Editorial

How the RPAR Process Is Working

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RPAR (Rebuttable Presumption Against Registration) was originally envisaged as an expedient mechanism by which EPA could reregister pesticides as mandated by Congress. In this reregistration process, all known data are examined for indications that a given pesticide might have unreasonable adverse effects on human health or the environment. If such evidence is found, EPA issues an RPAR, and a time follows during which the registrant and others may challenge the validity or applicability of the data. Furthermore, before a decision is made on the future of the pesticide, the adverse effects (risks) are weighed against the benefits derived from use of the pesticide.

The National Agricultural Pesticide Impact Assessment Program (NAPIAP), which is coordinated by the USDA and carried out in cooperation with the states and EPA, is a primary source of data on agricultural benefits and on exposure through agricultural use. The desired information, most of which must be sought on the state level, may be directly collected or, as is more often the case, assembled by teams of biologists and economists.

One would assume that since the RPAR process involves input from such a wide variety of interest groups, well-founded regulatory decisions would be made in a relatively short time and cause minimum dissatisfaction. Such has not been the case. The first major problem is the time factor. The process takes much longer than anticipated. According to my records, 24 RPARs have been issued (including some groups of pesticides) since NAPIAP became operational in 1977. Taking suspensions or cancellations out of the picture, the RPAR process has generated eight proposals of regulatory options and one final decision. What causes the delays?

First, contrary to what many had thought, the biological data necessary to development of economic impact assessments were not readily available. We are talking primarily about usage data—acres of a given crop, acres treated with the specified pesticide, and what would happen if the pesticide were not available. Second, many questions are raised during the complex economic analysis that to a biologist seem quite obvious and thus have not been addressed in the biological portion of the assessment report. This means that after that portion is considered complete, the team members must be contacted and recontacted to provide additional data. EPA has made some efforts to improve the data-gathering process through contracts. Generally, these have not created good working relations among the parties involved. In most cases, the data one person has trouble finding are just as difficult for someone else to locate. The irony of the situation is that invariably all parties converge on the same source for the information.

Another bottleneck is the limited number of economists relative to the number of biologists. This means that biological reports on some pesticides are put aside to wait their turn. This situation frequently leads to the need for some updating efforts on the part of the team biologists.

To top off a less-than-perfect situation, EPA is saddled with making numerous extrapolations from the risk data and then comparing what, for the most part, are hypothetical situations with the biological/economic impact, which also contains quite a few extrapolations. Reaching decisions based on these extrapolations is definitely not preferred.

The second major problem is the nature of the economic impact assessments. Because they are designed to address effects at the national level, the loss of a pesticide projected to have minor or moderate consequences can have serious impacts on local areas. This situation is likely with any pesticide used on crops not considered major and grown in diverse geographical areas with diverse pest problems. Closely related to this situation are minor or specialty crop uses, in which total loss resulting from inadequate pest control is not likely to seriously impact the nation's economy but may be catastrophic for a limited number of growers.

The final major problem is related to the concept of alternative pesticides. Pest control is a very dynamic situation; pest problems can change markedly from one growing season to the next. The pesticide that is second choice this year may be immensely beneficial next year. The growing field of pest management demands a variety of pest control measures, including pesticides; the greater the selection opportunities, the more flexibility available to design better pest control programs.

Let us focus on some possible solutions. There should be a sequence of events, not a group of simultaneous tasks. First, the basic question of whether the pesticide is a real risk needs to be examined. The data should be scrutinized and verified. If the data are not adequate, new research should follow, and no further activity in the RPAR process should take place until results of that research are available. One cannot ignore that a lot of educated guesswork is involved in assessing the likelihood of adverse effects actually occurring. This area is in its infancy and will undoubtedly grow in sophistication in the near future. In addition to their fate in the environment, the mode of action of these chemicals must be determined. Along with this, the routes of exposure should be identified, as well as the metabolic breakdown. Then feeding studies can be put in their proper perspective and the guesswork lessened.

If adequate and valid data indicate potential risks, the second step is to examine the actual exposure situations existing through use of the pesticide; this area has truly blossomed during the RPAR process, and EPA continues to place great emphasis on exposure for their decisions. The third step, taken if actual exposure constitutes a hazard, is determining if exposure can be reduced to an acceptable level.

When these three steps have been completed, there should be quite a few uses that, when label directions are followed, would not involve adverse effects. If some uses do, the fourth step should be taken—use benefits on a state-by-state basis. Arrangements could be made with states to provide information concerning the benefits of particular uses. Data could be assembled into a report at the federal level and then reviewed by a team of experts from the state and federal levels. Both the biological and economic information in the report would be used in deciding whether the benefits justified the risks.

I believe that following these four steps would significantly improve the RPAR process. Changes such as these rarely occur overnight, but a concerted effort could produce real progress.