UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: March 8, 2006

MEMORANDUM

SUBJECT: **ACETOCHLOR/ALACHLOR: Cumulative Risk Assessment for the Chloroacetanilides**. PC Codes:121601 & 090501, DP Barcode: D292317

Regulatory Action: Tolerance Reassessment
Risk Assessment Type: Cumulative Risk assessment /Aggregate

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ACTION: Complete the Chloroacetanilide Cumulative Risk Assessment.

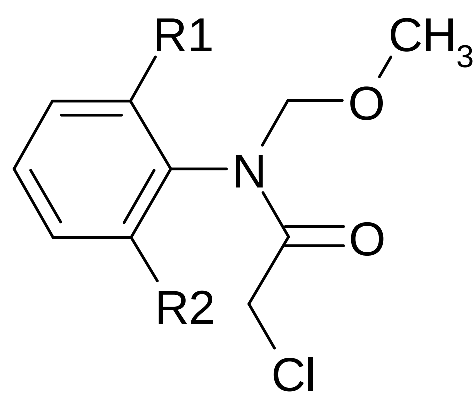
CONCLUSIONS:

1. A risk assessment of a Cumulative Assessment Group (CAG) consisting of the Chloroacetanilide pesticides acetochlor and alachlor has been conducted. MOE calculations have been made based on the endpoint of nasal olfactory epithelium tumors in rats, and using slightly refined values for food and drinking water,

2. Compared to a MOE of 100, defined as level of concern (LOC) for this risk assessment, the cumulated MOE values, greater than 13,000 for the subject CAG for all populations, are outside the Agency's level of concern.

3. Because these cumulative MOE values were obtained using high-end exposures, they are considered to be conservative. Additional MOE calculations in Appendixes 1 and 2 of the Cumulative Risk Assessment document, using more conservative approaches to estimation of drinking-water exposure, support the conclusions of this analysis by producing MOE values that exceed the LOC of 100 by nearly an order of magnitude or more.

CUMULATIVE RISK FROM CHLOROACETANILIDE PESTICIDES



U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division

March 8, 2006

CUMULATIVE RISK
FROM
CHLOROACETANILIDE PESTICIDES

Executive Summary

As part of the tolerance reassessment process under the Food Quality Protection Act (FQPA) of 1996, EPA must consider available information concerning the cumulative effects on human health resulting from exposure to multiple chemicals that have a common mechanism of toxicity.

This document contains the results of a cumulative risk assessment conducted for a group of chloroacetanilide pesticides that have a common mode of action for the production of **tumors of the nasal olfactory epithelium** in rats.

Previously, a common mechanism group (CMG) of chloroacetanilide pesticides consisting of acetochlor, alachlor and butachlor was defined by the Agency for nasal tumors, and evaluated by the FIFRA Science Advisory Panel (SAP, 1997). After consideration of the SAP comments, OPP's own reviews and the data underlying these reviews, as well as additional information received by the Agency from registrants or presented in the open literature since the 1997 SAP meeting, OPP published a paper in 2001 titled "The Grouping of a Series of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity" (http://www.epa.gov/oppfod01/cb/csb_page/updates/commechs.htm) (USEPA 2001). It was concluded in that document that Acetochlor, Alachlor, and Butachlor should be considered as a Common Mechanism Group due to their ability to cause nasal turbinate tumors via the generation of a common tissue reactive metabolite that leads to cytotoxicity and regenerative proliferation in the nasal epithelium. Sustained cytotoxicity and proliferation is needed to lead to neoplasia. Thus, the common mechanism effect is a systemic chronic endpoint.

For purposes of a cumulative risk assessment Acetochlor, Alachlor, and Butachlor, will be considered as a Common Mechanism Group. Butachlor, however, has no registered uses in the US and has been excluded from the risk assessment. Thus, the Common Assessment Group (CAG: a subset of the CMG), on which the risk assessment was conducted consists of Acetochlor and Alachlor only.

Development of nasal olfactory epithelium tumors in rats has been attributed to a non-linear, non-mutagenic mode of action (USEPA , 2004). Thus, as per the 2005 EPA Cancer Guidelines (USEPA 2005b) a Margin-of-Exposure (MOE) calculation has been

used for the cumulative risk assessment, as one would do for a threshold noncancer toxicity risk assessment. Because of the threshold approach that is being used for risk assessment, the uncertainty factors (UFs) of 10 (interspecies) and 10 (intraspecies) are used. In the absence of sensitivity issues the FQPA factor is 1. Thus, MOEs above 100 are considered to be outside of the Agency's level of concern (LOC).

Calculations for this document have involved:

- For each CAG member, determination of the Point-of-Departure (POD) for the nasal tumors and its respective dietary exposure (food and drinking water).

- Computations of the MOE value for the cumulative exposure using alachlor as the index chemical and using a relative potency factor (RPF) to express the contribution of acetochlor in equivalents of the index chemical.

For this cumulative assessment, POD values were determined as the No-Observed-Adverse-Effect-Level (NOAELs) for tumor formation. NOAELs for nasal tumor formation were found to be 10 mg/kg bw per day for acetochlor and 0.5 mg/kg bw per day for alachlor. These values were used in the MOE calculations. The POD value for alachlor, the index chemical, was 0.5 mg/kg bw per day. Based on comparison of tumor NOAELs, the relative potency of acetochlor was estimated as 1/20th that of alachlor, yielding an RPF value of 0.05. This RPF value was used in subsequent calculations to express acetochlor in alachlor-equivalent units.

There are no residential uses for alachlor or acetochlor, thus this risk assessment involved only two pathways of exposure (food and drinking water) and the oral route of exposure. Exposure was evaluated, as follows, using a limited degree of refinement:

- **Alachlor** values in food were the anticipated residues, as estimated in the alachlor RED document of 1998 (USEPA, 1998), adjusted with current (year 2004, Attachment 2) values for percent crop treated.

- **Acetochlor**, values in food were tolerance values corrected for processing factor and percent crop treated from the Acetochlor TRED (USEPA 2005c). These acetochlor values were converted into alachlor equivalents by multiplying them by 0.05 (the RPF for acetochlor). The alachlor equivalents from acetochlor were then added to their counterparts for alachlor.

- The **water** component was obtained from a data set generated by the Acetochlor Registration Partnership (ARP; the registrant for acetochlor) which **monitored both acetochlor and alachlor** occurrence in drinking water supplies relying on surface water sources over a seven year period (1995 – 2001). The single-year water Time-Weighed-Annualized-Mean (TWAM) concentrations of acetochlor, co-occurrent with alachlor, were converted into alachlor equivalents using RPFs and added to the co-occurrent alachlor TWAM concentration values. The single-year monitoring data for each site, now in alachlor equivalents, were averaged over the years of data availability (up to 7 years) to obtain a multi-year average. The **multi-year** average water concentrations were ranked from smallest to largest and the largest value was used for risk assessment. It is noted that most of the available data from the ARP represent finished drinking water; thus, exposure in the future could be higher if drinking water systems revert to treatment methods which less effectively reduce acetochlor or alachlor in drinking water.

Groundwater levels of alachlor and acetochlor were significantly lower than surface water sources, thus were not used in risk assessment.

Because the nasal olfactory epithelium tumors are a systemic chronic endpoint, a chronic dietary analysis was conducted. Multi-year averages for drinking water concentrations were used, as this is the standard practice at HED.

Acetochlor chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03). Results of the DEEM-FCID™ analysis produced cumulated MOEs, greater than 13,000 for all populations. Selected cumulated MOEs were:

- U.S. Population (Total): 40,119
- Non-Nursing infants: 13,175 (lowest MOE)
- All Infants (<1 year): 16, 464
- Females (13-19) not pregnant or nursing: 53,237 (highest MOE).

Compared to the MOE of 100 as the LOC , the cumulated MOE values reported in this document (in excess of 13,000) for the subject CAG are outside of the Agency's level of concern.

Because these cumulative MOE values were obtained using high-end exposures, they may be considered to be sufficiently protective and conservative. This conclusion is supported by subsequent analyses (detailed in Appendixes 1 and 2) using more conservative assumptions for chloroacetanilide concentrations in drinking water that give MOEs outside of the Agency's LOC:

- When **monitored single-year** TWAM concentrations of chloroacetanilides in water were used for DEEM-FCID™ analysis MOEs greater than 7,700 were obtained for all populations (Appendix 1).

● When **PRZM-EXAMS modeled estimates** of environmental concentrations of alachlor and acetochlor in drinking water (without correction for percent crop treated , PCT) were used for DEEM-FCID^{TM} analysis MOEs greater than 640 were obtained for all populations (Appendix 2). These values will increase to several thousand if correction for current values of percent crop treated (PCT) were to be incorporated in the analysis.

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Cumulative Risk Assessment of the Chloroacetanilides

I. Introduction

The passage of the Food Quality Protection Act (FQPA) in August 1996 led the Office of Pesticide Programs (OPP) to develop methodology to evaluate the risk from exposure to more than one pesticide acting through a common mechanism of toxicity. As defined in FQPA, those pesticides that induce adverse effects by a common mechanism of toxicity must be considered jointly. In other words, the exposures of concern are to include all relevant routes and sources based upon the use patterns of the pesticides in question. This multi-chemical, multi-pathway risk is referred to as cumulative risk.

The Agency's first step in developing a cumulative risk assessment was to develop methodologies and guidance on determining whether two or more chemicals share a common mechanism of toxicity. The reader is referred to the document, **Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity** (1/29/99) for additional information on this topic (see http://www.epa.gov/fedrgstr/EPA-PEST/1999/February/Day-05/6055.pdf).

Further guidance on conducting cumulative risk assessment was provided by EPA in 1999 and 2002. The **Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity** [1/14/02, see http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf, (USEPA 2002a)] and its precursor document **General Principles for Performing Aggregate Exposure and Risk Assessments** (10/29/99), see (http://www.epa.gov/pesticides/trac/science/aggregate.pdf) describe aspects of the exposure assessment that must be accounted for in developing an integrated cumulative risk assessment. Specifically, these guidance documents state that the cumulative assessment must account for temporal aspects of exposure such as those related to the time of year during which applications resulting in exposures are likely to occur, the frequency of application and period of re-application. In addition, these documents state that the assessment must appropriately consider demographic factors and patterns.

Based in part on the principles and suggested practices contained in the above guidance documents, the first cumulative risk assessment conducted by the Agency was for the **organophosphorus (OP) class of pesticides**. EPA published a revised cumulative risk assessment for these pesticides in June 2002 (USEPA 2002b). In this assessment, OPP developed and demonstrated in detail the methods, parameters, and issues that should be considered in estimating cumulative risk associated with common mechanism pesticides by multiple pathways of exposure. Various aspects of the hazard and dose-response assessment and the exposure analyses were presented to both the SAP and the public for comment numerous times over the course of several years. Both the SAP and the public provided helpful and insightful comments and ideas which were incorporated into the revised documents.

Following publication of the Cumulative Risk Assessment for the OP pesticides and in accordance with the requirements of FQPA, OPP conducted a preliminary cumulative risk assessment for the **N-methyl carbamate (NMC) class of pesticides**. The results of this effort appear in the document Estimation of Cumulative Risk from N-Methyl Carbamates: Preliminary Assessment (USEPA, 2005a).

The present document is regarded as a **screening-level cumulative risk assessment** of the chloroacetanilide pesticides. Namely, this risk assessment has been done using high-end exposure estimates and NOAELs have been used for hazard assessment.

As presented below, the selected endpoint for risk assessment (development of nasal tumors tumors in rats) has been attributed to a non-linear, non mutagenic mode of action involving sustained cytotoxicity and regenerative cell proliferation. Thus, as per the 2005 EPA Cancer Guidelines (USEPA 2005b) a Margin-of-Exposure (MOE) calculation has been used for the cumulative risk assessment, as one would do for a threshold noncancer toxicity risk assessment. Because of the threshold approach that is being used for risk assessment, the uncertainty factors (UFs) of 10 (interspecies) and 10 (intraspecies) are used. In the absence of sensitivity issues the FQPA factor is 1. Thus, MOEs above 100 are considered to be outside of the Agency's level of concern (LOC).

The high MOE values obtained in this risk assessment are, thus, outside the Agency's LOC and are considered to be adequate to satisfy any safety concerns. Additional refinement of the data could be required if more common mechanism compounds are identified or higher exposures are observed.

II. The Cumulative Risk Assessment Process

As elaborated in OPP's cumulative guidance document (USEPA 2002a), the cumulative risk assessment process unfolds in several steps. In brief, these include:

A. Identification of the Common Mechanism Group (CMG).
B. Determination of the Candidate Cumulative Assessment Group (CAG)
C. Determination of Points of Departure (dose response analysis)
D. Exposure analysis (exposure scenarios for all routes and durations, establish exposure input parameters).

E. Conduct final cumulative risk assessment.
F. Characterize the cumulative risk assessment.

The following sections will develop the process as applied to the chloroacetanilide pesticides.

III. Performing the Cumulative Risk Assessment

A. Identification of the Common Mechanism Group (CMG)

i. Introduction

A cumulative risk assessment begins with the identification of a group of chemicals, called a common mechanism group (CMG), that induce a common toxic effect by a common mechanism of toxicity. Pesticides are determined to have a "common mechanism of toxicity" if they act the same way in the body--that is, the same toxic effect occurs in the same organ or tissue by essentially the same sequence of major biochemical events.

The chloroacetanilide pesticides, have been previously evaluated by the Agency to determine if some of them comprise a common mechanism group. Details of the analysis appear in the document The Grouping of a Series of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity (USEPA 2001). In brief,

- **Acetochlor, Alachlor and Butachlor** may be grouped together based on a common end-point (nasal turbinate tumors in rats) and a known mechanism of toxicity for this endpoint. All three compounds produce tumors of the nasal olfactory epithelium in rats by way of a non-linear, non-genotoxic mode of action that includes cytotoxicity of the olfactory epithelium, followed by regenerative cell proliferation of the nasal epithelium that can then lead to neoplasia if cytotoxicity and proliferation are sustained (see more details below).

- **Acetochlor, Alachlor and Butachlor** may also be grouped together based on an common end-point and a known mechanism of toxicity (UDPGT induction). All three compounds produce tumors of the thyroid follicular cells in rats by way of a non-genotoxic mode of action that includes UDPGT induction, increased TSH, alterations in T3/T4 hormone production and thyroid hyperplasia.

The grouping of **Acetochlor**, **Alachlor**, and **Butachlor** based on a common mechanism of action was presented to the FIFRA Scientific Advisory Panel (SAP) as a draft on March 19, 1997. The SAP agreed with the Agency’s conclusion that there is sufficient evidence to support the proposed grouping for the nasal turbinate tumors and for the thyroid follicular tumors (USEPA, 1997).

The FIFRA SAP noted in their report (USEPA, 1997), additionally, that even though the evidence illustrated that a common mechanism could be used to group certain chemicals for the development of thyroid tumors, it was recommended that this endpoint **not be used** in combining margins of exposure because the toxic effects were noted at doses above the Maximum Tolerated Dose (MTD). While the full range of doses employed can be used to determine common mechanisms, endpoints occurring solely at doses above the MTD should not be used in risk assessments. Furthermore, humans are more refractory to the induction of thyroid follicular cells tumors due to prolong stimulation of thyroid stimulating hormone compared to rats.

Thus, for the purposes of this document, the induction of nasal olfactory epithelium tumors in rats was regarded as the most sensitive and relevant common mechanism endpoint to base the cumulative risk assessment of the chloracetanilides.

ii. Determination of the CMG

As summarized below, and illustrated for acetochlor, there is ample evidence (USEPA, 2004) that the development of nasal olfactory epithelium tumors in rats dosed with chloroacetanilides involves the following sequence of steps,:

- Acetochlor conjugates with glutathione (GSH) and is excreted in the bile.
- The conjugate is biotransformed to a series of sulfur-containing products. Enterohepatic circulation of these products creates a pool of metabolites that are delivered to the nose.
- Biotransformation to tissue-reactive and toxic metabolites. Metabolism by nasal enzymes, results in formation of a benzoquinoneimine, an electrophile and redox-active molecule.
- Binding of toxic metabolite to cellular proteins plus possible generation of oxidative stress .
- Cytotoxicity
- Regenerative cell proliferation.
- Sustained cytotoxicity and cell proliferation that results in neoplasia.

The following three events are considered key events for formation of nasal olfactory epithelium tumors by the proposed non-linear, non genotoxic mode of action (MOA):

QUINONE IMINE- FORMATION (PROTEIN BINDING) ➜ CYTOTOXICITY ➜ CELL PROLIFERATION

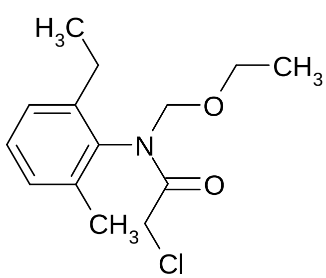
Based on the FIFRA SAP's recommendations (USEPA 1997), on OPP's 2001 paper on the MOA of chloroacetanilides (USEPA 2001) and in a more recent evaluation of the MOA of acetochlor/alachlor (USEPA 2004), the Common Mechanism Group (CMG) for the present document consists of acetochlor, alachlor and butachlor with formation of nasal olfactory epithelium tumors in rats as the common endpoint.

