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NAFTA Technical Working Group (TWG): Developmental Neurotoxicity study (DNT) Project







The Developmental Neurotoxicity study (DNT) assesses behavioural and neurobiological parameters in order to ascertain the effects of chemicals on the developing animal. When required, the results from this study play an important role in the determination/identification of toxicological endpoints for regulatory purposes.

The rodent DNT study paradigm has evolved over time with the most recent test guidelines updated in 2007 with the introduction of OECD guideline 426.1 Despite this, there has been a continued interest in developing additional guidance for evaluators responsible for assessing chemicals that trigger this kind of an assessment. From a regulatory perspective, such guidance would serve as a tool that could be referred to when evaluating and interpreting the study results.

As a NAFTA Technical Working Group (TWG) on Pesticides-inspired multi-governmental initiative, the development of this guidance has involved consultation with both governmental and non-governmental stakeholders, which includes experts in the area of DNT. The internal guidance document (IGD) itself is a result of a collaborative effort from an intergovernmental working group with the following members from the United States Environmental Protection Agency (US EPA) and Health Canada, respectively:

- Dr. Virginia Moser, Dr. Kathleen Raffaele, Dr. Kevin Crofton, and Dr. Mary Gilbert; and
- Dr. Wayne Bower and Mr. Francis Bailey.

The IGD is not meant to be prescriptive; however, it has been developed to provide background and the identification of design and test details for detailed clinical observations, motor activity, acoustic/ auditory startle response, and learning and memory data. While the underlying goal is to have a DNT IGD at the disposal of regulatory evaluators (US, Mexico and Canada), the information provided in this guidance could also be useful in the conduct of other research initiatives, whether retrospective or prospective, and relevant technical guidelines, such as the recently published OECD Extended 1-generation reproduction study guideline.

If you are interested in attaining a copy of the DNT IGD, it is available from the NAFTA TWG on Pesticides website. Alternatively, please contact the Pest Management Information Service.

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This report has been subjected to the U.S. Environmental Protection Agency, Office of Research and Development's peer and administrative review process and has been approved for publication.

¹ http://www.oecd-ilibrary.org/environment/test-no-426-developmental-neurotoxicity-study 9789264067394en; jsessionid=7bt5uldknlfjn.x-oecd-live-01