German Industry's Priorities for a Transatlantic Trade and Investment Partnership (TTIP)

Foreign Economic Policy

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Executive Summary

German Industry welcomes the launch of negotiations for a comprehensive and ambitious transatlantic trade and investment partnership (TTIP). A transatlantic agreement will have a significant economic impact on both economies by promoting economic growth and by creating new jobs. In addition, it will strengthen the transatlantic partnership politically and strategically by demonstrating transatlantic leadership and its positive impact on the global economy and the world trading system. The BDI has therefore long supported deeper transatlantic economic integration and will continue to advocate a high-quality agreement.

The full potential of the transatlantic market can only be realized if the agreement covers all sectors and addresses all barriers to trade. German Industry therefore expects specific progress in the three main negotiation areas market access, regulatory cooperation and global rules. All these components should be negotiated in parallel as part of a single undertaking.

In the area of **market access**, we advocate phasing-out and eliminating all industrial tariffs. The agreement should remove existing barriers to investments and services and should improve the movement of people in the transatlantic market. In addition, the TTIP should lead to a better access to public procurement markets at all levels of government and for a stand-still on all "Buy National" provisions.

In the area of **regulatory cooperation**, the agreement should develop processes and mechanisms to achieve regulatory coherence on a horizontal level, including early consultations, impact assessments and regulatory reviews. The agreement should further define an institutional process and procedural requirements for regulator-to-regulator cooperation after negotiations have been concluded. In addition, the TTIP should include substantial progress regarding regulatory cooperation for specific sectors and products. Harmonization or mutual recognition of existing regulations and standards should be realized wherever possible.
Regulatory coherence should build on the existing high level of consumer, safety, health, environmental, and data protection standards in the EU and the U.S.

The **development of global rules** will significantly strengthen the transatlantic partnership as well as the world trading system. We therefore call on the EU and the U.S. to negotiate ambitious rules, in particular with regard to IPR protection, access to raw materials and energy, competition rules and trade facilitation.

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The goal of this paper is to outline the priorities of German Industry for successful negotiations. We encourage negotiators to facilitate a transparent process and to build on the expertise provided by various stakeholders from industry and business representations, regulatory agencies, unions, NGOs and other groups. German Industry will continue to contribute to this discussion and will – in cooperation with its members and partners – provide advice and input to the governments and parliaments in Berlin, Brussels and Washington during negotiations.

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A. Nature of the Agreement

1. Ambitious and Comprehensive
   The agreement should be ambitious and comprehensive, as it has been outlined in the final report of the "EU-U.S. High Level Working Group on Jobs and Growth". Studies commissioned by the German Federal Ministry of Economics and Technology as well as by the European Commission clearly indicate that the full potential of economic benefits and welfare gains can only be realized if an agreement covers all sectors and addresses all barriers to trade. This is particularly true for small and medium-size enterprises (SMEs) that face de facto-barriers to market entry through NTBs and regulatory discrepancies.

   While recognizing that negotiations need to be pragmatic and that the agreement will address a number of sensitive sectors and subjects, this should not prevent an ambitious outcome on liberalization for industrial sectors.

   All components of the TTIP agreement should be negotiated in parallel and should be part of a single undertaking. Furthermore, the agreement should establish a permanent process of deepening transatlantic integration.

   The agreement should safeguard high data protection standards, particularly for digital data.

2. Openness
   The agreement should aim at developing rules and standards that could be adopted beyond the transatlantic market and that could serve as the basis for future global trade rules. Third countries should be allowed to adopt the rules developed within the TTIP. Only through an open agreement can the TTIP realize its strategic potential and advance the global trading system. For example, joint efforts to improve data and IPR protection could lead to an overall global improvement and higher global standards in these areas ("systemic reach"). Rules developed within the TTIP should not impose protectionist measures against third parties.

B. Market Access

3. Phasing-out and eliminating industrial tariffs
   The agreement should eliminate or phase out all industrial tariffs, including those for intermediate goods, without any exclusion of sectors or products. Transition periods –if necessary at all– should be limited. Even though tariffs in the transatlantic market place are low on average, some sectors and products still face high tariffs. This is also true for low-tariff sectors which are still faced with significant payments due to the large trade volume.
   The agreement should strive to achieve common business-friendly views on rules of origin, taking into account the calculation scheme for rules of origin of the EU and the interests of EU producers. In addition, German Industry calls for rules that, in view of existing or future

agreements of the EU with Canada and Mexico, would also discipline the cumulation of origin from North America. Moreover, rules of origin thresholds should be in line with existing EU and U.S. agreements.