Other chloroacetanilides were considered (USEPA, 1997), but the evidence was found to support only the three compounds selected.   Although the chloroacetanilide metolachlor distributes to the nasal turbinates, and might produce a quinoneimine, it is not apparent from currently available data that it shares the same target site in the nasal tissue as acetochlor, alachlor and butachlor. Although another chloroacetanilide, propachlor, produces a precursor of a quinoneimine, the available data do not support its tumorigenicity to the nasal turbinates.

B. Identification of the Candidate Cumulative Assessment Group (CAG).

Once the CMG is defined, a subset of this group, the Common Assessment Group (CAG) is selected, for which the cumulative risk assessment will be performed. This final selection incorporates into the CAG those pesticides from the Common Mechanism Group whose uses, routes, and pathways of exposure will present sufficient exposure and hazard potential to warrant inclusion in the quantitative estimates of risk.

The CMG subject of this document consists of acetochlor, alachlor and butachlor.   At present only alachlor and acetochlor are Registered pesticides in the US. There are no registered uses or import tolerances for butachlor.   Therefore no exposure, and hence, no risk is expected for butachlor .   **Thus, a cumulative risk assessment will be performed using a CAG comprising only acetochlor and alachlor** (Figure 1).



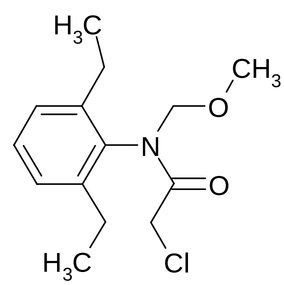


Figure 1. Structures of Acetochlor (left) and Alachlor (right)

C. Dose Response Analysis: Determination of Relative Potency Factors and Points of Departure.

The Agency's revised Guidelines for Carcinogen Risk Assessment (USEPA, 2005b) divide dose response assessment into two parts. The first is assessment of the dose response near the lower end of the observed range (the point of departure or POD). The second part is extrapolation of the dose-response curve from the POD into the low-dose range.

Once the POD is determined, it is used as the starting point for subsequent extrapolations and analyses. If data are available, biologically based dose-response (BBDR) modeling may be done to extrapolate to lower doses below the POD. In the absence of BBDR models, for linear extrapolation (i.e. genotoxic carcinogens), the POD may be used to calculate a *slope factor*, and for non-linear extrapolation (the present case for acetochlor and alachlor) the POD may be used in the calculation of a Margin of Exposure (MOE)

The revised Guidelines for Carcinogen Risk Assessment (USEPA, 2005b), discuss the relative advantages of several approaches to obtaining the POD for cancer risk assessment:

● *When tumor data are used*, a POD is obtained from the modeled tumor incidences. Conventional cancer bioassays, with approximately 50 animals per group, generally can support modeling down to an increased incidence of 1–10%. A *no-observed-adverse-effect level* (NOAEL) generally is not used for assessing the potential for carcinogenic response when one or more models can be fitted to the data.

● *When good quality precursor data are available and are clearly tied to the mode of action of the compound of interest*, models that include both tumors and their precursors may be advantageous for deriving a POD. Such models can provide insight into quantitative relationships between tumors and precursors, possibly suggesting the precursor response level that is associated with a particular tumor response level.

On the other hand, the Guidelines note, that if the precursor data are drawn from small samples or if the quantitative relationship between tumors and precursors is not well defined, then the tumor data will provide a more reliable POD.

In this document, tumor incidences will be used for POD determination because they constitute a robust set of data and use of observed tumor NOAELs will be used as a conservative screening approach. Since experimental NOAELs are determined by the doses selected by the investigator, the "true NOAEL" may actually be a higher value.

i. Determination of the POD using nasal tumor incidences.

Table 1 summarizes the incidences of nasal tumors in rats treated chronically with acetochlor or alachlor.

Table 1. Incidence of nasal tumors in rat chronic studies.

#	Study (MRID)	Dose Level (mg/kg/day)							
		Males				**Females**			
Acetochlor Tumors (Sprague-Dawley rats)									
#1	**PR-80-006 (00131088, 40484801)**	**0**	**22**	**69**	**250**	**0**	**30**	**93**	**343**
	papillary adenoma	0/69	1/70	6/69*	18/69**	0/69	0/68	2/70	1/69
	pap. adenocarcinom.	0/69	0/70	0/69	2/69	0/69	0/69	0/70	0/69
	Combined	ND	ND	ND	ND	ND	ND	ND	ND
#2	**ML-83-200 (40077601)**	**0**	**2**	**10**	**50**	**0**	**2**	**10**	**50**
	papillary adenoma[a]	1/58**	0/54	0/58	12/59**	0/69**	0/69	0/67	19/68**
#3	**88/SUC017/0348 (41592004)**	**0**	**0.67**	**6.37**	**66.9**	**0**	**0.88**	**8.53**	**92.1**
	papillary adenoma	0/69**	0/59	0/59	35/70**	0/69**	0/57	0/58	36/63**
	carcinom.	0/69	0/59	0/59	2/70	0/69	0/57	0/58	1/63
	Combined	0/69**	0/59	0/59	37/70**	0/69**	0/57	0/58	37/63**
Alachlor Tumors (Long-Evans rats)									
#1	**BD-77-421 (00091050)**	**0**	**14**	**42**	**126**	**0**	**14**	**42**	**126**
	Adenoma	0/46**	0/47	10/41	23/40**	0/47**	0/41	4/41	10/41**
	Carcinoma	0/27	0/20	1/21	0/19	0/34	0/28	1/34	0/22
	Combined	0/46**	0/47	11/41	23/40**	0/47**	0/41	5/41	10/41**
# 2	**EHL 800218 (00075709)**	**0**	**0.5**	**2.5**	**15**	**0**	**0.5**	**2.5**	**15**
	Adenoma	0/45**	0/47	0/45	11/45**	0/38**	0/38	1/43	9/34**

* = p≤0.05; ** = p≤0.01. ; [a] Only adenomas reported.

For **Acetochlor**, examination of the data in Table 1 indicates that the incidence of nasal tumors in Sprague-Dawley rats increases significantly with dose in all three studies.

- Study **PR-80-006** (MRIDs 00131088 and 40484801), does not define a NOAEL at 22 mg/kg/day for nasal olfactory epithelium tumors. Even though the incidence of papillary adenomas is only 1/70 and is not statistically significant *vs* controls, it is considered to be treatment-related due to the rarity of the tumor. It is likely that it is the beginning of the dose response, which reaches statistical significance for the two other higher doses in males.

- In study **ML-83-200** (MRID 40077601), likewise, the incidence of adenomas of the olfactory epithelium at the highest dose tested is statistically significantly higher than in controls. No carcinomas were reported. This study defines a NOAEL for adenomas of 10 mg/kg/day.

- In study **88/SUC017/0348** (MRID 41592004), the incidence of adenomas and combined adenomas/carcinomas of the olfactory epithelium at the highest dose tested is statistically significantly higher than in controls. No nasal tumors occurred at lower doses. Thus, the NOAEL for combined adenomas/carcinomas in female rats is 8.53 mg/kg bw/day. A similar pattern is evident for male rats: yielding a NOAEL for combined adenomas/carcinomas of 6.37 mg/kg bw/day.

Thus, the available data define a POD for acetochlor of 10 mg/kg/day for nasal tumors in S-D rats.

For **Alachlor**, examination of the data in Table 1, indicates that the incidences of nasal tumors in Long-Evans rats increases significantly with dose in both studies.

- Study **BD-77-421** (MRID 00091050), in Long-Evans rats, was conducted at dose levels of approximately 0, 14, 42 or 126 mg/kg bw/day using technical alachlor stabilized with 0.5% epichlorohydrin for the first eleven months of the study before a switch was made to stabilization with epoxidized soybean oil for the rest of the study. Epichlorohydrin is carcinogenic for male Wistar and Sprague-Dawley rats: when given in drinking water epichlorohydrin has been found to cause forestomach tumors (squamous cell papillomas and carcinomas) in Wistar rats (Konishi, et al.,1980). By the inhalation route, epichlorohydrin has caused squamous cell carcinomas of the nasal cavity (Laskin, et al., 1980). Although nasal tumors were observed in this study, these results are confounded by the nasal tumorigenic properties of epichlorohydrin. Results from the above study involving the administration of alachlor in the presence of epichlorhydrin will not be used for determining the POD for alachlor due to the confounding effect of the epichlorohydrin.

- In study **EHL 800218** (MRID 00075709), the incidences of adenomas of the nasal olfactory epithelium were statistically significantly increased in high-dose Long-Evans rats of both sexes (Table1). No carcinomas were reported.

Although the incidence of tumors in female rats at the mid-dose (2%) is not statistically significant, it may be considered toxicologically significant in view of the rarity of the tumors and the significantly increasing trend in the incidence of nasal tumors. Thus, for female rats the NOAEL for nasal tumors is 0.5 mg/kg bw/day.

Thus, the available data define a POD for alachlor of 0.5 mg/kg/day for nasal tumors in Long-Evans rats.

Determination of a Relative Potency Factor for Acetochlor.

The POD values (based on NOAELs) used in the risk assessment in this document are summarized in Table 2. The POD for acetochlor is 10 mg/kg/day and the POD for alachlor is 0.5 mg/kg/day. Relative Potency Factors (USEPA 2002a) were calculated using the ratio of POD values (based on NOAELs) for alachlor as (index chemical) and acetochlor. As shown in Table 2, the RPFs for alachlor and acetochlor are 1 and 0.05, respectively.

Table 2. Summary of POD values for Nasal Tumors in Rats Treated Chronically in the Diet with Acetochlor or Alachlor (Values from Table 1).

Compound	**POD (Mg/kg bw/day)**	**RPF[1]**	**Rat Strain/Sex**	**Comments**
Alachlor (Index Chemical)	0.5	1	Long-Evans / Female	A conservative value, the incidence of 1/43 at 2.5 may well be the beginning of the dose response of a rare tumor, and thus toxicologically significant.
Acetochlor	10	0.05	Sprague-Dawley / Male & Female	The incidence is 1/70 at 22 mg/kg/day in study PR-80-006. This effect is likely toxicologically significant.

[1] With Alachlor as index chemical; RPF = POD of alachlor divided by the POD of acetochlor. Acetochlor (in alachlor equivalents) = Concentration of acetochlor x RPF.

D. **Exposure Analysis**

This assessment is designed to determine if the two chemicals in the chloroacetanilide CAG (Acetochlor and Alachlor) pose a cumulative dietary risk. There are no residential uses for these two chemicals. Thus, this risk assessment involves :

- Only two pathways (food and drinking water) and the oral route of exposure.
- Because the endpoint of interest is a cancer endpoint that arises via a mode of action that requires prolonged exposure, only a chronic analysis was performed.

i. Inputs for Determination of Exposure from Foods and Water

i.a. Inputs From Foods.

Acetochlor. The qualitative nature of acetochlor residues in plants is understood based on the adequate metabolism studies. Tolerances have been established (see 40 CFR 180.470) for residues of alachlor in/on a variety of food and feed commodities:

- Field corn (forage, grain and stover)
- Sorghum (forage, grain and stover)
- Soybeans(forage, grain and hay)
- Wheat (forage, grain and straw)

Considering the data from the available animal metabolism and feeding studies and the calculated maximum theoretical dietary burdens (MTDBs) of 3.0-3.8 ppm for cattle and 0.04 ppm for poultry and swine, the Agency concluded that there is no reasonable expectation of quantifiable residues of acetochlor or its metabolites occurring in livestock commodities, thus no tolerances have been established for those commodities.

Alachlor. The qualitative nature of alachlor residues in plants is understood based on adequate metabolism studies. Tolerances have been established (see 40 CFR 180.249) for residues of alachlor in/on a variety of food and feed commodities:

- beans, which includes dry beans, lima beans, forage and fodder;
- corn, fresh sweet, and forage, fodder, and grain;
- eggs;
- milk;
- peanuts, forage, hay, and hulls;
- sorghum, fodder, forage, and grain;
- soybeans, forage, and hay;
- meat and meat byproducts of cattle, goats, hogs, poultry and horses.

i. b. Inputs from Water

Introduction.

The primary source data for the water component of this exposure assessment is a data set generated by the Acetochlor Registration Partnership (ARP; the registrant for acetochlor) which **directly evaluated both acetochlor and alachlor occurrence in drinking water supplies relying on surface water sources over a 7-year period (1995 – 2001).**

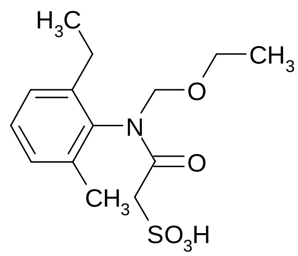
This assessment does not use ground water exposure levels because ground-water monitoring data show that both parent acetochlor and parent alachlor are less prevalent and usually at lower chronic levels in ground water than in surface water (USEPA, 2006).

Additionally, the ARP monitored water levels of the **sulfonic and oxanilic environmental degradates of acetochlor and alachlor** shown in Figure 2. These compounds, however, are not included in this cumulative risk assessment because extensive data are available (USEPA 2004b) to show that these compounds show a different toxicological profile than the respective parents and do not contribute to the development of nasal olfactory epithelium tumors in rats.

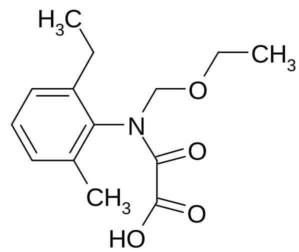
The ARP selected a total of 175 Community Water Supplies (CWSs) in nine mid-western and three Mid-Atlantic States for the acetochlor and alachlor surface water monitoring program. The selection process was designed to include a wide array of CWSs with watersheds in areas of corn production, with an emphasis on including worst-case watersheds i.e., smaller watersheds (not on the Great Lakes and Continental Rivers) in areas of high corn production. These watersheds are expected to have higher concentrations of acetochlor and alachlor after runoff events than larger watersheds which drain areas of both high and low corn production, because dilution would be greater for CWSs taking water from the Great Lakes and Continental Rivers. Data were collected to characterize each community water system included in the program. Since there were some CWSs replaced during the course of the 7-year study, a total of 189 systems were included in the study. Raw (pre-treatment) water was only collected and analyzed for selected systems; therefore, only 44 of the CWSs have monitoring data for residues in both treated and untreated water. Further details on the design of the Surface Drinking Water Supply (SDWS) study by the ARP can be found in "Drinking Water Exposure Assessment for Acetochlor" (M. Barrett, OPP/EFED Memorandum, 1/3/2005) and USEPA (2006).

The surface drinking water supply (SDWS) and state ground water (SGW) monitoring programs were designed to focus on areas of high acetochlor/alachlor use. The monitoring does not cover the entire geographic distribution of acetochlor use.

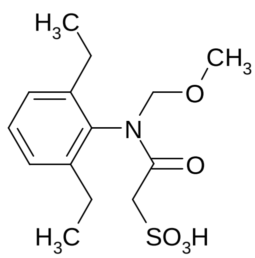
Geographic analysis of the SDWS site locations and acetochlor/alachlor use patterns seems to indicate that a number of high acetochlor/alachlor use areas were not monitored. This is especially true for the SDWS where the lack of sampling of raw (pre-facility treatment) water at most locations makes it difficult to isolate the effects of site-specific usage and vulnerability factors and water treatment processes on the observed residue levels. Additionally, important caveats for the monitoring data are described in more detail in the EFED Memorandum cited above.



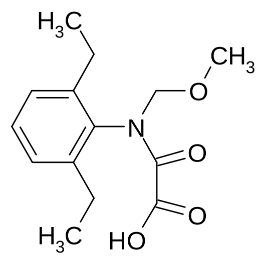
Acetochlor ethane sulfonic acid (Acetochlor ESA)



Acetochlor oxanilic acid (Acetochlor OXA)



Alachlor ethane sulfonic acid (Alachlor ESA)



Alachlor oxanilic acid (Alachlor OXA)

Figure 2. Environmental degradates of acetochlor and alachlor

Monitored Water Concentrations.

A chronic toxicity endpoint (nasal olfactory epithelium tumors) is used in this document for cumulative risk assessment of chloroacetanilides. Thus, multi-year monitored annual means for drinking water appear most appropriate for evaluation of risk relating to the selected chronic endpoint and are used for the calculations reported in this assessment. However, to further bracket the maximum potential risk associated with uncertainties in the cumulative exposure to acetochlor and alachlor in drinking water, two additional risk assessments using more conservative assumptions (one of them using PRZM/EXAMS modeling) are detailed in the Appendices.

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Prior to calculating the multi-year monitored annual means for drinking water, the single-year values were examined. The single-year co-occurring Time-Weighed Annualized Mean (TWAM) concentrations of acetochlor and corresponding alachlor in the ARP SDWS study were ranked separately in decreasing order of acetochlor and alachlor. The top six values for acetochlor appear in Table 3 and the top six values for alachlor appear in Table 4.

