



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

081901

JUN 15 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 15 1993

MEMORANDUM

SUBJECT: Response to letter from Ralph P. Burton, ISK Biotech to
Ms. Lois Rossi, USEPA/SRRD, dated 4/7/93; DP Barcode:
D190304; EFGWB # 93-622

FROM: James K. Wolf, Soil Scientist *James K Wolf*
Ground Water Technology Section
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

TO: Andrew W. Ertman
ReRegistration Branch
Special Review and Reregistration Division (H7507C)

THRU: Elizabeth Behl, Section Head *E Behl*
Ground Water Technology Section
and
Henry Jacoby, Chief *Henry Jacoby 6/14/93*
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

A letter was submitted on April 7, 1993 by ISK Biotech in response to a March 9, 1993 letter from the Reregistration Branch, requiring the that the registrant confirm in writing that EPA's recommendations had been incorporated into the final protocol for the ground-water monitoring study. ISK Biotech indicated in their letter that several points needed to be resolved, before they could make the commitment requested by the Reregistration Branch. This memorandum is to respond to ISK Biotech's points for clarification.

Several items should be mentioned, prior to addressing the registrants concerns. First, ISK Biotech does not have an approved Ground-Water Monitoring Study Protocol. A DRAFT protocol was submitted and reviewed, and a meeting was held to discuss some of the registrants responses. A revised protocol has not been submitted to my knowledge. Secondly, the registrant does not have an approved study site. I did received (correspondence dated March 12, 1993) from American Agricultural Services, Inc.(AASI), a



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DP BARCODE: D190304

REREG CASE # 0097

CASE: 819269
SUBMISSION: S438908

DATA PACKAGE RECORD
BEAN SHEET

DATE: 06/09/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 606 DATA PACKAGE
CHEMICALS: 081901 Chlorothalonil

100.00 %

ID#: 081901

COMPANY:

PRODUCT MANAGER: 71 WALTER WALDROP 703-308-8062 ROOM: CS1 3B3
PM TEAM REVIEWER: ANDREW W ERTMAN 703-308-8063 ROOM: CS1 32B5
RECEIVED DATE: 04/15/93 DUE OUT DATE: 07/14/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 190304 EXPEDITE: N DATE SENT: 04/15/93 DATE RET.: / /

CHEMICAL: 081901 Chlorothalonil

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 06/24/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	04/20/93	/ /
BRAN: EFGB	04/21/93	/ /
SECT: GTS	04/21/93	06/09/93
REVR : JWOLF	04/22/93	06/09/93
CONTR: EFG#93-06204	04/22/93	04/22/93

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: JIM WOLFE

This is a letter that ISK sent in response to our review of their Ground Water Monitoring study proocol. They are requesting clarification on several issues before going ahead with study initiation. The issues include 1) Is the Aerobic Soil Metabolism guideline satisfied? 2) Are the metabolites they plan to monitor OK? 3) Is the Terrestrial Field Dissipation requirement fulfilled? 4) Is it still EPA's position that groundwater monitoring satisfies the need for a long term field dissipation study? If you need more input or more time to adequately address these questions, give me a call at 308-8063. Thanks for your help.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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consultant for the registrant, information describing the tentative study site. On March 17, 1993, I telephoned Mr. Gary Fornecker of AASI, who was out of the office, to discuss this information. I latter talked to Dr. Lafayette Thompson of AASI, and indicated that the site selection-site location report should be formally submitted to the Registration Manager so that it could be issued a MRID number, BEAN sheet, and EFGWB number. To my knowledge this information has not been submitted. Additionally, no decision concerning the suitability of the site was discussed with AASI. General comments concerning the appropriateness of the information submitted were discussed.

The registrant should have an approved protocol and site prior to the initiation of the ground-water monitoring study. Initiating a study prior to site and protocol approval could ultimately result in the rejection of the study.

Responses to Registrants Concerns:

The registrant states that the following issues were resolved, which is not correct. These items were discussed, but the acceptability of the these issues is ultimately based upon what is in the protocol document and not what was discussed over the telephone (evidence of the need to formally submit information). These issues are not major and can probably be rectified rather easily, upon submission of the protocol.

