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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

February 19, 2009

MEMORANDUM

SUBJECT: Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held December 2-5, 2008 on the Scientific Issues Associated with Worker Reentry Exposure Assessment

TO: Debbie Edwards, Ph.D.
Director
Office of Pesticide Programs

FROM: Sharlene R. Matten, Ph.D. 2/19/09.
Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

THRU: Steven Knott, Executive Secretary Steven M. Knott
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

Frank Sanders
Director
Office of Science Coordination and Policy

Attached, please find the meeting minutes of the FIFRA Scientific Advisory Panel open meeting held in Arlington, VA on December 2-5, 2008. This report addresses a set of scientific issues associated with Worker Reentry Exposure Assessment.

Attachments

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SAP Minutes No. 2009-02

A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

The Agency's Evaluation of Worker Reentry Exposure Assessment

December 2-4, 2008
FIFRA Scientific Advisory Panel Meeting
held at
Potomac Yard I
Arlington, Virginia

NOTICE

These meeting minutes have been written as part of the activities of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP). The meeting minutes represent the views and recommendations of the FIFRA SAP, not the United States Environmental Protection Agency (Agency). The content of the meeting minutes does not represent information approved or disseminated by the Agency. The meeting minutes have not been reviewed for approval by the Agency and, hence, the contents of these meeting minutes do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

The FIFRA SAP is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act and established under the provisions of FIFRA as amended by the Food Quality Protection Act (FQPA) of 1996. The FIFRA SAP provides advice, information, and recommendations to the Agency Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment. The Panel serves as the primary scientific peer review mechanism of the Environmental Protection Agency, Office of Pesticide Programs (OPP), and is structured to provide balanced expert assessment of pesticide and pesticide-related matters facing the Agency. FQPA Science Review Board members serve the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP. Further information about FIFRA SAP reports and activities can be obtained from its website at http://www.epa.gov/scipoly/sap/ or the OPP Docket at (703) 305-5805. Interested persons are invited to contact Sharlene R. Matten, Ph.D., SAP Designated Federal Official, via e-mail at matten.sharlene@epa.gov.

In preparing these meeting minutes, the Panel carefully considered all information provided and presented by EPA, as well as information presented in public comment. This document addresses the information provided and presented by EPA within the structure of the charge.

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Potomac Yard I
Arlington, Virginia

Janice E. Chambers

Janice E. Chambers, Ph.D., D.A.B.T., A.T.S.
FIFRA SAP Session Chair
FIFRA Scientific Advisory Panel

Date: Feb. 19, 2009

Sharlene R. Matten, Ph.D.
Designated Federal Official
FIFRA Scientific Advisory Panel Staff
Date: Feb. 19, 2009

Federal Insecticide, Fungicide, and Rodenticide Act
Scientific Advisory Panel Meeting
December 2-4, 2008

The Agency's Evaluation of Worker Reentry Exposure Assessment Issues

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed its review of **the Scientific Issues Associated with Worker Reentry Exposure Assessment.** Advance notice of the SAP meeting was published in the *Federal Register* on **September 12, 2008**. The review was conducted in an open Panel meeting December 2-4, 2008 held at the Potomac Yard I, Arlington, Virginia. Dr. Janice E. Chambers chaired the meeting. Dr. Sharlene R. Matten served as the Designated Federal Official. Mr. Jack Housenger, Associate Director, Health Effects Division, Office of Pesticide Programs (OPP), provided opening remarks at the meeting. Presentations of technical background materials were provided by Mr. Matthew Crowley, Mr. Jeffrey Dawson, Mr. Jeffrey Evans, and Mr. Philip Villanueva, Health Effects Division, OPP. Invited presentations were made by representatives of the Agricultural Reentry Task Force (Stefan Korpalski, Grayson Research, LLC and Curt Lunchik, Bayer CropScience) and Dr. Joseph Frank, California Department of Pesticide Regulation.

Extensive investigation of hand-labor activities in agriculture and subsequent occupational, post-application exposure monitoring were conducted as a result of an EPA data call-in (DCI) in 1995. An industry task force, the Agricultural Reentry Task Force (ARTF), was formed to produce the data to satisfy the data requirements. In conjunction with the U.S Environmental Protection Agency (EPA), Health Canada's Pest Management Regulatory Agency (PMRA), and the California Department of Pesticide Regulation (CDPR), the Task Force proposed and conducted exposure monitoring studies for field workers engaged in hand-labor activities in a variety of crops across agriculture.

The data from the completed studies now comprise a generic database for use in conducting occupational post-application exposure assessment in all agricultural settings. Based on the types of crops and activities monitored, the database is organized into crop-activity groups, or clusters, designed to represent, and enable exposure assessment of all hand-labor activities that occur in agriculture.

During this meeting of the FIFRA SAP, the Agency provided an overview of occupational post-application monitoring studies conducted by the ARTF as well as the proposed organization, content, structure, and characteristics of the database. The overview contained discussions of the criteria used to define the appropriate activities to monitor, how crops and crop activities were grouped into clusters, how the completed data were interpreted and used, and the general methodology and assumptions underlying post-application exposure assessments. Finally, the regulatory agencies discussed the peer review process that was followed in developing and making decisions on the use of this database.

The Agency sought review and comment on three basic areas of post-application (farm worker) exposure assessment. These were: (1) the identification of activities for consideration in the assessment process; (2) grouping of similar activities for assessment purposes including no/low contact activities; and (3) consideration of workday duration in exposure calculations. The ARTF conducted an analysis of the data it generated in response to the DCI and, in most cases, the Agency concurred with this analysis and the conclusions drawn from these data, although in some cases, alternative analyses were presented for consideration by the Panel.

PUBLIC COMMENTERS

Oral statements were presented by:

1) Stefan Korpalski, Grayson Research, LLC and Curt Lunchik, Bayer CropScience on behalf of the Agricultural Reentry Task Force
2) Joseph Frank, Ph.D., California Department of Pesticide Regulation
3) Larry R. Holden, Ph.D. Sielken & Associates Consulting, Inc.
4) Douglas G. Baugher, Ph.D., EXP Corporation

Written statements were provided by:

1) Eric D. Bruce, Consultant and Stefan Korpalski, Grayson Research, LLC on behalf of the Agricultural Reentry Task Force
2) Matthew Keifer, M.D., M.P.H., University of Washington

SUMMARY OF PANEL DISCUSSION AND RECOMMENDATIONS

1. Topic A: Crop-Activity Grouping/Clustering

Question 1: The Panel was in general agreement that the expert and grower surveys are pragmatic and generally comprehensive approaches for identifying crop-specific hand labor activities. The Panel acknowledged that the expert and grower surveys do not necessarily represent the experience of all agronomic experts and growers, and the grower response rate for some crops was low; however, these shortcomings are not considered to be serious limitations because the intent of the surveys was to identify hand labor activities and to perform rough groupings. The surveys likely achieved these goals, although some crops and hand labor activities may have been missed. The data sources used here for identifying hand labor activities are better than anything that has been used before, and while some gaps may be present, the surveys are very comprehensive.

Question 2a: Most of the Panel found the clustering approach based on agronomic practices and transfer coefficients (TCs) to be reasonable given the overall complexity of the data. The approach appears to be practical, reflects the way the Agency labels pesticide products, and the overall approach is identical to that used by the European Union. Data in North America are very rich compared to the rest of the world in terms of the volume of information on work activities, dislodgeable foliar residue studies, and exposure measurements. Other reasonable methods of producing clusters would likely produce similar results. The Panel was concerned, however, about the absence of an explicit algorithm for assigning crop-activities into clusters, insufficient discussion of the mechanisms of exposures, especially dermal exposure due to the foliar "fallout" of pesticide-contaminated particles, and insufficient attention to ergonomics in creating clusters. One panel member was not convinced that the current cluster methodology, particularly using TC as the basis, was adequate and robust enough to group similar farm worker groups in the same cluster. The Panel suggested that the Agency consider other approaches for grouping and assessing such complex exposures; in particular probabilistic methods, alternative similarity analyses for categorical attributes, and the European collaborative efforts to assess biocide exposure. The Panel stated that the ARTF dermal exposure and dislodgeable foliar residue (DFR) data are valuable and largely untapped data sets for exploring mechanisms and other issues pertaining to worker pesticide exposure.

Question 2b: The Panel reviewed the proposed crop-activity clustering schemes summarized in Appendix B of this report. The Panel agreed with the Agency's proposed clusters with the following exceptions:

1) The Panel did not reach a consensus on whether to split the OH cluster into separate orchard-harvesting and orchard-thinning clusters because there were insufficient data. The Panel recommended that additional orchard-thinning data be collected should the Agency wish to consider separate clusters for orchard-harvesting and orchard-thinning.

2) The Panel did not reach a consensus to accept the Agency's proposal to split the GHf cluster into separate GHf and GHv clusters because there were several panelists who had substantial concerns about separate GHf and GHv clusters.

3) The Panel had reservations about creating a separate cluster for hand-harvesting nursery crops.

4) The Panel recommended a single cluster for mechanical harvesting of cotton.

5) The Panel determined that the TC data were too limited and too variable to justify splitting the DM cluster into additional clusters.

Question 3: The ARTF exposure monitoring studies clearly include repeated measurements on individuals and multiple studies within some crop-activities. Given these data characteristics, the Panel generally agreed that a mixed model analysis is more appropriate than non-parametric tests for determining reasonable groupings of TCs, assuming the sample size is adequate, the impact of censored data is limited, biases are adjusted for or can be handled to minimize bias, an appropriate covariance structure is specified, and adjustments for multiple comparisons are made as necessary. The Panel cautioned, however, that these statistical tests are being performed on clusters that have been defined *a priori* and thus assumptions typically underlying formal statistical tests are violated. The results of the mixed models (or the non-parametric tests), therefore, should only be considered to be indicators of potential studies that do not fit the pre-defined clusters. The Panel proposed two alternative mixed models to reduce over-fitting suspected in the Agency mixed model approach. The Panel's two alternative models and the Agency model each indicated that hand-thinning in orchards should be a separate cluster from hand-harvesting in orchards. In contrast to these analyses, a recent ARTF biomonitoring study conducted on orchard workers performing hand-thinning and hand-harvesting tasks indicated that these activities would be encompassed by the same cluster.

Question 4: The Panel generally agreed with the Agency on its "No TC" crop-activities with some possible exceptions as noted below. They indicated that the "No TC" list could be further sub-divided into three groups reflecting 1) crop-activities for which the TC approach may not be applicable, 2) crop-activities that are expected to have zero to negligible TCs based on available information, and 3) crop-activities for which no TC is available but exposure is likely measureable and a TC could be generated if a study were performed. The Panel recommended that descriptions of the "No TC" crop-activities be provided, including equipment used and the presence of features such as enclosed cabs that would limit contact with foliage or exposure to the fallout of pesticide-contaminated particles. Several panelists believed that the mechanically harvested orchard and trellis crops should be removed from the "No TC" list and be given the default value of 167 cm^2/hr from ARTF's study on workers mechanically harvesting almonds. Some specialty nursery and flower crops in Hawaii should probably be removed as well.

2. Topic B: Workday Duration

Question 1: The Agency primarily used two sources for workday estimates, a grower survey (Thompson, 1998) and a U.S. Department of Labor report (USDL, 2005) from the National Agricultural Worker Survey (NAWS). The Panel concurred with the Agency's scientific analysis that these datasets were adequate to establish a workday duration of 8 hour for generic dermal exposure assessment. However, the Panel noted that neither dataset was specifically designed to accurately collect workday duration information for specific hand-labor activities. Despite some limitations, these surveys represent the best available national data. The Panel suggested that the Agency may wish to incorporate data from the California Crop Profiles or data obtained from more recent NAW surveys to augment the Thompson (1998) grower survey and the 2005 NAWS. Another suggestion was to search the published literature related to ergonomics and examine information provided by the Agro Safety Center in California to aid estimations of workday duration.

Question 2: The Panel agreed with the Agency's proposed use of an 8 hour workday duration. The Panel also concurred with the Agency that the use of 8 hour workday duration in a generic dermal exposure assessment represented the high end of the distribution of actual multi-day exposures given the other assumptions used by the Agency to determine multi-day exposures, i.e., the maximum application rate is used, a re-entry worker is perfoming tasks resulting in potential re-entry pesticide exposure for the entire 8 hours, and the worker was exposed to the day 1 DFR on every exposure day. The Panel pointed out that these assumptions for multi-day exposures were very conservative and may lead to an overestimation of multi-day exposures. The majority of the Panel stated that the conservative approach using the deterministic model is protective for the majority of people. Some Panel members felt that a probabilistic approach for exposure assessment would allow a more protective calculation for multi-day exposures.

Question 3: The Panel agreed that the use of the 8 hour workday duration represents a large proportion of the exposure distribution profile, but does not adequately reflect exposures at the 90^{th} or 95^{th} percentiles of the distribution following a single day exposure. The data presented by the Agency suggested that the use of the central tendency of 8 hours for workday duration resulted in an estimated dermal exposure that fell at the 65^{th} percentile underestimating exposure for 35% of the population. The Panel stated that the Agency's estimates fell short of being "high end" estimates of exposure. Some Panel members felt that it was difficult to evaluate exposure and the "protectiveness" of the exposure estimate without also considering the toxicity of the individual chemical; however, the Panel recognized their charge was to deal only with those criteria of a generic dermal exposure assessment, not risk assessment. Overall, while the Panel recognized that an 8 hour workday might underestimate exposure in some cases, the Panel felt that variations associated with transfer coefficient estimates were a much greater source of uncertainty in the overall exposure prediction model.

DETAILED RESPONSES TO CHARGE QUESTIONS

1. Topic A: Crop-Activity Grouping/Clustering

In 1995, the Agency issued a data call-in (DCI) notice requiring the development of information on the exposure potential associated with labor activities in agriculture which occur in previously treated areas (e.g., harvesting). The central premise in the development and collection of such exposure monitoring data is that activities which exhibit similar magnitudes and patterns of exposure can be grouped together for exposure assessment purposes. It would also follow that crop-activity combinations not actually monitored, but that were similar from both ergonomic and agronomic perspectives, can be represented by those that were monitored. Based on this premise, the Agency has identified several key factors for consideration by the Panel. They include the identification of labor activities in agriculture, evaluation of the possible grouping approaches for similar crop-activity combinations, and categorization of certain activities as no/low contact in the Agency's Worker Protection Standard (40 CFR 170). Specifically, the Agency identified the following issues for the Panel to consider:

QUESTION 1: *Please comment on the strengths and limitations of the approaches and data sources used to identify the universe of hand labor activities for exposure assessment purposes. Please identify any activities that EPA has not listed for the crops included in the scope of the DCI.*

<u>Panel response:</u>

The Panel was in general agreement that the expert and grower surveys are pragmatic and generally comprehensive approaches for identifying crop-specific hand labor activities. The Panel acknowledged that the expert and grower surveys do not necessarily represent the experience of all agronomic experts and growers, and the grower response rate for some crops was low; however, these shortcomings are not considered to be serious limitations because the intent of the surveys was to identify hand labor activities and to perform rough groupings. The surveys likely achieved these goals, although some crops and hand labor activities may have been missed. The data sources used here for identifying hand labor activities are better than anything that has been used before, and while some gaps may be present, the surveys are very comprehensive.

The ARTF conducted a logical and thorough compilation of crops and activities for exposure assessment purposes. As a first step, a list of 90 crops important to both the United States and Canada was generated from the 1992 United States Census of Agriculture and the 1990 Canadian Census of Agriculture. As a second step, 288 agronomic experts were surveyed (and 578 questionnaires collected) for their opinions about hand labor activities required for crop production, the frequency and degree of contact with plant surfaces during these activities, and other factors potentially related to pesticide exposure among agricultural workers for the 90 selected crops. The expert survey was followed up by a larger survey of approximately 3850 growers (that generated 11,101 responses) to obtain similar information.