There were significant differences in the community water supply systems with the highest residues (TWAMs) of acetochlor and alachlor (Tables 3 and 4, respectively). All of the systems with the highest residues of alachlor had finished water sampled and were not among the sites for which raw water samples were collected and analyzed. Although the highest alachlor exposure levels were lower than for acetochlor, the difference was not great. The alachlor TWAM for the 518-US-OH site in 1997 was 0.590 ppb, slightly lower than the second highest TWAM observed for acetochlor (compare Tables 3 and 4. Four of the six highest alachlor TWAMs (Table 4) occurred in three different community water supply systems in the state of Kansas; this is a state which has relatively little corn production acreage compared to Illinois and several other Corn Belt states. This may reflect significant alachlor usage on sorghum, which is a more important crop in Kansas. Five of the highest acetochlor TWAMs (Table 3) occurred in the state of Illinois.

As shown in Tables 3 and 4, the highest co-occurring TWAM for Acetochlor in surface waters was the value from site 214-GI-IL (1.428 ppb, Table 3) and for Alachlor the highest value was found in site 518-US-OH (0.590 ppb, Table 4).

Table 3. Top six **co-occurring** single-year Time-Weighed Annual Mean concentrations (TWAM) of acetochlor and corresponding alachlor TWAMs in the ARP SDWS study.[1]

Site ID	Year	Water Type	Acetochlor TWAM (ppb)	Alachlor TWAM (ppb)
214-GI-IL	1996	Finished	**1.428**	0.009
168-PA-IL	1998	Raw	0.591	0.015
455-MO-OH	1997	Finished	0.584	0.121
166-NE-IL	1996	Finished	0.533	0.048
214-GI-IL	1998	Finished	0.489	0.009
168-PA-IL	1998	Finished	0.475	0.011

[1] Co-occurring acetochlor/alachlor concentrations were ranked in decreasing values for **acetochlor** for each year. The highest value for acetochlor (1.428 ppb) is in bold.

Table 4. Top six **co-occurring** single-year Time-Weighed Annual Mean concentrations (TWAM) of alachlor and corresponding acetochlor TWAMs in the ARP SDWS study [1] (No raw water samples were in the top six).

Site ID	Year	Water Type	Acetochlor TWAM (ppb)	Alachlor TWAM (ppb)
518-US-OH	1997	Finished	0.202	**0.590**
23-WE-KS	2001	Finished	0.004	0.406
340-NV-IN	1996	Finished	0.372	0.357
114-RI-KS	1997	Finished	0.002	0.345
125-TO-KS	1996	Finished	0.089	0.269
125-TO-KS	1999	Finished	0.115	0.234

[1] Co-occurring acetochlor/alachlor concentrations were ranked in decreasing values for **alachlor** for each year. The highest value for alachlor (0.590 ppb) is in bold.

Combined Co-occurring Acetochlor and Alachlor Concentrations

To conduct the risk assessment, the single-year, co-occurring, acetochlor and alachlor TWAM water concentrations in surface waters in the ARP SDWS study, were combined using Relative Potency Factors (RPF). The concentrations were combined using the RPF factor of 0.05 (in Table 2) for acetochlor with alachlor as the index chemical. The concentrations, expressed as "alachlor equivalents" , were averaged for each site over the years (up to 7 years) for which data were available and the averages were ranked in decreasing order (Table 5). **The maximum value for this ranking (0.286 ppm) was used for MOE calculations with DEEM-FCID™ .**

Table 5. Top ten **co-occurring** Multi-Year Time-Weighed Mean concentrations (TWAM) of alachlor and acetochlor in the ARP SDWS study **expressed as Alachlor equivalents**, [1] (No raw water samples were in the top ten).

Site ID	No. Of Years[2] with data	Water Type	Acetochlor TWAM (ppb)	Alachlor TWAM (ppb)	TWAM in Alachlor Equivalents (ppb)
340-NV-IN	2	Finished	0.205	0.276	**0.286**
125-TO-KS	7	Finished	0.069	0.158	0.155
23-WE-KS	4	Finished	0.004	0.147	0.147
114-RI-KS	3	Finished	0.001	0.144	0.144
408-DE-OH	6	Finished	0.129	0.110	0.104
518-US-OH	7	Finished	0.135	0.103	0.096
451-ML-OH	7	Finished	0.157	0.093	0.085
330-LO-IN	3	Finished	0.232	0.090	0.078
172-FA-IL	7	Finished	0.118	0.083	0.077
355-SC-IN	7	Finished	0.065	0.082	0.079

[1] Co-occurring acetochlor/alachlor concentrations (TWAMs) were converted to alachlor equivalents using an RPF (0.05) and ranked in decreasing values for **alachlor** for each year. The highest value for alachlor equivalents (0.286 ppb) is in bold and was used in risk assessment.
[2] Number of years for which water monitoring data were available during 1995-2001.

Table 6 summarizes the surface water multi-year TWAM concentrations (ppb) from the ARP SDWS study and their percentiles and median. The **combined concentrations**

Acetochlor plus Alachlor (in Alachlor equivalents) were used for the Margin-of-Exposure (MOE) calculations with **DEEM-FCID™** analysis.

Table 6. Summary of Surface Water Exposure Values for Acetochlor + Alachlor (in Alachlor equivalents) used for Risk Assessment[1,2].

Chemical	**Maximum Multi year TWAM (ppb)**	**Percentiles (ppb)**			**Median (ppb)**
		99.5th	**99th**	**95th**	
Acetochlor	0.282	0.235	0.208	0.125	0.015
Alachlor	0.276	0.162	0.148	0.074	0.008
Acetochlor + Alachlor (in Alachlor equivalents)[3]	0.286	0.166	0.149	0.078	0.009

[1] Multi year Time-Weighed Annualized Means (TWAM) in surface water from the ARP monitoring program for Chloroacetanilides (SDWS study). Values are maximum TWAM values (in ppb), 99.5th , 99th and 95th percentiles (in ppb) and median (in ppb) observed for all sites **(189 sites)** . Represents predominantly TWAMs calculated from a series of finished water samples, although for a minority of sampled systems the ARP also regularly monitored raw (pre-treatment) water.

[2] Data from EFED's Cumulative Drinking Water Exposure Assessment for Chloroacetanilides, USEPA (2006).

[3] Acetochlor concentration (in alachlor equivalents) = Acetochlor concentration x **RPF**.
Where RPF = $NOAEL_{Alachlor}$ **/** $NOAEL_{Acetochlor}$ = (0.5 mg/kg/day) **/** (10 mg/kg/day) = 0.05. NOAEL (i.e. POD) values were obtained from Table 2. Each acetochlor concentration was converted to alachlor equivalents and then added to its respective co-occurring alachlor concentration. Then, the sums were averaged for each site over the years of available data, ranked in descending order and the maximum TWAM was selected for risk assessment.

ii. DEEM-FCID™ Analysis of Exposure From Foods and Water.

Acetochlor chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96 and 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events.

Based on analysis of the 1994-96 and 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (less than 1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

DEEM-FCID™ Analysis of the Data.

As summarized below , two types of **DEEM-FCID™** runs were done: **(1) DEEM-FCID™** runs to obtain the cumulative Margin-of Exposure (MOE) and **(2) DEEM-FCID™** runs with each separate chemical to obtain MOE values for each chemical separately, to identify the risk-driving chemical.

1. Cumulative Margin-of-Exposure (MOE) values were obtained using the following commodity and water inputs:

- **Alachlor** commodity values were the anticipated residues, as estimated for the alachlor RED document of 1998, corrected for percent crop treated. The anticipated residue values are summarized in Attachment 1, obtained from USEPA (1998). The percent crop treated values that were used are current values (year 2004) determined by USEPA/OPP/BEAD and summarized in Attachment 2. It is noted that the anticipated residues used in this assessment are from field trial data,The anticipated residue values are summarized in Attachment 1, obtained from USEPA (1998). thus the fact that they were obtained 8-9 years ago does not make them obsolete as would be the case if monitoring data had been used.

- **Acetochlor** commodity values were tolerance values refined through the use of experimentally determined processing factors and average percent crop treated data These values were obtained from the acetochlor TRED (USEPA 2005c). These acetochlor values were converted into alachlor equivalents by multiplying them by 0.05 (the RPF for acetochlor). The alachlor equivalents from acetochlor were then added to their counterparts for alachlor (the index chemical).

Detailed guidance for these calculations appears in Section 9.5 (Expression of Cumulative Risk - Combining Multiple-Pathway Risk) of the Guidance on Cumulative Risk Assessment of Pesticide Chemicals (USEPA 2002b).

- For **Drinking Water** inputs multi-year averages were used. The Single-Year Water TWAM concentrations of acetochlor co-occurrent with alachlor from the ARP-SDWS study were converted into alachlor equivalents using RPFs and added to the co-occurrent alachlor TWAM concentration values. The monitoring data for each site were averaged over the years of data availability (up to 7 years) to obtain a multi-year average. The multi-year averages were ranked from smallest to largest and the highest value was used for risk assessment. The results of such calculations are shown in Table 5. The value used for risk assessment, in alachlor equivalents is **0.286 ppb** from site 340-NV-IN. Additionally, various percentiles and the median were calculated for the distribution of multi-year averages. These values are shown in Table 6.

2. MOE values were obtained for each chemical alone using the following commodity and water inputs:

- **Alachlor** commodity values were the same as above for (1).

- **Acetochlor** commodity values were the same above for (1), except that they were not converted to alachlor equivalents.

- **Water** values were multi-year average values for concentration for each chemical in the ARP SDWS study. For acetochlor the value was 0.282 ppb, (See Table 6). For alachlor the value was 0.276 ppb (See Table 6).

E. The Cumulative Risk assessment

This section contains the results of the DEEM-FCID™ runs performed as discussed in Section D.

The following Tables report MOEs for some populations, including the U.S. Population (Total) and the results for the population groups that have the **highest** and the **lowest** MOE values. The MOE values for additional populations appear in Attachments 4, 6, and 8.

i. Cumulative DEEM Analysis using the RPF Method (Attachments 3 and 4): Acetochlor expressed as Alachlor equivalents.

Commodity levels and water concentrations for acetochlor were converted into alachlor equivalents using the RPF factor of 0.05 (see Tables 2, 5 and 6) and added to those of alachlor. The combined surface water TWAM concentration used was 0.286 ppm, instead of the separate concentrations used for each chemical in case 2 below (0.282 ppb for acetochlor and 0.276 ppb for alachlor).

As shown in Table 7, the lowest MOE (non nursing infants) is 13,175 and the MOE for the U.S. Population (Total) is 40,119. Results for other populations not listed in the Table, appear in Attachment 4.

Table 7. **Cumulative MOE for Alachlor and Acetochlor using the RPF method. (Acetochlor is expressed as Alachlor equivalents):** Highest and Lowest chronic MOE values obtained using DEEM-FCID for various population subgroups exposed to Acetochlor or Alachlor.

Population subgroup	**Exposure (mg/kg/day)**	**Cumulated MOE (MOE_T)**
U.S. Population (Total)	0.000012	40,119
All infants (less than 1 year old)	0.000030	16, 464
Non-nursing infants	0.000038	13,175 (lowest)
Females (13-19) not preg. or nursing	0.000009	53,237
Children 1-2	0.000037	13, 595
Children 3-5	0.000028	17, 815
Children 6-12	0.000018	27,875
Youth 13-19	0.000010	47, 799
Adults 20-49	0.000010	52, 303
Females 13-49	0.000010	52, 171
Adults 50+ years old	0.000009	54, 027

[1] **Acetochlor** and **Alachlor** were refined as described in the text.

[2] Acetochlor was converted to alachlor equivalents using the RPF method. Acetochlor concentration (in alachlor equivalents) = Acetochlor concentration x **RPF.** . Where **RPF** = $NOAEL_{Alachlor}$ **/** $NOAEL_{Acetochlor}$ = (0.5 mg/kg/day) **/** (10 mg/kg/day), NOAEL (i.e. POD) values from Table 2. *For water*, each acetochlor concentration was converted to alachlor equivalents and then added to its respective co-occurring alachlor concentration. Then, the sums were averaged for each site over the years of data availability (up to 7 years), ranked in descending order and the maximum multi year average was selected for risk assessment. *For agricultural commodities*, each value was multiplied by the RPF of 0.05 (as described above and added to the respective value for alachlor.

[3] Parameters used for the chronic DEEM-FCID runs for **alachlor as the Index Chemical** were:
(a) Water concentration: Max.Multiyear TWAM, from Table 6 for (alachlor + acetochlor) in alachlor equivalents = 0.286 ppb.
(b) POD (i.e NOAEL) for Alachlor = 0.5 mg/kg/day (From Table 2).
(c) Anticipated residues for alachlor as summarized in USEPA (1998) and also in Attachment 1 and correction for percent crop treated from Attachment 2.

ii. DEEM analysis for Acetochlor (Attachments 5 and 6) and Alachlor (Attachments 7 and 8) as separate chemicals.

In order to identify the risk-driving compound in the cumulative analysis, MOE values were also obtained each compound separately. As summarized above, anticipated residues corrected for percent crop treated were used for alachlor and tolerance levels corrected for processing factors and percent crop treated were used for acetochlor.

Water concentrations for each chemical were the maximum multiple-year average concentration for all sites (0.282 ppb for acetochlor and 0.286 ppb for alachlor) in the ARP SDWS study.

As shown in Table 8, under the exposure conditions used, the MOE values for acetochlor are much higher than those for alachlor (nearly 10-fold). The lowest MOE for alachlor is 13,636 (Children 1-2 years) and the U.S. Population (Total) has an MOE of 40,813. All MOEs for acetochlor exceed 160,000 and the U.S. Population Total has an MOE of 392,207. From this information one may conclude **that alachlor, under the exposure levels covered, is the risk driving component of the cumulative assessment group (CAG).**

Table 8. **DEEM Analysis for Acetochlor alone and Alachlor alone:** Highest and Lowest chronic MOE values obtained using DEEM-FCID for various population subgroups exposed to Acetochlor or Alachlor.

Chemical	Population subgroup	Exposure (mg/kg/day)	MOE
Acetochlor [1]	U.S. Population (Total)	0.000025	392,207
	Non-nursing infants	0.000062	160,914 (lowest)
	Females (13-19) not preg. or nurs.	0.000026	377,562
	Seniors 55+	0.000015	676,613 (highest)
Alachlor [2]	U.S. Population (Total)	0.000012	40,813
	Non-nursing infants	0.000035	14,109
	Females (13-19) not preg. or nurs.	0.000009	56,016 (highest)
	Children 1-2 years	0.000037	13,636 (lowest)

[1] **Acetochlor** was refined as follows: Tolerance levels for RACs corrected for percent crop treated and for production factors, as shown in Table 11. **Alachlor** was refined as follows: Anticipated Residues [as summarized in Alachlor RED, Tables 18 and 19, December 1998, USEPA (1998)] corrected for percent crop treated, as shown in Table 12.

[2] Parameters used for the chronic DEEM-FCID runs for acetochlor were:
(a) Water concentration: Max. Multi year average concentration for Acetochlor (alone) = 0.282 ppb.
(b) POD (i.e. NOAEL) for Acetochlor = 10 mg/kg/day (From Table 2)
(c) Tolerances for acetochlor from 40CFR(§180.470) July 2004 Edition.

[3] Parameters used for the chronic DEEM-FCID runs for alachlor were:
(a) Water concentration: Max. Multi year average concentration for alachlor = 0.276 ppb.
(b) POD (i.e NOAEL) for Alachlor = 0.5 mg/kg/day (From Table 2).
(c) Anticipated residues for alachlor as summarized in Attachment 1 (From USEPA 1998) and correction for percent crop treated (See Attachment 2).

F. Characterization of the Risk Assessment

A cumulative risk assessment of a Cumulative Assessment Group (CAG) of Chloroacetanilide pesticides has been conducted. The CAG for this document consists of two chemicals: alachlor and acetochlor. An original member of the Common Mechanism Group, butachlor, has been excluded from the present risk assessment because at present there are no registered tolerances for this chemical.

The selected endpoint for risk assessment (development of nasal tumors in rats) has been attributed to a non-linear, non mutagenic mode of action involving sustained cytotoxicity and regenerative cell proliferation. Thus, as per the 2005 EPA Cancer

Guidelines (USEPA 2005b) a Margin-of-Exposure (MOE) calculation has been used for the cumulative risk assessment, as one would do for a threshold noncancer toxicity risk assessment. Because of the threshold approach that is being used for risk assessment, the uncertainty factors (UFs) of 10 (interspecies) and 10 (intraspecies) are used. In the absence of sensitivity issues the FQPA factor is 1. Thus, MOEs above 100 are considered to be outside of the Agency's level of concern (LOC).

i. Toxicological Considerations

The CAG members in this document were evaluated on their common mode of action for the production of tumors of the nasal olfactory epithelium in rats. Although this endpoint is observed in at least two strains of rats, it has not been observed in mice. Experiments conducted *in vitro* with primate tissues and other evidence, did not rule out that these tumors could also occur in humans (USEPA, 2004). No epidemiological cancer data are available.

The existing evidence is clearly supportive of the non-linear, non-genotoxic mode of action in the causation of tumors of the nasal olfactory epithelium in rats (USEPA 2004). Thus, in accordance with The Agency's revised Guidelines for Carcinogen Risk Assessment (USEPA, 2005b), an approach akin to the oral *reference dose* approach, MOE calculations, has being followed in this document to assess risk.

