Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan

[RIN 2070-ZA09]

I. Overview

Nonylphenol (NP) and nonylphenol ethoxylates (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's main use is in the manufacture of NPEs. NPEs are nonionic surfactants that are used in a wide variety of industrial applications and consumer products. NPEs, though less toxic than NP, are also highly toxic to aquatic organisms, and in the environment degrade to more environmentally persistent NP. NP has also been detected in human breast milk, blood, and urine and is associated with reproductive and developmental effects in rodents.

NPEs were once commonly used in household laundry detergents. EPA and the detergent manufacturers have cooperated to eliminate this use. However, NPEs are still widely used in large quantities in industrial laundry detergents and have some additional uses that lead to releases to water. Therefore, EPA intends to initiate action to address its concerns about potential ecological effects due to the manufacturing, processing, distribution in commerce, and uses of NP and NPEs. Additionally, EPA continues to have some concern about potential risk to human health. EPA anticipates that the actions put forward in this Action Plan will further reduce human exposure thereby reducing concerns associated with NP and NPEs.

As part of the Agency's efforts to address NP and NPEs, EPA also intends to evaluate the potential for disproportionate impact on children and other sub-populations.

II. Introduction

As part of EPA's efforts to enhance the existing chemicals program under the Toxic Substances Control Act (TSCA; 15 U.S.C. §2601 *et seq.*), the Agency intends to identify chemicals for Action Plan development based on their presence in humans; persistent, bioaccumulative, and toxic (PBT) characteristics; use in consumer products; production volume; or other similar factors. NP and certain oligomeric NPEs are highly toxic to aquatic organisms, are moderately bioaccumulative in mollusks, are persistent in the aquatic environment, and accumulate in soils and sediments (EPA, 2005). This Action Plan is based on EPA's initial review of readily available use, exposure, and hazard information on NP and NPEs. In developing the Action Plan, EPA considered which of the various authorities provided under TSCA and other statutes might be appropriate to address potential concerns regarding NP and NPEs. The Action Plan is intended to describe the courses of action the Agency is considering pursuing in the near term to address its concerns. It does not constitute a final Agency determination or other final Agency action. Regulatory proceedings indicated by the Action Plan will include appropriate opportunities for public and stakeholder input, including through notice-and-comment rulemaking processes.

III. Scope of Review

This Action Plan addresses uses of nonylphenols and nonylphenol ethoxylates that fall into the general chemical categories of alkylphenols and alkylphenol ethoxylates (APEs), respectively.

Chemical Abstract Service registry names and numbers (CASRNs) routinely used to refer to nonylphenols or nonylphenol ethoxylates may not accurately reflect the identity of those substances. The nine carbon nonyl group may be branched or linear and bind at various locations around the phenol ring (“ortho”, “meta” or “para”). Many manufacturers incorrectly use the linear identity when referring to the branched nonylphenol. CASRN 84852-15-3 corresponds to the most widely produced nonylphenol, branched 4-nonylphenol (referred to herein as NP). Note that NP is not a single chemical structure. It is a complex mixture of highly branched nonylphenols, largely mono-substituted in the *para-* position, but with small amounts of *ortho-* and di-substituted nonylphenols. In addition it includes small amounts of branched C_8 and C_{10} alkyl groups (Seidel 2004a). Much of the literature refers to the linear (or normal-) nonylphenol (CASRN 25152-52-3), often the specific *para-*regioisomer (i.e. 4-n-nonylphenol, CASRN 104-40-5). Many, but not all, references are inaccurate about the identity of the substances listed as nonylphenol. This is likely due to inaccurate identities in the source material. A supplier of nonylphenol may use CASRN 104-40-5, signifying 4-n-nonylphenol, while actually supplying branched 4-nonylphenol (CASRN 84852-15-3).

The mono- and di-ethoxy NPEs (NP1EO, NP2EO) do not appear on the TSCA inventory, but are among the degradation products of the polymeric NPEs and may be present with NP in the environment in appreciable concentrations.

