

COMPILED CONSULTATION RESPONSES

for

Drift Reduction Technology (DRT) Information Collection Request (ICR)

As described in the supporting 2012 Supporting Statement for this proposed ICR, EPA contacted five stakeholders to seek specific feedback on the practical utility of the voluntary information requested, the burdens or costs estimated by EPA, clarity of guidance provided, and collections methods. A fill-in-the-blank questionnaire was sent to all five stakeholders. Three of these stakeholders returned responses to EPA. Their responses are compiled in this document which is Attachment D. EPA merely compiled the responses, no changes were made.

Consultation Questions for Drift Reduction Technology (DRT) Information Collection Request (ICR)

Name of Respondent: [William E. Bagley]

Respondent's Affiliation: [Manager – Application Technology, Wilbur-Ellis Company]

(1) Publicly Available Data/Avoiding Duplication

- EPA is seeking data that will verify the effectiveness of drift reduction application technologies for agricultural pesticide sprays. The Agency and others have developed a protocol for testing of DRT technologies. Use of a standard protocol will allow for comparisons across technologies and products. Are similar data suitable for comparison available from any other source that is publicly-available, or already collected by another office at EPA or by another Federal agency?

Response [No]

- If yes, where can you find the data? Is this data a true (total) duplication, or given the data elements that are available, would they only partially meet our data needs?

Response []

(2) Clarity of Instructions

- The DRT protocol specifies the specific data to submit and how to format the data for submission. The ICR asks respondents to voluntarily provide specific data so that the Agency can use these data in a risk assessment. Do you understand the types of data that could be acceptable to EPA, and how to format and submit these data to EPA?

Response [No. There is no clear set of instructions of actual data needed and format for submission. This is probably the most concerning and confusing issue of the program.]

- The Agency is developing a webpage for the voluntary program. What information do you want on that webpage?

Response [A listing of the required data documents and the format that EPA would like to receive them in.]

(3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the

Internet. EPA has posted information on its website entitled, “Electronic Submissions (via formatted CD/DVD) to the Pesticide Program.”

(<http://www.epa.gov/pesticides/regulating/registering/submissions/#studies>)

- What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing electronic reporting?

Response [Yes, but this requires a clear understanding of data needed and a precise set of guidelines for data collection and submission formatting.]

- Is the information on the website sufficient so that you understand the process for submitting these studies electronically to EPA for review and evaluation?

Response [No]

- Are you keeping your records electronically? If yes, in what format?

Response [Both, because we do not completely understand what format will be acceptable by EPA. It is also confusing as to the requirements of quality control of data and the precise format needed by EPA.]

At this time, if the DRT study were submitted as part of an application for registration or amended registration of a pesticide product, then EPA would accept an electronic application.

- Would you be more inclined to submit your application as a CD/DVD rather than on paper?

Response [Not at this time, but would certainly adopt this practice if beneficial.]

- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Response [Greater ease in handling and sharing information. But security of the data is of the utmost importance.]

(4) Burden and Costs

- The Agency has assumed that respondents would not conduct the DRT studies themselves, but would pay a contractor to conduct the studies. Is that correct?

Response [Yes. The correct operational procedures and chain of custody are important. But to generate ethical and unbiased data it is essential to have a certified facility set up to handle test materials, operate equipment correctly and summarize the data in a standard format for submission.]

- Are the cost estimates for conducting the studies accurate?

Response [No. Since there is not a minimum set of operating procedures for collecting data and formatting information, there cannot be a true understanding of cost associated with this process.]

- The Agency assumes that once the respondent has paid the contractor to conduct the study(ies) that the respondent has no capital expenditures, or operation and maintenance costs associated with this activity. Is that correct?

Response [Yes. If there can be a clear understanding of data collection procedures, scope of needed data and required submission format.]

- Are there other costs that should be accounted for that may have been missed?

