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NEWSLETTER

SCC Regulatory NewsFlash, May 2020

REGULATORY NEWSFLASH

CHEMICALS

Inventory notification period for imports of chemicals into Russia and other EAEU countries has been extended to 1 August 2020 due to COVID-19

The implementation of the new chemical regulation for the Eurasian Economic Union (EAEU)* started on 11 November 2019 with the opening of the chemical inventory notification period in Russia. After the initial deadline expired on 1 January 2020, the Russian ministry communicated the extension of the important period until 1 May 2020. This has now been extended to **1 August 2020**.

Notification of the entire portfolio of manufactured or imported chemical substances ensures that manufacturers and importers benefit from the relatively light obligations for existing substances vs. the expected requirements for any new substances. For more information, please contact Dr Mathias Rietzel-Röhrdanz.

*The Eurasian Economic Union consists of these countries: Belarus, Kazakhstan, Armenia, Kyrgyzstan and Russia.

BIOCIDES

South-Korea amends the Consumer Chemical Products and Biocide Safety Management Law (K-BPR), allowing Only Representatives and changing important deadlines

The recent amendments of the K-BPR, as in force from March 24, will now allow non-Korean manufacturers to appoint a South Korea-based only representative (OR) to handle their substance approvals from January 1st, 2021. The amendment also removed notification deadlines for active substances, allowing companies to continue to notify active substances.

For each active substance a company wants to have approved, a so called approval plan must be submitted to NIER (Korean National Institute of Environmental Research). Originally the notification deadline was set at the end of 2020. In the recent amendment, this has been changed to 12 months after the notification. For more information, please contact Ji Yeong Kim.

MEDICAL DEVICES

One year delay in the implementation dates of the Medical Device Regulation (EU) 2017/745 due to COVID-19

An amendment relating to the dates of application of the new medical device regulation MDR (EU) 2017/745, decided by the European parliament on 17 April 2020, has been published and is in force. In the amendment, all dates referring to the original implementation date of 26 May 2020 have been replaced by 26 May 2021, with exception of the preparation of the guidelines on phthalates.

In addition to keeping the requirements for existing devices, this allows placing new or modified medical devices on the market under the Directives 93/42/EEC and 90/385/EEC up to this new implementation date next year. The deadlines for placing the UDI on the device and packaging, which were scheduled further in the future, remain unchanged.

If you have questions with respect to the impact on your company, please contact Dr Alexander Theis.

Do you have any comments, questions or suggestions?
Drop us an email at newsletter@scc-gmbh.de