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THE PESTICIDE REREGISTRATION DILEMMA AND ITS IMPACT

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Thank you for inviting me to participate in USDA's 68th Annual Outlook Conference. When Rusty Jesser told me the topic of this panel discussion, the pesticide reregistration dilemma, it immediately reminded me of the following famous quote: "We are continually faced by great opportunities brilliantly disguised as insoluble problems."

For that's exactly what the entire pesticide reregistration process is: a great opportunity. FIFRA 1988 deadlines are unforgiving, resources are finite, and the pressures tremendous; **however**, there couldn't be a better group of people assembled to tackle and solve the problem! The motivation and momentum is present to transform this seemingly insoluble problem into a great opportunity.

Industry's Dilemma

From industry's perspective, the dilemma is not whether to comply; we are completely committed to successful reregistration. Rather, the dilemma for pesticide manufacturers, or registrants, is whether or not to defend the reregistration of an active ingredient. And, for those active ingredients the registrant does decide to defend fully, the dilemma is what uses to defend.

What do I mean by defend? I mean re-register. The 1988 amendments to FIFRA mandated the reregistration of some 600 active ingredients first registered for use in the USA prior to November 1984. The data base — toxicology, environmental fate, ecological effects, residue chemistry, etc — for each active ingredient must be updated to meet current scientific standards by the 1997 deadline. EPA estimates that this will cost industry in excess of \$3 billion — a very conservative estimate according to industry experts considering that typical reregistration costs for a single active ingredient are in the range of \$5 — \$10 million.

Details of Industry's Dilemma

Well, exactly what forces are at work? The time frame (9 years) combined with the number of active ingredients (approximately 600) creates a tremendous demand on personnel, laboratory space, analytical capacity, field facilities and economic resources. And if this isn't bad enough, industry and government are competing for the same pool of scientists to accomplish these tasks. Moreover, there is a massive amount of money spent on defense of products in an already extremely competitive marketplace.

For example, in 1990 NACA member companies spent about \$800 million on research and development in the United States. \$250 million was on defense of old products! The remaining \$550 million was spent on discovery and development of new products.

Consequently, it is easy to see that the decision to defend or not to defend a product is based primarily on economic factors. It all boils down to the issue of competing resources. Registrants need to decide whether to use their resources defending old products or discovering new and improved products which are the lifeblood of the industry. Given the difficulty of the task, there will be casualties. The statutory requirements and deadlines of FIFRA '88 are very unforgiving and tight. Someone always ends up unhappy because industry can't do both. How can we maintain a product and produce a "better" one?

Thankfully, the process of reregistration has become more focussed in recent months. This past October NACA and EPA reached agreement as to the definition of reregistration; consequently, it is no longer a "moving target." It was decided that the requirements that were in place at the time of the passage of FIFRA '88 would be used to judge eligibility for reregistration. Before this agreement was reached, there was massive confusion because reregistration was an open-ended process. Now, the set of studies required to accomplish reregistration are fixed. The process can continue on a straight and even course.

With the definition of reregistration clarified and agreed upon, we can now focus our efforts on other important issues. For example, how rapidly can EPA assimilate this new information? EPA has assured everyone that the reregistration process will not interfere with progress on new product registrations. After all, the influx of new products is just as important as the reregistration of old ones.

In addition, NACA member companies operate a business. Since they have finite limits as to people, facilities and capital, they must make balanced business decisions. This means dropping some products. These will be the less profitable products and crop uses, seldom because of the risk or hazard they may pose, and not necessarily

due to unwillingness of the manufacturer to support them. Companies simply must prioritize their finite resources. Deciding which ones have to be cut has resulted in a major problem: the so-called "minor use" issue.

Minor Use Issue

Two principal points are involved in the minor use issue. One is timely communications and the other is time. First of all, we need to make sure we are communicating effectively and efficiently with the impacted parties, the growers. Secondly, impacted parties need to have enough time to "save" the product they need. Currently, they only have 60 – 90 days; in some cases, this may simply not be enough time.

