

Monsanto

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

April 24, 1997

Mr. Brian J. Hughes, Ph.D., MPH, DABT
Environmental Toxicologist
Risk Assessment and Toxicology Branch
Alabama Department of Public Health
201 Monroe Street, Suite 1310
Montgomery, Alabama 36104

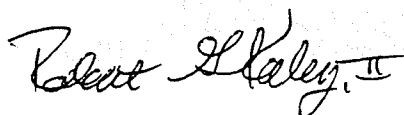
Dear Dr. Hughes:

Enclosed please find Monsanto Company's comments on two documents:

Health Consultation, Monsanto Company, Anniston, Calhoun County,
Alabama, CERCLIS NO. ALD004019048, January, 1996.

Health Consultation, Cobbtown/Sweet Valley Community, PCB Exposure
Investigation, Anniston, Calhoun County, Alabama, June 26, 1996.

Yours truly,



Robert G. Kaley, II, Ph.D.
Director, Environmental Affairs

Enclosures

cc: Stephen A. Cobb, Alabama Department of Environmental Management

DSW 133136

STLCOPCB4033094

Monsanto Company Comments on:

**Health Consultation
Monsanto Company
Anniston, Calhoun County, Alabama
CERCLIS NO. ALD004019048**

**Prepared by
Alabama Department of Public Health**

On January 17, 1996, the Alabama Department of Public Health (ADPH) issued a Health Consultation for the Monsanto Company plant in Anniston, Alabama. Monsanto believes that there are inaccuracies and erroneous assumptions and conclusions in this document and has prepared these comments to address those inaccuracies and errors. In summary, Monsanto believes that the Health Consultation overstates the potential for adverse health effects from exposure to PCBs in the vicinity of Monsanto's Anniston Plant and that the Department's conclusion that the area constitutes a public health hazard is erroneous.

Site Description (Pages 1-2)

The site description describes a "waste water discharge ditch" which joins a ditch described by ADPH as the East Drainage Ditch (EDD). The discharge ditch is described as originating from a limestone neutralization bed. This ditch does not carry "waste water" from processes at the plant. The ditch carried storm water runoff and non-contact cooling water. Furthermore, the storm water runoff and non-process cooling water no longer contact the former limestone neutralization beds (there were actually two), which have been removed from service and covered. In late 1996, the non-contact cooling water was diverted from this drainage system. The plant discharge at this point now only carries storm water runoff.

Site Background and History (Pages 3-6)

The description of the South Landfill (SL) may be misleading, because that term is used in the Health Consultation to denote the former landfill areas moved during the construction of Highway 202 as well as the existing closed landfill area and Solid Waste Management Units (SWMUs) which are located south of Highway 202. Monsanto recommends that the "South Landfill (SL)" designation be used for the existing closed landfill south of Highway 202.

The term Aroclor is a registered trade name for Monsanto's polychlorinated polyphenyl product line. The polychlorinated biphenyl (PCB) products were among those marketed under the Aroclor trade name. (The last line on page four inaccurately uses the term 'arochlor'.)

SWMU-4W is described as operating from 1973 to 1983 and as receiving PCBs. However, Monsanto ceased manufacturing PCBs at the Anniston facility in 1971. Materials containing PCBs were not disposed of in this SWMU.

The section describes the 1985 sampling of Snow Creek and drainage ditches. Monsanto cooperated fully with Alabama state agencies subsequent to the determination that PCBs were present in sections of Snow Creek and ditches at various levels. Monsanto submitted a remediation plan to the state; however, the state neither approved nor disapproved the plan in writing. Monsanto, however, did obtain an oral representation that the remediation plan could be implemented. In 1989 (not 1988), Monsanto voluntarily removed PCB-containing sediments from drainage ditches leading from the

plant and from a small section of Snow Creek. Monsanto also enclosed a short section of a drainage ditch in concrete and covered and sodded that area. The sediments were dewatered on the banks, temporarily staged on the South Landfill, tested for PCB levels (which were determined to be >50 ppm on average), and disposed of in an EPA-approved PCB disposal facility. Contrary to the statement in the Health Consultation, sediments remaining in the removal area were not tested for PCB levels.

Off-site (Page 7)

As mentioned above, the discharge from the Monsanto facility which joins the "EDD" is not a "waste water" discharge. At the time the Health Consultation was issued, any water in this ditch would be storm water runoff and non-contact cooling water.

This section somewhat mischaracterizes the course of the EDD after it crosses 10th Street. After crossing 10th Street, the ditch traverses an industrial site (the former site of the Anniston Concrete Company) and does not become accessible until it flows into the storm water drainage ditch which runs between 11th Street and the railroad tracks. Although access to the ditch along the railroad tracks is not restricted, it cannot be characterized as "moving through" residential neighborhoods.

The section also describes the presence of "toys" in Snow Creek at the confluence with the drainage ditch along the railroad tracks. Snow Creek is quite inaccessible at this location because of steep banks and poor footing. It seems more likely that any "toys" noted at the site were washed there by storm water runoff than that they were left by children playing in the creek at this location. The Health Consultation leaves an impression of opportunities for exposure to the sediments of the creek at the confluence point, while such exposures appear to be very unlikely.

DISCUSSION (Pages 8-9)

ADPH calculated "estimated exposure doses" to provide values to compare to "health guidelines" and ATSDR Minimum Risk Levels (MRLs). Monsanto previously commented on a draft risk assessment prepared by ADPH, from which, apparently, the estimates presented in this Health Consultation are derived. Monsanto previously noted that many of the assumptions used to calculate the estimated exposure doses are unrealistically high and present unrealistic worst-case estimates. In other cases, the Health Consultation presents exposure scenarios which are in disagreement with known facts. Furthermore, the Cancer Potency Factor used by ADPH to calculate cancer risks for potentially exposed populations has since been lowered by the United States EPA. Based on this reduction in the Cancer Potency Factor, all estimates of cancer risk are too high by approximately a factor of 3. (Monsanto's full comments on the draft risk assessment are attached.)

West End Landfill (Pages 9-14)

This section contains a number of unrealistic assumptions used to calculate estimated exposure doses and estimated risks. With respect to the soil, ADPH estimated that adult residents visited the actual landfill site two times a week for 68 years, even though ADPH is aware that the area has been fenced and inaccessible to the public for nearly 20 years. The 6-year exposure duration estimate for children is also unrealistic, because no children have had access to the site for nearly 20 years. Both of these assumptions result in unrealistically high estimates of health risks.

ADPH also assumed that workers at the site were exposed 8 hours/day for 32 years. This assumption is excessive even for those years when the site was an active landfill. Since 1960, it is unlikely that any worker was at the site for even an hour a week, based on conversations with APCO, the owner of the site from 1960 to 1993. Further, for both residents and workers, the single highest analytical result for PCB levels at the West End Landfill was used to calculate estimated risks. This procedure totally ignores all of the other analytical data available for the site, most of which indicates much lower levels of PCBs on the surface.

For the "WEL sediment" many of the same comments apply.

Finally, this section ignores the fact that at the time of the preparation of the Health Consultation, Monsanto had already begun a project to upgrade the cap of the West End Landfill under a plan approved by the Alabama Department of Environmental Management (ADEM). That project has now been completed. Thus, any potential for exposure for any residents or workers to affected soils or sediments from the West End Landfill has been eliminated, and the site presents no risk to residents in the surrounding area or to any workers who may be in the area.