Under FQPA, the potential for increased sensitivity to adverse effects from a pesticide to children during gestation and postnatal development must be considered. As discussed in the following lines, no evidence has been found that the developing fetus or young animal has increased sensitivity, compared to the adult, to chloroacetanilide - induced nasal olfactory epithelial tumors.

A rat multigeneration reproductive toxicity study on acetochlor (MRID 45357503), in which nasal tissues were examined microscopically in F0 and F1 parental animals, provides an opportunity to compare nasal olfactory epithelial tumor incidence from exposure during development to incidence in adult rats exposed in carcinogenicity studies on acetochlor, as shown below in Table 9.

The Table shows that a similar dose threshold for nasal epithelial hyperplasia and neoplasia was observed in all of the studies. No nasal tumors were observed in the reproductive study at 19-22 mg/kg/day. A single nasal tumor was seen in a male at 38 mg/kg/day in a carcinogenicity study. At $\geq$57 mg/kg/day, a positive dose-response for nasal tumor incidence was observed. A single finding of papillary hyperplasia was also seen in a carcinogenicity study at 20 mg/kg/day in males, but not in the reproductive study. The higher tumor incidence in F1 animals compared to F0 at mid and high dose probably reflected both higher F1 test material intake between postnatal Day 29 and Week 6 (during which food consumption was not recorded) and additional exposure time during gestation and lactation. However, the tumor incidence in the reproductive study was comparable to the carcinogenicity studies at similar dose levels. Tumor latency also was not affected by early exposure. In the reproductive study, tumors were observed in parental F0 and F1 rats at 130-154 days.

Table 9. : Comparison of nasal epithelial tumor incidence in the reproductive toxicity and carcinogenicity studies in the rat[1].

	MALES		FEMALES	
Study Type/MRID Dose in ppm	Dietary Intake (mg/kg/day)	Incidence of Nasal Tumors (%)	Dietary Intake (mg/kg/day)	Incidence of Nasal Tumors (%)
Reproductive toxicity[2]				
F0 200 ppm	21	0	22	0
F1 200 ppm	19	0	22	0
F0 600 ppm	57	0	65	0
F1 600 ppm	66	12	71	4
F0 1750 ppm	166	15	198	23
F1 1750 ppm	196	31	216	65
Chronic toxicity/carcinogenicity[3]	38	1	45	0
500 ppm	64	17	76	27
1000 ppm	131	53	150	57
1750 ppm				

[1] Table adapted from Table 5 of MRID 46081801. Intake values represent the average daily intake of acetochlor during the first ten weeks of the chronic toxicity/carcinogenicity studies and during the initial ten-week premating periods from the reproductive toxicity study.
[2] MRID 45357503
[3] Dose levels are taken from three different studies: MRIDs 00131088/40484801, 40077601 and 41592004.

The carcinogenicity studies on acetochlor show tumors in the interim (12-month) sacrifice animals, but no data are available at earlier times. However, a nasal epithelial cell proliferation study on acetochlor showed proliferation by 160 days (MRID 44496207). In published studies on alachlor in rats, nasal tumors were reported by 5-6 months of exposure, with increased cellular proliferation at 3-4 months (Gentner *et al.*, 2002). From these data, it is concluded that the POD of 10 mg/kg/day is adequately protective during development.

ii. Exposure Considerations

Evaluation of dietary exposure has been done with limited refinement and thus it considered to an overestimation of exposure overall. The calculated cumulative MOEs were greater than 13,000 for all population sub-groups and 40,119 for the Total U.S. Population.

To assess the significance of these MOEs, it is noted that compared to the MOE of 100, defined as the level of concern (LOC) for this cumulative risk assessment, the cumulated MOE values (greater than 13,000) reported in this document for the subject CAG, are well outside the Agency's LOC.

Table 10 shows how the MOE increases as smaller percentiles of the distribution of alachlor equivalents in water (See Table 8, alachlor + acetochlor) are utilized in cumulative MOE calculations. At the 99.5 percentile, all MOE values exceed 15,000.

Table 10. Cumulative MOEs for Various Populations at various percentiles of alachlor equivalents in water[1].

Population Group	MOE at Maximum Multi-year TWAM (ppb)	MOE at the following percentiles		
		99.5	99	95
U.S. Population	40,119	50,334	52,218	61,891
All Infants (less than1 year old)	16,464	22,649	23,921	31,259
Children (1-2)	13,595	15,142	15,390	16,519
Children (3-5)	17,815	20,336	20,788	22,757
Children (6-12)	27, 875	32,234	32,964	36,408
Youth (13-19)	47,799	57,923	59,714	68,573
Adults (20-49)	52,303	69,463	72,849	91,470
Females (13-49)	52,171	69,136	72,474	90,785
Adults (50+ years)	54,027	73,854	77,904	101,049

[1] The DEEM-FCID™ runs used the same food values used in Table 7. The maximum Multi-year TWAM concentrations in alachlor equivalents (0.286 ppb) and the percentiles shown in Table 6 (99.5, 99, and 95 percentiles) corresponding to multi-year TWAM concentrations of 0.166, 0.149 and 0.078 ppb, respectively, were used in the DEEM-FCID™ runs,

IV. Conclusions

A risk assessment of a Cumulative Assessment Group (CAG) consisting of the Chloroacetanilide pesticides acetochlor and alachlor has been conducted. MOE calculations have been made based on the endpoint of nasal olfactory epithelium tumors in rats, and using slightly refined values for food and drinking water, Compared to a MOE of 100, defined as level of concern (LOC) for this risk assessment, the cumulated MOE values, greater than 13,000 for the subject CAG for all populations, are outside the Agency's level of concern.

Because these cumulative MOE values were obtained using high-end exposures, they are considered to be conservative. Additional MOE calculations in Appendixes 1 and 2, using more conservative approaches to estimation of drinking-water exposure, support the conclusions of this analysis by producing MOE values that exceed the LOC of 100 by nearly an order of magnitude or more.

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VII. Appendices

To bracket the maximum potential risk associated with uncertainties in the cumulative exposure to acetochlor and alachlor in drinking water, two additional risk assessments have been performed using more conservative assumptions for the determination of exposure to chloroacetanilides in water.

The cumulative risk assessment done in the main text used **Monitored Multi-Year** TWAM concentrations of chloroacetanilides in drinking water. In contrast, the cumulative risk assessments in Appendices 1 and 2 used the following more conservative approaches for determination of exposure to chloroacetanilides in drinking water:

- The risk assessment in Appendix 1, uses **Monitored Single-Year** TWAM concentrations of chloroacetanilides in drinking water. Single-year TWAMs will contain still the higher values of water concentrations that get averaged out in obtaining the multi-year TWAMs.

- The risk assessment in Appendix 2 uses **PRZM-EXAMS modeled estimates** of environmental concentrations of alachlor and acetochlor in drinking water to address potential limitations in the monitored data.

Outside of inputs for drinking water, all other inputs to **DEEM-FCID™** are the same as those for the cumulative risk assessment in the main body of the this document: Both risks assessments in the Appendices use:

- The same POD values for nasal tumors in rats summarized in Table 2 of the main body of this document: Alachlor is the index chemical with a POD of 0.5 mg/kg bw/day and acetochlor has a POD of 10 mg/kg bw/day. The RPF to convert acetochlor exposure to alachlor equivalents is thus 0.05.

- The same **DEEM-FCID™** inputs for exposure to foods, described in Section D.i.a. (Input from Foods) of the main body of this document for alachlor and acetochlor.

A. Appendix 1.

Cumulative Risk Assessment: Use of Monitored Single-Year TWAM Concentrations of Alachlor and Acetochlor in Water.

i. Introduction.

The multi year monitored annual means for drinking water used in the main part of this document are generally most appropriate for evaluation of risk relating to chronic endpoints such as the nasal olfactory epithelium tumors identified as the common mode of action for chloroacetanilides. However, to allow for the potential of higher exposure at unmonitored sites or with change use patterns or weather conditions, we use in this Appendix the single-year annual means from modeling to estimate high-end lifetime exposure levels.

In general, the highest single-year exposure levels for acetochlor plus alachlor (in alachlor equivalents (0.6 ppb Tables A1-1 and A1-2 of this Appendix) were a little more than double the respective highest multi-year exposure levels (0.286 ppb, Tables 5 and 6 of the main document). Noteworthy is that most of the highest annual mean concentrations were observed from sets of finished water samples and all of the top ten exposure sites expressed as alachlor toxic equivalents were from finished water. Data on treatment effects on alachlor or acetochlor concentrations were available from some sites showing that treatment at these sites typically removed from 30 to 90% of the alachlor equivalent residues.

ii. Combined Co-occurring Acetochlor and Alachlor Concentrations

The risk assessment conducted in this Appendix uses the same POD values and **DEEM-FCID™** inputs for food as the risk assessment in the main body of the document Thus, this section focuses only on the specification of the **DEEM-FCID™** inputs for drinking water concentrations of the chloroacetanilides.

To conduct the risk assessment for this Appendix, the single-year, co-occurring, acetochlor and alachlor TWAM water concentrations in surface waters in the ARP SDWS study, were combined using Relative Potency Factors (RPF). The concentrations were combined using the RPF factor of 0.05 (in Table 2, of the main document) for acetochlor with alachlor as the index chemical. The concentrations, expressed as "alachlor equivalents" , were then ranked in decreasing order (Table A1-1, below), and the maximum value (**0.600 ppb**) corresponding to the site 518-US-OH for 1997 was used for the risk assessment in this Appendix.

Table A1-1. Top six **co-occurring** single-year Time-Weighed Annual Mean concentrations (TWAM) of alachlor and acetochlor in the ARP SDWS study **expressed as Alachlor equivalents**, [1] (No raw water samples were in the top six).

Site ID	Year	Water Type	Acetochlor TWAM (ppb)	Alachlor TWAM (ppb)	TWAM in Alachlor Equivalents (ppb)
518-US-OH	1997	Finished	0.202	0.590	**0.600**
23-WE-KS	2001	Finished	0.004	0.406	0.406
340-NV-IN	1996	Finished	0.372	0.357	0.376
114-RI-KS	1997	Finished	0.002	0.345	0.345
125-TO-KS	1996	Finished	0.089	0.269	0.273
125-TO-KS	1999	Finished	0.115	0.234	0.247

[1] Co-occurring acetochlor/alachlor concentrations (TWAMs) were converted to alachlor equivalents using an RPF (0.05) and ranked in decreasing values for **alachlor** for each year. The highest value for alachlor (0.600 ppb) is in bold and was used in risk assessment.

Table A1-2 summarizes the surface water single-year TWAM concentrations (ppb) from the ARP SDWS study. The table shows the maxima for alachlor and acetochlor alone and for combined concentrations of alachlor plus acetochlor (in alachlor equivalents) plus their percentiles. It is apparent that the concentrations of combined alachlor plus acetochlor decline very rapidly, so that the 99.5th percentile (0.240 ppb) is quite comparable to the maximum value for the multi-year TWAM concentration (0.286 ppb) used for the risk assessment in the main body of this document.

Table A1-2. Summary of Surface Water Exposure Values used for Risk Assessment[1].

Chemical	Maximum single-year TWAM (ppb)	Percentiles[3] (ppb)			Median (ppb)
		99.5th	99th	95th	
Acetochlor (alone)	1.428[2]	0.458	0.363	0.143	0.008
Alachlor (alone)	0.590	0.232	0.187	0.055	0.007
Acetochlor + Alachlor (in Alachlor equivalents)[4]	0.600	0.240	0.191	0.061	0.08

[1] Single-year Time-Weighed-Annualized-Means (TWAM) in surface water from the ARP monitoring program for Chloroacetanilides (SDWS study). Values are maximum TWAM values (in ppb), 95 th percentiles (in ppb) and medians (in ppb) observed for all sites. Represents predominantly TWAMs calculated from a series of finished water samples, although for a minority of sampled systems the ARP also regularly monitored raw (pre-treatment) water.

[2] Data from EFED's Drinking Water Exposure Assessment for Acetochlor (USEPA, 2006).
[3] Water data furnished by M. Barrett (EFED) on July 21, 2005.

[4] Acetochlor concentration (in alachlor equivalents) = Acetochlor concentration x **RPF**.
Where RPF = $NOAEL_{Alachlor}$ **/** $NOAEL_{Acetochlor}$ = (0.5 mg/kg/day) **/** (10 mg/kg/day) = 0.05. NOAEL (i.e. POD) values were obtained from Table 2. Each acetochlor concentration was converted to alachlor equivalents and then added to its respective co-occurring alachlor concentration. Then, the sums were ranked in descending order and the maximum TWAM was selected for risk assessment.

iii. DEEM-FCID™ Analysis of the Data.

As shown in Table A1-3 the lowest MOE (non nursing infants) is 7,713 and the MOE for the U.S. Population (Total) is 26, 204. Results for additional populations appear in Attachment 10.

TableA1-3 **Cumulative MOE for Alachlor plus Acetochlor using the RPF method with monitored single-year TWAM water concentrations:** Highest and Lowest chronic MOE values obtained using DEEM-FCID for various population subgroups exposed to Acetochlor or Alachlor[1, 2, 3].

Population subgroup	Exposure (mg/kg/day)	Cumulated MOE (MOE_T)
U.S. Population (Total)	0.000019	26,204
All Infants (Less than 1 year old)	0.000052	9,603
Non-nursing infants	0.000065	7,713 (lowest)
Females (13-19) not preg. or nursing	0.000014	35,590 (highest)
Children 1-2 years	0.000047	10,728
Children 3-5 years	0.000037	13,417
Children 6-12 years	0.000024	20,590
Youth 13-19 years old	0.000015	32,799
Adults 20-49	0.000016	31,768
Adults 50+ years old	0.000016	31,734

[1] **Acetochlor** and **Alachlor** were refined as described in the text.
[2] Acetochlor was converted to alachlor equivalents using the RPF method. Acetochlor concentration (in alachlor equivalents) = Acetochlor concentration x **RPF.** . Where **RPF** = $NOAEL_{Alachlor}$ **/** $NOAEL_{Acetochlor}$ = (0.5 mg/kg/day) **/** (10 mg/kg/day), NOAEL (i.e. POD) values from Table 2, in the main body of this document). *For water*, each acetochlor concentration was converted to alachlor equivalents and then added to its respective co-occurring alachlor concentration. Then, the sums were ranked in descending order and the maximum single-year TWAM was selected for risk assessment. *For agricultural commodities*, each value was multiplied by the RPF of 0.05 (as described above and added to the respective value for alachlor).

[3] Parameters used for the chronic DEEM-FCID runs for **alachlor as the Index Chemical** were:
(a) Water concentration: Max. TWAM, from Table A1-1 for alachlor = 0.600 ppb.
(b) POD (i.e NOAEL) for Alachlor = 0.5 mg/kg/day (From Table 2, in the main body of this document).
(c) Anticipated residues for alachlor as summarized in USEPA (1998) and also in Attachment 1 and correction for percent crop treated from Attachment 2.

iv. Conclusions.

A cumulative risk assessment has been done using **Monitored Single-Year TWAM Concentrations** of Alachlor and Acetochlor in drinking water. All other inputs to **DEEM-FCID^{TM}** analysis of the data are the same as those used cumulative risk assessment in the main body of this document.

Compared to an MOE of 100, defined as the level of concern (LOC) for this cumulative risk assessment, the cumulated MOE values, greater than 7, 700 for the subject CAG for all populations, are outside the Agency's level of concern.

B. Appendix 2.

Cumulative Risk Assessment: Use of Modeled (PRZM/EXAMS) Concentrations of Alachlor and Acetochlor in Drinking Water.

i. Introduction.

The main body of this document covers a cumulative risk assessment of chloroacetanilides using the maximum monitored multi year TWAM concentration of alachlor and acetochlor in drinking water (0.286 ppb in alachlor equivalents). Appendix 1 of this document adds conservatism to that assessment by using the maximum single-year TWAM concentration of alachlor and acetochlor in drinking water (0.600 ppb in alachlor equivalents). The present appendix adds further conservatism to the previous cumulative risk assessments by utilizing PRZM/EXAMS-modeled concentrations for the chloroacetanilides in drinking water to address potential limitations in the monitoring data. The PRZM/EXAMS modeling assumes high-use levels and conservative modeling inputs in vulnerable watersheds.

ii. Modeling Based Exposure Estimation.

Crop scenarios only for corn, sorghum, soybeans, sweet corn and dry beans are considered in this assessment since these uses accounted for approximately 99% of all national alachlor usage for the years 2001-2003 according to OPP's BEAD (sweet corn and dry bean use are reflected in the monitoring-based exposure only to the extent that their relatively modest usages intersect with the areas monitored). For acetochlor, only the corn use is registered currently, although applications for registrations on sorghum for grain and sweet corn have been submitted to and are currently being reviewed by EPA. PRZM scenarios were chosen to represent each of these uses by considering state-level use intensity (lbs ai/ A treated) averaged over the three years reported by BEAD in relation to the existing standard PRZM scenarios. Final cumulative modeling exposure was based on alachlor use on corn, sorghum and soybeans and acetochlor use on corn.

