EU-U.S. HIGH-LEVEL REGULATORY CO-OPERATION FORUM

Joint Report to the Transatlantic Economic Council Spring meeting

Brussels, 13 May 2008

TOWARDS ENHANCED CO-OPERATION BETWEEN THE EUROPEAN UNION AND THE UNITED STATES OF AMERICA ON THE SAFETY OF (IMPORTED) PRODUCTS

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EXECUTIVE SUMMARY

Product Safety is a matter of concern of both the United States of America and the European Union. Our economies are confronted with very similar challenges arising from imported consumer products. Thus, joint efforts and intensified cooperation on product safety matters are in our mutual interest.

In November 2007, the Transatlantic Economic Council identified the safety of imported products as a priority for future work. To that end, the EU-U.S. High-Level Regulatory Cooperation Forum was requested to develop a report aiming to identify possibilities for as well as constraints to better transatlantic information sharing in the field of product safety (with particular emphasis on safety concerns arising from imported products) and to issue concrete recommendations for improvement in various sectors.

The report has been co-ordinated by the Directorate-General for Enterprise and Industry of the European Commission and the U.S. Office of Management and Budget based on contributions from several Commission Directorates-General and U.S. regulatory agencies.

The report describes the regulatory system of the U.S. and of the EU in seven areas **(motor vehicles, pharmaceuticals, cosmetics, toys, electrical equipment for consumer use, other non-food consumer products and food)**, including **customs measures** relating to product safety. It confirms that the U.S. and the EU have sound and comprehensive regulatory frameworks for consumer product safety in place.

The report analyses in detail existing bilateral information exchange mechanisms in the field of consumer product safety. It shows that both the U.S. and the EU are dedicated to the timely sharing of relevant information and that there is a **good degree of useful cooperation** in various sectors. However, both sides have identified a clear **need to improve the existing cooperation** in the short and long-term with a view to effective information sharing, thereby improving public health and safety by increasing the overall efficiency of our respective market surveillance and enforcement systems.

Protection of confidential business information has been identified as the major issue to consider when increasing information exchange in all sectors and areas examined in the report. Even where advanced confidentiality agreements are already in place to allow for some sort of exchange of confidential information (for example, pharmaceuticals and cosmetics), there is still scope for improvement.

Engaging in a fuller exchange of confidential information requires legal changes in our systems and, hence, the necessary political will to implement such changes. First, in many cases the U.S. agencies concerned need to be given the statutory authority to engage in more extensive information exchange. Second, the EU and the Member States need to set up mechanisms to ensure that confidentiality is adequately protected across the network, so that the information received from the U.S. authorities can effectively reach all national market surveillance authorities and, conversely, information that is available at Member State level can also be fed into the circuit. Third, a mandate to expand the scope of existing information exchange agreements or to negotiate new enhanced agreements will be required. Such agreements should be based on reciprocity, define what types of information should be treated as confidential and provide for the necessary confidentiality safeguards.

The report contains a set of **detailed conclusions and specific recommendations** to advance transatlantic cooperation on the safety of products in all above areas.

The report will be presented for endorsement to the Transatlantic Economic Council meeting on 13 May 2008 in Brussels.

A. INTRODUCTION

In our economies, product safety is a critical issue. Our marketplaces are dynamic and products are transported around the globe. The U.S. and the EU are confronted with very similar challenges arising from imported food and non-food products. Large shares of consumer products that are in use in the European Union and the United States have their origin in third countries. During the last years imports from third countries have considerably increased.

Thus mechanisms to maximise the rapid detection of unsafe products imported into the U.S. and EU and an efficient exchange of mutual information on those products are in our common interest to ensure that consumers enjoy a high level of protection. We have good potential for joint cooperation aimed at sharing information to increase the overall efficiency of our respective market surveillance and enforcement systems.

In November 2007 high representatives of the European Commission and the U.S. government decided at the High-Level Regulatory Cooperation Forum in Washington DC to intensify their cooperation relating to the safety of imported consumer products. The Transatlantic Economic Council (TEC) of 9 November 2007 endorsed this initiative.

This joint report is based on contributions from various services of the European Commission and U.S. Regulatory Agencies. It gives an overview of the main elements of the regulatory systems in place in the EU and the U.S. to ensure product safety in a number of key product areas that are crucial for consumer health and safety: motor vehicles, pharmaceuticals, cosmetics, toys, electrical equipment for consumer use, other consumer products and food. In addition the report addresses customs measures applicable when the above categories of goods cross the border into the U.S. and EU. Finally the report identifies possibilities for and constraints to better transatlantic information sharing in the field of product safety with particular emphasis on safety concerns arising from imported products.

The report contains recommendations for an improved information exchange for presentation at the TEC meeting on 13 May 2008.

The coordinating services for this report have been DG Enterprise and Industry (DG ENTR) on the EU side and the Office of Management and Budget on the U.S. side.

B. OVERVIEW OF THE EU AND U.S. REGULATORY SYSTEMS REGARDING SAFETY OF CONSUMER PRODUCTS

I. Horizontal Legislation / General Principles

I.1 U.S.

I.1.1 General Principles

The U.S. regulates safety through a comprehensive set of strong food and product safety standards, which are explained in more detail below, while maintaining one of the most open food and product markets in the world. In addition, the U.S. is continually seeking ways to improve its import safeguards. Specifically, the Interagency Working Group on Import Safety, made up of senior U.S. Administration officials, was established by Presidential Executive Order on July 18, 2007, to conduct a comprehensive review of current import safety practices and determine where improvements can be made. More information on this Working Group, including its *Strategic Framework* and *Action Plan*, and import safety requirements in general, can be found at http://www.importsafety.gov/.

I.1.2 Consumer Products

The Consumer Products Safety Commission (CPSC) relies on four main statutes: **The Consumer Product Safety Act; the Federal Hazardous Substances Act; the Flammable Fabrics Act; and the Poison Prevention Packaging Act.** Generally, these statutes give the CPSC authority over "consumer products," which encompasses almost every consumer product that is not specifically covered by another agency's jurisdiction. With respect to imports, most provisions of these main CPSC-administered statutes apply equally to manufacturers, retailers and importers of consumer products.

Products found to not be eligible for entry into the U.S. may, under certain circumstances, be re-exported, destroyed, or otherwise disposed of by the subject firm and/or by Customs and Border Protection (CBP). Once products have entered the stream of commerce, they become the responsibility of the CPSC, which conducts a variety of market surveillance and other compliance-related activities to remove from the market both products that violate one or more mandatory safety standard as well as those that contain a defect that poses a substantial product hazard to American consumers.

The primary tool the CPSC uses to remove such violative and defective products from the market is the recall, the large majority of which are entered into voluntarily with the subject firm. Lesser or more extensive corrective actions may be called for by the CPSC, which generally enters into "corrective action plan" with the subject firm.

I.1.3 Customs

CBP, through authority granted by **the Tariff Act of 1930, the Trade Act of 2002, and the SAFE Port Act of 2006**, exercises its regulatory authority to require detailed advance electronic cargo information on arriving goods. Coupled with its general inspection and examination authorities, CBP may sample and hold merchandise on behalf of other Government agencies (for example, the Food & Drug Administration and the CPSC) that

have specific authority to determine the admissibility of these products. CBP also exercises enforcement authority through the use of bonding procedures as permitted by the general authority under 19 U.S.C. 1623. CBP also has authority under the Tariff Act to seize merchandise that is imported in violation of any health, safety or conservation prohibition.

To accomplish this, CBP works with other U.S. government departments and agencies to detect and stop unsafe product both at U.S. borders and prior to exportation to the U.S. Some of the areas where CBP has recently exercised enforcement and compliance activities include: fish, toys, lighters, electrical equipment, and flammable children's sleepwear.

When there is a concern that an unsafe product has entered into the U.S., CBP works with the regulatory agency to stop, detain and/or seize additional shipments which may be arriving into the U.S. CBP uses its automated systems to target these shipments prior to arrival in the U.S. If a product has entered into the commerce of the U.S. and is later found to be unsafe by CBP or a partner U.S. regulatory agency, CBP has the authority to demand that the merchandise be redelivered to CBP custody or control. If the merchandise is not redelivered, CBP will issue a monetary penalty against the importer of record.

I.1.4 Environmental Protection Agency Regulations Relevant to Imported Products

The U.S. Environmental Protection Agency (EPA) has legal authority for regulating imports in six program areas: toxic substances, pesticides, hazardous wastes, vehicles and engines, ozone depleting substances, and fuels, under the following statutory and regulatory authorities: **Toxic Substances Control Act (TSCA); Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Federal Food, Drug and Cosmetic Act (FFDCA); Resource Conservation and Recovery Act (RCRA) Subtitle C; Clean Air Act (CAA) section 203 and 211.** Certain export authorities exist under four of the program areas, including toxics, pesticides, hazardous wastes, and ozone depleting substances.

EPA and the CBP jointly implement regulations developed by CBP in consultation with EPA for TSCA and FIFRA. Under TSCA, EPA ensures that chemicals manufactured, imported, processed, or distributed in commerce, or used, or disposed of in the U.S. do not pose any unreasonable risk to human health or the environment. While TSCA covers a broad array of products, including articles composed of chemical substances or mixtures, TSCA exempts pesticides, tobacco or tobacco products, nuclear material, firearms and ammunition, food, food additives, drugs, cosmetics and devices. Under FIFRA, the Agency regulates the registration, distribution, sale, and use of pesticides in the U.S., (including imported pesticides) as well as limited regulation of pesticides exported from the U.S. In addition, under FFDCA, EPA sets permissible levels of pesticide residues in food.