The WEL Groundwater section concludes (on page 12) that the "groundwater pathway will not be evaluated at this time." This conclusion is appropriate, because PCBs have not been associated with groundwater from the West End Landfill or from the Monsanto facility more generally. Inexplicably, however, on page 22, Conclusion 8 reads:

Exposure to PCBs in groundwater at the WEL may cause noncancerous adverse health effects. Exposure to PCBs in groundwater may lead to a very high risk for cancer in adults and a high increased risk for cancer in children.

Persons reading only the Conclusions will be seriously misled by the inconsistency between the statement that the groundwater pathway has not been evaluated and this erroneous conclusion with respect to the groundwater.

The discussion of "WEL Waste Material" and the risk estimates are based on a single sample, which was not necessarily representative of the material previously exposed at the West End Landfill. In any case, this section is moot, because all of the previously exposed

waste materials have been collected and placed under the upgraded cap of the West End Landfill. There is no longer any potential for exposure to waste materials at the site.

Data Gaps for the WEL (Pages 13-14)

Many of the 'data gaps' described in this section have been addressed, and, in fact, many had been addressed by the time the Health Consultation was distributed. The WEL has been recapped in accordance with the Consent Order. Therefore, additional surface samples from the landfill and the adjacent areas would be irrelevant. The additional sampling suggested for the adjacent residences and schools has been completed and the results have been reported to both ADPH and ADEM. Additional sampling of environmental media associated with the WEL, if any, will be conducted in accordance with the RFI Work Plan for the Monsanto Anniston Plant.

Quality Assurance/Quality Control (Page 14)

The contention that the PCB data in the Anniston West End Landfill report 'should be used with caution' is not appropriate. The analytical methodology used to analyze the samples reported values for a series of PCB products designated by their Aroclor trade names. However, the Aroclor product designations merely indicate the presence of certain peaks in the gas chromatogram of the particular sample used to calculate the result. Therefore, the designation of a particular Aroclor product in the reported result does not necessarily indicate that the particular product was "identified" in the sample. More importantly, the reporting convention does not imply that other Aroclor products may have been present or absent. One cannot assume that other Aroclor products may have been present near some detection limit and imply that the reported result is therefore low. It is at least as likely that the reported result overestimates the actual levels of total PCBs present in the sample, because the congener content of the Aroclor mixtures overlaps significantly. (A PCB congener is one of the 209 individual chemical compounds which, as a group, comprise the PCBs. The term does not designate one of the various PCB product mixtures such as Aroclor 1260. The commercial PCB products, Monsanto's trade name for which was Aroclor, were complex mixtures of PCB congeners.)

East Drainage Ditch

EDD Soil (Page 15)

This section uses the term "Clydesdale community", which is not consistent with other descriptions.

There is no basis for the speculation that the "...contamination becomes more widespread because of past cleanup methods for the EDD and Snow Creek". In the first place, Snow Creek is about a mile from the area under discussion. Secondly, the sampling results confirm that generally PCBs are only detected in the areas directly adjacent to drainage ditches or in areas impacted by storm water flooding from those ditches.

EDD Sediment (Page 16)

This section again contains unreasonable assumptions of exposure scenarios which are used to calculate exposures and estimate risks. For example, ADPH estimates that residents "...visit the drainage ditch once a week." The drainage ditch is quite inaccessible throughout this area and is not particularly attractive. An estimated exposure frequency of 52 days per year is likely to be a large overestimate. This overestimate, coupled with the overestimate of soil consumption rates for both adults and children (no one is likely to consume sediment from the ditches, nor would the entire daily exposure to soil occur during a "visit" to the ditch), potentially results in huge overestimates of risk for both cancerous and noncancerous effects.

Data Gaps for the EDD (Pages 16-17)

As in the case of the WEL, much of the information reported to be "data gaps" has been acquired and reported to the state agencies, some of it before the Health Consultation was issued. The soil and sediment levels in the drainage ditches and in adjacent soils have been measured and reported as actual concentrations. These samples include many samples from the yards of former residents. PCBs are not associated with groundwater because they adhere so tightly to particulate matter. Therefore, there is little to be gained by monitoring groundwater for PCBs. In addition, there is no information to suggest that the groundwater in the EDD area is used for any purpose.

Quality Assurance/Quality Control (Page 17)

The comments on the Quality Assurance/Quality Control section for the WEL also apply to this section.

North Drainage Ditch (Pages 17-18)

In general, the comments made regarding the East Drainage Ditch area also apply to the subsections in this section, including the comments regarding exposure to sediments and quality assurance/quality control. In addition, extensive sampling of surface soils in the North Drainage Ditch area has been done, and the results have been reported to the residents and the state agencies.

Snow Creek (Pages 18-21)

In general, the comments made regarding the East Drainage Ditch area also apply to the subsections in this section, including the comments regarding exposure to sediments and quality assurance/quality control. In particular it seems most unlikely that residents "...visit the creek once a week." Snow Creek, especially where the drainage ditches leading from the Monsanto facility enter the Creek, is quite inaccessible. With regard to data gaps, the agency recommends acquiring information on levels of PCBs in Snow

Creek. Snow Creek is a very low-flow ditch under normal conditions, especially in the northern areas; consequently it is often very shallow. No fish of edible size are present in the creek, so fish are not a potential route of exposure to constituents which might be present in Snow Creek.

Choccolocco Creek

There are no specific comments on this section.

CONCLUSIONS (Pages 21-22)

Conclusion 1 indicates that ADPH has classified the area described in the Health Consultation as "...a public health hazard." Although the conclusions use the general term "adverse health effects" as the basis for the classification, in fact it is only the estimated cancer risks for certain exposure routes which appear to be the actual basis. In no case does the risk of noncancerous health effects merit consideration, except in Conclusion 3. (See below) As described above and in prior comments on the ADPH draft risk assessment, the cancer risk estimates are based on extremely conservative exposure estimates and do not represent realistic risk estimates. (In addition, the Cancer Potency Factor for PCBs has been reduced by the U. S. EPA subsequent to the release of this Health Consultation.) These considerations impact the findings reported in Conclusions 2 through 9.

Conclusion 3 reports conclusions based on exposure to groundwater at the West End Landfill. However, as noted above, on Page 12 of the Health Consultation, ADPH states that "...the groundwater pathway will not be evaluated at this time." Furthermore, PCBs are not associated with the groundwater at the West End Landfill. Therefore, Conclusion 3 is inconsistent with the body of the Consultation.

RECOMMENDATIONS (Pages 22-24)

Several of the recommendations had been completed by the time the Health Consultation was issued and several more have been completed subsequently. Specifically Recommendations 2, 3, 9, and 14, which suggested additional soil sampling, have been completed, and the results have been reported to appropriate state agencies.

Recommendation 7, which addresses groundwater monitoring in the WEL, does not accurately describe appropriate approaches to groundwater monitoring. Groundwater monitoring for the WEL and the rest of the Monsanto Plant has been addressed in the RFI Work Plan, which has been recently submitted to the ADEM.

As mentioned above, because fish do not provide a route of exposure for Snow Creek, there is no need to sample fish in Snow Creek, as suggested in Recommendation 18.

On June 21 representatives of the Monsanto Anniston plant met with representatives of Alabama Department of Environmental Management (ADEM) and Alabama Department of Public Health (ADPH). The meeting was requested by the Alabama agencies to solicit Monsanto's input on a preliminary draft risk assessment which is in the early stages of development by ADPH. Monsanto was asked to provide specific information about dates associated with plant activities and to share overhead photographs of the plant site.