Before determining a combined exposure to alachlor and acetochlor (as alachlor equivalents) exposure numbers were obtained for each herbicide from separate modeling runs. PRZM/EXAMS modeling used current maximum label rate, maximum number of applications per year and the minimum application interval. Additional model inputs are detailed in USEPA(2006).

Modeled cumulative exposure estimates are expressed as alachlor equivalents, the sum of alachlor use on corn, sorghum and soybeans and acetochlor use on corn adjusted by the relative potency factor (0.05). Separate estimates for expected environmental concentrations (EEC) of chloroacetanilide (in alachlor equivalents) were calculated for differing ratios of alachlor to acetochlor usage on corn. All cumulative estimates include correction for Percent Crop Area (PCA) and assume 100% of the crop area was treated with the assessed chemical (i.e. there was no correction for percent crop treated, PCT).

iii. PRZM/EXAMS Modeling Results

Cumulative multi year mean estimated environmental concentrations (EEC) of the subject chemicals (as alachlor equivalents) appear in Table A2-1. The three columns of EECs represent the assumptions of 1:0, 1:1, and 0:1 alachlor to acetochlor ratios of use on corn, respectively; assuming exclusivity of use (i.e. either alachlor or acetochlor, but not both, may be used on a given corn field).

The EEC value of 8.94 ppb (alachlor equivalents) for the 50%/50% alachlor to acetochlor scenario was used as drinking water input for **DEEM-FCID™** analysis for risk assessment. The value of 12.81 (for 100% alachlor) was not used as it pertained only to alachlor. As noted in USEPA(2006), the trend has been for the overall alachlor to acetochlor ratio of usage to continue to decline. Thus, the value of 8.94 ppb alachlor equivalents is likely to be more conservative than a value closer to the 5.07 ppb estimated for the 100% acetochlor use.

iv. DEEM-FCID™ Analysis of the Data.

As summarized above, the risk assessment in this appendix employs the same POD values and **DEEM-FCID™** inputs for food as the risk assessment in the main body of the text. The cumulative MOE for alachlor plus acetochlor, using the modeled EEC of 8.94 ppb alachlor equivalents as **DEEM-FCID™** inputs for water concentrations of the chloroacetanilides, is shown in Table A2-3.

The MOE value (not corrected for PCT) for the U.S. population is 2,556; the lowest MOE is 642 for non-nursing infants and the highest is 3,513 for youths 13-19 years old.

Because all EEC estimates assume 100% of the crop area for the three crops was treated with the assessed chemicals, exposure will be overestimated to the extent the actual PCT is less than 100%. For example, screening levels of PCT for alachlor for 2004 (Attachment 3) and for acetochlor for 2003 (USEPA 2005c) were;

- Alachlor: Corn 5%, Sorghum 15%, soybeans <2.5%.
- Acetochlor: Corn 25%

Thus, the actual MOEs are likely to be much larger than those depicted in Table A2-3.

Table A2-1. Cumulative multi year mean estimated environmental concentrations (EEC) of the subject chemicals (as alachlor equivalents).

Watershed Type	Pesticide	EEC (100% alachlor on corn)[1,2] ppb	EEC (50% alachlor, 50% acetochlor on corn) ppb	EEC (100% acetochlor on corn) ppb
High Corn[3]	Both	12.81	8.94	5.07
	Alachlor	12.81	8.89	4.97
	Acetochlor	0.00	0.05	0.10
High Sorghum	Both	5.67	5.31	4.95
	Alachlor	5.67	5.30	4.94
	Acetochlor	0.00	0.00	0.01

[1] All EEC values are presented as ppb in water. Data from USEPA (2006).
[2] The three EEC columns represent assumptions of 1:0, 1:1, and 0:1 alachlor: acetochlor ratios of use on corn, respectively; assuming exclusivity of use (i.e., either alachlor or acetochlor but not both may be used on a given corn field.)
[3] EEC sources used :
IL Corn scenario PRZM-EXAMS multi-year mean (High Corn EEC).
MS Corn scenario PRZM-EXAMS multi-year mean (High Sorghum EEC).
MS Soybean scenario PRZM-EXAMS multi-year mean (both EEC calculation sets).
KS Sorghum scenario PRZM-EXAMS multi-year mean (both EEC calculation sets).

v. Discussion of Monitoring-Based and Modeling Based Cumulative Exposure Estimates

The PRZM/EXAMS modeling in this cumulative assessment is based on estimating exposure concentrations in watersheds in two counties which have the potential to be among the highest exposure sites in the United States. Major reasons for higher (up to 20x) estimates being derived from the modeling are likely due to be the use of assumptions in the modeling input which may lead to overestimation, e.g.; assuming higher pesticide persistence and/or mobility than may actually occur or assuming pesticide usage levels (100% crop land treated with maximum allowable rates) that may not actually occur (and therefore are not reflected in the monitoring data).

The monitoring data automatically reflects actual rates and amounts of use of the pesticide. To the extent that usage of chloroacetanilide herbicides remains level or declines, the highest one-year exposure level observed should rarely if ever be exceeded for a lifetime exposure endpoint (as is being considered in this cumulative risk assessment). Should usage rates increase in the future, the monitoring estimates may no longer being reliable, but the modeling estimates should remain conservative. Future changes in weather or crop production regions resulting in scenarios which produce greater runoff of the pesticide are an unknown that could adversely affect the reliability of both monitoring-based and modeling-based exposure estimates.

vi. Summary of Exposure Considerations: Monitoring vs PRZM/EXAMS modeling

The highest alachlor equivalent single-year mean concentration observed in the ARP SDWS monitoring program is 0.6 ppb, The highest multi-year mean concentration is 0.286 ppb alachlor equivalents, occurring (at a site with only two years of data, Table ; the highest 7-year mean concentration was 0.16 ppb) (Table 5). Evaluation of the USGS NAWQA monitoring dataset indicates concentrations that are roughly equivalent for about the same monitoring period. Maximum cumulative exposure values (assuming maximum possible usage levels) estimated by computer simulation are 5 to 12 ppb alachlor equivalents. The latter value corresponds to an alachlor:acetochlor usage ratio of 1:0; the intermediate value of 8.94 was used for risk assessment, corresponding to an alachlor:acetochlor usage ratio of 1:1.

The modeled values exceed those developed from monitoring data by a factor of 10 to 20, and are likely to represent upper bound exposures to combined residues of alachlor and acetochlor. Given the number of maximum and high-end exposure assumptions discussed in the modeling exposure assessment sections, it is very likely that exposures in CWS across the country will not exceed predicted modeling levels. In addition, given the decline in alachlor use across the US and the lower toxicity of acetochlor, it is likely that the current annual cumulative alachlor equivalents exposure levels in the most vulnerable CWS watersheds may fall below the 0.6 to 12 ppb range estimated from monitoring data and computer simulation models. In the event there would be changes in the future to a higher level of usage of alachlor or, to a lesser extent, of acetochlor (e.g., from increased market share on currently registered crops or additions of new uses), exposure levels could increase, but would not be expected to exceed the levels estimated by modeling. Should a higher level of refinement be needed for this exposure assessment, more spatially explicit modeling or evaluation of monitoring data can be performed.

Table A2-3 Cumulative MOE for Alachlor and Acetochlor using the RPF method with modeled PRZM-EXAMS TWAM water concentrations: Highest and Lowest chronic MOE values obtained using DEEM-FCID for various population subgroups exposed to Acetochlor or Alachlor [1, 2, 3]. **Data corrected for PCA but not PCT.**

Population subgroup	Exposure (mg/kg/day)	Cumulated MOE (MOE_T)
U.S. Population (Total)	0.000195	2,566
All Infants (Less than 1 year old)	0.000628	796
Non-nursing infants	0.000779	642 (lowest)
Children 1-2 years	0.000138	1,625
Children 3-5 years	0.000282	1,775
Children 6-12 years	0.000193	2,593
Youth 13-19 years	0.000142	3,513 (highest)
Adults 20-49	0.000179	2,790
Adults 50+ years old	0.000188	2,653

[1] **Acetochlor** and **Alachlor** were refined as described in the text.

[2] Acetochlor was converted to alachlor equivalents using the RPF method. Acetochlor concentration (in alachlor equivalents) = Acetochlor concentration x **RPF.** . Where **RPF** = $NOAEL_{Alachlor}$ **/** $NOAEL_{Acetochlor}$ = (0.5 mg/kg/day) **/** (10 mg/kg/day), NOAEL (i.e. POD) values from Table 2, in the main body of this document). PRISM-EXAMS modeled values were used for water concentrations. 50/50 proportions of acetochlor/alachlor use were assumed. There was correction for PCA but not for PCT. *For agricultural commodities*, each value was multiplied by the RPF of 0.05 (as described above and added to the respective value for alachlor.

[3] Parameters used for the chronic DEEM-FCID runs for **alachlor as the Index Chemical** were:
(a) Water concentration: Max. TWAM, from Table A1-1 for alachlor = 0.600 ppb.
(b) POD (i.e NOAEL) for Alachlor = 0.5 mg/kg/day (From Table 2, in the main body of this document).
(c) Anticipated residues for alachlor as summarized in USEPA (1998) and also in Attachment 2 and correction for percent crop treated from Attachment 3.

vii. Conclusion

A cumulative risk assessment has been done using **PRZM/EXAMS-**modeled EECs of Alachlor and Acetochlor in drinking water. All other inputs to **DEEM-FCID™** analysis of the data are the same as those used cumulative risk assessment in the main body of this document.

The cumulated MOE values observed using the PRZM/EXAMS-modeled EECs are greater than 640 for the subject CAG for all populations. Compared to an MOE of 100, defined as the level of concern (LOC) for this cumulative risk assessment in the main part of this document, these values are outside the Agency's level of concern. Because PCT was not incorporated in the modeling, the reported MOEs are expected to be underestimates of the actual MOEs.

VII. Attachments

Attachment 1. Anticipated Residues in Plant and Livestock Commodities for Alachlor.

Attachment 2. Screening Level Usage analysis (SLUA) for Alachlor.

Attachment 3. DEEM **CRA** (Multi-year) Food and Water Residue Input File.

Attachment 4. DEEM **CRA** (Multi year) Food and Water Results File.

Attachment 5. DEEM **Acetochlor** Alone (Multi year) Food and Water Residue Input File

Attachment 6. DEEM **Acetochlor** Alone (Multi year) Food and Water Results File.

Attachment 7. DEEM **Alachlor** Alone (Multi-year) Food and Water Residue Input File

Attachment 8. DEEM **Alachlor** Alone (Multi year) Food and Water Results File.

Attachment 9. DEEM **CRA** (Single-Year) Food and Water Residue Input File.

Attachment 10. DEEM **CRA** (Single-Year) Food and Water Results File.

Attachment 11. DEEM **CRA** (PRZM-EXAMS) Food and Water Residue Input File.

Attachment 12. DEEM **CRA** (PRZM-EXAMS) Food and Water Results File.

Attachment 1 (page 1 of 3): Anticipated Residues in Plant and Livestock Commodities for Alachlor. From: Reregistration ELEGIBILITY Decision (RED) for Alachlor. U.S. EPA. Office of Prevention, Pesticides and Toxic Substances. EPA 738-R-020. December 1998, pages 81-83.

Table 18: Anticipated Residues, Plant Commodities: Calculations and Summary			
Average Residues from Alachlor Uses			
	Avg. Residue	Proc. Factor	Avg. Residue
Corn- 90% of use was preemergence at 4 lb ai/A, 10% of use was postemergence at 4 lb ai/A or sequential applications (4+2 lb ai/A)			
Corn grain	0.011		0.011
Corn meal		0.91[1]	0.010
Corn oil (refined)		0.12[1]	0.0014
Corn starch		0.19[2]	0.0022
Corn forage[7]	0.21		0.21
Corn silage[7]	0.22		0.22
Corn stover[7]	0.12		0.12
Sweet Corn K+CWHR			
preemergence 4 lb ai/A	0.007		0.007
Peanuts-35% of use was preemergence, 75% of use was cracking			
Peanut hulls[7]	0.38		0.38
Peanut nutmeat	0.15		0.15
Peanut meal[7]		1.37[3]	0.21
Peanut oil (refined)		0.06[3]	0.009
Peanut butter		0.70[3]	0.11
Peanuts, dry roasted		0.75[3]	0.11
Peanuts, oil roasted		0.83[3]	0.12
Sorghum preemergence 4 lb ai/A			
Sorghum grain	0.02		0.02
Sorghum forage[7]	0.29		0.29
Sorghum fodder[7]	0.29		0.29
Sorghum stover[7]	0.2		0.20
Soybeans preemergence 4 lb ai/A			
Soybean grain and soybean full fat and low fat flour	0.105		0.11
Soybean grain dust[7]		6.00[4]	0.63
Soybean hulls[7]		1.22[4]	0.13
Soybean toasted meal (feed)[7]		0.88[4]	0.092
Soybean defatted meal (food)		1.30[4]	0.137
Soybean oil (refined)		0.17[4]	0.018
Soybean protein concentrate		0.32[4]	0.034

Attachment 1 (continued, page 2 of 3):

Table 18: Anticipated Residues, Plant Commodities: Calculations and Summary			
Average Residues from Alachlor Uses			
	Avg. Residue	Proc. Factor	Avg. Residue
Soybean protein isolate		0.21[4]	0.022
Soybean defatted flour			0.090[5]
Soybean forage[7]	1.36		1.36
Soybean hay[7]	2.61		2.61
Dry Beans: preplant incorporated 3 lb ai/A			
Dry beans	0.048	0.20[6]	0.010
Dry lima beans	0.040	0.20[6]	0.008
Bean forage[7]	0.340		0.34
Bean vines[7]	0.396		0.40
Bean hay[7]	0.866		0.87

[1] MRID 00162939
[2] MRID 40788201
[3] MRID 40820601
[4] MRID 00154239, 00154240, 40947101, 41862901 41916301
[5] 4/7 defatted meal + 3/7 protein concentrates and isolates
[6] MRID 40820701
[7] Livestock feed only

In estimating anticipated residues for milk, poultry and eggs, anticipated residues as calculated in Table 18 were used in estimating the dietary burden. (See Table 7 for example of calculation.) Estimated dietary burdens based on these anticipated residues in livestock feeds for cattle, poultry, and swine were determined to be 0.49, 0.20, and 0.27 ppm, respectively. The anticipated residues in livestock commodities were then corrected for the expected recovery in each livestock tissue. Anticipated residue estimates for livestock commodities are listed in Table 19.

Table 19: Anticipated Residues in Livestock Commodities						
Alachlor Feeding Study Results			Estimated Residues			
	Feeding Level (ppm)	Residue (ppb)	Dietary Burden (ppm)	Residue Measured by Method (ppb)	% Residue of Concern Measured by Method	Total Residue of Concern (ppb)
BEEF						
muscle	4.20	1.20	0.53	0.15	38%	0.40
fat	4.20	1.90	0.53	0.24	70%	0.34

Table 19: Anticipated Residues in Livestock Commodities.						
Alachlor Feeding Study Results			Estimated Residues			
	Feeding Level (ppm)	Residue (ppb)	Dietary Burden (ppm)	Residue Measured by Method (ppb)	% Residue of Concern Measured by Method	Total Residue of Concern (ppb)
liver	4.20	7.80	0.53	0.98	58%	1.70
kidney	4.20	8.70	0.53	1.10	68%	1.61
milk	4.20	1.50	0.69	0.25	40%	0.62
POULTRY						
muscle	12.00	1.00	0.09	0.01	34%	0.02
fat	12.00	1.30	0.09	0.01	75%	0.01
liver	4.00	2.10	0.09	0.05	51%	0.09
eggs	4.00	6.90	0.09	0.16	60%	0.26
SWINE						
muscle	4.00	1.30	0.19	0.06	38%	0.16
fat	4.00	2.60	0.19	0.12	70%	0.18
liver	4.00	4.10	0.19	0.19	58%	0.34
kidney	12.00	7.40	0.19	0.12	68%	0.17

Since the dietary exposure assessment is based on field trial data, the anticipated residues are likely to overestimate the dietary exposure because the application rates and timing assumed in the dietary exposure analysis were at the highest rate on the label, which is not necessarily the typical rate used by the applicator. Additionally, residues are likely to degrade from the time that samples are obtained at the farm gate during transportation, processing and storage, prior to consumption. For the livestock commodities, the following assumptions were used: (1) all alachlor metabolite residues found in the livestock animal metabolism studies are residues of concern and (2) the percentage recovery of the analytical method in livestock commodities is based on the percentage of metabolites recovered in metabolism studies. Alachlor metabolites not identified specifically in the metabolism studies may also respond to the analytical method, so the analytical recovery may be higher than estimated.

Percent Crop Treated Data

Percent crop treated (CT) information are from a three year period 1993 - 1995. The FQPA amendments to Section 408(b)(2)(F) of the FFDCA require that if a tolerance relies on percent crop-treated data, that the Agency make a determination as to the reliability of the data. The percent crop treated estimates used by EPA are derived from Federal and private market survey data. Typically, the Agency considers the range of percent crop treated data from a period of several years, and uses

Attachment 2 (Page 1 of 3). Usage Report in Support of Reregistration for Acetochlor.
Screening Level Usage Analysis (SLUA) for (Alachlor)/(01/31/05)

What is a Screening Level Usage Analysis (SLUA)?
It is a summary report of the available usage information for a particular pesticide active ingredient being used on agricultural crops at a national level for the United States.