Production

Nonylphenol

U.S. demand for NP (which includes both production and imports less exports) is estimated to be 380 million pounds in 2010 (ICIS, 2007). This is well within the range for the reported production volume (manufactured volume plus imports) reported under the TSCA Inventory Update Rule (IUR) in 2006, which ranged from approximately 100 to 500 million pounds, based on reporting for the most widely produced branched and linear nonylphenol substances (i.e., CASRN 84852-15-3 and CASRN 25154-52-3, respectively).

Nonylphenol ethoxylates

NPEs are surface active agents (surfactants) that are part of the broader category of surfactants known as alkyphenol ethoxylates (APEs). NPEs represent approximately 80% to 85% of the volume of APEs.

U.S. demand for all surfactants in 2007 was 7.5 billion pounds (Rust and Wildes, 2008). U.S. and Canadian consumption of NPE surfactants has been estimated between 300 and 400 million pounds per year (EPA, 2008). In a study by ToxEcology in 2002, NPE surfactant consumption in Canada was estimated at approximately 29 million pounds. It is not clear if this estimate includes soap, so it may be an underestimate of total surfactant consumption by Canada. However, if Canadian consumption of NPEs is approximately 29 million pounds, then U.S. consumption of NPEs would range from approximately 270 to 370 million pounds.

IV. Uses and Substitutes Summary

The primary use of NP is as an intermediate in the manufacture of NPEs. NPEs are manufactured by reacting NP with ethylene oxide (EO) under basic conditions. The degree of ethoxylation depends on the molar ratio of NP to EO. All degrees of ethoxylation may be manufactured under the CASRN for the poly-ethoxylates (formally poly(oxy-1,2-ethanediyl), α-(4-nonylphenyl)-ω-hydroxy-, branched, CASRN 127087-87-0), as long as they are synthesized via polymerization reaction between NP and EO.

NP may also be reacted to form tris(4-nonyl-phenyl) phosphite (TNPP, CASRN 26523-78-4) an antioxidant used to protect polymers such as rubber, vinyl, polyolefins, and polystyrenics (Seidel 2004a). TNPP is also used as a stabilizer in plastic food packaging. Although it does contain residual NP, TNPP has been approved for this use by the Food and Drug Administration (FDA). FDA also lists NP as an indirect food contact substance (Vazquez-Duhalt, et al., 2005). Barium and calcium salts of NP are used as heat stabilizers for poly vinyl chloride (PVC) (Seidel 2004a). NP is also used as a catalytic diluent in epoxy resins (Seidel 2004a).

Surfactants are generally categorized based upon their electric charge in water. Categories of surfactants include anionic (negative), nonionic (no charge), cationic (positive), and amphoteric (positive and negative). NPEs are part of the nonionic category. Non-ionic surfactants, including NPEs, are used in a wide variety of applications including detergents, cleaners, degreasers, dry cleaning aids, petroleum dispersants, emulsifiers, wetting agents, adhesives, agrochemicals, including indoor pesticides, cosmetics, paper and textile processing formulations, prewash spotters, metalworking fluids, oilfield chemicals, paints and coatings, and dust control agents. NPEs are hydrophilic (“water-attracting”) at one end of the molecule and hydrophobic (“water-avoiding”) at the opposite end. The hydrophilic “head” attracts water and the hydrophobic “tail” attracts poorly soluble substances, such as oils and greases. This ability to simultaneously attract water and hydrophobic substances makes NPEs useful in the surfactant applications listed above, accounting for nearly 80% of consumption. Additional uses include: 1) phosphate antioxidants for rubber and plastics; and 2) miscellaneous uses, including lube oil additives. These uses each account for another 10% of total consumption (ICIS, 2007).

Alternatives to NPEs

There is enormous variability in the structure of non-ionic surfactants. Most non-ionic surfactants rely on polyethoxylation to provide the hydrophilic moiety. Others rely on glycerol (glycerin), glucosides, or other sugars, either as monosaccharides (e.g. sorbitol) or disaccharides (e.g. sucrose) (Seidel 2004c). The simplest substitution for NPEs is to use other APEs. NPEs are just one of many APEs available commercially, and other APEs are used for many of the same commercial purposes as emulsifiers, dispersants, and surfactants. The main alternatives for NPEs also include alcohol ethoxylates, both linear and branched, and glucose-based carbohydrate derivatives such as alkylpolyglucoside, glucamides, and glucamine oxides. Some surfactants may substitute for specific applications only, for instance, silicon surfactants are used in production of polyurethane foam while napthalene condensates are used in photofinishing solutions. In other cases, NPE can be replaced with a surfactant blend of alternative nonionics or a blend that include anionic or amphoteric surfactants. Market acceptance of these alternatives depends on a number of factors including cost and performance in the intended use. Many of these alternatives are less persistent and break down to chemicals which are less toxic than NP and may be deemed safer substitutes for NPEs by EPA (EPA 2010a).