Discussions during the meeting included a brief overview of the preliminary risk assessment, including summaries of various exposure scenarios and exposure assumptions. Although the risk assessment was clearly specified to be both preliminary and a draft, several aspects of the exercise require comment, even at this earliest stage of the process. Of specific concern are the preliminary and incomplete nature of the analytical results which have been incorporated, the unrealistic exposure scenarios which have been utilized, and the exclusive use of the cancer slope factor estimated from rodent studies on a single PCB mixture. In addition, this preliminary draft risk assessment ignores the large body of scientific literature which demonstrates that no chronic human health effects, with the possible exception of dermal effects and transient elevations in some liver enzymes, are associated with even high level, occupational exposure to PCBs. Finally, the retrospective nature of the draft risk assessment is inconsistent with sound risk management principles. These concerns are discussed in more detail in the following paragraphs.

Monsanto has also asked Dr. Renate Kimbrough, Senior Medical Associate, Institute for Evaluating Health Risks (IEHR) to provide a preliminary review of the draft risk assessment. Her review is attached as Appendix A.

A critical component of even the most preliminary attempt to estimate the risks associated with exposure to environmental chemicals is the availability of high quality analytical results. Until properly validated analytical data are available for media for which plausible routes of exposure can be defined, any attempt at risk assessment is premature and inappropriate. Ongoing work at the laboratory which has generated much of the data available for the Monsanto Anniston plant and its environs has demonstrated that EPA Method 8080 generates erroneously elevated results for total PCBs when the "summed Aroclor" method of quantitation is used. This problem arises from attempting to define selected GC peaks as representative of specific Aroclor products. As discussed in Jensen (1989), "If only 1 to three high peaks are selected, the results will be about twice as high as if a dozen peaks are selected." The laboratory is currently using a more appropriate method of quantifying the analytical results from Method 8080, as well as using EPA Method 680 (a GC/MS method) as a reference method. (A brief summary of the current analytical chemistry program for the samples collected at and near the Monsanto Anniston

plant is attached as Appendix B.) The particular method used to generate the analytical data reported by the State of Alabama and the efforts to provide quality assurance information for that data should also be reviewed.

The risk estimates provided in the preliminary draft risk assessment consistently rely on worst-case, unrealistic estimates of exposure. First, the estimates most often rely on the highest analytical result for a particular medium and a particular location. As such, those values do not represent appropriate bases for estimates of the potential for exposure to PCBs at the location as a whole. For example, at the West End Landfill, one of the estimates is based on an isolated sample, which is in no way representative of that area. The state is aware that the area in question has been fenced for twenty years and that a remediation plan has been submitted to eliminate any potential for exposure to PCBs at the West End Landfill. Another estimate is based on a selected data point which represents an area in the bottom of a ditch in a deeply wooded area to which there is no evidence of recent human access. This particular location has been temporarily remediated to minimize any potential for exposure at the particular point or downstream pending more permanent remediation steps. The state is also aware that the ground water sample used in the estimates is in ground water that is not a source of drinking water to anyone and, indeed, that the value used was an invalid collection from the monitoring well. No PCBs have been detected in properly collected samples from that well or any other monitoring wells at the plant. In all cases, there are sufficient data available from which to calculate more representative, or average, estimates of PCB levels at particular locations, rather than singling out the highest result from one point at the locations.

Second, the selection of extreme values for the levels of PCBs at the various locations is further compounded by unrealistic exposure scenarios. Although every scenario is unrealistically exaggerated, two examples are particularly instructive. Estimated risk for an APCO employee is based on an assumption of an exposure of 250 work days/year for 35 years to an isolated location which has been fenced for many years and which is known to have been visited at a much lower frequency and for short times only. (Information from Alabama Power Company indicates the location is typically visited less than one hour per week.) With reference to the wooded area noted in the previous paragraph, the preliminary draft calculates a number based on an assumed daily exposure to this inaccessible area for 60 years. As discussed below, even in the unrealistic event that the location was visited at all, it is unlikely that an adult or child visiting the site would consume sediment from the bottom of the ditch at any level, and certainly not at the levels assumed in the draft. Similar faulty assumptions regarding site access and potential for contact are relied upon in nearly every exposure scenario described in the preliminary draft.

Third, the unrealistic nature of the preliminary estimates is exaggerated by the adoption of exaggerated assumptions for estimates of intake of PCBs. As discussed above, it is inappropriate to assume a daily exposure for a number of years to locations that were, are, and will continue to be essentially inaccessible. The draft risk assessment assumes soil intake rates of 200 mg/day for a child and 100 mg/day for an adult. Soil intake rates have been studied extensively in recent years and remain imprecise. Some results indicate that few, if any, children consume soil at the levels assumed in the preliminary draft. Other sources report that adults consume essentially no soil, unless there is exposure to dust levels far above the nuisance level. There is no evidence of nuisance levels of dust at any of the locations near the Monsanto facility in Anniston. The assumption that any daily soil consumption for either an adult or a child is exclusively from locations near the Monsanto facility is also unrealistic.

Fish consumption assumptions also are worst-case estimates, unlikely to reflect fish consumption habits of average residents. Although Alabama has adopted 30 gram/day fish consumption as a representative value, that amount is for total consumption of fish, not for fish locally caught and consumed. There is no basis for an assumption that any person, let alone a representative resident, consumes only fish from Choccolocco Creek. Studies have shown that most consumers eat primarily, if not exclusively, fish purchased in stores supplied by non-local sources. The assumptions also ignore the effect of cooking method and time on the levels of PCBs in fish. In some cases, up to 80% of PCBs are removed by broiling or frying fish.

All of the calculations in the preliminary draft are based on an upper bound cancer potency (slope) factor of $7.7 \text{ (mg/kg/day)}^{-1}$ for PCBs. This value is based exclusively on rodent testing data on 60% chlorinated mixtures of PCBs. It is widely accepted that this value exaggerates risk estimates for less chlorinated PCB mixtures. The analytical data generated to date by both Monsanto and the state provide no basis to assume that the slope factor for 60% chlorinated mixtures is appropriate here. Recent information developed by the Pathology Working Group under the auspices of the Institute for Evaluating Health Risks (IEHR) suggests that a more appropriate cancer potency factor might be $1.9 \text{ (mg/kg/day)}^{-1}$, based on a reanalysis of PCB chronic feeding studies. Indeed, the state of New Jersey has recently adopted a value of $1.4 \text{ (mg/kg/day)}^{-1}$ and the U.S. EPA is considering a reduction in the value reported in the IRIS data base.

While worst-case estimates of exposure and dose and upper bound cancer slope factors can be mathematically combined to generate worst-case risk estimates, such an exercise does not take into account a major concern with regard to risk assessment, the relevance of animal data to actual human risks. While PCBs at high

doses have been associated with various toxicities in animal tests (including rodent liver cancer for 60% chlorinated mixtures), the human evidence consistently demonstrates that, with the limited exceptions of dermal effects and transient effects on liver enzyme levels, PCBs have not been associated with human health effects, even among relatively highly exposed workers. Dr. Renate Kimbrough and other experts have repeatedly noted this absence of health effects, especially among environmentally exposed persons. In particular, the epidemiological studies provide no consistent evidence that occupational exposure to PCBs is associated with cancer in humans. In light of the weight of the human evidence, risk assessment based on upper bound cancer potency factors derived from rodent studies of 60% chlorinated mixtures of PCBs is not well-founded.

