

## ISSUE PAPER

NUMBER 10

OCTOBER 1998

THE PROPOSED EPA  
PLANT PESTICIDE RULE

## SUMMARY

Under statutes developed for chemicals applied externally to plants, the U.S. Environmental Protection Agency (EPA) proposes to regulate genetically engineered plants containing genes for pest resistance that have been introduced by techniques of recombinant

deoxyribonucleic acid (rDNA). Plants with such genes would be designated pesticides. The Council for Agricultural Science and Technology (CAST) panel members, as well as other scientists, view this position as scientifically not defensible and, if instituted, likely to have serious consequences. The designation of plants as pesticides is indefensible on scientific grounds for many reasons including the following:

- Pest resistant plants produced by genetic engineering may be indistinguishable from plants bred for pest resistance by conventional methods. These latter plants are exempt from the EPA proposed guidelines even though the end results of recombinant DNA strategies are the same as conventional breeding.
- The proposed EPA regulations abrogate the principle enunciated by several scientific panels; namely, genetically modified crops should be judged on their safety, allergenicity, toxicity and other properties, and not the means by which the trait has been

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introduced. Thus, the properties of the modified plant, in terms of risk, are important, not the technique used to modify the plant.

- Numerous mechanisms exist in plants that confer resistance to pests. Some cases result from the ability to synthesize a new protein; in other cases, a pest resistance

pathway in the plant is activated. To lump these various mechanisms into one category and state that they must be regulated if they result from recombinant DNA technology is scientifically illogical.

- No evidence exists that the plant's level of resistance to pests creates hazards in the environment.

If the EPA rules go into effect, our panel foresees the likelihood of serious economic consequences in the food industry.

- Labeling plants as pesticides would undermine public confidence in the safety of the food supply. If plants are safe for human consumption, there is no reason to label them as pesticidal.
- Adoption of the proposed EPA regulations would discourage development of pest resistant minor crops or crops resistant to minor pests. This would delay the time until chemical pesticide use can be decreased.
- Enforcing the EPA regulations would increase the regulatory burden on all companies as well as on the

EPA. This increased paperwork and scientific data gathering could force small companies out of business or force them to change their business plans. The small companies are the ones most likely to develop pest resistance in those minor crop plants that large companies normally do not choose to develop.

### INTRODUCTION

The EPA proposes to regulate plants made resistant to pests by means of genetic engineering, under the same regulations developed for use of chemical pesticides applied to plants (U.S. Environmental Protection Agency, 1994). These plants would be designated as pesticides. This proposal has aroused deep concern in the scientific community.

In July 1996, the report *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests* was released. It presented statements of eleven professional scientific societies (EPSS) (Institute of Food Technologists, 1996) on the proposed regulations. In September 1996, an advisory panel of the Biotechnology Industry Organization (BIO—representing over 550 companies and affiliated organizations) responded to the key points in the EPSS report indicating the points on which they agreed and those on which they disagreed wholly or in part (Biotechnology Industry Organization, 1996). In February 1997, the EPSS responded to the BIO comments (Institute of Food Technologists, 1997).

In 1998, a panel of five members of the National Academy of Sciences was formed by the Council for Agricultural Science and Technology (CAST) and charged with examining the scientific merits of the BIO response to the major conclusions reached by the EPSS regarding the policy proposed by the EPA. We were asked to appraise the differing viewpoints based solely on scientific principles and to draft a document that assesses the scientific merits of the differing viewpoints. We have done so by stating our position as panel members on each issue. However, we note that many of the major points made by the EPSS and the response of BIO are not directly related to science, but rather to social and/or economic issues. In these cases, we have presented our views, but have not stated a position because we do not pretend to be experts on these issues.

Although the thrust of this document focuses on the points of difference, we note that BIO agreed with many

of the conclusions reached by EPSS and these are noted in the report with additional comments in some cases. The panel members believe it is imperative that BIO and the EPSS use the most recent scientific information and move forward toward their common goals.

### GENERAL CONSIDERATIONS

Because this report deals in large part with pests and pesticides, it is important to recognize certain general features of these agents and substances used for their control that often are overlooked.