4. Liberalizing Investments and Services, setting high standards of Investment Protection
   Investments and services are a key driver of the transatlantic economy and should be a key component of the TTIP. We therefore welcome the approach to liberalize market access for investment and services based on the highest levels of liberalization that both sides have negotiated to date. However, we call on the negotiators to go beyond these existing levels of liberalization and to open investments at all levels of government (federal, state, local) on a non-discriminatory national treatment basis. In particular, ownership restrictions and localization requirements for foreign investors in the U.S. should be removed.
   If both sides deem it necessary to include a chapter on investment protection, it needs to be a benchmark agreement in order to serve as a "gold standard" for future bilateral investment treaties (BITs) with other countries.

5. Granting access to public procurement at all levels
   Public procurement should be liberalized at all levels of government (federal, state, local), going beyond the WTO Agreement on Government Procurement (GPA). This should be done according to principle of national treatment. The agreement should also define products and services
   coming from either market as meeting "Buy National" criteria, preventing all discrimination from existing and future provisions (such as the "Buy American Provision" from 2009). At the very least, a standstill on any new "buy-national" requirements should be agreed at the outset of the negotiations.

   The EU and the US should ensure transparent, open and predictable procedural requirements.

   Any local content requirements (like the "Berry Amendment") should be eliminated for the parties to the TTIP.

   Bond requirements are an additional market barrier for European companies participating in public procurement contracts. Currently, bonds to the value of 200 per cent of the contract value have to be submitted by non-U.S. companies for U.S. tenders. These requirements constitute a particular entrance barrier for European companies and should be reduced.

6. Facilitating the movement of people
   The agreement should improve the movement of people in the transatlantic market by facilitating permanent and temporary work visas, by improving entry provision and by extending the Global Entry program. In addition, the agreement should enhance the mutual recognition of professional qualifications.

C. Regulatory Cooperation

7. Creating mechanisms for horizontal regulation
   The agreement should develop processes and mechanisms to achieve regulatory coherence, including early consultations, impact assessments and regulatory reviews. The agreement should further define an institutional process and procedural requirements for regulator-to-regulator cooperation after negotiations have been concluded ("living agreement"). Progress in this area requires an early and sustained involvement of industry and regulatory agencies.

   Regulatory coherence should build on the existing high level of consumer, safety, health, environmental, and data protection standards in the EU and the U.S.

   The paper on "Regulatory Cooperation in the EU-U.S. Economic Agreement", submitted by BUSINESSEUROPE and the U.S. Chamber of Commerce in October 2012, could serve as a blueprint for this approach. It calls for the full implementation by EU and U.S. authorities of the 2002 Guidelines for Regulatory Cooperation would be a step in the right direction.

   In addition, the Transatlantic Economic Council (TEC) should continue to serve as a platform for regulatory cooperation, e.g. through the "U.S.-EU High Level Regulatory Cooperation Forum". Regulatory cooperation should increase legal certainty, e.g. with regard to liability risks for exports to the U.S.

   Both parties should utilize and work within multinational standards development organizations and should adhere to the WTO's "Principles of International Standards", such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the United Nations Economic Commission for Europe (UNECE)

   Certificates issues by certification bodies (CB) should be accepted by all member countries of the International Commission on the Rules for the Approval of Electrical Equipment (IECEE) and their respective National Certification Bodies (NCBs). Transatlantic cooperation on product safety should be further promoted, e.g. by bilateral implementation of ISO and IEC standards on product safety and risk assessment.

8. Achieving harmonization or mutual recognition of sector-specific regulation
   An agreement should include substantial progress regarding regulatory cooperation for specific sectors and products. Harmonization or mutual recognition of existing regulations and standards should be realized wherever possible. In some sectors, like engineering, machinery, electronics and chemicals, it is necessary to align regulatory approaches before mutual recognition can be achieved.
   Respective regulatory agencies in the EU and the U.S. should assess existing regulations in order to determine to what extent regulatory frameworks are compatible with respect to their approach and their out-

comes, particularly in the area of safety standards. On this basis, regulatory coherence should be maximized, potentially resulting in full mutual recognition ("once approved – accepted everywhere").