The preliminary draft risk assessment calculations are based solely on retrospective worst-case exposure estimates. The retrospective approach not only incorporates unrealistic exposure scenarios, but also it ignores past and current actions, which have minimized or eliminated the potential for exposure altogether. Risk assessment is not a stand-alone activity. It must be considered as input into a larger risk management context. Risk management is a forward-looking process. Unless the risk assessment phase is also focused on present conditions and realistic future potentials for exposure, it cannot provide meaningful input into risk management decisions.

Monsanto Company is currently involved in extensive sampling programs to characterize the extent and magnitude of PCB levels at and near the Anniston plant. At the same time, work is ongoing to assure that the analytical data generated is as accurate as possible. Based on the results of the sampling programs and based on potential effective and pragmatic remediation alternatives, Monsanto will continue to work with state regulatory agencies to develop appropriate responses and remediation plans.

APPENDIX A

DSW 133148

STLCOPCB4033106



John A. Moore, President

Suite 402
1629 K Street, NW
Washington, DC 20006
Phone: (202) 289-8721
FAX: (202) 289-8530

July 7, 1995

Review by Renate D. Kimbrough, M.D. of a document entitled: "Preliminary Risk Assessment for Monsanto Chemical Company in Anniston, Alabama".

General Comments.

This document apparently is of a preliminary nature. In it an attempt is made to assess the risk of several landfills, a drainage ditch and a creek. No explanation was given in the document why the preliminary risk assessment was performed, whether a final risk assessment would evolve from it, or whether it would be commented on by other entities. It was also not stated why the risk assessment was based on past events.

Although the attempt of putting the theoretical risks of the different entities into perspective is commendable, the assumptions made in the preliminary risk assessment are unrealistic, partially based on hearsay and also on what appear to be at least in part unreliable analytical data. It is therefore recommended that this risk assessment not be utilized.

Specific Comments.

Some assumptions made in the risk assessment seem to be retrospective and based on the fact that the company has been in existence in Alabama since 1935. This begs the question of who this risk assessment is for. Is the risk assessment construed for citizens over the age of 60 who have lived their entire life around the plant?

The question that should be addressed is: what is the risk now?

Some of the assumptions listed in tabular form in the document as standards used in the calculations seem to have been derived from assumptions proposed by the U.S. EPA as default assumptions, but no reference is given. Such generic default assumptions are only suggested to be used if no better information is available.

All risk assessments should explain the uncertainties introduced into the risk assessment which was not done in this case. Such a discussion will help the risk assessor decide whether the approach is reasonable and realistic. In some instances the uncertainties

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may be so overwhelming that no credible risk assessment can be made as may be the case in the situation addressed here.

No explanation was given why specific assumptions were used. It is stated that the company has been in Alabama since 1935 and has manufactured PCBs. It is entirely unclear whether the present contamination existed in the early years of the "start up" of the company.

It is stated in the risk assessment that a drainage ditch is contaminated with PCBs and highly unlikely exposure scenarios are developed for it. The drainage ditch has very steep sides (not mentioned in the risk assessment) and is very deep with very little water in it most of the time. A small child would not venture into the ditch or if it fell into it would not be able to get out on its own accord. Thus, the likelihood that children would play in the ditch is rather remote. Adults would definitely not venture into the ditch on a regular basis. I would consider climbing into the ditch for recreational purposes rather abnormal behavior.

It is assumed in the risk assessment that people are exposed to the landfill and the drainage ditch 365 days a year and that a worker receives exposure for 250 days per year. The length of exposure for the general population is considered to be 60 years and for workers it ranges from 25 - 35 years. No allowance is made for the fact that the general population or the workers would not venture into these areas if it were raining or very cold. They really would have little reason to go there at all. Even if they did go there they would only walk through the area, they definitely would not sit down and eat dirt. Ingestion of soil is generally only a problem in small children, particularly toddlers because of their hand to mouth activities. It is also known that children under 6 usually stay pretty close to home and would not roam around on these various landfills or in ditches. Furthermore, the extensive literature on lead shows that hand to mouth activities disappear between the ages of 5 - 6.

It is assumed that adults drink 2 liters of water and children 1 liter. This is generally true except that the sources may vary. Some water may come from the tap and other water may be bottled water, soft drinks etc. The population in the area for which the risk assessment is performed is on city water. Drinking water is therefore not an issue since the ground water in the immediate area is not used as drinking water.

Thus, in summary there is no convincing support for the presumption that anybody received any exposure to PCBs which would have resulted in PCB uptake from direct contact with the drainage ditches or the landfills. This observation is supported by a number of studies which show that people living on PCB contaminated soil, do not accumulate higher body burdens of these chemicals when compared with the general population (Stehr-Green et al. Arch. Environ. Hlth. 43, 420, 1988; Baker et al. Am J. Epid. 112, 553,

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1980; Yaffe and Reeder. Canad. J. Publ. Hlth. 80, 325, 1989; Miller et al. Arch. Environ. Contam. Toxicol 20, 410, 1991).

Body burdens in the general population appear to be related to consumption of PCBs through the food chain. In workers occupational exposure inside the plant rather than environmental exposure outside the plant has contributed to PCB uptake in the past.

In addition to the highly unlikely exposure scenarios that were developed, the PCB levels used for soil, water, fish etc. are not well defined by the author of the preliminary risk assessment. It is unclear when these samples from which the PCB numbers are derived were actually obtained or in which laboratory the samples were analyzed. No information is given about the performance of the laboratory. It is also not explained whether these numbers represent averages, or the highest values ever measured and whether levels below the limit of detection were considered as well and how they were included in the calculations.

The quantitation used for the PCBs seems to be in error. PCBs are changed in the environment. Certain congeners are more easily degraded than others. Quantitating such PCB mixtures as Aroclor 1242, 1254 and 1260 and then adding them up produces erroneously high total PCB levels. Furthermore, no mass spectroscopy confirmation seems to have been performed on any of the samples whose analytical results were used in the risk assessment. High resolution GLC instruments with capillary columns are now also available. They could be used on a few selected samples to get a better handle on congeners and on quantitation. Particularly for the fish samples it should be determined whether contamination with DDE and other chlorinated aromatic compounds might have affected the PCB quantitation. Until some confirmation of these environmental measurements and their specific identification as PCBs has been made no credible risk assessment can be performed.

Recommendation.

It is recommended that prior to any attempts at a risk assessment a better understanding of present pathways of exposure be developed. Any PCB measurement results should be validated as to their accuracy and only current measurement results should be utilized for any future risk assessments.

Renate Kimbrough, MD

Renate D. Kimbrough, M.D., D.A.B.T.

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APPENDIX B

DSW 133152

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Savannah Labs Analytical Reports

As part of continuing efforts to refine the site characterization at and near the Monsanto Anniston facility, analytical and engineering personnel have reviewed the recent information developed by Savannah Labs to address the quantitative accuracy of EPA Method 8080, when applied to complex environmental mixtures of PCBs such as those encountered at or near the Anniston Plant. The results generated by the electron capture gas chromatographic (EC-GC) EPA Method 8080 were compared to results from EPA Method 680, which is a gas chromatographic/mass spectrometric (GC/MS) method. Results from analyses using the more refined EPA Method 680 were consistently and often substantially lower than results from analyses of the same sample extracts using EPA Method 8080 and an "Aroclor-based" calculation methodology.

