



UNEP



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**Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous
Chemicals and Pesticides in International Trade
Chemical Review Committee**

First meeting

Geneva, 11–18 February 2005

Item 7 (i) of the provisional agenda*

**Inclusion of chemicals in Annex III of the Rotterdam Convention:
review of notifications of final regulatory actions to ban
or severely restrict a chemical: 4-aminobiphenyl**

4-aminobiphenyl: supporting documentation from the Republic of Korea

Note by the secretariat

The secretariat has the honour to provide, in the annex to the present note, the supporting documentation provided by the Republic of Korea in support of its notification of final regulatory action on 4-aminobiphenyl.

* UNEP/FAO/RC/CRC.1/1.

Annex

4-aminobiphenyl

Focussed Summary of the Notification of a Final Regulatory Action by Republic of Korea

I. INTRODUCTION

Overview of the regulatory system

Under the Toxic Chemicals Control Act (TCCA), Ministry of Environment (MOE) is responsible for the restriction or prohibition of the severely Toxic Chemicals after consultation with relevant ministries. The National Institute of Environmental Research (NIER), an affiliated organization of MOE, conducts the hazard assessment of new chemicals or existing chemicals of concerns and then designates them as Toxic Chemicals if toxic to human health or the aquatic organisms, based on the designation criteria of TCCA.

The events that led to the regulatory action

No information

Significance of regulatory action

4-aminobiphenyl, its hydrochloride, and mixtures containing 0.1% or more of any of these chemicals are banned for manufacture, import and use as an industrial chemical due to risk of carcinogenic effect on humans.

Scope of the regulatory action

4-aminobiphenyl, its hydrochloride, and mixtures containing 0.1% or more of any of these chemicals are banned for manufacture, import and use as an industrial chemical due to risk of carcinogenic effect on humans. No remaining uses are allowed except the use for research or laboratory purposes.

II. RISK EVALUATION

Key findings of the national risk evaluation

Key data reviews consulted and a brief description

4-aminobiphenyl is a carcinogen to humans(IARC group 1). It can cause dyspnea and CNS depression. In experimental animals, it has produced bladder and liver tumors.

4-Aminodiphenyl appears to be one of the most potent of the known bladder carcinogens

Reference to national studies, eg toxicological and ecotoxicity studies

Toxicity :

Acute oral: LD₅₀ for rat 500, rabbit 690 mg/kg
LD₅₀ for mouse 205mg/kg

Mutagenicity: Ames test: positive
In vitro UDS in rat liver: positive
Mammalian micronucleous test: Inconclusive

Carcinogenicity : Carcinogenic to humans (IARC group 1)

- ACGIH. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs) for 1995-1996. Cincinnati, OH: ACGIH, (1995)
- IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. WHO, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).,p. S7 57 (1987)
- DHHS/NTP; Seventh Annual Report on Carcinogens (1994)

Summary of actual (or potential) human exposure and/or environmental fate (referred from HSDB)

4-Biphenylamine's production and use in organic research, in the detection of sulfates, as carcinogen in cancer research, and formerly as a rubber antioxidant may result in its release to the environment through various waste streams. If released to air, a vapor pressure of 5.791×10^{-4} mm Hg at 25 deg C indicates 4-biphenylamine will exist solely as a vapor in the ambient atmosphere. Vapor-phase 4-biphenylamine will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 hours. If released to soil, 4-biphenylamine is expected to have moderate mobility based upon an estimated Koc of 857. Aromatic amines are expected to bind strongly to humus or organic matter in soils due to the high reactivity of the aromatic amino group, suggesting that 4-biphenylamine may be immobile in some soils. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 1.5×10^{-7} atm-cu m/mole. A 0-50% biodegradation rate after 28 days using a static flask subculture sewage inoculum indicates that biodegradation of 4-biphenylamine may occur slowly. If released into water, 4-biphenylamine is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. An estimated BCF of 32 suggests the potential for bioconcentration in aquatic organisms is moderate. Occupational exposure to 4-biphenylamine may occur through inhalation and dermal contact with this compound at workplaces where 4-biphenylamine is produced or used. NIOSH considers 4-aminodiphenyl to be a potential occupational carcinogen.

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

It is expected that the regulatory action will significantly reduce the potential risk of carcinogenic effect to workers and others involved in dye manufacturing industry