A “pest” is generally understood to be an organism that harms crop plants, domestic animals, or other interests of people. Pests may be insects, nematodes, fungi, bacteria, plants considered to be weeds, animals such as deer and rabbits, and birds such as starlings. An organism may be a pest in some situations and not in others. For example, corn is a crop plant, but volunteer corn in a soybean field is a weed. Geese on airport runways and bathing beaches are pests, but are things of beauty when swimming on a lake. “Pest” refers to a group of organisms that cannot be defined by scientific taxonomy. “Pest” is a cultural concept and “pesticide” is therefore also a cultural concept.

The proposal to designate a living plant a pesticide is a major conceptual change that warrants critical examination. The appended letters “-cide” are derived from the Latin word *caedere*, which means “to kill,” and are generally understood to designate a substance that may be lethal. There is a general perception that a chemical pesticide is injurious to a broad range of organisms and likely to be harmful to humans and animals. Unfortunately, the term is used rather loosely in instances in which more exact terminology would be more appropriate. Thus, in most cases a particular pesticide may be specific for insects, nematodes, bacteria, fungi, or weeds and a more exact term should be used such as insecticide, nematocide, bactericide, fungicide, or herbicide. In general, pesticides affect not only target pests, but also may affect other organisms including those which are beneficial.

The naturally occurring resistances that have been characterized genetically in plants in most instances involve resistance to a specific organism or to a group of closely related organisms. Thus, to label a plant a pesticide if it contains genes for resistance to a nematode is

basically inaccurate because of a lack of specificity. Furthermore, if one follows the logic requiring a plant to be labeled a pesticide if it is resistant to a specific pathogen, then a chicken bred for resistance to a specific disease should likewise be called a pesticide.

The opinions of various groups on the desirability of releasing genetically engineered plants often depend on the interests and biases of these groups. They often raise scientific issues to instill fear in the public and raise support for their opinions. The problem frequently is not in the science, which may be correct though incomplete, but in the logic leading to the conclusions. Then the dispute remains unsettled. One common type of error in logic is concluding that lack of proof of an event *not* happening means that it *will* happen. For example, the inability to prove that a transformed plant will *not* become an uncontrollable weed does not mean that the plant *will* become a weed. The lack of proof does not even bear on the probability that the transformed plant will become a weed. Another common type of error is concluding by analogy. The fact that musk thistles became weeds after introduction into a new environment does not mean that transformed corn will become a weed. Most introduced plants have not become weeds. The basic genetic characteristics of the transformed plants are relatively unchanged and the attributes of genetically engineered plants are similar to the those of the parent organisms.

### MAJOR POINTS AND RESPONSES

Listed below are the major points made by the eleven professional scientific societies (EPSS), the response of the Biotechnology Industry Organization (BIO) to them, and comments by the CAST panel members.

- 1. It is scientifically indefensible to regulate the inherited traits of plants for pest and disease resistance under statutes developed specifically for chemical pesticides applied externally to plants.**

According to BIO, the EPA *does* have the authority to regulate compounds that are not chemical pesticides, such as pheromones, plant growth regulators, and naturally derived chemical pesticides.

The CAST panel recognizes that the BIO statement is certainly correct. However, the above statement by the

EPSS emphasizes the definition of the term “pesticide” in the regulations. The EPA proposes to interpret the term differently. There is no question that the original purpose of Congress was to regulate the use of specific chemicals that are pesticidal. In proposing to regulate *only genetically modified* plants that produce pesticidal substances, the EPA is inconsistent. If tobacco, which is known to contain the toxic pesticidal chemical nicotine, is safe enough to be exempt, how can the EPA justify regulating other plants?

**The CAST panel agrees with the position of the EPSS, as well as several other government panels: regulating the inherited traits of plants for pest resistance because these traits were introduced by genetic engineering and not through conventional breeding is scientifically invalid.**

- 2. All plants are able to prevent, destroy, repel, or mitigate pests. Further, all plants are resistant to most pests (susceptibility is the exception), although the actual mechanisms of pest defense are complex and the roles of specific substances remain largely unknown.**

**BIO and the EPSS agree on this point, and both recognize that it is scientifically true.**

- 3. Whereas specific genes can determine pest resistance, the ability to respond to and resist pests is a characteristic of the plant and cannot be separated for regulatory purposes from the plant itself.**

The CAST panel believes that a major component of the problem is the proposal by the EPA that a plant synthesizing a pest control compound be designated a pesticide. In view of the widely accepted conceptual understanding of the term “pesticide” as already discussed, this proposed change in terminology is not appropriate. An example cited by BIO is the plant in which the ability to synthesize the *Bacillus thuringiensis* (Bt) toxin has been introduced through recombinant DNA techniques. However, Bt is a product that has been widely accepted as “generally regarded as safe” (GRAS) and has been used safely on a wide scale on many crops for over forty years. Why is it necessary to regulate a plant producing Bt toxin

when the compound in itself is not hazardous to humans or animals other than specific insects?

