trade organizations—the Industrial Biotechnology Association and the Association of Biotechnology Companies—are developing positions. Also, John McTague, acting director of the Office of Science and Technology Policy, is slated to receive a staff report on the R&D needs of agriculture, including construction of test facilities.

Meanwhile, the Reagan Administration is expected to unveil on 15 April its regulatory matrix for the EPA and Department of Agriculture screenings of genetically engineered biotechnology products. Representative Don Fuqua (D–FL), chairman of the House Science and Technology Committee, introduced comprehensive legislation covering this area on 17 March. Besides installing the Biotechnology Science Coordinating Committee as a permanent fixture in OSTP, it sets up a research program to create and maintain a database for regulating biotechnology.

Neither the Administration's regulatory matrix nor Fuqua's bill lay out a specific scheme for intermediate facilities to test genetically altered microbes and plants at a level just below full field trials. And there is still a divergence of opinion among industry, academic, and environmental interests as to what test facilities actually are needed.

Harvey S. Price, a Gaithersburg, Maryland, consultant, notes that "A lot of industry people are afraid an intermediate facility will become a funnel for everything." But Jack Doyle, an analyst with the Environmental Policy Institute, says the industry is overly paranoid. "I don't think the environmental community will be that unreasonable."

The need for containing classes of microbial and plant products in secure test facilities must have strong scientific review, says Warren C. Hyer, Jr., managing director of the Association of Biotechnology Companies. The track record of traditional plant breeding and chemotechnology must be considered. "We are not starting from ground zero," observes Hyer.

Nevertheless, there appears to be growing recognition within industry that regulatory inaction also could be paralyzing. "Lots of people can do marvelous dreaming in terms of 'what-if' risks might occur—and this can delay the advance of this technology," says BioTechnica's Hardy. The way to avoid this trap, he contends, "is to bring the public sector into this situation . . . to provide comfort in terms of a broad, knowledgeable evaluation of what is going to be tested in field tests." ■ MARK CRAWFORD

Antagonists Agree on Pesticide Law Reform

Chemical companies agree to regulatory reforms; public interest groups will not block patent extensions for pesticides

AFTER a 14-year stalemate, the agricultural chemical industry and a coalition of public interest organizations have hammered out an agreement that could dramatically reform the nation's pesticide law. On 10 March, the two groups unveiled the details of a plan that would strengthen the government's regulatory authority over pesticides and tighten the safety requirements for these chemicals.

Legislation based on the plan was immediately introduced in the House and Senate, and hearings were held on 19 and 20 March by a House agriculture subcommittee. Berkley Bedell (D–IA), chairman of the subcommittee, says, "I'm well aware that this bill doesn't satisfy everyone. But [industry and the coalition] have come a long, long way."

The agreement has broad implications. Of the thousands of pesticides in use, only a small fraction actually have been fully tested for safety under the federal pesticide law. For the Environmental Protection Agency, the statute has often been regarded as more of a hindrance than a help. Commenting on the agency's ability to cancel use of a pesticide, John Moore, EPA's assistant administrator for pesticides and toxic substances, told a House subcommittee last year, "The current system needs to be looked at. . . . You can only go so far to make a silk purse out of a sow's ear."

The impasse over pesticide reform was broken because pesticide manufacturers badly want Congress to extend the patent life on their products to compensate for time spent gaining regulatory approval. Two years ago, Congress extended the patent life of pharmaceuticals on these grounds. But the consumer groups said they would block these attempts unless the industry agreed to some significant changes in pesticide law.

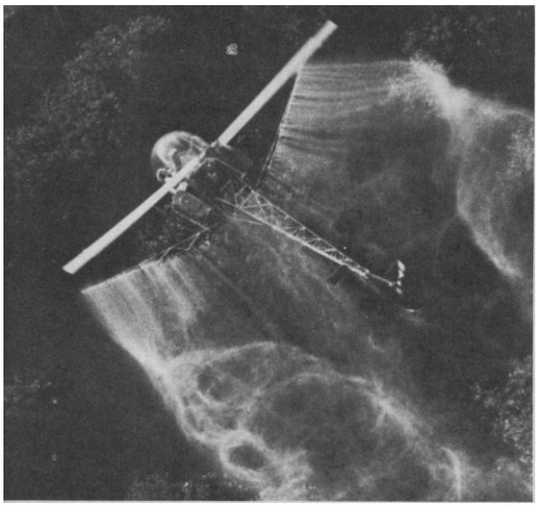
The agreement to change the pesticide law "required a tremendous amount of give and take on both sides," says Jack Early, president of the National Agricultural Chemical Association. One of the most significant provisions in the proposal would speed up the safety review of old pesticides. "The fundamental deficiency in the current regulation of pesticides is the absence of valid scientific data addressing health hazards," says Albert Meyerhoff, a senior attorney at the Natural Resources Defense Council, one of the 41 consumer groups that pushed as a coalition for reform.

The debate centers partly on 600 active ingredients that are used to create the thousands of pesticide formulations on the market. Although most of these key chemicals have been on the market for decades, only six have been fully tested according to federal law. Moore says that, without additional resources, the agency can only review an average of 25 per year to evaluate a chemical's risk to health and the environment. The completion of the review entails the evaluation of tens of thousands of toxicity studies.

Under the proposal, companies would pay up to $150,000 to reregister a chemical with EPA. The fee would serve a twofold purpose. The size of the fee would discourage companies from reregistering chemicals that are unlikely to gain approval, and it would also generate needed revenue to beef up EPA resources for evaluation. Meyerhoff estimates that the fees could raise $70 million for EPA.

The agreement would also give EPA the authority to regulate inert ingredients in pesticides for the first time. According to Moore and others, some chemicals classified as inert by companies may be as harmful as active ingredients. The proposal would require manufacturers to test some inerts and to list the specific compounds on the product label, neither of which is now required.

