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Committee on Technical Barriers to Trade

THEMATIC SESSION ON REGULATORY COOPERATION BETWEEN MEMBERS ON INTANGIBLE DIGITAL PRODUCTS

20 JUNE 2023, 10:00-13:00

Moderator's Report[1]

At the Ninth Triennial Review, Members agreed to continue to hold thematic sessions in conjunction with the TBT Committee's regular meetings from 2022 to 2024 to further deepen the exchange of experiences on specific topics. On this basis, the Committee agreed to hold a thematic session on regulatory cooperation between Members on intangible digital products.[2] Information about the speakers, presentations, and related materials is available on the WTO website.[3]

1 INTRODUCTORY REMARKS BY THE MODERATOR

1.1. Intangible digital products, such as software and other digitally encoded products that can be transmitted electronically, are an important and growing part of the modern economy and international trade. The emergence of these products composed of bits and bytes may challenge our concept of what a "product" is.

1.2. For example, the International Medical Device Regulators Forum defines the term "Software as a Medical Device" (SaMD) as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. Software as a Medical Device, that is not imbedded in a tangible medical device, is regulated by Health Canada, Canada's medical device regulator, under technical regulations that are similar to those used for "traditional" tangible medical devices. Is software as a medical device a "product"?

1.3. For instance, let us imagine that a company sells software that processes images to help detect breast cancer. That company provides the software to hospitals by email. In turn, these hospitals run this software on their regular non-specialized computer system. From a regulatory perspective, is there a difference between this cancer detecting software and an X-Ray machine? Is an app, that treats dementia by cognitive stimulation, that the company that creates it provides to its customers electronically, different from a dialysis machine?

1.4. Another example of a digital product is software a firm sells to its customers that they use to prepare their tax return. Historically, this "product" was sold on a tangible floppy disk. Today, however, customers download the software directly off the Internet onto their personal computer and it never exists in tangible form. Is this tax preparation software still a "product"?

1.5. When these new amorphous "products" are not related to traditional tangible products, they are spawning the development of novel regulatory measures. These measures are needed to support their development, address risks associated with their deployment and facilitate international trade in them. This is being reflected in Members' notifications, to this Committee, of new regulatory measures. Up to May 31 of this year, there have been 36 general software notifications, 12 notifications of software as a medical device and one AI notification. In addition, regulatory measures

[1] Mr Francis Dorsemaine (Canada). This Report is provided on the Moderator's own responsibility.
[2] G/TBT/46.
[3] WTO | Thematic Session on Regulatory Cooperation between Members on Digital Products.

applied to AI and software have been raised by Members in this Committee as Specific Trade Concerns.

2 GUIDING QUESTIONS

- What are the challenges and opportunities for trade in intangible digital products? How can standards, technical regulations and conformity assessment procedures help address these challenges and harness these opportunities?
- What is the impact of regulatory interventions on MSMEs in the area of trade in intangible digital products? How to ensure MSMEs are not disproportionately affected by such regulations, and what role can the TBT Committee play in this regard?
- What opportunities exist for regulatory cooperation and standards development between Members and stakeholders (both within and outside the WTO) in the area of emerging digital technologies and how can such cooperation help in avoiding unnecessary regulatory fragmentation in this area?

3 INTERVENTIONS

3.1. **Ms Heidi Lund** (European Union)[4] presented the report of the National Board of Trade of Sweden "Innovation, AI, Technical Regulation and Trade". This report analyses how digital innovations change the way in which industrial goods should be regulated. Ms Heidi noted that, as a result of such analysis, it was found that digital innovations increase regulatory complexity and challenge our current trade policy frameworks that rely heavily on the use of international standards and systems for conformity assessment, not necessarily always responding to the needs of fast developing digital innovations. In addition, digital innovation broadens the regulatory concerns applicable for industrial products, i.e., that digital products compliance is not only about product safety but also about cybersecurity, personal integrity and resilience, which is a huge change from the past. The report also concluded that the ability to really control and monitor changes in the properties of digital goods has been significantly weakened (companies and regulators alike*)* and that regulation of products with embedded digital technologies does not sufficiently consider complex supply chains and that challenges aspects of traceability, auditability and verification of product compliance. In addition, the report found that there is a risk that regulatory parameters on product safety, cybersecurity, integrity and resilience are blurred when risks are defined in the regulation of industrial goods. All these regulatory concerns are currently addressed by a multitude of approaches and various regulative proposals, but not necessarily in a coordinated and clear manner.

3.2. Ms Lund also outlined the following policy recommendations from the report: (i) decision-makers should invest in more mature regulations and improve their understanding of digital technologies; (ii) regulations should focus on the life-cycle perspectives as the characteristics of digital goods change over time; (iii) regulators need to improve methods for "continuous compliance" and, for this purpose, new capacities and skills are needed in the market surveillance and the enforcement of product safety and security. Against this background, she concluded that regulations should be better adapted to digital innovations in order to address risks associated with the deployment and use of digital technologies and to mitigate risks of regulatory fragmentation and trade barriers.