Several classes of resistance genes have been identified. Recent research has shown that genes that enhance pest resistance in plants may not be involved in the production of one specific compound or even a family of substances that could be remotely designated as pesticides. For example, transgenic plants that produce inhibitors of protease activity show promise for nematode control. This type of inhibitor is certainly not a pesticide in any sense of the word, even though it may be involved in resistance to nematodes. Resistance may also be gained by activating endogenous plant defense genes, which certainly requires the functioning of the intact plant.

**The position of the CAST panel is that it is scientifically untenable to consider that the diverse mechanisms involved in pest resistance in plants are of one type or one set of processes and therefore subject to the same rules. In all cases it is the plant that is resistant, although resistance can be achieved through a variety of mechanisms.**

**4. Evaluation of the safety of substances in plants should be based on the toxicological and exposure characteristics of the substance and not on whether the substance confers protection against a plant pest.**

Both groups agreed with this statement. It follows then that chemicals that are safe to use through application should be considered safe when they are synthesized by a plant, assuming that application and synthesis are carried out at the same stage in plant development. The prime example is Bt toxin.

**5. The EPA proposal will erode public confidence in the safety of the food supply by sending the message that all plants contain pesticides.**

Although this is an important concern, it cannot be argued on scientific grounds. The CAST panel members agree with the EPSS view for the following reasons. (1) BIO considers that the public already knows that many common foods contain toxic compounds because of Dr. Bruce Ames's publications seems weak. The CAST panel

doubts that the publications of Ames and his colleagues are widely known by the general public (Ames and Gold, 1989). (2) It is difficult to accept the notion that knowledge of the scientific literature will decrease public concern about consuming pesticides. In this regard, we note the negative public response to the U.S. Department of Agriculture (USDA) proposal that transgenic plants could be produced on certified organic farms. (3) The recent proposal of Austria and Luxembourg that all transgenic plant products imported into these countries should be banned further emphasizes the negative connotation that genetic engineering has in the minds of the general public.

**6. The EPA proposal will discourage the development of new pest resistant crops, thereby prolonging the use of synthetic pesticides.**

Again, this statement cannot be addressed using strictly scientific arguments, but several points can be made to question claims that no evidence exists to support the statement that the EPA proposal would discourage the development of pest resistant crops. It is a fact that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) has had a major negative impact on the development of chemical pesticides having a minor use. Companies are not in a position to make the expenditures needed for research, production, and registration of pesticides on minor crops. Furthermore, as stated in the EPSS response, "the land grant universities and the USDA through the Interregional Research Project No. 4 (IR-4) began to invest public funds to obtain data required for EPA-approved labels of minor use of chemical pesticides developed by the manufacturer for larger markets. The IR-4 program as it currently exists would be totally inadequate to accommodate the response to the number of varieties of minor crops or minor varieties of major crops with multiple market classes." Furthermore, John Sanford, chief executive officer of a small biotech company has stated: "The policy creates a major disincentive for all but a few companies and will force most companies to abandon efforts to develop genetic alternatives to pesticides."

**7. The EPA proposal will increase the regulatory burden for those companies and other organiza-**

**tions developing pest resistant varieties of crops, while also increasing federal and state bureaucracy.**

This issue, like issue numbers 5 and 6, cannot be supported solely on scientific grounds. However, it is true that the size of the staff in the designated section of the Animal and Plant Health Inspection Service (APHIS) did increase significantly after regulations were enacted that concerned genetically engineered crops. If decisions are to be made in a responsible and timely manner, a necessary prerequisite would be an adequate number of competent and well trained staff. Further, the argument made by the EPSS that the future will place heavy demands on the system for the following reasons seems valid: “The EPA proposed rule would potentially require a review or approval under FIFRA for each novel trait transferred to the variety from outside the genus (or range of sexual compatibility depending on the final rule). Even conservative estimates predict that, over the next one or two decades, most plant breeding programs will be working with parents with one or more traits transferred to the line originally outside the range of sexual compatibility of the crop species. The number of reviews and labels for even one variety would become prohibitive even for large market crops.”