EPA also administers the Clean Air Act (CAA), under which the Agency regulates emissions from mobile sources, such as new highway vehicles and trucks, and off-road engines and equipment, including the fuels used by highway vehicles or off-road engines and equipment. The standards apply to these products and fuels, whether built in the U.S. or imported into the U.S.

The Agency also implements the U.S.'s obligations under the "Montreal Protocol on Substances that Deplete the Ozone Layer," to control substances that deplete the Earth's protective ozone layer in the upper atmosphere. The Protocol and the CAA impose limits on the production and consumption of certain ozone-depleting substances (ODS), according to

specified schedules. EPA also cooperates under the Clean Air Act with FDA in determining whether an FDA-regulated product that releases an ODS, such as a metered dose inhaler, is an "essential use" of the ODS for which the U.S. should receive allocations under the Protocol.

Using a combination of various domestic regulatory programs, voluntary initiatives, and information sharing efforts, EPA carries out its statutory responsibilities. EPA works with foreign governments and private entities to promote compliance and assure import safety because product requirements established by EPA must be met by producers in countries exporting to the U.S.

Under TSCA, EPA has the authority to impose testing requirements, information reporting and recordkeeping obligations and restrictions relating to chemical substances and mixtures. Importers of chemical substances and mixtures must certify at the point of entry into the U.S. that the chemical substances in their shipment either comply with TSCA or are not subject to TSCA. TSCA allows for the seizure of a chemical substance, mixture or article if EPA has determined it presents an imminent hazard.

FIFRA requires that foreign establishments annually report the amount of pesticides and/or devices imported into the U.S. Importers must provide a Notice of Arrival with each pesticide imported.

Under the CAA, emissions from mobile sources, such as vehicles, engines (e.g., tractors, lawnmowers and generators), and equipment that are imported into the U.S. must meet EPA standards and must be covered by a valid certificate of conformity from EPA. In addition to certification, the CAA requires certified engines and vehicles to bear emission labels that identify the engine or vehicle as certified. For the import of fuels, importers of fuels for use in mobile sources (highway or off-road vehicles, engines, and equipment) are registered to import fuel and/or fuel additives into the U.S., and that fuel or fuel additives meet applicable CAA requirements.

Regarding controlled ODS, they are divided into two different "classes" of substances depending on the amount of ozone depletion caused by that substance, and controls across these two classes range from outright bans to restrictions (including an allowance tracking system) to limited exemptions. EPA tracks the ODS quantities that companies produce or import (as reflected in quarterly reports submitted to EPA) against their allocations for a year. Importers may also petition EPA for importing used or recycled ODSs with certain controls.

I.1.5 Occupational Products

The Occupational Safety and Health Administration (OSHA) is authorized to regulate workplace health and safety under **the Occupational Safety and Health Act of 1970 (OSH Act)**. This statute authorizes OSHA to promulgate safety and health standards, which place obligations on employers to protect their employees from workplace hazards. Employers must follow these standards, as well as the General Duty Clause of the OSH Act, which requires employers to furnish a place of employment free of recognized hazards likely to cause death or serious physical harm.

The Agency's authority therefore extends to any product that may be used at the workplace (e.g. electrical equipment, machinery, personal protective equipment, etc.), including products

that are capable of dual use at the workplace and by households (e.g. office equipment such as computers, printers, faxes, etc.).

I.2 EU

I.2.1 General Principles

In the European Union a comprehensive set of legal instruments is in place to ensure the free circulation of products while at the same time providing for high levels of health and safety to be respected. The effective functioning of the internal market is ensured through either EU-level harmonisation of health and safety requirements for the placing of products on the market or the mutual recognition of national requirements.

The so-called *Acquis Communautaire* for the free movement of products covers in particular obligations for economic operators, product safety requirements, conformity assessment procedures for products to be placed on the market, competences of conformity assessment bodies, control of products from third countries and market surveillance including the powers of market surveillance authorities to check, ban/forbid or remove unsafe products from the market and end users. Controls on product safety relate to all products placed on the EU market.

Since mid-80s, the vast majority of harmonising legislation developed at EU level has been based on the so-called "New and Global Approach", i.e. an approach based on mandatory essential health and safety requirements underpinned by voluntary harmonised standards developed by European Standardisation Organisations, a combination of conformity assessment procedures reflecting the level of product risk and a general obligation on the Member States to carry out post-market surveillance.[1] Under EU sectoral harmonising legislation the same safety requirements and conformity assessment procedures apply to the products within their scope, irrespective of whether they are intended for consumer or professional use.

The general legal framework for the marketing of products has been recently revisited. Specifically, a new Regulation setting out the requirements for accreditation and market surveillance is expected to be formally adopted in June by the European Parliament and the Council.[2] The Regulation, which is due to enter into force in 2010, strengthens the requirements for the enforcement authorities of the Member States to organise and carry out market surveillance on the basis of a common framework and, in particular, to perform or have performed appropriate checks on the characteristics of a product on an adequate scale before it is released for free circulation. Apart from that, specific provisions are foreseen that will allow market surveillance authorities to destroy products presenting a serious risk where they deem it necessary and proportionate.

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1 For additional information, please see : http://ec.europa.eu/enterprise/newapproach/index_en.htm.

2 Position of the European Parliament adopted on 21 February 2008 with a view to the adoption of the Regulation (EC) No …/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. Text available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+20080221+TOC+DOC+XML+V0//EN&language=EN

A Decision of the European Parliament and of the Council laying down a common framework for the marketing of products will also be adopted in parallel.[3] The Decision will provide a coherent basis for the development of future product legislation and the revision of existing legislation. *Inter alia*, the Decision lays down definitions and general obligations for economic operators and provisions concerning procedures to deal with products presenting a safety risk.

I.2.2 Consumer Products

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD)[4] applies in the European Union to non-food consumer products. 'Consumer product' means a product which is intended for consumers or is likely to be used by consumers under reasonably foreseeable conditions. Also covered are products supplied to consumers in the context of service provision for use by them.

The objective of the GPSD is to ensure that all consumer products put on the EU market are safe (whether product-specific legislation exists or not). At the same time, by way of certain harmonisation of requirements and transparency of actions taken, it aims at guaranteeing the free and undistorted movement of compliant goods inside the EU internal market. The Directive covers fully those consumer products which are not subject to sector-specific legislation (e.g., child-care products, furniture and lighters) and complements sector-specific legislation by applying to products covered by sector legislation (e.g., toys, cosmetics, machinery and electrical products) for those safety and risk management aspects not addressed in that legislation.[5]

The GPSD lays down a general obligation for producers to market only safe consumer products and establishes conformity assessment criteria and procedures based on producer's self-declaration of compliance. The producers must take the appropriate measures to prevent risks presented by the products they supply. The corrective measures include, for example, the necessary warnings, stopping of sales, withdrawal of the product from the market, and recall from consumers. Distributors should not supply products which they know are dangerous and must cooperate in monitoring and taking certain corrective measures. If producers and distributors become aware that a product they have supplied is dangerous, they must immediately inform the national authorities in those Member States where the product was put on the market.

Member States are obliged to establish market surveillance authorities to ensure that the general safety requirement is complied with. These authorities have mandatory recall power: they must have been given in each Member State adequate powers, and use these powers, to

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[3] Position of the European Parliament adopted on 21 February 2008 with a view to the adoption of Decision No …/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Decision 93/465/EEC. Text available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+20080221+TOC+DOC+XML+V0//EN&language=EN

[4] OJ L 11, 15.1.2002, p. 4. See also at: http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm.

[5] As e.g. coordination of market surveillance activities, obligations of economic operators, co-operation between economic operators and market surveillance authorities, the RAPEX information system.

take market surveillance and enforcement measures when necessary and notify the Commission of such measures (for example, sales ban, informing of consumers, withdrawal of the product from the market, recall from consumers, destruction of the product). Moreover, Member States shall establish penalties applicable to infringements of the Directive's provisions.

Notifications of measures against serious risks must reach the European Commission in the framework of RAPEX, the European rapid alert system for dangerous non-food products, which ensures that information about dangerous products identified in the Member States is quickly circulated between the RAPEX Members and the Commission, so that rapid action can be taken throughout Europe to prevent risks to consumer health and safety.[6]

Under the GPSD the Commission may adopt temporary EU-level measures in the case of a serious risk to the health and safety of consumers to trigger the same market surveillance and restrictive measures in all Member States with respect to the specified product or risk. To date, three such measures have been or are in the process of being adopted at Community level (on, respectively, phtalates, lighters and magnetic toys).

I.2.3 Customs

The corpus of Customs legislation in the EU is comprehensive.[7] Customs authorities may carry out all the controls they deem necessary to ensure that customs rules and other legislation are complied with. Customs controls for the purpose of the correct application of Community legislation may be carried out in a third country where an international agreement provides for this. Where controls are performed by authorities other than the customs authorities, such controls shall be performed in close coordination with the customs authorities.