What does it contain?
- Estimates of pesticide usage for a single active ingredient only.
- Estimates of pesticide usage for agricultural use sitescrops) only.
- Estimates of national level pesticide usage for the United States.
- Estimates of usage for use sites with reported pesticide usage only.
- Estimates of the average & maximum annual percent of crop treated with the pesticide for each agricultural use site.
- Estimates of the average annual pounds of the pesticide applied for each agricultural use site.

What assumptions can I make about the data reported?
- Average pounds of active ingredient applied - Values are calculated by merging pesticide usage data sources together; averaging by year, averaging across all years, & then rounding. (If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)
- Average percent of crop treated - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. (If the estimated value is less than 1, then the value is labeled <1.)
- Maximum percent of crop treated - Value is the single maximum value reported across all data sources, across all years, & rounded up. (If the estimated value is less than 2.5, then the value is labeled <2.5.)

What are the data sources used?
- United States Department of Agriculture's National Agricultural Statistics Service (USDA-NASS) - pesticide usage data from 1998 to 2003.
- National Center on Food and Agriculture Policy (NCFAP) - pesticide usage data from 1997 & is **only** used if data is not available from the other sources.
- Private pesticide market research - pesticide usage data from 1998 to 2003.

What are the limitations to the data?

- There may be instances where registered/labeled uses exist but are not surveyed by the available data sources.
- Lack of reported usage data for the pesticide on a crop does not imply zero usage.
- Cases may occur where usage on a particular use site is noted in the pesticide usage data, but not quantified. In these instances, no usage would be reported in the SLUA for that use site.

Attachment 3 (Page 2 of 3)

- The SLUA does not report estimates of pesticide usage for non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.). A separate request must be made to receive estimates of pesticide usage for non-agricultural use sites.

Who do I contact for further information and/or questions on this SLUA?

- (Jihad Alsadek, Economist, EAB)
- (Jihad Alsadek û 703-308-8140 & alsadek.jihad@epa.gov)

SAS Monday, January 31, 2005 10:45 1

Screening Level Estimates of Agricultural Uses of alachlor
Sorted Alphabetically

OBS	Crop	Lbs. A.I.	Percent Crop Treated Avg.	Max.
1	Apples	<500	<1	<2.5
2	Beans, Dry (NCFAP '97)	300,000		10
3	Beans, Green	6,000	5	15
4	Cabbage	<500	<1	<2.5
5	Corn	4,200,000	5	5
6	Cotton	20,000	<1	<2.5
7	Dry Beans/Peas	200,000	5	5
8	Grapefruit	7,000	5	5
9	Peanuts	30,000	<1	<2.5
10	Peas, Dry (NCFAP '97)	4,000	20	
11	Peas, Green	<500	<1	<2.5
12	Potatoes	2,000	<1	<2.5
13	Pumpkin	<500	<1	<2.5
14	Sorghum	1,500,000	10	15
15	Soybeans	1,300,000	<1	<2.5
16	Spinach	1,000	<1	<2.5
17	Sunflowers	30,000	<1	<2.5
18	Sweet Corn	200,000	15	20
19	Watermelons	2,000	<1	<2.5

Attachment 3 (Page 3 of 3)

All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.
Use of alachlor on this crop may also have occurred in other states.

(slua003k.sas a005a8n.sas alachlor)

Attachment 3. DEEM CRA (Multi-year) Food and Water Residue Input File.

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO (ALA EQUIVS)
1994-98 data
Residue file:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\CRA_Multiyear_Res_File.R98
Adjust. #2 used
Analysis Date 02-24-2006 Residue file dated: 02-24-2006/18:15:30/8
Reference dose (NOEL) = 0.5 mg/kg bw/day
Comment:Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
06030300	6C	Bean, black, seed	0.010000	0.050	1.000	
06030320	6C	Bean, broad, seed	0.010000	0.050	1.000	
06030340	6C	Bean, cowpea, seed	0.010000	0.050	1.000	
06030350	6C	Bean, great northern, seed	0.010000	0.050	1.000	
06030360	6C	Bean, kidney, seed	0.010000	0.050	1.000	
06030380	6C	Bean, lima, seed	0.008000	0.050	1.000	
06030390	6C	Bean, mung, seed	0.010000	0.050	1.000	
06030400	6C	Bean, navy, seed	0.010000	0.050	1.000	
06030410	6C	Bean, pink, seed	0.010000	0.050	1.000	
06030420	6C	Bean, pinto, seed	0.010000	0.050	1.000	
21000440	M	Beef, meat	0.000400	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000400	1.000	1.000	
21000450	M	Beef, meat, dried	0.000400	1.000	1.000	
21000460	M	Beef, meat byproducts	0.000400	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.000400	1.000	1.000	
21000470	M	Beef, fat	0.000340	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.000340	1.000	1.000	
21000480	M	Beef, kidney	0.001610	1.000	1.000	
21000490	M	Beef, liver	0.001700	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.001700	1.000	1.000	
40000930	P	Chicken, meat	0.000020	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.000020	1.000	1.000	
40000940	P	Chicken, liver	0.000090	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.000020	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.000020	1.000	1.000	
40000960	P	Chicken, fat	0.000010	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.000010	1.000	1.000	
40000970	P	Chicken, skin	0.000020	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.000020	1.000	1.000	
06030980	6C	Chickpea, seed	0.010000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.010000	1.000	1.000	
06030990	6C	Chickpea, flour	0.010000	1.000	1.000	
15001200	15	Corn, field, flour	0.000925	1.000	1.000	s
15001201	15	Corn, field, flour-babyfood	0.000925	1.000	1.000	s
15001210	15	Corn, field, meal	0.000875	1.000	1.000	s
15001211	15	Corn, field, meal-babyfood	0.000875	1.000	1.000	s
15001220	15	Corn, field, bran	0.001125	1.000	1.000	s
15001230	15	Corn, field, starch	0.000485	1.000	1.000	s
15001231	15	Corn, field, starch-babyfood	0.000485	1.000	1.000	s
15001240	15	Corn, field, syrup	0.000735	1.000	1.000	s
15001241	15	Corn, field, syrup-babyfood	0.000735	1.000	1.000	s
15001250	15	Corn, field, oil	0.000445	1.000	1.000	s
15001251	15	Corn, field, oil-babyfood	0.000445	1.000	1.000	s
15001270	15	Corn, sweet	0.007000	0.150	1.000	
15001271	15	Corn, sweet-babyfood	0.007000	0.150	1.000	
70001450	P	Egg, whole	0.000260	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.000260	1.000	1.000	
70001460	P	Egg, white	0.000260	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.000260	1.000	1.000	
70001470	P	Egg, yolk	0.000260	1.000	1.000	

70001471	P	Egg, yolk-babyfood	0.000260	1.000	1.000	
23001690	M	Goat, meat	0.000400	1.000	1.000	
23001700	M	Goat, meat byproducts	0.000400	1.000	1.000	
23001710	M	Goat, fat	0.000340	1.000	1.000	
23001720	M	Goat, kidney	0.001610	1.000	1.000	
23001730	M	Goat, liver	0.001700	1.000	1.000	
06031820	6C	Guar, seed	0.010000	1.000	1.000	
06031821	6C	Guar, seed-babyfood	0.010000	1.000	1.000	
24001890	M	Horse, meat	0.000400	1.000	1.000	
06032030	6C	Lentil, seed	0.010000	1.000	1.000	
27002220	D	Milk, fat	0.000620	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.000620	1.000	1.000	
27012230	D	Milk, nonfat solids	0.000620	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.000620	1.000	1.000	
27022240	D	Milk, water	0.000620	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.000620	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.000620	1.000	1.000	
06032580	6C	Pea, pigeon, seed	0.010000	1.000	1.000	
95002630	O	Peanut	0.150000	0.010	1.000	
95002640	O	Peanut, butter	0.110000	0.010	1.000	
95002650	O	Peanut, oil	0.009000	0.010	1.000	
25002900	M	Pork, meat	0.000160	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.000160	1.000	1.000	
25002910	M	Pork, skin	0.000160	1.000	1.000	
25002920	M	Pork, meat byproducts	0.000160	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.000160	1.000	1.000	
25002930	M	Pork, fat	0.000180	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.000180	1.000	1.000	
25002940	M	Pork, kidney	0.000170	1.000	1.000	
25002950	M	Pork, liver	0.000340	1.000	1.000	
60003010	P	Poultry, other, meat	0.000020	1.000	1.000	
60003020	P	Poultry, other, liver	0.000090	1.000	1.000	
60003030	P	Poultry, other, meat byproducts	0.000020	1.000	1.000	
60003040	P	Poultry, other, fat	0.000010	1.000	1.000	
60003050	P	Poultry, other, skin	0.000020	1.000	1.000	
26003390	M	Sheep, meat	0.000400	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.000400	1.000	1.000	
26003400	M	Sheep, meat byproducts	0.000400	1.000	1.000	
26003410	M	Sheep, fat	0.000340	1.000	1.000	
26003411	M	Sheep, fat-babyfood	0.000340	1.000	1.000	
26003420	M	Sheep, kidney	0.001610	1.000	1.000	
26003430	M	Sheep, liver	0.001700	1.000	1.000	
15003440	15	Sorghum, grain	0.002070	1.000	1.000	s
15003450	15	Sorghum, syrup	0.000070	1.000	1.000	aceto
06003470	6	Soybean, seed	0.001950	1.000	1.000	s
06003480	6	Soybean, flour	0.001738	1.000	1.000	s
06003481	6	Soybean, flour-babyfood	0.001738	1.000	1.000	s
06003490	6	Soybean, soy milk	0.001950	1.000	1.000	s
06003491	6	Soybean, soy milk-babyfood or in	0.001950	1.000	1.000	s
06003500	6	Soybean, oil	0.000350	1.000	1.000	s
06003501	6	Soybean, oil-babyfood	0.000350	1.000	1.000	s
50003820	P	Turkey, meat	0.000020	1.000	1.000	
50003821	P	Turkey, meat-babyfood	0.000020	1.000	1.000	
50003830	P	Turkey, liver	0.000090	1.000	1.000	
50003831	P	Turkey, liver-babyfood	0.000090	1.000	1.000	
50003840	P	Turkey, meat byproducts	0.000020	1.000	1.000	
50003841	P	Turkey, meat byproducts-babyfood	0.000020	1.000	1.000	
50003850	P	Turkey, fat	0.000010	1.000	1.000	
50003851	P	Turkey, fat-babyfood	0.000010	1.000	1.000	
50003860	P	Turkey, skin	0.000020	1.000	1.000	
50003861	P	Turkey, skin-babyfood	0.000020	1.000	1.000	
86010000	O	Water, direct, all sources	0.000286	1.000	1.000	s
86020000	O	Water, indirect, all sources	0.000286	1.000	1.000	s
15004010	15	Wheat, grain	0.000060	1.000	1.000	aceto
15004011	15	Wheat, grain-babyfood	0.000060	1.000	1.000	aceto
15004020	15	Wheat, flour	0.000060	1.000	1.000	aceto

15004021	15	Wheat, flour-babyfood	0.000060	1.000	1.000	aceto
15004030	15	Wheat, germ	0.000060	1.000	1.000	aceto
15004040	15	Wheat, bran	0.000060	1.000	1.000	aceto

Attachment 4. DEEM CRA (Multi year) Food and Water Results File.

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U.S. Environmental Protection Agency                                Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO  (ALA EQUIVS)
                                                               (1994-98 data)
Residue file name:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\CRA_Multiyear_Res_File.R
98
                                                   Adjustment factor #2 used.
Analysis Date 02-24-2006/18:41:35     Residue file dated: 02-24-2006/18:15:30/8
NOEL (Chronic) = .5 mg/kg bw/day
COMMENT 1: Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Percent of NOEL	Margin of Exposr 1/
U.S. Population (total)	0.000012	0.00%	40,119
U.S. Population (spring season)	0.000012	0.00%	40,540
U.S. Population (summer season)	0.000013	0.00%	39,041
U.S. Population (autumn season)	0.000012	0.00%	40,206
U.S. Population (winter season)	0.000012	0.00%	40,792
Northeast region	0.000012	0.00%	42,504
Midwest region	0.000013	0.00%	38,934
Southern region	0.000012	0.00%	42,855
Western region	0.000014	0.00%	35,850
Hispanics	0.000015	0.00%	34,027
Non-hispanic whites	0.000012	0.00%	41,259
Non-hispanic blacks	0.000012	0.00%	42,740
Non-hisp/non-white/non-black	0.000015	0.00%	33,389
All infants (< 1 year)	0.000030	0.01%	16,464
Nursing infants	0.000010	0.00%	48,127
Non-nursing infants	0.000038	0.01%	13,175
Children 1-6 yrs	0.000030	0.01%	16,508
Children 7-12 yrs	0.000017	0.00%	29,674
Females 13-19 (not preg or nursing)	0.000009	0.00%	53,237
Females 20+ (not preg or nursing)	0.000009	0.00%	52,829
Females 13-50 yrs	0.000010	0.00%	47,736
Females 13+ (preg/not nursing)	0.000012	0.00%	41,915
Females 13+ (nursing)	0.000014	0.00%	35,668
Males 13-19 yrs	0.000011	0.00%	43,704
Males 20+ yrs	0.000009	0.00%	53,580
Seniors 55+	0.000009	0.00%	54,056
Children 1-2 yrs	0.000037	0.01%	13,595
Children 3-5 yrs	0.000028	0.01%	17,815
Children 6-12 yrs	0.000018	0.00%	27,875
Youth 13-19 yrs	0.000010	0.00%	47,799
Adults 20-49 yrs	0.000010	0.00%	52,303

Adults 50+ yrs	0.000009	0.00%	54,027
Females 13-49 yrs	0.000010	0.00%	52,171

Attachment 5. DEEM Acetochlor Alone (Multi year) Food and Water Residue Input File

```
U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for ACETOCHLOR                      1994-98 data
Residue file:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\acetochlor_tolerance_plus_water_
PF_PCT.R98
                                                              Adjust. #2 used
Analysis Date 02-24-2006            Residue file dated: 02-10-2006/18:53:10/8
Reference dose (NOEL) = 10 mg/kg bw/day
Comment:DEEM analysis with foods & water (max TWAM)
--------------------------------------------------------------------------------
Food Crop                                     Residue      Adj.Factors      Comment
EPA Code  Grp  Food Name                       (ppm)
                                                            #1         #2
-------- ---- ------------------------------   ---------- ------     ------   -------
15001200 15   Corn, field, flour                0.050000   0.600      0.250   PF & %
  Full comment: PF & %CT, resp.
15001201 15   Corn, field, flour-babyfood       0.050000   0.600      0.250
15001210 15   Corn, field, meal                 0.050000   0.600      0.250
15001211 15   Corn, field, meal-babyfood        0.050000   0.600      0.250
15001220 15   Corn, field, bran                 0.050000   1.000      0.250
15001230 15   Corn, field, starch               0.050000   0.600      0.250
15001231 15   Corn, field, starch-babyfood      0.050000   0.600      0.250
15001240 15   Corn, field, syrup                0.050000   1.000      0.250
15001241 15   Corn, field, syrup-babyfood       0.050000   1.000      0.250
15001250 15   Corn, field, oil                  0.050000   0.600      0.250
15001251 15   Corn, field, oil-babyfood         0.050000   0.600      0.250
15003440 15   Sorghum, grain                    0.020000   1.000      0.070
15003450 15   Sorghum, syrup                    0.020000   1.000      0.070
06003470 6    Soybean, seed                     0.100000   1.000      0.170
06003480 6    Soybean, flour                    0.100000   0.750      0.170
06003481 6    Soybean, flour-babyfood           0.100000   0.750      0.170
06003490 6    Soybean, soy milk                 0.100000   1.000      0.170
06003491 6    Soybean, soy milk-babyfood or in  0.100000   1.000      0.170
06003500 6    Soybean, oil                      0.100000   0.200      0.170
06003501 6    Soybean, oil-babyfood             0.100000   0.200      0.170
86010000 O    Water, direct, all sources        0.000282   1.000      1.000   Modele
  Full comment: Modeled data
86020000 O    Water, indirect, all sources      0.000282   1.000      1.000   modele
  Full comment: modeled data
15004010 15   Wheat, grain                      0.020000   1.000      0.060
15004011 15   Wheat, grain-babyfood             0.020000   1.000      0.060
15004020 15   Wheat, flour                      0.020000   1.000      0.060
15004021 15   Wheat, flour-babyfood             0.020000   1.000      0.060
15004030 15   Wheat, germ                       0.020000   1.000      0.060
15004040 15   Wheat, bran                       0.020000   1.000      0.060
```

