

**Frequently Asked Questions
about
Listing of Nonylphenol Ethoxylates and Octylphenol Ethoxylates
to Annex XIV of REACH for Authorisation**

The European Commission announced the addition of nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPE) to Annex XIV, the list of chemicals subject to authorisation under the EU Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) legislation in the Official Journal of the European Union on June 14, 2017. This Regulation entered into force on July 4, 2017.

Following are frequently asked questions about this development in the European Union.

Q. Which Alkylphenol Ethoxylates have been listed for Authorisation under REACH Annex XIV?

The following alkylphenol ethoxylate compounds have been listed for authorization:

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated - Covering Well-defined Substances and UVCB Substances, Polymers and Homologues, more commonly known as octylphenol ethoxylates (OPE).
- 4-Nonylphenol, branched and linear, ethoxylated (NPE), described broadly as “4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]”.

Q. What is REACH?

REACH is the European Community Regulation on chemicals and their safe use ([EC 1907/2006](#)). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances.

REACH entered into force on 1 June 2007 and its provisions are being phased-in over 11 years. Additional information about REACH is available on the [European Chemicals Agency \(ECHA\)](#) website.

Q. What is Authorisation under REACH?

Authorisation is one of the REACH processes for managing the risks of hazardous substances. Substances that are subject to authorisation may not be used in the EU unless a company applies for and obtains authorisation to do so from the European Chemicals Agency (ECHA).

Substances which are subject to authorisation are listed in Annex XIV of REACH. For each substance included on Annex XIV, a deadline will be set after which use of that substance in the EU must stop (known as the 'sunset date'), unless authorised. Once the sunset date has passed for an Annex XIV substance, only uses which have been specifically 'authorised' by ECHA will be allowed.

Q. What are the important transitional dates for NPE and OPE under the authorisation process?

The latest application date for authorisation for NPE and OPE is July 4, 2019. The sunset date for these compounds is January 4, 2021.

Q. How is authorization under REACH different than risk evaluation or risk management of chemicals in the United States and Canada?

The process under REACH by which chemicals are named as Substances of Very High Concern (SVHCs) and which may subsequently be subject to authorisation is very different than the chemical assessment and management programs in the United States and Canada. The primary difference relates to the fact that the REACH process is entirely hazard-based and does not consider whether exposures to the chemical in question are likely to pose an actual risk to human health or the environment.

Chemical programs in the United States, under the Toxic Substances Control Act (TSCA) and in Canada, under the Canadian Environmental Protection Act (CEPA) are both risk-based programs. In addition to considering the intrinsic hazards of chemicals, the relevant laws in these two countries require that a risk assessment be conducted to determine what, if any, risk exists and whether risk management actions are required.

Q. What happens now that NPE and OPE have moved to the Authorisation list under REACH?

Now that OPE and NPE have been listed on REACH Annex XIV their use must be phased out in the EU by the sunset date of January 4, 2021. Once the sunset date has passed for an Annex XIV substance, only uses that have been specifically 'authorised' by ECHA will be allowed to continue.

Companies that want to continue using NPE and OPE after the sunset date of January 4, 2021 must apply to ECHA for specific authorization of their uses by the last application date of July 4, 2019.

Q. How is authorisation granted under REACH?

When authorisation is required for a given use of a chemical listed on Annex XIV, companies will need to apply to ECHA for that authorisation. Applications may be made by manufacturers, importers or downstream users and may be made by one or several applicants. Applications may cover one substance or a group of substances (where all the substances in the group share certain similar properties) and may be for one or several uses. If allowed, authorisations are granted for a finite period of time, referred to as the “review period”, after which the application for authorisation is reassessed.

Q. What should users of NPE and/or OPE do if they are interested in applying for authorisation for a use of these compounds?

Where there is interest in applying for authorisation for a use of NPE or OPE, users in the supply chain should discuss the situation with their supplier as soon as possible. Development of an authorisation application package can take some effort and time. The last date to submit an application to ECHA for authorisation for a use of NPE or OPE is July 4, 2019.

For information on applications for Authorisation [Link to ECHA Website for Instructions for Applying for Authorisation](#)

Q. NPE and OPE are not, carcinogenic, mutagenic, reproductive toxicants, persistent, bioaccumulative OR estrogenically active so why were they classified as SVHCs and subsequently listed in Annex XIV for authorisation?