V. Hazard Identification Summary

The Office of Pollution Prevention and Toxics (OPPT) assessed the human health and environmental effects hazards of NP, specifically CASRN 84852-15-3, which is branched, para-substituted NP (branched 4-nonylphenol), as part of its Hazard Characterization (HC) of 18 alkylphenols (http://www.epa.gov/chemrtk/hpvis/hazchar/Category_Alkylphenols_Sept2009.pdf) (EPA, 2009c). This CASRN is one of two nonylphenol CASRNs included in this Action Plan. The other CASRN, 25154-52-3, is for straight chain nonylphenol. Since very little straight chain nonylphenol is produced, OPPT's HC coverage of CASRN 84852-15-3 (and not of CASRN 25154-52-3) is used here. OPPT has evaluated the metabolism of NPEs in mammals and has concluded that they are metabolized to NP (EPA, 2007; EPA, 2010b).

Human Health Effects

The following discussion on human health effects is based on information contained in OPPT's HC of 18 alkylphenols (EPA, 2009c). NP's acute (oral and dermal) toxicity is low. NP is highly irritating and corrosive to the skin and eye, but does not have significant skin sensitizing potential. NOAELs (No Observed Adverse Effect Levels) and LOAELs (Lowest Observed Adverse Effect Levels) for systemic toxicity (based on body weight or body weight gain) in repeat dose rat oral toxicity studies range from 13 to 100 mg/kg-bw/day and from 43 to 400 mg/kg-bw/day, respectively. NOAELs and LOAELs in rat for reproductive toxicity (based on decreases in epididymal sperm density or testicular sperm head counts, increases in estrous cycle length, and decreases in ovarian weights) range from 13 to19 mg/kg-bw/day, and from 43 to 64 mg/kg-bw/day, respectively. Developmental rat NOAELs and LOAELs for offspring (based on accelerated vaginal opening in pups) range approximately from 13 to 19 mg/kg-bw/day and from 43 to 64 mg/kg-bw/day, respectively. Developmental NOAELs and LOAELs for rat maternal toxicity (based on decreased terminal body weights) range from 13 to 19 mg/kg-bw/day and from 43 to 64 mg/kg-bw/day, respectively. NP is not mutagenic in the Ames assay, *in vitro* chromosomal aberration assay, or *in vivo* micronucleus assay. There are no data on its carcinogenic potential.

Environmental Effects

Aquatic Toxicity:

The available acute and chronic toxicity data of NP to aquatic organisms indicates NP is highly toxic to fish, aquatic invertebrates, and aquatic plants. The 28-day no observed effect concentration (NOEC) of CASRN 84852-15-3 for fish ranges from 0.05 to 0.07 mg/L and the 28-day lowest observed effect concentration (LOEC) ranges from 0.12 to 0.19 mg/L. A 33-day NOEC for fish is 0.007 mg/L and the 33-day LOEC is 0.014 mg/L. The 21-day NOEC for aquatic invertebrates ranges from 0.10 to 0.24 mg/L (EU, 2002; Canada, 2002; EPA, 2005).

For NPEs, toxicity to aquatic organisms tends to decrease with increasing degree of ethoxylation. For example, acute toxicity to killifish was 1.4 mg/L, 3 mg/L, 5.4 mg/L, 12 mg/L and 110 mg/L for NP, NP1EO (i.e., NPE with one ethoxylate group), NP6.4EO (i.e., NPE mixture with an average of 6.4 ethoxylate groups), NP9EO and NP16.6EO, respectively (Canada, 2002). Environment Canada, based on a comprehensive analysis of available toxicity data for NP and NPEs, developed Toxic Equivalency Factors (TEFs) for NP and NPEs, as follows: NP =1; NP1EO and NP2EO =0.5

(i.e., half as toxic as NP); NP3EO to NP8EO also = 0.5 (a conservative estimate because of inadequate data); NP9EO and greater = 0.005 (i.e., 100 times less toxic than NP) (Canada 2002).

