

Possible EU Assessment of Human Health or Environmental Risks of Chemical Substances

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Several chemical substances will be evaluated for possible regulatory action in the European Union in the next three years.

On 27 October 2016, the European Chemicals Agency (ECHA) announced its proposal under the EU's REACH Regulation to evaluate 117 chemical substances suspected of posing a risk to human health and the environment. Each substance listed on the final Action Plan for 2017-2019 will be evaluated by an assigned Member State which may recommend: a) harmonized classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitizers or other effects; b) identification of the substance as a substance of very high concern; c) restrictions on the use of the substance; or d) actions outside the scope of REACH, such as proposals for EU occupational exposure limits, national measures or voluntary industry actions. These recommendations are submitted to the Commission, potentially prompting regulatory initiatives.

Of the 117 substances proposed for review, 22 are chemicals that were not previously listed. One of these new substances, butan-1-ol (also known as 1-Butanol or n-Butanol), is used as an ingredient in perfumes and as a solvent for the extraction of essential oils. According to the draft Action Plan, butan-1-ol is suspected to have reprotoxic properties, and is of further concern due to its widely dispersed use, broad consumer uses, potential for worker exposure, and high tonnage. The substance is tentatively assigned to Hungary for review in 2017. Another newly added substance is ethyl 4-hydroxybenzoate, which is used as an antifungal preservative and a food additive. The substance is suspected to be a potential endocrine disruptor and is tentatively assigned to Germany for review in 2019.

Other substances newly added to the draft Action Plan include: 2,4,6-tri-tertbutylphenol, 2,2-dimethylpropan-1-ol (tribromo derivative), dicyclohexyl phthalate, 2-furaldehyde, butanone and benzoic acid.

Noteworthy substances previously listed on the draft Action Plan are graphite/Multi-Wall Carbon Nanotubes (MWCNT) and synthetic graphite in tubular shape, which, according to ECHA, are suspected carcinogens and are of further concern due to their wide dispersive use, exposure on environment, consumer use and cumulative exposure. They are tentatively assigned to Germany for review in 2018.

The draft Action Plan was submitted on 13 October 2016 to all Member State competent authorities and the ECHA Member State Committee for additional input. ECHA is expected to issue the final

Action Plan for 2017-2019 by the end of March 2017. Substances can be added to or removed from the draft Action Plan until such time.

Located in the heart of the European Quarter, the Brussels office of Kelley Drye, together with our Environmental Practice Group, is well positioned to advise and assist clients with any inquiries or concerns regarding the current evaluation process under REACH and/or other EU legislation applicable to chemical substances. Kelley Drye's Environmental Law Practice Group specializes in providing comprehensive solutions to complex problems. We have decades of experience advising companies and industry trade organizations with respect to chemical management requirements and related compliance and litigation matters.