- Summary of the Interim Report -Nonylphenol

August 2003

National Institute of Technology and Evaluation Study Group for Risk Assessment & Management of Nonylphenol

1. Introduction

Nonylphenol (NP) is mainly used as binders for ink and an intermediate material for production of nonylphenolethoxylate (NPE), which is one of the surfactants used in cleaning agents. And NP is also used as intermediate of anti-oxidants for rubber. However, it is a substance that has raised public concern for its toxic effect on fish and its suspected endocrine disrupting characteristics.

Given these concerns, international organizations such as the OECD and EU as well as domestic governmental agencies have issued various assessment reports on the toxicity of NP, and a number of industries have taken voluntary actions to refrain from using NP where possible.

Therefore, it is an important task to gather scientific information so that appropriate management of NP is implemented while not losing sight of its benefits. In order to achieve this goal, it is necessary to clarify the current status of the production, use, and disposal of NP, the concentrations in the environment and the level of ecological risk in Japan, as well as to assess the risk in detail so that specific management measures can be proposed.

In November 2001, the National Institute of Technology and Evaluation (NITE) established the Study Group for Assessment and Management of Nonylphenol with the aim of gathering information. The group consists of experts from industry, academia and local government authorities.

The interim report includes the following information: information on the identification of NP; material information such as physico-chemical properties; the results of the assessment of known hazards and the risk of NP as provided by domestic organizations (such as the Ministry of Economy, Trade and Industry (METI) and Ministry of the Environment (MOE)) and overseas organizations (such as EU, U.S.EPA, Environment Canada, Health Canada); the amounts of NP produced, imported, and exported (from 1997 to 2001) and the amounts used by each industrial field and application (from 1995 to 2000); the amounts of NPE produced, imported, and exported (2000) and the amounts used by each industrial field and application (from 2000 to 2001); concentrations of NP and NPE in the atmosphere, rivers (from 1998 to 2001), and sediments of rivers (1998 to 2001); concentrations of NP in lakes, seawater, and underground water (1998 to 2001); the environmental monitoring data on the concentrations of NP, NPE, and nonylphenoxycarboxylic acid (NPEC) in treated sewage water and sludge (1998 to 2001); Pollutant Release and Transfer Register (PRTR) data on NP and NPE for 2001; the emission scenario that estimates the amounts of NP and NPE released into the environment over their life cycles; estimation of the concentrations of NP in rivers obtained from the water system exposure model that complements the environmental monitoring data; status of voluntary actions taken to NPE by related industries including the Japan Surfactant Industry Association; and case examples of actions taken to NP and NPE by Aichi Prefecture and Osaka Prefecture.

Seven meetings of the Study Group have been held since November 2001, and invaluable data were presented by the group members. It seems to contribute to risk assessment by collecting the necessary information for the in-depth risk assessment.

This report summarizes the interim report prepared by the Study Group.

2. General information

The interim report provides information on chemical identification, general information, and physicochemical properties, as well as the degradation pathway of NPE in the environment, since the main use of NP is in the production of a surfactant, NPE.

NP is synthesized by the reaction of phenol with propylene trimers, giving para-substituted isomers as a major product. NP has a melting point of -10^{-10} , a boiling point of $293-297^{-10}$, and is a highly viscous liquid with a light yellow color. When conducting risk assessment of NP, it is good practice to take into account both NP and NPE, since NP is the starting material and one of the resulting degradation products of NPE after release into the environment.

3. Existing reports on hazard and risk assessment

Results of hazard and risk assessment conducted in Japan and overseas are reviewed and summarized below.

3.1 Existing Japanese assessment reports

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The following Japanese assessment reports are reviewed.

- METI, Management Committee and Examination Committee of Chemical Substance Council (2002), Hazard assessment of some chemical substances which have been "suspected to be endocrine disrupters"
- 2) Chemicals Evaluation and Research Institute (CERI) (2002), Initial Risk Assessment Report for Chemical Substances (A preliminary version) No.1, Nonylphenol (sponsored by NEDO)
- 3) MOE (2002), Study Group for Endocrine Disrupting Chemical Substances, "Report on the test results of the endocrine disrupting effects of nonylphenol in fish"
- 4) MOE (2002), ENVIRONMENTAL RISK ASSESSMENT OF CHEMICALS

3.1.2 Conclusions of the assessments

The following conclusions were reached in the assessment reports.

1) Individual assessment report by METI

No further testing is required at present for human health because enough information to identify the effects of NP on the endocrine and reproductive system is available. Alternatively, risk reduction measures based on the risk assessment shall be taken into account since NP shows reproductive and developmental toxicities leaving endocrine disrupting effects out of consideration.