Potassium Bromide Application:

The Branch is interested in the utilization of conservative tracers, such as potassium bromide, to allow for an estimate of travel time. It is not our intent to adversely impact the test crop. However, after further discussion with other members of the Branch's Ground Water Technology Section and the fact that no evidence has been provided by the registrant to support their concern that the potassium bromide would adversely affect the peanut test crop, the Branch will require tracer applications at the time of the first and last BRAVO applications.

Apparently, excessive amounts of potassium may limit calcium uptake by the peanut plant; thus the K:Ca balance can be important. However, the soil can be fertilized with calcium which will not only raise the soil pH, but also increase calcium supplies in the soil (Chapman, S.R. and L.P. Carter. 1976. Crop Production: Principles and Practices. W.H. Freeman Company, San Francisco.) Additionally, I discussed this concern with a USDA scientist who has worked with peanuts. He stated that another USDA scientist working with peanuts and potassium bromide indicated that phytotoxicity would not be a problem, but calcium may be required as mentioned above (which is apparently necessary for peanut production under normal conditions).

The registrant must clearly state the application rate of potassium bromide to be used, as 40 to 400 pounds per acre is a rather broad range. The method of bromide analysis and detection limit should be specified. The application rate should be based upon the method of analysis and the corresponding detection limit. The method of analysis and detection limit and limit of quantification must be stated by the registrant. The presence of background levels of bromide would also need to be considered when determining the type and rate of tracer to apply.

Precipitation/Irrigation:

The letter from ISK describes irrigation to supplement precipitation as follows:

"The test site shall have an irrigation system and a typical pattern for the crop(s) shall be followed. Irrigation water will be applied in a uniform pattern over the test site and proportioned so there is no run-off. Irrigation methods will be used to provide 125% of the thirty (30) year average cumulative rainfall of the most recent 2 months (current and previous). Biweekly irrigation events will be based on the monthly average when 125% of the 30 year cumulative average of the most recent 2 months is not obtained. This pattern will continue throughout the duration of the field portion of the study."

On May 20, 1993, I telephoned Dr. L. Thompson of AASI for some addition clarification. A FAX was sent on May 21 by Dr. Thompson to help alleviate confusion. The modification received in the FAX are inserted in bold in the above paragraph.

A primary rationale for the registrants concern regarding irrigation is to not put an excessive quantity of irrigation water on the test site. The EFGWB generally concurs with the registrant; the intent of supplemental irrigation is not to put on an excessive amount of water on, but to supplement precipitation. However, the registrants discussion concerning the addition of irrigation to supplement precipitation is not acceptable as stated. There are two primary reasons why the irrigation protocol is unacceptable:

- 1) The first reason is the lack of specific information concerning the historical precipitation record at the study site. The type of information that the registrant should submit should include: meteorological station location where historical precipitation data were collected and relative location of that station to the study site, source of the data, mean monthly precipitation, number of years of record, monthly maximum and minimum, standard deviation, cumulative total, and 125 percent of mean monthly, and annual cumulative total, which are given as an example (cf. Table 1). This will establish "target" precipitation values. [The source of data given as an example is the meteorological data from MLRA 133a [1948 to 1983] in the USEPA

PRZM/PIC/PIRANHA models]. The registrant should, however, use the most appropriate data available for their study site.

2) The second reason deals with the scheduling of irrigation. The cumulative mean monthly precipitation (CUMP), 125% of cumulative precipitation (CUMREQP), and the one standard deviation above the mean monthly cumulative precipitation (CUMHP) and one standard deviation below the mean cumulative monthly precipitation (CUMLP) are plotted in Figure 1. As can be seen in Figure 1, the CUMREQP line lies approximately halfway between the CUMP and the CUMHP lines. Thus, at least for the example presented, the registrants request to irrigate, when precipitation is inadequate to meet 125% of the cumulative mean monthly (yearly) precipitations is acceptable to EFGWB. The biweekly irrigation seems reasonable and is therefore acceptable.

Our concern is under the conditions that a large amount of precipitation would occur, resulting in a condition where the cumulative sum of irrigation + precipitation would exceed the value of 125 percent times the cumulative monthly mean precipitation for an excessive period of time. For example, a hurricane could result in excessive amounts of precipitation over a several-day-period which could result in the total seasons rainfall being received at this time. We therefore recommend that if cumulative precipitation exceeds the "target" cumulative precipitation, the next biweekly period would be delayed until after the rainfall event, and at this time the "target" cumulative precipitation and actual cumulative precipitation + supplemental irrigation would be zeroed, and the biweekly period restarted. We believe this is important because excessive amounts of precipitation will either runoff or enter the soil. The water which enters the soil will recharge the soil water content to somewhere between "field capacity" and saturation, and the rest will be drainage. Simplistically speaking the rainfall which is partitioned into the soil water recharge will be available for consumptive use by a plant, whereas that lost as drainage or runoff will not (e.g., seasonal water needs would not be met by one large event). Evapotranspiration will continue to occur over time, even if the target cumulative rainfall does not occur during the next two week period, supplement biweekly irrigations will be needed to achieve the "target" of 125 percent of the cumulative 30 year mean monthly precipitation.