Method 8080 is most appropriately applied to the analysis of samples containing individual Aroclor products or simple mixtures of those products. Results are quantitated by attempting to assign a few unique GC peaks to particular Aroclor products, calculating concentrations for each individual "Aroclor", and then summing those individual "Aroclor" concentrations. This method of calculation (summing "Aroclors") is inappropriate for complex mixtures of PCBs, because results are erroneously elevated. The erroneous elevations arise from the fact that in complex mixtures, the analyst is unable to assign peaks which are truly unique to a particular Aroclor mixture. Therefore, some GC peaks may make multiple contributions to the calculation of total PCBs by summing "Aroclors". The GC/MS Method 680 does not identify and quantitate specific Aroclor mixtures in complex samples, but rather it measures contributions to the total PCB concentration from each congener class (PCBs with the same number of chlorines per biphenyl molecule) and sums the results to give the total concentration of PCBs.

During the analytical chemistry phase of the 'Area A Soil Sampling Program', Savannah Laboratories recognized the potential bias associated with attempting to quantitate analyses using the "summed Aroclor" methodology. Initial observations indicated that this upward bias was most apparent in regions of the chromatograms where Aroclor 1248 and Aroclor 1254 eluted. Therefore, beginning with results reported in Table 3 of the Geraghty & Miller report for Area A, the laboratory used a combined response factor for Aroclor 1248 and 1254. Those results are denoted by an asterisk (*) in Table 3. Total PCBs were then calculated by Geraghty and Miller for inclusion in Table 3. This calculation method was also used by Savannah Laboratories for quantitation of the PCBs in the 'Off-site Sediment (Snow Creek) Sampling Program'.

Further investigation by Savannah Labs has demonstrated that an alternative calculation methodology to quantitate results generated by EC-GC Method 8080 is more appropriate for these complex samples.

In this alternate methodology an average response factor is calculated for the total area of the peaks for all PCB peaks (Area Under the Curve (AUC)) in the PCB standard mixture, and this factor is applied to the total area under the curve in the chromatograms of the samples. This technique provides a more accurate measure of the total PCBs present in the sample and avoids the errors introduced by attempting to sort out and quantitate individual Aroclor mixtures and then summing those results (the "summed Aroclor" method). The accuracy of this approach is demonstrated by the agreement between the results calculated using this alternate methodology and results obtained using the GC/MS Method 680 on selected samples. This alternate calculation methodology is referred to as the "total area under the curve (AUC)" method in further discussion below.

Based on the results of these analytical investigations, the following program will be instituted:

For the "Off-site Sediment Sampling" (Snow Creek) program, all results are reported using an average response factor for Aroclor 1248 and Aroclor 1254. Those results have been communicated to Geraghty & Miller, which incorporated them into the final report on that program. The prior calculations using the "summed Aroclor" method are attached as an appendix.

The Area A report has already been issued using the average response factor for Aroclor 1248 and 1254 for the results reported in Table 3. That report will stand as issued, with the understanding that some of the results in Tables 1 and 2 may be erroneously elevated, as discussed above.

All future samples will be analyzed using Method 8080 and the "total area under the curve" method of calculation. Ten to twenty percent of the analyzed samples will be reanalyzed using Method 680 to provide quality assurance that there is agreement between results obtained using the two analytical methods. If any paired samples differ by more than a factor of 2, the original data will be reviewed to assess the discrepancy. Standard Reference Materials (SRMs) for PCBs in sediment (available from NIST) will be submitted as blind samples to Savannah Labs to serve as verification samples for EPA Method 8080 and the "total area" quantitation.

This program should produce accurate analytical results for all ongoing sampling programs.

Monsanto Company Comments on:

**Health Consultation
Cobbtown/Sweet Valley Community
PCB Exposure Investigation
Anniston, Calhoun County, Alabama
June 26, 1996**

**Prepared by
Alabama Department of Public Health**

On June 26, 1996, the Alabama Department of Public Health (ADPH) issued a "Health Consultation" for the Cobbtown/Sweet Valley Community in Anniston, Alabama. Monsanto believes that there are inaccuracies and erroneous assumptions and conclusions in this document and has prepared these comments to address those inaccuracies and errors. In summary, Monsanto believes that the Health Consultation overstates the potential for adverse health effects from exposure to PCBs in the Cobbtown/Sweet Valley area and that the Department's conclusion that the area constitutes a public health hazard is erroneous.

BACKGROUND AND STATEMENT OF ISSUES

This document pertains to an area designated as the Cobbtown/Sweet Valley Community. However, in the Health Consultation previously prepared for the Monsanto Company site by ADPH, the same area is designated as the East Drainage Ditch (EDD). Using consistent names for the area in the various documents would help avoid confusion.

Site Description & Background (Pages 1-2)

The second paragraph describes sampling results south of Highway 202 across the road from the intersection with Zinn Parkway. The paragraph states that no samples were obtained in the highway median in that area and implies that samples should be taken along Zinn Parkway. Samples were taken in the Highway 202 median in an eastward direction to determine the extent of readings in excess of the measurement level of the immunoassay procedure used to detect PCBs. Initial sampling was not done along Zinn Parkway because the PCBs are associated with drainage patterns in areas near the Monsanto Plant, and the drainage from the area south of Highway 202 all flows through drainage ditches which had been extensively sampled. In addition, subsequent sampling of the Zinn Parkway area confirmed that PCBs were not present above the measurement level of the assay. Further, it is not clear that the drainage pattern suggested in the last paragraph of this section accurately reflects the drainage from the South Landfill area south of the Zinn Parkway intersection.

DISCUSSION (Page 2-3)

The last full paragraph on page 3 states that "a pica child ... was used as the most conservative estimate of risk at the site." ADPH has extensive knowledge of the former residents of the area, and there is no information known to Monsanto which would suggest such a child exists in the area. This use of most conservative estimates is an example of the unrealistic nature of the risk estimates calculated for this area. (Other examples are cited in Monsanto's comments on the draft risk assessment, which are attached.)

The effect of the conservative nature of the risk estimates is exemplified by the description of the noncancerous adverse health effects "in pica children" exposed to "the highest levels of PCBs in surface soil", which is described on the bottom of page 4 to the top of page 5.

Four Squares [sic] Christian Academy Playground Surface Soil (Page 6)

Many additional samples have been collected in this area, and analysis has shown that, in general, PCBs are not detected in the surface soils, even in the area of the purported abandoned well. The results have been communicated to the state agencies.

Surface water (Page 7)

The section suggests that "...surface water is carrying significant amounts of PCBs..." It is important to note that the trace levels of PCBs detected in some samples of storm water were generally within one order of magnitude of the drinking water standard for PCBs. Further, most of the samples in which PCBs were detected were collected during high storm water flow events, when sediment scouring is likely. Therefore, the available data do not suggest that PCBs are being transported from the site at any level at all times.

It also is excessive to suggest that residents are accidentally ingesting water from the drainage ditches at all, let alone receiving their entire daily consumption of drinking water from the ditches for 52 days a year.

Groundwater (Page 8)

The "City of Jackson" should be the "City of Jacksonville".

Environmental Data Gaps (Pages 9-10)

Many of the data gaps suggested in this section have been addressed, and, in fact, many had been addressed by the time this document was issued. Specifically, residential yards in areas designated A, B, C, and D were sampled in compliance with a consent order between ADEM and Monsanto, which was signed March 8, 1996. The results of that sampling program were supplied to the state prior to the June 26, 1996, issuance of this report.