2) Initial Risk Assessment Report (A preliminary version) by CERI

The following conclusions regarding human health and the environment were reached:

• In-depth risk assessment for human health are not necessary at present.

• It is necessary to conduct in-depth risk assessment for aquatic organisms in the environment based on detailed information related to the effects on aquatic organisms and the behavior and concentrations of NP and NPE in the environment.

3) Report on the test results of the endocrine disrupting effects of nonylphenol on fish by MOE

The following conclusion regarding the environment was reached:

It is possible that NP may have some influence on the ecosystem through its endocrine disrupting effects on fish in Japanese waterways.

4) ENVIRONMENTAL RISK ASSESSMENT OF CHEMICALS issued by MOE

• The following conclusions regarding human health and the environment were reached: No conclusion was reached regarding the effects on human health of drinking tap water and underground water.

There is need for an in-depth risk assessment for the freshwater environment, and for further information on the seawater environment. It is possible that NP in seawater may have some influence on the environment.

3.2 Existing risk assessment reports compiled outside Japan

The following risk assessment reports were reviewed.

- 3.2.1 Risk assessment reports compiled outside Japan
 - 1) European Union (EU) (2001), European Union Risk Assessment Report. 4-Nonylphenol (branched) and Nonylphenol.
 - 2) USEPA (1996), RM-1 Document for para-nonylphenol.
 - 3) Environmental Canada and Health Canada (2000), Canadian Environmental Protection Act, Priority Substances List, Assessment Report, Nonylphenol and its ethoxylates.

3.2.2 Conclusions

The following conclusion regarding the environment was reached:

1) EU Risk Assessment Report (Extract of conclusion iii) applied to the surface water compartment

- There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account. This conclusion applies to the aquatic (surface water) compartment for the following life cycle stages (as well as to regional concentrations derived from all sources):
 - Production of NP;
 - Production of phenol/formaldehyde resins;
 - Production of epoxy resins;
 - Production of other plastic stabilizers;
 - Production of phenolic oximes;
 - Production of NPE;
 - Formulation of NPE; and
 - NPE use in all applications (i.e. agriculture; captive use by the chemical industry; civil engineering; electrical engineering; industrial and institutional cleaning; leather processing; metal extraction and processing; mineral fuel and oil industry; paint production and use; photographic industry; polymer industry; pulp, paper and board industry; textile industry).

2) US EPA RM-1 Document

- 4-NP is acutely and chronically toxic to aquatic organisms. Overall, the risks due to acute and chronic effects on pelagic organisms do not appear to be widespread. But there are some impacted areas where both pelagic and benthic organisms could be affected. This risk assessment only addressed the risks of 4-NP. Although the parent, NP 1&2-EOs, and its degradated carboxylic acid are less toxic by at least an order of magnitude, in some areas there may be additive risk due to the presence of all of the compounds.
- 4-NP and the ethoxylates are weakly estrogenic.
- 4-NP has a low to moderate bioconcentration potential in freshwater fish. There are reports of higher BCF potential in marine fish and invertebrates.
- Although not readily biodegradable under laboratory condition, 4-NP is not as persistent as once thought. This is based on actual measurements. Publicly Owned Treatment Works in the U.S. seem to have a very high efficiency in removing 4-NP.
- 3) Environmental Canada and Health Canada Priority Substances List, Assessment Report
 - NP and its ethoxylates from untreated or partially treated textile mills that discharge directly to the aquatic environment occur at levels that are likely to cause harmful effects on aquatic organisms. Additionally, discharges from municipal wastewater treatment plants and pulp and paper mills

contribute NP and NPEs to the environment at levels that are of concern at a limited number of sites. Although, based on current use and treatment practices, the risk to the aquatic environment of NP/NPEs in municipal effluents is not high, the concentrations in the environment, especially near outfalls, may approach levels of concern.

• The potential for adverse effects due to exposure to NP/NPEs is generally associated with industrial and municipal effluents in Canada. The increased use of NPEs or related alkylphenols in the future could lead to more widespread concern for the effects of these chemicals. The use of NP/NPEs in Canada, therefore, should be managed to minimize their exposure and threat to Canadian ecosystems.

4. Status of production and use

The production volume of NP in 2001 was 16,110 tons, of which 6,279 tons was exported, while 1,861 tons was imported. Production has been tending to decrease year by year.

Approximately 60% of the NP production is used in the production of surfactants (NPE). Approximately 40% is used in the production of anti-oxidants for rubber, phenol resins used in laminated sheets, the binder for inks, and stabilizers for epoxy resins. NP was formerly used as an additive for plastics, but is not being used for plastics produced in Japan at present.

