



Joint Minutes of the Third Meeting of the Committee on Technical Barriers to Trade under the Agreement between the European Union and Japan for an Economic Partnership

Tokyo and Brussels (by video-conference), 26 April 2022

The third meeting of the Committee on Technical Barriers to Trade under the Agreement between the European Union (“EU”) and Japan for an Economic Partnership (“EPA”) took place on 26 April 2022, by video-conference.

In this meeting, Japan and the EU provided updates on the topics discussed in the second meeting and exchanged views on some of their regulatory plans and practices, allowing for a fruitful discussion on matters related to Chapter 7 of the EPA (Technical Barriers to Trade: “TBT”). On Japan’s side, participants from MOFA, METI, MHLW, MAFF, MLIT and the Mission of Japan to the European Union were represented; and there were participants from DG TRADE, DG MOVE, DG GROW, DG ENV, DG SANTE as well as the EU Delegation in Tokyo from the EU side.

The enclosed meeting agenda was adopted (cf. attachment).

With regard to the EU Directive on the **Deployment of Alternative Fuels Infrastructure (AFIR)**, Japan requested that it not exclude specific types of technical specifications and standards other than Combined Charging System (CCS), to offer a variety of choices for users. Japan also requested that the EU keep Japan updated on this topic and to ensure transparency by conducting public consultations with an adequate time frame during the development process of the Directive, so that foreign stakeholders could fully examine the regulatory contents and submit comments therein.

In reply, the EU stated that, as already mentioned in previous meetings, the AFIR proposal does not prevent the use of other standards than those adopted by European Standardisation Organisations (ESOs). As in the past, the proposed Regulation makes mandatory the standards adopted by ESOs supplementing the technical specifications set out in the AFIR proposal through the relevant Delegated Regulations, but this does not exclude any other standards. The EU also explained that a new standardisation mandate (M/581) has been given to the ESOs to develop European standards based on the technical specifications set out

in the Annex II of the AFIR proposal. The EU would like to invite Japanese standardisation organisations to cooperate with the ESOs in the development of common technical solutions/standards to be applied in electromobility and alternative fuels infrastructures. Both sides confirmed that they would continue cooperation and discussions in this area.

In the discussion of the **Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)**, the EU explained that a grace period was allowed for medical devices to continue to be in circulation until May 2025, in parallel with MDR certified devices and that a staggered set of transition periods for IVDs was also in place. An adjustment period was currently ongoing but the Medical Device Coordination Group (MDCG) was continuing to closely monitor the situation.

Upon request from the EU to explain the state of play of the directions of pharmaceuticals and medical devices in Japan, Japan explained that since the revision of the **Pharmaceutical Affairs Law** in August 2021, electronic methods such as GS1 barcodes have been used for ethical drugs, and users can read the up-to-date directions with their electronic devices by using a free application.

The EU expressed appreciation that Japan has published an English translation of the **QMS Ministerial Ordinance**, which will be effective in reducing the development lag of medical devices. Japan explained its continued efforts to ensure transparency and predictability of its regulation through active participation in international regulatory harmonisation fora for medical devices, such as IMDRF and ISO/IEC technical committees.

Japan requested information on the development of a specific methodology for the calculation of **carbon footprint of batteries**, including calculation rules, examples of application, use of calculation results from other countries as well as on future timelines of the development. Japan also requested that transparency be ensured by conducting public consultations in developing this battery regulation and its delegated act. In addition, Japan provided information on the study for the sustainability of batteries including carbon footprint in Japan. The EU responded that three draft proposals (of European Commission, European Parliament and European Council) were on the table for the batteries regulation, and hopefully there would be a political agreement towards the end of the year. There are different opinions especially on which batteries to be covered and the timing of application and, to a certain extent, on methodology. The preparation of the detailed methodology has already started by the Commission's Joint Research Centre and the process for the delegated act will include consultation.

Japan asked for information on the latest state of play regarding the Commission proposal for EU harmonised **front-of-pack nutrition labelling (FOPNL)** and mentioned its particular concerns on its consistency with the TBT Agreement, the possibility that existing FOPNL systems such as Nutri-Score would be adopted, and the next steps for the European Food Safety Authority (EFSA). In response, the EU explained that the adoption of the proposal by the Commission is scheduled towards the end of this year and will be followed by the ordinary legislative procedure for adoption of legislation involving the Council and the European Parliament. The EU provided Japan with updates on ongoing preparations accordingly, including on EFSA advice. The EU explained that the Commission proposal for a revision of the Food Information to Consumers Regulation, once adopted, would be notified to the WTO for consultation in accordance with international obligations. The EU further explained that the Commission proposal, announced in the Farm to Fork strategy, would be based on scientific advice, an impact assessment and stakeholder consultations. Japan asked the EU to take into account Japan's comments on TBT aspects. Japan indicated that, for instance, the Nutri-Score evaluates the nutritional value of a food based on a 100g/100ml reference value, but pre-packed soy sauce and miso are not consumed by 100g/100ml but in smaller portions. Japan asked the EU to be kept updated. In response to that particular point, the EU stated that at this stage, no choice of scheme has been made. The EU also explained that they were aware of the issue regarding the reference value for FOPNL schemes (100g/ml or portion-based) and that some EU producers were raising the same point (e.g. in relation to olive oil or other products). Following Japan's questions, the EU explained that the impact assessment covers pre-packaged foods that are required to bear a nutrition declaration.

The EU argued that it is difficult for the EU manufacturers to enter **Japanese railway market** and that the situation is reportedly getting worse. One difficulty relates to the fact that there is no official conformity assessment system in Japan, and many railway operators conduct their own conformity assessments based on their own technical use, leading to some lack of predictability and opacity. The EU then suggested that Japan considers the establishment of a mandatory standard and conformity assessment mechanism. Japan clarified that there has been no change in the laws related to railway, so Japan does not perceive that the access to Japanese market has got worse for EU manufacturers. Japan also explained that although it is not subject to government procurement, three JR Honshu companies (JR East, JR Tokai, and JR West), JR Kyushu, and other companies of interest to the EU manufacturers have conducted their procurement in accordance with their transparent and fair policy, and these companies have published information on the procurement process, the flow of procurement procedures and procurement plans on their respective websites in multiple languages. For Japan to take further action, Japan requested that the EU provide information on specific examples of

market access barriers and specific difficulties. In response to the EU's request to move this issue from the Technical Experts Group (TEG) to the EPA framework, Japan responded that it would need further consideration on the issues and would like to address them in the TEG interim report, which will be compiled soon.

Under AOB, there was a discussion on the EU proposal for a regulation on deforestation-free products. The two sides explained their respective positions as regards whether or not the said regulation would fall under the scope of TBT rules.

The EU and Japan Co-Chairs expressed appreciation for the productive meeting and reaffirmed the willingness to continue to build better understanding and cooperation in the TBT area.
