

# A P E R E S E A R C H C O U N C I L

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## **REGULATORY STATUS OF ALKYLPHENOLS AND THEIR ETHOXYLATES IN THE UNITED STATES, CANADA AND THE EUROPEAN UNION**

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Alkylphenols (APs) and alkylphenol ethoxylates (APEs) have been the subject of considerable attention in the scientific literature, the media and by regulatory agencies. As part of its mission, the Alkylphenols & Ethoxylates Research Council (APERC) makes available updates on the status of different initiatives. The following is an update on the regulatory status of APs and APEs in the United States, Canada and Europe.

### **UNITED STATES**

There are no present or pending regulatory restrictions on the manufacture, processing or use of APs and APEs by the United States government. In 1996, US EPA evaluated the risk of nonylphenol (NP) and concluded that NP is generally not present at levels of concern in US waters.<sup>1</sup> Early in 2004, EPA recommended an acute ambient Water Quality Criterion (WQC) for NP of 27.9 ug/l and a chronic freshwater criterion of 5.9 ug/l.<sup>2</sup> These environmental standards are expected to be finalized in 2005.

Recent studies conducted by the US Geological Survey<sup>3,4</sup> indicate that the trace levels of NP and nonylphenol ethoxylates (NPEs) generally found in US rivers and streams are in line with the findings of previous studies and are with few exceptions below the draft WQC for NP. Given the widespread use of NP/NPEs, these results likely reflect the compound's treatability and biodegradation as well as the use of good disposal practices and the high standard of wastewater treatment in the United States.

It is relevant to note that EPA WQC values do not represent enforceable regulatory limits; rather, these values are considered in the adoption of state level water quality standards

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<sup>1</sup> Rodier, D., US EPA. (1996). RM1 Document on Nonylphenol.

<sup>2</sup> US EPA. (2004, January 5). Draft Ambient Aquatic Life Water Quality Criteria for Nonylphenol. 69 Fed. Reg. 340.

<sup>3</sup> Kolpin, D.W., Furlong, E.T., Meyer, E.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., and Buxton, H.T. (2002). Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance. Environmental Science & Technology, 36, 1202-1211.

<sup>4</sup> Lee, K.E., Barber, L.B., Furlong, E.T., Cahill, J.D., Kolpin, D.W., Meyer, M.T., and Zaugg, S.D. (2004, November). Presence and Distribution of Organic Wastewater Compounds in Wastewater, Surface, Ground and Drinking Waters, Minnesota, 2000-02. US Geological Survey Scientific Investigations Report 2004-5138. <http://water.usgs.gov/pubs/sir/2004/5138/>

used in setting industry and municipal wastewater treatment facility specific discharge permits.

The Alkylphenols & Ethoxylates Research Council (APEREC) wholeheartedly endorses EPA's efforts to establish WQC for NP. To view APEREC's comments on the draft NP WQC go to: [http://www.aperc.org/docs/aperc\\_comments\\_npwqc040504.pdf](http://www.aperc.org/docs/aperc_comments_npwqc040504.pdf).

Additional information on EPA's draft NP WQC document can be found at: [www.epa.gov/waterscience/criteria/nonylphenol](http://www.epa.gov/waterscience/criteria/nonylphenol).

## CANADA

In 2001, Environment Canada and Health Canada conducted a Risk Assessment for NP and NPEs pursuant to the Canadian Environmental Protection Act (CEPA). The Assessment considered the environmental fate and effects of NP/NPEs, their human safety and issues relating to endocrine activity.

CEPA requires the evaluation of a chemical's risk potential under three different sections of the law, which includes consideration of the toxicological properties of a substance as well as its concentrations or nature of entry in the Canadian environment. The Canadian Assessment concluded that NP/NPEs were **not toxic** under either Section 64(b) posing "no danger to the environment on which life depends;" **not toxic** under Section 64(c) posing "no danger to human health from environmental exposure" and were "not considered a priority ... to reduce public exposure through control of sources that are addressed under CEPA." The Assessment did conclude that NP/NPEs **were toxic** under CEPA Section 64(a) because of the environmental presence of NP and NPEs from untreated or partially treated textile mill effluents that discharge directly to the aquatic environment and because of discharges of NP and NPEs "from a select number of municipal wastewater treatment plants and pulp and paper mills."

In addition to the risk assessment activities, Canada has also issued environmental quality guidelines (EQGs)<sup>5</sup> for NP and its ethoxylates for the protection of aquatic life utilizing the protocol developed by the Canadian Council of Ministers of the Environment. The EQG for NP in freshwater is 1.0 ug/L and was derived by multiplying the Lowest Observable Effect Concentration (LOEC) for the most sensitive organism, which was 10.3 ug/L for rainbow trout, by an extra safety factor of 10.<sup>6</sup>

While the Canadian EQG is slightly lower than the values proposed by EPA, studies of the actual levels of NP/NPEs that occur in the Canadian environment generally do not exceed even this conservative guideline, and where they do, are usually associated with a select number of inefficient or inadequate wastewater treatment facilities. Nonetheless,

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<sup>5</sup> Additional information on Canada's Environmental Quality Guidelines program can be found at [http://www.ccme.ca/publications/can\\_guidelines.html](http://www.ccme.ca/publications/can_guidelines.html).

<sup>6</sup> Canadian Council of Ministers of the Environment. (2001). Canadian Water Quality Guidelines for the Protection of Aquatic Life Nonylphenol and Its Ethoxylates.

Environment Canada has proposed a regulation<sup>7</sup> requiring that Pollution Prevention (P2) plans be prepared and submitted by Canadian manufacturers and importers of certain types of products that contain NP/NPEs.

