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EU publishes TTIP negotiating positions for five key sectors to increase transparency

I. Introduction

On 14 May 2014, in the run-up to the fifth negotiating round taking place 19-23 May 2014 in the US, the European Commission has published its negotiating position in the ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiation for the following five key sectors: chemicals, cosmetics, motor vehicles, pharmaceutical products, and textiles and clothing.

The publication of these papers is part of an effort to improve transparency in the negotiating process, following severe criticism by the civil society. The papers shed some light on the Commission's negotiating priorities and areas where a certain level of regulatory convergence may be achieved. To a large extent, these draw from contributions prepared by the respective industry sectors on both sides of the Atlantic as to which issues should be covered under TTIP. The papers give an indication of how regulatory commitments could be embodied within the future agreement, and therefore on the possible structure of the future agreement. It seems increasingly likely that, next to a "horizontal" text applicable to all sectors, a set of separate, sectoral annexes reflecting the specific outcome for these sectors may be included.

II. Chemicals

The chemicals position paper[1] acknowledges that "neither full harmonization nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and EU". EU focus is therefore on identifying and agreeing on "all possibilities for regulatory co-operation/ convergence within the limits of the existing basic legal frameworks". To that effect, the paper identifies "four main areas… in which a higher degree of convergence may be sought", as follows:

- Co-operation in prioritising chemicals for assessment and assessment methodologies;
- Promoting alignment in the classification and labelling of chemicals;
- Co-operation on new and emerging issues, such as endocrine disruptors, nanomaterials or mixture toxicity; and
- Enhanced information sharing and protection of confidential business information (CBI).

The paper suggests ways to implement mechanisms for mutual consultation and cooperation. For example, regarding enhanced information sharing and protection of CBI, the Commission proposes the identification of possible obstacles to exchanging (confidential) data and benefits of such exchange, and perspective for reciprocity. It also suggests that TTIP could include a periodical

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[1] See http://trade.ec.europa.eu/doclib/html/152468.htm.

review of the functioning of these mechanisms.

Finally, the paper calls for "future convergence" of the parties' regulatory regimes, in the form of an "effective bilateral cooperation and consultation mechanism" in the horizontal regulatory chapter, through which the parties could consult and comment on each other's regulations before adoption. This may, in the long term, lead to an increased level of convergence, in particular in the area of risk management.

III. Cosmetics

The elements laid down in the cosmetics paper[2] largely build upon the issues discussed in the context of the ICCR forum (International Cooperation on Cosmetics Regulation). Focus is on the following areas:

- Mutual recognition of substances that are either authorized (positive list) or prohibited in cosmetics (negative list). UV filters are listed as an example where the EU and US could explore mutual recognition of scientific findings on their safety;
- Mutual recognition of good manufacturing practices, in line with the international standard for cosmetics (ISO 22716);
- Development and acceptance of validated alternative tests methods to animal testing;
- Harmonization of test methods and requirements;
- Greater alignment of labelling requirements (in particular by using the International Nomenclature for Cosmetics Ingredients as a basis); and
- Reinforced regulatory cooperation within ICCR, but also on emerging issues such as nanotechnologies or alternative test methods.

IV. Motor Vehicles

The negotiation position for motor vehicles[3] identifies this as one sector where very substantial efficiency gains and cost savings are possible by addressing regulatory divergences in addition to eliminating tariffs, without lowering safety or environmental protection levels. It recognizes that the levels of safety required by both sides are "broadly comparable" and that equivalence of outcome is achieved even if technical divergences exist. The paper also stresses that a joint EU-US approach could have the potential to create a basis for "genuine international leadership" globally on motor vehicle regulations through reinforcement of the UNECE framework.

Accordingly, the ultimate objectives pursued by the TTIP negotiations for this sector should in the EU's view be twofold:

- the recognition of motor vehicles (as well as their parts and components) manufactured in compliance with the technical requirements of one party as complying with the technical requirements of the other party – to be achieved gradually after the conclusion of TTIP, but based on a built-in agenda;
- a significant strengthening of EU-US cooperation in the framework of the 1998 UNECE Agreement, including on new technologies, with the objective of developing Global Technical Regulations in the future.

The paper suggests a number of methodological steps that could help achieving both objectives, by identifying which precise regulations are equivalent as a first step.

V. Pharmaceutical Products

The negotiation position[4] for pharmaceuticals acknowledges the existence of well-established regulatory cooperation between the EU and the US in the pharmaceutical area. The EU suggests the following ways to reinforce these

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[2] See http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152470.pdf.

[3] See http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152467.pdf.

[4] See http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152471.pdf

processes:

- Establishing bilateral commitments that would facilitate pharmaceutical products authorization processes and optimize agencies' resources, in particular in the areas of Good Manufacturing Practice (GMP) inspections and exchange of confidential and trade secret information;
- Fostering additional harmonization of technical requirements, for example as regards authorizations for biosimilars, paediatrics, and generics, and by harmonising the terminology used for pharmaceutical products; and
- Reinforcing joint approaches on scientific advice and evaluation of quality by design applications in order to avoid unnecessary clinical trials/testing replication.

VI. Textiles and Clothing

The Commission is proposing to reinforce existing cooperation as follows:[5]

- Labelling requirements: the EU is looking to minimize the number of compulsory labels to be affixed to the products, to achieve the approximation or alignment of the names used to designate textile fibers on the basis of ISO standards, to harmonize or mutually recognize care instruction symbols, to promote the use of non-permanent labels to fulfil legitimate requests for additional labelling information, and to see the acceptance of country of origin marking or labelling requirements designating the whole territory of a party (such as "made in the EU");
- Convergence and/or harmonization of approaches to guarantee product safety and consumer protection: the EU's proposals in this area aim for approximation on issues such as textiles' flammability, the establishment of a common list of substances prohibited in textiles and the technical requirements for certain specialized textile and clothing products (such as technical textiles, personal protective equipment or children's clothing); and
- Standards approximation: this part of the proposal deals more specifically with standards which can be used to demonstrate compliance with technical requirements, as these are different in the EU and US and are seen as an important trade barrier. The paper suggests a mechanism for the comparison and possible approximation/harmonization of such standards, with the involvement of the relevant standardization organizations. This could cover standards to test burning behavior and flammability, child safety, technical textiles, protective clothing or textile floor coverings.

VII. Next steps

Both the EU and US have, on numerous occasions (including stakeholder meetings and press briefings in the fringes of earlier negotiating rounds), requested stakeholders to keep presenting their views and concerns, and ideally to present joint papers with concrete ways to achieve regulatory cooperation and convergence. The publication of these five position papers reflects such views, but of course does not exclude further input from stakeholders.

The next round of TTIP negotiations is taking place in the United States from 19-23 May 2014, and regulatory cooperation and convergence will be discussed. In view of the European Parliament elections (also taking place in May), the negotiations are expected not to result in important breakthroughs on sensitive TTIP negotiating areas (including on tariffs, public procurement, financial services regulation, ISDS), but the discussions are likely to focus on a wide range of technical issues.

The following round is reported to take place in Brussels in July.

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[5] See http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152469.pdf