National Pollutant Release Inventory Submittal Form
- Proposal for a Modification to the NPRI -

Please complete this form to propose a modification to the National Pollutant Release Inventory (NPRI) and forward to :

Attention: Co-ordinator for Proposals for Modifications (NPRI)
Consulatations and Outreach
The National Pollutant Release Inventory
Environment Canada
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- Section 1 -

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City: Hull		**Prov/Terr: PQ**	**Postal code:**
Telephone: 997-3248		**Fax:997-7121**	**e-mail: maya.berci@ec.gc.ca**
Please indicate the details of the proposal:			
Modification Requested *(X)*		**Substance Name & CAS # (if applicable)**	**Other (e.g. suggested threshold, reporting condition, other)**
Addition of Substance	**x**	*N*-Nitrosodimethylamine (NDMA)	ATH - 10 grams, release based
Deletion of Substance	☐		
Change to reporting threshold	☐		
Change to reporting condition	☐		
Change to reporting requirements	☐		
Other type of modification	☐		
Proposed timing for the Change (proposed year for implementation): 2004			

Industry Sectors to be affected by the change:

The knowledge concerning the types of industry sectors that could incidentally produce/release NDMA and would be affected by this addition is incomplete.

Industrial sectors/sources identified in the PSL Assessment Report (identified from a PSL2 Use Pattern Survey or scientific literature) or that have reported to ARET or the TRI include: rubber manufacturers, tire manufactures, organic chemical producers, pesticide manufacturing and pesticides contaminated with NDMA, drinking water and wastewater treatment plants, land application of sewage sludge, food processing and food processing waste, leather tanning manufacturers, foundries and dye manufacturing, waste disposal (used oil recycling or refining and incineration).

- Section 2 -

* This section must be completed for proposals for the addition or deletion of NPRI substances.

Decision Factors[1]

1. *Does the substance meet the NPRI criteria, that is:*

   (i) Is the substance manufactured, processed or otherwise used (M,P,O)[2] *in Canada?*
   (ii) Is the substance of health and/or environmental concern?
   (iii) Is the substance released to the Canadian environment?
   (iv) Is the substance present in the Canadian environment?

The first two criteria are intended to be absolute, in the sense that a substance must be M,P,O in Canada, and of health and/or environmental concern, to be added to the NPRI; and similarly, if these criteria are not satisfied for a substance currently on the NPRI, it should be deleted.

The third and fourth criteria indicate that there should be reasonable expectation that a substance is being or may be released into the Canadian environment in order that it be added to or retained on the NPRI. In general, however, unless there is evidence or analysis to the contrary, it can reasonably be assumed that a substance that is M,P,O in Canada is likely to be released, and therefore present, in the Canadian environment.

There are no industrial or commercial uses of NDMA in Canada. NDMA is not imported into Canada and is not listed on the Domestic Substances List (DSL). The PSL2 Assessment Report indicated that in the past, NDMA was used in Canada and other countries in rubber formulations, as a fire retardant and in the organic chemical industry as an intermediate, catalyst, antioxidant, additive for lubricants and softener of copolymers.

While there are no direct uses of NDMA, there are many sources, as it is produced naturally as a result of biological, chemical or photochemical processes. It may form in water, air and soil by ubiquitous, naturally occurring precursors found in these media, classified as nitrosatable substrates (secondary amines) and nitrosating agents (nitrites**).** Through similar reactions it is also produced inadvertently as a by-product and contaminant in a range of industrial situations, and in the processing, preservation and/or preparation of food (see above).

NDMA was determined to be toxic as a consequence of its risk to human health. Based upon laboratory studies in which tumours have been induced in all species examined at relatively low doses, NDMA is clearly carcinogenic, with a very strong likelihood that the mode of action for the induction of tumours involves direct interaction with genetic material. Qualitatively, the metabolism of NDMA appears to be similar in humans and animals; as a result, it is considered highly likely that NDMA is carcinogenic to humans, potentially at relatively low levels of exposure. Long-term studies have shown that NDMA primarily affects the liver.

The acute and chronic effects of NDMA have been studied in a variety of species of plants and animals. Short term studies have shown that NDMA is moderately toxic to wildlife as well as laboratory and domestic animals.

<u>NPRI Substances that may Contain NDMA as a Contaminant During Manufacture, Processing or Otherwise Use</u>

Some evidence suggests that there are measurable levels of NDMA contamination in dimethylamine (DMA) products (e.g. chemical production of DMA based solvents such as dimethylformamide, dimethylacetamide). DMA is on the NPRI at the 10 tonne reporting threshold. Substance was added in 1999. A total of three

[1] These decision factors are applicable to candidate substances at both 10-tonne and alternate thresholds.
[2] For the purposes of the NPRI, the definition of M,P,O includes by-products. A by-product is an NPRI substance that is incidentally manufactured, processed or otherwise used at a facility and is released to the environment and transferred off site for disposal.

companies have filed reports on DMA since 1999, two of which also report NDMA to ARET (Chinook Group Ltd. and Safety Kleen).
Chemical Name: Dimethylamine CAS RN: 124-40-3

Year	#of reports submitted	Total Releases
1999	2	100 kg
2000	2	240 kg

2. Do facilities contribute significant releases of the substance?

There are various ways in which 'significant' can be characterised. The concept relates not only to the proportionate quantity of a substance released by NPRI reporting facilities, but also to the potential for health or environmental impacts. In other words, even if facilities do not account for a major proportion of total releases, facility releases may nonetheless be significant depending on such factors as location, timing, concentration, and the hazard associated with the substance.

