

To: [redacted] (TRADE)
Subject: FW: EU-Japan FTA: chemicals

From: [redacted] (TRADE)
Sent: Monday, September 11, 2017 4:09 PM
To: [redacted]
Subject: RE: EU-Japan FTA: chemicals

Dear [redacted],

Sorry for my late reply. I hope you had a nice summer.

I've just talked with colleagues regarding your request below concerning several NTBs and how they are tackled in the EU-Japan FTA. Unfortunately, I cannot yet provide you with a full picture on all the aspects that you have raised, but I have now some information at least on the MRL issue that I would like to share with you.

Would you have time for a phone call tomorrow (12/9) afternoon at 16.30? Thursday (14/9) afternoon at 16.00 would also be possible for me if this should be more convenient for you.

We might also take this opportunity to go through other pending issues.

Best regards,

[redacted]

From: [redacted] [[mailto:\[redacted\]](mailto:[redacted])]
Sent: Friday, August 25, 2017 3:33 PM
To: [redacted] (TRADE)
Cc: [redacted]
Subject: RE: EU-Japan FTA: chemicals

Dear [redacted]

I am coming back to you regarding the EU-JP agreement.

We would like to know if you would have more information on what has been agreed on the NTB for chemicals.

Please find below a list of our NTB's with Japan that we also shared with Mr. Petriccione in May.

Many thanks,

Best regards,

[REDACTED]

Bovine gelatine: Japanese requirements for bovine gelatine are divergent from the OIE TAHC (World Organization for Animal Health - Terrestrial Animal Health Code) and do not allow the use of raw materials from certain countries or regions, such as the EU, whereas the OIE TAHC does not prohibit the trade of this type of gelatine. It is now easier to import beef product to Japan, and therefore bovine gelatine for food purposes. However, market access for bovine gelatine for pharmaceuticals is not yet 100% granted.

Definition of polymers: The definition of polymers in Japan is not fully aligned with the OECD definition, hence leading to different classification and sometimes new/additional registration requirements. This is consequently time and money consuming.

Site Accreditation: A site accreditation is necessary only for non-domestic manufacturers of pharmaceutical ingredients in Japan, increasing the administrative and cost burden for foreign manufacturers.

Registration of new chemical substances: Extensive and detailed clarification is required by the Japanese authorities for the registration of new chemical substances. This leads to excessive time to market for new product registrations of up to more than three years. However, both the EU and Japan apparently agreed, in the context of the FTA talks, not to deviate from international standards regarding chemical testing requirements for the registration of new substances. While this is a positive sign, the follow-up of this agreement must be ensured.

Maximum residue levels (MRL's): MRL's are the legal maximum level of a certain plant protection product in or on a specific crop. MRLs vary from country to country and can cause barriers to trade. In the case of Japan three issues are especially critical: bureaucratic and time-consuming process to establish MRL's in Japan; differences in the definition of MRL's, and; international standards are also not always taken into account in case of trade disputes. However, Japan apparently agreed, in the context of the FTA talks, to establish specific deadlines to establish MRL's, and is revising MRL standards for conformity with international standards. While these are positive signs, we must ensure the follow-up of these improvements.

From: [REDACTED]
Sent: vendredi 7 juillet 2017 10:48
To: [REDACTED]@ec.europa.eu' [REDACTED]@ec.europa.eu>
Subject: RE: EU-Japan FTA: chemicals

Thank you [REDACTED].

Best regards,

[REDACTED]

From: [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
[mailto: [REDACTED] <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
Sent: jeudi 6 juillet 2017 17:16
To: [REDACTED] >
Subject: RE: EU-Japan FTA: chemicals

Dear [REDACTED],

I just spoke with one of our colleagues involved in the tariff side of the EU-JP agreement: Apparently, there will be almost 100% tariff liberalisation for chemicals (HS 28-39) already upon entry into force, with a few very limited exceptions for sensitive products on both sides. More detailed info can only be shared at a later stage.

With regard to RoO and RegCo, we have contacted the responsible colleagues and wait for their feedback – I'll get back to you on this asap.

Regards,

[REDACTED]

From: [REDACTED] <[\[mailto:\[REDACTED\]\]](mailto:[REDACTED])>
Sent: Thursday, July 06, 2017 11:23 AM
To: [REDACTED] (TRADE)
Subject: EU-Japan FTA: chemicals

Dear [REDACTED]

As the political agreement on the EU-Japan FTA will be signed today, I was wondering if you could give us more information what has been decided on chemicals.

We would be interested to have more information on Market Access, Rules of Origin and regulatory cooperation for chemicals.

Many thanks in advance,

Best regards/Meilleures salutations

[REDACTED]

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