The preparation and implementation of P2 Plans under this Notice applies only to parties in Canada that:

- (1) *Manufacture or import soap and cleaning products, or processing aids used in textile wet processing, or pulp and paper processing aids; and,*
- (2) *Purchase or otherwise acquire 2000 kg or more of NP and/or NPEs annually in these specific products during at least one calendar year between January 1, 2003 and December 31, 2012.*<sup>8</sup>

The Pollution Prevention Notices does not apply to Canadian manufacturers or importers of products that do not fall into one of the three use areas of concern. For example, this Notice will not affect NP/NPEs use in paints, coatings, resins and adhesives, construction, automotive and metal fabrication, personal care products, and drugs and medical devices such as spermicides. In addition, products that are exported from Canada to another country have been exempted from the P2 planning requirements.

The Risk Management Objective stated in Canada's proposed Notice is a 50% reduction of the total mass of NP and NPEs used and/or imported annually by the end of 2007 and a reduction of 95% by the end of 2010.<sup>9</sup> While there are no P2 or use reduction requirements for octylphenols (OP) and octylphenol ethoxylates (OPEs), Environment Canada does not view these compounds as suitable replacements for NP/NPEs.

Proposed guidance on preparing P2 plans as well as information on waivers and time extensions can be found in the proposed Canada Gazette Notice. The current expectation is that the Notice will be published in late 2004 and that P2 plans will need to be prepared and implementation initiated no later than June 30, 2005.

## APERC'S VIEW ON CANADIAN RISK MANAGEMENT

APERC contends that Environment Canada is relying on an unnecessarily narrow and restrictive definition of P2 Planning in its risk management of NP and NPEs. The definition of P2 Planning in the Canadian Environmental Protection Act of 1999 is much broader than product use reduction and encompasses "the use of processes, practices,

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<sup>7</sup>Environment Canada. (2004). Revised Draft: Notice Requiring The Preparation And Implementation Of Pollution Prevention Plans In Respect Of Nonylphenol And Its Ethoxylates Contained In Products.  
<http://www.ec.gc.ca/nopp/docs/p2plans/npe/en/products.cfm>.

<sup>8</sup> The Notice does not apply to manufactures and importers who have totally eliminated the use of NP and NPEs from the subject products by the publication date of the Notice in the Canada Gazette and have not recommenced using NP or NPEs for these activities after the Notice has been published or while it is in force. Also, parties that are subject to the requirements of the Pollution Prevention Planning Notice, code P2TMENPE, targeting the wet processing textile industry are not subject to the P2 Notice for the products described above.

<sup>9</sup> The base year from which these reductions are to be calculated is 1998, or the first calendar year after 1998 when the party subject to the Final Notice purchased or otherwise acquired 2,000 kg or more of NP and/or NPEs, for the applications subject to P2 planning.

materials, products, substances or energy that avoid or minimize the creation of pollutants and waste and reduce the overall risk to the environment or human health.”

It is APERC’s view that product use reduction ignores the root causes behind environmental levels of concern. For example, aquatic concentrations of NP/NPEs usually only reach levels of concern relative to Canadian Environmental Quality Criteria in situations where wastewater treatment is lacking, inadequate or inefficient. In other words, high levels of NP/NPEs are generally symptoms of a broader problem with the disposal and treatment of industrial and/or household waste. As NP/NPEs are biodegradable and highly treatable in activated sludge wastewater treatment plants, imposing a requirement for product use reduction only serves to create a false sense of accomplishment. Rather, risk management for AP/APEs should be based on environmental monitoring at a watershed level, *i.e.*, comparing ambient environmental levels to Environmental Quality Guidelines and correcting treatment and practices at the priority sources and at the same time, controlling discharges of all pollutants found in effluent from wastewater treatment plants. In sum, product use reduction should be a strategy of last resort for treatable and biodegradable compounds.

To view the comments submitted by APERC on Environment Canada’s risk management strategy and proposed P2 requirements see: <http://www.aperc.org/canada.htm>.

## **EUROPEAN UNION**

The European Union (EU) conducted a Risk Assessment on NP, which considered the environmental fate and effects of NP and NPEs as well as their human safety and issues relating to endocrine activity. The EU approach to calculating the environmental risk of these compounds relied on a very conservative risk calculation rather than taking a statistical approach using the abundant available data on these compounds. The EU Risk Assessment also used conservative techniques to estimate environmental releases and exposures rather than relying on actual environmental monitoring information.

The European Parliament, favoring a precautionary risk management approach, approved Market and Use Restrictions for NP/NPEs, which were published on July 17, 2003 in the Official Journal of the European Union. The following specific restrictions are supposed to come into force at the EU Member Country level by January of 2005:

*Nonylphenol and Nonylphenol Ethoxylates may not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0.1 % by mass for the following purposes:*

- (1) *Industrial and institutional cleaning except:*
  - *controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,*
  - *cleaning systems with special treatment where the washing liquid is recycled or incinerated;*
- (2) *Domestic cleaning;*

- (3) *Textiles and leather processing except:*
  - *processing with no release into wastewater,*
  - *systems with special treatment where the process water is pretreated to remove the organic fraction completely prior to biological wastewater treatment (degreasing of sheepskin);*
- (4) *Emulsifier in agricultural teat dips;*
- (5) *Metal working except:*
  - *Uses in controlled closed systems where the washing liquid is recycled or incinerated;*
- (6) *Manufacturing of pulp and paper;*
- (7) *Cosmetic products;*
- (8) *Other personal care products except:*
  - *Spermicides;*
- (9) *Co-formulants in pesticides and biocides.*

The United Kingdom is currently conducting a risk assessment on OP.