The breadth of crops, activities, and opinions assembled are clear strengths of the approach taken by the ARTF. The biggest limitation of this survey approach is that while agronomists and growers know the hand-labor activities involved in crop production, they were not industrial hygienists or ergonomists knowledgeable about human exposure to chemicals. The ARTF assumed that they (the ARTF) understood the mechanisms of exposure, that their questions assessed those mechanisms, and that their survey participants could accurately interpret those questions and provide consistently useful answers. That the questions focused on direct "[foliar] contact potential" as virtually the only means of exposure suggests that the first assumption was not well founded. That the crop contact potentials (CPs) were not good predictors of transfer coefficients (TCs) measured in the field attests to the weakness of the last two assumptions.

One panel member addressed several omissions in Exhibit C (of the Agency's issue paper) that pertained to specific crops grown in Hawaii with unique cultural production practices that may impact worker exposure. Dracaena is a major Hawaiian crop grown on several thousand acres that has crop architecture more similar to corn than to other nursery crops. Dracaena is grown in the field, then cut and transplanted into greenhouses prior to sale. The principal hand-labor activities involving major contact with Dracaena leaves are transplanting, topping, and fertilizing. Palms are another important crop grown in Hawaii and other states not mentioned in Exhibit C. In some cases, palms are grown to smaller size and then dug up to be used in landscaping situations. Foliage contact associated with harvest could be significant in this situation. In other situations foliage contact is minimal since palms are grown to very large sizes and dug up with front-end loaders then trucked to big hotels and commercial sites. Foliage contact would be minimal in these cases. Only smaller palm production for landscape uses should be listed in Exhibit C. Shadehouse crops, e.g., Anthuriums, cover about 600 acres in Hawaii and involve foliar contact. Anthuriums are a low-growing waxy flower crop. Orchids and other flower crops are also grown in shadehouses. The Panel also noted that persimmons, sorrel, and macadamia nuts were not listed as crops in Exhibit C.

The Panel was unclear if certain activities involving hand labor should be included in the current list (Exhibit C), such as post-harvest handling or sorting/grading of the harvested crop and the handling of treated seed. According to the Agency, exposure resulting from these activities would be handled using an approach other than the TC. The Panel also pointed out that the harvesting of papayas, currently listed in Exhibit C with a designation of "full"foliage contact, would be better described as "low" foliage contact.

The Panel was concerned about the identification of new crops and changes in hand labor activities going into the future. Agriculture is a dynamic industry. The surveys used are already a decade old and some agricultural practices and labor activities have likely changed since the surveys were conducted. The Panel suggests that the Agency look at agricultural practices in other countries as possible indicators of emerging trends. Recent versions of the National Agricultural Workers Survey (NAWS) ask agricultural workers about crop-specific hand-labor activities they perform. These data are not yet available, but could be a valuable source of information in the future to complement expert and grower surveys of hand-labor activities.

The Panel stated that the interpretation of the cluster coding was not always intuitive. The Panel recommended that a list of the Cluster Codes used in naming the crop-activity clusters, such as in Table 1 below, be created both as a convenience to readers and to check for code duplications (i.e., the letter "t" was used for both "tramper" and "tobacco" sub-categories). The Panel also recommended that a dictionary or glossary be developed that contains expanded definitions/descriptions of the hand-labor activities that the ARTF and the Agency agree are included in each term, including photos where available. This descriptive document should also explain why certain activities appear in multiple cluster abbreviations, and those abbreviations that cover multiple activities. For example, in Exhibit C:

> HS not only covers scouting but also covers pruning and weeding.
> SW not only covers weeding but also covers pruning.
> TP not only covers pruning but also covers scouting and weeding.
> WlH not only covers harvest but also covers scouting and weeding.

Other examples of incomplete explanations included: 1) why the Wm cluster (waxy leaf plants of medium height) had an activity abbreviation, yet many specific activities associated with these plants are listed in Exhibit C, including harvesting, scouting, and weeding, 2) why "bird control" is abbreviated as either HS, OW, or TP for various crops, 3) how "thinning" fruit is different than "thinning plants", and 4) why the activity "tying" is included in multiple cluster codes (i.e. GHv, GN, HH, SH, THb, THg, TP, and Wm) for various crops.

Table 1. List of Abbreviations for Crop-Activity Cluster Discussed in the Agency's Issue Paper ("Scientific Issues Associated with Worker Reentry Exposure Assessment")

Agronomic Term		Ergonomic Term		Activity Term		Sub-category Term	
C =	cotton	l =	low height	H =	harvest	b =	berries
D =	sod	m =	medium height	I =	irrigation	f =	flowers
G =	greenhouse	x =	intense contact	M =	maintenance	g =	grapes
H =	hairy leaves			N =	nursery	m =	module builder
O =	orchard			P =	pruning	n =	nut
S =	smooth leaves			S =	scouting	p =	picker operator

Agronomic Term		Ergonomic Term	Activity Term		Sub-category Term	
T =	trellis		W =	weeding	r =	row conditions
W =	waxy leaves				s =	solid stand
					t =	tramper
					t =	tobacco
					v =	vegetables

QUESTION 2: *The ARTF has recommended various crop-activities be grouped together or clustered for the purposes of estimating exposure and has proposed and conducted or purchased one or more exposure monitoring studies to be used to represent each cluster. The regulatory agencies also agree with the concept of clustering like crop-activity combinations for this purpose. Please comment on the following:*

a. The methods used by ARTF for the purposes of creating clusters for exposure assessment purposes.

Panel response:

Most of the Panel found the clustering approach based on agronomic practices and transfer coefficients (TCs) to be reasonable given the overall complexity of the data. The approach appears to be practical, reflects the way the Agency labels pesticide products, and the overall approach is identical to that used by the European Union. Data in North America are very rich compared to the rest of the world in terms of the volume of information on work activities, dislodgeable foliar residue (DFR) studies, and exposure measurements. Other reasonable methods of producing clusters would likely produce similar results. The Panel was concerned, however, about the absence of an explicit algorithm for assigning crop-activities into clusters, insufficient discussion of the mechanisms of exposures, especially dermal exposure due to the foliar "fallout" of pesticide-contaminated particles, and insufficient attention to ergonomics in creating clusters. One panel member was not convinced that the current cluster methodology, particularly using TC as the basis, is adequate and robust enough to group similar farm worker groups in the same cluster. The Panel recommended that the Agency provide evidence that demonstrates workers belonging to one cluster do have similar dermal exposure, as measured, to the same pesticide. Of course, the definition of similarity of dermal exposure needs to be clearly stated so it would not bias the outcomes of the validation. The Panel suggested that the Agency consider other approaches for grouping and assessing such complex exposures; in particular, probabilistic methods, alternative similarity analyses for categorical attributes, and the methods used in European collaborative efforts to assess biocide exposure. The Panel stated that the ARTF dermal exposure and DFR data are valuable and largely untapped data sets for exploring mechanisms and other issues pertaining to worker pesticide exposure.

Absence of an Algorithm for Assigning Crop-Activities into Clusters

The Panel commented that it was surprising that the provided material did not present an explicit algorithm that would allow someone to assign each identified crop-activity into the most appropriate cluster. Three approaches to an algorithm were implied in the material presented to the Panel, but they are inconsistent and none appears to be written as the definitive method.

1) Based on the sequence by which the clusters were introduced in the written material, one might anticipate that ARTF or the Agency began such an algorithm by categorizing first, by setting (e.g. greenhouse, field crop, orchard, trellis, turf) or, in some cases, by activity (e.g. mechanical cotton harvesting, irrigation); next, in some cases, by leaf texture (i.e. waxy, smooth or hairy), and finally by creating subcategories of settings or activities within those already specified.

2) The "ARTF Database Users' Manual" (Agency background reference "h") suggests that a user might follow an algorithm in which users would presumably know the desired cluster in which their crop-activity would fall (that would only work if the list generated in Appendix B of Agency background reference "h" actually contained all crop-activities and all of these were already properly categorized by a method that has not yet been fully explained in one succinct document).

3) The text of reference "h" (p. 20 - 36) suggests that such a classification algorithm would start by considering whether the activity is a "special situation" (five are listed including "No TC Assigned"). Then one must decide into which of "five distinct agronomic groups" the activity would fall.

Mechanisms of Exposure

Several Panel members were concerned that the focus in creating clusters has been more on statistics (correlations and significant differences) and agronomics than on the mechanisms of exposure underlying the clusters. For real clusters to exist, the mechanisms of exposure must be sufficiently common within a cluster to result in similar within-cluster TCs and sufficiently dissimilar between clusters to result in dissimilar between-cluster TCs. Statistics can either illuminate these patterns (the approach taken by the ARTF and the Agency so far) or statistics could validate a model of exposure (an approach not yet seen in ARTF or Agency materials). While the ARTF has used statistics quite nicely to identify 28 clusters from among the 47 exposure monitoring studies conducted thus far, they have not yet laid out a clear path forward by which they can (or have) reliably extrapolated these few measured crop-activities to the much wider universe of about 4500 unmeasured crop-activities. The surprises and exceptions within the TC data and clusters suggest that there is not a complete understanding of underlying exposure mechanisms. Rather than relying only on statistics and agronomics, clarifying the dominant mechanisms of exposure (or even providing a mechanistically-based explanation for the surprises and exceptions) would seem like a more robust path toward the development of an explicit algorithm for assigning TC values to unmeasured crop-activities. The lack of an underlying model of exposure is a major weakness of the proposed clusters. This is not to say that the proposed clusters (or the methods used to establish them) are wrong, just that not all crop-activities included within some clusters are well justified.

For the concept of a transfer coefficient to be valid in any setting, one or more underlying physical mechanisms of exposure must follow predictive or at least reproducible relationships within that setting. Three primary mechanisms are suggested for the transfer of residues from the crop to the worker:

1) Direct transfer of residue from the foliage or crop to a worker's clothing or skin upon contact with the plant surfaces (virtually the sole focus of the ARTF).

2) Direct transfer of contaminated foliar moisture to a worker's clothing or skin upon contact with wet foliage (largely discounted by the data in Section 10 of Agency background reference "g").

3) Indirect transfer of residues via contaminated particulate matter (organic and inorganic) dislodged from the foliage when it is disturbed (without necessarily involving human contact with the foliage or crop) that is airborne briefly, but then quickly falls down and deposits on a worker's clothing or skin (a mechanism virtually not addressed by the ARTF).

All three of the above mechanisms also rely on a secondary mechanism to move the residues through the worker's clothing to their skin. These mechanisms are described in more detail below. The Panel clarified what is meant by "penetration." The ARTF and the Agency refer to this movement as "penetration" (without necessarily attributing a mechanism to it), although in industrial hygiene jargon "penetration" refers specifically to the passage of a vapor, liquid, or solid material through openings in chemical protective clothing (*cf.* "permeation" being the movement of a chemical through the protective material itself, e.g. by diffusion or filtration).

1) Foliar Contact

The Panel stated that foliar contact is likely to be the main mechanism (and perhaps only mode) of exposure for low, manually-harvested crops such as strawberries, tomatoes, and for many greenhouse activities. Technically, for direct transfer to function and the pesticide to migrate through clothing, the residue is probably transferred from the leaf surface to a person via leaf tissue, plant oils, or contaminated particulate matter. If direct physical transfer is the main mechanism, one could hypothesize that the TC would depend upon the amount of foliage that a worker contacts per hour (which varies among crops) and the fraction of dislodgeable residue transferred per unit of foliage contacted. The fraction transferred might also vary with both the pressure and lateral forces involved in that contact, e.g., higher forces would be involved in handling sod, versus merely contacting foliage incidental to the task, and lateral forces imply "rubbing" the foliage in some way. These secondary mechanisms (i.e. pressure and lateral force) illustrate an alternative way to interpret the TC differences for cabbage harvesters (ARF050) and cabbage weeders (ARF037).

2) Contact with wet foliage
The Panel acknowledged that a widely accepted practice is to let a pesticide application dry before reentering a treated field; however, subsequent dew or light rain could re-suspend or dissolve a dried foliar residue back into new water on foliar surfaces. In comparison to how pesticides might be bound to dry foliage, contaminated water should be very easy to transfer from foliage to skin or clothing. (The ability of the residue to transfer to people via water would depend upon the DFR, the water solubility of the pesticide or/and the wettability of the foliar dust, the amount of foliar contact to create a direct dose, and the nature of the clothing or the use of gloves to mitigate that potential dermal exposure [PDE] into a lower total dermal exposure [TDE]). Thus, one could hypothesize that wet foliage would have a higher TC than dry foliage with the same DFR. One example from the ARTF data that supports this hypothesis is that the TC value for wet tobacco foliage was approximately twice that of the other tobacco hand harvesting studies. Another potential example is that the presence of wet foliage could explain why setting irrigation pipe had the highest rate (%) of penetration by residues through clothing (Table 2, Agency background reference "d"). However, Section 10 of Agency background reference "g" rather clearly showed that the pattern in tobacco was the exception rather than the rule. Overall, the ARTF data are equivocal on whether water on foliage creates a higher "potential dermal transfer coefficient" (to outer clothing), and the data are not sufficient to support the hypothesis that water consistently increases the permeation of residues through clothing or causes a significantly higher total dermal transfer coefficient.

3) Fallout
The Panel observed that several studies provided good evidence for the indirect deposition or fallout of pesticide-contaminated foliar dust onto a worker's skin as an important mode of transfer and exposure, especially in (but not limited to) tall crops (above head height) (Popendorf and Leffingwell, 1977; Popendorf, 1980; Popendorf et al., 1982; Popendorf and Leffingwell, 1982). Examples of the influence of this mechanism include ARTF's observations regarding dermal exposure patterns while hand harvesting tobacco and the consistently measurable TC for workers mechanically-harvesting almonds without any direct foliar contact. Fallout is probably related to the high airborne pesticide concentration measured in crops with overhead foliage (Section 12, Agency background reference "g"). Out of a total of 126 days in which geometric mean air concentrations were reported (Table 50, reference "g"), air concentrations exceeded 0.01 μg/L on only 32 days and 26 (81%) of these occurred in crops that were above head high while working (e.g., orchards, trellis crops, or sweet corn). Because aerosol samplers only collect the small diameter portion of the particles that can fall onto the worker, these results are only an indicator of the potential presence of the fallout mechanism. This mechanism also calls into question the inclusion of other mechanically-harvested orchard and trellis crops in the "No TC Assignment" cluster (Charge Question 4 and Table 24 in the Agency's scientific issue paper).

From the foregoing discussion, dermal exposure associated with hand-labor activities for the various crop-activities could be described (for simplicity) by one of three categories:

1) Dermal exposure mainly due to direct skin/clothing contact with foliar and crop surface residues.

2) Dermal exposure mainly due to residue deposition from foliar or crop residue "fallout."

3) Dermal exposure via a combination of direct skin/clothing contact with foliar and crop surface residues and deposition from foliar/crop residue "fallout".

The extensive and high quality ARTF data for DFR, PDE, TDE and other background details within the ARTF records provide an untapped resource to explore and validate these exposure mechanisms. The Panel was not shown how the data would be used to explore the importance of each of these mechanisms within any cluster or across clusters. In the end, these mechanisms could play a central role in future algorithms for assigning a TC value to other crop-activities.

Ergonomics

The Panel stated that the ARTF-proposed clusters and the Agency-suggested alternative clusters make precious little use of ergonomics, relying instead on agronomics and statistics. The ARTF and Agency focus on agronomically-based clusters is logical given the nature of the industry, and it may even make sense in terms of the structure of the label instructions that are provided to pesticide users. The lack of applying ergonomic analyses to clustering crop-activities or to validating some noted exceptions to the resulting TC clusters is compounded by the lack of an algorithm that explicitly covers those exceptions when assigning all of the other (~ 4500) crop-activities in Exhibit C.

