

**Consultations Regarding an Information Collection Activity:  
Notice of Supplemental Distribution of a Registered Pesticide Product**

**U.S. Environmental Protection Agency**

**Responses :**

Brian Anson  
Regulatory Affairs OTC Project Manager  
Perrigo R&D Company  
502 Eastern Ave, Plant 6  
Allegan, MI 49010  
269-673-1375  
[banson@perrigo.com](mailto:banson@perrigo.com)

(1) Publicly Available Data

- Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency? **Unknown**
- If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?) **Unknown**

(2) Clarity of Instructions

- ☐ This Information Collection Request (ICR) is intended to require that respondents provide certain data pertaining to Supplemental Distribution agreements so that the Agency can utilize them.
- ☐ Based on the instructions on EPA Form 8570-5, is it clear what you are required to do and how to submit such data? If not, what suggestions do you have to clarify the instructions? **Instructions are clear. No suggestions.**
- ☐ Do you know that you are required to maintain the Notice of Supplemental Distribution records for the life of the distribution agreement? **No**
- ☐ Is it difficult to submit information in ways that are clear, logical and easy to complete? **No**

(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 Confidential Business Information (CBI) that might be transmitted over the Internet.

- ☐ What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms, /XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic submission of EPA Form 8570-5? **Electronic alternatives would be a preferred option if available. Environmentally, plastic might not be the best alternative to paper.**
- ☐ Are you keeping your records electronically? If yes, in what format? **Some records are kept electronically in Adobe and Word.**

Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time,

- ☐ would you be more inclined to submit CBI on diskette than on paper? **Yes if secure.**
- ☐ what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? **If information was already saved in an electronic file it would reduce time and materials. It would allow easier revision of information. If information is not already saved in an electronic file then time and resources would be spent getting files into the proper electronic format to save to disk.**

(4) Burden and Costs

- ☐ Are the labor rates in the ICR accurate? **Unknown**
- ☐ The Agency assumes there is no capital cost associated with this activity. Is that correct? **Unknown**
- ☐ Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate? **Yes** If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.
- ☐ Are there other costs that should be accounted for that may have been missed? **Unknown**

Berma Johnson  
Compliance/Regulatory Affairs Manager  
Brulin & Company, Inc.  
P.O.Box 270

Indianapolis, IN 46206  
317-923-3211 (3391)  
[bjjohnson@brulin.com](mailto:bjjohnson@brulin.com)

(1) Publicly Available Data

- Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency? **Not to my knowledge.**
- If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?)

(2) Clarity of Instructions

- ☐ This Information Collection Request (ICR) is intended to require that respondents provide certain data pertaining to Supplemental Distribution agreements so that the Agency can utilize them.
- ☐ Based on the instructions on EPA Form 8570-5, is it clear what you are required to do and how to submit such data? If not, what suggestions do you have to clarify the instructions? **I have done this for years, but I think there are things missing for the new user: 1. There is no address for submission of the completed form (other than Washington, DC 20460); 2. If the registrant does not have a company number it says to apply for one on letterhead to the Registration Division – but no address given; 3. Under conditions, #2 – with repackaging agreements this is not always the case, and 4. I think it should require a printed name – too often signatures are unreadable.**
- ☐ Do you know that you are required to maintain the Notice of Supplemental Distribution records for the life of the distribution agreement? **Yes, but how would a new user know this?**
- ☐ Is it difficult to submit information in ways that are clear, logical and easy to complete? **No**

(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 Confidential Business Information (CBI) that might be transmitted over the Internet.

What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms, /XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic submission of EPA Form 8570-5? **No – I want original signatures**

Are you keeping your records electronically? **No** If yes, in what format?

Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time,

would you be more inclined to submit CBI on diskette than on paper? **No**

what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? **None**

(4) **Burden and Costs**

Are the labor rates in the ICR accurate? **I don't know**

The Agency assumes there is no capital cost associated with this activity. Is that correct? **Yes**

Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate? **Time – yes, labor rates – I don't know.** If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates.

Are there other costs that should be accounted for that may have been missed? **postage and paper?**