

Canadian Environmental Protection Act, 1999

**Follow-up Report on a PSL1 Substance for Which
Data Were Insufficient to Conclude Whether the Substance
Was “Toxic” to Human Health**

3,5-Dimethylaniline

August 2004

SYNOPSIS

3,5-Dimethylaniline has historically been used principally as an intermediate in the manufacture of azo dyes.

3,5-Dimethylaniline was included on the first Priority Substances List (PSL1) under the 1988 *Canadian Environmental Protection Act* (CEPA 1988) for assessment of potential risks to the environment and human health. As outlined in the Assessment Report released in 1993, relevant data identified before October 1992 were considered insufficient to conclude whether 3,5-dimethylaniline was “toxic” to human health as defined in Paragraph 11(c) under CEPA 1988.

Neither additional monitoring data nor adequate studies in experimental species or humans relevant to assessment of the human health risks for the likely critical endpoint for 3,5-dimethylaniline were identified during the period following the release of the PSL1 Assessment Report and prior to December 2000. However, predictions from quantitative structure–activity relationship (QSAR) modelling indicate, with a moderate to high degree of confidence, that 3,5-dimethylaniline is likely to be carcinogenic and mutagenic in animals. Information on the presence of this substance in formulations imported into Canada has not been identified.

3,5-Dimethylaniline is not included on the Domestic Substances List; its importation and manufacture are therefore subject to Section 81 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and the New Substances Notification Regulations.

3,5-Dimethylaniline was not believed to be produced in or imported into Canada until it was recently notified under the New Substances provisions of CEPA 1999. The information was evaluated in the context of two Schedule 1 notifications. The use proposed is as a reaction intermediate where releases are not anticipated. The structural concerns remain but will be considered further at the next level of notification. Owing to low exposure potential, risk is low.

An evaluation of the exposure potential as well as the potential effects on human health and the environment will be performed prior to the importation or manufacture of the substance when additional notification under the New Substances Notification Regulations is submitted. Should a suspicion of toxic to human health or the environment be identified at that time, appropriate control measures under CEPA 1999 will be introduced.