EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Deputy Director-General for the Food Chain

Brussels,
SANTE/E.3/PC/gb

NOTE TO TRADE COUNCELLORS OF THIRD COUNTRY MISSIONS/REPRESENTATIONS TO THE EU

Subject: **Impact of the Biocidal Products Regulation (EU) No 528/2012 of 22 May 2012 on the import of manufactured goods into the EU**

Regulation (EU) No 528/2012 on the making available on the market and use of biocidal products[1] (the BPR) applies since 1 September 2013. This regulation however contains provisions which apply not only to biocidal products but also to **manufactured goods** if they have been treated with or incorporate a biocidal product.

Such manufactured goods are defined as *treated articles* under Article 3(1)(l) of that Regulation and a specific legal regime apply to them.

I want to draw your attention to this specific regime, as it could have a significant impact on trade if economic operators do not take the benefit of the current period of transition to make goods compliant for export to the EU.

Article 58(2) of the BPR indeed specifies that a treated article can only be placed on the EU market if it has been treated with active substances which have been approved in the EU for that purpose. This provision also applies to and is critically relevant for treated articles imported from third countries.

Third country manufacturers of goods such as IT or electronic equipment, furniture, textiles, automobiles must be made fully aware of the provisions of the BPR on treated articles.

[1] Regulation (EU) No 528/2012, OJ L 167, 27.6.2012, p.1.

Pursuant to Article 94 of the BPR, there is currently a period of transition but, from **1 March 2017 onwards**, non-compliant treated articles will no longer be allowed on the EU market[2].

For currently non-compliant treated articles, different options are available to manufacturers. They can in particular switch to substances approved or undergoing evaluation in the EU or submit either themselves or through a third party, an application for the approval of the active substance used for the treatment or incorporated in the article to the European Chemicals Agency by 1 September 2016.

Given the importance of these provisions, my services have developed a list of 'Frequently asked questions on treated articles' that are available on the Commission website[3]. We remain at your disposal should you have further questions on the matter at SANTE-BIOCIDES@ec.europa.eu.

Last but not least, I would like to call on your assistance to communicate this information as widely as possible and in particular to the various economic operators and industry associations, with whom you may have contacts.

I thank you for your attention and kind assistance.

Yours sincerely,

Ladislav MIKO

Cc: WTO TBT national enquiry points, EU Commission delegations trade correspondents

[2] Article 94 of the BPR provides for a transitional measure, which aims at ensuring that only articles treated with actives substance approved or for which an application for approval has been submitted by 1st September 2016, are placed on the EU market beyond 1st March 2017.

[3] Note for Guidance: https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22.