REACHUP REGULATORY NETWORK ITALY SRL

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REACHUP
Regulatory services

NEWSLETTER

Newsletter RNI srl 16.10.2020

REGISTRATION UPDATE DEADLINES CLARIFIED

ECHA
EUROPEAN CHEMICALS AGENCY

The European Commission has published a draft of an implementing regulation which clarifies the meaning of 'without undue delay' related to registration updates under REACH. The draft includes deadlines for different scenarios which may trigger the need for registrants to update their dossiers. The deadlines only concern REACH Article 22(1). The registrants must track and monitor all relevant information to ensure that

their registrations are up to date within their respective deadlines. The authorities of each Member State can request this data during inspections and as the deadlines are included in the legal text, they can more easily check if the update has been made on time.
The implementing regulation is expected to be published in the Official Journal of the European Union by the end of autumn and will enter into force 60 days later.

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RAC ADOPTED 10 OPINIONS ON HARMONIZED CLASSIFICATION AND LABELLING

The 10 substances for which RAC has approved the new classification and labelling are:

- Pyridalyl (ISO); 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether (EC -; CAS 179101-81-6)
- 2,4,6-tri-tert-butylphenol (EC 211-989-5; CAS 732-26-3)
- Pendimethalin (ISO); N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine (EC 254-938-2; CAS 40487-42-1)
- Ammonium bromide (EC 235-183-8; CAS 12124-97-9)
- Methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (EC 201-297-1; CAS 80-62-6)
- Pyridine-2-thiol 1-oxide, sodium salt; pyrithione sodium; sodium pyrithione (EC 223-296-5; CAS 3811-73-2)
- N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl1H-pyrazole-4-carboxamide; isoflucypram (EC -; CAS 1255734-28-1)
- 2-(2-methoxyethoxy)ethanol; diethylene glycol monomethyl ether (EC 203-906-6; CAS 111-77-3)
- Bisphenol A; 4,4'-isopropylidenediphenol; BPA (EC 201-245-8; CAS 80-05-7)
- Dimoxystrobin (ISO); (2E)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-N-methylacetamide; (E)-2-(methoxyimino)-N-methyl-2-[a-(2,5-xylyloxy)-otolyl]acetamide (EC -; CAS 149961-52-4)

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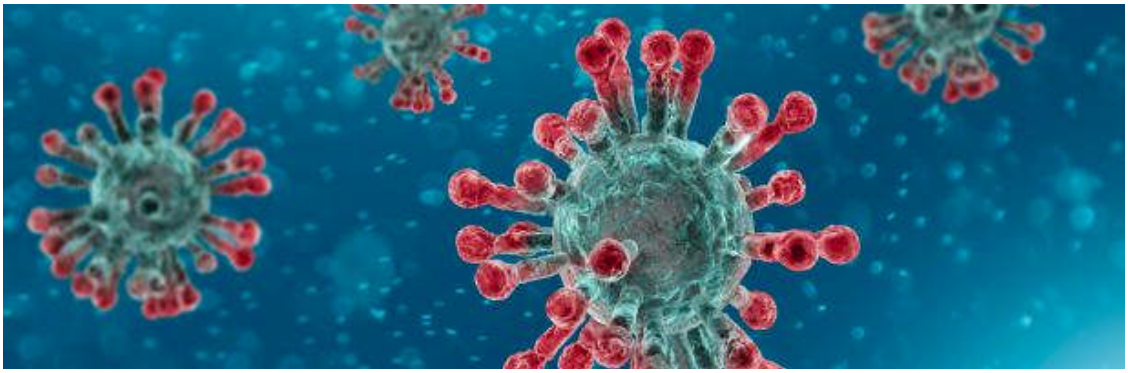
ITALY: THE MINISTRY OF HEALTH REACTIVATES THE DEROGATION PROCEDURES ART.55 FOR 15 DAYS FROM 9 OCTOBER 2020.



Through a decree of 7 October 2020, the Italian Ministry of Health communicates that the applications for derogation procedure of art. 55 (1) BPR of biocied products (PT1-PT2-PT4) can be yet submitted, but with new methods which also include the payment of stamp duty.
Products with a WHO identical composition are considered approved with a tacit agreement mechanism after 15 days from the submission of the decalaration according to Annex 3. Even the products for which an application has been sent by 15 July 2020 are considered approved with a silent consent mechanism after 15 days from the submission ofthe declaration according to Annex 4. The labels must contain the specific indications described in Annex V.
The validity of products already authorized will be extended by 180 days from the expiry date of the temporary authorization issued, without making changes to the already authorized labels.

Companies interested in still using the derogation procedure are invited to complete their applications as soon as possible due to the deadline at 23 October 2020. RNI srl is available to support companies in this process.
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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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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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