both governments and the financial industry to correct the continuing market failures and recognized the urgent need for them to take action on financial consumer protection, notably in its resolution of June 2009¹⁰⁸

¹⁰⁶ Statement of Sheila C. Bair, Chairman of the Federal Deposit Insurance Corporation, on Modernizing Bank Supervision and Regulation before the US Senate Committee on Banking, Housing and Urban Affairs, March 19, 2009

¹⁰⁷ FIN. CRISIS INQUIRY COMM'N, THE FINANCIAL CRISIS INQUIRY REPORT: FINAL REPORT OF THE NATIONAL COMMISSION ON THE CAUSES OF THE FINANCIAL AND ECONOMIC CRISIS IN THE UNITED STATES xvii-xxv (2011), *available at* http://c0182732.cdn1.cloudfiles.rackspacecloud.com/fcic_final_report_full.pdf.

¹⁰⁸ TACD resolution on financial services regulation June 2009
http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=214&Itemid=40

and through the subsequent 2010 Ljubljana declaration on consumers and financial services,¹⁰⁹ to which it is a signatory.

TACD is continuing its engagement in the field of consumer protection in financial services and will be holding a one-day conference for consumer organizations, government and regulator representatives, as well as other stakeholders, in June 2011 in Brussels. The aim of the conference is to evaluate the new initiatives in the field of financial sector reform and address the unresolved issues and urgent needs for further action.

Building on these initiatives, Consumers International, the global federation of consumer organizations, and its members launched a campaign in late 2010 calling on the Group of 20 to take action to improve consumer protection in financial services. In November¹¹⁰ 2010, G 20 leaders meeting in South Korea made the following commitment in the Seoul Action Plan¹¹¹:

Enhancing consumer protection: We asked the Financial Stability Board to work in collaboration with the OECD and other international organizations to explore, and report back by the next summit, on options to advance consumer finance protection through informed choice that includes disclosure, transparency and education; protection from fraud, abuse and errors; and recourse and advocacy.

The FSB and OECD are due to present their report to G20 leaders at the summit in France in November 2011.

Additionally the G20 finance ministers at their meeting in February 2011 requested that the FSB and OECD develop common principles on consumer protection in financial services. The French presidency of the G20 has also announced that a high level conference on consumer protection in financial services will be held in October 2011, the results of which would be expected to contribute to the final report.

Recommendations

In the context of the discussions described above, TACD calls on the governments of the US and EU to work with the FSB and OECD to implement the commitment made in the G20 Seoul Action Plan to “report on options to enhance consumer protection” in financial services.

Specifically, the TACD urges the US and EU governments to collaborate with the FSB and OECD to develop a strong set of recommendations drawing on those listed below¹¹²; support

¹⁰⁹ Ljubljana declaration on consumers and financial services, May 2010

http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=291&Itemid=40

¹¹¹ G-20 Seoul Summit document, Action Plan para 41, G 20 Seoul. 2010

¹¹² These recommendations draw on those developed by Consumers International, which are outlined in their publication “Safe, fair and competitive markets in financial services: recommendations for the G20 on the enhancement of consumer protection in financial services”, March 2011.

<http://www.consumersinternational.org/media/669348/cifinancialreport2011.pdf>

their adoption at national and where appropriate international levels, and establish suitable processes to review their implementation.

1. Information design and disclosure

Consumers should receive clear, sufficient, reliable, comparable and timely information about financial service products. Severe failure to meet these criteria should cause a contract to be voidable. Contracts must include clear up front pricing so that consumers can appreciate the cost of the product before becoming obligated to pay. Financial service providers should be responsible for testing the quality and comprehensibility of the information provided, with additional audits conducted by national regulators.

Standard formats (such as Key Information Documents) should be used for the presentation of information about financial service products so that consumers can easily compare products.

2. Contracts, charges and practices

Many financial service products are now so complex that consumers, regulators and even the financial service providers themselves cannot understand them. This complexity needs to be managed and, if necessary, overly complex products should be kept off the market. Regulators should introduce a requirement of comprehensibility and prohibit products that are not comprehensible. They should require the availability of simple standard financial service products, and key financial service products should be required to meet minimum standards of consumer protection.