D. Global Rules

9. Strengthening the protection of Intellectual Property Rights

As innovative and knowledge-based economies, the EU and the U.S. have a common interest in the high level of protection of intellectual property worldwide. They should therefore act as strategic partners to promote the robust protection of intellectual property rights on a global level.

Any agreement should therefore reflect a shared commitment to the protection of intellectual property rights (IPR), both within the EU and U.S, and with regard to joint approaches to third countries and in international negotiations.

The agreement should foster IPR protection based on the principles already enshrined in the transatlantic IPR Working Group within the TEC. It should strengthen the cooperation on IPR vis-à-vis third countries, in particular with some emerging economies. EU-U.S. alignment on IPR is crucial in times when pressure on IPR policies is increasing. A common understanding on the flexibilities provided in TRIPS would be welcome. The EU and the U.S. should also improve their cooperation on combating cyber-attacks, counterfeiting as well as industrial espionage and the infringement of trade secrets. The U.S. and EU should harmonize approaches so that businesses operating in both jurisdictions will not face conflicting requirements.

Realistic improvements in the protection of intellectual property could be achieved in the following areas:

- At present, the IPR protection mechanism of the U.S. Customs and Border Protection only allows registering trademark rights. The TTIP should therefore develop a border mechanism to register U.S. design patent rights that would allow the seizure at the U.S. border of goods that are protected by design rights.
- The agreement should help drive the quality and efficiency of the patent acquisition process and sharpen the focus in both the U.S. and EU on processing patents that are most important via a multi-tiered patent process. In order to enhance cooperation in innovative sectors, both sides should also reduce the costs for patent applications as well as for patent litigation.
- At present a new design or technology created in the U.S. needs first to be filed in the U.S., whereas the EU does not require a patent or a design created in the EU to be filed locally first (exceptions only with permission from U.S. Patent and Trademark Office). This discrepancy should be addressed in the context of the agreement as it is burdensome for European companies and creates advantages for U.S. companies. Furthermore, U.S. patents are often granted without prior publication, thus creating uncertainties for European compa-

nies. Thus, the obligatory publication of U.S. patent applications would be very welcome.

- The agreement should protect companies on both sides from so-called "patent trolls". For instance, abusive litigation could be eliminated or reduced by shifting the costs of lawsuits -at least in part- to the losing party.

10. Ensuring access to raw materials, eliminating overall export tariffs
    Raw materials and energy are key components of competitiveness. The agreement should therefore ensure the export of raw materials and energy within the transatlantic market according to free trade principles. As an example, the TTIP should ensure that the export of liquefied natural gas (LNG) to the EU is permitted by the U.S. government without any delay or risk of withdrawal of export licenses, thereby providing investment security for EU companies.
    In general, export tariffs can hurt growth and jobs. Consequently, the nature of an agreement needs to go beyond current WTO rules on export restrictions. Furthermore, it should lead to a common approach and strategy to develop an international framework for reducing export restrictions on a global level.

11. Competition Rules
    The agreement should develop fair competition rules, including the treatment of state-owned enterprises and the effective control of subsidies.
    The EU and the U.S. have adopted a memorandum of understanding on the application of positive comity principles in the enforcement of their competition laws. The close cooperation in the area of competition policy should be continued and strengthened, especially regarding the evaluation of economic and market conditions and the timing of merger reviews and proposed merger remedies. Restrictive approaches may produce negative effects on market entries and exits, thereby constituting a trade barrier. Confidential information should not be exchanged between the agencies without prior consent of the companies concerned (confidentiality waiver).

12. Trade Facilitation
    The existing customs procedures and border enforcement cause high additional costs for companies on both sides of the Atlantic. The EU and U.S. should work to enhance electronic customs procedures and to cooperate towards implementing a system of standardized customs processes. This should include efficient central customs clearance, taking into account the participation in international supply chain programs, the harmonization of "pre-shipment" notifications and reporting requirements and the harmonization of customs and security related standards. This is particularly important regarding the movement of goods, as the lack of alignment of custom procedures harms transatlantic and global supply chains.

13. Extraterritoriality

    The agreement should in principle ban regulations partly or wholly designed to develop extra-territorial effects, especially with regard to U.S.

controls on the exports of "dual use" and military products by foreign companies that export from non-US territory ("EAR"/ ITAR regulations).