One notable implication of ergonomics is the role of crop height in exposure and the TC values. Crop height was considered in the expert and growers surveys, and was mentioned in the material presented to the Panel by both ARTF and the Agency. Crop height categories established at the outset of the surveys were modified during data analysis (Agency background reference "n" p. 17-18) to be either "Low" or "High" if the height was less than or more than "waist high (3-3.5 feet)," respectively. While this difference should affect the ratio between lower and upper body dermal exposures, a height categorization of either less than or more than *head high while conducting the activity* is likely to have even a greater effect on total exposure and the final TC than categorizing at waist height. For instance, during some reentry activities, the worker's head (and essentially the rest of the body) is likely to be under the height of the foliage if it is greater than 6 feet tall. However, that is also true for work on trellis plants where workers would be performing hand-labor tasks while bending or stooping beneath plants that are less than 6 feet tall. This nuance is also an example of the difference between an "agronomic" approach and an "ergonomic" approach. A greater focus on ergonomics could help to justify the current proposals, justify the handling of observed exceptions or illuminate the need for additional clusters. Moreover, ergonomics could help clarify the rationale for placing the various crop-activities within the cluster abbreviations. Further work involving ergonomics should also help clarify the mechanisms of exposure.

Limitations to relying on DFR

The Panel generally agreed that use of the DFR by the ARTF and the Agency was (and still is) the most appropriate existing technology upon which to base TC values; however, the DFR method is not without its limitations. For instance, the water wash step may remove more residue from some crops than is truly available to be transferred to a worker via any of the mechanisms previously discussed herein; alternatively, the water wash step may destroy a water labile pesticide or its toxic metabolite, which may account for some otherwise inexplicable harvester poisonings (O'Malley and McCurdy, 1990). A vacuum collection technique was developed in the early 1970's to sample the more readily available foliar residue, but it was too time-consuming to be practical and was not tested in diverse enough field settings (only in orange grove settings) or chemicals (only parathion) to demonstrate if it had any predictive advantages (Popendorf et al., 1975). A more practical (and more obscure) method was previously developed to assess radioactive contamination of surfaces (Royster and Fish, 1967). Should some future researcher be interested in improving the state-of-the-art with respect to foliar residues, they might consider exploring the value of Royster and Fish method for improving upon the prediction of reentry hazards.

Alternative Approaches for Creating and Assessing Clusters

A single point estimate (typically the geometric or arithmetic mean) was used to represent the TC for each cluster. Members of the Panel suggested alternative probabilistic methods to accommodate uncertainty and variability as alternatives to this approach.

One panel member commented that the classification of biocide exposures in Europe has similar challenges to that of re-entry exposures to pesticides in North America. These biocides include a range of non-plant protection pesticides (e.g. public health pesticides, vertebrate control products, disinfectants, masonry biocides, timber treatments). These varied uses result in 23 high-level use scenarios with exposure data for only some of them. A solution to this biocide exposure problem involved a collaborative European effort of several agencies and countries with strong exposure assessment experience. This collaboration produced the Bayesian Assessment Toolkit (BEAT)[1]. BEAT is a computerized worker exposure database that maintains data in terms of exposure distributions. These BEAT models are combined with subjective assessments by the user answering simple questions which make it possible for the BEAT model to ascertain the similarity/non-similarity between the new scenario under consideration and all available data distributions. The output can be a new distribution or a point estimate for the new scenario. This probabilistic approach takes into account both uncertainty and variability. This panelist suggested that the Agency consider the BEAT model as a possible alternative approach for creating clusters.

The initial ARTF approach to clustering involved conducting a hierarchical similarity analysis where the crop/region/activity/height/foliage combinations identified in the expert survey were the objects to be clustered and the contact potential (CP) for nine body regions resulting from the expert survey were the attributes for measuring similarity. All attributes were weighted equally. Euclidean distance was used as the similarity metric and the

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[1]European Commission, Human Exposure to Biocidal Products Technical Notes for Guidance, January 2008 http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ON_HUMAN_EXPOSURE/TNsG%20-Human-Exposure-2007.pdf

average linkage method was used to link clusters. Although this clustering approach was ultimately abandoned by the ARTF when the CP data did not agree well with actual measured TCs, the CP attributes most appropriately could be considered to be categorical rather than continuous. Clustering methods are now available for categorical attributes, see the literature on latent class factors for classification (Badeen-Roche et al.,1997; Hagenaars and McCutcheon, 2002) and the poLCA method implemented as a package in the R [R Development Core Team (2008)] environment (Linzer and Lewis, 2007). Whether these alternative clustering approaches would produce better initial clusters is debatable given the subsequent findings of low correlation between CPs and TCs.

A Panel member also suggested that the Agency use an upper bound TC instead of a central tendency TC for risk assessment purposes, although another Panel member thought that given the degree of variability in the data, the estimated upper percentile would be quite far from the central tendency and might produce very conservative risk assessments. The Panel agreed that clustering exposures based on TCs should be considered an on-going process that is not complete until sufficient evidence is available that demonstrates workers in a particular assigned cluster have similar measured dermal exposures to a given pesticide. The Panel suggested that exposure monitoring validation studies would be needed to determine if workers in unmonitored crop-activity combinations have been assigned to the correct cluster. Where discordance is found, the factors contributing to the cluster misclassification need to be identified and taken into account. The Panel recognized that monitoring all crop-activity combinations would be monumental and impractical; however, the Agency could establish a priority list for validation and monitoring studies that should be conducted as part of on-going cluster evaluation.

<u>Number of Clusters and the Notion of "Super-Clusters"</u>

Some Panelists questioned the value of trying to parse the TC data into smaller and smaller clusters based only on statistics. In other words, just because one can find a statistical difference between certain subgroups of activities does not mean that they always have practical significance. For instance, one should keep in mind that the geometric standard deviation of the TC within most clusters is about 1.7, corresponding to a typical span of 8-fold within a typical cluster. If one rank-orders the 28 clusters proposed in Table 9 of Bruce and Korpalski (2008) by TC value, one can note that over half of the arithmetic mean TDE-TC values (16 of the 28 values) differ from their next higher TC by less than 15%; and conversely, barely more than one quarter of these mean TDE-TC values (9 of 28) differ by more than 25%.

This line of reasoning led the Panel to ask another question: How well does the clustering scheme proposed by ARTF reduce the variability within the universe of exposures across all the activities studied by ARTF? One possible informative test of the viability of any cluster assignment would be to compare the collective accuracy of all of the measured TCs against the assigned TCs for each cluster using such a selection algorithm. Such a comparison could be a linear correlation analysis to see how much of the overall variance among the TC values (the R^2 value) is explained by various combinations of clustered TC values. For example, if each of the 825 measured TCs were its own cluster, the R^2 would be 1.0; and if all measured TCs were in one cluster, the correlation would be zero (slope = 0). What is the R^2 for the 28 clusters proposed by ARTF? How would the R^2 be changed if the number of clusters were increased to 47 (the number of settings studied by ARTF) or reduced to 12 or 9 (as suggested below)? One Panel member commented that this was almost a Pareto analysis.

One alternative number of clusters is suggested by the above rank-ordered list. If that list were divided into groups only when the intervening difference is more than 25% and those groups were combined, the proposed 28 clusters could be reduced to as few as 9 to 12 "super-clusters." Such super-clusters would allow statistically similar, but agronomically different activities to be combined into fewer administrative groups that can be considered to have the same TC. While some or many of these larger groups may be too diverse to be manageable, the following two such super-cluster groups suggested by one panel member are examples that might be considered (see Appendix A):

1) Group 1 = SH, SSs, CHm and HHt (that span a full spread of 34%)
2) Group 2 = OW, HS, and SW (that span a full spread of 39%)

Miscellaneous Comments

Two of the ARTF studies (AR1008 Cauliflower: scouting and AR1027 Tomato, fresh: scouting) each had a sample size less than 10, which may be insufficient to adequately describe these crop-activity combinations. When presenting data with repeated measurements on workers, both the total number of monitoring units and the number of unique individuals should be reported in tables.

b. Statistical, agronomic, or other support for or against (1) the ARTF-proposed clusters; (2) the Agency evaluation of the ARTF-proposed clusters, and (3) the Agency-suggested alternative cluster schemes outlined below. Please include the rationale and reasoning for any Panel-recommended changes or modifications. The SAP Review Code in the list refers to Table 3 (attached as Appendix B), which provides a summary of the ARTF clusters, the Agency-suggested alternatives, and relevant page numbers in the Agency's background document.

i. Hairy Leaf Field Crops (clusters HH, HHt, and HS) [SAP Review Code A]

Panel Response: Concur with ARTF proposal.

ii. Smooth-*leaf Field Crops (clusters SH, SSR, SSS, SW and Sx) [SAP Review Code B]*

Panel Response: Concur with ARTF proposal. One panelist expressed some concern about placing hand harvesting sweet corn in its own cluster (Sx) in part because the placement was based on solid stand conditions. Sweet corn can also be planted in rows; however, the separate cluster for hand harvesting sweet corn would be conservative in terms of the TC and the Panel member was agreeable to the Sx cluster proposal.

iii. Waxy-leaf Field Crops (clusters WIH, WIS, and Wm) [SAP Review Code C]

Panel Response: Concur with ARTF proposal.

iv. Orchard Crops

1. Cluster OH and the Agency suggestion for a separate cluster for thinning [SAP Review Code D-1]

Panel Response: The Panel was split on whether or not it is appropriate to have separate clusters for orchard thinning and orchard hand-harvesting. Several panelists agreed that the non-parametric and mixed model analyses (both those performed by the Agency and those performed by two Panel members) suggested that thinning should be a separate cluster from hand harvesting. The Panel cautioned, however, that such analyses amount to "data snooping" since the clusters were established *a priori*. If the non-parametric or mixed model analyses are employed, then an adjustment for multiple comparisons, such as Bonferroni, Scheffes, or Tukey-Kramer should be applied. On the other hand, several Panel members thought that thinning and hand-harvesting should remain in the same cluster because the mechanisms of exposure have not been fully described; e.g. dustier conditions in the orchard might increase the hand-harvesting exposures to the level of the thinning exposures. A panel member suggested that the Agency and ARTF take a more detailed look at the thinning exposure conditions for indicators explaining why thinning levels were higher than hand harvesting given the testimony of a public commenter, a former orchard grower, who believed that hand harvesting had more plant surface contact than thinning. A panel member also noted that the biological monitoring data presented by Mr. Curt Lunchik of Bayer CropScience (part of ARTF) supports retaining thinning and hand-harvesting in the same cluster, an assessment opposite to that indicated by the non-parametric and mixed model analyses. More data, or a better explanation of the presented data, would be needed for the Panel to reach consensus on this question.

2) Clusters OHn and OW crop [SAP Review Codes D-2 and D-4]

Panel Response: Concur with ARTF proposal for separate OHn and OW clusters.

3) Cluster OP [SAP Review Code E-3]

Panel Response: Concur with Agency recommendation to combine TP and OP clusters.

Additional Panel Comments related to Orchard Crops

One panelist was concerned that ARTF's estimated TCs for orange harvesting were less than one half of the values for TCs found in prior research in both Florida and California (Nigg et al., 1984 and Popendorf, 1985, respectively). This situation was heightened later in the meeting after the panelist realized that all of the ARTF DFR values (and subsequent TC values) were based on two-sided leaf areas; that is, the area upon which mg/cm^2 was calculated counted both sides of each leaf punch. This nuance is consistent with the referenced method, Iwata et al. (1977), but it was not easy to find in the Agency's background documents.[2] If the TCs based on 1970s research were translated into two-sided residues [3,4], the TC for both California and Florida orange harvesting would have been about 10,000 cm^2/hr versus 2760 cm^2/hr from ARF028.[5] The buildup of foliar dust during the dry summer season and the date of the ARTF sampling (which turned out to be May 21st to June 3rd) could at best explain only a portion of the difference seen in Figure 1 to which dates have been added. However, Nigg et al. (1984) felt that foliar dust was not important because their TC (in Florida) was similar to that in California. Thus, the overall difference between the median TC for orange harvesting based on the ARTF data and the 1970s research is about 4-fold, which may be statistically significant based on the number of harvesters in all of these studies. And to broaden this comparison, many of the TCs estimated by Krieger et al. (1992) [6] in 1992 were larger than the current ARTF values by an even greater ratio (see Table 2 and Figure 1 below).

Table 2. Comparison between TCs estimated by Krieger *et al* in 1992 and TCs from the ARTF.

TCs from Krieger et al. 1992			TCs from ARTF		Ratio of TC estimated in 1992 to TC by ARTF
Crop	Work task	Transfer Factors (cm^2/h)	Cluster	Transfer Coefficient (cm^2/hr)	
Tomato pole	Harvester	21,000	HH	548	38.3
Lettuce	Cutter	13,000	WIH	1356	9.6
Strawberry	Harvester	2,375	SH	1076	2.2
Peach	Harvester	39,000	OH	1721	22.7
Grape	Harvester	17,500	THg	7462	2.3

[2] See Agency background reference "b" page 10 of 38: "5.14.1 Sample Collection: ... Each sample will consist of approximately 400 cm^2 leaf surface area (counting both sides of the foliage)" and Agency background reference "g" page 9 of 238: "DFR: Dislodgeable Foliar Residue (μg/cm^2): residue available for transfer from treated plant foliage per square centimeter of leaf surface (includes both sides)." and p. 45 of 238: "Samples of leaf punches (400 cm^2 total two-sided surface area) collected 1 day after application were dislodged with the following four DFR techniques: ..."

[3] Nigg, H.N., J.H. Stamper, and R.M. Queen. 1984. The Development and Use of a Universal Model to Predict Tree Crop Harvester Pesticide Exposure. Journal of the American Industrial Hygiene Association. 45(3): 182-186.

[4] Popendorf, W. 1985. Advances in the Unified Field Model for Re-entry Hazards. Chapter. 23 of *Risk Determination of Agricultural Pesticide Workers from Dermal Exposure.* ACS Symposium Series, American Chem. Soc., Washington, D.C., 323-340.

[5] See Agency background reference "h", page 35, Table 8. Their median TC for oranges in Florida was only 609 cm^2/hr.

[6] Krieger, R.I., J.H. Ross, and T. Thongsinthusak. 1992. Assessing Human Exposures to Pesticides. Reviews of Environ. Contam. Toxicol. 128:1-15 (cited in Ross, J., Driver, J., Lunchick, C., Wible, C., and Selman, F. 2006. Pesticide Exposure Monitoring Databases in Applied Risk Analysis. Arch. Envir. Contam. Tox., v. 186, pp. 107-132, see item "m" in the Agency's background documents).

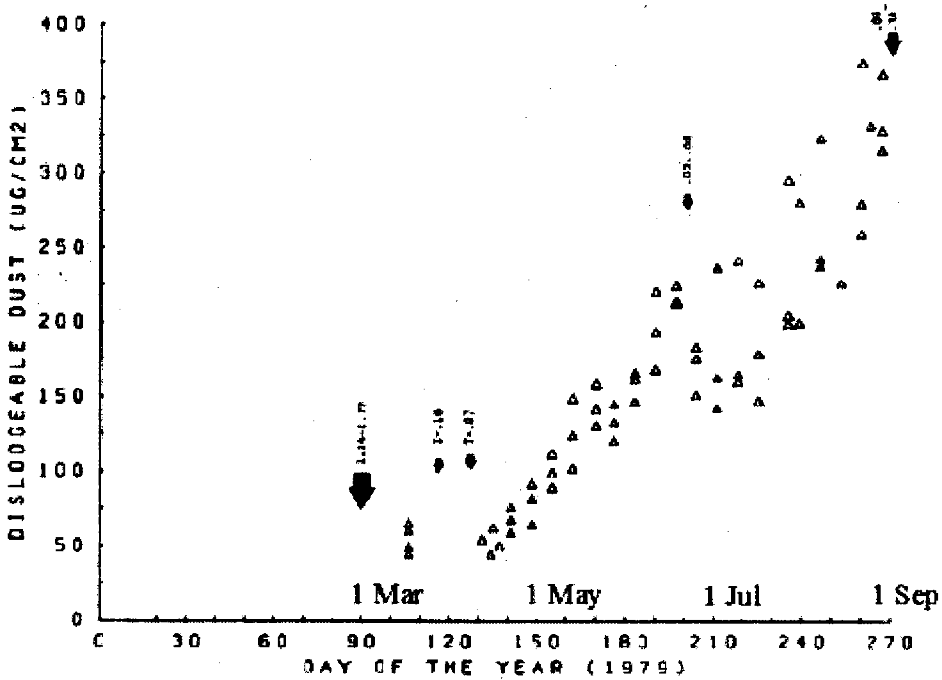

Figure 1. Dislodgeable foliar dust levels of weekly samples within three citrus groves during the summer of 1979. Reprint of Figure 16 from Popendorf and Leffingwell (1977).

v. *Trellis Crops*

1. Cluster THb [SAP Review Code E-1]

Panel Response: Concur with ARTF proposal.