Attachment 6. DEEM Acetochlor Alone (Multi year) Food and Water Results File.

```
U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for ACETOCHLOR                      (1994-98 data)
Residue file name:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\acetochlor_tolerance_plus_water_
PF_PCT.R98
                                                    Adjustment factor #2 used.
Analysis Date 02-24-2006/19:01:10     Residue file dated: 02-10-2006/18:53:10/8
NOEL (Chronic) = 10 mg/kg bw/day
COMMENT 1: DEEM analysis with foods & water (max TWAM)
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Percent of NOEL	Margin of Exposr 1/
U.S. Population (total)	0.000025	0.00%	392,207
U.S. Population (spring season)	0.000026	0.00%	389,031
U.S. Population (summer season)	0.000027	0.00%	373,685
U.S. Population (autumn season)	0.000025	0.00%	402,977
U.S. Population (winter season)	0.000025	0.00%	405,066
Northeast region	0.000023	0.00%	441,111
Midwest region	0.000027	0.00%	371,253
Southern region	0.000025	0.00%	396,985
Western region	0.000027	0.00%	370,738
Hispanics	0.000029	0.00%	349,586
Non-hispanic whites	0.000025	0.00%	404,820
Non-hispanic blacks	0.000027	0.00%	370,887
Non-hisp/non-white/non-black	0.000027	0.00%	371,089
All infants (< 1 year)	0.000049	0.00%	202,383
Nursing infants	0.000016	0.00%	630,390
Non-nursing infants	0.000062	0.00%	160,914
Children 1-6 yrs	0.000051	0.00%	195,033
Children 7-12 yrs	0.000038	0.00%	259,840
Females 13-19 (not preg or nursing)	0.000026	0.00%	377,562
Females 20+ (not preg or nursing)	0.000018	0.00%	553,328
Females 13-50 yrs	0.000023	0.00%	442,705
Females 13+ (preg/not nursing)	0.000022	0.00%	459,752
Females 13+ (nursing)	0.000024	0.00%	419,157
Males 13-19 yrs	0.000034	0.00%	295,184
Males 20+ yrs	0.000020	0.00%	489,163
Seniors 55+	0.000015	0.00%	676,613
Children 1-2 yrs	0.000050	0.00%	200,888
Children 3-5 yrs	0.000054	0.00%	186,331
Children 6-12 yrs	0.000040	0.00%	251,336
Youth 13-19 yrs	0.000030	0.00%	331,081
Adults 20-49 yrs	0.000022	0.00%	462,509
Adults 50+ yrs	0.000015	0.00%	660,144
Females 13-49 yrs	0.000021	0.00%	468,331

Attachment 7. DEEM Alachlor Alone (Multi-year) Food and Water Residue Input File