E. Industry-specific positions

Automotive Industry

The elimination of tariffs and the enhancement of regulatory cooperation both have a high priority for the automotive industry and should be negotiated in parallel.

Current regulatory differences impose high costs for the EU and U.S. auto industries. The EU Commission's recent impact assessment points out that U.S.- EU regulatory differences constitute significant NTBs and that considerable economic gains can be achieved through regulatory convergence. In addition, existing tariffs in the automotive sector still cause unnecessary costs for the EU and U.S. auto industries. To realize the full economic potential of the TTIP, tariffs should be completely eliminated. The automotive industry therefore requests a comprehensive approach, which should – among other issues – include the elimination of tariffs and non-tariff barriers (NTBs) as well as improving regulatory convergence. These priorities are directly linked and should thus be followed in parallel, under a single undertaking.

Greater auto regulatory convergence between the EU and U.S. would strengthen the automotive industry and the sector's economic contribution in both regions. Even though the EU and the U.S. effectively address the same motor vehicle safety and environmental challenges, regulations differ significantly, e.g. in the areas of test procedures, safety requirements (brakes, seatbelts, rear visibility, among others) as well as environmental requirements and consumer information.

With regard to existing regulation, mutual recognition should be presumed unless it is demonstrated that a regulation is deficient from the perspective of safety or environmental outcome. Mutual recognition would imply that vehicles in compliance with either the U.S. or EU safety or environmental regulations are considered to offer the same level of safety and environmental performance in both markets. Product liability risks resulting from different legal environments in the EU and the U.S. need to be addressed in such a way that mutual recognition is effectively applied with legal certainty. With regard to future regulations, and where mutual recognition cannot be achieved, we recommend a joint auto regulatory harmonization process under the UNECE WP 29 umbrella that involves regulators from both sides.

Chemical Industry

The chemical industry calls for the full elimination of tariffs, joint and practicable rules of origin as well as for enhanced regulatory cooperation. Today, approximately 700 million euros in tariff revenues are paid by European chemical companies to the U.S. for import tariffs, a large percent-

age being intra-company trade. Tariff elimination would make these resources available for investments, innovation and for more affordable products.

Given the huge transatlantic differences in chemicals regulation, the long term aim of regulatory cooperation should lie in achieving convergence. If comparable regulations are adopted on both sides of the Atlantic, the cost of compliance could eventually be reduced through mutual recognition.

In the short term, the following subjects could be addressed:

- Co-operation in prioritization of chemicals for assessment and assessment methodologies;
- Promoting alignment in classification and labeling of chemicals;
- Co-operation on new and emerging issues;
- Enhanced information sharing and protection of confidential business information (CBI).

With regard to developing new regulations, the overriding principle should be that both sides agree to consult and cooperate with each other at an early stage. If, for example, the EU and the U.S. can agree on one definition (nanotechnology, endocrine disruptors), this will positively influence a potential convergence of the ensuing regulations. It is important that the two sides commit themselves to co-operating. Such a commitment does not call the regulatory autonomy of both sides into question. A commitment to cooperate cannot be seen as a commitment to results but as a process to try hard to achieve comparable rules.

Engineering Industry

Regulatory divergence and a lack of regulatory transparency is a key barrier to trade for engineering companies from both sides of the Atlantic. The agreement should therefore provide for a reliable common legal framework for the engineering industry in line with the principle of consensus-based (technical) standards, in particular regarding mechanical safety and electrical safety. The alignment of regulatory approaches and harmonization of technical requirements is the basis for the mutual recognition aimed for.

In the machinery sector, there are many ISO standards which have undergone national implementation in various regions of the world and which are available as a standard document issued by a national standardization body. A promising example for such a national implementation is ISO 12100 (health and safety requirements and risk assessment), which contains such technical requirements and requirements for risk assessment and risk reduction as part of the conformity assessment procedure of machines. Since ISO 12100 has also been implemented as an ANSI standard, there is broad transatlantic consensus about these defined requirements on the safety of machinery.

Referring to the electrical safety, the easiest and fastest way to achieve harmonization of standards is to implement the familiar IEC standards as accepted standards in bilateral U.S.-EU trade and to ensure the appropriate

application in the U.S. Eventually, the U.S. is represented by ANSI on the relevant IEC standards bodies, and American standardization experts are actively working on the relevant standards.