2. Cluster THg and the Agency suggestions to further separate into clusters for hand harvesting wine grapes (THwg) and table/raisin grapes (THg) as well as utilizing the hand harvesting table/raisin grape cluster to represent girdling [SAP Review Code E-2]

Panel Response: The Panel decided to support the Agency's recommendation to have separate clusters for hand-harvesting table/raisin grapes and hand-harvesting wine grapes despite the fact that the ARTF data contain no table grape harvester exposure data, and the raisin and wine TC data overlap. This decision was based, in part, on observational research conducted in the California central valley in the 1970's (Popendorf and Spear, 1974) indicating that the TC for wine harvesters would be expected to be greater than the TCs for raisin harvesters and for table grape harvesters. By splitting the grape harvesting group as the Agency recommended, the wine grape TC will be greater than the table/raisin grape TC meaning that the table grape harvesters should be protected by a somewhat higher TC without any additional data.

Although the Panel agreed to split the cluster, several panelists originally had reservations. One Panel member suggested that a mixed model statistical approach be used to estimate cluster-associated variability. A second panelist stated that the grape harvest TC data were incomplete in that they did not include measurements for table grapes or other grape varieties (e.g., Thompson, Concord) and different cultural practices between grape varieties may lead to different worker exposures. In response, several panelists recommended that the Agency consult with horticulturists who specialize in grape production to better understand the degree of worker contact in the production of different grape varieties. In the end, the Panel agreed to support separate clusters for table/raisin grapes and wine grapes.

3. Cluster TP and the Agency suggestion to group with cluster OP (see Figure 31) [SAP Review Code E-3]

Panel response: Concur with Agency recommendation to combine TP and OP clusters.

4. Cluster Tx [SAP Review Code E-4]

Panel response: Concur with ARTF proposal.

vi. *Greenhouse and Nursery Crops*

1. Clusters GHf and GHv [SAP Review Code F-1]

Panel response: The Panel was split on the issue of separate greenhouse flower hand harvesting (GHf) and greenhouse vegetable (GHv) clusters. Some Panel members concurred with the ARTF proposal for separate GHf and GHv clusters; however, several other Panel members were not comfortable with separate GHf and GHv clusters. These differences were based, in part, on the absence of TC data for hand activities performed in the cultivation of greenhouse vegetables including row spacing implications. The ARTF proposal to separate flower and vegetable hand-labor activities in greenhouses was largely based on agronomic and ergonomic assessments.

Two panel members mentioned that there might be some tomato greenhouse studies and fluorescent tracer data that might aid this discussion, although no details were provided. Some panel members were concerned about the potential for narrow rows and close spacing in greenhouse vegetable production systems that would exacerbate exposure because of increased contact with plants. These panelists noted that some specification of allowed row spacing within the definition of GHv activities might be needed to separate the GHv cluster from the GHf cluster. While changes in cultural practices in greenhouse vegetables have reduced contact with plant foliage over time within newer greenhouses, one panelist commented that exposure data from Europe suggested that greenhouse practices, in some cases, have not improved that much. Narrow row spacing for vegetables in the greenhouse would be very similar to the narrow row spacing often used for flowers grown in the greenhouse and therefore the worker exposures would be very similar. Overall, many questions remain as to the effect of greenhouse cultural practices on dermal exposure. The Panel stated that additional data on dermal exposure and DFRs for greenhouse vegetable hand-labor activities would help evaluate whether GHf and GHv should be separate clusters.

One panel member addressed foliage contact with specific greenhouse (or shadehouses) crops grown in Hawaii. Both orchid and anthurium production would require low foliage contact during harvesting, suggesting that the GN cluster would be appropriate. Orchids are grown in greenhouses to a very large extent in Hawaii, particularly on the Big Island. Unlike other flowers, harvesting orchid flowers is not a contact intensive activity. It is a delicate procedure in which only the flower stem is harvested. The TC for orchids may be closer to pinching chrysanthemums in which case the GN cluster may better represent harvesting crops like orchids, rather than the GHf cluster.

2. Cluster GN and the Agency suggestion to have an additional cluster for hand-harvesting nursery crops (GHn) [SAP Review Code F-2]

Panel response: The Panel also had reservations about splitting hand harvesting of nursery stock (ARF044) out of the GN cluster to create its own cluster. The TC data for hand harvesting nursery stock overlaps with the TC data for other activities in the GN cluster. The effect of aisle or plant spacing on some of the observed differences should be examined before making a decision. Information about aisle and plant spacing should be added to any definition of a greenhouse cluster. Narrow row spacing might lead to greater worker foliar contact and increased exposure. In general, a good understanding of the variation in cropping practices in greenhouses is required to address this question. One Panel member suggested that it might be helpful to look at this question using a mixed model analysis.

vii. Crop Irrigation (cluster I) [SAP Review Code G]

Panel response: Concur with ARTF proposal.

viii. Mechanical Harvesting Cotton (clusters CHp, CHm, and CHt) [SAP Review Code H]

Panel response: The Panel recommended a single cluster for mechanical harvesting of cotton. This recommendation is based on the limited TC data (i.e. <10 observations) for several cotton mechanical harvesting hand-labor activities (i.e. module builder operator, raker, and tramper) and the potential for a worker to perform several cotton mechanical harvesting activities within a day. The module builder operator and the picker operator/raker TC data overlap considerably, and the two activities are probably both essential parts of any harvest team. If these activities were separated, and the resulting REIs were proportional to the individual TCs, on the day post-application that a field first becomes safe for a cotton module builder to begin work, it would not yet be safe for a cotton picker operator or raker to work in that field (and even less so for a tramper). Unless the tramper (or to a lesser extent the cotton picker operators and rakers) can be provided personal protective clothing to allow them to work as soon as it is safe for cotton module builders to, in effect, reenter a treated field, one might as well consider collapsing all of the cotton subcategories into one harvest activity based on the most exposed individual, *i.e.*, the tramper.

ix. Turf (clusters DH and DM) [SAP Review Code I]

Panel response: The Panel generally agreed that the TC data are too limited to justify splitting the DM cluster into additional clusters. The TCs in the DM cluster span several orders of magnitude, and while a much narrower TC spread in a cluster would be desirable (e.g. less than one order of magnitude), the Panel recognized that golf maintenance workers perform a variety of hand-labor tasks within a day and that it may not be practical or possible to split the DM cluster to reduce the variability. The difficulty of separating golf course maintenance workers into separate hand-labor activity clusters is further supported by an Agency-convened meeting of golf course operators who "generally agreed that job rotations are common place." One Panel member believed, however, that given the wide range of the TC data, the TC paradigm (i.e. one crop/hand-activity per day) likely does not apply to the DM cluster. Another Panel member suggested that the Agency consider assigning a more conservative TC (e.g. the 75^{th} percentile) than the GM (or AM) to clusters with unusually high variability in order to better protect persons at the upper end of such wide distributions.

QUESTION 3: *As indicated in the background document, the Agency recognizes the limitations associated with using certain statistical tests (such as the nonparametric Wilcoxon and Kruskal-Wallis tests) to provide a broad rationale for the separation or combination of studies to form clusters. Specifically, these tests do not adequately account for or consider a number of complex features of the data such as repeated measurements on the same worker and nesting. Again, as stated in the text, a mixed model approach that incorporates the hierarchical nature of the data is likely to be more appropriate and to more definitively address the issues of interest regarding the degree to which specified crop-activity combinations might be combined. In Exhibit F, the Agency provides a case study example of this alternate (mixed model) approach for determining reasonable groupings of transfer coefficients (TCs) from exposure studies involving various crop activities thought to be ergonomically and/or agronomically similar.*

The Agency believes the proposed approach illustrated in Exhibit F uses more appropriate statistical and quantitative procedures for determining which exposure monitoring studies can or should be combined. Please discuss thoughts and/or concerns with the analytical *approach outlined in Exhibit F and on the annotated SAS code provided as an attachment to Exhibit F. Please provide feedback on the results of the case study which indicates that it would not be inappropriate to consider TC values associated with hand harvesting activities in orchards to be distinct from TC values associated with hand thinning activities in orchards (see SAP Review Code D-1 in Table 3 below and Figure 25 in the Agency's background document).*

<u>Panel response:</u>

The ARTF exposure monitoring studies clearly include repeated measurements on individuals and multiple studies within some crop-activities. Given these data characteristics, the Panel generally agreed that a mixed model analysis is more appropriate than non-parametric tests for determining reasonable groupings of TCs, assuming the sample size is adequate, the impact of censored data is limited or can be handled to minimize bias, an appropriate covariance structure is specified, and adjustments for multiple comparisons are made as necessary. The Panel cautioned, however, that these statistical tests are being performed on clusters that have been defined *a priori* and thus, assumptions typically underlying formal statistical tests are violated. The results of the mixed models or non-parametric tests, for that matter, should only be considered to be indicators of studies that do not fit the pre-defined clusters. The Panel proposed two alternative mixed models to reduce over-fitting suspected in the Agency mixed model. The Panel's two alternative models and the Agency model each indicated that hand-thinning in orchards should be a separate cluster from hand-harvesting in orchards. In contrast, however, to these analyses, results of a recent biomonitoring study of orchard workers performing hand-thinning and hand-harvesting indicated that hand-thinning and hand-harvesting activities could both be described by the same cluster (presentation by C. Lunchik, Bayer CropScience on behalf of ARTF, see Public Docket EPA-HQ-OPP-2008-0673).

When evaluating differences between clusters, the Panel cautioned that analysts are looking at statistical testing within a group of studies that have already been placed with each other in a clustering methodology that used both statistical and agronomic factors. The expectation is that the studies in this group will be similar because the cluster has been designed to group similar studies. Therefore, the *P*-value resulting from the statistical test cannot be interpreted as in normal testing. The statistical test is used as one way of measuring how far the studies are from each other. In this situation, the assumptions typically underlying formal statistical tests are violated. These results should only be considered as an "indicator" of potential studies that "don't fit" the general group statistical characterizations. Given that the expectation going into the analysis is for "no differences," differences that do show up with very low *P*-values should be examined carefully for exclusion from the group. If the process is iterated, it might be possible to split out another study, and then another with the eventual result that all studies might eventually be in their own group, defeating the original goal of the clustering process. As a result, the use of formal statistical methods needs to be done sparingly and with caution.

When performing parametric and non-parametric tests, the Panel indicated that it is also important to examine areas of non-agreement. Some consideration should also be given to developing confidence intervals around the point estimates. Most clusters span one order of magnitude. A sense of "how different" studies have to be to make a difference of practical importance would help in assessing the appropriateness of the proposed clusters.

Alternative Mixed Model #1

At least two panel members were concerned about the mixed model analyses described in Exhibit F (Supplemental Statistical Analysis for ARTF Cluster OH). The basic concern is that the random intercepts/random slopes approach may be over-fitting the data. Figures 2-4 show plots of the mixed model predictions against the observed log (exp) values for each of the three mixed models presented by the Agency. Given the large amount of variability in most of the studies in the OH cluster, one would not expect predictions to be so close to the observed values. One concern with over-fitting the data is that predictions from these models may work extremely well with these data, but may provide poor fit with respect to any other data set. One panel member proposed an alternative mixed model analysis that is illustrated using the OH cluster (see Appendix C).

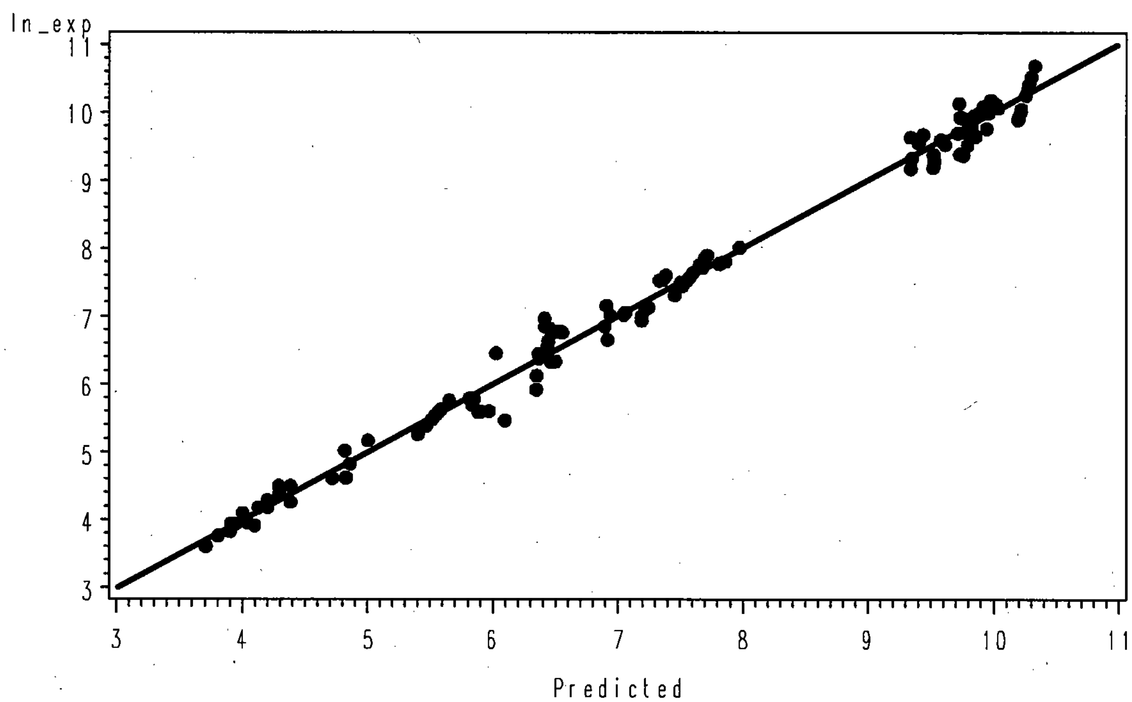

Figure 2. Plot of observed log(exp) versus predicted for Model 1 in Exhibit F.

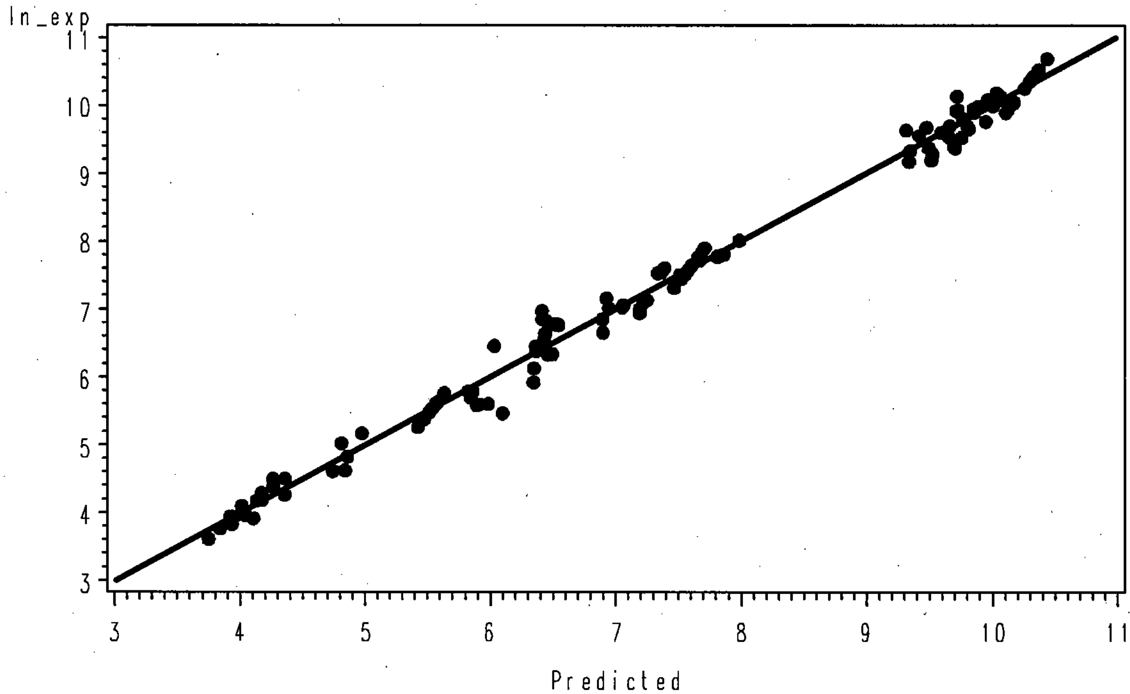

Figure 3. Plot of observed log(exp) versus predicted for Model 2 in Exhibit F.

