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Report/Article Title Agent Orange Exposure Study - Decision Tree/Time Table

Journal/Book Title

Year 0000

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Description Notes

AGENT ORANGE EXPOSURE STUDY -- Decision Tree / Time Table

CDC examines TCDD levels in paired fat/blood samples; lab undergoes external quality control review. Data sent to AOWG/OTA for review. CDC requests DOD to permit ESG to participate in protocol development for a TCDD validation study (see last page).

AOWG/OMB/OTA review (2-4 weeks) 8/31/86

fat/
blood
correlation

NG GO 9/30/86

Domestic Policy Council considers recommendation to cancel AOE Study

CDC prepares TCDD validation protocol -- to IRB & OMB to review new herbicide exposure questions 10/10/86

AOWG/OMB/OTA review (4 weeks)

protocol

Modify * GO 11/15/86

NG

* "START" of validation study 11/15 - 12/30/86

Final selection of 500 "high" and 300 "low" exposure men from among 5000 qualifying men with data already at CDC. Names to contractors for location, interview, exam &/or bleeding of at least 400 cooperators. (See option paper.) "START" + 1 mo. Interview (& exam) data returned with blood specimens weekly. Complete study and prepare report. "START" + 4-6 mo.

6/87

- (New data from other sources)
- VES mortality/morbidity data->
- VA, Ranch Hand, etc. data-->

CDC peer review (2-4 weeks)

all
data--
recommend

NG GO

7/87

To next page for AOWG/OTA review

From previous page

AOWG/OMB/OTA review (2-4 weeks)

CDC
summary
report

NG

GO

"START" + 8 mo.
8/87

Domestic Policy Council
considers recommendation
to cancel AOE Study

CDC re-writes Agent Orange Exposure Study protocol sections on
exposure estimation and submits for review. "START" + 9 mo.
9/87

AOWG/OMB/OTA review (4 weeks)

Modify

protocol

GO

"START" + 10 mo.
10/87

Start Agent Orange Exposure Study "START" + 10 mo.
Finish data analyses, available for peer review "START" + 28 mo.
Final reports for publication/release to agencies "START" + 34 mo.
10/89

Notes for the Agent Orange Exposure study time table:

- o The time table shown on the previous pages depend on the timeliness of the 5 separate review cycles indicated.
- o The three tasks involving ESG in protocol development for the 400-man TCDD validation study are:
 - a. Providing to CDC a copy of ESG's new tape showing unit location data developed during their recent 7-battalion pilot study, thus allowing CDC to use more accurate estimates of probable exposure.
 - b. Receiving the ID's and names from CDC of 300 "low exposure" candidates and verifying that they qualify for this category.
 - c. Receiving the ID's and names from CDC of 500 "high exposure" candidates and verifying that they qualify for this category.

The task of utmost urgency in preparing the protocol is the copy of the tape with improved unit location data. The other two tasks are important to serve as a guide to CDC in determining the final "cut points" to put into the protocol (along with data to defend those points). Any delay in the above will delay the delivery of the TCDD validation protocol to AOWG/OTA for review.