



## **Joint Minutes of the Second 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), 17 February 2021**

The second 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 17 February, 2021, by video-conference.

In this meeting, Japan and the EU provided updates on the topics discussed in the first 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 side, participants from MOFA, METI, MOF, NTA, MHLW and the Mission of Japan to the European Union were represented; and there were participants from DG TRADE, DG GROW, DG SANTE, DG MOVE as well as the EU Delegation in Tokyo from the EU side.

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

The EU provided Japan with updates on ongoing preparations for the timely implementation of the Medical Device Regulation. Japan welcomed the EU’s decision to postpone the implementation date of this Regulation and acknowledged the increase in capacity of notified bodies. It requested the EU side to clarify whether the medical products with valid certificates under existing Medical Device Directive would be admitted in the EU until the Regulation would be fully implemented and requested that the EU publish, in advance, relevant guidance for business stakeholders to comply with the MDR. The EU confirmed that there would be a transition period until May 2024 during which time medical devices with valid certificates issued under the old Directives could be marketed provided they have not undergone substantial modifications. The EU explained its ongoing work on the guidance documents and would provide the URL of the webpage where these documents are posted, in order to assist the Japanese authorities in tracking developments in this area.

The EU also explained the state of play and prospects as regards the regulation (restriction) of microplastics and of siloxane substances D4-D5-D6. Actions on

microplastics will target their intentional addition to products. Siloxanes are to be regulated because there are persistent, bioaccumulative and toxic substances. The EU underlined that useful exchanges of views on these topics have taken place in the context of the chemicals WG under the EU-Japan Industrial Policy Dialogue. Japan requested the EU to take the opinions from business stakeholders into account in the course of the public consultation process. The EU side confirmed that comments received in the public consultation process are included in the regulatory file. The EU will provide a written answer to the questionnaire submitted by Japan at the first meeting.

Japan provided the EU updates on its efforts to comply with the POPs Convention and explained the state of play and schedules for amendments of relevant regulations. The EU recognised Japan's efforts on this topic, and informed them that on its side it has already restricted the relevant substances. Both sides confirmed their readiness to share relevant information with each other.

Following the initial discussion at the first meeting of the committee, the EU proposed to establish some cooperation activities on "lot codes" and non-alteration of labels between the Parties. The EU side referred to the relevant article in the Japan-UK EPA and enquired about the intentions of Japan as regards its implementation. Both sides confirmed that they would explore the possibility for such cooperation activities, taking the future discussion between Japan and third countries into account. In this context, Japan informed the EU that it does not have detailed information on the alteration of labels of beverages placed on the Japanese market and asked the EU to share relevant information on facts such as the scale of the issue and the place where the alteration of labels takes place .

As regards the use instructions of medical devices in Japan ("tempu-bunsho"), Japan presented the current state of play. Upon a request from the EU side, Japan clarified that the requirement to provide paper-based instructions with the first delivery of products applies only with regard to deliveries to medical institutions.

The EU explained the background and the state of play of the envisaged Alternative Fuels Infrastructure Directive. Japan expressed its concern about the Directive referring to the possibility where the Directive would exclude specific types of technical specifications and standards for the charging infrastructure in the EU, and asked the EU to keep Japan updated on this topic and to ensure transparency in developing this Directive. The EU explained that, under the Alternative Fuels Infrastructure Directive, alternating current (AC) normal and high power recharging points, and direct current (DC) high power recharging points for electric vehicles shall be equipped, for interoperability purposes, at least with a connector or socket outlet conforming to standards EN 62196-2 and EN 62196-3. Therefore, the Directive does not prevent in any way the addition of

connectors or socket outlets based on other standards. The upcoming revision of the Directive is expected to follow the same approach. The EU also explained that this approach could be followed also with regard to other technical specifications and standards.

Japan explained Japan's Good Clinical Practice (GCP) for medical devices in relations to ISO 14155 and its efforts to shorten the "device lag". For the GCP issue, Japan clarified that Japan had already accepted ISO 14155 as one of the standards that is equivalent to GCP. The EU side informed Japan about claims from industry that trials in compliance with the ISO standard are not always accepted. Both sides concluded that the EU would provide specific detailed information if any, and both sides confirmed that, on that basis, they would share information at their disposal.

Japan informed the EU about a newly issued report from Japan's Business Council for Trade and Investment Facilitation last year, and asked the EU side to consider the opinions from business stakeholders as much as possible. Japan confirmed to keep sharing the annual report with the EU in a timely manner.

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