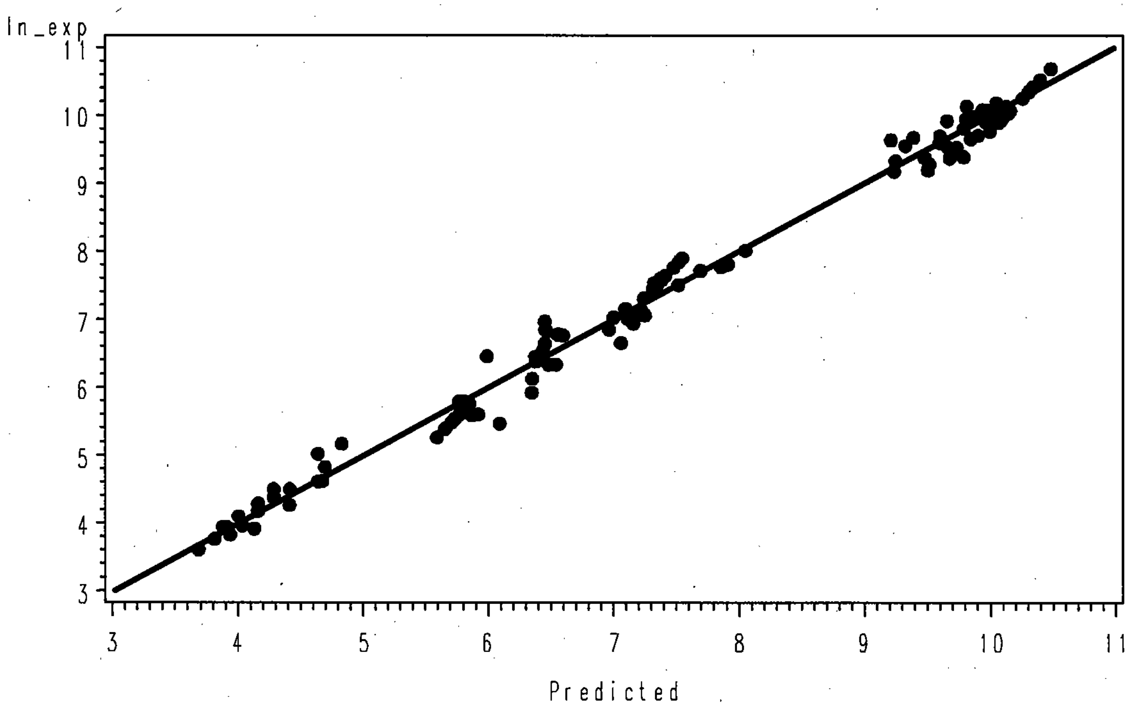

Figure 4. Plot of observed log(exp) versus predicted for Model 3 in Exhibit F.

Alternative Mixed Model #2

An independent analysis by a second Panel member of the orchard harvest (OH) cluster data addressed in Exhibit F employed an alternative general linear mixed model (GLMM) parameterization:

$$\ln(TC)_{ijk} = \beta_0 + \beta_1 \cdot I_{AR1002} + \cdots + \beta_7 \cdot I_{AFR041} + \mu_{j(i)} + \varepsilon_{ijk}$$

where:

I_i are fixed effect indicator variables for study i (reference is ARF042);

$\mu_{j(i)} \sim N(0, \tau^2)$ are random effects for subjects j, nested within study i;

$\varepsilon_{ijk} \sim N(0, \sigma^2)$ are random errors independent of the $\mu_{j(i)}$.

This model assumes that the individual studies effect on the natural logarithm of the transfer coefficient are "fixed" and accounts for the intraclass correlation of multiple subject measures within each of the individual studies. The model imposes no time dependent structure on the covariance of the multiple observations on each individual subject.

Using the Mixed procedure in SAS V9.1.3 [see http://www.sas.com/presscenter/guidelines.html], parameters of this model and least squares means of lnTC (and standard errors) were in turn, estimated for each of the eight study sites. Table 3 presents the estimated means and standard errors for this model as well as for the repeated measures model assuming a first order autoregressive (AR1) covariance structure for within-individual measurements.

The estimated least squares means of lnTC (shown in Table 3) are virtually identical under the two model alternatives and both sets of model results for Scheffe-adjusted tests of the differences of least squares means (not shown) lead to the same conclusion. Within the cluster of eight studies, Study AR1003 has a significantly higher mean than the remaining group of seven studies.

Table 3. Comparison of Results for Two Alternative Models of lnTC

Study ID	Repeated Measures (AR1)		Random Intercept Model	
	LS Mean	SE(LSMean)	LS Mean	SE(LSMean)
AR1002	7.23	0.13	7.23	0.13
AR1003	8.11	0.08	8.11	0.08
AR1014	6.94	0.09	6.94	0.10
AR1021	6.92	0.12	6.92	0.11
ARF025	7.25	0.14	7.28	0.13
ARF028	7.91	0.14	7.92	0.13
ARF041	6.45	0.14	6.41	0.13
ARF042	7.00	0.14	6.99	0.13

QUESTION 4: *Please comment on the classification of crop-activity combinations in Agency Exhibit C, identified with a cluster code of "No TC", as involving no or very low exposure. Please identify any crop-activity combinations classified as "No TC" in Exhibit C which should be categorized differently because of their associated exposure potential. Likewise, please identify any combinations which should be categorized as "No TC" which are currently included in other clusters. Please explain the basis for any such recommendations.*

Panel response:

The Panel generally agreed with the Agency on its "No TC" crop-activities with some possible exceptions as noted below. The Panel finds that the number of crop-activities in the "No TC" category is rather large. The current list of crop-activities with a "No TC" designation is potentially misleading because it includes crop-activities that might be further subdivided into three distinct groups:

1) Those crop-activities for which the concept of a TC may not apply, such as activities where exposure might be more dependent upon an event that is not a consistent function of time, e.g., spreading bins or training;

2) Those crop activities with no TC data, but such data could be generated if a study were done, e.g., digging peanuts or fertilizing; and

3) Those crop-activities that the Agency considers to have minimal or negligible TCs based on available information,

The type of activity and the potential for contact with plant material is not always obvious from the one or two word descriptor used for the crop-activities with a "No TC" designation in Exhibit C of the Agency's issue paper. The Panel recommended that descriptions of the "No TC" crop-activities be provided, including the equipment used and the presence of features such as enclosed cabs that would limit foliar contact and/or exposure from fallout. A photo, where available, of the crop-activity would also be useful.

The rationale for some of the "No TC" designations for certain crop-activities was unclear. A brief description of each "No TC" activity is recommended. Some examples of "No TC" activities that need further clarification are: 1) Hand-pruning (e.g., almonds, pecans, and pistachios) – need to clarify how hand-pruning activities with "no TC" differ from hand-pruning activities with "TCs," 2) Transplanting – need to clarify whether there are any pesticide residues remaining on the plant prior to transplanting and the extent of dermal contact, 3) Irrigation – need to clarify that this distinction applies to "non-hand line" irrigation, 4) Vine Training (e.g., squashes, melons) – need to clarify the extent of dermal contact, 5) Defoliation (burndown) – need to clarify whether workers (e.g., scouts) have any dermal contact following application of the defoliant, and 6) Topping – need to clarify whether this is manual or mechanical.

In Hawaii, the "No TC" designation for fertilizing nursery and flower crops is inappropriate as slow-release fertilizers are added by hand to individual pots of orchids and anthuriums at various intervals over the 3-4 year period the plants are in the greenhouse, and the workers brush the foliage as they apply the fertilizer.

All mechanically harvested orchard and trellis crops are likely to involve exposures to residues via the fallout of pesticide-contaminated particles onto the operator's skin (unless they are in fully-enclosed cabs). Support for this belief includes both 1) prior research and photographic evidence that the indirect deposition or fallout of pesticide-contaminated foliar dust onto a worker's skin can be an important mode of transfer and exposure in California and 2) the ARTF's own TC of 167 cm^2/hr calculated for workers mechanically harvesting almonds, but without any direct foliar contact. Therefore, all mechanically harvested orchard or trellis crops should be assigned the TC for mechanically harvested almonds (167 cm^2/hr) unless other data indicate lower exposures. The Panel thought it advisable to acknowledge that mechanical protection (enclosed cabs) will reduce the indirect exposure due to fallout.

2. Topic B: Workday Duration

The Agency discussed its methodology for assessing post-application exposures with an emphasis on the workday duration input. A central tendency value of 8 hours per day is typically used by the Agency. The data also show, as seen in several sources, certain portions of the population work longer over the course of a day (e.g., 10 or 12 hours). However, the Agency believes that, in most cases, employing a central tendency estimate of 8 hours per day yields an appropriately protective estimate of risk because of the combined impact of several other inputs in the exposure and risk assessment process. Specifically, the following issues have been identified for the Panel to consider:

QUESTION 1: *Please comment on the strengths and limitations of the data sources used to quantify the duration of a workday for farm workers, as well as any additional sources of information that could be used for the analysis of farm worker workday duration. If any are identified, please comment on the possible impacts they might have on the results of the analysis conducted by the Agency.*

Panel Response:

The Panel concurred with the Agency's proposed use of the datasets to establish a workday duration for generic dermal exposure assessment. The Agency primarily used two sources for workday estimates, a grower survey (Thompson, 1998) and a U.S. Department of Labor report (USDL, 2005) from the National Agricultural Worker Survey (NAWS). The data from Thompson (1998) were over a decade old, while the data used in the USDL (2005) were from surveys conducted in 2001-2002. USDL data (i.e., from NAWS) collected in different years also showed changes in workday duration. The USDL report published in 2000 indicated the average work week for farm laborers was 38 hours, while the report from 2005 reported an average work week of 42 hours. Neither dataset was specifically designed to accurately collect workday duration information. The Panel commented that the results of the NAWS might be subject to some error because participants were asked to recall hours worked during the last work week (i.e., participants may forget how many hours they worked or that week may not have represented a typical work week). Additionally, the data are somewhat old, and given that the agricultural industry is dynamic and the practices are constantly evolving, they may not be representative of today's practices. Despite the above limitations, these datasets are robust because they have large sample sizes, represent a diversity of geographic regions, and incorporate perspectives of both growers and workers. These surveys represent the best available national data. The Panel suggested that the Agency may wish to incorporate data from the California Crop Profiles or data obtained from more recent NAW surveys to augment the Thompson (1998) grower survey and the 2005 NAWS. Another suggestion was to search the published literature related to ergonomics and examine information provided by the Agro Safety Center in California to aid estimations of workday duration.

The data in the two datasets were presented as hours worked per week and were quite variable by individual worker. The variability of these data should somehow be identified, acknowledged, or incorporated into the generic value. Using the assumption that a typical workweek was 5 days, the Panel concurred that a reasonable estimation of the central tendency of workday duration was 8 hours. However, one Panel member expressed concerns that the only justification for considering a workday as 8 hours is because it is commonly accepted in economics. An unintentional consequence of using 8 hours as a generic input for dermal exposure calculations is that others might think this was a value for a "safe" workday.

QUESTION 2: *Please comment on the Agency's conclusion that using 8 hours per day for exposure assessment purposes and given the conservativeness of the other inputs results in estimates of farm worker exposures at the high end of the distribution of actual multi-day exposures. To the extent that the Panel believes that this is not the case, please suggest alternative approaches.*

Panel Response:

The Panel agreed with the Agency's proposed use of an 8 hour workday duration. The Panel also concurred with the Agency that the use of an 8 hour workday duration in a generic dermal exposure assessment represented the high-end of the distribution of actual multi-day exposures given the other assumptions used by the Agency to determine multi-day exposures, i.e., maximum application rate is used, a re-entry worker is performing tasks resulting in potential re-entry pesticide exposure for the entire 8 hours, and the worker is exposed to the day 1 DFR on every exposure day. The Panel pointed out that these assumptions for multi-day exposures were very conservative and may lead to an overestimation of multi-day exposure. Most of the Panel stated that the conservative approach using the deterministic model is protective for the majority of people.
The importance of extending exposure duration beyond 8 hours per day in the dermal exposure (DE) calculations, and subsequently in the reentry interval (REI) calculations, was debated. Some Panel members felt that a probabilistic approach for exposure assessment would allow a more protective calculation for multi-day exposures. Others felt that calculations using an 8 hour workday would overestimate true exposure by about 1.5 times; however, using a 12 hour workday, the exposure estimate would approach the true value. In the end, the Panel indicated that the deterministic approach was conservative for the majority of workers. Using an 8 hour workday would provide an additional level of protection at the upper end of the exposure distribution profile that some in the Panel preferred. The biomonitoring data tends to verify the conservativeness of this approach.

Most panel members agreed that the workday duration and the exposure derived from that workday were dependent upon the exposure scenario, and as such exposures will vary considerably. Some panel members indicated that if the maximum application rate scenario is not applicable to multi-day exposures, then perhaps it should not be used. However, if this exposure scenario (i.e., 8 hours) is the most realistic in the field then it should be used. Overall, the Panel felt that a change in the duration of exposure would have little effect on the overall generic dermal exposure estimate. Data comparing propagation of error results to Monte Carlo method results supports this conclusion [See Appendix D].

The Panel also debated whether the plateau effect observed in the plot of exposure rate versus time in the Spencer et al. (1995) data, and its re-analysis by Ross et al. (2000) should be a significant consideration for addressing this charge question. This experimental evidence indicates that the dermal dose rate (mg/hr) decreases with the length of the workday. The decrease has been described as a "plateau-effect" in which the dosing rate measured within about the first 2 hours is higher (by about 1.5×) than the dosing rate measured over the subsequent 6 hours. As shown in a presentation to the Panel by S. Korpalski, representing ARTF, (see Public Docket EPA-HQ-OPP-2008-0673), virtually all of the ARTF studies exceeded 2 hours. Thus, the effect of the plateau has been incorporated within the ARTF's TC calculations. Based on Spencer's and similar data (Zweig et al., 1985; Fenske and Lu, 1994), the Panel concluded that any extrapolation of the dose rates and TC values from any of the ARTF studies that had measurements of less than 8 hours to 8 hours (or more) would be conservative. While the magnitude of this additional level of protection is not as large (a fraction of the 1.5× mentioned above) as the 1.5× increase in TC values estimated by further extrapolation of exposure from an 8 to a 12 hour work day, the plateau-effect would still be a benefit.

The effect of dermal absorption rate on the appropriateness of using an 8 hour generic criterion for workday was also discussed. Kissel and Fenske (2000) pointed out that the current approach of taking a percentage of the dermal dose as absorbed in re-entry worker exposure assessment has an "implicit and highly implausible assumption that absorption is independent of residence time on the skin." These authors proposed an alternative method and recommended that regulatory assessments should take account of the time dependent nature of dermal absorption. Assuming that washing shortly after work efficiently removes pesticide from skin would give lower exposure estimates of absorbed dose than models that ignore time. This was further demonstrated by Doran et al. (2003), whose time dependent approach gave a better match to biological measurements of azinphosmethyl than did the traditional time independent approach. Washing practices of affected workers is just one more uncertainty associated with assumptions of exposure and absorption.

