

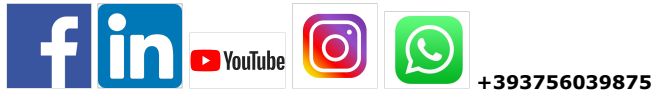
REACHUP REGULATORY NETWORK ITALY SRL

contact us at: info@reachup.it - www.reachup.it



Newsletter RNI srl 18.10.2021

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Download here our services brochure



RNI has activated the transmission service with digital certification of regulatory practices for Spanish authorities.

RNI can be found on pages 202 and 203 of Chemical Watch's Global Service Providers Guide 2021, at the following [link](#)

In order to verify the VAT number associated with the UFI code in most European countries, press [here](#)

INDIA: BIS PRODUCT CERTIFICATIONS



Under BIS Act 2016, BIS Rules 2018 and BIS (Conformity Assessment) Regulations 2018, the provisions for Grant of Licence (GoL) are addressed. It covers BIS license for both domestic and foreign manufactures for chemical products listed in Scheme I that are placed on the Indian market. India has regulated import of 52 chemicals that requires BIS license to be obtained within 180 days from the date of inclusion of such chemicals in Scheme I (India BIS list) as defined in Quality Control Orders (QCO(s)). Under BIS Act 2016 Rules & BIS (Conformity Assessment) Regulations, 2018, foreign manufacturers can submit India BIS application using an Authorised India Representative. Domestic manufacturers also need to submit application under this rule.

For the complete list of substances press [here](#)

INDIA REACH: DRAFT OF CHEMICALS (MANAGEMENT AND SAFETY) RULES



India-REACH is India's chemical regulation currently in draft stage known as "Draft Chemicals (Management and Safety) Rules, 20xx" or CMS Rules 20xx. The rules shall come into force on the date of their publication in the official gazette, expected to come in force upon WTO Notification expected in 2021 and shall apply to all Substances, Substances in Mixtures/Articles and Intermediates that are Manufactured, Imported, Placed or intended to be Placed in Indian Territory above 1 tonne per year. These Rules covers safety procedures for the Manufacture, handling and Import of Hazardous Chemicals and preparedness and management of chemical accidents related to hazardous chemicals. Under CMS Rules, 20xx, Foreign entities can submit notification and its annual update, registration, and other compliances for priority substances by appointing an Authorised Representative in India to fulfill legal obligations required. In addition, local companies are required to comply with requirements of hazardous chemicals.

For the draft Regulation of the 07.09.2020 press [here](#)

EUROPEAN COMMISSION: INTRODUCTION OF THE NEW IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION



Today, the European Commission has proposed a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation to prevent disruption in the supply of these essential healthcare products. The proposal does not change any requirements of the In Vitro Diagnostic (IVD) Regulation in substance but only changes the transitional provisions to allow the Regulation's progressive rollout. The length of the proposed transition periods depends on the type of device: higher risk devices such as HIV or hepatitis tests (class D) and certain influenza tests (class C), have a transition period until May 2025 and 2026, whilst lower risk ones such as class B and A sterile devices, have a transition period until May 2027. The IVD Regulation introduces substantial changes in the regulatory framework for in vitro diagnostic medical devices, giving to the notified bodies an important role. The proposed amendments will not delay the application of the Regulation to CE marked in vitro diagnostic medical devices that do not require the involvement of a notified body (i.e. class A non-sterile devices) and to 'new' in vitro diagnostics (i.e. those not covered by a certificate or declaration of conformity issued under Directive 98/79/EC). Regulation (EU) 2017/746 is envisaged to apply in full to those devices from 26 May 2022.

The deadlines change depend on the type of the device:

- 26 May 2025 for class D devices;
- 26 May 2026 for class C devices;
- 26 May 2027 for class B devices;
- 26 May 2027 for class A devices placed on the market in sterile condition.

For more information press [here](#)



Our UK - BREXIT services cover the fulfillments of national regulations in the UK which will come into force after the release.

RNI srl provides the services listed for EU companies and for UK based companies:

- DUIN notification for GB importers of substances and mixtures **UNTIL 27.10.2021**
- New UK REACH registrations according to new deadlines
- Compliance with new UK regulations (REACH, CLP; BPR, etc.)
- Exclusive Representation Services in UK for Italian / EU companies (OR service)

In collaboration with our partner LANDILEX, we also offer [legal consultancy](#).

For more information press [here](#).

KKIDIK (TURKISH REACH): LATE PREREGISTRATION ACCEPTED BY TURKISH AUTHORITY ONLY EARLY 2021

ACT NOW IF YOU LOST THE LAST DEADLINE



In 2017, Turkey published and consolidated the text of the KKIDIK regulation regarding chemicals that can be placed on local national market. The scheme adopted follows the European REACH regulation in many prescriptions, so much so that it is often referred to as Turkey-REACH.

One of the significant differences is that there is only one registration deadline for all tonnage bands, set for 31/12/2023.

At this stage, the possibility is open to pre-register by 31/12/2020 but the Turkish government seems to accept late preregistration until 31.12.2023.

Moreover, in the last quarter of 2021 The MoEU will add a sub-tool into the KKS in order to generate Chemical Safety Report.

As for REACH EU, applicants must be Turkish legal entities. Non-Turkish companies that want to keep the market will have to appoint a local OR (only Representative). RNI srl can offer this service.

SEA UPDATES:

The SEA CLP like Regulation has been updated, adding 110 new substances to the Harmonized List of classification and labeling "and new hazard classifications. Furthermore, only polymers must be notified and not their ingredients.

For more information press the here

For more information, contact us at info@reachup.it



AssICC has signed an agreement with the associated company RNI (ReachUp Regulatory Network Italy) srl, which offers advice on product regulations for the European and extra-European markets.

Thanks to the stipulated agreement, for all the companies associated with AssICC will be reserved a 10% discount on the RNI srl services.

For more info visit the [webpage](#)



From this month, REACHUP offers import and export worldwide consultant services on TRADE ITALIAN AGENCY. You can access on the ICE online vetrina previous registration.

The link of the page is reported [here](#)



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