Although the contribution to overall exposure from industrial sources is expected to be low, this statement can not be supported until the substance is added to the NPRI. Based on the carcinogenicity concerns noted above, [As NDMA is a potent carcinogen,] very small amounts of release could be significant. The Assessment Report concluded that "On the basis of limited information from short-term monitoring surveys of ambient air and water near industrial facilities, the priority for investigation of options to reduce exposure to NDMA in the vicinity of such point sources is considered high. It is recommended, therefore, that there be additional investigation of the magnitude of exposure of populations in the vicinity of point sources to assist risk management actions".

3. Does inclusion of the substance support one or more of the objectives of NPRI?

The following are the NPRI objectives:

- To identify priorities for action
- To encourage voluntary action to reduce releases
- To allow tracking of progress in reducing releases
- To improve public understanding
- To support targeted regulatory initiatives

NDMA is considered to be "toxic" as defined in Section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). It is a Track 2 substance. The risk management strategy is currently under development and addition of NDMA to the NPRI is a part of that strategy. Addition of NDMA to the NPRI supports many of the objectives above, particularly to support regulatory initiatives and to identify priorities for action.

4. Is the substance reported elsewhere? Or if it is reported elsewhere, is there nonetheless additional value in reporting to the NPRI?

If a substance is reported elsewhere, the value of adding it to the NPRI, or of deleting it from the NPRI, would be considered in relation to whether:

- The information on the substance is as readily available to the public as it would be through the NPRI;
- The information is available at the facility level;
- The information is comparable in terms of quality and comprehensiveness as that required by the NPRI; and
- The type of data is comparable (e.g., absolute quantities versus concentration).

If a substance that is reported elsewhere is to be included or retained on the NPRI list, to the greatest extent possible, efforts will be made to consolidate reporting under the NPRI (assuming potential compatibility of data requirements)[3].

PSL II Use Pattern Survey reported a combined total of 1.7 kilograms of NDMA emitted in air and water for 1996. Eight companies responded to the survey. Out of these eight companies, four of them were participants in the Accelerated Reduction/Elimination of Toxics (ARET) program . For the same year (1996), ARET participants reported 3 kg of total emissions of NDMA to the environment. ARET companies achieved a 94% reduction in emissions level from 1993 to 1997 and projected a 100% reduction by year 2000 (87 grams). Actual reductions did not achieve 100% reduction by 2000. Increases above projected values (136 instead of 117g) were due to the release to water from one chemical producer, but releases from this facility dropped dramatically in 2001 (9 grams). The Canadian Chemical Producer's Association have reported 0 tonnes of emissions for NDMA in their 1998 Emissions Inventory Report and projected the same for 1999 and 2003.

NDMA is on the TRI. The reporting thresholds for this chemical are 25,000 pounds for manufacturing or processing and 10,000 pounds for otherwise using. There was one report filed for this chemical in 2000 by the U.S. Filter Recovery Services but it was a Form A report which does not include releases. The fugitive air release from U.S. Filter Recovery Services in 1999 was in the range of 1-10 pounds. Safety Kleen data for 1998 shows a fugitive release to air of 111 pounds, and a release of 18 pounds from the stack (air). There was no reports filed in the years 1994-1997.

ARET is a voluntary mechanism that in this case is not deemed to be comprehensive enough to support risk management actions.

5. Is the substance already on the NPRI in some form? If it is already on the NPRI in some form, is there nonetheless additional value in including it in another form?

When considering adding a substance in another form (e.g., tetraethyl lead as a separate listing from lead and its compounds), the potential for double-counting will be avoided. For example, a compound will not be both listed as an individual substance, and included as part of an aggregate category. To the extent possible, substances will be listed with their Chemical Abstracts Registry (CAS) numbers.

NDMA is not on the NPRI in another form.

[3] In sum, the NPRI is recognised as a key national emissions database; and where a substance falls within the NPRI's mandate, efforts will be devoted to ensuring a single window approach through the NPRI.

- Section 3 -

* This section must be completed for proposals for a change to the reporting threshold of a NPRI substance.

An alternate threshold of 10 grams, release-based is proposed for consideration by stakeholders. Ten grams was chosen as releases reported to ARET are in the order of grams. Releases reported to the TRI are in the order of 1-10 pounds. A release-based threshold was chosen as the substance is incidentally manufactured.

As this substance is not a Track 1, an LOQ based threshold is not appropriate. However, NPRI has yet to determine a reasonable reporting threshold for carcinogens, as well as a reasonable alternate threshold for Track 1 substances where LOQs will not be developed. An ATH needs to be developed that is not activity-based for when activities cannot be adequately determined, and is not MPO based for when the substance is incidentally manufactured. NDMA is a good example of a very highly hazardous substance that falls into this category.

This is a difficult substance for risk managers due to the state of knowledge surrounding industrial releases of NDMA. It will also be a challenging substance for NPRI, as for the possible exception of DMA manufacturing, it will presumably be difficult for NPRI to provide guidance to stakeholders.