Bioconcentration Factor (BCF):

The measured BCF for fish is low, ranging from 87 to 344. However, the BCF for mussel ranges from 14 (low) to 3,400 (moderate) (EPA, 1996).

VI. Physical-Chemical Properties and Fate Characterization Summary

NP is a clear to pale yellow viscous liquid at room temperature with moderate water solubility and moderate vapor pressure (Ahel and Geiger, 1993; EU, 2002; Seidel, 2004b). NP has moderate volatility, and, while air concentrations of NP are generally expected to be low (EU, 2002), research has shown that in some locations there may be water-to-air volatilization that results in significant atmospheric concentrations of NP substances (Canada, 2002). In the atmosphere, NP will be degraded rapidly by hydroxyl radicals and is not expected to be persistent in air (EPA, 2009). NP is primarily found in the environment as a degradation product of NPEs. NPEs are released most often to sewage treatment plants, and are degraded to shorter-chain NPEs, including NP1EO and NP2EO in active sewage sludge; these short-chain NPEs are then further degraded to NP (EPA, 2005). NP is expected to adsorb strongly to soils and sediments. In sewage treatment plants, NP is expected to partition to sludge, and when released to the aquatic environment, is expected to partition mainly between water and sediment (EPA, 2005; Canada, 2002). In the surface layer of natural waters, NP can be photolyzed with a half-life of 10-15 hours (Canada, 2002). NP and NPEs that are present in natural waters or landfills may also potentially leach into groundwater (Canada, 2002). NP undergoes biodegradation, but not readily, and is considered persistent in the aquatic environment (Canada, 2002). NP also exhibits moderate bioaccumulation potential in aquatic organisms (Canada, 2002; EPA 2005).

NPEs are clear to light orange oily liquids or waxy solids, and are considered to be chemically stable and unreactive (SEPA, 2010). NPEs show a gradual, linear increase in water solubility with greater degree of ethoxylation (for example the reported water solubility of NP5EO is 9.48 mg/L; of NP12EO, 42.5 mg/L) (Ahel and Giger 1993; Brix et al. 2001). There are conflicting reports in the literature on the biodegradability of NP and NPEs. They are not readily biodegradable using standard tests, but are inherently biodegradable (Canada, 2002; EU, 2002). After a period of acclimation, NPEs, in sewage sludge or the natural environment, can undergo biodegradation to shorter-chain NPEs involving stepwise loss of ethoxy groups to lower NPE congeners (Maguire, 1999). In the environment the long-chain NPEs biodegrade relatively quickly to short-chain NPEs and NP, which are much more resistant to further degradation (Canada, 2002; EU, 2002). When in water, NPEs can also undergo photo-induced degradation (Canada, 2002).

VII. Exposure Characterization Summary

Releases

NPs and NPEs are not listed in the Toxic Release Inventory (TRI). No readily available, quantitative release data in the U.S. were found for NPs and NPEs. Based on information from the European Union (EU) and Canada (EU, 2002 and Environment Canada, 1999), there are environmental releases of NPs and NPEs to water during their manufacture and uses including:

Release of NP

- during production of NPEs
- during production of nonylphenol/formaldehyde
- during production of epoxy resins
- during production of plastic

Release of NP and NP

- in industrial and institutional cleaning products
- during agricultural use

Release of NPEs

- from emulsion polymerization processes
- in textiles processes including wool scouring
- from paper processes
- from printed circuit boards manufacturing processes
- from metal extraction, refining and processing industry
- during paints, lacquers and varnishes manufacturing processes
- from use in deicer formulations

Human Exposure

There are no U.S. Occupational Health and Safety Administration (OSHA) Permissible Exposure Limits (PELs) or National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs) for NP or NPEs. No readily available, quantitative occupational exposure monitoring data in the U.S. were found for NP and NPEs.

Based on IUR data, the total number of workers reasonably likely to be exposed to NP or NPEs during manufacturing and industrial processing and use may be 1,000 or greater. There may be additional potentially exposed industrial workers who are not included in this estimate. This estimate also does not include potentially exposed commercial workers, such as employees of laundries or cleaning services, since the IUR does not collect such data.