3.3. **Mr Jason Matusow** (United States)[5] spoke about standardization and conformity assessment in relation to the unique requirements of digital services. He first provided two concrete examples to explain how digital services are affecting traditional goods. His first example was about refrigerators with screens and sensors that enable digital services applications from different providers. Such applications are of dynamic nature and represent business opportunities for MSMEs that provide cross-border digital services. His second example was about the new business model of jet engine manufacturers who provide engines at no cost to the airlines but instead sell "air operating time" due to digital services. The digital service model is based on the fact that engines are loaded with sensors generating enormous amount of data that can be applied with machine learning and AI systems for predictive maintenance capabilities. All actors in the engine supply chain as well as airline, government of a given country would like to have access to such data (to, for example, better understand air traffic safety concerns or assess pilot's performance). These

[4] Senior Adviser, Department for Trade Agreements and Technical Rules, National Board of Trade, Sweden.
[5] General Manager, Corporate Standards Group, Microsoft Corporation.

examples demonstrate how data generated in and around a device can create local value and distributed economic opportunities and how underlying platforms become enablers of a new type of digital service ecosystem.

3.4. In addition, Mr Matusow noted that current market surveillance and conformity assessment procedures do not properly address such challenges associated with digital services. He therefore stressed the importance of developing coherent certification and labelling systems and promoting capacity building within the policy-making community. He also emphasized the need for the extension of TBT principles to digital services as a unique case as they differ from both goods and traditional services as contemplated existing agreements.

3.5. **Ms Humera Malik** (Canada)[6] spoke about trade barriers and AI regulations from the perspective of SMEs. She noted that SME AI software companies face various regulatory challenges such as: (i) high compliance costs; (ii) lack of technical expertise to navigate complex regulations; (iii) difficulties in understanding regulations across markets; and (iv) divergent regulatory approaches to AI regulations. In this context, Ms Malik noted that simplified and internationally harmonized regulations and conformity assessment procedures, financial incentives and technical assistance would help small companies to improve their regulatory compliance. In addition, she stressed that SMEs should have a voice in the process of developing regulations and standards on AI.

3.6. **Mr Aitor Montesa Lloreda** (European Union)[7] spoke about the regulation of digital technologies under the TBT Agreement focusing on specific challenges that cybersecurity and AI measures pose to the TBT Agreement framework. He noted that the TBT Agreement covers measures that apply to digital technologies, including measures that to a large extent affect the supply of services, such as measures on cybersecurity or AI systems, provided that they impose technical requirements, or set up standards or conformity assessment procedures, with regard to products.

3.7. With respect to cybersecurity, he said that many countries encourage manufacturers or providers of ICT products to take protective measures at the earliest stages of design, at the time of placing on the market and throughout the lifetime of the product, to ensure that such products adapt to future cybersecurity requirements. In addition, cybersecurity certification plays an important role in increasing trust and security in ICT products and should be designed in line with the TBT Agreement. With respect to AI systems, he explained that they may pose risks not only to the traditional public interests normally pursued by the measures covered by the TBT Agreement, such as health and safety, but also to human dignity, private life and personal data, among others. Regulators may thus subject AI systems embedded in products to mandatory requirements which should be non-discriminatory, proportionate, and effective, in line with the TBT Agreement. To ensure trustworthiness, high-risk AI systems could be subject to a conformity assessment prior to their placing on the market and whenever a change may affect its compliance with relevant requirements.

3.8. Relatedly, he noted that there is a high risk of regulatory fragmentation on cybersecurity and AI, and, therefore, international standardisation should play a strong role in the development of regulations on such issues. At the same time, it is important to be aware of the limits of standardisation in this area considering divergences in the societal values that are prevalent in each jurisdiction.

3.9. **Ms Rebecca Anselmetti** (United Kingdom)[8] described the UK approach to AI regulation. She said that while AI has a great potential of benefitting the society, we need to be conscious of emerging risks associated with the AI use. Against this background, the United Kingdom has developed AI regulatory framework which will help to (i) enable responsible innovations; (ii) avoid unnecessary burdens for businesses and regulators; (iii) foster public trust in AI; (iv) keep pace with ever-evolving nature of AI; and (v) design clear rules on AI. Among the important components of AI framework will be the cross-cutting principles for responsible AI with good governance across the life cycle and tools for trustworthy AI (e.g. technical standards and assurance).

[6] CEO, Canvass AI, Canada.

[7] Deputy Head of Unit, Regulatory cooperation and Public procurement, DG TRADE, European Commission.

[8] Senior Policy Advisor, Office for Artificial Intelligence.

3.10. Ms Anselmetti also highlighted the importance of international collaboration and interoperability in the area of AI. In this context, she noted that the United Kingdom recognizes the importance of working closely with global partners to shape international governance and regulation on AI. She also added that tools for trustworthy AI will play a critical role in enabling the responsible adoption of AI by supporting the implementation of regulatory framework and boosting international interoperability. Relatedly, Ms Anselmetti announced that the United Kingdom will host the first global AI summit in 2023 to drive international action to guarantee safety and security of AI.