Therefore, international standards of ISO or IEC should be applied or recognized in the U.S. so that requirements for machine and plant safety, electrical safety and requirements demanded from the Occupational Safety and Health Administration (OSHA) could be harmonized.

Furthermore harmonization should be achieved within the certification procedures. A preliminary step would be the mutual recognition of test reports and certificates by the approved U.S. certifiers (e.g. NRTL, nationally recognized testing laboratories) which currently is not legally defined.

But as a minimum, the agreement should provide a clear definition of the technical requirements legally obligatory for U.S. market access to overcome the lack of transparency that manufacturers currently have to battle.

Finally, further harmonizing of substantive patent and trademark laws would particularly benefit European SME doing business in the U.S.

Pharmaceutical Industry

Regulatory convergence should be considered a key priority, where continued efforts to address regulatory differences and duplicated requirements impeding efficiency in global drug development should be sought. Alignment of regulatory processes can reduce redundant testing and optimise use of limited regulatory agency resources, while speeding up patient access to new, innovative medicines. Priorities in this area should include amongst others: mutual recognition of Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) for inspections conducted in the EU, U.S. and third countries; extension of parallel scientific advice towards a joint advice statement applicable to all medicines; greater regulatory compatibility for submitting single paediatric plans; efficient parallel assessment of Quality by Design applications.

The TTIP should ensure that government pricing and reimbursement policies do not create obstacles to pharmaceutical trade. To this end, an annex on pharmaceuticals, drawing on the specific annex included in the EU-Korea FTA and in line with the EU Transparency Directive, should address key issues relating to government pharmaceutical pricing and reimbursement policy and procedures. Particular emphasis should be put on greater transparency, adequate value and rewards for innovation.

IPR protection has a high priority for the pharmaceutical industry, especially regarding a greater alignment on patentability standards, regulatory data protection, patent enforcement, use of trademarks, and data disclosure. Furthermore, TTIP provides the opportunity to reaffirm a number of high-level intellectual property principles and to set out a globally consistent set of IP protections as a means of encouraging growth and trade. The industry is also looking forward to achieving the full elimination of remaining tariffs, building on the WTO “zero-for-zero initiative” on active

ingredients and drug products to cover all remaining tariff lines. Other chapters of interest are rules of origin and public procurement.

Information and Communication Technologies (ICTs) Industry

The ICT industry is a key driver of the transatlantic and global economy. The connection of digital and manufacturing processes is a trend in all industry sectors and the core of what we call "Industry 4.0". ICT and ICT-related services should therefore be a key component of the agreement.

In the area of market access, the agreement should

- eliminate tariffs for all ICT products, some of which are not yet covered by the WTO Information Technology Agreement (ITA), e.g. consumer products;
- provide for transparent and business-friendly rules of origin;
- remove ownership restriction for foreign investors in the U.S.;
- improve access to public procurement and prevention of discrimination through "Buy National" criteria;
- abolish localization requirements: ICT service suppliers should not be required to use local infrastructure or establish a local presence, as a condition of supplying services. Exceptions regarding sensitive data or national security concerns must be allowed but need to be clearly defined and should not be applied for protectionist purposes.

In the area of regulatory cooperation, key aspects for the ICT industry are

- creating a level-playing field regarding network access
- recognizing the EU "self-declaration of conformity" (SDOC) in the U.S.
- facilitating international data protection and data traffic without creating distortions of competition in different markets. The high level of protection for European consumers is based on EU rights and is not is not disposable. Therefore, it should be ensured that the processing of personal data of data subjects residing in the European Union has to take place according to EU law. Data protection is usually not considered as a trade barrier and typically falls under the exception as provided for by Article XIV of the General Agreement on Trade in Services (GATS).

The ICT industry considers cyber security as a policy priority worldwide. To ensure a high common level of security across the EU, minimum security requirements must be defined in such a way as to target the same level of security and to guarantee a level playing field along the value chain of all players involved operating in Europe or providing services to European customers. This is essential to enhance trust in the safety of new services, such as cloud services.

