

## **IFSTP Satellite Meeting of the 4th European Congress of Toxicologic Pathology 2006: Definition of No-Observed-Adverse-Effect-Level (NOAEL) in Toxicology Studies**

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### **Summary**

IFSTP organized a satellite meeting entitled Definition of NOAEL in Toxicology Studies on September 26-27, 2006 in La Grande Motte, France, in conjunction with the 4th European Congress of Toxicologic Pathology. This meeting is part of a series of IFSTP's activities associated with toxicological pathologies to discuss the timely topic of this field. La Grande Motte is an excellent resort area located close to Montpellier and the city is near a beautiful beach with a yacht harbor and pyramid style of high buildings (photo).

NOAEL was selected as the topic because it is an important part of nonclinical risk assessment and has been paid attention to not only toxicological pathologists but also regulatory agencies.

The meeting's objectives were to discuss (1) what constitutes a NOAEL? (2) how do two individuals determine a different NOAEL from the same data set? (3) the impact of dose selection on the NOAEL (4) should NOAEL be established for non-neoplastic data in a carcinogenicity study? (5) similarities/differences in the use of the NOAEL in the regulation of medicines versus environmental chemicals/agrochemicals.

The meeting opened with introductory remarks by Dr. Y. Konishi followed by the first session, Pharmaceuticals, chaired by Dr. H. E. Black. Four speakers presented their own work, reviewed ideas and experimental results as follows:

The No-Observed-Adverse-Effect-Level (NOAEL) in drug safety evaluations

M. A. Dorato

Establishing the NOAEL in Reproductive Toxicity Studies for a New Medicine

D. A. Beckman

Low Dose Carcinogenicity of Genotoxic Carcinogens

S. Fukushima, H. Wanibuchi, M. Wei, K. Morimura, A. Kinoshita

Establishing the NOAEL in Repeat Dose Toxicity Studies for a New Medicine: Issues That May Arise

H. E. Black

The second session was Agrochemicals and chaired by Dr. F. Schorsch. Also, in this session four speakers presented their way of thinking and ideas as follows:

Recognition of Adverse and Non-Adverse Effects in Toxicity Studies: a problem of consistency

R. Lewis

NOAEL for Reproductive Toxicology Studies for Agrochemicals (Including Consequences for Ecotoxicology Risk Assessment)

S. Reader

The Interpretation of Liver Enlargement in Pesticide Regulatory Toxicity Studies

D. J. Andrew

Use of NOAEL Values for Conducting Risk Assessment of Agrochemicals: Classical and New Approaches

K. Z. Travis

The meeting was closed with the remarks by Dr. W. Kaufmann.

The meeting was of great interest and very successful with active discussions about the NOAEL principle and fostered development and exchange of ideas, along with considerable collaborations among toxicology pathologists from academia, industry, and government. Further progress of the NOAEL principle for low dose exposure of chemicals such as food additives is expected. The six original manuscripts presented in the meeting are contained in this issue.

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