For the purpose of checks for conformity with the rules on product safety, in the case of products imported from third countries, controls by customs focus on goods that are intended to be placed on the Community market.[8] When, in the context of checks which they carry out on goods declared for release for free circulation, the customs authorities find products that could cause a serious and immediate risk to health or safety, or the product is not accompanied by a document or not marked in accordance with the Community or national rules on product safety applicable in the Member State in which release for free circulation is sought, they must detain the goods and immediately notify the national authority responsible for monitoring the market. These authorities will take a decision on the goods within three

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6 See more at: http://ec.europa.eu/consumers/safety/rapex/index_en.htm.

7 Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1) as last amended by Council Regulation (EC) No 1791/2006 of 20 November 2006 (OJ L 363, 20.12.2006, p. 1); Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1) as last amended by Commission Regulation (EC) No 214/2007 of 28 February (OJ L 62, 1.3.2007, p. 6). For additional information, please see: http://ec.europa.eu/taxation_customs/common/legislation/legislation/customs/index_en.htm#.

8 Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries OJ L 40, 17.2.1993, p. 1. (Regulation 339/93 will be repealed by the new Regulation cited at footnote 2)

working days. Goods introduced into the customs territory of the Community that are not intended for use in the Community and are not placed on the Community market do not fall under the EU product safety conformity requirements.

Customs controls, other than spot-checks, are based on risk analysis using automated data processing techniques, with the purpose of identifying and quantifying the risks and developing the necessary measures to assess the risks, on the basis of criteria developed at local, national, Community and, where available, international levels. At Community level this is enshrined in the so called risk management framework, which consists of three core elements: a Community risk management system, common priority control areas and common risk criteria and standards for harmonised application of controls.

Member States and the Commission use the Risk Information Form (RIF) to exchange risk related information between customs administrations throughout the Community. Implementation work on this framework is in progress and certain pilot actions have been carried out in this field. Apart from that, risk information on unsafe and counterfeited products has been spread Community-wide and the RIF system has been linked to the RAPEX and RASFF (Rapid Alert System for Food and Feed) databases so that key rapid alert warnings related to consumer products (food and non food) are transcribed into the customs risk analysis systems via RIF.

With regard to actions to improve the communication and co-operation between customs and market surveillance authorities, explicit provisions to the need of close coordination between customs and other authorities performing controls have been incorporated into the so called security amendments of the Community Customs provisions.[9]

Improving communication and cooperation was also subject of a Customs 2013 Seminar held in April in Austria, entitled "Preventing Imports of Dangerous Products". Customs and Market Surveillance representatives from all EU Member States, the European Commission, Croatia, Turkey, Norway, Switzerland and the U.S. participated.

In order to further improve co-operation, and so increase the protection offered, the seminar recommended a package of practical actions to be implemented in the near future as well as issues for medium term consideration. These include enhancing of cooperative network between Customs and Market Surveillance authorities, improving risk management and sharing experience, knowledge and best practices on co-operation and controls.

Political support and resource availability were indicated as important to make significant progress.

[9] Regulation (EC) No 648/2005 of the European Parliament and of the Council of 13 April 2005 amending Council Regulation EEC No 2913/92 establishing the Community Customs Code, (OJ L 117, 4.5.2005, p. 13).

II. Sectoral Legislation

II.1 Motor Vehicles

II.1.1 U.S.

The National Traffic and Motor Vehicle Safety Act of 1966 (the Safety Act), now codified at 49 U.S.C. §§ 30101 et seq., authorizes the National Highway Traffic Safety Administration (NHTSA) to issue the Federal motor vehicle safety standards (FMVSS), which establish minimum requirements for safety systems and components on motor vehicles and for certain items of motor vehicle equipment.

The Safety Act applies to motor vehicles and motor vehicle equipment. The most obvious examples of motor vehicles are passenger automobiles, trucks, and motorcycles. "Motor vehicle equipment" is broadly defined to include systems, parts, components, and accessories to motor vehicles as well as devices and articles used to safeguard highway users (such as motorcycle helmets).

Although all motor vehicles are covered by some or all of the FMVSS, the standards apply only to these specific items of equipment: tires, rims, brake fluid, brake hoses, child restraint systems, motorcycle helmets, glazing, rear impact guards for trailers, lighting equipment, seatbelt assemblies, triangular reflective warning devices, platform lift systems for the mobility impaired, compressed natural gas cylinders, and pressure vessels and explosive devices used in automatic crash protection systems. However, all items of motor vehicle equipment, including those not covered by the FMVSS, are subject to the Safety Act's provisions concerning safety defects, which require the manufacturer to provide notification of defects to NHTSA, distributors, and owners and to provide a remedy for owners.

The Department of Transportation (DOT)'s primary mechanism for the control of unsafe motor vehicles and equipment is the safety recall, which can be based on the product either being noncompliant with the FMVSS or having a safety-related defect. In 2007, manufacturers conducted more than 700 recalls involving over 14 million vehicles and more than 5 million items of equipment.

NHTSA does not certify motor vehicles or equipment or issue "type" approvals. Manufacturers must certify that their products comply with applicable FMVSS. Manufacturers have an obligation under the Safety Act to exercise reasonable care when issuing their certifications and to inform NHTSA and conduct a recall when they determine that their products do not meet the FMVSS. NHTSA's Office of Vehicle Safety Compliance also selects samples of new motor vehicles and equipment for compliance testing and inspection. Where tests indicate possible noncompliance, NHTSA investigates further and, where warranted by all of the facts, works to persuade the manufacturer to conduct a recall.

NHTSA's Office of Defects Investigation reviews complaints from consumers, data from manufacturers, and other sources of information to look for defect trends in vehicles or equipment. Among the information NHTSA receives from manufacturers are notices of recalls they have conducted in foreign countries, technical service bulletins issued by manufacturers to address problems with their products, and data required to be submitted under NHTSA's Early Warning Reporting (EWR) rule. EWR data, submitted quarterly, include aggregate data on production, warranty claims, property damage claims, consumer

complaints, death and injury claims, and copies of field reports submitted by company employees. Where NHTSA's analysis of the data suggests that a safety defect may exist, NHTSA investigates and, where appropriate, may take action to persuade the manufacturer to conduct a recall. As with noncompliance, a manufacturer that determines its product has a safety-related defect must inform NHTSA promptly and conduct the recall.

Neither of these offices, however, conducts inspections at manufacturing plants. The enforcement process rests on the statutory mandate that manufacturers certify that their products meet the standards and report any noncompliance or safety defects. NHTSA's enforcement activities serve to monitor the manufacturers' performance of these duties and to influence or compel action when necessary for safety.

Motor vehicles imported into the U.S. annually have to comply with NHTSA's standards. Foreign manufacturers certify that these vehicles comply with the FMVSS and each vehicle contains a label bearing that certification. NHTSA's Office of Enforcement (including both the Office of Vehicle Safety Compliance and the Office of Defects Investigation) has not experienced particular difficulties with regard to foreign vehicle manufacturers that distinguish them from domestic manufacturers. Foreign vehicle manufacturers intending to sell their vehicles in the U.S. generally work cooperatively with NHTSA, much like domestic manufacturers, and do not have a disproportionate number of recalls for defects or noncompliance. Manufacturers in China and India may be offering vehicles for sale in the U.S. in coming years, and NHTSA is beginning to reach out to these new entrants to the U.S. market to ensure they understand their obligations.

NHTSA has encountered a number of defects and noncompliance in recent years concerning imported products such as tires, motorcycle helmets, headlamps, glazing, fuses, and wheels. As imported equipment has increased in volume, NHTSA has developed a focused enforcement effort through the Office of Vehicle Safety Compliance to ensure that the imports meet the FMVSS. As a result, equipment recalls increased significantly in 2006. In 2007, for example, that office and the Office of Defects Investigation directed a great deal of attention to imported tires.

However, neither of those offices has field inspectors or personnel stationed at borders or ports. Moreover, given the level of proof generally necessary to establish either non-compliance or a safety-related defect, those offices must ordinarily conduct investigations (which may include testing) before being in a position to support the need for a recall. Also, identifying and making contact with the original manufacturer of imported equipment and all of the importers that might be importing its products has proven challenging. For that reason, NHTSA is attempting to expand its impact through finding better ways to identify noncompliance or defects in imported equipment and to deter such defects or noncompliance through expanded outreach and educational efforts with manufacturer organizations, including foreign manufacturers and importers. NHTSA is drafting recommended best practices for importers.

II.1.2 EU

In the European Union the marketing of motor vehicles is based on **Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 on establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles** ("Framework

Directive").[10] This legislation provides for a comprehensive Community type-approval system for motor vehicles.[11]

The type-approval system includes a set of rules which are designed to ensure that vehicles and their components placed on the EU market comply with the specific legislation relating to those products. This system does not stop at an ex-ante control (i.e., before the product is placed on the market) but also provides for instruments ensuring the continuous conformity of production with the relevant legislation and, where necessary, the speedy adaptation of that legislation to technical progress.

The type-approval system is based on but not limited to an ex ante control: in order to obtain EC type-approval, the product of a manufacturer must be in conformity with the requirements set out under the relevant legislation. Before applying for an approval, the manufacturer must successfully complete a preliminary assessment by the governmental authority to ensure that all the necessary mechanisms for checking the conformity of the production are in place before he may launch the production. In addition, the manufacturer must certify the conformity of each product with the approved type by issuing either a certificate of conformity in the case of a vehicle or by putting an EC type-approval mark in the case of components.

Conformity of production is not only controlled ex ante, but also throughout the production process: it is the responsibility of the manufacturer to carry out regular checks throughout the production process under the surveillance of the Member State which has granted the approval. The latter has to verify that adequate arrangements continue to apply to ensure conformity of production[12]. The Member State may also carry out checks and tests on samples taken in the premises of the manufacturer including the production facilities.

