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Common Sense in Pesticides and Toxics Control

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Over a year ago when I testified before Congress during my nomination hearings, I stated that I saw my nomination as an opportunity to contribute to two goals which I believe are vital to the future of the Agency: protection of the public health and the environment and cultivation of sound science as a data base for regulatory decision making. Since that time, I have seen considerable progress towards these goals.

In assuming responsiblity for the pesticide program, I recognized that protecting health and the environment meant reducing backlogs of actions on pesticides and improving turnaround times to meet statutory deadlines. The Presidential Task Force on Regulatory Relief reinforced these goals and provided impetus and focus for this policy direction.

The emphasis of the Task Force was that the system should be made more efficient and less burdensome, but without changing its basic function of ensuring that pesticides marketed in this country meet standards adequate to protect public health and the environment.

In addition to these basic concerns, I recognized the importance of improving both industry and public perception of the Agency's credibility by taking a non-adversarial approach to problem solving, and ensuring that regulatory decisions rest on a firm foundation of scientific evidence. We have taken a number of positive steps to lessen the negative effects of an adversarial stance toward industry while retaining a firm control posture.

We are now conferring with pesticide registrants at the beginning of the registration process which establishes a clear understanding of what will be required and avoids later misunderstandings. The Agency is also negotiating with registrants to the extent possible to resolve individual chemical problems. The goal is to come to quick, voluntary label changes which achieve appropriate risk reduction measures without expensive, time consuming formal review procedures.

Negotiations also play a big part in EPA's investigative process into pesticides called Rebuttable Presumption Against Registration (RPAR). This formal review involves weighing risks and benefits of pesticides suspected of causing unreasonable adverse effects to human health and the environment. The burden of rebutting evidence that a particular pesticide causes unreasonable risks rests with the company registering the product. Ultimately, based upon negotiations with the registrant to reduce exposure, if possible, and upon all the evidence needed to make a scientific decision, the agency does one of three things: Allows the pesticides unrestricted use, imposes some restrictions or bans the product outright.

During the past year, we have been able to conclude 15 RPAR's. Among these is the recent decision to ban most uses of toxaphene. This action finally resolved five years of internal review by facing up to and dealing with significant environmental problems that toxaphene poses: Chronic effects on fish, birds, and mammals; acute toxicity to acquatic organisms and animal tests which suggest that toxaphene could be an oncogenic (tumor) risk to humans.

Important savings for the Agency may be possible by involving the industry in developing the documents for Registration Standards, which establish the health and safety data requirements for registering or reregistering pesiticide products based on a specific active ingredient. A pilot program involving five companies is presently underway.

We have streamlined and improved a number of pesticide registration procedures to reduce backlogs, cut down on the number of times the industry needs to interact with the agency, achieve speedier decisions and thus facilitate the registration process. Some of these actions are:

- expanding the policy of waiving the submission of performance of effectiveness data for the registration of all non-public health use products;
- the elimination of agency approval for supplemental registration by different firms marketing the same product for identical uses;
- modifying the testing requirements for child-resistant packaging to simplify them while maintaining a practical level of protection;
- and eliminating agency review of final printed labels.

Not only have backlogs been overcome, but we have reviewed and reached decisions on 68 percent more new chemicals this year than last, on 56 percent more old chemicals and 61 percent more tolerance petitions (residues of pesticides allowed to remain on raw food or feed products).

The pesticides industry expressed strong concern about the potential burden and inflexibility of data requirements imposed as rules. I decided that flexibility could be introduced into the requirements by separating testing protocols from data requirements, resulting in two packages.

The first is a rule setting out the "when" and "what" of data requirements for various types of pesticides and use patterns. This rule sets down for the first time in a clear, concise, and usable form, the data which the Agency requires to support pesticide registration. In terms of regulatory relief, this new rule is principally an efficiency measure, which gives the industry the benefit of knowing exactly what the Agency requires for registration.