QUESTION 3: *Please comment on whether the Agency's approach to single-day exposure assessments results in farm worker exposure estimates that fall in the high end of the distribution of actual single day exposures. To the extent the Panel thinks that is not the case, please suggest alternative approaches that may generate such estimates.*

Panel response:

The Panel discussed and agreed that the use of the 8 hour workday duration represents a large proportion of the exposure distribution profile, but does not adequately reflect exposures at the 90^{th} or 95^{th} percentiles of the distribution following a single day exposure. The data presented suggested that the estimated dermal exposure for the 8 hour workday duration is not a central tendency estimate, but actually represents the 65^{th} percentile of exposure resulting in underestimation of exposure for 35% of the population. The Panel felt that it was not transparent how the current approach represents the high-end exposure scenarios. The Panel sought clarification of what the Agency meant by a "high-end" of exposure. The Agency clarified that the upper end distribution they were seeking to reflect was the top 5-10% of the distribution. The Panel concluded that the proposed estimates fell short of this goal. Some Panel members noted that it was difficult to evaluate exposure and the associated "protectiveness" of this exposure estimate without also considering the toxicity of the individual chemical; however, the Panel recognized their charge was to deal only with those criteria of a generic dermal exposure assessment, not risk assessment. Overall, while the Panel recognized that an 8-hr workday might underestimate exposure in some cases, the Panel felt that variations associated with transfer coefficient estimates were a much greater source of uncertainty in overall exposure prediction models.

One panel member pointed out that the discussion on page 94 of the Agency's issue paper contained several small conceptual errors described below. None of these errors, however, invalidated (in fact, the latter two strengthen) the conclusions made both on page 96 that the central tendency estimates currently used are sufficiently conservative and on page 97 that "the use of 8 hours is an appropriate estimate for workday duration for multi-day exposure assessments."

- The result of each of the 10,000 Monte Carlo simulations is a random combination of daily exposure distributions. Thus, each percentile actually represents the distribution of all workers on a single day and should not be confused with repeated daily exposures of one worker. One of the differences is that one person's weight does not vary from day-to-day as much as the variability of the whole population.

- The need to truncate the distribution of hours within the simulation is actually very unlikely. The maximum expected deviation in 10^4 simulations is slightly less than 3.85 which (times a 2.28 hour standard deviation in Table 27) equals 17 hours, a result that is both realistic and similar to two of the mechanical tasks in Figure 39 (p. 87).

- The need to truncate the distribution of TC values is also unlikely since 1 value out of a simulated population $N = 10^4$ with a GSD of 1.67 will be about the same distance from the mean as would be expected for 1 value within a very well populated cluster of $N = 40$ with a GSD of 2.25 (and 1 out of $N = 20$ with a GSD of about 2).

One limitation in the simulation is that all the scenarios assume the same day-1 DFR. However, real DFRs are variable. If one were to consider the variability within a submitted set of pesticide specific DFR values (or simulate a variable set of DFR values), that real-world variability would also add to the variability of that outcome in much the same way as shown by the simulation (the extent of that effect depends upon what DFR the Agency will use).

The example below provides an alternative way to interpret the results of the Monte Carlo simulation without the need to envision a statistical distribution. The following ratios compare the mean dose predicted using the deterministic method (2.46 mg/kg-day, see p. 93 of the Agency's issue paper) with the mean dose predicted from using each of the simulation methods. The value of the ratio indicates by how much the deterministic dose (2.46 mg/kg-day) exceeds the simulated mean dose values.

$$\frac{2.46 mg/kg-day}{1.99 mg/kg-day} = 1.24 \text{ degree of over-estimation using MC simulation}$$

$$\frac{2.46 mg/kg-day}{1.88 mg/kg-day} = 1.31 \text{ degree of over-estimation using Scenario A}$$

$$\frac{2.46 mg/kg-day}{1.59 mg/kg-day} = 1.55 \text{ degree of over-estimation using Scenario B}$$

Because the deterministic method over-estimates the mean dose values predicted by all of these simulations, the current method can be considered protectively conservative.

A Propagation of Error analysis conducted by one Panel member (see Appendix D) showed that the variability in the length of the workday [WD] only contributes about 28% to the total variability in the total dermal exposure [TDE] predicted using the Monte Carlo methods referred to above. For comparison the variability in TC values within the SH cluster used in those simulations contributes 48% to the total variability in the TDE. In some cases, the mean TC values may not be "high-end" estimates of exposure. Use of "high" TC values, e.g., 95th percentiles, may therefore be better for estimating "high-end" exposures.

A couple of panel members commented on the issue of cumulative exposures for multiple chemicals having a common mechanism of toxicity. The notion of cumulative exposures further suggests (as in the case of occupational workers with relatively high exposures to many pesticides) the potential need for high-end TC values for single day exposure assessments. The Panel recognized that this issue is considered part of hazard assessment and was outside the exposure assessment issues discussed at this meeting.

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w. U.S. EPA (2000). Science Advisory Council For Exposure Policy 3.1, Agricultural Transfer Coefficients (Original 5/7/98 revised 8/7/2000).

x. U.S. EPA, (1993). Pesticide Rejection Rate Analysis: Occupational and Residential Exposure: [EPA Document 738-R-93-008]

APPENDICES

Appendix A: Example of "Super-Clusters" based on data from Table 9 of "Development of the ARTF Transfer Coefficient Database" by E.D. Bruce and S.J. Korpalski (2008).

Cluster Code	Cluster Description	Total Sample Size	Sample Size for TDE	AM TDE TC (cm^2/hr)	GM TDE TC (cm^2/hr)	% Δ between AM	% Δ within between super cluster
Tx Sx	Trellis crops: intense contact activities Smooth-leaf field crops: intense contact activities	30 18	30 17	19,297 17,589	16,633 16,263	10%	9%
THg DH	Trellis crops: hand harvesting grapes and similar contact activities Sod: mechanical harvesting, scouting, transplanting, and hand weeding	35 18	35 17	7,462 6,666	6,132 6,183	136% 12%	11% 161%
CHt	Cotton, mechanical harvesting: tramper (based on boll residues)	4	4	5,045	3,513	32%	one cluster
GHf	Greenhouse floriculture hand harvesting: all flowers and methods	32	31	4,746	2,286	6%	
Wm	Waxy-leaf field crops, medium height: all activities, plus full foliage weeding	55	53	4,240	3,893	12%	24% 67%
DM	Golf courses: maintenance activities	44	44	3,717	808	14%	
CHp	Cotton, mechanical harvesting: picker operator and raker (based on boll residues)	20	14	2,355	1,936	58%	
I	Irrigation, any crop where hand line is possible	15	15	1,851	1,001	27%	31% 108%
OH	Orchard crops: hand harvesting and similar contact activities	138	131	1,721	1,399	8%	
THb	Trellis crops: hand harvesting caneberries and similar contact activities	15	15	1,422	1,330	21%	
WlH	Waxy-leaf field crops, low height: hand harvesting and similar contact activities	15	15	1,356	1,139	5%	14% 54%
GHv	Greenhouse vegetables: hand harvesting and similar contact activities	30	30	1,232	1,118	10%	
SH	Smooth-leaf field crops: hand harvesting and tying	55	55	1,076	944	14%	
SSs CHm	Smooth-leaf field crops: scouting in solid stand conditions Cotton, mechanical harvesting: module builder operator (based on boll	39 6	39 6	1,073 903	960 472	0% 19%	29% 41%

Cluster Code	Cluster Description	Total Sample Size	Sample Size for TDE	AM TDE TC (cm^2/hr)	GM TDE TC (cm^2/hr)	% Δ between AM	% Δ within between super cluster
	residues)						
HHt	Hairy-leaf Tobacco: hand harvesting and canopy management	24	24	800	732	13%	
TP	Trellis crops: hand pruning, scouting, and similar contact activities	15	15	635	524	26%	
OP	Orchard crops: hand pruning, scouting, and similar contact activities	30	30	582	493	9%	15% 59%
HH	Hairy-leaf field crops: hand harvesting and similar contact activities	39	39	548	527	6%	
WlS	Waxy-leaf field crops, low height: scouting and similar contact activities	5	5	332	259	65%	one cluster
GN	Greenhouse and nursery crops (others): all activities AND transplanting all crops	45	45	231	190	44%	
SSr	Smooth-leaf field crops: scouting in row conditions	22	20	213	165	8%	21% 183%
OHn	Orchard crops: mechanically harvesting nuts	10	10	187	167	14%	
OW	Orchard crops: hand weeding and similar contact activities	10	10	98.5	84.4	90%	
HS	Hairy-leaf field crops: scouting and similar contact activities	15	14	94.5	88.6	4%	33% 207%
SW	Smooth-leaf field crops: hand weeding, thinning, and similar contact activities	32	32	70.7	55.8	34%	
No TC	Activities with no TC assigned	N/A	N/A	N/A	N/A		

Appendix B. Table 3 – Agency's Reference Table for Charge Question 2(b)

Table 3: Reference Table for Charge Question 2 (b)

ARTF Study			ARTF Proposal		Agency Proposal		SAP Review Code	Page No.
Category/ Study Code	***Crop***	***Activity***	***Cluster Code***	***Description***	***Summary of Agency Review of ARTF Proposal***	***Cluster Code***		
Hairy-leaf, Field Crop Clusters								
ARF045	Cucumbers	Hand Harvesting	HH	Hairy-leaf field crops: hand harvesting and similar contact activities	The Agency concurs with ARTF's proposal	HH	A	54-59
ARF049	Summer Squash	Hand Harvesting						
ARF024	Tobacco	Hand harvesting	HHt	Hairy-leaf (Tobacco): hand harvesting and canopy management	The Agency concurs with ARTF's proposal	HHt		
ARF022	Sunflowers	Scouting	HS	Hairy-leaf field crops: scouting and similar contact activities	The Agency concurs with ARTF's proposal	HS		
Smooth-leaf, Field Crop Clusters								
ARF051	Tomato	Tying	SH	Smooth-leaf field crops: hand harvesting and tying	The Agency concurs with ARTF's proposal	SH	B	50-54
AR1001	Strawberry	Hand Harvesting						
AR1023	Tomato	Hand Harvesting						
AR1024	Strawberry	Hand Harvesting						
AR1025	Cotton	Scouting	SSr	Smooth-leaf field crops: scouting in row conditions	The Agency concurs with ARTF's proposal	SSr		
AR1027	Tomato	Scouting						
ARF009	Corn	Scouting	SSs	Smooth-leaf field crops: scouting in solid stand conditions	The Agency concurs with ARTF's proposal	SSs		
ARF021	Dry Pea	Scouting						
AR1006	Cotton	Hand weeding	SW	Smooth-leaf field crops: hand weeding, thinning, and similar contact activities	The Agency concurs with ARTF's proposal	SW		
AR1018	Cotton	Hand weeding						
AR1019	Dry Pea	Hand weeding						

ARF010	Sweet Corn	Hand harvesting	Sx	Smooth-leaf field crops: intense contact activities	The Agency concurs with ARTF's proposal	Sx		
Waxy-leaf, Field Crop Clusters								
ARF050	Cabbage	Hand harvesting	WIH	Waxy-leaf field crops, low height: hand harvesting and similar contact activities	The Agency concurs with ARTF's proposal	WIH	C	59-61
AR1008	Cauliflower	Scouting	WIS	Waxy-leaf field crops, low height: scouting and similar contact activities	The Agency concurs with ARTF's proposal	WIS		
ARF011	Cauliflower	Scouting	Wm	Waxy-leaf field crops, medium height: all activities, plus full foliage weeding	The Agency concurs with ARTF's proposal	Wm		
ARF012	Cauliflower	Hand harvesting						
ARF037	Cabbage	Hand weeding						
Orchard Crop Clusters								
ARF025	Apples	Hand Harvesting	OH	Orchard crops: hand harvesting and similar contact activities	The Agency generally concurs with ARTF's proposal. However, one potential alteration to the proposed crop grouping could be an additional cluster for orchard crop thinning. The Agency believes this activity may be more contact-intensive and therefore could be considered separately in exposure assessments.	Possibly create a separate cluster for orchard crop thinning	D-1	63-69
ARF028	Oranges	Hand Harvesting						
ARF041	Oranges	Hand Harvesting						
ARF042	Grapefruit	Hand Harvesting						
AR1002	Peaches	Hand Harvesting						
AR1003	Apples	Thinning						
AR1014	Peaches	Hand Harvesting						
AR1021	Peaches	Hand Harvesting						
AR1016	Almonds	Mechanical Harvesting	OHn	Orchard crops: mechanically harvesting nuts	The Agency concurs with ARTF's proposal	OHn	D-2	
ARF033	Olives	Hand Pruning	OP	Orchard crops: hand pruning, scouting, and similar contact activities	*See Agency review comment for ARTF Proposal for Cluster TP*	*See OP/TP*	***See E-3***	
ARF047	Apples	Hand Pruning						

AR1017	Peaches	Propping	OW	Orchard crops: hand weeding and similar contact activities	The Agency concurs with ARTF's proposal	OW	D-4	
Trellis Crop Clusters								
ARF020	Blackberries	Hand harvesting	THb	Trellis crops: hand harvesting caneberries and similar contact activities	The Agency concurs with ARTF's proposal	THb	E-1	69-76
ARF048	Juice/Wine Grapes	Hand harvesting	THg	Trellis crops: hand harvesting grapes and similar contact activities	The Agency is considering to further separate the THg cluster by having separate transfer coefficients for hand harvesting wine grapes and table/raisin grapes, respectively. The Agency also proposes to utilize the revised THtg cluster to represent girdling.	THwg	E-2	
AR1020	Table / Raisin Grapes	Hand harvesting				THtg		
AR1022	Table / Raisin Grapes	Hand harvesting						
ARF023	Table / Raisin Grapes	Scouting	TP	Trellis crops: hand pruning, scouting, and similar contact activities	The Agency is considering combining similar activities conducted in trellises and orchards. The respective ARTF-proposed clusters OP and TP, representing activities such as scouting and hand pruning, are very similar because shears or other devices would be used which preclude some level of contact with the treated plants. Also, corresponding to Review Code E-2, girdling would be removed from this cluster.	OP/TP	E-3	
AR1015	Table / Raisin Grapes	Cane turning	Tx	Trellis crops: intense contact activities	The Agency concurs with ARTF's proposal	Tx	E-4	
Greenhouse and Nursery Crop Clusters								
ARF055	Solidasters, Snapdragons, Lillies	Hand Harvesting	GHf	Greenhouse and nursery floriculture hand harvesting: all flowers and methods	The Agency concurs with ARTF's proposal	GHf	F-1	40-45
ARF020	Blackberries	Hand Harvesting	GHv	Greenhouse vegetables: hand harvesting and similar contact activities	The Agency concurs with ARTF's proposal	GHv		
ARF051	Tomatoes, fresh	Tying						

ARF039	Chrysanthe-mums	Pinching	GN	Greenhouse and nursery crops: all activities	The Agency generally concurs with ARTF's proposal. However, the Agency believes that there could be support for additional separation of hand harvesting nursery crops from other nursery crop activities.	GN	F-2	
ARF043	Nursery Stock Citrus Trees	Hand Pruning						
ARF044	Nursery Stock Citrus Trees	Hand Harvesting		All crops: transplanting		GHn		
Crop Irrigation Cluster								
ARF036	Potatoes	Irrigation	I	Irrigation, any crop where hand line is possible	The Agency concurs with ARTF's proposal	I	G	78-80
Mechanical Harvesting Cotton Clusters								
AR1004	Cotton	Mechanical Harvesting	CHp	Cotton, mechanical harvesting: picker operator and raker (based on boll residues)	The Agency concurs with ARTF's proposal	CHp	H	61-63
			CHm	Cotton, mechanical harvesting: module builder operator (based on boll residues)	The Agency concurs with ARTF's proposal	CHm		
			CHt	Cotton, mechanical harvesting: tramper (based on boll residues)	The Agency concurs with ARTF's proposal	CHt		
Turf Clusters								
ARF035	Sod	Mechanical Harvesting	DH	Sod: mechanical harvesting, scouting, transplanting, and hand weeding	The Agency concurs with ARTF's proposal	DH	I	76-78
ARF057	Golf Course Turf	Maintenanc e	DM	Golf courses: maintenance activities	The Agency concurs with ARTF's proposal	DM		

Appendix C: An Alternative Mixed Model Analysis for the OH Cluster.