The “Framework Directive” includes several safeguard clauses[13] which allow for adequate action in case of problems. The type-approval system allows Member States to react immediately, should they find that a vehicle or a component presents a serious risk to road safety, the environment or public health despite the fact that new vehicles and components are in conformity with existing legislation. The same applies where the Member State finds that the vehicle or component does not conform to the approved type, despite being accompanied by a certificate of conformity of the manufacturer or duly marked. The legislation contains provisions on the process to be carried out in such cases, including a consultation mechanism where the Member State who issued the EC type-approval plays a key role.

The Framework Directive also lays down the rules applying to the recall of vehicles[14], in particular the collaboration between manufacturer, approval authority and the other Member States concerned.

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10 OJ L 263, 09.10.2007, p.1.

11 See: http://ec.europa.eu/enterprise/automotive/directives/index.htm.

12 Article 12 of the Framework Directive.

13 Articles 29 et seq. of the Framework Directive.

14 Article 32 of the Framework Directive.

Concerning, in particular, the safety of imported products, it has to be noted that the type-approval system equally applies to them. Imported products have therefore to comply with all EC relevant requirements in order to get an EC type-approval and enter the EC market

II.2 Food, Pharmaceuticals and Cosmetics

II.2.1 U.S.

The Food and Drug Administration (FDA) carries out responsibilities under the following statutory provisions and the regulations (21 CFR) promulgated under the **Federal Food, Drug, and Cosmetic Act, Filled Milk Act, Federal Import Milk Act, Public Health Service Act, Sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981**, and functions vested in the Secretary of Health and Human Services in the **Controlled Substances Act; section 409(b) of the Federal Meat Inspection Act, section 24(b) of the Poultry Products Inspection Act**, and under the **Egg Products Inspection Act**. Additional delegations of authority from the Secretary of Health and Human Services to the Commissioner of Food and Drugs can be found in **FDA's Staff Manual Guide 1410.10**.[15]

FDA is responsible for ensuring that foods (including dietary supplements) are safe, wholesome and sanitary; human and veterinary drugs, human biological medical products, and human medical devices are safe and effective; cosmetics are safe; electronic products that emit radiation are safe; and that products made of combinations of these categories of product meet the standard of the component that is the primary mode of action of the combination product. FDA enforces the same standards for products marketed in the U.S. whether the product comes from domestic manufacturing sites, foreign manufacturing sites, or is assembled domestically or internationally with components from various localities around the world.

Some of FDA's specific responsibilities include foods (truthful labeling; systems that assure safety of all food products (except meat and poultry); bottled water; drugs (product premarket authorizations; OTC and prescription drug labeling; drug manufacturing standards; post-marketing pharmacovigilance to detect new serious adverse events associated with these products); biologics (product premarket authorizations; safety of the nation's blood supply, tissue transplants; research to establish product standards and develop improved testing methods; post-marketing pharmacovigilance to detect new serious adverse events associated with these products); medical devices (premarket authorization of new devices; manufacturing and performance standards; tracking reports of device malfunctioning and serious adverse reactions); radiation-emitting electronic products (radiation safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems (such as baggage x-ray equipment at airports), laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps; accrediting and inspecting mammography facilities); cosmetics (product safety standards and labeling); and veterinary products (livestock feeds; pet foods; veterinary drugs and devices).

FDA performs pre-market reviews and inspections of manufacturing and clinical trial sites to assess the clinical safety and effectiveness and manufacturing quality of new medical products and the safety of new food ingredients. Post-market surveillance is performed to ensure the safety of consumers who use FDA-regulated products.

[15] For a listing of the laws that FDA enforces or that affect FDA see http://www.fda.gov/opacom/laws/.

Authorizations: FDA requires pre-marketing authorization for new drugs, biologics, certain medical devices, food additives and color additives. These marketing authorization applications generally include information on chemistry, manufacturing and controls, drug product, drug substance, facilities and equipment, production system, case report, safety and efficacy data, active components, packaging, and proposed labeling.

Conformity Assessment procedures: FDA employs a comprehensive system of domestic, foreign, and border inspections and product sampling and analysis to ensure compliance with applicable requirements. FDA works with State and local authorities to perform inspections through a variety of vehicles, including contracts and commissioning, to perform domestic inspections mostly in the food and animal feed areas.

Alerts: FDA issues public alerts to inform consumers of public health threats, including matters involving imminent danger to health or gross deception of the consumer.[16] In addition, FDA issues publicly available Import Alerts concerning imported products that appear violative.[17]

Recalls and Product withdrawals: Recalls are an alternative to an FDA-initiated court action for removing or correcting violative, distributed products. The regulations set forth procedures for the FDA to monitor recalls and assess the adequacy of a manufacturer's recall efforts. Recalls may be undertaken by the manufacturer on its own or at the request of FDA. Recalls are considered voluntary actions by the manufacturer, except that FDA may order the recall, retention, distribution or cessation of manufacturing for human cell, tissue, and cellular and tissue-based products (HCT/Ps) depending on the health risk.

II.2.2 EU

II.2.2.1 Food

The general framework of current EU food safety policy was established by **European Parliament and Council Regulation (EC) 178/2002 of 28.1.2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety** ("Food Law").[18]

Regulation 178/2002 pursues the dual objective of ensuring a high level of protection of human health and consumers' interest while guaranteeing the free movement of food and feed in the EU. To that end, it sets out requirements for all stages of food/feed production and distribution (integrated "farm to fork" approach). It also establishes the principles of risk analysis in relation to food and feed as well as the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA).

Establishing consumer confidence is a primary goal of EU food policy. Transparency of legislation and effective public consultation are essential elements of building such

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[16] See http://www.fda.gov/opacom/7alerts.html.

[17] See http://www.fda.gov/ora/fiars/ora_import_alerts.html.

[18] OJ L 31, 1.2.2002, p. 1. Additional information is available at: http://ec.europa.eu/food/food/index_en.htm.

confidence. Better communication about food safety and the evaluation and explanation of potential risks, including full transparency of scientific opinions, are of key importance.

Pursuant to the Regulation, feed and food operators have primary responsibility for food safety while Member States are under an obligation to ensure surveillance and control of these operators. The Commission tests the performance of Member States' control capacities and capabilities through audits and inspections.

A Rapid Alert System for Food and Feed (RASFF) involving the Member States, the Commission, the EFSA as well as Norway, Liechtenstein and Iceland is operated under DG Health and Consumer Protection (DG SANCO)'s management to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.[19] Whenever a member of the network has any information relating to the existence of a serious direct or indirect risk to human health, this information is immediately notified to the Commission under the RASFF. The Commission immediately transmits this information to the members of the network.

The Commission informs its trading partners when it is known that a product subject to a notification has been exported to their territory from the EU or when a product originating from a particular country has been the subject of a notification, so as to allow it to take corrective measures and thus avoid repetition of the problem. The Commission publishes a weekly overview of alert notifications, information notifications and border rejections. [20]

The public version of RASFF includes information on the type of product and the identified problem, the levels found, the origin of the product and the notifying Member States. The Commission does not publish trade names and the identity of individual company in these overviews as this information is considered as being business confidential. Such information is only made available to the members of the network with a view to allowing them to decide about measures appropriate to the identified/suspected risk. Provision of further information at national level is decided by each Member State individually, on a case by case basis and in justified cases, such as the need to recall or withdraw a product, or to avoid consumption of an already purchased product.

The EU is seeking a reciprocal approach from its trading partners with a view to identifying as soon as possible adverse risk for the EU consumers. Pursuant to Article 50(6) of Regulation 1078/2002, participation in RASFF may be opened up to third countries on the basis of agreements based on reciprocity and including confidentiality measures equivalent to those applicable in the EU.

II.2.2.2 Pharmaceuticals

Pharmaceuticals in the EU are governed by **Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products**

[19] See http://ec.europa.eu/food/food/rapidalert/index_en.htm.

[20] See http://ec.europa.eu/food/food/rapidalert/index_en.htm.

code for human use[21] and a parallel **Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products.**[22]

Regulation (EC) No. 726/2004 of the European Parliament and of the Council lays down procedures for the authorization and supervision of centrally authorized medicinal products for human and veterinary use and establishes the European Medicine Agency.[23] In order to guarantee the quality, safety and efficacy of medicines, a medicinal product may only be placed on the market in the European Union when a marketing authorization has been issued either by the competent authority of a Member State for its own territory or by the Commission when an authorization has been granted for the entire Community.

II.2.2.3 Cosmetics

In the EU the Cosmetics sector is regulated by Council **Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products**.[24] The Cosmetics Directive is based on the principle that the person responsible for placing the cosmetic product on the Community market is liable for the product's safety. To this end, this person must keep available to the competent authorities, by means of a "product information file", information demonstrating the safety of the product. In particular, the assessment of the safety for human health of the finished product, taking into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure must be available within this "product information file", which is checked on an *ad hoc* basis by the competent authorities.

This principle of responsibility is supplemented by detailed regulation of selected individual cosmetic ingredients. Indeed, the Cosmetics Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic products may not contain, outside the restrictions and conditions laid down (Annex III). The Directive also contains "positive lists" for colorants (Annex IV), preservatives (Annex VI) and UV filters (Annex VII). Concerning these groups of ingredients, only the substances listed in the respective annex are allowed for use in cosmetics in the EU. Adaptations of these annexes require the prior consultation of the Scientific Committee on Consumer Products to ensure that the regulation takes into account the present state of scientific knowledge.