Several additional points concerning irrigation should also be considered. First, according to Dr. Thompson, peanuts in this area are not irrigated. Also, the mean monthly precipitation for the example given is relatively the same all year; although, evapotranspiration will be much greater, in the summer months than during the other seasons. Thus, irrigation is to be applied only to supplement precipitation (to reach a desired amount of 125% of cumulative mean monthly precipitation). However, in many locations, for example Utah, rainfall patterns show much greater seasonal variability, with the majority of the precipitation

occurring during the non-growing season. Under these conditions irrigation is required as part of the standard agricultural practice (e.g., not only supplement precipitation but also to meet consumptive use requirements). These conditions would necessitate the calculation of a crop's consumptive use (ET) in addition to precipitation in order to determine irrigation requirements (schedule, frequency, application rate and duration). Therefore, utilizing irrigation to supplement the precipitation to achieve 125% of the mean monthly cumulative precipitation alone would not be acceptable under these conditions.

The registrant should also briefly describe the type of irrigation system to be used (e.g., center pivot) and application rate, and source and quality of irrigation water. Specifically the registrant states that irrigation water will be applied in a uniform pattern over the test site and proportioned so there is no run-off. How will this be accomplished?

Additional Concerns by the Registrant

The registrant questions the integrity of the study because ".... all of the analytical effort to detect and quantify soil degradation products will be based upon studies which have not been accepted by the Agency.....".

Question 1, page 2

This question addresses two aerobic soil metabolism studies submitted by the registrant, but which have not been reviewed by the Branch. These studies are reviewed by other Sections in the Branch; therefore, I am unable to comment on these studies.

Question 2, page 2

The registrant proposes to analyze both the soil and water samples for the following:

Chlorothalonil (parent) 2,4,5,6-tetrachloroisophthalonitrile

Chlorothalonil Degradates

- 4-hydroxy-2,5,6,-trichloroisophthalonitrile (SDS-3701)
- 3-carbamyl-2,5,6-trichlorobenzamide (SDS-46851)
- 2-hydroxy-5-cyano-3,4,6-trichlorobenzamide (SDS-47525)
- 3-cyano-2,4,5,6-tetrachlorobenzamide (SDS-19221)

but not for degradates:

- 3-cyano-2,5,6-trichlorobenzamide (SDS-47524)
- 3-cyano-2,4,5-trichlorobenzamide (SDS-47523) an isomer of (SDS-47524).

Based upon available information and an informal discussion with Brinson Conerly-Perks, this proposal is acceptable to the Ground Water Section. The following additional requirements were

developed with consultation with Chemistry Review Section personnel:

1. Careful attention must be used to develop a good material balance;
2. Retain samples for future analysis if unforeseen questions concerning analytical results arise;
3. The detection limits and limits of quantification must be stated and meet with EFGWB approval.

Table 1. Summary of precipitation data and irrigation requirements for MLRA 133a for the years 1948 to 1983 (all units in cm).

MONTH	Precipitation				Irrigation	
	Mean ¹	Cumulative	High ²	Low ³	Required ⁴	Cumulative
January	10.45	10.45	15.03	5.88	13.07	13.07
February	12.19	22.64	18.59	5.79	15.24	28.31
March	15.17	37.81	21.96	8.38	18.96	47.27
April	11.81	49.62	20.30	3.31	14.76	62.03
May	9.75	59.37	15.78	3.71	12.19	74.21
June	9.30	68.67	13.78	4.81	11.62	85.83
July	12.52	81.19	17.18	7.86	15.65	101.48
August	8.28	89.46	12.73	3.82	10.35	111.83
September	11.67	101.13	18.69	4.66	14.59	126.42
October	5.82	106.95	11.41	0.24	7.28	133.69
November	9.01	115.96	18.08	-0.07	11.26	144.95
December	12.62	128.58	19.00	6.25	15.78	160.73