The Study Group reviewed information on the use of NPE that may have effects on the ecosystem. NPE is produced by the reaction of NP with ethylene oxide. In 2000, 26,127 tons of NPE were produced in Japan. Imports and exports were 532 tons and 13,147 tons, respectively. Domestic consumption was 13,512 tons used as a nonionic surfactant.

NPE is widely used in various fields of industry as a surfactant due to its excellent properties. In 2001, about 2,700 tons of NPE were used as an emulsion polymerization and dispersing agent in the rubber and plastic industry, which is the largest user of NPE. About 2,100 tons were used as emulsifying agents for cutting and rolling in the machinery and metal-working industry, while about 2,000 tons were used as a professional cleaning agent, and about 1,800 tons were used as a cleaning agent, lubricant, and level dyeing agent in the textile industry. In addition to these major applications, NPE is used in various industrial fields for such applications as a spreading agent for agricultural chemicals and fertilizers and a water reducing agent in the construction and civil engineering industry. NPE has not been used in household detergents since 1998 due to the voluntary actions implemented by industry.

5. Environmental monitoring

The national government and local governments have measured the concentrations of NP and NPE in local rivers and in water discharged from sewage treatment plants etc.

5.1 Concentrations in the atmosphere

Only a limited number reports on NP concentrations in the atmosphere are available. It may be possible that NP evaporates into the atmosphere where the concentration of NP in the surface water is high, but it is rare for NP to be transferred to a remote place in the atmosphere. On the other hand, NPE does not easily evaporate and the distribution ratio in the atmosphere is considered to be very low.

5.2 Concentrations in rivers

It was observed that the concentrations of NP and Nonylphnol n-ethoxylates (NPnEOs) in rivers tended to decrease in the period from 1998 to 2000. NP had been detected at concentrations in a range of nd to several μ g/L. Concentrations of NPE and NPEC were higher than those of NP. This indicates that the

released NPE is decomposed stepwise and generates intermediate products.

5.3 Concentrations in sediments in rivers

NP had been detected at concentrations in a range of nd to several thousands $\mu g/kg$, and NPE had been detected at concentration in a range of several $\mu g/kg$ to several tens $\mu g/kg$ in river sediments. The concentrations of NP tend to be higher than those for NPnEOs (n = 1 to 4).

5.4 Concentrations in lakes, seas, and underground water

The concentrations of NP in lakes were nd to $0.2 \mu \text{ g/L}$ in 2000, with a trend towards decreasing concentrations in the period from 1998 to 2000.

The concentrations of NP in seas were nd to $0.1 \,\mu$ g/L in 2000, and concentrations have been gradually decreasing in the period from 1998 to 2000.

The number of underground water samples in which NP was detected decreased in the period from 1998 to 2000, and it was not detected at all in the 25 sampling spots in 2000.

5.5 Concentrations in treated sewage water and sludge

In treated sewage water, NP was detected at concentrations in a range of nd to several μ g/L, and NPnEOs (n=1 to 4) were detected at concentrations in a range of nd to several tens μ g/L. The concentrations of NPnEOs (n=1 to 4) were higher than those of NP at many sewage treatment plants. During the sewage treatment process, NPEC was found to be generated from NPE.

6. PRTR data

6.1 Outline of the releases and transfers of NP

The total for releases and transfers reported by 116 facilities in 30 prefectures which produce, process or use NP was approximately 160,000 kg in FY2001. The breakdown of the total is 538 kg discharged to the atmosphere, 2,484 kg into public water systems, 4 kg to the soil, 156,640 kg transferred off-site as waste and 20 kg transferred to sewage.

The estimate releases of outside notification were 11,203 kg from listed industries (i.e. from small and medium enterprises (SME)).

6.2 Outline of the releases and transfers of NPE

The total for releases and transfers reported by 411 facilities in 39 prefectures which produce, process or use NPE was about 1,196,521 kg in FY2001. The breakdown of the total is 11,396 kg discharged to the atmosphere, 295,196 kg into public water systems, 4 kg to the soil, 606,415 kg transferred off-site as waste and 282,772 kg transferred to sewage.

The estimate releases of outside notification were 729,488 kg/y from listed industries (i.e. from SME), 946,899 kg from non-listed industries and 83,931 kg from households in a total of 47 prefectures.

7. Emission Scenario

An emission scenario for NP and NPE was developed based on the data which are the amounts of use by applications obtained from NP manufactures and Japan Surfactant Industry Association (JSIA) described in Chapter 4 and PRTR data described in Chapter 6 in order to estimate the amount released into water at each stage of the life cycle, including production, formulation, and use.

Two methods were employed to estimate releases of NP and NPE.

