

Dairy Industry Concerns with NPE

Stan Palmer

Ecolab Food & Beverage

Area Vice President Agri

May 14, 2015

Recent Industry Activity

- ◆ Fall 2013
 - Inquiries from NMPF and processors as to what is NPE
 - Multiple Requests for confirmation of NPE content in Ecolab products
 - Customers impacted: Large cheese and protein powder producers in the US as well as Fonterra in NZ.
- ◆ Driver:
 - Large protein powder user making baby formula that is exported to China sets limits on NPE content of incoming powder (< 0.3 ppm)
 - Rumors of academic paper being published in China on NPE impact in infant formula because of research indicating potential hormone like activity
- ◆ Other impacts
 - Ecolab and Customers: NPE residue is a major issue related to our environment and it is of major economic concern to milk powder exporters and the farms that ship milk to those exporters

NPE Restrictions – North America

EPA Status – Toxicological and Ecological Findings

- ▲ **Why is EPA concerned about these chemicals (NP and NPEs)?**
 - NP and NPEs are produced in large volumes, with uses that lead to widespread release to the aquatic environment.
 - NP is persistent in the aquatic environment, moderately bioaccumulative, and extremely toxic to aquatic organisms. NP has also been shown to exhibit estrogenic properties in in vitro and in vivo assays. NP's main use is in the manufacture of NPEs.

NPE Restrictions – North America

EPA Status – Toxicological and Ecological Findings

- ▲ **Why is EPA concerned about these chemicals (NP and NPEs)?**
 - NPEs are nonionic surfactants that are used in a wide variety of industrial applications and consumer products. Many of these, such as laundry detergents, are “down-the-drain” applications. Some others, such as dust-control agents and deicers, lead to direct release to the environment. NPEs, though less toxic and persistent than NP, are also highly toxic to aquatic organisms, and, in the environment, degrade into NP.
 - NP and NPEs have been found in environmental samples taken from freshwater, saltwater, groundwater, sediment, soil and aquatic biota. NP has also been detected in human breast milk, blood, and urine and is associated with reproductive and developmental effects in rodents.

NPE Restrictions – North America

EPA Status – NPE Action Plan (August 2010)

What action is EPA taking?

- May 9, 2012 -- Through its Design for the Environment program, EPA released a final [alternatives assessment](#) identifying eight safer alternatives to nonylphenol ethoxylates.

EPA is initiating both voluntary and regulatory actions to manage potential risks from NP and NPEs. EPA intends to:

- ✓ 1. Support and encourage the ongoing voluntary phase-out of NPEs in industrial laundry detergents. In discussions with EPA, the [Textile Rental Services Association of America \(TRSA\) agreed to expedite a phase-out of NPEs in industrial laundry detergents](#) (3 p., 197 kb.) [About PDF](#)). The phase out, which has already begun, is being coordinated with [EPA's DfE Safer Detergents Stewardship Initiative \(SDSI\)](#) program and would end the use of NPEs in industrial laundry detergents by 2013 for liquid detergents and 2014 for powder detergents. In addition, EPA intends to encourage the manufacturers of all NPE-containing direct-release products (e.g., firefighting gels and foams, dust-control agents and deicers) to move to NPE-free formulations. EPA will develop an alternatives analysis and encourage the elimination of NPE in other industries that discharge NPEs to water, such as the pulp and paper processing and textile processing sectors, where safer alternatives may be available. DfE also intends to expand the scope of SDSI, and encourage those industries to make commitments under SDSI. For detergent uses, the DfE-sponsored [CleanGredients database](#) [EXIT Disclaimer](#) offers a source of ready alternatives that are functionally equivalent to NPEs based on performance characteristics and safer because they meet the DfE criteria for safer surfactants.
- ✓ 2. Initiate rulemaking to simultaneously propose a significant new use rule (SNUR) under [TSCA section 5\(a\)](#) and a test rule for NP and NPEs under [TSCA section 4](#). The proposed SNUR would designate use of NPEs in detergents and cleaning products a significant new use, which would require submission of a significant new use notice (SNUN) to EPA at least 90 days before beginning that use. This gives EPA the opportunity to take other regulatory action if appropriate. The proposed test rule would require development of the information necessary to determine the effects that NPEs and NP have on human health or the environment. [EPA issued an advance notice of proposed rulemaking \(ANPRM\) for NP and NPEs on June 17, 2009](#). However, EPA intends to evaluate how releases and exposures are mitigated through the phase-out action; and would finalize any proposed testing actions accordingly.
3. Consider initiating rulemaking under [TSCA section 5\(b\)\(4\)](#) to add NP and NPEs to the Concern List of chemicals that present or may present an unreasonable risk of injury to health or the environment.
4. Initiate rulemaking to add NP and NPEs to the [Toxics Release Inventory \(TRI\)](#), which would require facilities to report releases of these chemicals to the environment.