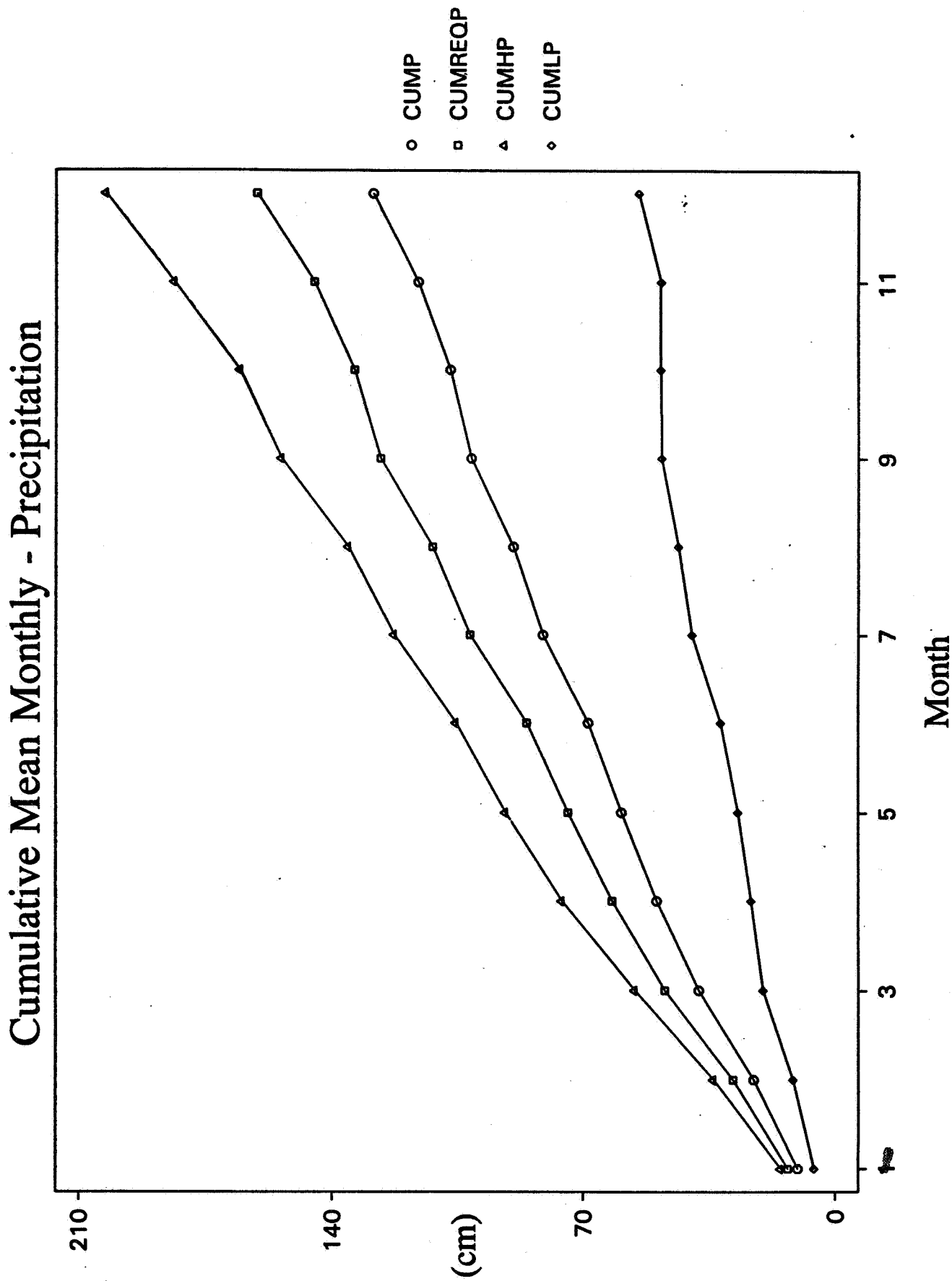
¹ Monthly mean for the 36 year period.

² Monthly mean plus the monthly Standard Deviation.

³ Monthly mean minus the monthly Standard Deviation.

⁴ Monthly mean for the 36 year period times 1.25 (125 percent of $\approx$ 30 year average).

Figure 1.



MLRA 133a (Years 1948 to 1983)