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**10**  
YEARS  
ANNIVERSARY



**REACHUP**  
Regulatory services

NEWSLETTER

**Newsletter RNI srl 05.02.2021**

**MEDICAL DEVICES: PUBLISHED THE NEW ISO 10993-23**

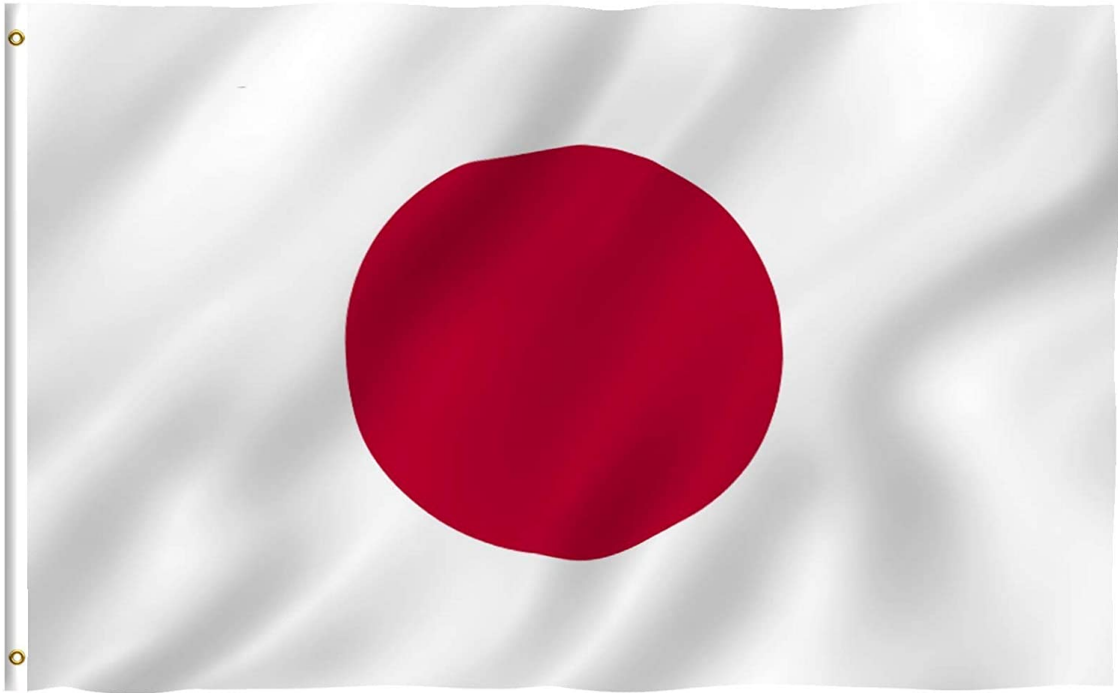


The new ISO 10993-23 to assess the irritation potential of medical devices has been published. The most important point introduced by the new standard is the use of in vitro systems for predicting the skin irritation potential of the medical device and its constituent materials. The document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential for producing irritation according to ISO 10993-1 and ISO 10993-2.

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## **JAPAN ANNUNCES 32 STRONG MUTAGENIC CHEMICAL SUBSTANCES**

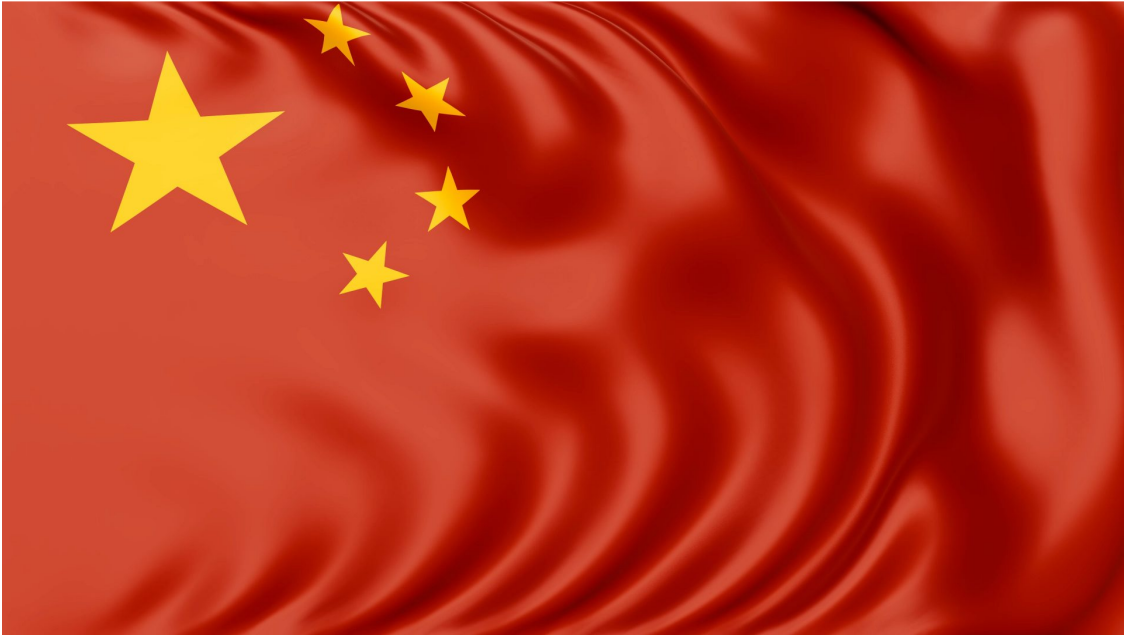


In December 2020, the Japanese Ministry of Health, Labor and Welfare released two public notices, announcing a total of 32 substances which are deemed to be strong mutagenic chemicals. 27 substances are new chemical substances notified under the Industrial Safety and Health Law (ISHL) and published in 2019 or 2020 and 5 are existing chemical substances under the ISHL. According to the Guidelines, in the production and handling of these substances, businesses are required to take measures, such as those concerning protective equipment, ventilation and personnel training, as well as the indication of “strong mutagenicity for microorganisms” on SDSs and labels. They are also required to preserve the information of relevant personnel (a recommended preservation period is 30 years).

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## **CHINA IMPLEMENTS GUIDELINES FOR THE USE OF KEY CHEMICAL SUBSTANCES IN CONSUMER PRODUCTS**



On November 19th, 2020, the Standardization Administration of China (SAC) published the Guidelines for the Use and Control of Key Chemical Substances in Consumer Products, which will come into force on June 1st, 2021. It is formulated on EU REACH but it also contains references about national standards on consumer product quality and safety, as well as international regulations and standards on restricting the use of certain chemicals in consumer products, such as EN71, a set of European Product Safety standard that applies to all toys sold in the EU.

The Guidelines provides principles and recommendations for the use and control of key chemical substances in consumer products, and applies to consumer goods, including products' parts, components, packaging, etc.

Products which are subject to special regulation, such as food, cosmetics, and special equipment, are not included in its application scope.

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## **HSE UPDATED GUIDELINE ON SYSTEMS USED FOR DISINFECTION DURING PANDEMICS**



**Health and Safety  
Executive**

The webpage has advice on systems used to disinfect premises during the pandemic. It explains the legal requirements and provides the latest information, including joint advice from public health bodies on risks to health that can be created by using walk-through spraying or misting systems.

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## **EBB: JOB OPPORTUNITY**



On behalf of our historical partner EBB, we would like to recommend this job opportunity for the position of Senior Technical & Regulatory Officer at the following link.

For more details on the open position click [here](#)

[Read more](#)

## **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](#)

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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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