The National Occupational Exposure Survey (NOES), conducted from 1981 to 1983, estimated 306, 211 workers were potentially exposed to NPs and 1,961,225 workers were potentially exposed to NPEs. The Survey lists the linear isomer, but EPA believes the branched isomer is more accurate.

The following exposure information is based on information obtained from the EU (EU, 2002). It is not known if the processes and associated exposures in the U.S. would be similar to those in the European countries.

The EU Risk Assessment indicated the manufacturing and use of NP as a chemical intermediate is carried out in closed systems. Occupational exposure may occur during sampling, maintenance and product filling to drums and tankers (EC, 2002). Occupational exposure was estimated at about 0.9 mg/m^3 (8-hour TWA) for both production and use of NP (EC, 2002).

During the manufacture of specialty paints, the EU identified two activities where potential exposure to NP may occur: during loading of the NP into the solvent, and during coupling and uncoupling of the pipe work during product loading into tins. The inhalation exposure was estimated to be 0.091 mg/m^3 (8-hour TWA), and the dermal exposure was estimated to be from 0 to 0.1

mg/cm^2/day. During the use of these paints, the EU identified two exposure points: mixing of the paint, and spray application. Dermal exposure during mixing was estimated to range from 0.01 to 0.24 mg/cm^2/day, and inhalation exposure during spraying was estimated to be 9.1 mg/m^3 (8-hour TWA) (EC, 2002).

No quantitative worker exposure data were found during the production of epoxy resins using NP. However, NP is blended directly into the hardening component of the epoxy resin and filled into tubes for use (EC, 2002), indicating potential exposures may occur from adding the NP to the mixer.

No readily available quantitative information on exposure to NP or NPEs were found for use of NP in the manufacturing of NPEs or the processing or uses of NPEs in industrial and institutional cleaning products, emulsion polymerization, textiles, pulp and paper, electrical and electronic products, metal extraction, refining and processing industry or lacquers and varnishes industry.

General population exposure to NP (either directly or as a metabolite of NPE) has been confirmed by biomonitoring data from breast milk (Ademollo et al., 2008), umbilical cord blood (Chen et al., 2008) and urine (Calafet et al., 2008). The maximum level of NP found in the breast milk was 56.3 μg/L, leading to an estimated maximum dose for an infant of 3.9 μg /kg/day (Ademollo et al., 2008). Exposure is a result of the presence of NP and NPEs in detergents, cleaners, agricultural and indoor pesticides, food packaging and cosmetics. These are potentially products of concern for women and children. For example, small children crawling on floors would be exposed to NPEs and NP in floor and carpet cleaners.

Estimates of human exposure are available for several of these sources. These include exposures from: diet_0.1 μg/kg/day from a reported 7.5 μg/day with the conversion done for a 70 kg person (Guenther et al. 2002); hair dye_0.1 μg/kg/day; food containers_2 μg/kg/day; and indoor pesticides_0.35 μg/kg/day (EU, 2002). The EU report also estimates NP exposure due to environmental sources to be 5 μg/kg/day, with 70% – 80 % of this due to fish and shellfish consumption (EU 2002). A biomonitoring study of breast milk also found a positive correlation between seafood consumption and levels of NP (Ademollo et al., 2008). Significant exposure could also result from hard surface cleaners and their residue. The largest estimated exposure (4.4 mg/kg/day) was due to living near a textile factory that used NP and NPEs (EU, 2002). The appropriate exposure factors for drinking water ingestion of water across all ages ranges from a mean of 0.926 L/day to the 95th percentile factor of 2.544 L/day (EPA, 2009). If the measured value of 1 μg/L (EPA, 2001) for alkylphenols in drinking water is combined with the mean drinking water estimate of 0.926 L/day; the result is an estimated exposure of 0.01 μg/kg/day. Based on this analysis, EPA believes that drinking water should not be the main source of exposure, a view shared by other sources (EU, 2002; Soares et al. 2008).