**8. The EPA proposal would limit the use of rDNA technology for the development of pest resistant plants to those applicants who can pay the increased costs associated with additional regulation. This proposal would deny the benefit of this technology to applicants for niche markets likely to be developed by small companies and public plant breeding programs.**

BIO argues that this would not be the case because companies need to collect all of the data available to support registration with the EPA, even in the review scenario proposed by the EPSS.

Under the present guidelines of the USDA, genetically engineered plants containing rDNA pest resistance genes are not subject to regulation unless they contain some plant pest properties and they were isolated from a plant pest or they confer the potential for the plant to be a pest.

The report of the EPSS emphasizes the need to conform to the recommendations of the National Research Council report *Field Testing Genetically Modified Organisms: Framework for Decisions* (National Research Council, 1989). This report recommends that decisions on field testing of pest resistant plants be based solely on risk assessment rather than on the mechanism by which genes conferring pest resistance are introduced. The CAST panel members strongly support this view. However, the EPA-proposed rules do not embrace this concept. Therefore, with some exemptions, all plants produced by recombinant DNA procedures would be subject to regulations requiring companies and other public and private organizations involved to complete the same evaluation procedures as those required for chemical pesticides applied to plants.

These proposed EPA rules, therefore, increase the prospect of delay, or worse, lack of approval. Further, collection of all the data necessary to apply for approval will incur considerable expense and will require a significant time commitment. Large companies, which traditionally have more financial resources and support personnel, often focus on a few major crops that represent the best opportunity for a profitable return on investment. However, small companies, in part because of intense competition from large companies, frequently focus on various minor crops for niche markets with less profit potential. These small companies lack the support personnel that major corporations can maintain. If approval of engineered pest resistant plants is required, a disproportionately heavy burden is placed on small companies. One obvious solution for small companies is to abandon attempts to engineer minor crops for pest resistance.

**9. The EPA proposal would handicap the United States in competition for international markets because of U.S. government policy that new pest resistant varieties be identified as containing their own pesticides.**

According to BIO, corporations in the United States would not be handicapped in selling their products overseas if such crops were designated to contain genes conferring pest resistance.

The CAST panel members find it difficult to accept

the viewpoint that labeling certain crops as having pesticidal properties because they contain genes that enhance pest resistance would not have a negative impact. Although not a scientific argument, the CAST panel members recognize that the European Union proposes to require labeling of all imported genetically engineered products. To designate plant products as pesticidal would only reinforce arguments the proponents of such labeling espouse, namely that genetically engineered crops are dangerous. Countries that may be considering similar rules might very well be encouraged to enact such rules because they fear genetically engineered pesticides.

**10. The EPA proposal would limit the use of valuable genetic resources and new technologies to improve crop protection from pests and diseases.**

**BIO notes that the data required for the EPA registration will have to be generated to assure product quality and safety.**

The CAST panel members cannot respond to the BIO statement on scientific grounds because it is basically an economic issue. It appears that EPA regulators and BIO consider several hundred thousand dollars (the minimum costs required for obtaining EPA registration) a modest sum, whereas public sector scientists and small companies do not. However, as already noted, there is ample anecdotal evidence that developmental costs, regulatory requirements, liability fears, and other related factors have had a major influence on decisions by companies as to whether to invest the sums required for research, product development, and sales.

**11. Federal and nonfederal oversight of plants should be based on accepted standards for rDNA research and field testing of plants. These include nongovernmental peer review and recommendations/guidelines provided by the U.S. National Academy of Sciences, the Organization of Economic Cooperation and Development, and the U.S. Department of Agriculture.**

**BIO believes that this statement does not recognize the regulatory role of the USDA.**

The CAST panel members agree that BIO is correct: the Animal and Plant Health Inspection Service (APHIS) of the USDA *does* regulate plants with genes introduced by rDNA techniques. Over the past twelve years, the USDA has gained considerable experience in assessing the environmental risks of plants developed by these techniques. As a result of this experience, the USDA has adopted performance standards first for field testing six crop species and now for the majority of crop species. This concept is far different from what the EPA proposes.

The U.S. Food and Drug Administration (FDA) is the primary agency responsible for ensuring the safety of commercial food and food ingredients. Unlike the policy proposed by the EPA, the policy of the FDA is to regulate genetically modified food products in the same way as foods produced by other means.

