Recommendation 93-5

Procedures for Regulation of Pesticides

(Adopted December 10, 1993)

The Environmental Protection Agency cannot accomplish its substantive mission in regulating pesticides without change and improvement in the Agency's regulatory procedures. The Conference recommends the adoption of a more coordinated and strategic procedural framework for the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). EPA needs procedures that create multiple and reinforcing incentives for regulatory compliance by registrants, for timely and accurate decision making by EPA, and for effective public participation.

The Re-registration Process

The re-registration of existing pesticides under contemporary risk assessment standards, and the removal of unacceptable pesticides from the marketplace, are examples where procedures can hinder the agency's prospects for success in its substantive mission. Re-registration of existing pesticides, which Congress originally directed to be completed by 1976, became sufficiently delayed so that Congress in 1988 amended FIFRA specifically to force the completion of re-registration by 1998. Yet subsequent delays in the re-registration process may cause EPA to miss this congressional deadline. To some extent, the delay may reflect the underlying difficulty and resource-intensiveness of the risk assessment enterprise with which EPA has been charged. There are some 50,000 pesticide products that are separately formulated from 642 identified active ingredients. Although EPA has tried to expedite its task by focusing re-registration on some 402 "cases" (composed of single or related active ingredients), each case can require evaluation of 100-150 separate studies, every one of which may pose further questions of scientific protocol and interpretation. It may be that EPA's Office of Pesticide Programs needs more personnel to match its regulatory task.

Whatever the case for additional resources (a question not addressed by the Conference), there is a more basic need for timely and adequate data from registrants -- all else in the re-registration process depends on this. Yet the re-registration process does not now provide sufficient procedural incentives to encourage submission of timely and adequate data. In general, because registrants continue to market their products during re-registration, they have little to lose by regulatory decisions that are reached later rather than sooner. Although the 1988 FIFRA Amendments require registrants to identify data gaps, and commit to fill them, the

1988 Amendments do not provide the agency with sufficient tools to police tardy or inadequate data submissions.

As to tardiness, the 1988 Amendments authorized the agency to suspend registrations of those registrants that fail to submit data. But EPA must first provide non-submitters with 30-days' notice in response to which registrants can demand a limited hearing (which must be held within 75 days); the 1988 Amendments further provide that registrants suspended for not submitting data can have their registrations "reinstated" upon submission of the data. Some registrants, ironically, have used these suspension procedures as a means of obtaining penalty-free and self-awarded extensions of time. In the 7 months between August 1991 and February 1992, for example, EPA found it necessary to issue 70 Notices of Intent to Suspend for non-submittal of data, yet in the majority of these instances (53) the registrants merely submitted their data prior to exhausting their procedural rights and were no worse off for having missed their deadlines. To create an additional disincentive for untimely data submissions it is necessary to make lateness costly to the registrant. To this end, the Conference recommends that Congress authorize EPA to impose civil money penalties for untimely data.

As to the adequacy of data, EPA may now have the theoretical (but untested in court) capacity to suspend or cancel the registration of those pesticides for which inadequate data have been submitted. However, the more common response to inadequate data is a "data call-in," through which the agency demands that studies be redone -- a source of additional delay that the agency has identified as significant. Even with respect to its highest priority pesticides, EPA has in the recent past found 50 percent of studies to be either inadequate, "upgradable," or otherwise requiring supplementation. Although the cost of redoing studies should provide some incentive for registrants to ensure that their studies meet EPA's quality criteria, it does not seem to provide a sufficient incentive. In fairness to some registrants, there is evidence that EPA itself may be partially to blame for the high rates of data rejection. In 1992, an internal agency review found that misinterpretation of data requirements and poor guidance from EPA case managers were in part responsible for the inadequacy of data submissions. The Conference therefore recommends EPA promulgate and communicate clear data standards and guidance on the data expected from registrants. To help prevent the submission of inadequate data even after sufficiently clear agency guidance has been given, the Conference recommends Congress authorize EPA to levy administrative civil money penalties upon registrants submitting data that fail to meet previously announced standards. This will not only create incentives for registrants to take the extra steps necessary to ensure the adequacy of their submittals, but it will also create incentives for the agency to make clear its expectations.