Because of a concern about over-fitting the data by the models used in the Agency's Exhibit F, one panelist proposed an alternative analysis. The proposal falls much closer to the nonparametric analyses the Agency and ARTF performed than it does to the analyses given in Appendix F. One of the problems with the nonparametric analyses that were considered in the report is that each observation is being treated as independent of all other observations, whereas this is recognized to not be true due to many of the subjects being measured on multiple days. Statisticians would call these measurements repeated measurements as each subject is measured repeatedly. The proposed analysis is based on the model

$$LN(TC)_{ijk} = \mu + S_i + \varepsilon_{ijk} \ , \qquad \text{(C.1)}$$
$$i = 1,2,\ldots,I;\ j = 1,2,\ldots,J_i;\ k = 1,2,\ldots,t$$

where $LN(TC)_{ijk}$ is the natural log of the transfer coefficient for the *k*th time point for the *j*th subject from the *i*th study. The parameter μ represents an overall mean, S_i represents an effect due to the *i*th study, and ε_{ijk} represents an error component. The model assumes that there are I studies, J_i subjects in the *i*th study and measurements taken at t possible time points for the *j*th subject in the *i*th study (Note: most subjects will not have data at all t time points). In the OH cluster, t represents the total number of days between the first measurement and the last one in all studies combined. Next let $\mathbf{Y}_{ij}$ be the $t \times 1$ vector of the log TC values for the *ij*th subject, and let $\boldsymbol{\varepsilon}_{ij}$ be the corresponding $t \times 1$ vector of errors. The proposed model also assumes that

$$\boldsymbol{\varepsilon}_{ij} = \begin{bmatrix} \varepsilon_{ij1} \\ \varepsilon_{ij2} \\ \vdots \\ \varepsilon_{ijt} \end{bmatrix} \sim N\left(\begin{bmatrix} 0 \\ 0 \\ \vdots \\ 0 \end{bmatrix}, \sigma^2 \begin{bmatrix} 1 & \rho & \rho^2 & \cdots & \rho^{t-1} \\ \rho & 1 & \rho & \cdots & \rho^{t-2} \\ \vdots & \vdots & \ddots & & \vdots \\ \rho^{t-1} & \rho^{t-2} & \cdots & & 1 \end{bmatrix} \right) \qquad \text{(C.2)}$$

That is, the model assumes that the log(TC) measurements have equal variances at all time points for each study in the cluster, and that the correlation between day measurements decreases according to an autoregressive pattern of lag 1. This covariance structure is often referred to as an AR(1) structure. For additional details about the analysis of repeated measures experiments, see Milliken, George A., and Johnson, Dallas E., (2009) [*Analysis of Messy Data, Vol. 1, Designed Experiments.* 2nd Edition, CRC Press/Chapman Hall (to be available in March 2009; to get a preprint of the relevant chapters contact dejohnsn@ksu.edu] .

The OH data has measurements taken on days 0, 1, 2, 3, 4, 5, 6, 7, 8, 34, 39, and 45 depending on the study. No subject has measurements taken on all of these days. To make the above model a reasonable one, the days on which measurements were recorded, so that the first day for each study is Day=1, and the subsequent days are the actual number of days between the first and the subsequent day on which a measurement was made. For example, Study AR1002 had measurements taken 0 DAA and 7 DAA, so these were recoded to 1 and 8, respectively. Study AR1003 had measurements taken 1 DAA and 8 DAA, and these were also coded to 1 and 8, respectively. Study AR 1014 had measurements taken 34 DAA, 39 DAA, and 45 DAA, and these were recoded to days 1, 5, and 11, respectively. Study ARF025 had measurements on 1 DAA, 2 DAA, and 3 DAA, and these were coded as 1, 2, and 3, respectively. Study ARF028 had measurements taken 2 DAA, 3 DAA, and 4 DAA, and these were also recoded to days 1, 2, & 3, respectively. Finally, Studies ARF041 and ARF042 had measurements on 5 DAA, 6 DAA, and 7 DAA, and these were also recoded to days 1, 2, and 3, respectively. Under the assumption that TC values do not depend on the amount of DFR available, the day recoding should be acceptable, and the recoding is being done primarily to get an accurate reflection of the actual number of days between measurements for each subject.

A relatively minor error in the Mixed Model analysis that Johnson presented on December 4th at the SAP meeting was found and is now corrected in this report. The error is relatively minor in that it does not change the overall conclusions. The days on which measurements are being made in all studies combined after recoding were days 1, 2, 3, 5, 8, and 11. The SAS-MIXED procedure was discovered to be treating these as days 1, 2, 3, 4, 5, and 6, respectively. To fix this error, the Day data for the first subject was created so that all 11 days were present with missing TC values for the days that this subject was not actually measured. Thus all days are present for this subject, but no TC data is available to use for days 4, 6, 7, 9, and 10. The SAS commands used to create these dummy data and concatenate them to the original data file, and then sort the data lines with respect to STUDY_ID and SUB_ID, and DAY are described in C.3 below:

(C.3.)

```
DATA TC1;
 INPUT STUDY_ID $ SUB_ID DAY LOGTC;
 LINES;
AR1002 1 2 .
AR1002 1 3 .
AR1002 1 4 .
AR1002 1 5 .
AR1002 1 6 .
AR1002 1 7 .
AR1002 1 8 .
AR1002 1 9 .
AR1002 1 10 .
AR1002 1 11 .
DATA TC2; SET WE.DEJ TC1;
 LOGTC=LOG(TC);
 RUN;
PROC SORT DATA=TC2; BY STUDY_ID SUB_ID DAY;
RUN;
```

Next, the data were analyzed using the model (C.1) proposed above with the following SAS-MIXED procedure commands (C.4).

```
PROC MIXED DATA=TC2;
 CLASS SUB_ID STUDY_ID DAY;
  MODEL LOGTC=STUDY_ID /SOLUTION DDFM=KR outpred=we.pred4;
   REPEATED DAY/SUBJECT=SUB_ID TYPE=AR(1) R=2, 28, 65;
    LSMEANS STUDY_ID/PDIFF ADJUST=SCHEFFE CL;
   ESTIMATE 'OVERALL MEAN' INTERCEPT 1/CL;
   ESTIMATE 'MEAN AFTER REMOVING STUDY AR1003'
        INTERCEPT 7 STUDY_ID 1 0 1 1 1 1 1 1/ DIVISOR=7;
   ESTIMATE 'MEAN AFTER REMOVING AR1003 & AR1028'
        INTERCEPT 6 STUDY_ID 1 0 1 1 1 0 1 1/DIVISOR=6;
   ESTIMATE 'MEAN OF AR1003 & AR1028 COMBINED '
        INTERCEPT 2 STUDY_ID 0 1 0 0 0 1 0 0/DIVISOR=2;

RUN;
```

(C.4.)

Comments on some of the options in the MIXED procedure commands are discussed below. First DAY is included in the CLASS statement to allow for the identification of the days on which measurements are made for any subject. DAY is not included in the model statement. Thus DAY is used to model the covariance structure of the repeated measures, but DAY is not explicitly used in estimating the study means. The DDFM=KR option is used to approximate denominator degrees of freedom and to correct the estimated standard errors of fixed effect parameters according to the Kenward-Rogers adjustment available in SAS-MIXED. The OUTPRED=WE.PRED4 option outputs predictions and residuals from the model to a SAS data file named WE.PRED4. The REPEATED option is used to tell the MIXED procedure that there are repeated measurements for each subject identified by the SUBJECT=SUB_ID option and that DAY is the variable that identifies the times at which repeated measures occur. The TYPE=AR(1) option tells the MIXED procedure to use an autoregressive covariance structure for the repeated measures that has lag equal to 1. This corresponds to the covariance structure given in (C.2) above. The R=2, 28, 65 option prints out the estimated covariance matrices for subjects 2, 28 and 65. This option is used for illustrative purposes only, and actually produces estimated covariance matrices for the data set's SUB_IDs 2, 32, and 85, respectively. The LSMEANS option produces estimated least squares means for each study in the OH cluster, estimated differences between study least squares means, and Scheffe adjusted *p*-values for pairwise comparisons between studies. The CL option gives Scheffe adjusted 95% confidence limits on the least squares means, and on each of the pairwise differences. The ESTIMATE options will be described later in this appendix.

Table C.1 gives the estimates of the covariance parameters for the model in C.1 with the assumptions in C.2. Here the estimates are: $\hat{\sigma}^2 = 0.1449$ and $\hat{\rho}$=0.7007.

Table C.1. Estimates of the covariance parameters.		
Covariance Parameter Estimates		
Cov Parm	**Subject**	**Estimate**
AR(1)	Sub_ID	0.7007
Residual		0.1449

Tables C.2 – C.4 give the estimated covariance matrices for SUB_IDs 2, 32, and 85. Note that the diagonal elements in Tables C.2 – C.3 should be equal to $\hat{\sigma}^2 = 0.1449$ as they are. Next note that SUB_ID 2 had repeated measures on days 1 and 8. According to the covariance structure in Eq. (C.2), the (1,2) element in Table C.2 should be equal to $\hat{\sigma}^2(\hat{\rho}^7) = (0.1449)(0.7007)^7$=(0.1449)(0.0829)=0.0120. Similarly, SUB_ID 32, had measurements on days 1, 5, and 11. Thus the (1,2) element of Table C.3 should be $\hat{\sigma}^2(\hat{\rho}^4) = (0.1449)(0.7007)^4$=(0.1449)(0.2411)=0.0349 and the (1,3) element should be $\hat{\sigma}^2(\hat{\rho}^{11-1}) = (0.1449)(0.7007)^{10}$=(0.1449)(0.0285)=0.0041. These both agree with the printed values in Table C.3. The (2,3) element in Table C.3 should be $\hat{\sigma}^2(\hat{\rho}^{11-5}) = (0.1449)(0.7007)^6$=(0.1449)(0.1184)=0.0171 as it is. For SUB_ID = 85 in Table C.4, the (1,2), and 2,3) values should be $\hat{\sigma}^2(\hat{\rho}^{2-1}) = (0.1449)(0.7007)$ =0.1015 as they are, and the (1,3) value should be $\hat{\sigma}^2(\hat{\rho}^{3-1}) = (0.1449)(0.7007)^2$=(0.1449)(0.4910)=0.0711 as it is.

Table C.2. Estimated Covariance Matrix for Sub_ID 2		
Row	**Col1**	**Col2**
1	0.1449	0.01202
2	0.01202	0.1449

Table C.3. Estimated Covariance Matrix for Sub_ID 32			
Row	**Col1**	**Col2**	**Col3**
1	0.1449	0.03494	0.004136
2	0.03494	0.1449	0.01715
3	0.004136	0.01715	0.1449

Table C.4. Estimated Covariance Matrix for Sub_ID 85			
Row	Col1	Col2	Col3
1	0.1449	0.1015	0.07116
2	0.1015	0.1449	0.1015
3	0.07116	0.1015	0.1449

Table C.5 gives a test for the equality of the eight study means in the OH cluster. The equality of the study means is rejected at the 0.0001 significance level. All study means can be compared to one another to identify which studies are different from one another.

Table C.5. A test for the equality of all Study Means				
Type 3 Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Study_ID	7	53.1	24.46	<.0001

Before comparing study means to one another Table C.6 gives the estimated least squares means for each study along with unadjusted confidence limits. One will need to exponetiate each of these estimates and/or confidence bounds to get estimated TC values. The estimated TC value for Study AR1003 is exp(8.1096) = 3326 approximately, and the lower and upper 95% confidence bounds for the TC in study AR1003 are 2808 and 3940, respectively.

Table C.6 Study Least Square Means and Unadjusted Lower and Upper Confidence Limits									
Least Squares Means									
Effect	Study_ID	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
Study_ID	AR1002	7.2348	0.1231	58.7	58.76	<.0001	0.05	6.9884	7.4812
Study_ID	AR1003	8.1096	0.08512	82.5	95.27	<.0001	0.05	7.9402	8.2789
Study_ID	AR1014	6.9527	0.08650	40	80.38	<.0001	0.05	6.7779	7.1276
Study_ID	AR1021	6.9249	0.1204	82.5	57.52	<.0001	0.05	6.6855	7.1644
Study_ID	ARF025	7.2495	0.1458	45.9	49.73	<.0001	0.05	6.9561	7.5430
Study_ID	ARF028	7.9055	0.1458	45.9	54.23	<.0001	0.05	7.6120	8.1989
Study_ID	ARF041	6.4568	0.1458	45.9	44.29	<.0001	0.05	6.1634	6.7503
Study_ID	ARF042	7.0063	0.1458	45.9	48.06	<.0001	0.05	6.7129	7.2998

Table C.7. Pairwise comparisons among the study means with Scheffe adjusted *p*-values. The studies compared to AR1003 have been high-lighted.

Differences of Least Squares Means										
Effect	Study_ID	Study_ID	Estimate	Standard Error	DF	t Value	Pr > |t|	Adjustment	Adj P	Alpha
Study_ID	AR1002	AR1003	-0.8747	0.1497	65.6	-5.84	<.0001	Scheffe	0.0003	0.05
Study_ID	AR1002	AR1014	0.2821	0.1505	51.5	1.87	0.0665	Scheffe	0.8288	0.05
Study_ID	AR1002	AR1021	0.3099	0.1722	69.5	1.80	0.0763	Scheffe	0.8571	0.05
Study_ID	AR1002	ARF025	-0.01469	0.1908	50.9	-0.08	0.9389	Scheffe	1.0000	0.05
Study_ID	AR1002	ARF028	-0.6706	0.1908	50.9	-3.51	0.0009	Scheffe	0.1141	0.05
Study_ID	AR1002	ARF041	0.7780	0.1908	50.9	4.08	0.0002	Scheffe	0.0345	0.05
Study_ID	AR1002	ARF042	0.2285	0.1908	50.9	1.20	0.2366	Scheffe	0.9830	0.05
Study_ID	AR1003	AR1014	1.1568	0.1214	56.9	9.53	<.0001	Scheffe	<.0001	0.05
Study_ID	AR1003	AR1021	1.1846	0.1474	82.5	8.03	<.0001	Scheffe	<.0001	0.05
Study_ID	AR1003	ARF025	0.8600	0.1688	53.3	5.09	<.0001	Scheffe	0.0025	0.05
Study_ID	AR1003	ARF028	0.2041	0.1688	53.3	1.21	0.2320	Scheffe	0.9820	0.05
Study_ID	AR1003	ARF041	1.6527	0.1688	53.3	9.79	<.0001	Scheffe	<.0001	0.05
Study_ID	AR1003	ARF042	1.1032	0.1688	53.3	6.54	<.0001	Scheffe	<.0001	0.05
Study_ID	AR1014	AR1021	0.02778	0.1482	64.5	0.19	0.8519	Scheffe	1.0000	0.05
Study_ID	AR1014	ARF025	-0.2968	0.1695	44.3	-1.75	0.0869	Scheffe	0.8738	0.05
Study_ID	AR1014	ARF028	-0.9527	0.1695	44.3	-5.62	<.0001	Scheffe	0.0005	0.05
Study_ID	AR1014	ARF041	0.4959	0.1695	44.3	2.93	0.0054	Scheffe	0.3070	0.05
Study_ID	AR1014	ARF042	-0.05358	0.1695	44.3	-0.32	0.7534	Scheffe	1.0000	0.05
Study_ID	AR1021	ARF025	-0.3246	0.1891	58.4	-1.72	0.0913	Scheffe	0.8849	0.05
Study_ID	AR1021	ARF028	-0.9805	0.1891	58.4	-5.19	<.0001	Scheffe	0.0019	0.05
Study_ID	AR1021	ARF041	0.4681	0.1891	58.4	2.48	0.0162	Scheffe	0.5317	0.05
Study_ID	AR1021	ARF042	-0.08136	0.1891	58.4	-0.43	0.6685	Scheffe	1.0000	0.05
Study_ID	ARF025	ARF028	-0.6559	0.2062	45.9	-3.18	0.0026	Scheffe	0.2069	0.05
Study_ID	ARF025	ARF041	0.7927	0.2062	45.9	3.85	0.0004	Scheffe	0.0580	0.05
Study_ID	ARF025	ARF042	0.2432	0.2062	45.9	1.18	0.2442	Scheffe	0.9844	0.05
Study_ID	ARF028	ARF041	1.4486	0.2062	45.9	7.03	<.0001	Scheffe	<.0001	0.05
Study_ID	ARF028	ARF042	0.8991	0.2062	45.9	4.36	<.0001	Scheffe	0.0174	0.05
Study_ID	ARF041	ARF042	-0.5495	0.2062	45.9	-2.67	0.0106	Scheffe	0.4316	0.05

Table C.7 gives pairwise comparisons between the study means. The comparisons that involve Study AR1003 have been highlighted in yellow. One can see that the mean of study AR1003 is significantly larger than all other study means except for study ARF028 supporting the Agency's conclusion that AR1003 should be separated from the other studies in the OH cluster. An examination of the adjusted *p*-values also suggests that ARF028 is significantly higher than all other studies except for ARF025. Perhaps the agency may wish to consider combining studies ARF028 and AR1003 into one cluster, and the remaining six studies into a second cluster. Figure C.5 shows a plot of the observed Log TC values against the predicted value for each study. One can note that the locations of the plots on the abscissa are the least squares means for each of the studies.