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[21] OJ L 311, 28.11.2001 p. 67. Directive as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004, p. 34). For an exhaustive list of all pieces of pharmaceutical legislation in the EU, please see http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/eudralex_en.htm.

[22] OJ L 311, 28.11.2001 p. 1. Directive as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 (OJ L 136, 30.4.2004 p. 58).

[23] OJ L 136, 30.4.2004, p. 1.

[24] OJ L 262, 27.9.1976, p.169, as last amended by Commission Directive 2008/42/EC of 3 April 2008 amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and III thereto to technical progress (OJ L 93, 4.4.2008, p. 13). For an unofficial consolidated version of Directive 76/768/EEC and the full list of its amendments and technical adaptations, please see http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm. For further information about the Directive and its practical application, see http://ec.europa.eu/enterprise/cosmetics/html/cosm_legal_intro.htm.

The Cosmetics Directive is currently under revision.[25]

II.3 Toys

II.3.1 U.S.

Toy safety requirements are laid down in the **Consumer Product Safety Act** (see Section B.I.1.2 above).

II.3.2 EU

Safety of toys and their free movement within the EU are regulated by **Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys**[26]: This Directive applies the method of the so-called "New and Global Approach", whose key concept consists in laying down in the legislation the essential safety related requirements, while the technical specifications of products meeting these requirements are set out in voluntary harmonised standards developed by the European Standards Organisations. According to the Directive toys may be placed on the EU market only if they do not jeopardize the safety and /or health of users. Safety requirements as laid down in the Directive itself refer to chemical, mechanical or electrical properties as well to rules on flammability and hygiene. Member States are required to take all necessary steps to ensure that non-compliant toys are not placed on the market.

Toys have to undergo a conformity assessment procedure to demonstrate that they comply with all the essential safety requirements. In general the manufacturer carries out the conformity assessment when he applies the harmonised standards covering all the relevant safety requirements for the toy. In case harmonised standards do not (yet) exist or have not been (fully) applied by the manufacturer, the conformity assessment has to be carried out by a third party in order to receive an EC type-examination certificate. By affixing the CE-marking the toy manufacturer declares that the toy complies with the provisions of the Directive.

Conformity of toys with the requirement of the Directive is also subject of post-marketing market surveillance under the responsibility of the EU-Member States. Where a Member State ascertains that a toy is likely to jeopardize the safety or health of a person, it has to take all appropriate measures to withdraw the product from the market, or to prohibit or restrict their placing on the market. The GPSD also applies to toys in relation to those aspects that are not more specifically covered in the Toys Directive (e.g. coordination of market surveillance activities, obligations of economic operators, cooperation between economic operators and market surveillance authorities, RAPEX, etc.).

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[25] Proposal for a regulation of the European Parliament and of the Council on cosmetic products; COM (2008)49 final of 5.2.2008 - 2008/0025 (COD). See more at: http://ec.europa.eu/enterprise/cosmetics/html/cosm_simpl_dir_en.htm.

[26] OJ L 187, 16.7.1988, p. 1. Directive as amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p.1). For further information about the Directive and its practical application, see http://ec.europa.eu/enterprise/toys/index_en.htm.

Currently the Toys Directive is being revised to cope with the new challenges posed by the global economy and technological developments.[27] The revision focuses on enhanced safety requirements for toys and intends to improve the effectiveness of its enforcement.

II.4 Electrical Equipment for Consumer Use

II.4.1 U.S.

Safety requirements for electrical equipment are laid down in the **Consumer Product Safety Act** (see Section B.I.1.2 above) and, to the extent that equipment is used at the workplace, in OSHA's regulations.

Specifically, the **Introduction to Subpart S of OSHA regulations** (the primary standards regulating the safety of electrical products in general industry workplaces) states: "This subpart addresses electrical safety requirements that are necessary for the practical safeguarding of employees in their workplaces." 29 C.F.R. § 1910.301. The requirements in Subpart S are not applicable to equipment found in certain installations, such as installations of communication equipment under the exclusive control of communication utilities. OSHA has no authority to regulate the safety of electrical products used outside of the workplace.

This section will focus only on the specific regulatory requirements in place for electrical products in the workplace, and not on the many other regulatory programs developed under the OSH Act. OSHA's authority is limited to the workplace; the Agency does not specifically regulate consumer products. The primary standards regulating the safety of electrical products in general industry workplaces are in 29 CFR § 1910, Subpart S. Subpart S, with limited exceptions, requires that all electrical equipment used in workplaces be "approved" (*i.e.*, tested and certified) by independent third parties under its Nationally Recognized Testing Laboratory (NRTL) Program. Under the NRTL Program, OSHA recognizes independent laboratories to perform product approval activities based on OSHA's requirements; the Agency then assumes ongoing auditing functions to ensure that the NRTLs continue to operate in accordance with Program requirements.

The NRTL Program is a "pre-market" approval system for electrical products in the workplace, which means that approval by an NRTL occurs before the product enters the market. As a condition of that approval, the NRTL then performs follow-up inspections of the manufacturing process to ensure that all units of the product comply with appropriate test standards before entering the market. This is in contrast to the "post-market" systems used by some countries, which relies on government-run surveillance systems to test and inspect electrical products for compliance with regulatory requirements after they enter the market. Because the NRTL Program relies on pre-market approval of electric products used in the workplace and NRTL-based inspections of the manufacturing process, OSHA does not engage in post-market surveillance activities such as: 1) testing products for conformity with safety standards; 2) recalling products or banning their important or distribution in the United States; and 3) levying fines and other penalties against manufacturers that are not adequately testing their products.

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[27] COM (2008) 9 final of 25.1.2008. For additional information on the revision, see http://ec.europa.eu/enterprise/toys/2008_108_directive.htm.

II.4.2 EU

European Parliament and Council Directive 2006/95/EC of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits ("Low Voltage Directive")[28] lays down safety requirements for electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. These voltage ratings refer to the voltage of the electrical input or output, not to voltages that may appear inside the equipment. For most electrical equipment, the health aspects of emissions of electromagnetic fields are also under the domain of the Low Voltage Directive.

The Low Voltage Directive can be considered as a precursor of the so-called "New and Global Approach" to technical harmonisation. In broad terms, it provides for both, a conformity assessment procedure to be applied to equipment before being placed on the market and essential health and safety requirements which such equipment must meet either directly, by means of harmonised standards developed by European standardisation organisations or any other technical specification leading to an equivalent level of safety.

For electrical equipment within its scope, the Directive lays down the essential requirements with respect to health and safety covering all risks (i.e. not only electrical but also mechanical, chemical, etc.), thus ensuring that electrical equipment is safe in its intended use. Guidelines on application and Recommendations are available, as well as European Commission opinions within framework of the Directive.

In respect of conformity assessment, there is no third party intervention, as the manufacturer undertakes the conformity assessment. However, there are so-called Notified Bodies (i.e. conformity assessment bodies designated by the Member States and "notified" to the Commission) under the Directive, which may be used to provide reports in response to a challenge by a national authority as to the conformity of the equipment.

The GPSD also applies to electrical equipment for consumer use in relation to those aspects that are not more specifically covered in the Low Voltage Directive (e.g. coordination of market surveillance activities, obligations of economic operators, cooperation between economic operators and market surveillance authorities, RAPEX, etc.).

[28] OJ L 374, 27.12.2006, p. 10. Directive 2006/95/EC codifies old Low Voltage Directive 73/23/EEC and repeals it as from 16 January 2007. For further information about the Directive and its practical application, see http://ec.europa.eu/enterprise/electr_equipment/lv/index.htm.

C. ASSESSMENT OF THE EXISTING BILATERAL INFORMATION EXCHANGE MECHANISMS IN THE FIELD OF CONSUMER PRODUCT SAFETY

I. General Non-Food Consumer Product Safety Matters

The European Commission (DG SANCO) and the U.S. CPSC agreed in February 2005 on **"Guidelines for Information Exchange and on Administrative Cooperation"** to strengthen transatlantic cooperation in the field of consumer product safety. The CPSC has regular and frequent contacts (by telephone, 2 x per month) with DG SANCO to discuss mutual product safety issues. They encompass regular exchanges of: (i) scientific, technical, and regulatory information; (ii) information on emerging issues of significant health and safety relevance; (iii) information on standardization activities and cooperation in comparatively assessing specific product safety standards and in initiating standardization activities; (iv) general information on market surveillance and enforcement activities; (v) information on risks identified and measures taken with respect to products originating from each of their respective territories; (vi) information in case of major withdrawal/recall operations of mutual interest; and (vii) information on risk assessment and product testing.

Today, only publicly available information on product safety issues is exchanged. Due to statutory restrictions, the CPSC is not free to disclose case or product specific information with outside parties without a waiver from the companies involved. For this reason, the CPSC does not release case specific information to the European Commission if that information has not already been made public. Once a recall of a product which is known to be sold in Europe has been announced, however, the CPSC sends an e-mail notice of the recall to DG SANCO. DG SANCO, in turn, informs the CPSC of recalls and other corrective measures taken in the EU with respect to dangerous products originating in the U.S. the CPSC would welcome recall notices from DG SANCO of dangerous third country products which are known to be sold in the U.S.