The second package will consist of testing protocols, the "how to" develop data, covering twelve scientific disciplines. These documents will be guidance, not rules, which allows for the use of other scientifically valid methods that may already be available or will be developed in the future. This approach allows for flexibility to develop data with the most up-to-date methods. These guidelines will be available early next year from the National Technical Information Service.

I firmly believe that sound regulatory decisions must have a basis in objective scientific information. To help ensure this is the case, procedures were developed and published to provide for scientific peer review of studies which are important in making regulatory decisions. An example of this is the highly emotional and polarized fire ant issue. With several decisions on fire ant control pending, I decided to co-sponsor with the U.S. Department of Agriculture a symposium of experts in the field to bring together the latest information and advice on the multifaceted problem. The symposium, held in June 1982 in Atlanta, provided a wealth of information for EPA and other agencies to consider in future fire ant related program decisions.

The actions to regulate pesticides taken so far show: New products and new uses of old products reach the market faster; both producers and potential users are better able to plan ahead if the Agency can be relied on to act within its stated target dates, whether self-imposed or statutory; and in numerous cases, because difficult but firm decisions

were made and not delayed as was prevalent in the past Administration, the health and safety of the public and the environment was enhanced.

Considerable progress was also made during the 1982 Fiscal Year in the implementation of the Toxic Substances Control Act (TSCA).

A number of projects, some of which had been on the agenda for years were finally completed. Included were major asbestos and PCB rulemaking decisions, the publishing of nearly 100 test guidelines, proposed exemption criteria for reviewing new chemicals, and negotiated agreements for chemical testing. Throughout this period, the TSCA Inventory of Chemicals in Commerce was updated to include over 58,000 chemicals.

During this year, the Agency has established a set of firm priorities in order to effectively and efficiently protect public health and the environment: meet all statutory and court deadlines, clean-up backlogs, and reduce unnecessary regulatory burdens. These priorities were largely met and the TSCA program personnel reflected a commitment to high quality scientific analysis in carrying out their responsibilities to protect human health and the environment.

In the area of regulatory reform, policy reforms emphasize focusing resources on chemicals of greatest potential concern, negotiated agreements where appropriate, flexibility when possible, and encouragement of small business initiatives. Regulatory changes have reduced unnecessary regulatory burdens, and provided for exemptions to requirements when such exemptions did not adversely affect health or environmental protection. Administrative changes were created to meet legislative and judicial time schedules. As a measure of our success during the past year, for the first time since TSCA became effective, all statutory and court imposed deadlines were met for every section of the law.

With respect to our enforcement and compliance programs, over the last year four trends have become keystones: a decreased emphasis on "adversarial enforcement" and more emphasis on technical assistance towards compliance; delegation of enforcement authority to the states; vigorous enforcement of serious violators; and avoidance of unnecessary restrictions on the regulated community.

Both compliance inspections and enforcement actions have flourished in this atmosphere. For example, FY'82's enforcement actions are nearly 50 percent higher than FY'81 while compliance inspections are up almost 100 percent.

During FY'82, EPA continued to be actively involved in international efforts to harmonize chemical testing and assessment activities.

For example, the Agency participated in the work of the multi-national Chemicals Program of the Organization for Economic Cooperation and Development (OECD). EPA provided experts to work groups responsible for developing further OECD test guidelines, for updating previously adopted guidelines, and for work under the Hazard Assessment project. The Agency was designated to head the U.S. delegation to the second High Level Meeting of the Chemicals Group where the Environmental Ministers of OECD nations will provide for further work on implementation of OECD Principles of Good Laboratory Practice, information exchange between member nations, trial use of Data Interpretation Guides, and an OECD Existing Chemicals Program.

EPA has also spent a significant amount of time preparing for its annual bilateral consultation with the Commission of the European Communities in October of 1982. Issues of mutual concern in the areas of new and existing chemicals under TSCA and the Sixth Amendment of the European Economic Community's Directive in Classification, Packaging, and Labelling of Dangerous Substances are to be agenda items.

These are some of the highlights of what I consider to be a highly productive fiscal year. It is my expectation that the new year will be equally so.□