Whatever the additional tactical advantages that the agency may gain by improving its own ability to enforce data timeliness and adequacy, the sheer number of studies and the innumerable decisions requiring agency discretion suggest that more global incentives are needed to ensure that registrants themselves have a stake in timely and adequate data. The danger is that the re-registration process now has become, even with the best of intentions, an analytical treadmill powered by the rhythms of data call-ins, subsequent requests for data waivers and time extensions, submission of data that do not always meet EPA's standards for adequacy, and further data call-ins that restart the sequence. The Conference believes that the unique demands of the re-registration process justify congressional consideration of a "hammer" provision that would legislatively impose an automatic suspension of all "List A" pesticides (those high-priority pesticides to which there is greatest human exposure) for which there are still significant data gaps within the registrant's control, and of which the registrant is aware -- subject to a provision for a registrant to petition for reinstatement. Such a provision would not only provide an overarching incentive for registrants to favor the completion rather than postponement of their data obligations, but it would also better align the re-registration process with FIFRA's central procedural presumption--that, in the face of uncertainty, applicants (especially those seeking to reregister pesticides with extensive human exposure) should bear the burden of proof in establishing that their pesticides do not pose unreasonable risks.

Suspension and Cancellation Hearings

Apart from improvements in the re-registration process, the Conference urges Congress to substitute a relatively informal decision making process for the formal adjudicatory hearings registrants can now demand in cancellation and suspension matters. In the past, formal hearings under FIFRA have averaged 1,000 days to complete. These hearings can directly impose on EPA significant resource costs and can also indirectly discourage the agency from aggressive prehearing negotiations with registrants (lest the registrant "take EPA to hearing"). It is not surprising EPA has long sought alternatives to cancellation hearings. For years, it sought to identify problem pesticides for heightened regulatory attention in a "Special Review" process. There is little need for procedural formality in these types of decisions. At issue in most cancellation and suspension proceedings are scientific data concerning risks and benefits, disputes over which can generally be well-ventilated when EPA gives registrants detailed reasons for the agency's actions and then provides registrants with sufficient time to file responsive written comments and supporting documentation. For those cases where oral testimony or cross-examination is justified, the benefits of more formal procedures can be

preserved by providing registrants an opportunity to show cause why such procedures are warranted. Accordingly, the Conference recommends Congress pattern cancellation and suspension proceedings on a basic notice-and-comment model, with more formal procedures available only if a party will be demonstrably prejudiced by the informal procedure.

Labeling and Phase-down Procedures

Although the re-registration process and adjudicatory hearings are the most visible aspects of pesticide regulation in need of procedural improvement, they are not the only places where procedural reform is important. Since the late 1980's, EPA has in fact sought to reduce the risks of pesticides through private negotiations with registrants over label changes that impose restrictions on use. Such regulatory action has the potential to attain interim risk-reduction quickly when warranted by available data, without going through the cumbersome Special Review and cancellation procedures, even when complete re-registration may still be years away. But there are also disadvantages to relying so heavily on private negotiations with registrants -- chief among them the lack of participation among the various interested publics in crafting label changes. In the early 1980's, similar concern about privately negotiated Special Review and pre-Special-Review decisions seriously undermined the agency's credibility and slowed regulatory progress. In 1985, EPA adopted procedures to open the door for information from, and participation by, the public in those processes.[1] The Conference recommends that EPA adopt analogous procedures to regularize and open the agency's negotiated label program. In addition, because label changes are effective in reducing risk only if they are actually implemented in the field, the Conference recommends procedures to facilitate feedback from registrants, pesticide users, and all other interested persons on the effectiveness or ineffectiveness of the interim risk-reduction measures EPA has adopted. Moreover, the Conference recommends that EPA's Office of Pesticide Programs (OPP) establish regular channels of communication with EPA's Office of Enforcement and Compliance Assurance to inform that office of all label changes and of any material information received by OPP on noncompliance with such changes.