Exchange of confidential information between the Commission and the CPSC would require a new agreement, determining precise rules and procedures and specifying all the necessary guarantees for confidentiality. On the EU side, the Commission could seek a mandate from the Member States in the Council to negotiate an agreement about reciprocal information sharing with adequate confidentiality guarantees based on Article 12(4) of the GPSD.[29] On the U.S. side, progress depends on the pending bill to reform the CPSC and whether it will permit the CPSC to exchange confidential information with foreign government authorities, under certain conditions and limitations. Once the legislation is enacted, the CPSC will need to create implementing policies. The time frame for the creation of implementing policies is unclear but would depend on the priorities created by the legislation and the Commission.

In addition, the U.S. EPA pesticide and industrial chemical regulators share information on product safety across many product classes regulated by EPA, sometimes in coordination with other agencies, with EU countries and others through a number of mechanisms. Under the

[29] Article 12(4) of the GPSD reads as follows: *"Access to RAPEX shall be open to applicant countries, third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to arrangements defined in these agreements. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Community."*

Regulatory Cooperation Roadmap, the U.S. and EC engage in informal and periodic dialogue in the chemicals sector. The objective is to facilitate improved risk reduction by sharing experiences and expertise in the sound management of chemicals while promoting regulatory convergence and burden sharing on scientific, technical and related challenges and issues of mutual interest. One initial focus is on the exchange of information. This includes status updates and an overview of current challenges and issues including, for example, REACH implementation projects (RIPs), categories guidance and analytical framework for High Production Volume (HPV) chemicals, the use and application of computational tools and emerging issues including respective chemicals-related stewardship with manufactured nanomaterials.

II. Customs

Existing agreements between the EU and the U.S. on customs cooperation currently do not specifically refer to safety and control of products, nor have any such expansions been discussed so far.

The initial **Customs cooperation agreement** refers to customs cooperation of the widest possible scope and in particular cooperation in establishing and maintaining channels of communication between the customs authorities to facilitate the secure and rapid exchange of information (on a non-systematic basis); facilitating effective coordination between their customs authorities; and any other administrative matters related to the Agreement that may from time to time require joint action.

According to Article 15 of the Community Customs Code all information which is by nature confidential or which is provided on a confidential basis shall be covered by the duty of professional secrecy and shall not be disclosed by the competent authorities without the express permission of the person or authority providing it. The communication of information shall, however, be permitted where the competent authorities are obliged to do so pursuant to the provisions in force, particularly in connection with legal proceedings. Any disclosure or communication of information shall fully comply with prevailing data protection provisions, in particular European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data[30] and Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.[31]

Information exchange would require determining precise rules on which data exactly needs to be transferred and how, and specifying all necessary guarantees for data security.

The U.S. CBP has Customs Mutual Assistance Agreements (CMAAs) with 58 countries, which provide a negotiated basis to exchange a full range of information identified on a case by case basis. As for other nations, 19 U.S.C. 1628 and 19 CFR 103.34 provide statutory and regulatory authority for the CBP Commissioner to exchange the same information as above with any Customs or law enforcement administration. Both the CMAAs and § 1628 require a law enforcement purpose to support the exchange. To create new agreements related to

[30] OJ L 281, 23.11.1995, p. 31.

[31] OJ L 8, 12.1.2001, p. 1.

mutual import safety concerns, § 1628 would be a basis for CBP to establish an agreement (MOU/MOA) for a recurring exchange of such information.

CBP participates with the EU on matters of import safety and, as indicated earlier, as such participated in the Customs 2013 Seminar on Preventing Imports of Dangerous Products. CBP is also interested in expanding its partnership programs with the international trade community in the area of import safety, developing good importer practices for traders to secure their supply chain and secure the entire product life-cycle.

III. Motor Vehicles

In June 2003, NHTSA and DG ENTR reached an agreement through an **Exchange of Letters concerning regulatory cooperation in the field of motor vehicle safety**. This agreement calls for cooperation in the development and post-implementation review of technical regulations through measures such as annual meetings, information sharing, contributions to the harmonization of standards through the United Nations Economic Commission for Europe (UNECE) World Forum for the Harmonisation of Vehicle Regulations (so-called WP. 29 process), and sharing research and development plans. The agreement does not specifically address information sharing with regard to the control of unsafe products.

At present, no exchange of information between the EU and the U.S. on safety of products takes place in the field of motor vehicles. This is due to the fact that the market surveillance mechanism, including the implementation of the safeguard clauses as laid down in the Framework Directive, is mainly managed by the EU Member States and thus information on safety of products is mainly retained by the national type-approval authorities. Furthermore the typology of the car fleet in the EU and the U.S. market is to a large extent different.

NHTSA and DG ENTR are currently negotiating an **updated agreement that would reinforce the existing Exchange of Letters** and would include certification and enforcement as a specific area of cooperation.

Consistent with the Exchange of Letters, both NHTSA and DG ENTR currently exchange information concerning vehicle safety issues within the remits of their respective jurisdictions. These exchanges often occur in connection with the development of Global Technical Regulations as part of the UNECE WP. 29 process. Exchanges also occur in connection with research and development issues. The exchanges involve both meetings and the sharing of relevant documents.

The current exchanges are not designed to identify unsafe or defective products. However, the Exchange of Letters does not preclude the exchange of information on these subjects, and NHTSA would be pleased to engage in whatever exchanges may be useful to ensuring the safety of imports.

Generally, there are no legal or practical constraints on the exchange of information between the U.S. and EU on safety issues related to motor vehicle and equipment imports. NHTSA's extensive database on its investigations is largely available to the public.[32] However, certain information submitted to NHTSA by individuals or corporations may be confidential under U.S. laws due to privacy or confidential business information reasons. NHTSA believes,

[32] See www.nhtsa.dot.gov.

however, that sufficient information sharing to enable the EU to benefit from NHTSA's data could occur without running afoul of these restrictions. For example, NHTSA could share the nature and source of any alleged defect or noncompliance under investigation or already the subject of a recall, including specific information about the manufacturer's identity.

IV. Food

In the sanitary and phytosanitary area, the European Community and the United States of America have concluded an **agreement on sanitary measures to protect public and animal health in trade in live animals and animal products**. The Agreement has been in force since 1 January 1999.[33] It aims to facilitate trade in live animals and products between the EU and the USA by establishing a mechanism for the recognition of equivalence of respective sanitary measures and to improve communication and cooperation on sanitary measures.

An **implementation plan on the sharing of confidential information** between the European Commission (DG SANCO) and the U.S. FDA was signed on 23 September 2005.[34]

Under this Agreement, the Commission informs FDA when if it is known that a product subject to a notification has been exported to the U.S. or when a product originating from the U.S. has been the subject of a notification.

However, the legal obligation on both parties to protect confidential business information prevents certain commercially sensitive data from being exchanged in the framework of the existing Agreement.

The balance between two crucial and sometimes mutually opposed concepts - openness and the protection of commercial information – is always a difficult one to strike. A framework agreement based on reciprocity, covering the protection of commercially sensitive information and setting up clear criteria for information exchange would need to be developed to overcome difficulties derived from the implementation of the current "confidentiality agreement" and expand the scope of the exchange of information to food and feed products originating in third countries. In the EU, Article 50(6) of Regulation 1078/2002 provides the legal basis for negotiating such an agreement.[35]

It should also be noted that, with regard to food and animal feeds Member States possess the majority of information relating to inspections, recalls, import refusals, etc. Under the existing arrangements, FDA can, upon request, obtain additional non-public information contained in RASFF alerts. One problem with such notifications has been the need to try to

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[33] OJ L 118, 21.4.1998, p. 3.

[34] With regard to mechanisms to ensure confidentiality, FDA has also entered into confidentiality arrangements with EFSA, and eight EU Member States (Belgium, Denmark, France, Germany, Ireland, the Netherlands, Sweden, and the United Kingdom). See http://www.fda.gov/oia/default.htm. FDA handles all exchanges of non-public information under its Staff Manual Guide 2830.3

[35] Article 50(6) of Regulation 1078/2002 reads as follows: "*Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.*"

determine which notifications truly involve issues that could adversely impact public health and which thus require immediate response from those refusals which simply represent technical violations which, in themselves, do not pose a significant, if any, threat to public health. Information beyond the RASFF alert must come from Member States.

As concerns FDA, almost every type of information that FDA uses to carry out their respective regulatory responsibilities is available for exchange under the confidentiality and other arrangements between FDA and EU actors. This includes non-public information such as investigative information, commercial confidential information, and agency pre-decisional information.

These exchanges relate to product authorizations; post-marketing safety reports including adverse event reports; results of manufacturing, laboratory, and clinical study inspections; import refusal and product recall information; investigative information, and agency pre-decisional deliberations relating to reviewing scientific evidence, adopting regulatory policies, or publishing regulations or other regulatory documents.

Using these authorities and agreements, FDA is involved in almost daily interactions with its European counterparts. The systems in place allow for routine exchange of non-public information and for ad hoc exchanges as needed. Included are systems to allow early warnings of known safety issues that could significantly affect public health and/or result in significant international press coverage.

FDA cannot, however, share non-public information with the EU for communication to the Member States through the RASFF system, because not all Member States have committed to maintain the confidentiality of information shared by FDA through the RASFF system to the extent required by law and regulation in the U.S.

