UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OK OK

DATE: August 9, 1978

SUBJECT: Roundup (glyphosate) - EPA Reg. No. 524-308

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THRU: Acting Deputy Chief
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Action Type: Data validation

I have checked the validation of 8 studies involving Monsanto's Roundup (glyphosate) formulations and have accepted all of them, but one, as valid. These studies are outlined in Table I (attached).

In the case of 6 valid studies, there are either no discrepancies between the raw data and the IBT Report to Monsanto (final report), or the existing discrepancies are insignificant.

The 21-day dermal toxicity study with male rabbits (BTL 73-19) is also accepted as valid, although there are no raw data on food consumption, diet preparation, skin dosing and reactions. In this study, emphasis has been placed on the effects of Roundup on testes, as a result of skin penetration or absorption of this material. Therefore, the absence of the raw data, mentioned above, does not appear to be critical to the objectives of this study.

The 21-day oral toxicity study with male rabbits (BTL 74-7) is rejected for the following reasons:

1. Absence of raw data on clinical chemistry, hematology and urine analyses.

2. Absence of raw data on organ weights, except for testes' weights for 5 rabbits. (There were 40 rabbits in this study).

According to Dr. Robert L. Roudabush from Monsanto who validated this study, the primary purpose of this study was to determine whether or not Roundup caused testicular atrophy. Dr. Roudabush, therefore,

concluded that the absence of the raw data, mentioned above, did not invalidate the study. He also commented in his Validation Statement that "the scientific integrity of a study should not be doubted because of the inability to observe all primary recording of data".

In 1974, this study was detailed for IBT by Dr. George J. Levinskas, Monsanto's Director of Environmental Assessment and Toxicology (Exhibit F), and no mention was made of the effects on testes as a primary objective of this study (p. 010 of the final report). On the contrary, a large number of parameters was to be tested, including those for which there are no raw data.

The final report contains pages of detailed data. As a scientist, Dr. Roudabush must certainly know that when one tests, observes or weighs in a scientific study, one makes a record of what one sees. Therefore, of concern here is not the inability to observe the "primary recording of data", but the absence of these data.

It is also somewhat difficult not to doubt the scientific integrity of a study when the IBT stated that it took specimens from the uteri (of male rabbits) for histopathological examinations (p. 017 of the final report).

8/23/78

Table I. Outline of Validated Studies on ROUNDUP

	Study	BTL No.	IBT No.	Final report	Accepted as valid
1	Acute inhalation (rats)	72-87	T-2279	11-7-72	Yes
2	Acute oral (rabbits)	72-108*	A-2277	12-6-72	Yes
3	Four-day static fish toxicity (carp)	73-30	665-03629	7-26-73	N.A.
4	Four-day static fish	72-104	R-2278	11-2-72	N.A.
5	Twenty one-day dermal	73-19	A-2468	1-11-73	Yes
6	Twenty one-day oral toxicity (male rabbits)	74-7	601-05044	1-16-74	No
7	Toxicity and reproduction study (leghorn chickens)	73-33	651-03917	6-18-74	Yes
8	Residue study (male rabbits)	73-32	651-0318	1-16-74	Yes

*Appears as 72-109 on Monsanto's list of laboratory reports.
N.A. - Not applicable for human safety evaluation.