Response [Yes. The true cost can only be established once the required record keeping, operational parameters of data collection, scope of data needed and required submission format be established by EPA.]

Consultation Questions for Drift Reduction Technology (DRT) Information Collection Request (ICR)

Name of Respondent: John Jachetta, Ph.D.

Respondent's Affiliation: Dow AgroSciences LLC

(1) Publicly Available Data/Avoiding Duplication

- EPA is seeking data that will verify the effectiveness of drift reduction application technologies for agricultural pesticide sprays. The Agency and others have developed a protocol for testing of DRT technologies. Use of a standard protocol will allow for comparisons across technologies and products. Are similar data suitable for comparison available from any other source that is publicly-available or already collected by another office at EPA or by another Federal agency?

Response: There are numerous wind tunnel and drift studies available in the public literature. However, these data have been collected with a variety of methods, many of which do not fulfill the protocol and may not be useful for risk management decisions. In some instances, field drift studies are performed to support registration and submitted to the EPA as operational validation information; this information is often unique to the particular product and its labeled mitigation.

- If yes, where can you find the data? Is this data a true (total) duplication, or given the data elements that are available, would they only partially meet our data needs?

Response: The publically available droplet spectra data for almost all nozzles is developed by spraying water. While this information is useful in assessing equipment, many of these studies do not take into account formulation effects on droplet spectrum and therefore additional opportunities to reduce drift are lost. In this way, nozzle droplet spectra data can only partially meet the Agency's goals for drift reduction. As currently written, the scope of the protocol for testing of DRT technologies is overly narrow and should incorporate more than physically-based technology. The DRT program should allow the assessment of chemistry-based drift reduction as part of a complete DRT system. Nozzles and other physical means can reduce drift by creating very coarse to ultra coarse droplets; however, there is a trade off with reductions in spray coverage and potentially efficacy. Formulations which are specifically optimized for drift reduction can overcome the loss in efficacy by allowing applicators to select an appropriate nozzle for efficient pesticide delivery and pair it with the appropriate chemistry to achieve higher amounts of drift reduction. To account for both the physical equipment and chemistry-based drift reduction technology, the DRT program could use a tiered approach. The first tier could list physical equipment DRT star ratings, while the second tier would allow manufactures to optimize and test their formulation technology to determine the additional decrease in driftable fines and setback reductions. The reduction in droplets below a cut off (such as <141 μm) could thus be compared to a benchmark and used in risk assessments to determine reductions in buffer distances versus a reference. Manufacturers could list the equivalent technologies and combinations on the label with the DRT star rating and buffer distances as suggested by the Supporting Statement for an Information Collection Request (ICR). Allowing registrants to demonstrate their drift reduction technology will allow them to invest in technology that maximizes the benefit to the grower and the environment while receiving credit for the latest advances in formulation technology. The tiered approach would also give the industry flexibility

to encourage the adoption of drift reduction technology by providing incentives to implement and develop new formulation-based technologies to minimize drift.

(2) Clarity of Instructions

- The DRT protocol specifies the specific data to submit and how to format the data for submission. The ICR asks respondents to voluntarily provide specific data so that the Agency can use these data in a risk assessment. Do you understand the types of data that could be acceptable to EPA, and how to format and submit these data to EPA?

Response: The generation and formatting of the data is clear. However, it remains uncertain how the data will be used in risk assessments. The current Agency drift assessments make quite selective use of this information and quickly default to conservative assumptions. For example, when both wind tunnel data and field research are submitted to the Agency, only the nozzle employed in that single field study is credited for drift reduction even though many nozzles may have been tested and found useful in the wind tunnel work. As a consequence, though the benefit and incentives to nozzle manufactures for participating in the DRT program are apparent; it is far less clear how plant protection companies can contribute to the Agency's goals by submitting data to the program. Many publically available articles demonstrated that spray solution has an effect on the droplet spectra. Because nozzles are combined with formulations and adjuvants, the program should give incentive to companies to optimize their label, formulation, and best use practices so that the greatest environmental benefit of the program can be achieved. As the DRT program exists today, there are no incentives to advance formulation science in the area of drift reduction and full advantages of the DRT opportunity cannot be realized.