Environmental Exposure

Ecological receptors have the potential for significant exposure to NP and NPE for two reasons: 1) facilities that manufacture products containing NP or NPEs are discharging them into surface waters (Ellis et al., 1982); and 2) NP and NPEs tend to partition to sediments and accumulate (Naylor et al., 1992). Both freshwater and saltwater invertebrates, plants and fish are sensitive to this category of chemicals and have demonstrated toxicity to it in varying degrees. EPA's Office of Water has derived freshwater and saltwater water quality criteria (WQC) for NP. The acute and chronic

WQC for freshwater species are 28 μg/L and 6.6 μg/L, respectively. The acute and chronic WQC for saltwater species are 7 μg/L and 1.7 μg/L, respectively (USEPA, 2005). A range of surface water and sediment levels of NP and NPEs have been measured in US waters. APEs are widely used as industrial laundry detergents and frequently found in wastewater and sewage treatment plant effluents (Ying et al. 2002). Surface waters near 11 different industrial discharges ranged in concentration of NP from 2 to 1617 μg/L (Shackelford et al., 1983). Surface water and sediments measured in the Great Lakes contained NP concentrations from 0.01 to 0.92 μg/L for water and 37 μg/g to 300 μg/g for sediments (Bennett et al., 1997). Surface water samples collected along the Ohio River measured for total NPEs ranged from 0.13 to 1.0 μg/L for water, from 250 to 1020 μg/g for sediments, and from 32 to 920 μg/g for carp, a bottom dwelling fish (Rice et al., 2003). Some of the measured surface water concentrations particularly those near industrial discharges exceed the WQC for freshwater species living in the water column. NP and NPEs in the freshwater and saltwater ecosystems have the potential for ecological effects on all trophic levels of aquatic species exposed to them (USEPA, 2005).

VIII. Risk Management Considerations

General Considerations

EPA has identified a number of issues that it has taken into consideration in the development of an Action Plan for NP and NPEs:

1) NP and the short-chain NPEs (NP1EO and NP2EO) are persistent, moderately bioaccumulative, and extremely toxic to aquatic organisms. EPA has established water quality criteria for NP of 6.6 μg/L for acute exposures and 1.7 μg/L for chronic exposures; Environment Canada has also established a concern level for NP (and NPEs, as expressed in NP Toxic Equivalency (TEQ) units) of 0.7 μg/L for indefinitely chronic exposures (EPA, 2005, Canada, 2002). The long-chain NPEs, while less "PBT", are also highly toxic and degrade to the more toxic and persistent short forms of NPEs and NP in the environment. Internationally, Canada and the EU have acted to regulate NP and NPEs, and the United Nations Environment Programme (UNEP, 2003) has identified NP as a chemical of global concern in its Regionally-based Assessment of Persistent Toxic Substances (http://www.chem.unep.ch/pts/gr/Global_Report.pdf).
2) NPEs are generally sold as mixtures; substances represented by CASRNs under the IUR cover a broad spectrum of these substances. There appear to be possible reporting inaccuracies regarding what is actually manufactured. Original TSCA inventory substances identified as straight-chain substances have often been found to be branched-chain forms. PMN submissions for straight-chain NPEs have also been found to be branched and are corrected during the PMN review process.
3) NPEs frequently contain a mixture of substances with C6 to C12 (hexyl to dodecyl) alkylphenol ethoxylates; these "APEs" could also be sold as easily manufactured substitutes for NPEs. These substances are anticipated to have similar properties as NPEs. EPA notes, however, that for many uses of NPEs, safer substitutes are available and use of these substitute chemicals should be encouraged.
4) It appears that a large proportion of use and subsequent environmental release is associated with industrial laundries; however, more analysis is needed to understand other TSCA (and non-TSCA) uses and releases.
5) EPA's Office of Pesticide Programs (OPP) also conducted an assessment of NPEs (EPA, 2010b). OPPT and OPP have worked together to ensure that the toxicological conclusions in both documents are consistent.