To date, because the EU institutions cannot bind individuals when they are working in their Member State capacities, the EU has not been able to share with all Member States some of the non-public information the FDA has shared with them. This has caused awkwardness and disconcert within the EU and the Member States. Work is under way to address this matter, and; hopefully, a scheme whereby adequate provision will exist to allow such sharing will be implemented in the near future.

On the FDA's side, there remain, however, some legal and practical constraints to exchanging information, despite FDA's comprehensive efforts at exchanging information with EU counterparts and successful use of FDA regulation 21 C.F.R. § 20.89.

Specifically, FDA is not permitted to share, outside of the U.S Department of Health and Human Services, trade secret information without the consent of the manufacturer, even with a confidentiality agreement in place.[36] Since certain parts of product applications and manufacturing inspections frequently contain trade secrets, FDA cannot share complete information on an expedited or confidential law enforcement or public health basis. This requires often extraordinary human, time, and capital resources to redact materials so that they can be sent without violating these trade secret prohibitions. Other prohibitions on disclosing information are contained in 21 U.S.C. § 360j(c) (medical device application information) and 21 U.S.C. § 360i(b)(2) (identity of adverse event filers). Finally, FDA has not been given the

[36] See 21 U.S.C. § 331(j).

authority to exchange classified information, such as food defense risk assessments. FDA's efforts at product safety assurance, both from a resource perspective and an informational perspective, would be well served by having such prohibitions eliminated when a properly executed confidentiality agreement is executed between FDA and a counterpart foreign competent authority that has the authority to protect the information to the same extent as the FDA.

In addition, the very practical problem exists of how to integrate our various information collection and use systems. Information of interest and concern to the EU may not be of concern to the U.S. and vice versa. For example, information about global distribution of domestically detected problem products is not always available given FDA's investigatory limitations. We need to figure out how to coordinate foreign use and mandatory disclosure of information: information that is still being considered in one country may become for the basis for a decision in the other country and become subject to disclosure under foreign legal requirements.

Lastly, the usual communication difficulties arise in the need for translations or for thorough knowledge of the jargon and legal or scientific significance of certain findings or statements in the foreign context.

FDA considers that the old prohibitions on information sharing are inapposite given the needs of regulators to collaborate on global product safety issues. Instead of product-related public health problems being largely domestic in nature, almost all such problems are now global. FDA needs greater legal flexibility in the appropriate sharing of complete product information, including trade secret information, with counterpart foreign competent authorities that have the authority and ability to maintain the same level of confidentiality as does FDA.

V. Pharmaceuticals

There is already considerable experience in the field of regulatory co-operation between the FDA and European Commission administrations responsible for regulation in the pharmaceutical sector. Since 1989 this has been in the context of regular bilateral meetings between representatives of DG ENTR and representatives of the FDA.

Closer exchange of information was facilitated by the **Confidentiality Arrangements** concluded on 12 September 2003 between the EU (European Commission and EMEA) and the U.S. (FDA and the Department of Health and Human Services) in the context of regulatory co-operation and transparency between the U.S. Government and the European Commission.

In order to allow for a successful exchange of information and documents between the EU and the FDA in accordance with the terms of these Confidentiality Arrangements, an **Implementation Plan** was agreed among all parties and finalised on 16 September 2004. The objective of the Implementation Plan was to describe the processes by which each party will undertake information and documents exchange as envisioned by the Confidentiality Arrangements, as well as a process for the monitoring of the implementation of this Implementation Plan. An extension of the Confidentiality Arrangements for a period of five years was signed on 15 September 2005. The Implementation Plan was last updated in June 2007, taking into account experience gained, as well as, proposals identified to further

improve its operation.[37]

This involves staff exchanges, participation in each other's advisory committees, participation in policy drafting working groups, and the development of technical level working groups called "clusters" that have evolved into monthly working groups that address safety, efficacy, manufacturing quality and other policy issues regarding orphan drugs, pediatric drugs, pharmacogenomics, post-marketing product safety, and oncology drugs.

On the EU side, because of the combination of centralized and decentralized systems, the EU is not always the repository for information of use to FDA. For example, drug products can still be authorized either through the centralized or decentralized process, although certain classes of product are limited now only to the centralized process. The EU (EMEA) will only possess authorization, inspection, and adverse event information relating to products authorized through the centralized process. EU Member States possess information relating to products authorized through the decentralized process.

As mentioned under the previous section, there however remain some legal and practical constraints to exchanging information, despite FDA's comprehensive efforts at exchanging information with EU counterparts and successful use of FDA regulation 21 C.F.R. § 20.89.

VI. Cosmetics

Some co-operation between the U.S. FDA and the European Commission's DG ENTR has been established with an exchange of letters signed by two high level officials on July 2, 2007, entitled **"confidentiality arrangement"** This arrangement allows exchange of information between the parties that may be shared including, but not limited to the following:

1. Advance drafts of laws, regulations, guidance documents, guidelines, procedures and other technical documents available to the individual Participants related to cosmetics.
2. Information on the process of validation and regulatory acceptance of alternative non-animal testing methods.
3. Information in the framework of RAPEX.
4. Post-marketing data and information that could have an impact on the public health, such as vigilance data or information about impending regulatory actions.
5. Information on quality defect or product recalls of these products known by the FDA to have been manufactured or distributed in the EU, and vice versa.
6. Inspection reports and product sample test results describing the compliance of a cosmetic manufacturing facility with regulatory requirements.

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[37] Other specific bilateral arrangements include: A common application format for orphan medicinal product designation in the European Union and the United States (June 2007); Principles of Interactions Between EMEA and FDA Pediatric Therapeutics (June, 2007); Guiding Principles for Joint FDA EMEA Voluntary Genomic Data Submission Briefing Meetings (May 21, 2006); General Principles EMEA - FDA Parallel Scientific Advice Meetings Pilot Program (September 2004).

With regard to mechanisms to ensure confidentiality, FDA has also entered into confidentiality arrangements with eight EU Member States (Belgium, Denmark, France, Germany, Ireland, the Netherlands, Sweden, and the United Kingdom). See http://www.fda.gov/oia/default.htm. FDA handles all exchanges of non-public information under its Staff Manual Guide 2830.3.

7. Information related to Scientific Opinions.
8. Information on ongoing and emerging regulatory issues of health and safety in the field of cosmetics in the U.S. or the EU, such as nanotechnology.

As mentioned under Section C.V, there however remain some legal and practical constraints to exchanging information, despite FDA's comprehensive efforts at exchanging information with EU counterparts and successful use of FDA regulation 21 C.F.R. § 20.89.

VII. Toys

At present, there is **no specific formal agreement** governing the exchange of information between the EU and the U.S. on toys safety **beyond the general agreement between DG SANCO and the CPSC**. Following the recalls of toys in 2007, an ad-hoc informal exchange of views on ongoing EU/U.S. initiatives takes place between EU and U.S representatives where both sides exchange information about their ongoing legal and practical initiatives to enhance toys safety.

In addition to the information already made available to each other under the DG SANCO-CPSC cooperation agreement, the following information generated from the operation of the Toys Directive could be exchanged on the EU side:

(i) safeguard measures (i.e. final, legally binding measures restricting or prohibiting the placing on the market of unsafe toys) taken by the Member States pursuant to the Directive. These measures are notified to the Commission, which then has to issue an opinion as to whether the measure was justified or not. Information relating to safeguard measures could, however, only be shared after formal adoption of the Commission opinion (in quick cases, between 6 and 9 months from receipt of the notification). Where the requirements for RAPEX notification are also met, the same measure is notified under both the safeguard procedure and RAPEX.

The Commission regularly exchanges information derived from safeguard notifications to the Chinese authorities for Chinese-originated products and the same data could be shared with the U.S. The information exchange with the Chinese authorities presently only involves the notification and photos and not also the test reports, as such information is considered as commercially sensitive.

In order to overcome the legal constraints to the sharing of Member State test reports, a specific agreement providing for reciprocity and the necessary confidentiality guarantees would have to be negotiated. Member States should be party to any such agreement;

(ii) share findings of surveys on unsafe toys resulting from cross border market surveillance projects involving several Member States.

VIII. Electrical Equipment for Consumer Use

At present, there is **no specific formal agreement** governing the exchange of information between the EU and the U.S. on the safety of consumer electrical equipment **beyond the general agreement between DG SANCO and the CPSC**. However, contacts have been

initiated between the CPSC and the Chair of the Member States' Administrative Cooperation Group (a forum aiming to facilitate cooperation between national market surveillance authorities). Interest has been expressed for considering a bilateral cooperation agreement along the lines of that already in place between DG SANCO and the CPSC.

In addition to the information already made available to each other under the DG SANCO-CPSC cooperation agreement, the following information generated from the operation of the Low Voltage Directive could be exchanged:

(i) safeguard measures (i.e. final, legally binding measures restricting or prohibiting the placing on the market of unsafe electrical products) taken by the Member States pursuant to the Directive. The Commission receives an average of about 500 safeguard notifications each year. This information could be exchanged after completion of the procedure, which in virtually all cases is three months from notification of the national measure to the Commission. Pursuant to the Directive, if no Member State raises objections against the notified measure, the measure stands. If objections are raised, then the Commission must undertake a detailed assessment and make an opinion as to whether the measure was justified or not. The latter scenario, however, has almost never materialised so far. Where the requirements for RAPEX notification are also met, the same measure is notified under both the safeguard procedure and RAPEX.

