REACHUP REGULATORY NETWORK ITALY SRL

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Newsletter RNI srl 13.12.2021

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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

LATIN AMERICA: CHEMICAL INVENTORIES

The table below shows the Latin American countries where are present bill proposals or Decrees:

Country	Type of Proposal	Status	Proposal
Argentina	Legislative	Pending in Congress	Bill 4339-D-2019: www.hcdn.gob.ar/proyectos/proyecto.jsp?exp=4339-D-2019ob.ar/proyectos/proyecto.jsp?exp=4339-D-2019
Brazil	Legislative	Pending in Congress	PL 6120/2019: https://www.camara.leg.br/proposicoesWeb/prop_mostrarintegra;jsessionid=node09hdzmwj95lnj1vpi44p8s5bzt1163617.node0?codteor=2118254&filename=Parecer- CMADS-06-12-2021 Dec 6, 2021 –Vote by Bill *Relator* to approve as revised
Chile	Agency Action	Enacted	Decree 57/2021: https://www.bcn.cl/leychile/navegar?idNorma=1155752 Resolution 777/2021 –Official List of Classifications of Substances https://www.bcn.cl/leychile/navegar?idNorma=1164063
Colombia	Agency Action	Enacted	Decree 1630/2021: https://dapre.presidencia.gov.co/normativa/normativa/DECRETO%201630%20DEL%2030%20DE%20NOVIEMBRE%20DE%202021.pdf
Mexico	Legislative	Not yet Drafted	Link to 2019 Policy: http://csg.gob.mx/descargas/MundoQuimico/Acuerdo_CSG_SQ_csb_lrb-2_12_19.pdf
Peru	Legislative	Drafted – not yet presented in Congress	Last version of Draft not publicly available

RNI PARTNER: AMBIENTELEGAL

EUDAMED: REGISTRATION PORTAL OF MEDICAL DEVICES

Eudamed is the IT system developed by the European Commission to implement the Regulation (EU) 2017/745 on medical devices (MDR) and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), which will improve transparency and sharing information on devices available on the EU market. This database will be multi-purpose, it will function as a collaborative system for registration, notification and dissemination of information also available to the public.

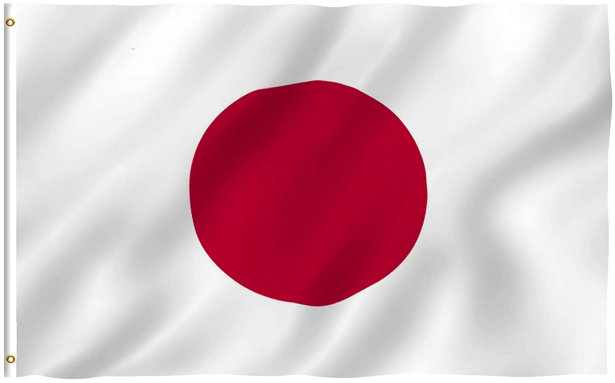
Eudamed consists of interconnected modules and a public website:

- registration of the actors,
- UDI and device registration,
- notified and certified bodies,
- clinical investigations and performance studies,
- surveillance and post-marketing surveillance,
- market surveillance.

Currently, the use of Eudamed takes place on a voluntary basis only for modules that are gradually made accessible. A section open to the public is also foreseen for the same modules.
From 1st December 2020 the Actor Registration module is available and since 4th October 2021 the modules on UDI/device registration and the module on Notified Bodies and Certificates are available.

For more information press here

JAPAN: REVISION OF LIST OF POISONOUS AND DELETERIOUS SUBSTANCES



On 1st December 2021, the Japanese Ministry of Health, Labor and Welfare (MHLW) met to consider the revision of the "List of poisonous and deleterious substances" designated under the Poisonous and Deleterious Substances Control Act (PDSCL): the consultation will end on 30 December 2021. The review will begin at the end of January 2022 and will be implemented in February 2022.

For more information press here

UK: LATE DUIN IS POSSIBLE

On 27th October the possibility to notify DUIN (Downstream Import Notification) in the UK expired. Companies that submitted their notifications for their substances in time to the HSE, will benefit from extended UK REACH registration deadlines as follows: 27 October 2023, 2025, and 2027 depending on the annual tonnage and the hazards of the substance. However, companies that have not notified their substances by the deadline and wish to continue importing EU REACH registered substances into the UK market at 1 tonne or more per year can still submit DUIN late notifications.

UK-based importers and UK-based only representatives appointed by non-UK suppliers (such as non-UK manufacturers / formulators) may submit DUIN notifications late. When the designated OR sends the late DUIN, the GB downstream users will be covered by this DUIN and will not have to send their own.

The HSE recommends doing this as soon as possible.

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:

- For national authorization applications still under evaluation in the UK, submitted by companies based in the EU, it is necessary that the latter appoint their own OR (based in the UK) by 31.12.2021 to continue the authorization process.
- LATE DUIN notification for GB importers of substances and mixtures **is possible after 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 AUTORITHY 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

OUR OFFICE WILL BE CLOSED FROM 24TH TO 31TH DECEMBER.

RNI SRL WISHES ALL HAPPY HOLIDAYS!

ASSOCIAZIONE ITALIANA COMMERCIO CHIMICO

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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