The second paragraph of this section intends to describe a removal action undertaken by Monsanto on sections of drainage ditches leading from the Monsanto Plant towards Snow Creek. Monsanto cooperated fully with Alabama state agencies subsequent to the determination that PCBs were present in sections of Snow Creek and ditches at various levels. Monsanto submitted a remediation plan to the state; however, the state neither approved nor disapproved the plan in writing. Monsanto, however, did obtain an oral representation that the remediation plan could be implemented. In 1989, Monsanto voluntarily removed PCB-containing sediments from drainage ditches leading from the plant and from a small section of Snow Creek. Monsanto also enclosed a short section of

a drainage ditch in concrete and covered and sodded that area. The sediments were dewatered on the banks, temporarily staged on the South Landfill, tested for PCB levels (which were determined to be >50 ppm on average), and disposed of in an EPA-approved PCB disposal facility. Contrary to the statement in the Health Consultation, sediments remaining in the removal area were not tested for PCB levels.

Toxicology of PCBs (Pages 12-13)

This section presents an overview of the toxicology and characteristics of PCBs. It appears to be largely based on ATSDR's *Toxicological Profile for Selected PCBs...*, which is a summary of scientific literature concerning PCBs. On page 13, the Health Consultation states that PCBs "...have been shown to cause elevations in blood fats..." Scientific information suggests that the association of PCB blood levels and measures of blood lipids is a result of the tendency for PCBs to be associated with those lipids, so that persons with higher blood lipid levels would be expected to have higher PCB levels because of PCBs' solubility in the lipids.

The final paragraph of this section alludes to suggestions that PCBs are associated with certain cancers in humans. Although some individual epidemiology studies report isolated excesses of various cancer types, there are no consistent findings in the studies which would provide convincing evidence that PCBs are associated with cancer in humans. In fact, the opposite is the case: if the PCB epidemiology studies are evaluated in accordance with accepted principles, there is evidence that PCBs are not associated with cancers in humans at exposure levels encountered in occupational settings, where exposures were much higher than exposures anticipated for environmental settings.

CONCLUSIONS (Pages 13-15)

Monsanto believes that the Health Consultation overstates the potential for adverse health effects from exposure to PCBs in the Cobbtown/Sweet Valley area and that the Department's conclusion that the area constitutes a public health hazard is erroneous.

While the statement in Conclusion 2 that the NDD (North Drainage Ditch) floods after rain may be correct, the NDD is not located in nor associated with the Cobbtown/Sweet Valley area. The bases for Conclusions 3 and 8 have been addressed in previous comments. It is not clear that the "new drainage ditch" referred to in Conclusion 3 is either new or carries storm water runoff from the area east of the South Landfill. Additional sampling in the Four Square Christian Academy Playground did not confirm that there is opportunity for exposure to PCB-containing soils on the playground.

Conclusions 13 and 14 discuss correlations between PCB blood levels in children and soil levels and dust levels. It is important to note, however, that no one who was under 28 years of age had blood PCB levels over 20 ppb. Further, the number of children tested was small, so that the reported correlations are not particularly robust.

RECOMMENDATIONS (Pages 15-16)

Several of the recommendations had been completed by the time the Health Consultation was issued and several more have been completed subsequently. Specifically, Recommendations 2,3,4, and 5, which suggested additional soil sampling, have been completed, and the results have been reported to appropriate state agencies.

Recommendation 1 has been addressed by several measures undertaken by Monsanto. In October 1995, Monsanto offered residents in the area immediately east of the Anniston Plant an opportunity to participate in a Property Purchase Program, which was initiated to facilitate management and control of the soils and sediments in the area. That Program was extended to residents on Montrose Avenue in the spring of 1996. For persons who elected not to participate in the Property Purchase Program, Monsanto offered temporary relocation and cleaning of their homes. Monsanto is currently implementing measures to assure isolation and containment of PCB-containing soils and sediments in the area.

Recommendations 9, 10, 11, and 12 were repeated from the "Health Consultation, Monsanto Company, ...January, 1996", and were addressed in Monsanto's comments on that Health Consultation.

On June 21 representatives of the Monsanto Anniston plant met with representatives of Alabama Department of Environmental Management (ADEM) and Alabama Department of Public Health (ADPH). The meeting was requested by the Alabama agencies to solicit Monsanto's input on a preliminary draft risk assessment which is in the early stages of development by ADPH. Monsanto was asked to provide specific information about dates associated with plant activities and to share overhead photographs of the plant site.

Discussions during the meeting included a brief overview of the preliminary risk assessment, including summaries of various exposure scenarios and exposure assumptions. Although the risk assessment was clearly specified to be both preliminary and a draft, several aspects of the exercise require comment, even at this earliest stage of the process. Of specific concern are the preliminary and incomplete nature of the analytical results which have been incorporated, the unrealistic exposure scenarios which have been utilized, and the exclusive use of the cancer slope factor estimated from rodent studies on a single PCB mixture. In addition, this preliminary draft risk assessment ignores the large body of scientific literature which demonstrates that no chronic human health effects, with the possible exception of dermal effects and transient elevations in some liver enzymes, are associated with even high level, occupational exposure to PCBs. Finally, the retrospective nature of the draft risk assessment is inconsistent with sound risk management principles. These concerns are discussed in more detail in the following paragraphs.

Monsanto has also asked Dr. Renate Kimbrough, Senior Medical Associate, Institute for Evaluating Health Risks (IEHR) to provide a preliminary review of the draft risk assessment. Her review is attached as Appendix A.

A critical component of even the most preliminary attempt to estimate the risks associated with exposure to environmental chemicals is the availability of high quality analytical results. Until properly validated analytical data are available for media for which plausible routes of exposure can be defined, any attempt at risk assessment is premature and inappropriate. Ongoing work at the laboratory which has generated much of the data available for the Monsanto Anniston plant and its environs has demonstrated that EPA Method 8080 generates erroneously elevated results for total PCBs when the "summed Aroclor" method of quantitation is used. This problem arises from attempting to define selected GC peaks as representative of specific Aroclor products. As discussed in Jensen (1989), "If only 1 to three high peaks are selected, the results will be about twice as high as if a dozen peaks are selected." The laboratory is currently using a more appropriate method of quantifying the analytical results from Method 8080, as well as using EPA Method 680 (a GC/MS method) as a reference method. (A brief summary of the current analytical chemistry program for the samples collected at and near the Monsanto Anniston

plant is attached as Appendix B.) The particular method used to generate the analytical data reported by the State of Alabama and the efforts to provide quality assurance information for that data should also be reviewed.

The risk estimates provided in the preliminary draft risk assessment consistently rely on worst-case, unrealistic estimates of exposure. First, the estimates most often rely on the highest analytical result for a particular medium and a particular location. As such, those values do not represent appropriate bases for estimates of the potential for exposure to PCBs at the location as a whole. For example, at the West End Landfill, one of the estimates is based on an isolated sample, which is in no way representative of that area. The state is aware that the area in question has been fenced for twenty years and that a remediation plan has been submitted to eliminate any potential for exposure to PCBs at the West End Landfill. Another estimate is based on a selected data point which represents an area in the bottom of a ditch in a deeply wooded area to which there is no evidence of recent human access. This particular location has been temporarily remediated to minimize any potential for exposure at the particular point or downstream pending more permanent remediation steps. The state is also aware that the ground water sample used in the estimates is in ground water that is not a source of drinking water to anyone and, indeed, that the value used was an invalid collection from the monitoring well. No PCBs have been detected in properly collected samples from that well or any other monitoring wells at the plant. In all cases, there are sufficient data available from which to calculate more representative, or average, estimates of PCB levels at particular locations, rather than singling out the highest result from one point at the locations.