The agreement would also tighten the standards for approval of many pesticides. Specifically, it would close what critics claim is a significant loophole resulting in the sale of chemicals that have not been fully tested. At present a new chemical must pass very stringent criteria to win EPA approval, but



Dusting with Pesticide

The proposal would speed up the review of hundreds of pesticides.

companies can bypass these requirements by claiming that the chemical is so similar to an existing product that further toxicity testing is not required. They make similar arguments when they want to promote a new use for an existing product. But because the old chemicals have not been fully evaluated in the first place, the gaps in safety data rarely get filled. The agreement would make it much tougher to qualify as a "me-too" chemical.

The proposal would also accelerate a special review process that EPA relies on to ban a pesticide. Under present law, EPA has taken as long as 7 years to cancel a pesticide, as in the case of ethylene dibromide (EDB). The EDB review dragged on because chemical manufacturers and the U.S. Department of Agriculture blocked a proposed ban under procedures allowed by the special review regulations. The agreement would shorten the whole process to 1 year by imposing strict deadlines on each step along the way.

For the first time, members of the public would have the right to examine health and safety data on a pesticide *before* the agency decides whether to approve it. At present, this information is only available after a pesticide is approved, but by then, it is very difficult to reverse a decision.

The bill goes a long way in addressing EPA's complaints about the pesticide law. "This is the best shot for reform in years," says Moore. Nevertheless, he objects strongly to the numerous deadlines that would be imposed on the agency. "A few things just won't work," he says. To fill in the missing toxicity information on old chemicals will take an enormous effort, more than the 6 years allotted in the bill, in his opinion. And even if reregistration fees are charged, the agency would still come up short by $100 million to complete the review, Moore told the subcommittee on 20 March.

He also testified that EPA "was unequivocably opposed" to the way the proposal would change the special review process. The bill does not address a basic defect in the special review process but simply compresses a flawed procedure into a shorter time span. He suggests that the right to administrative review be eliminated, which could trim years off the process. If opponents want to challenge an agency decision, then they can sue EPA, just as they can now.

Moore also opposes keeping the same requirement that triggers a special review. The agency presently only considers the hazard of a chemical to start a special review. The risk of exposure should also be taken into account, he testified. Otherwise, "we would have to begin a special review even if we already know that exposure is so low that the risk is insignificant."

Several issues that may prove to be sticking points are not addressed in the legislation. The consumer coalition wants to see regulations concerning ground water in the bill, but have not yet settled the matter with the chemical trade association. Meyerhoff also notes that "we haven't made peace yet with the farm groups."

Mark Maslyn, assistant legislative director for the American Farm Bureau Federation, says that his members are worried that the proposal might reduce the availability of specialty pesticides used for crops other than commodities. A company may choose not to register a modest-selling product because of the $150,000 registration fee and that product may be crucial to a certain grower, Maslyn says. Steven Schatzow, director of EPA's office of pesticides, says, however, that the argument was a "red herring" because most herbicides used in small volume are made from popular active ingredients.

Maslyn would like to see the issue of product liability addressed in the pesticide reform bill. He says that under current law, a farmer can be sued if he follows a pesticide's labeling instructions. "That's not right," he says. "We want the liability to rest with the chemical companies if the chemicals were used properly." But, he adds, "We're having some trouble writing that legislative language."

Other groups outside the coalition, such as the Environmental Policy Institute, have serious reservations that the industry should win extra patent life on their products in trade for these other reforms.

The coalition and the chemical industry both acknowledge that the bill may be buffeted in Congress. But they have pledged that any changes must be mutually agreed upon. "This legislation is a delicate balance of hard choices, " says Nancy Drabble, an attorney for Public Citizen's Congress Watch. ■ **MARJORIE SUN**

Briefing:

OMB Offers to Delay Indirect Cost Cuts

Facing a barrage of criticism from members of Congress, Joseph R. Wright, deputy director of the Office of Management and Budget, has offered to delay for 3 months implementation of a proposal to cap the administrative costs that universities charge as overhead on government research grants. Testifying before a subcommittee of the House Committee on Science and Technology on 20 March, Wright made clear, however, that he regards such a delay—from 1 April to 1 July—as a stay of execution; it does not signal a change of mind.

The proposal, published by OMB in the 12 February *Federal Register*, would limit the amount of administrative overhead charged by universities on government grants to 26 percent of the direct cost of doing the research. For fiscal year 1987, the ceiling would drop to 20 percent (*Science*, 7 March, p. 1059). OMB has said that the proposal would save $100 million in FY 1986 and $200 million in FY 1987, but some university groups contend that the cuts are likely to be much deeper than that.

In his testimony, Wright noted that indirect costs have risen faster than direct costs, growing from 24 percent of total federal support for academic R&D in 1974 to 31 percent in 1984. "This represents," he claimed, "an annual shift of over $400 million from research to university overhead."

University administrators testified that the costs are real, and argued that if OMB's proposal were to be implemented, universities would end up subsidizing federal research programs. They were particularly chagrined, however, by the way OMB proposed the cuts.

Universities were not consulted before the proposal was published, they were given only 30 days to respond, and the cuts were scheduled to be implemented in 45 days. Asked by subcommittee chairman Doug Walgren (D–PA) to respond to this complaint, Wright pointed to a foot-thick pile of reports on indirect costs that have been produced over the years, and noted that "this was not something that just came out of the blue."

Nevertheless, said Wright, "if it would help to extend implementation from April 1 to July 1, I would be happy to do that." However, he said OMB is not willing to extend the period for universities to comment on the proposal.

University groups thus seem unlikely to force a change of heart on OMB and are