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Government of Canada / Gouvernement du Canada

MEMORANDUM **NOTE DE SERVICE**

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TO / A: Dr. C.T. Miller,
Co-ordinator,
Task Force for Re-assessment
of Chemical Safety

FROM / DE: Dr. D.B. Davies,
Task Force for Re-assessment
of Chemical Safety

SECURITY - CLASSIFICATION - DE SÉCURITÉ

OUR FILE – N / RÉFÉRENCE

YOUR FILE – N / RÉFÉRENCE

DATE: November 19, 1980

Revised: June 16, 1981

SUBJECT / OBJET: AUDIT AND VALIDATION OF THE IBT STUDY: "42-DAY NEUROTOXICITY STUDY WITH CGA-15324 TECHNICAL IN ADULT CHICKENS"

NAME OF LABORATORY:	INDUSTRIAL BIOTEST LABORATORIES
LABORATORY REPORT NO:	IBT NO. 8580-11187
REPORT DATE:	JULY 25, 1978
COMMON NAME OF COMPOUND:	PROFENOFOS
OTHER NAME(S)	CURACRON, SELECRON COMPANY CODE: CGA-15324
FORM OF TEST MATERIAL:	TECHNICAL GRADE
PETITIONER:	CIBA-GEIGY CORP.
TYPE OF STUDY:	NEUROTOXICITY
SPECIES, BREED AND STRAIN:	HENS
FILE UNDER:	PROFENOFOS
RECOMMENDATION:	INVALID

OVERALL COMMENTS

Although the raw data from the present study generally support the findings given in the final report, the study is adjudged invalid owing to deficiencies in experimental design and conduct, which are highlighted below:

1) The dosing regimen employed in the neurotoxicity study was poorly contrived and lacks scientific merit. For treatment at Day 21, doses were adjusted downward to 17.1 mg/kg from those administered on Day 0, namely 30 mg/kg and 45.7 mg/kg. Justificiation for this reduction was based upon the high incidence of mortality witnessed among test birds dosed at the higher levels. The higher doses were selected on the basis of mortality data generated in preliminary studies, from which an LD_{50} of 45.7 mg/kg was estimated. There is no evidence that the dose level of 17.1 mg/kg approached the LD_{50} value. No mortalities were observed among birds administered the lower dose. The possibility exists, therefore, that animals were not adequately challenged upon second treatment.

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