The Conference also urges Congress to consider providing EPA with a new procedural device designed to accommodate a safer pesticides policy: The ability by informal procedures to order the phase-down of existing pesticides when there are available for use safer, effective pest

[1] 40 CFR Part 154, Subpart B.

management products or practices.[2] Empowering the agency to develop an informal phase-down mechanism would have several procedural advantages. First, ordering the phase down of an existing pesticide on relative risk grounds will cause less stigmatization of an existing product than would a cancellation proceeding based on the traditional, more absolutist ``unreasonable risk'' judgment. Second, phase-down procedures provide for an incremental style of decision making in which EPA's reasoned judgments about comparative risk can be tested and reevaluated without making irreversible decisions about existing pesticides in cancellation proceedings. Finally, phase-down procedures based on relative risk can reinforce and integrate EPA's pesticide programs under FIFRA with other federal environmental programs.

Recommendation

I. Adequacy and Timeliness of Data

A. EPA should adopt, whenever possible, rules setting clear standards for pesticide re-registration data and should communicate those standards to registrants.

B. Congress should authorize EPA to impose administrative civil money penalties on registrants for the failure to submit data by any applicable deadline, or for submitting data (even if timely) that do not comply with the data standards adopted by EPA.[3]

C. Congress should consider imposing an automatic suspension of “List A” (high priority) pesticides for which there still remain, by a date to be set by Congress, previously identified and significant gaps in data within the registrant's control, and of which the registrant is on notice. Once suspended, pesticides could be reinstated through a petition process.

II. Informal Procedures

A. Congress should eliminate the provisions in FIFRA allowing for formal adjudicatory hearings in proposed suspension or cancellation actions and should provide instead an informal procedure, including notice in the Federal Register, that informs registrants and others of the specific grounds on which EPA bases its proposed action and that provides a reasonable

[2] Without taking any position on the substantive questions involved in determining the relative safety and effectiveness of pest control measures, the Conference notes EPA's interest in both the present and prior presidential administrations in developing such a substantive capability.

[3] Imposition of penalties should be through formal adjudication. See Conference Recommendation 93-1 “Use of APA Formal Procedures in Civil Money Penalty Proceedings,” 58 FR 45409 (Aug. 30, 1993).

opportunity to file written comments and data. Only if a party will be demonstrably prejudiced by the written notice-and-comment process should the agency be required to grant the right to introduce oral testimony or to subpoena and cross-examine witnesses.

B. Congress should consider providing EPA the authority to order a phase-down in the use of any registered pesticide through an informal notice-and-comment procedure in which EPA considers such factors as the relative risks and benefits of the pesticide at issue when compared with alternative pest management products and practices.

III. Public Participation

A. EPA should regularize and open for broader public participation its informal procedures for achieving interim risk reduction through pesticide label changes. EPA should inform the public, through a Federal Register notice, when it commences private label negotiations with registrants. EPA should simultaneously open a public "negotiation docket" into which interested persons may submit comments they believe might be relevant, for consideration by EPA and the registrants during their negotiations. If, after negotiations with registrants, EPA proposes a label change, it should publish a notice of the proposed change in the Federal Register and provide the public an opportunity to file written comments. The notice should include a concise, general statement of the proposed label's basis and purpose, including a summary of the material aspects of the agency's negotiations with registrants.

B. After requiring a label change, EPA should establish and publicize the availability of a "compliance docket," for any input about the effectiveness or ineffectiveness of interim risk-reduction measures. In addition, EPA's Office of Pesticide Programs (OPP) should communicate to EPA's Office of Enforcement and Compliance Assurance the adoption by OPP of label changes and any material information received by OPP in its compliance docket.

Citations:

59 FR 4675 (February 1, 1994)

__ FR _____ (2011)

1993 ACUS 31