    The Commission regularly exchanges information derived from safeguard notifications to the Chinese authorities for Chinese-originated products and the same data could be shared with the U.S. The information exchange with the Chinese authorities presently only involves the notification and photos and not also the test reports, as such information is considered as commercially sensitive;

(ii) share findings of surveys on unsafe electrical products resulting from cross border market surveillance projects involving several Member States. The most recent such projects have involved household portable lamps, cord extension sets and lighting chains (the last one still ongoing).

Based on experience, it appears that both the EU and the U.S. have the same problems with cheap consumer products, mainly imported from China. For most products, however, it would appear that different design and constructional solutions are applied by manufacturers due to the different voltage range in the EU and the U.S. In such cases, the benefit of the information exchange would be negligible.

In conclusion, the European Commission would very much value the participation of CPSC and any other relevant agency in the relevant meetings between Member States market surveillance authorities so that trust and confident can be built upon.

In order to overcome the legal constraints to the sharing of Member State test reports, a specific agreement providing for reciprocity and the necessary confidentiality guarantees would have to be negotiated. Member States should be party to any such agreement.

There are no existing or planned agreements between the EU and the U.S. regarding safety and control of electrical products used in the workplace. There is no formalized information exchange between the EU and the U.S. specifically on product safety issues regarding electrical equipment used in the workplace. However, there have been ongoing discussions

between DG ENTR and OSHA since Fall 2007 on conformity assessment for electrical products in the TEC framework. While they are not directly related to the issue of information exchange about the safety of electrical products, these discussions could provide a starting place for talks on how such an exchange might take place.

As described above, OSHA's authority is limited to workplace safety and health, and OSHA's standards pertaining to the safety of electrical equipment apply only to those products used in the workplace. As the EU does not employ such a distinction and regulates the safety of electrical products in the same way and to the same requirements regardless of end use, this mismatch in regulatory capability between the EU and the U.S. presents a practical obstacle to an exchange of information about the safety of electrical products.

D. CONCLUSIONS AND RECOMMENDATIONS

I. General

- Both the U.S. and the EU are dedicated to the timely sharing of relevant information and there is already a good degree of useful cooperation in various sectors. There is, however, a clear need to improve the existing cooperation in the short and long-term with a view to effective information sharing, thereby increasing the overall efficiency of our respective market surveillance and enforcement systems. To that end, this report has identified a few specific topics both the U.S. and the EU feel would be useful for further exploration.

- Protection of confidential business information has been identified as the major issue to consider when increasing information exchange in all sectors and areas examined in this report. Even where advanced confidentiality agreements are already in place to allow for some sort of exchange of confidential information (for example, pharmaceuticals and cosmetics), there is still scope for improvement.

- Although the criteria for confidentiality in the U.S. are often set by statute and would therefore be difficult to change, it would be useful to undertake an analysis of the criteria applied in the EU and the U.S. to determine whether a piece of information should be treated as confidential or not, and to undertake an analysis of whether the process of determining whether information should be treated as confidential could be made more efficient.

- The EU and the U.S. should continue to develop their internal systems for communicating developing safety concerns. Systems based on classifications of recalls are a particular concern, as often recalls are classified much after the recall has actually occurred. Likewise, comfort with sending signals of developing concerns need to be enhanced, even when these signals do not end in enforcement action. Both the U.S. and the EU are better served when officials can confidentially share early warnings that potentially significant public health issues are developing.

- Ultimately, engaging in a fuller exchange of confidential information requires legal changes in our systems and, hence, the necessary political will to implement such changes.

II. General Non-Food Consumer Product Safety Matters

- The existing "Guidelines for Information Exchange and on Administrative Cooperation" between DG SANCO and the CPSC already allow an exchange of non-confidential information on risks identified and measures taken with respect to products originating from each of the EU and U.S. respective territories.

- Exchange of confidential information between DG SANCO and the CPSC, including on products originating in third countries, would require additional statutory authority for the CPSC and a new agreement based on reciprocity, determining precise rules and procedures and specifying all the necessary guarantees for confidentiality.

- As a first step, following the CPSC gaining statutory authority for confidential information sharing and within the existing cooperation framework, DG SANCO and CPSC will explore the elements of a common understanding (i) regarding the practical value of early and more detailed exchanges of confidential product safety information; and (ii) of the necessary confidentiality arrangements.

- On the basis of such a common understanding, DG SANCO and the CPSC will examine the feasibility of an agreement on the exchange of confidential product-related information.

III. Customs

- The existing agreements between the EU and the U.S. on customs cooperation currently do not specifically refer to safety and control of products. Information exchange in this field would require a new agreement, determining precise rules on which data exactly needs to be transferred and how, and specifying all necessary guarantees for data security.

- Both sides agree that the benefits of further international cooperation in the product safety area should be explored. At the same time, before considering any new agreement on information exchange between customs authorities, it is proposed that in the immediate future efforts should be focused as a matter of priority on fostering cooperation between customs and market surveillance authorities in their respective territories and on jointly developing best practices in the field. In the EU, efforts will be intensified *i.a.* towards establishing interoperable IT systems and common check lists between customs and market surveillance authorities, ensuring exchange of targeted information between/from the Customs' Risk Information Form (RIF) platform and the RAPEX and RASFF databases.

- Both sides note that extensive discussions on information exchange have taken place in the framework of the EU-U.S. joint initiative on combating counterfeiting. It is therefore proposed to work with the EU-U.S. IPR Group on this issue so as to learn from their experience. Specifically, drawing on the positive results of the pilot project "Operation Infrastructure" on counterfeited integrated circuits carried out in 2007 in the framework of the IPR initiative, both sides will explore the feasibility of a similar joint pilot project in the field of product safety. Such a project would provide useful directions as to how to further bilateral cooperation between EU and U.S. customs authorities in this area.

- The CBP notes that the EU and the U.S. used CIRCA, a secure website maintained by the EU as the database for the information exchange on the IPR Operation Infrastructure. There are limitations to this database, and there have been issues with using it, but the system has already been approved so an import safety information exchange could be implemented immediately using this system. CBP proposes using an appropriate system for secure information exchange, and working with the EU/U.S. IPR group on this issue, as the IPR group has been discussing information exchange for some time. This group is ahead of the import safety initiative by several years. As such, once the base import safety issues are addressed, information exchange could proceed relatively quickly.

- Given that the system to exchange information on IPR enforcement has already been used and tested, it is recommended to consider starting a pilot project on import safety issues based on the experience gained with this system in the near future.

IV. Motor Vehicles

- Quick adoption and implementation of the Memorandum of Cooperation between DG ENTR and NHTSA.

- DG ENTR and NHTSA will discuss in the framework of the Memorandum what information on product safety could be of mutually beneficial use

- Meetings between EU and U.S. relevant officials on how to improve information exchange in this area within their respective area of competence would be a useful first step. The parties could discuss methods of cooperation focused on maximizing the rapid and efficient implementation of safety requirements for products offered for import into both jurisdictions and related exchange of information.

V. Food

- The existing "Confidentiality Agreement" between DG SANCO and FDA already allows an exchange of information on risks identified and measures taken with respect to food and feed products originating from the EU and U.S. respective territories.

- Given the widespread trade in food products today, often through difficult to trace mechanisms such as the internet, it is often difficult to know in real time, or at all, the location of a potentially affected product. One potential way to address this is to engage in routine notifications of all significant food safety concerns and allow other countries to use other information to help determine if such product(s) are in their jurisdictions and then to take appropriate action.

  Exchange of confidential information between DG SANCO and FDA, including on products originating in third countries, would require determining precise rules and procedures.

- As a first step, within the existing cooperation framework, DG SANCO and FDA will seek a common understanding (i) regarding the practical value of early and more detailed exchanges of confidential product safety information; and (ii) of the necessary confidentiality procedures.

- On the basis of such a common understanding, DG SANCO and FDA will explore the possibility to improve the exchange of confidential product-related information, including providing access to RASFF Window for FDA.

VI. Pharmaceuticals

- The existing Confidentiality Arrangements between DG ENTR and EMEA, on the EU side, and FDA and the Department of Health and Human Services, on the U.S. side, provide an adequate framework for information exchange regarding product safety

- The Commission will explore with the Member States the possible extension of the existing information exchange under the Confidentiality Arrangements to nationally authorized products that are not subject to the so-called arbitration or referral in accordance with European Community procedures.

VII. Cosmetics

- The recently signed (July 2007) Confidentiality Arrangements between DG ENTR and FDA provide an adequate framework for information exchange regarding product safety. Both sides will periodically review the operation of these arrangements with a view to identifying any need for further improvement of the existing information exchange mechanisms.

VIII. Toys

- DG ENTR, DG SANCO and the CPSC will set up a Toy Safety Working Group, subject to consensus on its working level, meeting arrangements, and outcomes, to function as a focal point to discuss toy import safety related matters, including (i) identifying what information on safety of toys that is available to them could be of mutually beneficial use and (ii) exploring the feasibility of specific cooperation and confidentiality arrangements complementing the existing "Guidelines for Information Exchange and on Administrative Cooperation" between DG SANCO and the CPSC.

IX. Electrical Equipment for Consumer Use

- DG ENTR and the CPSC will pursue ongoing talks with a view to (i) identifying what information on safety of consumer electrical equipment that is available to them could be of mutually beneficial use and (ii) exploring the feasibility of specific cooperation and confidentiality arrangements complementing the existing "Guidelines for Information Exchange and on Administrative Cooperation" between DG SANCO and the CPSC.