''This clarification is necessary to reflect the capabilities of the vast majority of separators sold today,'' wrote Wu.

Finley of NACWA also raised this point, calling it a fundamental flaw in the proposed rule. She said the 50-utility study looked at removal efficiencies of total mercury, while the dental amalgam separators deal with removal of particles. ''It's like comparing apples to oranges,'' she said.

BY AMENA H. SAIYID

To contact the reporter on this story: Amena H. Saiyid in Washington at asaiyid@bna.com

To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com

Comments on the EPA proposed pretreatment rule for the dental sector, identified by Docket No. EPA-HQ-OW-2014–0693, are available at http://regulations.gov.

REACH

EU Chemicals Agency Seeks Input On Two 'Substances of Very High Concern'

The European Chemicals Agency (ECHA) is calling for comments through April 16 on the listing under the European Union's REACH regulation of two chemicals as ''substances of very high concern'' (SVHCs), a designation that ultimately could lead to use of the substances being prohibited.

The first substance is 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with 0.3 percent of dihexyl phthalate, which is used as a plasticizer and lubricant and was nominated by the Swedish authorities as an SVHC on the basis of its reprotoxic properties.

The substance currently is not registered under REACH and is little used in the European Union, according to the SVHC dossier that Swedish authorities submitted.

The second proposed SVHC listing is a group of substances under the heading 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof].

The Netherlands proposed the listing of the group of substances on the basis that they are very persistent and very bioaccumulative. Two of the substances in the group are registered under REACH, including one substance with the trade name Karanal, which is used in cosmetics, according to the SVHC dossier the Netherlands provided.

ECHA said that information should be included on the identity of the substances, their uses, any risks they pose and possible substitutes for them.

Substances listed as SVHCs can be prioritized for inclusion in Annex XIV of REACH, which means their use could be banned in the EU, unless specific continued-use authorizations are granted.

So far, 161 substances have been listed as SVHCs and 31 have been added to Annex XIV of REACH (Regulation No. 1907/2006 on the registration, evaluation and authorization of chemicals).

ECHA published the consultation documents March 2.

BY STEPHEN GARDNER

To contact the reporter on this story: Stephen Gardner in Brussels at correspondents@bna.com

To contact the editor responsible for this story: Greg Henderson at ghenderson@bna.com

The ''substances of very high concern'' consultations are available at http://bit.ly/PX02Yn.

REACH

Companies in Europe Advised to Monitor ECHA Substance Evaluation Appeals

A transition has started in the type of case heard by the Board of Appeal of the European Chemicals Agency (ECHA), which oversees the European Union's REACH law, according to speakers during a webinar hosted by the Brussels office of Steptoe & Johnson LLP.

Whereas in the past five years appeals filed to the Board of Appeal have largely concerned ECHA decisions relating to substance registrations and fee payments, cases now are starting to be filed on substance evaluation decisions, Steptoe & Johnson representatives said.

Substance evaluation is the REACH process under which authorities in EU member states investigate substances that are thought to pose potential environmental or health risks.

Evaluations can lead to ECHA issuing legally binding requests to registrants to carry out tests or to provide additional information on substance properties. Ultimately, evaluations could lead to substances being restricted or banned under REACH (Regulation No. 1907/2006 on the registration, evaluation and authorization of chemicals).

Steptoe partner James Searles said ECHA requests to registrants for more substance information could be ''complex and potentially costly,'' and Board of Appeal substance evaluation rulings would be ''highly important'' to ensure the validity of ECHA's requests.

First Evaluation Appeals. The ECHA Board of Appeal received the first petitions over substance evaluation decisions in 2014 (38 CRR 632, 6/9/14).

ECHA has said six evaluation-related appeals have been filed to date.

Most recently, ECHA published an announcement March 3 of an appeal BASF filed in December 2014 concerning an ECHA decision requiring the company to carry out tests to determine certain properties of triclosan, an antibacterial substance that is widely used in consumer products.

BASF argued that ECHA's decision did not take into account the possibility of using non-animal tests to generate information on triclosan and that the decision would lead to the ''unnecessary sacrifice of animals.''

Searles said ECHA decisions following substance evaluations might be considered disproportionate if they involved the registrant taking action that was not necessary to meet the objectives of the evaluation, was inadequate for meeting the objectives, or was not the ''least onerous'' way to meet the objectives.

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Companies that receive an ECHA decision following a substance evaluation also should check that no breach of REACH is involved, Searles said.

This could be the case, for example, if ECHA breaches its duty to provide an ''adequate statement of reasons for the request,'' or if ECHA requires animal testing that would contravene the REACH principle of minimization of the use of animals, he added.

