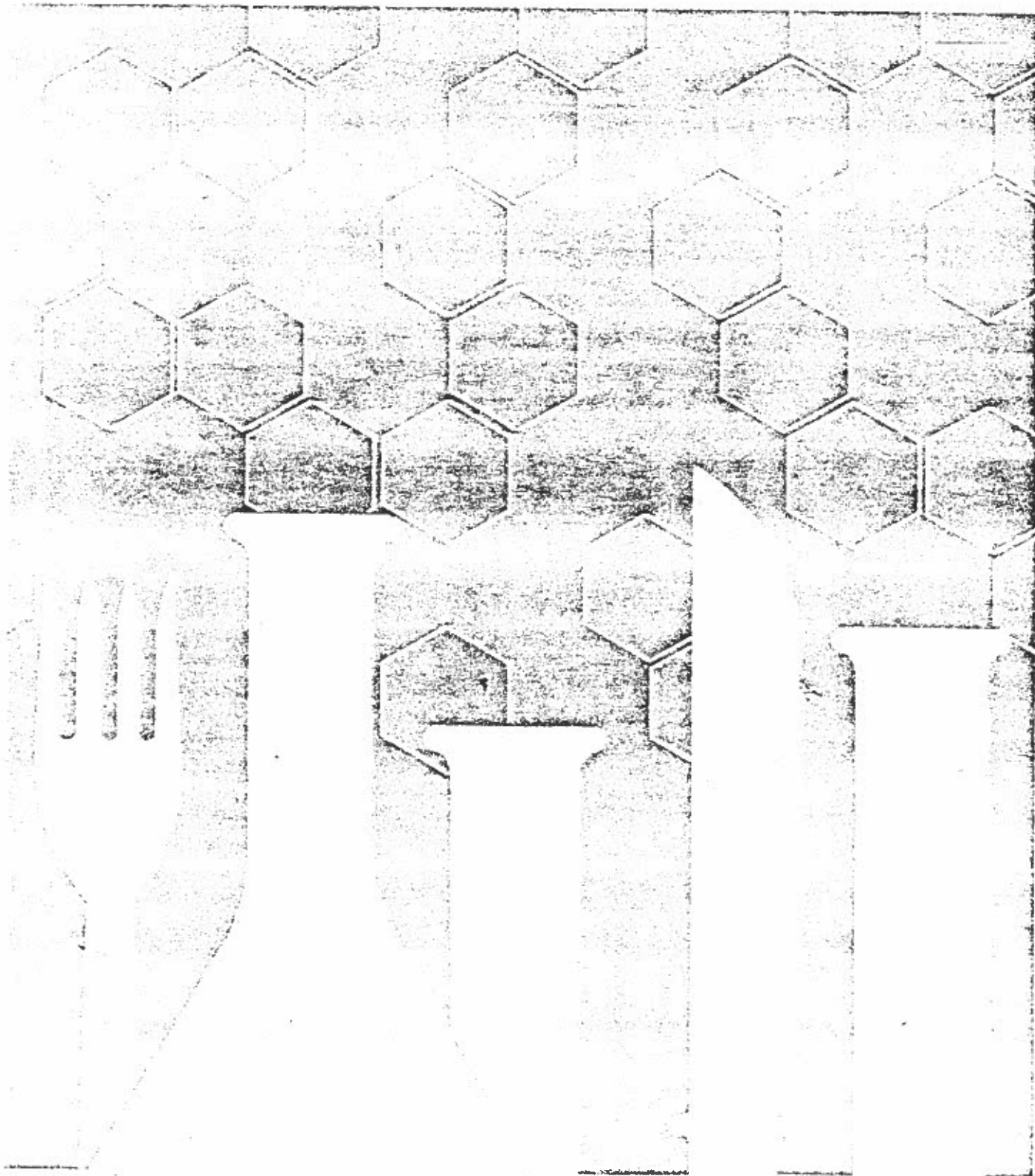


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# HOW EPA SPELLS "RELIEF"

Lawrence S. Ebner

Regulatory relief. Better science. More negotiations.

That is the new pledge of allegiance for all who have — or want — a job at the Reagan EPA.

Anyone in the pesticide industry who has dealt with the Agency during the past twelve years will agree that regulatory relief, better science and more negotiations are precisely what is needed. EPA for too long has postured itself as the unyielding adversary of industry, often making the political decisions first, and only then constructing elaborate (but sometimes flimsy) scientific rationales for its actions. The pronouncements of the new administration, therefore, very well may herald a new era of cooperation between EPA and industry and result in reasonable governmental regulation of an industry that to a high degree regulates itself.

