**Echols, Mabel E.**

**From:** Rusch, George
**Sent:** Thursday, March 12, 2009 11:47 AM
**To:** FN-OMB-OIRA-Submission
**Cc:** Woodall.George
**Subject:** Regulatory Review procedure

Dear OMB Regulatory Review Process Coordinator:

Thank you for offering us the opportunity to comment on the Federal Regulatory Review Process. I have been involved in regulatory reviews on many levels. First, as the Director of Toxicology for Honeywell, my employer, I have supported the submission of PMN applications to EPA. Second, as chair of the Federal Advisory Committee on Acute Exposure Guideline Levels for Hazardous Substances, I have had the opportunity to participate in many reviews. Last, at the request of non-Honeywell groups, I have testified on risk assessment approaches at an OMB hearing. I am submitting comments on the Regulatory Review process I have witnessed relative to a PMN application submitted by my company. The PMN was for a new, potentially important product. To be sure that our toxicology program would address the areas of concern to EPA, in January 2006 we held a meeting with representatives from both the PMN office and the Air Office. During that meeting, we described in detail the proposed toxicology program and asked for comments. The comments we received were minimal and generally supportive. In July 2007, we submitted our PMN. The toxicology program had followed the outline we had described 18 months prior to the submission. We therefore expected a favorable review and possibly a consent order to complete the outstanding tests in the program. Instead, a day or two before the 90 day review period was to expire, we received a call asking for an extension. We granted this and several thereafter. The PMN has now been under review for 21 months even though Congress had specified a 90 day review period with a possible extension to 180 days. With one possible exception, during this whole process we have never been given any guidance from the PMN office, on what we should do to expedite the process. The calls to request extensions always come at the last minute and the reason is that the review process is very complex requiring several meetings and it takes time to organize these meetings. If we had been provided with a detailed explanation for the reasons necessitating the request for the delay, we might have been in a position to provide information that might address these issues and help expedite the process. However, information of this type is never volunteered by the PMN office and it sometimes appears that the policy is to maintain a separation between the applicants and the reviewers. As near as I can determine, an EPA scientist is given a section of the application to read, that section (e.g. a single report out of 15 or more) is reviewed. The reviewer must then discuss it with his or her supervisor, then with the PMN coordinator, then at a meeting within that group, then at a meeting of people from that division, then at a meeting of all groups involved in the review. Finally, if everyone is comfortable with the decisions, the application will be approved.

In contrast to this is the procedure followed by the Federal Advisory Committee that I chair. Our documents are written by outside toxicologists in much the same way a PMN application is drafted. These Technical Support Documents (TSDs) are circulated to the full committee of approximately 25-30 people, representing several federal and state agencies, special interest groups, academia and industry, for their review. We hold a meeting to discuss the document, and develop 15 exposure guidance levels for each chemical, publish a summary in the Federal Register for comment respond to these comments and send the final document to the National Research Council for peer review. In cases where there are concerns about the contents or risk assessment presented in the document, it is sent back to the author for revision and the process repeated. We have been meeting for 12 years and during that time, we have completed reviews on over 225 chemicals. We are considered to be the global standard for this process.

The key differences are that our committee always invites stakeholders to participate in the meetings and to engage in a dialog with the committee members. While we may have short pre-meetings to address some questions raised by scientists who have reviewed the applications in detail, these are on the same day as the full review, and all issues are discussed at the full review. In over half of our reviews we reach consensus and in almost all of the reviews over 85% of the committee approves the recommendations. Even here, when there is a difference of opinion, each committee member is asked to share his or her views with the full committee. Unless we need additional data that is not available, even without a mandate to complete our reviews within a set time period, most reviews are completed within one meeting (60 days from submission of the TSD) and it is rare that a review will not be completed within two meetings (5 months). A review process like this, with the applicant being present to resolve questions, could readily be used by the PMN office. In my opinion, by using this procedure, with open discussions, the review of the PMN described above could have been completed within no more than 3 meetings and no longer that 6 months.

My comments, while using one example, are not meant to imply that anyone was not doing their job, instead that the process, with its lack of openness and multiple reviews is cumbersome and could easily be streamlined. This would result in reducing the time spent and cost for the PMN review as well as providing a better service to applicants. I thank you for your consideration of my comments.

Sincerely,
George M. Rusch, Ph.D., DABT, FATS