Practical Issues. Anne Croxon, REACH regulatory manager for International Flavors & Fragrances Inc., said substance evaluation and ECHA's issuance of decisions to registrants involves short deadlines and could be ''resource intensive'' for recipients of decisions.

International Flavors & Fragrances filed in May 2014 an appeal against a substance evaluation decision arguing, similarly to BASF, that the decision breached the principle of proportionality and would lead to unnecessary animal tests.

Croxon said contesting a substance evaluation decision could involve practical difficulties, such as coordinating a response from multiple registrants of a substance within a short period, or agreeing on sharing of costs.

Steptoe partner Ruxandra Cana said though appeals related to REACH substance evaluation were a new area, the ECHA Board of Appeal has established a good reputation from previous petitions related to substance registrations and fees.

''We can testify to their complete independence from the other services'' of ECHA, Cana said.

The Steptoe webinar took place Feb. 24.

BY STEPHEN GARDNER

To contact the reporter on this story: Stephen Gardner in Brussels at correspondents@bna.com

To contact the editor responsible for this story: Greg Henderson at ghenderson@bna.com

The European Chemicals Agency appeals are available at http://echa.europa.eu/regulations/appeals.

REACH

EU, South Korean REACH Data Deadlines Might Swamp Available 'Only Representatives'

There may not be enough qualified ''only representatives'' to meet the demand for their services caused by deadlines in the European Union's and Korea's REACH chemical regulations, according to the president of an only representative association.

The possible shortage of only representatives, also called ORs, that can register chemicals for chemical manufacturers located outside Europe or South Korea was one of many challenges speakers described March 4 at a Baltimore global chemical regulation conference.

''Asia does not have sufficient ORs,'' Dieter Drohmann, president of the Brussels-based Only Representatives Organization, said at GlobalChem. The annual conference is organized by the American Chemistry Council, which represents major U.S. chemical manufacturers, and the Society of Chemical Manufacturers & Affiliates (SOCMA), which represents those that make small batches of chemicals.

The need for only representatives resulting from Korea's adoption of a REACH program, combined with the number of chemical manufacturers that will need only representatives to register their chemicals in Europe by 2018, may overwhelm the capacity of OR service providers, Drohmann said.

''The earlier you start [preparing] the better,'' said Matti Vainio, head of the European Chemicals Agency's Risk Management Implementation Unit.

Big Workload. Drohmann and Vainio were among many speakers at this year's GlobalChem who focused on the obligations chemical manufacturers face as countries around the world implement new chemical laws and regulations.

The two speakers participated in a session on Europe' registration, evaluation and authorization of chemicals, or REACH, regulation ((EC) No. 1907/2006). The regulation applies throughout the European Union as well as in Iceland, Liechtenstein and Norway.

Under REACH, chemicals that are made in or imported into the EU, Iceland, Liechtenstein or Norway in volumes between 1 and 100 metric tons (2,204–220,460 pounds) must be registered by May 31, 2018, to remain on the market.

The European Chemicals Agency (ECHA) expects many small and medium-size manufacturers to be among the companies that will register 25,000 or more chemicals by 2018, Vainio said.

70,000 Dossiers Expected. ECHA expects to receive up to 70,000 dossiers as part of the registration packages for those chemicals, he said.

By comparison, Vainio said, the largest number of registrations ECHA has yet received were for the first deadline, 2010, when manufacturers of approximately 3,400 chemicals submitted 20,000 dossiers.

Drohmann also briefly discussed the Act on the Registration and Evaluation of Chemicals, known as Korea REACH, which came into force Jan. 1 (39 CRR 87, 1/19/15).

Once South Korea finalizes the first batch of chemicals it will list under Korea Reach, manufacturers will have two years to register them. The Ministry of Environment released a preliminary list of 518 existing chemicals Oct. 31, 2014 (38 CRR 1192, 11/10/14).

Both Europe's and South Korea's REACH allow foreign manufacturers to register their chemicals through only representatives, which become legally responsible for compliant registrations.

The European REACH regulation states that ORs should be qualified, but there are no official criteria to demonstrate qualification, Drohmann said. Members of his organization are required to meet specified criteria, including having insurance and complying with the organization's antitrust rules.

He urged chemical manufacturers to become familiar with the Best Practice Guide his organization has developed and provides access to for free.

Hurdles Anticipated. Paul Ashford, a chemist and consultant who founded Caleb Management Services Ltd. (which the Anthesis Consulting Group acquired in 2014), and Robert Mott, global regulatory manager for Sun Chemical Corp., warned first-time registrants to anticipate unexpected hurdles as they register their chemicals.

For example, defining a chemical's identity has proven far more difficult than many companies anticipated, Ashford said.