One was estimation of the amounts of release to water using emission factors based on the expert

judgment and applying the factors to the amounts of use by applications obtained from NP manufactures and JSIA.

Another was estimation of the amounts of release to water by redistributing PRTR data by industry categories to the applications set by JSIA.

The table below shows the amounts of NP and NPE released into water estimated by these two methods.

and amounts used and released into water bodies					
Life cycle stage, applications		Amount used in 2001 (tons)	Amount released (tons/y)		
			Method 1	Method 2 (PRTR data)	
				notification	outside notification*
NP	production	16,110	0.0003	0.003	0
	formulation and processing	6,400**	-	2	11
NPE	production	14,455	-	0.6	0
	formulation and processing		-	0.6	-
Industrial use Products containing NPE	Rubber and plastics industry	2,726	30	0.04	86
	Machinery and metal-working industry	2,136	23	20	38
	Textile industry	1,853	20	60	250
	Industrial & Institutional cleaners [*]	2,068	870	-	550
	Agricultural chemical industry (biocide, fertilizer, and feedstuff etc)*	983	410	-	410
	Civil engineering and construction industry	912	10	0.09	4.4
	Paint and ink industry	798	0	0	1.7
	Laundry industry	577	240	3	230
	Paper and pulp industry	548	6.0	200	4.1
	Leather industry	287	3.2	2	1.1
	Cosmetic and pharmaceutical industry*	252	110	-	73
	Petroleum and fuel industry	198	0	0.005	20
	Food industry	175	1.9	-	1.3
	IT-related industry	48	0.53	-	-
	Environmental preservation	17	0.19	-	-
	Others	877	9.6	0.8	91

TableAmounts of NP and NPE shipped by applicationand amounts used and released into water bodies

* It is assumed that all the estimate releases of outside notification from listed and non-listed industries are made into aquatic environments.

** FY2000

- : Not investigated.

(NP: nonylphenol, NPE: nonylphenolethoxylate)

By comparing the amounts of release of NP and NPE obtained by the two different methods, it is seen that there are large discrepancies between the results of rubber and plastic industry; civil engineering and construction industry; Laundry industry; and paper and pulp industry. This means that further investigation of facts is required to obtain more accurate estimation for the amounts of release.

Since the comparison between the amounts used by applications and those of release shows that the ratios of release from the paper and pulp industry; I & I cleaners; agricultural chemical industry and cosmetics and pharmaceuticals industry are high, it is necessary to further investigate the actual status of use in these applications depending on the effects of NP and NPE on the environment.

In addition, it is further necessary to elucidate the conditions of NP and NPE at sewage treatment plants and waste treatment sites to clarify the total life cycle of these substances.

8. Concentration calculation using models

Since the observation sites and actual observation times are limited for NP exposure data, the data that have been gathered are not sufficient for the ecological in-depth risk assessment. In order to save labor and costs required for large-scale monitoring, analysis using a computer model (AIST-SHANEL) has been undertaken in an attempt to estimate the concentrations of NP in the aquatic environment.

The distribution of NP in the Tama River was analyzed in detail from geographical and seasonal perspectives, revealing that estimated NP concentrations using the computer model were higher than observed concentrations, indicating that some modifications to the parameters are required.

9. Voluntary actions taken by industry

Since there are concerns about the risk NP poses to the aquatic environment, Japanese industries have taken voluntary actions to replace as much NPE as possible with polyoxyethylene alkyl ether (AE). Such efforts will result in limiting the use of NPE only for those applications for which there is no substitute because of its beneficial properties.

10. Case examples of actions taken by local governments

Actions taken by the local governments in Aichi and Osaka have been reviewed as case examples. Both local governments continue to monitor the concentrations of substances, including NP, in surface water and in sediments because these concentrations were found to be high in the investigation conducted by the central government.

The Aichi prefectural government has established a policy based on the results of own investigation and the views of MOE. In accordance with the policy, Aichi prefectural government continues to monitor concentrations in the environment as well as compiling scientific information by gathering data from governmental institutes and other organizations. In particular, the Aichi prefectural government has taken a leadership role with respect to business firms located along the Nikko River, where NP was detected at higher concentrations in the study of 1998, in order to reduce the use of surfactants containing NPE and to replace NPE with other feasible substitutes.

In the meantime, the Osaka prefectural government is gathering information on endocrine disruptors and is cooperating with the central government in a nationwide study. The Osaka prefectural government also intends to ascertain the facts about releases of NP and NPE by utilizing the PRTR data, and to take measures to keep NP concentrations in the aquatic environment lower than the predicted no effect concentration, if necessary.

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August 2003: 1st printing of 1st edition in Japanese November 2007: Translating Japanese to English



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