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REACHUP
Regulatory services

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COMPLETENESS CHECKS ON CSR WILL START FROM 2 NOVEMBER 2020

ECHA
EUROPEAN CHEMICALS AGENCY

At the end of December 2019, ECHA had announced its intention to activate an in-depth manual check on the content of Chemical Safety Reports (CSRs) submitted with the REACH registration dossiers, starting from May 2020.

The aim is to ensure that the CSRs contain all the elements required by the regulation. The review will focus on the assessment of key endpoints for toxicological assessments.

Due to the COVID-19 emergency, the start date of the checks had been postponed to October 2020, to allow companies in difficulty to have more time to make the necessary documents compliant.

On 30 September 2020, ECHA announces a new postponement. The completeness check on CSRs will start from 2 November 2020, after the release of the latest updated version of the IUCLID6 software, scheduled for the end of October 2020.

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BREXIT NEWS ON BIOCIDES

From 1st January 2021, the day after the end of the Brexit transition period, the new national regulation for biocidal products will come into force in the UK. The new UK regime will reflect the current EU BPR framework, but will make itself completely independent. Some features will be removed and replaced by full British features. The BPR principles and the evaluation rules on substances and products adopted up to now remain unchanged.
The new reference authority for the submission of active substance or product dossiers will be Health and Safety Executive (HSE), which also replaces the role of ECHA.
New IT tools will be made available to HSE and industry to replace the existing EU portals.
How data can be submitted to the HSE to meet the legislative requirements for the BPR regulations will be communicated as soon as it becomes available.

In any case, companies will have to re-submit to HSE the information previously submitted to ECHA or other competent authorities. The aim is to build a new UK database to be made available exclusively to HSE to support the authorizations of products and active substances, replacing the ECHA databases.
No fee will be required for these resubmission operations.
Under the UK national regime, the authorization holders will have to be established in the UK. To allow companies to make the necessary decisions, there will be a transitional period of one year for existing authorization holders (legal entity to be established in the UK by 1 January 2022).

Companies holders of a product authorization already issued and valid in Great Britain will continue to be so and their authorization will remain valid after 1 January 2021 until its normal expiry date. However, the authorization holder will need to be established in the UK within one year (by 1 January 2022) to continue to remain on the local market.

Applications for authorization of a biocidal product still under evaluation will continue to be evaluated by HSE until the end of the transition period. At the end of this, the HSE will continue, where possible, to process applications to grant a national authorization. However, the information supporting the original application will need to be sent back to HSE to allow the UK authority to complete the assessment, as it will no longer have access to the ECHA portals.
If an application is being evaluated in another EU country or Switzerland as part of a Union authorization or mutual recognition process at the end of the transition period, it will need to be resubmitted to the HSE to apply for a national authorization in the UK.
For both cases, the date of the original application will be recognized for the purpose of complying with the deadlines set by the BPR.

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END OF THE EMERGENCY PROCEDURE FOR THE REGISTRATION OF BIOCIDES IN ROMANIA

On 30 September 2020, the window for submitting requests for authorization of biocidal products according to the emergency procedure adopted by Romania closed.

During this phase it was possible to submit a reduced dossier to the national military authority which had been in charge of managing the procurement of disinfectants and medical devices in the most critical phases of the pandemic.

It is now possible to submit applications for registration of biocidal products, based on active substances not yet approved according to BPR, through the standard national procedure in accordance with Article 89 of the BPR.

RNI srl can provide this support service through expert staff present in Romania.

For more information contact us at info@reachup.it

KKIDIK (TURKISH REACH): PREREGISTRATION DEADLINE SET ON 31/12/2020.

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.

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.

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