3.11. **Mr Jesse Riddell** (Australia)[9] presented on the role of international standards for responsible AI. He noted that while we do not yet fully understand the nature of AI, different countries are already developing regulatory solutions to harness the benefits and respond to the risks associated with AI. In order to avoid regulatory divergence across countries, he said, consensus-based international standards must be the essential component in developing AI regulations. The use of international standards will also facilitate free flow of digital solutions, ensure harmonization and interoperability and promote trustworthiness and confidence in emerging technologies. In this context, he provided an overview of work of ISO/IEC JTC 1/SC 42 Artificial Intelligence, the international technical committee that sets standards in the area of AI. The committee has already published 17 standards and currently works on developing 30 more standards on AI.

3.12. In addition, Mr Riddell noted that national and international collaboration and capacity building is necessary to uplift standards awareness and adoption. With these considerations in mind, Australia established the Responsible AI Network that is aimed at uplifting the practice of responsible AI across Australia's commercial sector and jurisdictions.

4 COMMENT BY THE MODERATOR

4.1. It was a pleasure to moderate the discussion around regulatory cooperation between Members on Intangible Digital Products. I would like to thank Members for putting forward an excellent group of experts and effectively making my role an easy one. I would also like to thank all speakers for their insightful and thought-provoking contributions, as well as the participants for their active engagement in the discussion and for the many questions you posed to our speakers. Finally, I would like to express my sincere appreciation to the Secretariat and the interpreters for your support throughout the process.

4.2. Over the past few days, I have received very positive feedback from participants. With this in mind, I believe that the TBT Committee should continue and deepen its discussions and work on this important topic.

4.3. I have been asked to share with you a number of key takeaways from the thematic session:

- In contrast to "traditional" goods, regulating intangible digital products present unique challenges given that their properties or functions may constantly change throughout their life cycle or that they entail addressing various "non-typical" risks or concerns that may vary in relevance across Members (e.g. privacy, ethics, morality, and other "societal" values). In this context, speakers stressed that regulators should invest in more mature regulatory measures to account for unique characteristics of intangible digital products.

- Although we do not yet fully understand the benefits and risks of emerging digital technologies, various regulations are nonetheless currently being developed at national or regional levels. This, coupled with the unique nature of these technologies of raising non-typical (and potentially country-specific) risks, is resulting in a sort of global regulatory "spaghetti bowl". There is, therefore, a real danger of regulatory fragmentation in this area, which can, in turn, block opportunities and benefits associated with such novel products, undermine public trust, and lead to an increase in the digital divide.

- In this context, one clear message was about the importance of international standards as a fundamental piece of the regulatory puzzle, including as a basis for AI regulations (e.g. for promoting "responsible" AI). Consensus-based international standards are key for ensuring the necessary interoperability across markets, which would facilitate innovation, trade, and the free flow of digital solutions.

[9] Senior Manager, International Partnerships, Standards Australia.

- At the same time, we need to be aware of the limits of standardisation in this area, as these new digital technologies raise certain "non-typical" risks and concerns. This means that standardisation may not be always suitable for addressing certain regulatory divergences in this area, in particular in terms regulations addressing "societal values" the relative importance of which may vary across Members. By no means does this imply that standardization has no place here, as one could still focus on harmonizing "technical solutions" as a pathway to address concerns.

- Relatedly, speakers said that, while standards move quicker than the law, technological innovations move even quicker than standards. With this in mind, we need to be realistic about the fact that the development of international standards on, for example AI, won't happen overnight and that we should therefore adapt our regulatory approaches and solutions accordingly.

- Speakers also highlighted the importance of closer international cooperation as an effective way to shape international and inclusive digital governance. Indeed, international collaboration is essential to promote standards' awareness and adoption. Relatedly, speakers noted that regulators should not operate in a vacuum, but rather work closely with tech industries, including SMEs, as well as civil society to develop high-quality regulations and standards.

- This underscores the importance of the TBT Agreement for regulations on intangible digital products, as the Agreement can ensure that Members do not create discriminatory or unnecessarily trade-restrictive regulations on these products. In addition, leveraging and complying with powerful transparency obligations under the TBT Agreement can help to ensure regulatory harmonization in this area or, if harmonization is not possible, to seek other forms of regulatory coherence and cooperation.

- We also discussed the need and particular importance for capacity building within policy makers to better understand digital technologies. Regulators need to have capacities and skills in the form of, for example, methods for traceability, auditability, market surveillance and enforcement of regulations on these new products. This is particularly important for digital technologies that, as mentioned earlier, constantly evolve in a very fast pace.

- Finally, and I have deliberately left this to the end, we heard about regulatory challenges faced by SMEs such as high compliance costs, lack of technical expertise to navigate complex regulations, difficulties in understanding regulations across markets and divergent regulatory approaches to AI regulations. In this context, the SME representative noted that simplified and internationally harmonized regulations and technical assistance would help small companies to improve their regulatory compliance. As I noted earlier, it was stressed that SMEs should have a voice in the process of developing regulations and standards on intangible digital products.

4.4. As you can see, this was a very productive and comprehensive thematic session. My thanks once again to the Secretariat for your support. I very much look forward to future discussions and work at the TBT Committee on this important topic.