In addition, two sensitive communication dilemmas also exist. First, when should a registrant publicly state — to friend and competitor alike — they are going to drop a product? This is crucial because of the announcement's effect on the marketplace. Secondly, registrants have occasionally changed their minds. In some rare instances, manufacturers have told the user community that they are going to defend a particular product. However, after reviewing data, conducting some tests, and further interaction with EPA, the registrant has decided not to reregister a product. Naturally, this upsets growers.

The Impact of the Minor Use Crisis on Industry

The effect of these reregistration casualties on minor crop pesticide registrations is certainly being felt in the U.S., and repercussions are spreading beyond our borders. Cancellation of a product or even a specific use will most probably lead to revocation of applicable food crop residue tolerances, affecting production of those crops in foreign countries for export to the U.S. Numerous groups within agriculture and the food industry are raising the hue and cry about loss of the "minor uses". This process of public involvement appears a bit chaotic at the moment. It is certainly painful for many farmers who have lost or are in danger of losing vital crop protection chemicals. Nevertheless, we hope the result will be a healthy concern for and involvement in continued availability of crop protection products by all within the agricultural community.

The Impact on Industry: What NACA is Doing

NACA is cooperating with EPA and USDA to inform minor crop producers of uses that will be dropped and products that will be canceled. This should allow affected growers additional time to become involved in saving the products they need or seek appropriate alternatives to avoid disruption of crop production. In March of this year NACA established a fax network to more than 300 leaders in agricultural organizations nationwide (and some overseas), to inform the nation of impending changes in pesticide registrations as quickly as our member companies advise us. In other words, when a registrant advises EPA of their intent to drop a product in connection

with reregistration, this information gets communicated to agricultural leaders. These leaders in turn pass the information on to their constituents. While this effort — and USDA's mailing system to more than 2,000 impacted parties — in and of themselves don't solve the individual minor use problems, they do help to inform and bring together those who can.

Conclusion

If current trend continues and there is no legislative or administrative relief with regards to deadlines and data requirements, the minor use issue will be exacerbated. We will continue to be frustrated. However, we believe legislative remedy will move in Congress in 1992.

The unofficial White House Minor Use Report, released earlier this year, clearly outlines a series of solutions to these problems:

1. **EPA** must revise definition of minor use and be more flexible with data requirements.
2. **USDA** must continue acting on behalf of minor crop producers by attaching more importance to the minor crops industry and by allocating more resources for collection of production and economic data.
3. **NACA** member companies must continue giving early warning of intention for voluntary cancellation and continue cooperating with third party registrations.
4. **Congress** must maintain close oversight and introduce further legislative steps where necessary.
5. **Growers** need to form a coalition, be "unyielding" in efforts to gain attention of policy makers, and must be willing to make substantial commitments to keep products on the market.

Many of these solutions are already happening, and we are making a lot of progress. We have not let our frustration impede us from seeking successful and practical answers. Due to the past efforts of Jack Parnell and, currently, Dan Haley and the AMS shop at USDA, people are talking to each other. We are all in the same room. Hey, you've got to start somewhere!

What has NACA done? How have we contributed to the process? As all of you in this room know, just last week, technical corrections to the 1990 Farm Bill were passed. Included was a formula that revised the fee structure for pesticide manufacturers so that EPA could meet its 1988 goal of \$14 million a year. This clearly demonstrates the pesticide industry's commitment to the reregistration process.

The minor use issue will be addressed next year by Congress and I guarantee you that NACA member companies will continue to work with grower groups and Congress to try to find workable, practical solutions to current problems.

Thank you for the opportunity to be with you today.

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The National Agricultural Chemicals Association is the not-for-profit trade organization of manufacturers, formulators and distributors of agricultural crop protection and pest control products. NACA's membership is composed of companies that produce, sell and distribute virtually all the active compounds used in crop protection chemicals.