Second, the selection of extreme values for the levels of PCBs at the various locations is further compounded by unrealistic exposure scenarios. Although every scenario is unrealistically exaggerated, two examples are particularly instructive. Estimated risk for an APCO employee is based on an assumption of an exposure of 250 work days/year for 35 years to an isolated location which has been fenced for many years and which is known to have been visited at a much lower frequency and for short times only. (Information from Alabama Power Company indicates the location is typically visited less than one hour per week.) With reference to the wooded area noted in the previous paragraph, the preliminary draft calculates a number based on an assumed daily exposure to this inaccessible area for 60 years. As discussed below, even in the unrealistic event that the location was visited at all, it is unlikely that an adult or child visiting the site would consume sediment from the bottom of the ditch at any level, and certainly not at the levels assumed in the draft. Similar faulty assumptions regarding site access and potential for contact are relied upon in nearly every exposure scenario described in the preliminary draft.

Third, the unrealistic nature of the preliminary estimates is exaggerated by the adoption of exaggerated assumptions for estimates of intake of PCBs. As discussed above, it is inappropriate to assume a daily exposure for a number of years to locations that were, are, and will continue to be essentially inaccessible. The draft risk assessment assumes soil intake rates of 200 mg/day for a child and 100 mg/day for an adult. Soil intake rates have been studied extensively in recent years and remain imprecise. Some results indicate that few, if any, children consume soil at the levels assumed in the preliminary draft. Other sources report that adults consume essentially no soil, unless there is exposure to dust levels far above the nuisance level. There is no evidence of nuisance levels of dust at any of the locations near the Monsanto facility in Anniston. The assumption that any daily soil consumption for either an adult or a child is exclusively from locations near the Monsanto facility is also unrealistic.

Fish consumption assumptions also are worst-case estimates, unlikely to reflect fish consumption habits of average residents. Although Alabama has adopted 30 gram/day fish consumption as a representative value, that amount is for total consumption of fish, not for fish locally caught and consumed. There is no basis for an assumption that any person, let alone a representative resident, consumes only fish from Choccolocco Creek. Studies have shown that most consumers eat primarily, if not exclusively, fish purchased in stores supplied by non-local sources. The assumptions also ignore the effect of cooking method and time on the levels of PCBs in fish. In some cases, up to 80% of PCBs are removed by broiling or frying fish.

All of the calculations in the preliminary draft are based on an upper bound cancer potency (slope) factor of $7.7 \text{ (mg/kg/day)}^{-1}$ for PCBs. This value is based exclusively on rodent testing data on 60% chlorinated mixtures of PCBs. It is widely accepted that this value exaggerates risk estimates for less chlorinated PCB mixtures. The analytical data generated to date by both Monsanto and the state provide no basis to assume that the slope factor for 60% chlorinated mixtures is appropriate here. Recent information developed by the Pathology Working Group under the auspices of the Institute for Evaluating Health Risks (IEHR) suggests that a more appropriate cancer potency factor might be $1.9 \text{ (mg/kg/day)}^{-1}$, based on a reanalysis of PCB chronic feeding studies. Indeed, the state of New Jersey has recently adopted a value of $1.4 \text{ (mg/kg/day)}^{-1}$ and the U.S. EPA is considering a reduction in the value reported in the IRIS data base.

While worst-case estimates of exposure and dose and upper bound cancer slope factors can be mathematically combined to generate worst-case risk estimates, such an exercise does not take into account a major concern with regard to risk assessment, the relevance of animal data to actual human risks. While PCBs at high

doses have been associated with various toxicities in animal tests (including rodent liver cancer for 60% chlorinated mixtures), the human evidence consistently demonstrates that, with the limited exceptions of dermal effects and transient effects on liver enzyme levels, PCBs have not been associated with human health effects, even among relatively highly exposed workers. Dr. Renate Kimbrough and other experts have repeatedly noted this absence of health effects, especially among environmentally exposed persons. In particular, the epidemiological studies provide no consistent evidence that occupational exposure to PCBs is associated with cancer in humans. In light of the weight of the human evidence, risk assessment based on upper bound cancer potency factors derived from rodent studies of 60% chlorinated mixtures of PCBs is not well-founded.

The preliminary draft risk assessment calculations are based solely on retrospective worst-case exposure estimates. The retrospective approach not only incorporates unrealistic exposure scenarios, but also it ignores past and current actions, which have minimized or eliminated the potential for exposure altogether. Risk assessment is not a stand-alone activity. It must be considered as input into a larger risk management context. Risk management is a forward-looking process. Unless the risk assessment phase is also focused on present conditions and realistic future potentials for exposure, it cannot provide meaningful input into risk management decisions.

Monsanto Company is currently involved in extensive sampling programs to characterize the extent and magnitude of PCB levels at and near the Anniston plant. At the same time, work is ongoing to assure that the analytical data generated is as accurate as possible. Based on the results of the sampling programs and based on potential effective and pragmatic remediation alternatives, Monsanto will continue to work with state regulatory agencies to develop appropriate responses and remediation plans.

APPENDIX A

DSW 133164

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John A. Moore, President

Suite 402
1629 K Street, NW
Washington, DC 20006
Phone: (202) 289-8721
FAX: (202) 289-8530

July 7, 1995

Review by Renate D. Kimbrough, M.D. of a document entitled: "Preliminary Risk Assessment for Monsanto Chemical Company in Anniston, Alabama".

General Comments.

This document apparently is of a preliminary nature. In it an attempt is made to assess the risk of several landfills, a drainage ditch and a creek. No explanation was given in the document why the preliminary risk assessment was performed, whether a final risk assessment would evolve from it, or whether it would be commented on by other entities. It was also not stated why the risk assessment was based on past events.

Although the attempt of putting the theoretical risks of the different entities into perspective is commendable, the assumptions made in the preliminary risk assessment are unrealistic, partially based on hearsay and also on what appear to be at least in part unreliable analytical data. It is therefore recommended that this risk assessment not be utilized.

Specific Comments.

Some assumptions made in the risk assessment seem to be retrospective and based on the fact that the company has been in existence in Alabama since 1935. This begs the question of who this risk assessment is for. Is the risk assessment construed for citizens over the age of 60 who have lived their entire life around the plant?

The question that should be addressed is: what is the risk now?

Some of the assumptions listed in tabular form in the document as standards used in the calculations seem to have been derived from assumptions proposed by the U.S. EPA as default assumptions, but no reference is given. Such generic default assumptions are only suggested to be used if no better information is available.

All risk assessments should explain the uncertainties introduced into the risk assessment which was not done in this case. Such a discussion will help the risk assessor decide whether the approach is reasonable and realistic. In some instances the uncertainties

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may be so overwhelming that no credible risk assessment can be made as may be the case in the situation addressed here.

No explanation was given why specific assumptions were used. It is stated that the company has been in Alabama since 1935 and has manufactured PCBs. It is entirely unclear whether the present contamination existed in the early years of the "start up" of the company.

