

April 30, 2001

Chair, CEQ; Director OSTP
Executive Office of the President
17th and G St N. W.
Washington, DC 20500

Sirs:

The American Phytopathological Society welcomes the opportunity to comment on Federal environmental regulations pertaining to agricultural biotechnology. APS members are heavily engaged in biotechnology and have been pioneers in plant biotechnology. Some of the assessments use genes, promoters, markers and terminator elements derived from microorganisms with which we have significant great experience. Thus, we believe the comments attached will be particularly useful.

The American Phytopathological Society (APS), founded in 1909, is the premier educational, professional and scientific society dedicated to the promotion of the plant health and plant disease control for the common good. The Society represents more than 5,000 microbiologists, including scientists and science administrators in academic, industrial and government institutions working in a variety of areas, including applied and environmental plant pathology, food, horticultural and forestry science, and biotechnology, including basic and applied research on producing transgenic plants resistant to pathogens and abiotic stresses.

Some of our comments go beyond the scope of the questions because a more holistic approach is needed. Where appropriate, some of these comments are made. For example, in our opinion, it is most useful to consider the uses of the seeds, leaves, fruits, and nuts of plants, in addition to production and environmental questions. A carefully grown edible plant that is not examined for allergenic potential relative to its parent is cause for concern to many consumers and is one of the bases of rejection of such foods or feed.

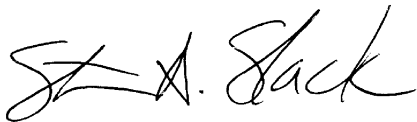
In general, these assessments are very well done, given the difficulties of integrating and consolidating information and data. Illustrations of data in the report, or as an appendix, could be considered helpful, so that independent data searches are not needed.

Perhaps the most significant message the agencies could provide is an illustration of the lack of comparable data in conventional plants. Narrative messages to that effect are not examined by critics of biotechnology. In that regard, perhaps it is time for the agencies to seek reexamination of GRAS foods, since the assumption of safety is a false one. This is particularly the case with allergens; should not modern science be applied to these foods and the foods be labeled accordingly? It is said by some that if the same criteria were applied to GRAS foods as for biotechnology products, that many of our foods would be taken off the market. Such comments should be considered for inclusion in assessments.

We do not believe additional laws and oversight mechanisms are needed, as long as the agencies have flexibility in interpretation of existing statutes, use the best scientific information available, and listen to stakeholders. We do not believe these agencies should make social policy; that is a role for the congress. Thus, in general, we are supportive of the participating agencies that took part in assembling the case studies.

Please feel free to call upon us for elaboration or further comments.

Sincerely,

A handwritten signature in black ink that reads "S.A. Slack". The signature is written in a cursive, flowing style.

Steven A. Slack
President APS

attachments

Introduction

Comment 1.

III. Background on Agricultural Biotechnology Paragraph 1, 2nd Sentence

For example, new crop varieties have been developed that are able to reduce, in many cases, chemical insecticide applications and allow for the utilization of more environmentally benign herbicides.

This sentence, while it may be true, is extremely misleading. Reduce pesticide applications could apply to fewer treatments or use of less total pesticide. Assessments of claims that pesticide reductions were related to adoption of bioengineered crops in many cases compared apples and oranges. If you assume application rates of each pesticide active ingredient (pound per acre of active ingredient) are the same used by growers employing traditionally bred crops versus those using bioengineered crops, changes in the number acre-treatments imply proportional changes in pounds of active ingredients used. However, since average application rates vary significantly across pesticide active ingredients, the net effect of substituting one for another may be an increase or decrease in total pounds of formulated product used. Therefore, changing the mix of pesticide products used while decreasing the number of acre-treatment can actually increase total pounds of active ingredients applied.

Additionally use of the term *more environmental benign* implies that the environment is being harmed by use of herbicides. Pesticides (including herbicides) are the most regulated products in the world. When a herbicide is approved for use on a crop it is deemed safe to use by the most stringent requirements applied by the EPA and other worldwide regulatory authorities. Perhaps the inappropriate use of pesticides requires that pesticides be more benign.

A more appropriate sentence might be: *For example, new crop varieties (and are they actually considered "varieties" ??) have been developed that allow farmers to choose the best combination of tools to control harmful crop pests while continually protecting the environment.*

Comment 2.

IV. The Coordinated Framework for U.S. Regulation of Biotechnology. Paragraph 5, Bullet number three:

The type of possible hazards (e.g. does it have the potential to harm plants or contain new genetic material that might cause a plant to become a noxious weed, or does it have the potential to release pollutants into the atmosphere or bodies of water);

This language presumes that in risk or safety assessments guilt is presumed until proven innocent. This sentence could be more approximately stated.

