NEWS on diagnostics

2020 Special Edition:
Regulatory Updates

Welcome to this special edition of News on Diagnostics. This volume will cover updates* on the regulations that can affect the diagnostics industry.

REACH Regulation

REACH stands for the Registration, Evaluation, Authorisation and Restrictions of Chemicals (**echa.europa.eu/REACH**) and is an EU regulation that entered into force in 2007. REACH aims to ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles. REACH affects manufacturers making and/or importing products into the EU, with our company being one of these suppliers.

Every year, chemicals are evaluated, and depending on the results of that evaluation, are added to the list by the European Chemicals Agency (ECHA).

Four new candidate substances have been added to the Substances of Very High Concern (SVHC) list – they are typically used in polymer production.

These chemicals can be found here: **https://echa.europa.eu/-/four-new-substances-added-to-candidate-list**

Periodic review of the agency website is recommended since importers and producers of articles containing substances added to the candidate list typically have six months from the date of its inclusion to notify ECHA.

*Updates are current at the time of the newsletter writing. Any subsequent changes to the regulations, may not be fully reflected in this newsletter.

IVDR updates

The implementation date for IVDR remains May 2020. Several additional guidance documents are being prepared, and one has been published. In December 2019, the Medical Device Coordination Group (MDCG) released a document to clarify the Guidance on sampling of Medical Device Regulation (MDR) Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation.

The full document can be found here (**https://ec.europa.eu/docsroom/documents/38669**)

A list of other guidance documents endorsed by the EU, can be found here **https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en**

It is important to note that the vast majority (at present) are for MDR, with documents related to IVDR to be published as soon as is practical.

Ongoing guidance development documentation can be found here **https://ec.europa.eu/docsroom/documents/38862**

NANDO database for IVDR Notified Body (NB) designation.

At present, only three NB are designated under IVDR

- BSI Assurance UK Ltd (United Kingdom) - designated October 2019
- BSI Group The Netherlands B.V. (Netherlands) – designated November 2019
- DEKRA Certification GmbH (Germany) – designated 10 October 2019

As Notified Bodies are added, you can find them here, on the NANDO database

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

The approval of Notified Bodies, is at present, focused on the MDR (due to come into force 22 May 2020), which is delaying designation under the IVDR.

ISO 17511

ISO 17511 deals with *in vitro* diagnostic medical devices — requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples. This document is currently under development, despite its projected publication of March 2020. You can keep up to date with this important ISO standard here **https://www.iso.org/standard/69984.html**

BPR and the use of ProcClin™ preservatives

The Biocidal Products Regulation [BPR, Regulation (EU) 528/2012] concerns the placing on the market and the use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, such as pests or bacteria, by the action of the active substances contained in the biocidal product. The BPR regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

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Lit. No. MK_NL6387EN
31333
04/2020