**The CAST panel members believe that the USDA should continue to regulate all plants with genes introduced by rDNA techniques and the present policy of giving responsibility to the FDA to ensure the safety of food and food ingredients should be maintained. These two governmental agencies have developed the expertise and experience to carry out these regulatory functions.**

**12. Regulatory oversight should focus on high probability risk rather than hypothetical or unrecognizable risk and should be sufficiently flexible to keep pace with new scientific developments.**

**On this extremely important point, there is general agreement by all concerned parties.**

**13. The level of risk of a plant variety to the environment or public safety is determined by the characteristics of the plant, not by the novelty or initial lack of familiarity, the source of the gene(s) that produces a plant defense substance or initiates a pest-defense reaction, or the method by which a gene for pest defense is transferred into the variety.**

**BIO believes that the source of the genes does matter.**

The CAST panel members believe the above state-

ment by the EPPS is scientifically accurate. The CAST panel also agrees with BIO that it is true that the function of the gene in its source organism likely indicates its function in the transformed organism. However, to predict the ecological impact of a gene in a new host species is difficult because of the complexity of ecological interactions. It would be counterproductive to establish a rigid set of regulations to be followed with the assumption that reliable predictions can ensue. Certainly, the ecological impact does not depend on how the gene was introduced into the plant or on the intended use of the end product.

Under similar environmental conditions, the ecological impact of a gene intended to produce an industrial product should be considered from the same perspective as one intended to produce a "pesticide." Market conditions also should be considered in regard to human safety. Transformed plants and their products may not always be marketed in their traditional or designated markets. On occasion, overproduction of certain major and minor crops has resulted in "dumping" these crops on the market.

Introduction of transformed plants into the environment is strongly opposed by a number of special interest groups. In part, this may be for financial reasons, e.g., the protection of organic growers and in part, from the fear that the transformed plants will impact ecosystems in some significantly negative manner. These fears are based on analogies to ecological disasters that have occurred in the past following the introduction of foreign species of plants and animals. However, these occurrences are not analogous to the current situation in which plants have been modified in a defined way by introducing one or more well-characterized genes. The basic genetic characteristics of the plant are relatively unchanged and the behavior of genetically engineered plants is similar to the parent organisms.

The support of BIO for the well-defined regulations governing commercialization of transformed plants may in part reflect the understandable desire of industry to be protected against possible liability claims. However, it is doubtful that the EPA can produce data indicating that government regulations will protect the safety of the public food supply or prevent environmental mishaps more effectively than the efficient self-governing system time-tested by the plant breeding community over many

decades.

**The CAST panel agrees with the statement of the EPPS that to evaluate the level of risk of a modified plant to the environment or public safety, one must look at the characteristics of the modified plant and not where the modifying gene(s) came from, or by what means it was introduced into the plant.**

**14. Genes and the substances encoded by them that confer resistance characteristics to plants are not the equivalent of "pesticides" as defined by FIFRA.**

The term "pesticide," defined as a preparation that may be lethal to pests such as certain insects, fungi, nematodes, and bacteria, is currently accepted and understood in the scientific and industrial community as well as by the public in general. The EPA designates a living plant a pesticide if it has been made resistant to pests through rDNA technology. The CAST panel members believe that for the EPA to change the basic definition of the term to encompass the new rules proposed by the EPA is neither appropriate nor justified scientifically. The proposal to designate a living plant as a pesticide is a major conceptual change that must be examined critically. There is a general perception that a pesticidal chemical is injurious to a broad range of organisms and likely to be harmful to humans and animals. Further, the language of the proposed EPA rule is so vague that "active ingredient" could apply to DNA or RNA.

**In particular, the CAST panel members reject the concept that DNA and RNA are pesticides.**

**The position of the CAST panel is to limit the term "pesticide" to chemicals that either kill or inhibit the growth of pests or pathogens when applied to these organisms. It should not apply to a plant that contains genes for pest resistance.**

**Federal regulatory proposals should be guided by policies that encourage research and its application, resist unduly burdensome regulations, and also minimize public anxieties about hypothetical hazards. The EPA proposed rules fail to meet any of these desirable objectives.**

The CAST panel members are encouraged by the recent meeting of members of BIO and the EPSS on August 19, 1998 to resolve differences in their positions on the EPA proposal. Hopefully, this document will aid to further this process.

The viewpoints expressed in this report are those of the panelists speaking as concerned citizens and do not necessarily represent the views or policies of the organizations that employ them.

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ISSN 1070-0021

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