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Dr. Hana Pohl
Division of Toxicology
Agency for Toxic Substances and Disease Registry
Mailstop F-32
1600 Clifton Road, NE.
Atlanta, Georgia 30333

COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS ON DRAFT ATRAZINE INTERACTION PROFILE, 69 FR 76768 (DEC. 22, 2004)
(By First-Class Mail and Email)

Dear Ms. Pohl:

On behalf of The Center for Regulatory Effectiveness (ACRE@), I submit the following comments on the Agency for Toxic Substances and Disease Registry=s (AATSDR@) draft Interaction Profile for Atrazine, Deethylatrazine, Diazinon, Simazine, and Nitrate (ADraft Profile@). The Draft Profile was published for public comment in the above-referenced *Federal Register* notice.

Based on ATSDR=s *Federal Register* notice, CRE understands that ATSDR views the *Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures* (AGuidance Manual@) as a final document that is not subject to public comment in this proceeding.[1]

CRE=s comments are summarized as follows.

[1] 69 FR 76768 (Dec. 22, 2004).

- $ ATSDR=s Draft Profile, and any final profile, must meet the requirements of the Data Quality Act (ADQA@) and the applicable DQA Guidelines.[2]

- $ The Draft Profile does not meet the DQA Accuracy and Reliability requirements. The only way it could possibly meet these requirements is for ATSDR to clearly state that the Draft Profile=s conclusions and analyses may not be accurate and reliable. Any final Profile similar to the Draft would have to include the same disclaimer.

- $ The Draft Profile does not meet the DQA Utility requirement because it is of no practical value to anyone given that it may not be accurate or reliable. Any final Profile similar to the Draft profile would not meet the DQA Utility requirement for the same reason.

- $ CRE cannot find any statutory authority for the Draft Profile or for any final Profile.

In light of the above comments, CRE recommends that ATSDR withdraw the Draft Profile and not publish any final Profile.

THE DRAFT PROFILE DOES NOT MEET THE DQA ACCURACY AND

[2] The DQA is codified at 44 U.S.C ' 3516 Historical and Statutory Notes. The relevant DQA Guidelines are the government-wide Guidelines published by the Office of Management and Budget (AOMB@), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=R2-59-filed.pdf; the Department of Health and Human Services (AHHS@) Guidelines, http://www.hhs.gov/infoquality/part1.html; and the joint Guidelines published by ASTDR and the Centers for Disease Control and Prevention (ACDC@), http://www.thecre.com/pdf/20021026_hhs-cdc-dqfinal.pdf

RELIABILITY REQUIREMENTS

The DQA, the OMB Guidelines, the HHS Guidelines, and the CDC/ATSDR Guidelines all impose the same Accuracy and Reliability requirements on the Draft Profile and on any final Profile.[3] These requirements must be met before publicly disseminating the Draft profile and any final Profile.[4]

For example, the CDC/ATSDR DQA Guidelines state:

> ACDC will ensure that disseminated information meets the standards of quality set forth in the OMB, HHS and CDC guidelines. It is CDC=s policy to ensure and maximize the quality, objectivity, utility, and integrity of information that it disseminates to the public. We strive to provide information that is accurate, reliable, clear, complete, unbiased, and useful.@

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[3] *E.g.*, OMB Guidelines, Parts II, III, V; HHS Guidelines, Part I. A through D; CDC/ATSDR Guidelines, Parts III, V.

[4] *E.g.*, CDC/ATSDR Guidelines, Part II.

ACDC provides assurance that information is accurate, reliable, and unbiased.@[5]

The above-quoted Guidelines include ATSDR within their use of the term CDC, and Aall practices and procedures specified [in the Guidelines] apply to both agencies.@ [6]

ATSDR cannot assure or ensure that the Draft Profile information on the health effects of these mixtures is Aaccurate@ and Areliable.@

For example**,** the Draft Profile states, AToxicological data or PBPK models are not available for the complete mixture of concern.@[7]

The Draft Profile also states, AToxicological and mechanistic data, but no PBPK models, were available for some of the binary mixtures. With the exception of the data for the joint action of the triazines, these data were fairly limited.@[8]

With regard to atrazine and diazinon, the Draft Profile states, ANo studies of this binary mixture in mammals were located.@ [9]

With regard to simazine and diazinon, the Draft Profile states, ANo studies of this binary mixture were located.@[10]

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[5] CDC/ASTDR Guidelines, Parts II, V.A.

[6] CDC/ATSDR Guidelines, Part I.

[7] Draft Profile, at p. 5.

[8]Draft Profile, at p. 5.

[9] Draft Profile, at p. 7.

[10] Draft Profile, at p. 9.

With regard to atrazine and nitrate, the Draft Profile states, ANo full report on the joint toxic action of atrazine and nitrate or nitrite on carcinogenic endpoints or of the carcinogenicity of N-nitrosoatrazine has been published in the peer-reviewed literature.@ The Draft Profile also states, AFew data are available regarding the genotoxicity of N-nitrosamines in mammalian cells, so correlations between mammalian genotoxicity and carcinogenicity cannot be established..... [11]

The Draft Profile summarizes the current state of knowledge and evidence regarding all these mixtures as follows:

> ANo epidemiological or toxicological studies of the complete mixture are available. No PBPK models are available for the complete mixture or for any of the submixtures. Some information and studies are available for binary mixtures of the components, but they are not adequate to support a quantitative assessment of interactions. Therefore, the WOE [weight of the evidence] approach is appropriate (ATSDR 2001a, 2001b) to predict the potential impact of interactions.@ [12]

CRE=s question after reading the Draft Profile is: Weight of what evidence?

There are no data or valid model results addressing the health effects of the mixture ATSDR is assessing in the Draft Profile. Yet the Draft Profile reaches conclusions about those effects.