It is stated in the risk assessment that a drainage ditch is contaminated with PCBs and highly unlikely exposure scenarios are developed for it. The drainage ditch has very steep sides (not mentioned in the risk assessment) and is very deep with very little water in it most of the time. A small child would not venture into the ditch or if it fell into it would not be able to get out on its own accord. Thus, the likelihood that children would play in the ditch is rather remote. Adults would definitely not venture into the ditch on a regular basis. I would consider climbing into the ditch for recreational purposes rather abnormal behavior.

It is assumed in the risk assessment that people are exposed to the landfill and the drainage ditch 365 days a year and that a worker receives exposure for 250 days per year. The length of exposure for the general population is considered to be 60 years and for workers it ranges from 25 - 35 years. No allowance is made for the fact that the general population or the workers would not venture into these areas if it were raining or very cold. They really would have little reason to go there at all. Even if they did go there they would only walk through the area, they definitely would not sit down and eat dirt. Ingestion of soil is generally only a problem in small children, particularly toddlers because of their hand to mouth activities. It is also known that children under 6 usually stay pretty close to home and would not roam around on these various landfills or in ditches. Furthermore, the extensive literature on lead shows that hand to mouth activities disappear between the ages of 5 - 6.

It is assumed that adults drink 2 liters of water and children 1 liter. This is generally true except that the sources may vary. Some water may come from the tap and other water may be bottled water, soft drinks etc. The population in the area for which the risk assessment is performed is on city water. Drinking water is therefore not an issue since the ground water in the immediate area is not used as drinking water.

Thus, in summary there is no convincing support for the presumption that anybody received any exposure to PCBs which would have resulted in PCB uptake from direct contact with the drainage ditches or the landfills. This observation is supported by a number of studies which show that people living on PCB contaminated soil, do not accumulate higher body burdens of these chemicals when compared with the general population (Stehr-Green et al. Arch. Environ. Hlth. 43, 420, 1988; Baker et al. Am J. Epid. 112, 553,

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1980; Yaffe and Reeder. Canad. J. Publ. Hlth. 80, 325, 1989; Miller et al. Arch. Environ. Contam. Toxicol 20, 410, 1991).

Body burdens in the general population appear to be related to consumption of PCBs through the food chain. In workers occupational exposure inside the plant rather than environmental exposure outside the plant has contributed to PCB uptake in the past.

In addition to the highly unlikely exposure scenarios that were developed, the PCB levels used for soil, water, fish etc. are not well defined by the author of the preliminary risk assessment. It is unclear when these samples from which the PCB numbers are derived were actually obtained or in which laboratory the samples were analyzed. No information is given about the performance of the laboratory. It is also not explained whether these numbers represent averages, or the highest values ever measured and whether levels below the limit of detection were considered as well and how they were included in the calculations.

The quantitation used for the PCBs seems to be in error. PCBs are changed in the environment. Certain congeners are more easily degraded than others. Quantitating such PCB mixtures as Aroclor 1242, 1254 and 1260 and then adding them up produces erroneously high total PCB levels. Furthermore, no mass spectroscopy confirmation seems to have been performed on any of the samples whose analytical results were used in the risk assessment. High resolution GLC instruments with capillary columns are now also available. They could be used on a few selected samples to get a better handle on congeners and on quantitation. Particularly for the fish samples it should be determined whether contamination with DDE and other chlorinated aromatic compounds might have affected the PCB quantitation. Until some confirmation of these environmental measurements and their specific identification as PCBs has been made no credible risk assessment can be performed.

Recommendation.

It is recommended that prior to any attempts at a risk assessment a better understanding of present pathways of exposure be developed. Any PCB measurement results should be validated as to their accuracy and only current measurement results should be utilized for any future risk assessments.

Renate Kimbrough, MD

Renate D. Kimbrough, M.D., D.A.B.T.

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APPENDIX B

DSW 133168

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Savannah Labs Analytical Reports

As part of continuing efforts to refine the site characterization at and near the Monsanto Anniston facility, analytical and engineering personnel have reviewed the recent information developed by Savannah Labs to address the quantitative accuracy of EPA Method 8080, when applied to complex environmental mixtures of PCBs such as those encountered at or near the Anniston Plant. The results generated by the electron capture gas chromatographic (EC-GC) EPA Method 8080 were compared to results from EPA Method 680, which is a gas chromatographic/mass spectrometric (GC/MS) method. Results from analyses using the more refined EPA Method 680 were consistently and often substantially lower than results from analyses of the same sample extracts using EPA Method 8080 and an "Aroclor-based" calculation methodology.

Method 8080 is most appropriately applied to the analysis of samples containing individual Aroclor products or simple mixtures of those products. Results are quantitated by attempting to assign a few unique GC peaks to particular Aroclor products, calculating concentrations for each individual "Aroclor", and then summing those individual "Aroclor" concentrations. This method of calculation (summing "Aroclors") is inappropriate for complex mixtures of PCBs, because results are erroneously elevated. The erroneous elevations arise from the fact that in complex mixtures, the analyst is unable to assign peaks which are truly unique to a particular Aroclor mixture. Therefore, some GC peaks may make multiple contributions to the calculation of total PCBs by summing "Aroclors". The GC/MS Method 680 does not identify and quantitate specific Aroclor mixtures in complex samples, but rather it measures contributions to the total PCB concentration from each congener class (PCBs with the same number of chlorines per biphenyl molecule) and sums the results to give the total concentration of PCBs.

During the analytical chemistry phase of the 'Area A Soil Sampling Program', Savannah Laboratories recognized the potential bias associated with attempting to quantitate analyses using the "summed Aroclor" methodology. Initial observations indicated that this upward bias was most apparent in regions of the chromatograms where Aroclor 1248 and Aroclor 1254 eluted. Therefore, beginning with results reported in Table 3 of the Geraghty & Miller report for Area A, the laboratory used a combined response factor for Aroclor 1248 and 1254. Those results are denoted by an asterisk (*) in Table 3. Total PCBs were then calculated by Geraghty and Miller for inclusion in Table 3. This calculation method was also used by Savannah Laboratories for quantitation of the PCBs in the 'Off-site Sediment (Snow Creek) Sampling Program'.

Further investigation by Savannah Labs has demonstrated that an alternative calculation methodology to quantitate results generated by EC-GC Method 8080 is more appropriate for these complex samples.

In this alternate methodology an average response factor is calculated for the total area of the peaks for all PCB peaks (Area Under the Curve (AUC)) in the PCB standard mixture, and this factor is applied to the total area under the curve in the chromatograms of the samples. This technique provides a more accurate measure of the total PCBs present in the sample and avoids the errors introduced by attempting to sort out and quantitate individual Aroclor mixtures and then summing those results (the "summed Aroclor" method). The accuracy of this approach is demonstrated by the agreement between the results calculated using this alternate methodology and results obtained using the GC/MS Method 680 on selected samples. This alternate calculation methodology is referred to as the "total area under the curve (AUC)" method in further discussion below.

Based on the results of these analytical investigations, the following program will be instituted:

For the "Off-site Sediment Sampling" (Snow Creek) program, all results are reported using an average response factor for Aroclor 1248 and Aroclor 1254. Those results have been communicated to Geraghty & Miller, which incorporated them into the final report on that program. The prior calculations using the "summed Aroclor" method are attached as an appendix.

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This program should produce accurate analytical results for all ongoing sampling programs.