NPE and OPE are polymeric surfactants, which are not CMR, PBT or vPvB. The commercial polymers are not estrogenically active. NPE and OPE were classified as SVHC primarily on the basis that NP and OP, which have been designated SVHCs, potentially can occur during the degradation of their ethoxylates in the environment. In other words, the polymers are considered an “environmental source” of these SVHC compounds.

CEPAD has submitted comments to ECHA objecting to the proposals and pointing out that these alkylphenols have only weak estrogenic activity of a potency that is between 3 and 6 orders of magnitude less than that of oestradiol [the human female hormone]. Naturally occurring phyto-oestrogens are even more potent than nonylphenol in laboratory tests. While these compounds are toxic to fish and other aquatic species, their effects are clearly not comparable to actual estrogens.

NPEs and OPEs do not warrant prioritization under Annex XIV because they do not themselves meet the criteria for inherent toxicity specified under Article 57(f). Furthermore, NPE/NP and OPE/OP are adequately controlled with existing regulations.

Q. What do we know about the risk of NPEs and OPEs and their degradants to the aquatic environment?

In the case of NP/NPE and OP/OPE, environmental concentrations in surface waters in the EU as well as in the United States and Canada are generally below levels of concern for any type of adverse effects in fish or other aquatic organisms.

Levels of concern are determined based on governmental standards established for these compounds by the relevant governmental authority. There are Environmental Quality Standards (EQS) in the EU, US EPA Water Quality Criteria (WQC) in the US, and Environmental Quality Guidelines (EQGs) in Canada. ^{1,2,3}

Q. Is it true that there was no concern for human health effects expressed in the reports that proposed NPE and OPE as SVHCs and subsequently for addition to Annex XIV?

It is true that none of the reports that nominated AP/APE compounds as SVHC under Annex XV and for authorisation under Annex XIV raised any concern with the human health effects of these compounds. None of these compounds are carcinogenic, mutagenic or reproductive toxicants.

Q. Were there objections to the proposal to add OPE and NPE to the Authorisation list under REACH Annex XIV?

The Alkylphenols & Ethoxylates Research Council (APERC), a North American based industrial consortium and the European Council for Alkylphenols and Derivatives (CEPAD) jointly submitted comments to ECHA objecting to the proposals to identify OPE and NPE as SVHC and for authorisation based on their view that these compounds do not meet the relevant criteria under Article 57.

Other comments from trade groups representing companies that use these compounds also objected to their addition to Annex XIV.

These same organizations objected to the designation of OP and NP as SVHCs. For more information about the basis for these objections, see [APERC Frequently Asked Questions about SVHCs for Manufacturers and Downstream Users](#)

Q. Where can I access the legislation that added NPE and OPE to Annex XIV, the Authorisation list?

The Official Journal of the European Union entry for Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemical (REACH) can found at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:150:FULL&from=EN>

¹ European Parliament and Council (2008, December 16). [Directive 2008/105/EC on environmental quality standards in the field of water policy](#), amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC. 348/84 EN [Official Journal of the European Union](#) 24.12.2008

² Environment Canada (EC) Environmental Quality Branch National Guidelines and Standards Office. (2001). Canadian Environmental Quality Guidelines for Nonylphenol and its Ethoxylates. Scientific Supporting Document (Water, Sediment, and Soil)

³ US Environmental Protection Agency (US EPA). (2005). Aquatic life ambient water quality criteria - nonylphenol. Report 822-R-05-005. US Environmental Protection Agency, Washington, DC, USA. <http://www.epa.gov/waterscience/criteria/nonylphenol/final-doc.pdf>

Q. Will CEPAD support the preparation of authorisation applications in the value chain?

CEPAD is a Cefic industry association advocating for the safe use of alkylphenols. CEPAD is not in a position to further assist any consortium formation or preparation for authorization in the value chain. However, we recommend users of OPE/NPE to get organised immediately in order to prepare authorisations where they are needed. For this you should communicate with your upstream supplier and your own value chain.

The information in this FAQ document is provided as guidance regarding the requirements for companies impacted by the listing of NPE and OPE on Annex XIV of REACH. It is not intended as regulatory or legal advice. All companies should review and comply with relevant regional, national and local regulations.

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