- The Agency is developing a webpage for the voluntary program. What information do you want on that webpage?

Response: Posting of nozzles and their drift reduction capabilities is obviously useful, but only in a limited way, as this information does not reflect the true drift reduction capability in the field. We find that programs like LERAP are severely hindered because the spray solution is not taken into account; the effectiveness of any nozzle technology is dependent on the formulation used. However there is still value in providing nozzle data using baseline chemistry like water to provide guidance on the current technologies available. Nonetheless, the product label remains the best vehicle to communicate drift reduction technologies that utilized the full range of environmental advantages available through both equipment and chemistry-based drift reduction technology

(3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet. EPA has posted information on its website entitled, "Electronic Submissions

(via formatted CD/DVD) to the Pesticide Program.”
(<http://www.epa.gov/pesticides/regulating/registering/submissions/#studies>)

- What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing electronic reporting?

Response: Electronic submissions have many advantages in both the delivery and storage of information. While the formatted CD/DVD-based submissions have clear advantages over paper-based submission in many areas for both the industry and EPA, the Agency may consider the additional advantages of a secure server for internet-based submissions. It is difficult to believe that this will even be a question ten years from now.

- Is the information on the website sufficient so that you understand the process for submitting these studies electronically to EPA for review and evaluation?

Response: Yes, the great majority of our data submissions employ electronic submissions via the formatted CD/DVD.

- Are you keeping your records electronically? If yes, in what format?

Response: Yes, as pdf-files or in spreadsheet form.

At this time, if the DRT study were submitted as part of an application for registration or amended registration of a pesticide product, then EPA would accept an electronic application.

- Would you be more inclined to submit your application as a CD/DVD rather than on paper?

Response: Yes; electronic submissions employing the formatted CD/DVD are standard practice at Dow AgroSciences.

- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Response: Electronic submissions facilitate global use of the data or studies to support registration actions around the world, therefore the advantages are significant.

(4) Burden and Costs

- The Agency has assumed that respondents would not conduct the DRT studies themselves, but would pay a contractor to conduct the studies. Is that correct?

Response: Yes. However, crop protection companies are greatly hindered by the lack of wind tunnels in the U.S. that meet the protocol requirements. We have performed tests at the University of Nebraska wind tunnel and have had great success demonstrating drift reduction.

The EPA may consider working with wind tunnels in the U.S. and certify them for the DRT program. Certifying wind tunnels would add transparency to the process and give companies confidence that testing their technology will fulfill the DRT data collect requirements. Additionally, data quality should be assured through the use of GLP and not some other QA/QC mechanism as currently outlined in the DRT protocols, this simply increases the difficulty and expense of the studies with no advantage or gain for any party.

- Are the cost estimates for conducting the studies accurate?

Response: They are accurate only if the tests can be performed within the U.S. (see response below).

- The Agency assumes that once the respondent has paid the contractor to conduct the study(ies) that the respondent has no capital expenditures, or operation and maintenance costs associated with this activity. Is that correct?

Response: No. While the Agency's assumption is correct for the conduct of a specific drift study, these studies do not exist in a vacuum. This assumption does not consider the associated tasks and considerable support necessary for the development of risk assessments, the implementation of identified mitigation and advances in labeling.

- Are there other costs that should be accounted for that may have been missed?

Response: Additional costs are very likely; however these costs cannot be estimated because the end-use product label language and the utility of the data for risk assessments have not been made clear. Substantial investments in time and expert personal are expected to be necessary in developing new risk assessments and mitigation, this investment is only increased by the absence of Agency direction on data utility. Further, if crop protection companies are forced to send product out of the country to perform wind tunnel trials because of the lack of suitable facilities in the US, then significant additional costs will be accrued for research, permits and shipping.

