

Date: Fri, 29 Jun 2007 09:56:56 +0200
To: Neepa Choksi
Cc: David Allen, Doug Winters
Subject: Re: RE ICCVAM/NICEATM FR Notice: LLNA Nomination and Request for Data

Dear Neepa,

In response to the NICEATM request published in the Federal Register notice, vol. 72, N° 95, on May 17th, 2007 and further to the e-mails we have exchanged on this subject, Bayer CropScience is submitting data from a number of studies conducted using the LLNA assay with different types or pesticide formulations. This data is submitted specifically to address the following questions: (1) the evaluation of the LLNA as a stand-alone assay for determining potency for the purpose of hazard classification, and (2) the ability of the LLNA for testing mixtures and aqueous solutions”.

In our studies, the LLNA study protocol includes the addition of a positive control spiked into the tested formulation in order to demonstrate the ability of the assay to detect sensitizer in such formulations and thus the validity of the results.

The data is submitted in two forms in the attached zipped file:

1. detailed summaries of the data obtained with several formulations using both the LLNA and another validated method for evaluation of the sensitization potential of the pesticide formulation (Buehler tests with 3 or 9 inductions, Maximized M&K test) are provided for 11 different pesticide formulations (EC, SL, EW, OF, WG, SC).
2. full reports of most of the studies from the above list where the LLNA assay showed a positive response while the classical methods were negative.

Please note that, for confidentiality reasons, the names of the active ingredients contained in the different formulations have been blinded.

We hope that this data will be useful to the evaluation conducted by the NICEATM. Please do not hesitate to use me as your contact for any queries or questions on our data and studies.

Cordialement / Best regards / Mit freundlichen Grüßen

Eric

Dr Eric DEBRUYNE
BAYER CropScience
Head of Experimental Toxicology
Sophia Antipolis Research Centre

355, rue Dostoievski - BP153
F-06903 Sophia Antipolis Cedex
FRANCE
Phone: +33 (0)4 92 94 34 37 (direct line)
Assistant: +33 (0)4 92 94 34 80 (Marie-France)
FAX: +33 (0)4 93 95 84 54
Cell phone: +33 (0)6 72 75 92 67
E-Mail: eric.debruyne@bayercropscience.com