```
U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for ALACHLOR                        1994-98 data
Residue file:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\alachlor_Avg_Res_SLUA_PCT_Water.
R98
                                                             Adjust. #2 used
Analysis Date 02-24-2006            Residue file dated: 02-10-2006/19:05:02/8
Reference dose (NOEL) = 0.5 mg/kg bw/day
Comment:Risk Assessment using Average residues
--------------------------------------------------------------------------------
```

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
06030300	6C	Bean, black, seed	0.010000	0.050	1.000	
06030320	6C	Bean, broad, seed	0.010000	0.050	1.000	
06030340	6C	Bean, cowpea, seed	0.010000	0.050	1.000	
06030350	6C	Bean, great northern, seed	0.010000	0.050	1.000	
06030360	6C	Bean, kidney, seed	0.010000	0.050	1.000	
06030380	6C	Bean, lima, seed	0.008000	0.050	1.000	
06030390	6C	Bean, mung, seed	0.010000	0.050	1.000	
06030400	6C	Bean, navy, seed	0.010000	0.050	1.000	
06030410	6C	Bean, pink, seed	0.010000	0.050	1.000	
06030420	6C	Bean, pinto, seed	0.010000	0.050	1.000	
21000440	M	Beef, meat	0.000400	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000400	1.000	1.000	
21000450	M	Beef, meat, dried	0.000400	1.000	1.000	
21000460	M	Beef, meat byproducts	0.000400	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.000400	1.000	1.000	
21000470	M	Beef, fat	0.000340	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.000340	1.000	1.000	
21000480	M	Beef, kidney	0.001610	1.000	1.000	
21000490	M	Beef, liver	0.001700	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.001700	1.000	1.000	
40000930	P	Chicken, meat	0.000020	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.000020	1.000	1.000	
40000940	P	Chicken, liver	0.000090	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.000020	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.000020	1.000	1.000	
40000960	P	Chicken, fat	0.000010	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.000010	1.000	1.000	
40000970	P	Chicken, skin	0.000020	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.000020	1.000	1.000	
06030980	6C	Chickpea, seed	0.010000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.010000	1.000	1.000	
06030990	6C	Chickpea, flour	0.010000	1.000	1.000	
15001200	15	Corn, field, flour	0.011000	1.000	1.000	
15001201	15	Corn, field, flour-babyfood	0.011000	0.050	1.000	
15001210	15	Corn, field, meal	0.010000	0.050	1.000	
15001211	15	Corn, field, meal-babyfood	0.010000	0.050	1.000	
15001220	15	Corn, field, bran	0.010000	0.050	1.000	
15001230	15	Corn, field, starch	0.002200	0.050	1.000	
15001231	15	Corn, field, starch-babyfood	0.002200	0.050	1.000	
15001240	15	Corn, field, syrup	0.002200	0.050	1.000	
15001241	15	Corn, field, syrup-babyfood	0.002200	0.050	1.000	
15001250	15	Corn, field, oil	0.001400	0.050	1.000	
15001251	15	Corn, field, oil-babyfood	0.001400	0.050	1.000	
15001270	15	Corn, sweet	0.007000	0.150	1.000	
15001271	15	Corn, sweet-babyfood	0.007000	0.150	1.000	
70001450	P	Egg, whole	0.000260	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.000260	1.000	1.000	
70001460	P	Egg, white	0.000260	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.000260	1.000	1.000	

70001470 P	Egg, yolk	0.000260	1.000	1.000	
70001471 P	Egg, yolk-babyfood	0.000260	1.000	1.000	
23001690 M	Goat, meat	0.000400	1.000	1.000	
23001700 M	Goat, meat byproducts	0.000400	1.000	1.000	
23001710 M	Goat, fat	0.000340	1.000	1.000	
23001720 M	Goat, kidney	0.001610	1.000	1.000	
23001730 M	Goat, liver	0.001700	1.000	1.000	
06031820 6C	Guar, seed	0.010000	1.000	1.000	
06031821 6C	Guar, seed-babyfood	0.010000	1.000	1.000	
24001890 M	Horse, meat	0.000400	1.000	1.000	
06032030 6C	Lentil, seed	0.010000	1.000	1.000	
27002220 D	Milk, fat	0.000620	1.000	1.000	
27002221 D	Milk, fat - baby food/infant for	0.000620	1.000	1.000	
27012230 D	Milk, nonfat solids	0.000620	1.000	1.000	
27012231 D	Milk, nonfat solids-baby food/in	0.000620	1.000	1.000	
27022240 D	Milk, water	0.000620	1.000	1.000	
27022241 D	Milk, water-babyfood/infant form	0.000620	1.000	1.000	
27032251 D	Milk, sugar (lactose)-baby food/	0.000620	1.000	1.000	
06032580 6C	Pea, pigeon, seed	0.010000	1.000	1.000	
95002630 O	Peanut	0.150000	0.010	1.000	
95002640 O	Peanut, butter	0.110000	0.010	1.000	
95002650 O	Peanut, oil	0.009000	0.010	1.000	
25002900 M	Pork, meat	0.000160	1.000	1.000	
25002901 M	Pork, meat-babyfood	0.000160	1.000	1.000	
25002910 M	Pork, skin	0.000160	1.000	1.000	
25002920 M	Pork, meat byproducts	0.000160	1.000	1.000	
25002921 M	Pork, meat byproducts-babyfood	0.000160	1.000	1.000	
25002930 M	Pork, fat	0.000180	1.000	1.000	
25002931 M	Pork, fat-babyfood	0.000180	1.000	1.000	
25002940 M	Pork, kidney	0.000170	1.000	1.000	
25002950 M	Pork, liver	0.000340	1.000	1.000	
60003010 P	Poultry, other, meat	0.000020	1.000	1.000	
60003020 P	Poultry, other, liver	0.000090	1.000	1.000	
60003030 P	Poultry, other, meat byproducts	0.000020	1.000	1.000	
60003040 P	Poultry, other, fat	0.000010	1.000	1.000	
60003050 P	Poultry, other, skin	0.000020	1.000	1.000	
26003390 M	Sheep, meat	0.000400	1.000	1.000	
26003391 M	Sheep, meat-babyfood	0.000400	1.000	1.000	
26003400 M	Sheep, meat byproducts	0.000400	1.000	1.000	
26003410 M	Sheep, fat	0.000340	1.000	1.000	
26003411 M	Sheep, fat-babyfood	0.000340	1.000	1.000	
26003420 M	Sheep, kidney	0.001610	1.000	1.000	
26003430 M	Sheep, liver	0.001700	1.000	1.000	
15003440 15	Sorghum, grain	0.020000	0.100	1.000	
06003470 6	Soybean, seed	0.110000	0.010	1.000	
06003480 6	Soybean, flour	0.110000	0.010	1.000	
06003481 6	Soybean, flour-babyfood	0.110000	0.010	1.000	
06003490 6	Soybean, soy milk	0.110000	0.010	1.000	
06003491 6	Soybean, soy milk-babyfood or in	0.110000	0.010	1.000	
06003500 6	Soybean, oil	0.018000	0.010	1.000	
06003501 6	Soybean, oil-babyfood	0.018000	0.010	1.000	
50003820 P	Turkey, meat	0.000020	1.000	1.000	
50003821 P	Turkey, meat-babyfood	0.000020	1.000	1.000	
50003830 P	Turkey, liver	0.000090	1.000	1.000	
50003831 P	Turkey, liver-babyfood	0.000090	1.000	1.000	
50003840 P	Turkey, meat byproducts	0.000020	1.000	1.000	
50003841 P	Turkey, meat byproducts-babyfood	0.000020	1.000	1.000	
50003850 P	Turkey, fat	0.000010	1.000	1.000	
50003851 P	Turkey, fat-babyfood	0.000010	1.000	1.000	
50003860 P	Turkey, skin	0.000020	1.000	1.000	
50003861 P	Turkey, skin-babyfood	0.000020	1.000	1.000	
86010000 O	Water, direct, all sources	0.000276	1.000	1.000	Multiy
Full comment: Multi year Ave TWAM					
86020000 O	Water, indirect, all sources	0.000276	1.000	1.000	Multiy
Full comment: Multi year Ave TWAM					

Attachment 8. DEEM Alachlor Alone (Multi year) Food and Water Results File.

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U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for ALACHLOR                       (1994-98 data)
Residue file name:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\alachlor_Avg_Res_SLUA_PCT_Water.
R98
                                                        Adjustment factor #2 used.
Analysis Date 02-24-2006/18:57:00     Residue file dated: 02-10-2006/19:05:02/8
NOEL (Chronic) = .5 mg/kg bw/day
COMMENT 1: Risk Assessment using Average residues
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Percent of NOEL	Margin of Exposr 1/
U.S. Population (total)	0.000012	0.00%	40,813
U.S. Population (spring season)	0.000012	0.00%	41,596
U.S. Population (summer season)	0.000013	0.00%	39,792
U.S. Population (autumn season)	0.000012	0.00%	40,708
U.S. Population (winter season)	0.000012	0.00%	41,265
Northeast region	0.000012	0.00%	43,434
Midwest region	0.000012	0.00%	40,349
Southern region	0.000011	0.00%	44,113
Western region	0.000014	0.00%	35,173
Hispanics	0.000016	0.00%	30,682
Non-hispanic whites	0.000012	0.00%	42,911
Non-hispanic blacks	0.000011	0.00%	43,585
Non-hisp/non-white/non-black	0.000015	0.00%	34,155
All infants (< 1 year)	0.000028	0.01%	17,621
Nursing infants	0.000010	0.00%	51,227
Non-nursing infants	0.000035	0.01%	14,109
Children 1-6 yrs	0.000031	0.01%	16,357
Children 7-12 yrs	0.000017	0.00%	29,199
Females 13-19 (not preg or nursing)	0.000009	0.00%	56,016
Females 20+ (not preg or nursing)	0.000009	0.00%	54,593
Females 13-50 yrs	0.000011	0.00%	47,417
Females 13+ (preg/not nursing)	0.000012	0.00%	41,713
Females 13+ (nursing)	0.000015	0.00%	33,824
Males 13-19 yrs	0.000011	0.00%	45,092
Males 20+ yrs	0.000009	0.00%	55,118
Seniors 55+	0.000009	0.00%	55,311
Children 1-2 yrs	0.000037	0.01%	13,636
Children 3-5 yrs	0.000029	0.01%	17,467
Children 6-12 yrs	0.000018	0.00%	27,470
Youth 13-19 yrs	0.000010	0.00%	49,690
Adults 20-49 yrs	0.000009	0.00%	53,970
Adults 50+ yrs	0.000009	0.00%	55,460
Females 13-49 yrs	0.000009	0.00%	54,053

Attachment 9. CRA (Single-Year TWAM)-DEEM Food and Water Residue Input File (Page 1 of 3).

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO (ALA EQUIVS)
1994-98 data
Residue file:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\Cum_acet_ala_Avg_Res_SLUA_PCT_Water(equiv).R98
Adjust. #2 used
Analysis Date 09-16-2005 Residue file dated: 09-16-2005/16:31:17/8
Reference dose (NOEL) = 0.5 mg/kg bw/day
Comment:Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
06030300	6C	Bean, black, seed	0.010000	0.050	1.000	
06030320	6C	Bean, broad, seed	0.010000	0.050	1.000	
06030340	6C	Bean, cowpea, seed	0.010000	0.050	1.000	
06030350	6C	Bean, great northern, seed	0.010000	0.050	1.000	
06030360	6C	Bean, kidney, seed	0.010000	0.050	1.000	
06030380	6C	Bean, lima, seed	0.008000	0.050	1.000	
06030390	6C	Bean, mung, seed	0.010000	0.050	1.000	
06030400	6C	Bean, navy, seed	0.010000	0.050	1.000	
06030410	6C	Bean, pink, seed	0.010000	0.050	1.000	
06030420	6C	Bean, pinto, seed	0.010000	0.050	1.000	
21000440	M	Beef, meat	0.000400	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000400	1.000	1.000	
21000450	M	Beef, meat, dried	0.000400	1.000	1.000	
21000460	M	Beef, meat byproducts	0.000400	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.000400	1.000	1.000	
21000470	M	Beef, fat	0.000340	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.000340	1.000	1.000	
21000480	M	Beef, kidney	0.001610	1.000	1.000	
21000490	M	Beef, liver	0.001700	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.001700	1.000	1.000	
40000930	P	Chicken, meat	0.000020	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.000020	1.000	1.000	
40000940	P	Chicken, liver	0.000090	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.000020	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.000020	1.000	1.000	
40000960	P	Chicken, fat	0.000010	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.000010	1.000	1.000	
40000970	P	Chicken, skin	0.000020	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.000020	1.000	1.000	
06030980	6C	Chickpea, seed	0.010000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.010000	1.000	1.000	
06030990	6C	Chickpea, flour	0.010000	1.000	1.000	
15001200	15	Corn, field, flour	0.000925	1.000	1.000	s
15001201	15	Corn, field, flour-babyfood	0.000925	1.000	1.000	s
15001210	15	Corn, field, meal	0.000875	1.000	1.000	s
15001211	15	Corn, field, meal-babyfood	0.000875	1.000	1.000	s
15001220	15	Corn, field, bran	0.001125	1.000	1.000	s
15001230	15	Corn, field, starch	0.000485	1.000	1.000	s
15001231	15	Corn, field, starch-babyfood	0.000485	1.000	1.000	s
15001240	15	Corn, field, syrup	0.000735	1.000	1.000	s
15001241	15	Corn, field, syrup-babyfood	0.000735	1.000	1.000	s
15001250	15	Corn, field, oil	0.000445	1.000	1.000	s
15001251	15	Corn, field, oil-babyfood	0.000445	1.000	1.000	s

15001270	15	Corn, sweet	0.007000	0.150	1.000	
15001271	15	Corn, sweet-babyfood	0.007000	0.150	1.000	
70001450	P	Egg, whole	0.000260	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.000260	1.000	1.000	
70001460	P	Egg, white	0.000260	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.000260	1.000	1.000	
70001470	P	Egg, yolk	0.000260	1.000	1.000	
70001471	P	Egg, yolk-babyfood	0.000260	1.000	1.000	
23001690	M	Goat, meat	0.000400	1.000	1.000	
23001700	M	Goat, meat byproducts	0.000400	1.000	1.000	
23001710	M	Goat, fat	0.000340	1.000	1.000	
23001720	M	Goat, kidney	0.001610	1.000	1.000	
23001730	M	Goat, liver	0.001700	1.000	1.000	
06031820	6C	Guar, seed	0.010000	1.000	1.000	
06031821	6C	Guar, seed-babyfood	0.010000	1.000	1.000	
24001890	M	Horse, meat	0.000400	1.000	1.000	
06032030	6C	Lentil, seed	0.010000	1.000	1.000	
27002220	D	Milk, fat	0.000620	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.000620	1.000	1.000	
27012230	D	Milk, nonfat solids	0.000620	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.000620	1.000	1.000	
27022240	D	Milk, water	0.000620	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.000620	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.000620	1.000	1.000	
06032580	6C	Pea, pigeon, seed	0.010000	1.000	1.000	
95002630	O	Peanut	0.150000	0.010	1.000	
95002640	O	Peanut, butter	0.110000	0.010	1.000	
95002650	O	Peanut, oil	0.009000	0.010	1.000	
25002900	M	Pork, meat	0.000160	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.000160	1.000	1.000	
25002910	M	Pork, skin	0.000160	1.000	1.000	
25002920	M	Pork, meat byproducts	0.000160	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.000160	1.000	1.000	
25002930	M	Pork, fat	0.000180	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.000180	1.000	1.000	
25002940	M	Pork, kidney	0.000170	1.000	1.000	
25002950	M	Pork, liver	0.000340	1.000	1.000	
60003010	P	Poultry, other, meat	0.000020	1.000	1.000	
60003020	P	Poultry, other, liver	0.000090	1.000	1.000	
60003030	P	Poultry, other, meat byproducts	0.000020	1.000	1.000	
60003040	P	Poultry, other, fat	0.000010	1.000	1.000	
60003050	P	Poultry, other, skin	0.000020	1.000	1.000	
26003390	M	Sheep, meat	0.000400	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.000400	1.000	1.000	
26003400	M	Sheep, meat byproducts	0.000400	1.000	1.000	
26003410	M	Sheep, fat	0.000340	1.000	1.000	
26003411	M	Sheep, fat-babyfood	0.000340	1.000	1.000	
26003420	M	Sheep, kidney	0.001610	1.000	1.000	
26003430	M	Sheep, liver	0.001700	1.000	1.000	
15003440	15	Sorghum, grain	0.002070	1.000	1.000	s
15003450	15	Sorghum, syrup	0.000070	1.000	1.000	aceto
06003470	6	Soybean, seed	0.001950	1.000	1.000	s
06003480	6	Soybean, flour	0.001738	1.000	1.000	s
06003481	6	Soybean, flour-babyfood	0.001738	1.000	1.000	s
06003490	6	Soybean, soy milk	0.001950	1.000	1.000	s
06003491	6	Soybean, soy milk-babyfood or in	0.001950	1.000	1.000	s
06003500	6	Soybean, oil	0.000350	1.000	1.000	s
06003501	6	Soybean, oil-babyfood	0.000350	1.000	1.000	s
50003820	P	Turkey, meat	0.000020	1.000	1.000	
50003821	P	Turkey, meat-babyfood	0.000020	1.000	1.000	
50003830	P	Turkey, liver	0.000090	1.000	1.000	
50003831	P	Turkey, liver-babyfood	0.000090	1.000	1.000	
50003840	P	Turkey, meat byproducts	0.000020	1.000	1.000	
50003841	P	Turkey, meat byproducts-babyfood	0.000020	1.000	1.000	

50003850	P	Turkey, fat	0.000010	1.000	1.000	
50003851	P	Turkey, fat-babyfood	0.000010	1.000	1.000	
50003860	P	Turkey, skin	0.000020	1.000	1.000	
50003861	P	Turkey, skin-babyfood	0.000020	1.000	1.000	
86010000	O	Water, direct, all sources	0.000600	1.000	1.000	s
86020000	O	Water, indirect, all sources	0.000600	1.000	1.000	s
15004010	15	Wheat, grain	0.000060	1.000	1.000	aceto
15004011	15	Wheat, grain-babyfood	0.000060	1.000	1.000	aceto
15004020	15	Wheat, flour	0.000060	1.000	1.000	aceto
15004021	15	Wheat, flour-babyfood	0.000060	1.000	1.000	aceto
15004030	15	Wheat, germ	0.000060	1.000	1.000	aceto
15004040	15	Wheat, bran	0.000060	1.000	1.000	aceto

Attachment 10. CRA (Single-Year TWAM) - DEEM Food and Water Results File (Page 1 of 2)

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U.S. Environmental Protection Agency                             Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO  (ALA EQUIVS)
                                                               (1994-98 data)
Residue file name:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\Cum_acet_ala_Avg_Res_SLU
A_PCT_Water(equiv).R98
                                                  Adjustment factor #2 used.
Analysis Date 09-16-2005/16:38:22     Residue file dated: 09-16-2005/16:31:17/8
NOEL (Chronic) = .5 mg/kg bw/day
COMMENT 1: Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
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Population Subgroup	Total Exposure mg/kg body wt/day	Percent of NOEL	Margin of Exposr 1/
U.S. Population (total)	0.000019	0.00%	26,204
U.S. Population (spring season)	0.000019	0.00%	26,464
U.S. Population (summer season)	0.000020	0.00%	25,105
U.S. Population (autumn season)	0.000019	0.00%	26,549
U.S. Population (winter season)	0.000019	0.00%	26,801
Northeast region	0.000018	0.00%	28,088
Midwest region	0.000020	0.00%	25,597
Southern region	0.000018	0.00%	27,843
Western region	0.000022	0.00%	23,224
Hispanics	0.000022	0.00%	22,516
Non-hispanic whites	0.000019	0.00%	26,917
Non-hispanic blacks	0.000018	0.00%	27,807
Non-hisp/non-white/non-black	0.000023	0.00%	21,656
All infants (< 1 year)	0.000052	0.01%	9,603
Nursing infants	0.000018	0.00%	27,120
Non-nursing infants	0.000065	0.01%	7,713
Children 1-6 yrs	0.000040	0.01%	12,647
Children 7-12 yrs	0.000023	0.00%	21,871
Females 13-19 (not preg or nursing)	0.000014	0.00%	35,590
Females 20+ (not preg or nursing)	0.000016	0.00%	31,112
Females 13-50 yrs	0.000017	0.00%	29,626
Females 13+ (preg/not nursing)	0.000018	0.00%	27,226
Females 13+ (nursing)	0.000023	0.00%	21,564
Males 13-19 yrs	0.000016	0.00%	30,655
Males 20+ yrs	0.000015	0.00%	32,761
Seniors 55+	0.000016	0.00%	31,752
Children 1-2 yrs	0.000047	0.01%	10,728
Children 3-5 yrs	0.000037	0.01%	13,417
Children 6-12 yrs	0.000024	0.00%	20,590
Youth 13-19 yrs	0.000015	0.00%	32,799
Adults 20-49 yrs	0.000016	0.00%	31,768
Adults 50+ yrs	0.000016	0.00%	31,734
Females 13-49 yrs	0.000016	0.00%	31,771

Attachment 11. DEEM **CRA** (PRZM-EXAMS) Food and Water Residue Input File.

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO (ALA EQUIVS)
1994-98 data
Residue file:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\Cum_acet_ala_999_Avg_Res_SLUA_PCT_Water(equiv).R98
Adjust. #2 used
Analysis Date 02-24-2006 Residue file dated: 02-24-2006/19:11:27/8
Reference dose (NOEL) = 0.5 mg/kg bw/day
Comment:Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
06030300	6C	Bean, black, seed	0.010000	0.050	1.000	
06030320	6C	Bean, broad, seed	0.010000	0.050	1.000	
06030340	6C	Bean, cowpea, seed	0.010000	0.050	1.000	
06030350	6C	Bean, great northern, seed	0.010000	0.050	1.000	
06030360	6C	Bean, kidney, seed	0.010000	0.050	1.000	
06030380	6C	Bean, lima, seed	0.008000	0.050	1.000	
06030390	6C	Bean, mung, seed	0.010000	0.050	1.000	
06030400	6C	Bean, navy, seed	0.010000	0.050	1.000	
06030410	6C	Bean, pink, seed	0.010000	0.050	1.000	
06030420	6C	Bean, pinto, seed	0.010000	0.050	1.000	
21000440	M	Beef, meat	0.000400	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000400	1.000	1.000	
21000450	M	Beef, meat, dried	0.000400	1.000	1.000	
21000460	M	Beef, meat byproducts	0.000400	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.000400	1.000	1.000	
21000470	M	Beef, fat	0.000340	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.000340	1.000	1.000	
21000480	M	Beef, kidney	0.001610	1.000	1.000	
21000490	M	Beef, liver	0.001700	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.001700	1.000	1.000	
40000930	P	Chicken, meat	0.000020	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.000020	1.000	1.000	
40000940	P	Chicken, liver	0.000090	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.000020	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfoo	0.000020	1.000	1.000	
40000960	P	Chicken, fat	0.000010	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.000010	1.000	1.000	
40000970	P	Chicken, skin	0.000020	1.000	1.000	
40000971	P	Chicken, skin-babyfood	0.000020	1.000	1.000	
06030980	6C	Chickpea, seed	0.010000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.010000	1.000	1.000	
06030990	6C	Chickpea, flour	0.010000	1.000	1.000	
15001200	15	Corn, field, flour	0.000925	1.000	1.000	s
15001201	15	Corn, field, flour-babyfood	0.000925	1.000	1.000	s
15001210	15	Corn, field, meal	0.000875	1.000	1.000	s
15001211	15	Corn, field, meal-babyfood	0.000875	1.000	1.000	s
15001220	15	Corn, field, bran	0.001125	1.000	1.000	s
15001230	15	Corn, field, starch	0.000485	1.000	1.000	s
15001231	15	Corn, field, starch-babyfood	0.000485	1.000	1.000	s
15001240	15	Corn, field, syrup	0.000735	1.000	1.000	s
15001241	15	Corn, field, syrup-babyfood	0.000735	1.000	1.000	s
15001250	15	Corn, field, oil	0.000445	1.000	1.000	s
15001251	15	Corn, field, oil-babyfood	0.000445	1.000	1.000	s
15001270	15	Corn, sweet	0.007000	0.150	1.000	
15001271	15	Corn, sweet-babyfood	0.007000	0.150	1.000	
70001450	P	Egg, whole	0.000260	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.000260	1.000	1.000	
70001460	P	Egg, white	0.000260	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.000260	1.000	1.000	

70001470	P	Egg, yolk	0.000260	1.000	1.000	
70001471	P	Egg, yolk-babyfood	0.000260	1.000	1.000	
23001690	M	Goat, meat	0.000400	1.000	1.000	
23001700	M	Goat, meat byproducts	0.000400	1.000	1.000	
23001710	M	Goat, fat	0.000340	1.000	1.000	
23001720	M	Goat, kidney	0.001610	1.000	1.000	
23001730	M	Goat, liver	0.001700	1.000	1.000	
06031820	6C	Guar, seed	0.010000	1.000	1.000	
06031821	6C	Guar, seed-babyfood	0.010000	1.000	1.000	
24001890	M	Horse, meat	0.000400	1.000	1.000	
06032030	6C	Lentil, seed	0.010000	1.000	1.000	
27002220	D	Milk, fat	0.000620	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.000620	1.000	1.000	
27012230	D	Milk, nonfat solids	0.000620	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.000620	1.000	1.000	
27022240	D	Milk, water	0.000620	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.000620	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.000620	1.000	1.000	
06032580	6C	Pea, pigeon, seed	0.010000	1.000	1.000	
95002630	O	Peanut	0.150000	0.010	1.000	
95002640	O	Peanut, butter	0.110000	0.010	1.000	
95002650	O	Peanut, oil	0.009000	0.010	1.000	
25002900	M	Pork, meat	0.000160	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.000160	1.000	1.000	
25002910	M	Pork, skin	0.000160	1.000	1.000	
25002920	M	Pork, meat byproducts	0.000160	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.000160	1.000	1.000	
25002930	M	Pork, fat	0.000180	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.000180	1.000	1.000	
25002940	M	Pork, kidney	0.000170	1.000	1.000	
25002950	M	Pork, liver	0.000340	1.000	1.000	
60003010	P	Poultry, other, meat	0.000020	1.000	1.000	
60003020	P	Poultry, other, liver	0.000090	1.000	1.000	
60003030	P	Poultry, other, meat byproducts	0.000020	1.000	1.000	
60003040	P	Poultry, other, fat	0.000010	1.000	1.000	
60003050	P	Poultry, other, skin	0.000020	1.000	1.000	
26003390	M	Sheep, meat	0.000400	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.000400	1.000	1.000	
26003400	M	Sheep, meat byproducts	0.000400	1.000	1.000	
26003410	M	Sheep, fat	0.000340	1.000	1.000	
26003411	M	Sheep, fat-babyfood	0.000340	1.000	1.000	
26003420	M	Sheep, kidney	0.001610	1.000	1.000	
26003430	M	Sheep, liver	0.001700	1.000	1.000	
15003440	15	Sorghum, grain	0.002070	1.000	1.000	s
15003450	15	Sorghum, syrup	0.000070	1.000	1.000	aceto
06003470	6	Soybean, seed	0.001950	1.000	1.000	s
06003480	6	Soybean, flour	0.001738	1.000	1.000	s
06003481	6	Soybean, flour-babyfood	0.001738	1.000	1.000	s
06003490	6	Soybean, soy milk	0.001950	1.000	1.000	s
06003491	6	Soybean, soy milk-babyfood or in	0.001950	1.000	1.000	s
06003500	6	Soybean, oil	0.000350	1.000	1.000	s
06003501	6	Soybean, oil-babyfood	0.000350	1.000	1.000	s
50003820	P	Turkey, meat	0.000020	1.000	1.000	
50003821	P	Turkey, meat-babyfood	0.000020	1.000	1.000	
50003830	P	Turkey, liver	0.000090	1.000	1.000	
50003831	P	Turkey, liver-babyfood	0.000090	1.000	1.000	
50003840	P	Turkey, meat byproducts	0.000020	1.000	1.000	
50003841	P	Turkey, meat byproducts-babyfood	0.000020	1.000	1.000	
50003850	P	Turkey, fat	0.000010	1.000	1.000	
50003851	P	Turkey, fat-babyfood	0.000010	1.000	1.000	
50003860	P	Turkey, skin	0.000020	1.000	1.000	
50003861	P	Turkey, skin-babyfood	0.000020	1.000	1.000	
86010000	O	Water, direct, all sources	0.008940	1.000	1.000	s
86020000	O	Water, indirect, all sources	0.008940	1.000	1.000	s
15004010	15	Wheat, grain	0.000060	1.000	1.000	aceto
15004011	15	Wheat, grain-babyfood	0.000060	1.000	1.000	aceto

15004020	15	Wheat, flour	0.000060	1.000	1.000	aceto
15004021	15	Wheat, flour-babyfood	0.000060	1.000	1.000	aceto
15004030	15	Wheat, germ	0.000060	1.000	1.000	aceto
15004040	15	Wheat, bran	0.000060	1.000	1.000	aceto

Attachment 12. DEEM **CRA** (PRZM-EXAMS) Food and Water Results File

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U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for CUMULATIVE ALA + ACETO  (ALA EQUIVS)
                                                                (1994-98 data)
Residue file name:
C:\AProtzel\ALBERTO\Cumulative\Chloroacetanilides\DEEM_Files\Cum_acet_ala_999_Avg_Res_SLUA_PC
T_Water(equiv).R98
                                                   Adjustment factor #2 used.
Analysis Date 02-24-2006/19:13:40     Residue file dated: 02-24-2006/19:11:27/8
NOEL (Chronic) = .5 mg/kg bw/day
COMMENT 1: Cumulative (Aceto) + Ala (Avg. res+ SLUA PCt) + Water in ala equiv
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
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Population Subgroup	Total Exposure mg/kg body wt/day	Percent of NOEL	Margin of Exposr 1/
U.S. Population (total)	0.000195	0.04%	2,566
U.S. Population (spring season)	0.000193	0.04%	2,589
U.S. Population (summer season)	0.000209	0.04%	2,395
U.S. Population (autumn season)	0.000189	0.04%	2,649
U.S. Population (winter season)	0.000189	0.04%	2,651
Northeast region	0.000178	0.04%	2,806
Midwest region	0.000197	0.04%	2,535
Southern region	0.000185	0.04%	2,702
Western region	0.000223	0.04%	2,243
Hispanics	0.000222	0.04%	2,255
Non-hispanic whites	0.000190	0.04%	2,630
Non-hispanic blacks	0.000185	0.04%	2,705
Non-hisp/non-white/non-black	0.000239	0.05%	2,096
All infants (< 1 year)	0.000628	0.13%	796
Nursing infants	0.000232	0.05%	2,153
Non-nursing infants	0.000779	0.16%	642
Children 1-6 yrs	0.000285	0.06%	1,754
Children 7-12 yrs	0.000183	0.04%	2,739
Females 13-19 (not preg or nursing)	0.000138	0.03%	3,630
Females 20+ (not preg or nursing)	0.000192	0.04%	2,610
Females 13-50 yrs	0.000187	0.04%	2,675
Females 13+ (preg/not nursing)	0.000189	0.04%	2,641
Females 13+ (nursing)	0.000267	0.05%	1,875
Males 13-19 yrs	0.000146	0.03%	3,433
Males 20+ yrs	0.000173	0.03%	2,894
Seniors 55+	0.000188	0.04%	2,655
Children 1-2 yrs	0.000308	0.06%	1,625
Children 3-5 yrs	0.000282	0.06%	1,775
Children 6-12 yrs	0.000193	0.04%	2,593
Youth 13-19 yrs	0.000142	0.03%	3,513
Adults 20-49 yrs	0.000180	0.04%	2,780
Adults 50+ yrs	0.000188	0.04%	2,653

Females 13-49 yrs	0.000179	0.04%	2,790