Consultation Questions for Drift Reduction Technology (DRT) Information Collection Request (ICR)

Name of Respondent: [Greg Kruger]

Respondent's Affiliation: [University of Nebraska-Lincoln]

(1) Publicly Available Data/Avoiding Duplication

- EPA is seeking data that will verify the effectiveness of drift reduction application technologies for agricultural pesticide sprays. The Agency and others have developed a protocol for testing of DRT technologies. Use of a standard protocol will allow for comparisons across technologies and products. Are similar data suitable for comparison available from any other source that is publicly-available, or already collected by another office at EPA or by another Federal agency?

Response [While I am not familiar with the data available at the EPA and other federal agencies, there is considerable data from good research which exists and should be further investigated prior to potential duplication of new data. While the burden of proof on whether the data is produced in a manner which is acceptable should be investigated, there is likely a lot of data that already exists which could save time, money and other resources from being used if the studies were conducted in a sufficient manner to support the needs of the DRT program. We have conducted numerous studies and some are likely sufficient to meet the needs of the DRT program and I hope that they will be considered without needing to repeat them. I suspect that there are other facilities which also have data available which could be used as well.]

- If yes, where can you find the data? Is this data a true (total) duplication, or given the data elements that are available, would they only partially meet our data needs?

Response [I suspect that data exists that will meet the needs of the DRT program while there is a lot of data which is only partial in nature and will need to be repeated. I think that the EPA will have a lot of work initially sorting out studies which were conducted in an acceptable manner prior to the release of the protocol and there will be some studies which need to be repeated to complete the dataset or conducted slightly different to meet the required specifications.]

(2) Clarity of Instructions

- The DRT protocol specifies the specific data to submit and how to format the data for submission. The ICR asks respondents to voluntarily provide specific data so that the Agency can use these data in a risk assessment. Do you understand the types of data that could be acceptable to EPA, and how to format and submit these data to EPA?

Response [The data required is specific and clear. If there is a format that would help streamline evaluation of DRTs is unclear. As those testing DRTs and submitting data on DRTs become more familiar with the process, it will likely become more efficient.]

- The Agency is developing a webpage for the voluntary program. What information do you want on that webpage?

Response []

(3) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet. EPA has posted information on its website entitled, "Electronic Submissions (via formatted CD/DVD) to the Pesticide Program."

(<http://www.epa.gov/pesticides/regulating/registering/submissions/#studies>)

- What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing electronic reporting?

Response [I think electronic submissions would be great; I am in favor of pursuing electronic reporting.]

- Is the information on the website sufficient so that you understand the process for submitting these studies electronically to EPA for review and evaluation?

Response []

- Are you keeping your records electronically? If yes, in what format?

Response [We keep all of our records in Word, Excel and in Adobe PDF files.]

At this time, if the DRT study were submitted as part of an application for registration or amended registration of a pesticide product, then EPA would accept an electronic application.

- Would you be more inclined to submit your application as a CD/DVD rather than on paper?

Response []

- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Response [The electronic submission process would make things much more efficient.]

(4) Burden and Costs

- The Agency has assumed that respondents would not conduct the DRT studies themselves, but would pay a contractor to conduct the studies. Is that correct?

Response [I expect most companies that produce DRTs will work with an external contractor, but there will likely be some companies that conduct their own studies if possible.]

- Are the cost estimates for conducting the studies accurate?

Response [I believe the cost estimates to be accurate. The costs are likely a minimum for testing though.]

- The Agency assumes that once the respondent has paid the contractor to conduct the study(ies) that the respondent has no capital expenditures, or operation and maintenance costs associated with this activity. Is that correct?

Response [That is probably correct for companies that are working with an external contractor.]

- Are there other costs that should be accounted for that may have been missed?

Response [There will be the cost of putting together the data package once the studies are conducted.]