Different regulatory frameworks in the EU and the U.S. have led to a competitive disadvantage for European players. In particular, this situation has led to the dominance of Over The Top (OTT) players in the Digital Economy value chain, leading to imbalances that need to be addressed. In addition, European companies investing in the U.S. are in some cases subject to burdensome foreign ownership requirements. Such requirements should be

removed and European investors granted a level playing field with their U.S. competitors. Furthermore, the immense demand for mobile data and increased bandwidths underscores the urgency for an additional spectrum for mobile services.

Food and Drink Industry

Both the elimination of existing as well as the prevention of new regulatory and non-tariff trade barriers is a top priority for the food and drink industry. The recognition and transparency of regulatory processes is particularly important at the EU, the U.S. federal and the U.S. state level. There are more than 2,700 state and municipal authorities in the U.S., which require particular safety certifications or adherence to particular environmental rules for products sold within their jurisdictions. These requirements are not always consistent with each other and not always transparent. Food imports are often confronted with additional state-level requirements leading to obstacles to trade. Current implementation of the U.S. Food Safety Modernization Act (FSMA) has increased costs and risks for food exporters, for example through periodic registration and inspection of companies. The industry would therefore welcome a more transparent and predictable regulatory and legal environment in both markets, e.g. with regard to the FSMA.

With regard to quality standards for food – such as requirements for consumer and environmental protection and animal welfare – as well as SPS standards, a harmonization based on internationally and scientifically accepted standards should be negotiated. The very strict U.S. import provisions for processed animal food, meat and meat products constitute trade barriers for EU producers and should be eased. The industry would welcome a constructive dialogue on the recognition of Geographical Indications (GI) that are protected in the EU. In addition, the implementation of a "technical solution" for minimal traces of unapproved genetically modified organisms in agricultural EU-imports could facilitate EU-U.S.-trade.

Defence and Security Industry

Defence and security are excluded from the WTO Government Procurement Agreement (GPA) and from all other trade agreements to which the EU is a party. There are good reasons for these exclusions. Acquisition of military capability through the purchase of equipment and services by sovereign states is not a simple matter of open competitive procurement. Neither in Europe nor in the U.S. does the Defence and Security sector command the necessary maturity for allowing for a comprehensive opening of each other's defense markets. However, in case negotiations on Defence and Security should be opened, it is indispensable to cover (at least but not only) the following areas: strictly mutual recognition of standards and regulatory requirements; harmonization of requirements; comprehensive and unhampered access to each other's markets; recognition of enterprise affiliation; limited application of ITAR regulations; reduction of extraterritorial effects of national legislations; and the protection of intellectual property rights.

Textile and Clothing Industry

The U.S. is the third biggest target market of German textile and clothing exports outside the E.U. Given the comparatively high customs duties in the U.S. that are levied on many textile products originating in the EU and a fragmented U.S. tariff classification system, the textile and fashion industry demands a full and mutual elimination of tariffs.

Complex regulatory provisions in the field of environment, consumer protection and labeling constitute serious non-tariff barriers and significantly obstruct exports and market access, in particular for SMEs. Regulatory barriers to trade should be reduced and compliance costs of exporting companies should be limited as far as possible by a harmonization of regulatory provisions or a mutual recognition of standards, certifications and testing methods, respectively. Likewise, constraints in public procurement that discriminate against foreign textile and clothing suppliers in the form of local content criteria should be abolished in order to ensure a level playing field for both sides. With regard to rules of origin, the German textile and clothing industry favors a set of generally simple and liberal rules, which recognize technological progress and avoid administrative costs for economic operators.

In the light of the above, all barriers to trade and issues related to the textile and clothing sector should be comprehensively covered by the negotiations and without any restrictions. The German textile and clothing industry therefore rejects potential exemptions for the industry through a textile-specific chapter.

Medical Devices Industry

Regulatory convergence should be considered a key priority in the medical devices sector. Efforts should be maintained to address differences in regulatory procedures and duplicated requirements impeding efficient regulatory processes. The alignment of regulatory processes can reduce redundant testing and optimise use of limited regulatory agency resources, while speeding up patient access to new, innovative medical devices. Any alignment of regulatory provisions and approval processes needs to build on existing European quality and safety standards.
The creation of a centralized European approval agency for medical devices is opposed by German Industry. Therefore, it should not be presumed in the context of transatlantic regulatory cooperation.

Comprehensive preparatory discussions with active participation of regulatory authorities have taken place in the framework of the Global Harmonization Task Force (now “International Medical Device Regulators Forum”). TTIP should build on these achievements, which already form a consensus among EU and US regulatory bodies.