Based on its own statements in the Draft Profile, ATSDR cannot assure the public that its health effects assessments are accurate and reliable. Those assessments may be right or they may be wrong. There=s no way of telling without data and model results.

The only conceivable way of meeting the DQA Accuracy and Reliability requirements is for the Draft Profile and any final Profile to state that ATSDR cannot, given the lack of data and valid model results, assure the accuracy and reliability of the health effects assessment being disseminated. This disclaimer might be sufficient under the DQA requirement that Ain disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation.@[13]

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[11] Draft Profile, at p. 19.

[12] Draft Profile, at p. 14.

[13] OMB Guidelines, Part V.3.A; HHS Guidelines, p. 14.

In other words, ATSDR might be able to comply with the DQA by accurately and reliably stating that the Draft and any final Profile may not be accurate or reliable.

CRE is also perplexed as to why ATSDR is doing this. The Agency states that it produced the Draft Profile for the following reasons:

> AThe atrazine, deethylatrazine, diazinon, nitrate, and simazine mixture was chosen as the subject for this interaction profile based on analyses of frequently occurring mixtures in groundwater. As part of the National Water-Quality Assessment Program of the U.S. Geological Survey, untreated groundwater samples were collected from 1,255 domestic (rural) wells and 242 public water-supply wells, and analyzed for 60 volatile organic compounds (VOCs), 83 pesticides, and nitrate (Squillace et al. 2002). The most frequently occurring four-chemical mixture in these groundwater samples consisted of two triazine herbicides and a metabolite (atrazine, simazine, and deethylatrazine), plus nitrate. Concentrations of the 144 monitored chemicals were screened against drinking water standards and health advisories.Nitrate was the chemical that most frequently exceeded its standard or criterion (maximum contaminant level [MCL] for nitrate = 10 mg/L as nitrogen). Atrazine and simazine did not exceed their MCLs (0.003 and 0.004 mg/L, respectively). Diazinon was the most frequently detected organophosphorus insecticide, and exceeded its drinking water health advisory (0.0006 mg/L) in one well.@[14]

The study relied upon, Squillace *et al*.(2002), actually states that VOCs were detected more frequently than pesticides. Why were pesticides singled out rather than an assessment of VOC mixtures? Diazinon was found in only one well. Therefore, the assessment of a mixture of diazinon with anything in ground water does not appear to be the best use of resources and tax dollars by an Agency that is supposed to be evaluating the effects of substances in combination with other substances with which they are commonly found (Preface to Draft Profile). The Draft Profile has no utility in protecting public health.

THE DRAFT PROFILE AND ANY SIMILAR FINAL PROFILE CANNOT MEET THE DQA UTILITY REQUIREMENT

The DQA and all the applicable DQA Guidelines require that the Draft and any final Profile be useful to its intended users.[15] CRE does not know whom ATSDR intended to use the Draft Profile, but CRE doubts its usefulness to anyone. Until there are accurate and reliable data

[14] Draft Profile, at p. 1.

[15] OMB Guidelines, Part V.2; HHS Guidelines, Part I.D.2.b; CDC/ATSDR Guidelines, Part V.A.

and valid model results, any mixture assessment is mere speculation. Such speculation is not useful to the public, to the manufacturers of these products, to risk assessors or to regulatory decision makers.

CRE SEES NO STATUTORY AUTHORITY FOR THE DRAFT OR ANY FINAL PROFILE

ATSDR cites both CERCLA and the FQPA as its authority to prepare and publish the Draft Profile.[16] CRE does not know any provision of these two acts that authorizes ATSDR=s preparation of an Interaction Profile when, as is the case with the Draft Profile:

1) that Profile is not tied to any CERCLA hazardous substance release site;

2) that Profile includes several substances that are not listed CERCLA hazardous substances; and

3) no other federal agency, state or Native American tribe has requested that ATSDR prepare that Profile.[17]

ATSDR itself acknowledges that the Guidance Document the Agency uses in the Draft Profile is intended for use at Ahazardous waste sites@:

> The *Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures* is intended to assist environmental health scientists and toxicologists in determining whether exposure to chemical mixtures at hazardous waste sites may impact public health. It serves a basis for interaction profiles, as the basis for health assessments and health consultations. The systematic method outlined in the Guidance Manual integrates ATSDR=s interaction profiles, toxicological profiles, and research on chemical mixtures into a practical screening approach for potential health hazards. The conclusions from this exposure-based screening assessment of mixture hazard can then be taken into account along with biomedical judgment, the community-specific health outcome data, and community health concerns, to determine the public health implications and follow-up activities for a hazardous

[16] 69 FR 76768 (Dec. 22, 2004).

[17] *See* 42 U.S.C. ' 9604(i).

waste site.[18]

What Ahazardous waste sites@ are known to contain the mixtures addressed by the Draft Profile?

CONCLUSION

There is a very real risk that the public will believe the Draft Profile accurately and reliably assesses the health risks of these mixtures. Given the absence of any data or valid models, the only possible way that the Draft and any similar final Profile can avoid this risk is to clearly and prominently state that they cannot be assumed to be, and in fact may not be, accurate and reliable.

With or without this disclaimer, CRE cannot see any usefulness or statutory authority for the Draft Profile or for any similar final Profile.

Consequently, CRE recommends that ATSDR withdraw the Draft Profile and not publish any final Profile.

CRE also requests that ATSDR explain, with citations to specific statutory provisions and regulations, its authority to prepare the Draft Profile, and to explain the funding source for the Draft Profile.

Scott Slaughter
The Center for Regulatory Effectiveness

[18] http://www.atsdr.cdc.gov/interactionprofiles/ipga.html