Conflict of interest in the provision of advice and sale of financial services needs to be addressed. Commissions and related charges must be fair in amount and be made transparent at an early stage. Financial advice to consumers should be subject to a fiduciary duty to act in the customer's best interests. . Advisers should seek to minimize, appropriately manage, and fully disclose any conflicts of interest. Disclosure of conflicts should occur at a time that enables the consumer to make an informed choice among advisers.

Additionally, there should be protection against inappropriate marketing methods.

The following practices should be cause for appropriate sanctions, including in the most egregious cases, for a contract to be voidable:

- failure to gain the informed consent of the consumer
- unfair or unreasonable fees and costs charged to consumers and included in consumer contracts for financial services products
- clauses in financial service contracts that result in consumers' waiving core consumer protections, and
- the sale of financial services that are unsuitable for the consumer.

3. The structure and functions of national financial consumer protection bodies

Under the UN guidelines for consumer protection, all governments have a responsibility to protect and promote consumer rights.¹¹³ Governments should each establish a national body

¹¹³ *UN Guidelines for Consumer Protection* Adopted 1985, expanded 1999, re-adopted in General Assembly decision 54/449 ; UN 2003

that has consumer protection as an explicit regulatory objective with full authority to investigate, halt and remedy violations of consumer protection law, including where necessary the right to define specific practices or products as unfair, deceptive or otherwise illegal.

The body should have effective regulatory power over every financial institution, product and provider and, in response to a serious failure to abide by consumer protection rules, it should have the power to remove an institution's license or, in response to lesser abuses, impose penalties sufficient to discourage repetition. The body should have sufficient funding and resources to conduct the tasks assigned to it.

The body should be independent of the industry, free from conflicts of interest and include a balance of members with industry and consumer expertise and include staff with broad knowledge and expertise. It should be transparent and should clearly publicize occasions where it has taken action against specific practices and products or misleading financial promotions either industry wide or against specific firms. Reputational regulation should be initiated to allow consumers to choose providers based on firms' record of treating customers fairly. There should be strong links with other consumer protection bodies (including representatives of consumers) to ensure that experience and expertise in consumer protection is shared. Representatives of the consumer interest should be integrated into the governance of the sector at national level. Consumer organizations should have a right to initiate a formal procedure at the consumer protection agency if they have arguments and cases for a serious consumer detriment / provider misconduct aimed at a multitude of consumers.

4. International Trade Agreements Should not Undermine Financial Regulation

Financial services strictures under the World Trade Organization (WTO) and other international trade agreements could undermine financial regulation. Financial Transaction Taxes (FTT), capital controls, bans on risky financial services and size limits on banks are some of the policies at risk as provisions of the WTO General Agreement on Trade in Services (GATS) prohibits whole categories of regulation in committed services sectors.

Unless WTO limits on non-discriminatory financial regulations are removed and/or a meaningful safeguard for prudential measures is inserted, U.S. and EU governments should lead the G20 in halting further demands for more WTO financial services liberalization in the Doha Round.

5. Redress and dispute resolution systems

Access to dispute resolution and redress is one of the eight consumer rights. Still, there is a serious risk that such systems are absent, not acting independently and neutrally, or being overwhelmed by the sheer number of complaints relating to financial services. This underlines the importance of preventing complaints arising through the introduction of effective upstream consumer protection.

Governments should ensure that consumers have access to adequate redress mechanisms, which are "expeditious, fair, inexpensive and accessible."¹¹⁴ Ideally, there should be one clearly identifiable scheme for redress per sector. Consumers should be proactively informed about the

¹¹⁴ UN Guidelines *op cit.* Art 32

availability of such a system. Governments should also provide collective redress mechanisms in order to reduce the demand for individual proceedings.

Findings from these redress mechanisms should be synthesized and reported to regulators in order to inform future regulation and enforcement.

6. Promoting competition in financial services

The financial crisis led to a significant reduction in competition in the financial services sector, which was already suffering from a high level of market concentration. Competition is an important consumer issue, and TACD strongly recommends that the G20 take action to promote competition on terms that enhance consumer protection in financial services.

