



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

Brussels, 15 November 2019

The first 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 15 November 2019 in Brussels.

EU participants from the Directorates-General TRADE, AGRI, SANTE and GROW, and from the EU Delegation to Japan, had a fruitful exchange of views with Japanese participants from MOFA, METI and the Mission of Japan to the European Union, on matters related to Chapter 7 of the EPA (Technical Barriers to Trade).

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

The committee confirmed that it would work in accordance with the rules of procedure of the Joint Committee, which would apply *mutatis mutandis*.

Japan provided a description of its cooperation activities on issues related to standardisation namely with ASEAN countries, particularly with regard to pharmaceutical and medical devices, automobiles and testing laboratories. The EU referred to existing cooperation through CEN/CENELEC, bilaterally as well as with other countries and international organisations.

Japan explained the state of play as regards the legislative procedure for the revision of the Pharmaceutical and Medical Devices Act, which could be concluded by the end of 2019. Japan explained that, if the revision Act was adopted, it would come into force within two years, after determining implementing measures. The EU Delegation in Tokyo and the relevant ministry in Japan will liaise on the implementing measures.

Japan expressed concern about the implementation of the EU’s new medical devices regulation. The EU explained the state of play, and referred, in particular, to the process of designation of notified bodies and the transition period, as well as proposed amendments with regard to class-1 devices. The EU will share with

Japan internet links to webpages with up-to-date information on the regulation, including the designation of notified bodies, and will inform them about legislative developments. Both sides confirmed their willingness to continue their discussions.

The EU and Japan exchanged information on their regulatory plans concerning chemical substances that could be restricted, and they confirmed they will exchange information on their respective plans in writing. They reaffirmed the usefulness of their exchanges in the context of the chemicals WG. The EU described, in detail, its domestic process for the restriction of substances and the average timeframe of such a process. The EU provided Japan with information on the state of play on substances D4-D5-D6. As regards microplastics, the EU will provide written answers to the questions submitted by Japan. Both sides confirmed they will continue their discussions.

The EU referred to existing recommendations by Japanese authorities raising awareness of undesirable cases resulting from the alteration of lot codes in product labels, particularly for alcoholic beverages, and it suggested further discussion on a possible means of rendering their practice more effective. Japan explained the steps that have already been undertaken, including the notice issued by three relevant ministries. In response to a question from Japan, the EU clarified that it did not seek an alignment of Japan with the EU regulation on lot codes. Japan confirmed they will convey the suggestion to the relevant ministries. Both sides confirmed their willingness to continue their discussions.

The EU informed Japan about its new regulation on market surveillance and compliance of products. The EU explained that Article 4 includes a requirement on economic operators to have, in some cases, a representative in the EU for a limited number of product categories, and the regulation calls for international cooperation on market surveillance, which might be of relevance for the EPA.

The Committee took note of the existing good bilateral cooperation in the context of the WG on standardisation and conformity assessment under the auspices of the EU-Japan industrial policy dialogue. In this context, both sides acknowledged the importance of aligning the Committee with discussions in other relevant EU-Japan dialogues.

Japan informed the EU about a report from Japan's Business Council for Trade and Investment Facilitation, reflecting business views and concerns on some aspects of EU regulations, requesting the EU to take these concerns into account. Japan confirmed they would share the report with the EU.