For sure, the Agency will be less trigger-happy under the Reagan Administration. But to assume, as some gleefully have, that the Agency will just fade away is wishful thinking. To the contrary, pesticide producers and users will have to shoulder a heavier burden than ever in ensuring that their products do not pose unreasonable risks to man or the environment.

The registration standards program is a good example of how regulatory relief means greater industry responsibility. It's no secret that the so-called generic standards system has been bogged down badly within EPA ever since the Agency proposed it late in 1979 as the ultimate method for clearing out the logjam of pesticide reregistrations under FIFRA §3(g). The new Administration still seems to be committed to the idea of establishing a regulatory standard for each active ingredient, and requiring all registered products to meet the applicable stan-

dard. Manufacturers rather than EPA, however, now will be expected to take the lead in developing detailed standards. Instead of waiting years for the Agency to establish particular standards, industry will have the burden of going forward with proposed criteria and supporting data. The result should be more (and presumably better) registration standards sooner.

Label Improvements (including state-of-the-art application and safety techniques) and evaluation of the efficacy of old and new pesticide uses are additional areas in which manufacturers and users will be expected by EPA to take the initiative.

The whole matter of better science also is one for which industry will have to assume greater responsibility. John Todhunter, EPA's new Assistant Administrator for Pesticides and Toxic Substances, repeatedly has emphasized that the quality and credibility of the scientific assessments underlying the Agency's regulatory decisions need to be improved. Dr. Todhunter pledges to get the politics and emotion out of science at the Agency. He has promised to initiate a peer review system for EPA staff scientists and to require them to utilize realistic assessments of human risk.

Thus, for example, if a pesticide is suspected to be a carcinogen, EPA presumably will look favorably upon retrospective epidemiological studies showing no increased incidence of cancer among workers in pesticide manufacturing or formulating facilities. Also, the Agency should be happy to receive real-world user or consumer pesticide exposure data, and cancer risk assessments derived from a variety of low-dose risk extrapolation models. Hopefully, regulatory actions no longer will be based solely upon debatable histological data from studies of laboratory animals, upon unrealistic "worst-case" assumptions about the levels or duration of applicator exposure, or upon the excessively conservative one-hit cancer risk extrapolation model.

In view of budgetary constraints and



personnel cutbacks, industry cannot complacently rely upon EPA to generate the sort of data and expert opinion that will make better science a reality at the Agency. That must be a burden voluntarily assumed by the regulated community.

Principal manufacturers and users of pesticides who have been under the cloud of the rebuttable presumption against registration ("RPAR") review process, long have recognized the potential value of preparing persuasive presentations of comprehensive scientific data and opinion for the Agency's consideration. Even if at times in the past EPA has viewed such submissions as little more than a final hurdle to overcome in seeking to justify the regulatory actions that it plans to take the FIFRA Scientific Advisory Panel has, on the basis of such industry information, increasingly attempted to hold the Agency staff to a higher standard of scientific credibility. Now that the Administration wants to ensure better science at EPA, there will be more need than ever for industry to develop and present the type of pertinent and accurate data that will put the Agency in a position to make the best and most reasoned decisions.

Finally, there is the matter of negotiations between the Agency and industry. Ever since the advent of the RPAR process in 1975, EPA has moved slowly toward the recognition that adjudicatory proceedings do not afford the best forum for eliciting scientific information and making regulatory decisions. With the new Administr-

*Mr. Ebner is a partner with the law firm of McKenna, Conner & Cuneo and specializes in pesticide regulation and other aspects of environmental law.*

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tion, EPA apparently is now firmly convinced that it would rather regulate than litigate.

Pesticide manufacturers and users, too, most certainly would prefer to avert lengthy and expensive formal proceedings. As long as the Agency's (negotiated) final regulatory decisions are acceptable, there should be no need to resort to the statutory rights afforded to pesticide registrants or

others adversely affected by Agency actions. To make the system work, it will be incumbent upon industry to seek out the decision makers at EPA and to engage them in timely and meaningful discussions about pending regulatory actions. If the Agency is true to its words, its staff will listen and react accordingly, particularly if presented with sound reasoning and detailed scientific information. This means that industry will have to mar-

shal its best managerial, technical and legal resources to interface with EPA. In turn, this will require an aggressive, albeit non-adversarial, approach to cooperative regulatory problem-solving. Needless to say, this will not be a hospitable climate for procrastinators who would rather come to grips with Agency concerns another day.

How, then, does the Reagan EPA spell relief? — I-N-D-U-S-T-R-Y.