The G20 should recognize that it is counterproductive to allow competition law to be overridden in the interests of financial stability, as it results in the creation of even larger institutions and increases the probability of taxpayers' needing to provide support in the future. In addition, steps to support financial institutions which are "too big to fail" can distort competition.

The G20 should therefore encourage member countries to instigate independent competition inquiries into the increases in concentration and reduction of competition caused by the financial crisis and recommend that national governments apply 'public interest tests' to the disposal of their stakes in the banking sector. This should include specific objectives to make competition stronger after disposal of the stakes so that some of the increase in concentration is reversed.

Additionally, to encourage new entrants, governments and regulators should take steps, such as those pertaining to comparability of products, portability of account numbers and others, to ease switching of accounts for consumers. Finally, regulators should encourage '*reputational regulation*' by publishing details of complaint numbers, compensation and enforcement action so consumers can choose a provider of retail financial products based on their track record.

7. Measures to promote stability and safety of consumers' deposits and investments

The financial crisis dramatically highlighted how new banking practices are exposing consumers to enormous risk. Rather than manage risk, the structure and practices of the financial services sector magnified risks to a level that threatened the collapse of the sector itself.

TACD urges the US and EU to support a G20 leader agreement to use leverage control to reduce risky activity rather than starve consumers and businesses of access to credit. These measures should be complemented with the use of non-operating holding company (NOHC) structures to address contagion and counterparty risk directly, including maintaining demarcation between investment banking and retail banking reducing risk of cross-contamination through legal separation of operations. Living wills for financial entities should be introduced and should contain provisions for the treatment of customers so that financial institutions can fail without causing catastrophic damage to consumers or the economy.

Credit ratings agencies should be liable for the validity of their analyses and should be answerable to prudential supervisors. In particular it is necessary to purge the conflicts of interest between the carrying out of analyses by these agencies and the subsequent public reports on the one hand, and, on the other, payment by financial services providers for an

evaluation which will have an impact on the value of those same businesses. The agencies need to move more to a role of independent auditing as is customary for businesses in many jurisdictions, so that the auditors themselves have a public responsibility for the validity of their reports.

Greater transparency and accountability in financial transactions will also help to reduce risk. Actions should include developing systems to assess consumers' capacity to take on financial commitments, giving consumers access to risk data regarding individual financial service providers and ensuring that loan assignees should be liable for the practice of the original credit granter.

Deposit protection schemes should provide cover for each separate brand and create a seamless transition of essential banking services with consumers maintaining access to deposits used for transactional banking. Any payment from the protection scheme regarding deposits held in savings accounts should be made within seven days. Measures should also be introduced to provide flexible cover for temporary high balances.

And insolvency procedures should be reformed so that the rank of creditors is changed to put depositors at the top.

8. Access to basic financial services and the role of new forms of service

Universal access to free or affordable basic financial services should be a specific aim of government policy on financial services. New innovations and technologies are already making great strides in this area, increasing access but also raising new challenges for consumer protection. Governments should seek to encourage innovation in safe, effective, low cost methods for banking inclusion whilst supporting the development of consumer protection.

With regard to the important issue of remittances, the EU and US should support G20 development of the General Principle on Remittances (2007) with a view to introducing a stronger consumer orientation, with consumer protection as a primary objective.

9. Conclusion: ongoing international co-operation on financial consumer protection including reviews of implementation

There is now an urgent need for stronger international co-operation on financial consumer protection. The financial crisis showed that weak consumer protection in one country can pose a risk to other countries and the global dimension of financial services means that financial market conduct regulators around the world now face similar issues and challenges.

The G20 should therefore support the establishment of a permanent international organization to enable national financial consumer protection bodies to compare notes, share good practice and develop minimum international standards and guidelines based on the recommendations in this report, and review their implementation. The new organization should have consultative status with other international financial regulatory bodies and actively co-operate with these organizations and consumer organizations in the development of research, institutional capacity, guidelines and agreements, fraud monitoring and scrutiny of industry practices.

The new organization should have a network structure with representatives from national financial consumer protection bodies and the resources to establish a Secretariat. An independent consumer panel should also be established made up of representatives from independent consumer organizations with competence in financial consumer protection to monitor advise and challenge the work of the organization.