Priorities in this area should include:

- acceptance of the successful ISO 13485 audits performed by both parties as basis for the respective regulatory procedures;

- a harmonized format for technical documentations as a means of demonstrating quality system compliance based on the results achieved by the Global Harmonization Task Force (now "International Medical Device Regulators Forum");
- a single model for a medical device marketing application with electronic submission capabilities based on the results achieved by the Global Harmonization Task Force (now "International Medical Device Regulators Forum")

As a minimum goal, these three steps should lead to the comprehensive mutual recognition of the results of regulatory procedures during regulatory approval processes in the EU and the U.S. Ideally, they would result in full mutual recognition of the respective medical products ("once approved – accepted everywhere"). Any alignment of regulatory provisions and approval processes needs to build on existing European quality and safety standards.

Finally, TTIP should promote the recognition and acceptance of a globally harmonized solution for a Global Unique Device Identification and associated databases for medical devices.

Sugar industry

Since the EU Council´s negotiating directive allows for a special treatment for the most sensitive products, the German sugar industry recommends excluding sugar and products with high sugar content from the scope of the negotiations on a free trade agreement between the EU and the USA. This position is also shared by the U.S. sugar industry. Further tariff or import concessions would disrupt the EU sugar market and lead to further closure of sugar factories and job losses.

Furthermore, the German sugar industry emphasizes that effective and strict rules of origin must be applied in order to avoid triangular trade (in particular with the NAFTA-countries). The current rules of origin applying for the Generalized System of Preferences for the developing countries should be used as a basis.

Cosmetics Industry

In the area of cosmetics, we support the recognition of the International Cooperation on Cosmetics Regulation (ICCR) as a tool for further harmonization. Different classification of cosmetics and cosmetic ingredients is a costly and unnecessary barrier to trade that has absolutely no health consequences. Mutual recognition of diverging classification (e.g. toothpaste, anti-dandruff, antiperspirant, etc.) and of EU positive list materials (e.g. UV filters) would decrease such complexity.

Likewise, diverging labeling provisions result in extra costs with no health consequences. The U.S. should fully adopt INCI Nomenclature and end its requirement to use the term 'water' rather than 'aqua.'

Concerning test methods of cosmetics ingredients, animal testing is currently being phased out in some regulatory jurisdictions, such as the European Union. The EU and U.S. should work together to assure that the TTIP avoids trade barriers and allows for the continued marketing and trade in new and innovative cosmetics products in the EU and the U.S.

Shipping Industry

The German shipping industry calls upon EU and U.S. negotiators to lift the Jones Act for European specialized types and maritime products. The industry suggests that the EU negotiate free market access for passenger ships, Ro Ro vessels and other complex specialized ship types and products. The "Jones Act" requires all waterborne shipping between U.S. ports to be carried out by vessels built in the U.S. and owned, registered and operated by Americans. In addition, by lifting this restriction for specific products from Europe, U.S. operators would benefit from lower costs and better energy efficiency.

Financial Industry

Market access should be improved by strengthening national treatment of financial institutions in both markets and by removing existing barriers and preventing new obstacles to trade in financial services, arising from either the EU and federal U.S. level, or at the EU Member State level and at the U.S. state level, respectively.

Another key issue is achieving more regulatory consistency by agreeing on common standards, mutual recognition, substituted compliance, equivalence decisions or similar legal methods. The existing Financial Market Regulatory Dialogue (FMRD) led by DG Internal Market and the U.S. Department of Treasury should be strengthened. FMRD participants should be included in negotiations on TTIP disciplines fostering increased regulatory consistency.

Financial stability and investor protection can be safeguarded through an appropriate definition of prudential carve out measures. Such measures should be confined to regulations which cannot be bridged by the above-mentioned legal methods for improving regulatory consistency.

About the BDI

The BDI is the umbrella organization of German Industry and industry-related service providers. It is the voice of 38 sector associations, 15 regional offices and 100,000 companies with a workforce of eight million. The BDI has representative offices in Brussels and in Washington, DC ("Representative of German Industry and Trade"). German businesses employ approximately 600.000 American workers and conversely U.S. majority owned affiliates account for about 600.000 jobs in Germany. Germany is the sixth-largest U.S. export market, while the United States is the second-largest export destination for Germany.