Potential Impacts on Children

There are potential children's health concerns related to NP and NPEs. NP exposure over several generations has been observed to cause slight changes in the estrous cycle length, timing of vaginal opening, ovarian weight, and sperm/spermatid count in laboratory animals (EU, 2002). NP exposure over several generations has been observed to cause slight but statistically significant changes in the estrous cycle length, timing of vaginal opening, ovarian weight, and sperm/spermatid count in laboratory animals beginning in 30-100 mg/kg/d dose groups (EU, 2002; Chapin et al., 1999). These findings are consistent with the observation that NP has estrogenic activity (EU, 2002), but a mode of action analysis has not been conducted. Data on children's exposure are limited, though children may have greater exposure to NP and NPEs because they consume more food, drink more water, and breathe more air per pound than adults. While biomonitoring data are also limited, a recent Italian study found maximum exposures from human breast milk of 3.9 µg /kg/day (Ademollo, 2008).

IX. Next Steps

In conducting this review of NP and NPEs, EPA considered a number of potential risk management actions, including regulatory actions under TSCA sections 4 and 5, requiring reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313, and voluntary actions through such programs as Design for the Environment (DfE).

Based on its screening-level review of hazard and exposure information, EPA intends to initiate actions to protect the environment from exposure to NP and NPEs due to manufacture (including import) use, or disposal of commercial NP and NPEs. In addition, as part of the Agency's efforts to address these chemical substances, EPA also intends to evaluate the potential for disproportionate impact of exposure to NP and NPEs on children and other sub-populations.

On the basis of existing information, the Agency believes that the following actions would be warranted:

1. Supporting and encouraging the voluntary phase out of the use of NPEs in industrial laundry detergents.
    a. In discussions with EPA, the Textile Rental Services Association of America (TRSA), whose members represent a large majority of the industrial launderers in the U.S., agreed to expedite a phase out of the use of NPEs in industrial laundry detergents. The phase out, which has already begun, would end the use of NPEs in industrial laundry detergents by 2013 (for liquid detergents) and 2014 (for powder detergents).
    b. The phase-out of detergents in industrial laundry detergents and other products will also be coordinated with EPA's DfE Safer Detergents Stewardship Initiative (SDSI) program which has had great success in obtaining public commitment by consumer product manufacturers to end the use of NPEs in household laundry detergents. EPA intends to encourage any industrial launderers who are not members of TRSA to also join this effort.
2. Initiating rulemaking to simultaneously propose a TSCA significant new use rule (SNUR) and a test rule for NP and NPEs.
    a. The proposed SNUR would propose to designate use of NPEs in detergents and cleaning products as 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 regulatory action if appropriate. EPA plans to publish the proposed SNUR at the end of 2011; with the effective date of the final SNUR timed to coincide with the anticipated completion of the phase-out of NPEs in industrial laundry detergents.
   b. The proposed test rule under section 4 of TSCA would propose to require development of the information necessary to determine the effects that NPEs and NP may have on human health or the environment. EPA has already issued an advance notice of proposed rulemaking (ANPRM) for NPEs and NP (published 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.
   c. EPA also intends to evaluate the utility of issuing a SNUR for the straight-chain NPEs that EPA believes are no longer being manufactured. Many commercial NPEs are identified as linear nonyl isomer, but EPA believes that these may be misidentified branched forms. In part, the intent of the SNUR would be to eliminate discrepancies on the TSCA inventory and improve accuracy in reporting under the IUR.
   d. In addition, EPA will consider SNURs for additional uses, depending on the results of an ongoing use and exposure analysis.
3. Consider initiating rulemaking under TSCA Section 5(b)(4) of TSCA to add NP and NPEs to the list of chemicals that present or may present an unreasonable risk of injury to health or the environment. EPA plans to publish a notice of proposed rulemaking by the end of 2011.
4. Initiating rulemaking in late 2011 to add NP and NPEs to the TRI list. At present, neither NP nor NPEs are on this EPCRA section 313 list of toxic chemicals.
5. Supporting and encouraging the elimination of other uses of NP and NPEs, followed by regulatory actions as necessary.
   a. 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. As TRSA implements its phase-out commitment through SDSI, it will provide an example for other product sectors to follow, especially those with “direct releases” to the environment. The DfE-sponsored CleanGredients database offers a source of ready alternatives—functionally equivalent to NPEs based on performance characteristics and safer because they meet the DfE Criteria for Safer Surfactants. (For more information, visit http://www.epa.gov/dfe/pubs/projects/formulat/sdsi.htm.)
   b. EPA will develop an alternatives analysis and encourage the elimination of NPE use 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.

X. References

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