Previous Actions:

[Read the citizens TSCA section 21 petition regarding NP and NPEs \(PDF\)](#) (17 pp. 920 kb, [About PDF](#)).

[Read about EPA's response to the section 21 petition](#)

NPE Restrictions – North America

EPA Status – Latest Activity (Fall 2013)



OFFICE of INFORMATION and REGULATORY AFFAIRS
 OFFICE of MANAGEMENT and BUDGET
 EXECUTIVE OFFICE OF THE PRESIDENT

Reginfo.gov

U.S. General Services Administration 

Search: Agenda Reg Review ICR

Home
Unified Agenda
Regulatory Review
Information Collection Review
FAQs / Resources
Contact Us

View Rule

[Printer-Friendly Version](#) [Download RIN Data in XML](#)

EPA/OCSP

RIN: 2070-AJ96

Publication ID: Fall 2013

Title: Certain Nonylphenols and Nonylphenol Ethoxylates; Significant New Use Rule

Abstract: EPA intends to propose a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for related chemicals known commonly as nonylphenols (NPs) and nonylphenol ethoxylates (NPEs). The SNUR would require persons who intend to manufacture, import, or process certain NP and NPE chemicals for an activity that is designated as a significant new use by the proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs to prevent unreasonable risk to human health or the environment. The NP and NPE chemicals that would be subject to this SNUR are toxic to aquatic organisms, and can be used in a variety of industrial and consumer applications that lead to releases to the environment.

Agency: Environmental Protection Agency(EPA)

Priority: Other Significant

RIN Status: Previously published in the Unified Agenda

Agenda Stage of Rulemaking: Proposed Rule Stage

Major: No

Unfunded Mandates: No

CFR Citation: [40 CFR 721](#)

Legal Authority: [15 USC 2604\(a\)](#); TSCA 5(a)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2014	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Small Entities Affected: No

Federalism: No

Included in the Regulatory Plan: No

RIN Information URL: <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans>

Dairy Farm Implications

- ◆ Current primary complexing agent for iodine teat dips outside of Europe – NPE
 - Cost effective
 - Stable in iodine formulas
 - Provides good surfactancy
 - Also used in Chlorhexidine based teat dips

Dairy Farm Implications

- ◆ Global concern with NPE related to the environment and human health
 - Global supplier limit <0.3ppm in milk powder
 - Use of NPE iodine teat dips pre and/or post milking can leave an NPE residue in raw milk
 - Other sources of NPE on the dairy can be laundry detergents, general purpose cleaners, deicers and fly sprays.

Dairy Farm Implications Case Study 2014

- ◆ Large Ecolab Customer – Processor and Producer
 - Dairy Processor; cheese, milk powder, and ingredient
 - Dairy Farm, multi-site, 10,000 cows
- ◆ Processor's customer tells them they need to reduce the NPE level in their milk powder
- ◆ Processor assumes the plant is the source. Membrane cleaner has NPE

Dairy Farm Implications Case Study 2014

- ◆ Eliminated the NPE based cleaner and replaced with **NPE Free** membrane cleaner
- ◆ NPE still measurable in the milk powder
- ◆ Their dairy farms were pre-dipping with ½% iodine. Replaced with **NPE Free** non-iodine pre-dip product
- ◆ Measurable NPE still present after pre-dip replacement.
- ◆ Not until the post dip was changed to a **NPE Free** non-iodine formula, did the detectable level of NPE go away.

Industry Response

◆ Current industry activity

- Fonterra put NPE limits on July 1, 2014 for their NZ milk supply
- Major cheese manufacturer in US has sent letters to all their producers putting a ban on NPE residue in all incoming milk effective August 1, 2014
- California and TX/NM are implementing **NPE Free** requirements.
- Expect other processors to implement NPE residue limits in their milk supply in the months to come

Teat Dip Manufacturer Actions

- ◆ Non Iodine NPE Free products
 - Many Proven Formulations
 - Prior wide use and acceptance by dairy farmers
 - Competitively Priced
- ◆ Iodine Based NPE Free products
 - Some manufacturers have had **NPE Free** iodine based products been for many years
 - Some have had **NPE Free** formulations available in Europe
 - Others are working through the reformulation challenge

Dairy Farm Actions

- ◆ Convert to teat dips not including NPE
 - Non-iodine teat dips without NPE
 - Iodine based dips with alternative complexing agent
 - Two new iodine teat dip concentrates without NPE
 - Some cost implications because of higher cost of NPE alternatives

Dairy Industry Concerns with NPE

Closing Comments

- ◆ This problem is real and is not going away
- ◆ Our industry is taking action, well in advance of possible regulatory action
- ◆ There are many products with proven micro efficacy for dairy farmer use
- ◆ New **NPE Free** Iodine based formulations are being tested and sold, with some success.

Dairy Industry Concerns with NPE

- ◆ Are there any questions?
- ◆ Thank You for your invitation