

INDUSTRY TASK FORCE II ON 2,4-D RESEARCH DATA

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Endocrine Disruptor Screening Program (EDSP)

The Industry Task Force II on 2,4-D Research Data¹ (2,4-D Task Force) is responding to the Federal Register Notice Vol. 72, No. 116 June 18, 2007, pages 33486 – 33503 in reference to the Endocrine Disruptor Screening Program.

2,4-Dichlorophenoxyacetic acid (2,4-D) is included on the “Draft list of chemicals for Tier 1 screening in the EDSP”. Further EPA has established a pesticide active ingredients priority list based on exposure potential. 2,4-D is included on the four total pathways priority list.

Definitive endocrine disruptor data are not presently available to remove 2,4-D from the Tier 1 listing or to move 2,4-D to Tier 2. However, there are studies in progress that upon completion and review would allow you to transfer the pesticide 2,4-D to a low priority for EDSP evaluation.

As part of the EPA-OPP’s 2,4-D reregistration data call-in, the Agency has required a repeat multi-generation rat reproduction study addressing concerns for endocrine disruption (thyroid and immunotoxicity measures). Following extensive discussion and coordination with EPA/OPP/HED and EPA/OPP/SRRD, the 2,4-D Task Force is addressing the data requirement by use of a new research design called the ACSA tiered

¹ The Industry Task Force II on 2,4-D Research Data is organized under U.S. pesticide law to provide funding for many new research studies required to respond to the U.S. and Canadian pesticide re-registration programs. The 2,4-D Task Force is made up of those companies owning the technical registrations on the active ingredient in 2,4-D herbicides. They are Nufarm, Ltd., Atanor, S.A., PBI-Gordon Corp and Dow AgroSciences.

approach (Agricultural Chemical Safety Assessment). The ACSA testing design was developed by the International Life Sciences Institute (ILSI) with the goal of more toxicological end points relevant for risk assessment to include endocrine disruption testing. Private sector, academia, government and other institutions participated in the ILSI development process.

For ACSA testing of 2,4-D, the reproduction rangefinder study is currently in progress, and includes an expanded five dose pharmacokinetics evaluation to titrate the level of 2,4-D in the animal's blood, milk and pup blood levels. Following completion of this unprecedented pK study, a definitive study is planned for an extended one-generation reproduction evaluation including endocrine disruption end points. The reproduction study will determine how much 2,4-D is transferred to offspring through milk and food, and the effect, if any, on the thyroid (T3/T4 at the terminal sacrifice) and other parts of the body relevant to endocrine activity. It is estimated that the endocrine information from this study will equal or exceed the planned EDSP Tier 2 evaluation.

It is noteworthy that the ongoing ACSA testing will complement an extensive existing toxicological database on 2,4-D that is already one of the largest and most diverse for any chemical. Please transfer the pesticide 2,4-D to a low priority for EDSP evaluation awaiting the outcome of reproductive and endocrine disruption studies in progress.

We appreciate the opportunity to comment.

Regards,

A handwritten signature in black ink that reads "Larry E. Hammond". The signature is fluid and cursive, with the first and last names being the most prominent.

Larry E. Hammond
Chairman, Technical Committee
Industry Task Force II on 2,4-D Research Data

cc: 2,4-D Task Force members
John Conner, Jr., legal