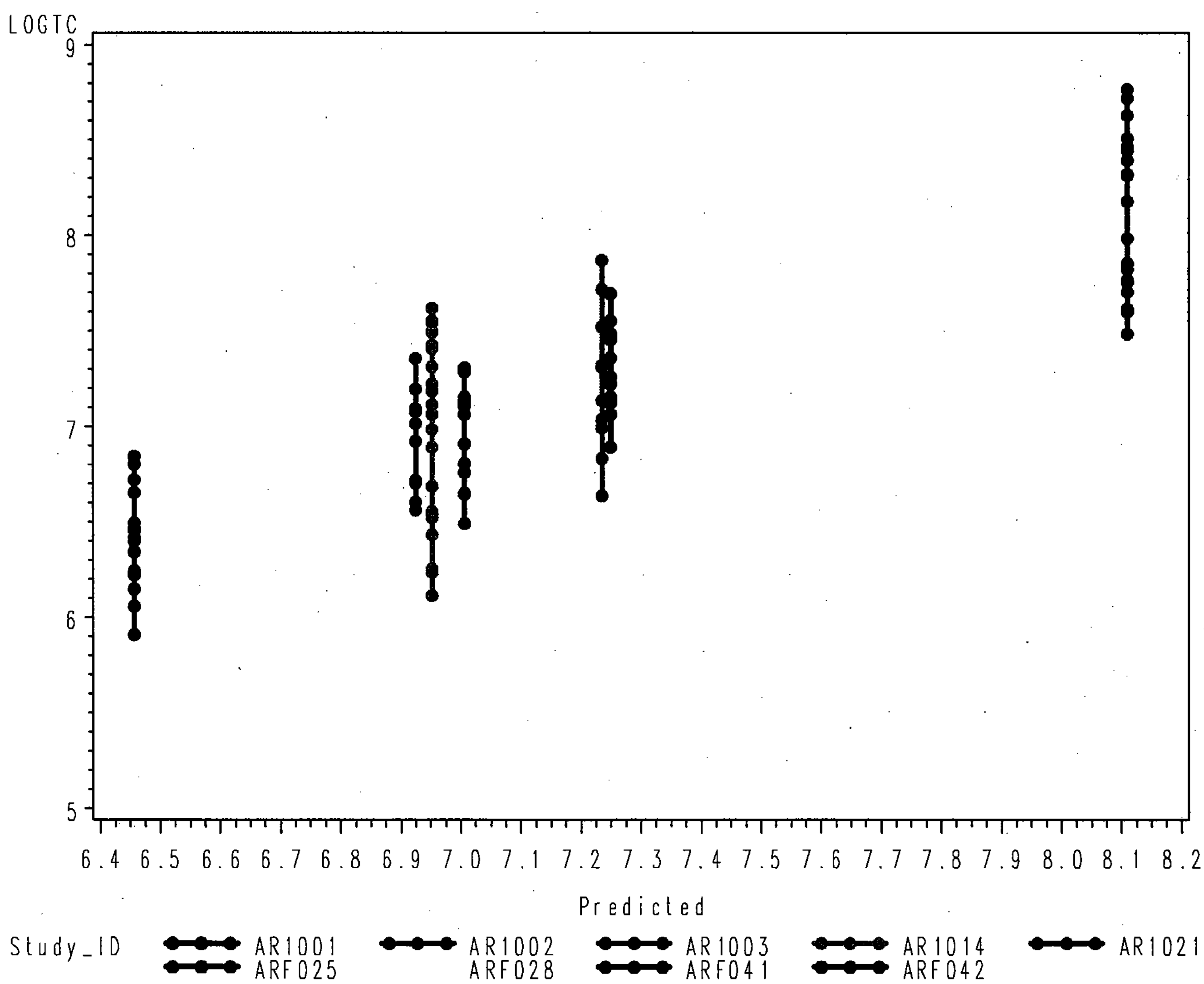

Figure C.5. Observed log TC values versus predicted value for each ARTF OH study.

Finally, consider the ESTIMATE options given in the SAS – MIXED commands described earlier in this appendix. The first ESTIMATE option gives the estimated value of LOG(TC), if one were to combine all eight of the studies in the OH cluster. The second ESTIMATE option gives the estimated value of LOG(TC), if one were to remove study AR1003 from the cluster. The third ESTIMATE option gives the estimated value of LOG(TC), if one were to remove both AR1003 and ARF028 from the cluster. And the fourth ESTIMATE option gives the estimated value of LOG(TC) for a cluster containing studies AR1003 and ARF028. The results of these four estimate options are given in Table C.8. To get these in the TC scale, one will need to exponentiate each of the estimates and/or confidence bounds.

Table C.8 Results of the four ESTIMATE options:								
Estimates								
Label	Estimate	Standard Error	DF	t Value	Pr > |t|	Alpha	Lower	Upper
OVERALL MEAN	7.2300	0.04496	51.7	160.80	<.0001	0.05	7.1398	7.3203
MEAN AFTER REMOVING STUDY AR1003	7.1044	0.04993	50.3	142.30	<.0001	0.05	7.0041	7.2046
MEAN AFTER REMOVING AR1003 & AR1028	6.9709	0.05294	51.3	131.68	<.0001	0.05	6.8646	7.0771
MEAN OF AR1003 & AR1028 COMBINED	8.0075	0.08441	53.3	94.87	<.0001	0.05	7.8382	8.1768

Appendix D: The Propagation of Small Random Errors

The "Propagation of Error theory" provides researchers and other collectors of environmental data with a powerful tool with which to investigate or predict the effect that random error, uncertainty, or variability in individually measured or controlled variables has on the precision or variability of a calculated result.[1-3] For instance, the theory can be applied:

1) to anticipate the expected magnitude of experimental or methodological uncertainty in a result (R) to be measured using a new procedure;

2) to compare the predicted methodological variability with either the natural variability expected in an environment or the magnitude of variability observed within a set of results (e.g., a set of measured contaminant concentrations);

3) to apportion measured variability within a set of results to or among multiple independent variables used within the method or technique; or/and

4) to identify the major source(s) of experimental variability within a given experimental procedure or analytic method for the purpose of improving the precision of that method.

In any of the above uses, a propagation of error analysis would start with an estimate of the uncertainty or imprecision of each measured component (referred to herein generically as "X_i"), evaluate its propagation through the equation, and yield the individual and combined effects of these imprecisions upon the calculated result (referred to herein generically as "R"). The effect of any correlation between components (i.e., where the magnitude of errors in one variable will depend upon the value of another interdependent variable within the equation) can also be assessed, although such inter-correlations are often not easily predicted.

This method is generally (but not exclusively) applied as a "parametric" method by assuming that errors are distributed around a central value in a way that can be described by some parameter like a standard deviation or geometric standard deviation.[3-4] The accuracy with which the propagation of error theory can predict the precision of R depends critically upon the ability of the user to define the precision (or imprecision) of each component in a consistent manner. For example, one could use the standard deviation [S], the geometric standard deviation [GSD], the 95% confidence limits [either $\pm 1.96S$ or $GSD^{1.96}$], or the range (the latter might be considered non-parametric). It is important not to interchange among these optional parameters within a given error analysis. Given consistently defined estimates of the precision of each variable, the calculated precision in R will be a reliable predictor of that chosen definition.

When R is calculated using an equation of k variables abbreviated as X_i (with the subscript "i" varying incrementally from 1 to k) with each variable having an estimated uncertainty or imprecision (expressed herein generically as S_i), then Error Propagation theory holds that the uncertainty of the result S_R (or more specifically its variance S_R^2) may be estimated by Equation 1 [2-3] where $\delta R/\delta X_i$ is the partial differential of the equation used to calculate R with respect to each independent X_i, and and ρ_{XiXj} is the inter-correlation coefficient between any two variables that are inter-correlated. When the errors are independent of each other (i.e., when $\rho = 0$), Equation 1 can be simplified greatly by the deletion of the right-hand summation.

$$S_R^2 = \sum_{i=1}^{k}\left[\left(\frac{\partial S_i}{\partial X_i}\right)^2 S_i^2\right] + \sum_{j=1}^{k,k\neq i}\left[2\rho_{X_iX_j}\frac{\partial R}{\partial X_i}\frac{\partial R}{\partial X_j}S_i\,S_j\right] \qquad \text{[Eqn. 1]}$$

It is also often useful but sometimes more cumbersome to apply this basic Error Propagation theory to determine the geometric variance of log-normally distributed data. It is possible to make a logarithmic transformation of some calculation formulas (especially of rational equations) to provide a direct estimate of the relative variance of R throughout a potentially wide range of X_i. Unfortunately, the mathematics of the logarithmic approach can easily become unwieldy for certain otherwise simple equations such as $R = X_1 + X_2$. But one useful and common example is worth pointing out. The generic relative variance for a rational equation in which each of the variables appears only as a multiplier or divider with a power (such as X_1^{Y1} x $X_2^{Y2)}$ is shown in Equation 2.

$$\left[\frac{S_R}{R}\right]^2 = \sum_{i=1}^{k}\left[Y_i \times\left(\frac{\partial S_i}{\partial X_i}\right)\right]^2 \qquad \text{[Eqn. 2]}$$

It is *useful* to note in Equation 2 that the predicted result's relative variance $[S_R/R]$ is simply the sum of the squares of the relative errors of each component $[S_i/X_i]$ times the square of the power of that respective variable within the original calculation formula $[Y_i]$. This relationship yields two *useful* "rules of thumb" applicable either to interpreting the contribution that each variable adds to the variance of the result or to improving the experimental error most efficiently:

1) If the relative precision of all component variables are either equal or unknown but assumed equal, the variable with the largest power will have the greatest influence on the precision of the result (and vice versa, the variable with the lowest power will have the least influence on the precision of the result). In experimental design, allocate resources to lower the variance of those variables that appear with the largest powers (e.g., squares, cubes, etc.) and disregard those with the smallest powers (e.g., square-roots, etc.).

2) If the formula is linear (where all powers are unity), the variable with the largest relative error will have the greatest influence on the precision of the result (and *vice versa*, the variable with the lowest relative error will have the least influence on the precision of the result). In experimental design, allocate resources to lower

the variance of the component with the highest relative error since the predicted relative variance is simply the sum of the component variances.

It can also be shown that for small variations (GSD = 1.35), the normal and lognormal distributions are practically indistinguishable.[4] Thus, in practice it is usually adequate to determine the standard deviation S_R using Equation 1 within a relatively narrow region of each X_i, and then divide S_R by the corresponding R to yield the relative precision S_R/R. An important limitation to this latter approach is that the conclusion may be valid only within the vicinity of the assumed set of operating conditions. Hewson and Martin[5] apparently used this method without explaining it to calculate "total error" values for their low respirator protection factors, but they did not explore the wider range of experimental conditions encountered by others, as reviewed by Popendorf et al.[5] Even this limitation can be overcome by calculating an array of S_R/R values to cover any desired range of X_i and R values of interest to a given investigator. As stated above, the only real trick to applying this method is to define the errors of each variable accurately and consistently.

Equation 3 is used to predict the total dermal exposure to a field worker reentering a treated field (using the Agency's notation in Section 4.3.3 of the Agency's issue paper). The application of Equation 2 to Equation 3 results in Equation 4.

$$TDE = \frac{DFR \times TC \times WD}{BW} \qquad \text{[Eqn. 3]}$$

$$\left[\frac{S_{TDE}}{TDE}\right]^2 = \left[\frac{S_{DFR}}{DFR}\right]^2 + \left[\frac{S_{TC}}{TC}\right]^2 + \left[\frac{S_{WD}}{WD}\right]^2 + \left[\frac{S_{BW}}{BW}\right]^2 \qquad \text{[Eqn. 4]}$$

The geometric standard deviation values entered into Equation 4 (shown below as Equation 5a-d) are based on the variances used by the Agency in their Monte Carlo simulations presented in Table 27 of the Agency's issue paper. That document defined TC and BW values as lognormal (except that the standard deviation was given for body weight [BW] that had to be equated to a geometric standard deviation of 1 + 20.5 kg/77.9 kg = 1.26). That document defined WD values as normal with a mean of 8.23 hours and a 95th percentile of 12 hours (from which a standard deviation of (12hr - 8.23hr)/1.65hr = 2.28 hours was estimated; and to be consistent with the lognormally distributed variables above, WD was further assumed herein to be lognormal, and its geometric standard deviation was approximated to be 1 + 2.28 hr/8.23 hr = 1.28. The role of the variance of any pesticide's dislodgeable foliar residues is initially not specified herein because it is chemical specific and was not used in the Agency's simulations; however, a typical variance is added at the end to represent the full but small importance of work duration overall.

$$\left[\frac{S_{TDE}}{TDE}\right]^2 = \left[\frac{S_{DFR}}{DFR}\right]^2 + 1.67^2 + 1.28^2 + 1.26^2 \qquad \text{[Eqn. 5a]}$$

$$\left[\frac{s_{TDE}}{TDE}\right]^2 = \left[\frac{s_{DFR}}{DFR}\right]^2 + 2.79 + 1.64 + 1.59 \qquad \text{[Eqn. 5b]}$$

$$\left[\frac{s_{TDE}}{TDE}\right]^2 = \left[\frac{s_{DFR}}{DFR}\right]^2 + 5.82 \qquad \text{[Eqn. 5c]}$$

$$\left[\frac{s_{TDE}}{TDE}\right]^2 = 2.4^2 + 5.82 = 5.76 + 5.82 \doteq 11.6 \qquad \text{[Eqn. 5d]}$$

The result of Equation 5c (shown without the contribution of variability within DFR values) is equivalent to a predicted geometric standard deviation in TDC of 2.4 (the square-root of 5.82). As discussed at the meeting, the variance estimated via a propagation of error analysis is larger than the variance estimated by a Monte Carlo simulation. In this case, a geometric standard deviation of 2.4 estimated by this analysis is larger than the geometric standard deviation estimated from the ratio of the simulated 84th percentile of about 3.9 to the 50th percentile of 1.99 = 1.96. However, this analysis indicates that the variability in the length of the workday [WD] only contributes about 1.64/5.82 = 28% of the variance of the predicted TDE to a constant residue. That contribution would be even less if a realistic value for the variance in DFR was included in the analysis. For instance, when a typical DFR GSD of 2.4 from the SAP presentation by Korpalski (see Public Docket EPA-HQ-OPP-2008-0673) is used in Equation 5d, the variability in the workday would only contribute about 1.64/11.6 = 14% of the total variance in a realistic TCE.

The above text is based on Popendorf, W. 1995. Error Analysis in Assessing Respiratory Protection Factors. J. Appl. Occup. Envir. Hyg. 10(7):606-615.

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