The assessment of the safety (e.g. evaluation of the parameters of the new genetic material with regard to potential safe use in proximity to plants, animals, soil, air, and water);

Comment 3.

V. The Coordinated Framework for U.S. Regulation Biotechnology.

Paragraph 6

There is no reference to regulation by USDA. USDA's Animal Plant Health Inspection Service (APHIS) oversees field and agricultural environmental testing of crops produced using biotechnology. This table should be revised by CEQ/QSTP to reflect regulatory oversight by USDA.

This is a serious omission and hopefully can be corrected in future versions if possible.

CASE STUDY II-Bt Maize

The American Phytopathological Society is pleased to comment on this case study, which involves the usage of parts of plant pathogens and plant pathology risk assessments in its overview.

In general, this is a very comprehensive report and well done. It would have been helpful to separate out more clearly what was actually done in 1996 and thereafter for MON810 from current policy in effect now. Nevertheless, the document is generally well written and informative. We comment only on the text, not the web sites that were not accessed as part of this evaluation.

In the introductory material, we note that the NIH Guidelines are applicable to all contained facilities, not only laboratories, but also e.g. to greenhouses and animal pens.

Comprehensiveness and rigor of environmental assessment.

We note that on pg.1 that the subtitle is incomplete and it is not clear what the rest of the title would be. To our knowledge, field corn (maize) is simply *Zea mays* and has not been reclassified. We do not believe the reference to flowers is accurate, in that it is precisely because both male and female flowers are produced on the same plant that detasseling is used to produce hybrid corn and why hybrid corn is a product of high proprietary value.

There is a discrepancy between risk assessments between EPA and USDA in language as presented here: EPA operates under the principle or standard of no unreasonable adverse effects on the environment versus APHIS, which indicates that it uses a no environmental risk criterion (separate from plant pest risk) that must be met after confined field release is terminated (p.35). It leaves open for criticism transient effects, which may be deleterious but equivalent to the cultivation of non-transgenic plants. An absolute standard in biology cannot be met. This is in contrast to p.36, under notification, which does use less stringent language: 'effectively eliminate the potential for significant impact to the environment' and FONSI for the EAs.

It is not clear what APHIS would do if a plant becomes more susceptible to pathogens or pests than its conventional counterpart after commercialization. Indirectly, such plants could contribute to spreading plant pests.

The document deals upfront with current practices of non-segregation of transgenic corn from conventional corn, which is a large trade issue today.(p.3).

It was prudent to develop a time-limited registration of five years based on novelty (p.5). Even so, data and concerns about Bt insect resistance caused EPA to modify some approval conditions before re-registration in 2001.

We continue to object to regulation of genetic material (p.6) versus the product, a decision not based on scientific evidence. It is interesting that no note is taken that EPA published an exemption from the requirement for tolerance under FFDCa for the consumption of DNA, based on no known evidence of any deleterious effect in animals or humans, and daily consumption of large quantities of DNA.

We note the conservative deregulation of plants in the permit process to one of notification, based on experience over space and time. Certain classes of plants which raised safety issues, and for which the experience base was small still required -and continue to do so- a permit for field testing.(p.8)

Worker exposure and the beneficial environmental analysis are considered relative to alternatives, which are positive comments regarding the lowered exposures of growers to chemical pesticides.

(p.22).

There are some contradictory statements re the use of the majority of harvested MON810 maize and its use as food.(p16) Missing from the analysis is any role of FDA: perhaps if it were consulted early on, the current questions regarding allergenicity could have been more forcefully addressed. The current discrepancy between the views of EPA and FDA potentially could have been avoided.

The time of exposure to non-target organisms is not mentioned, i.e. whether applicable to growing seasons and residues..

On p.17, there is no mention of the monarch butterfly as ‘other organisms are chosen as needed’: Was the monarch butterfly an issue in 1995? The issue is well presented later in the text (p.25-26).

The potential problem of cross-resistance of insects and the relative lack of information is well presented. Outcrossing and resistance in general are appropriately considered.

Reduction in exposure of non-target insects is referred to by a potential change in promoter sequences to affect expression (p.28) but omitted is the potential for differential site and temporal expression in future constructs. Such constructs would be expected to lower risks considerably with respect to gene transfer and non-target effects.

APHIS appears to be asking appropriate questions (p.55). We note that APS members have been consultants to APHIS and offered expert comments as needed. However, we note that although effects on soil microflora and microfauna are called for in assessment, we are not aware of any substantive statements made as to findings, except collembolas.

It is not indicated what would occur if one or more risk factors are negative, except for resistance management.

Comprehensiveness and strength of statutory authority.

This appears to be well spelled out in the assessment. Further, the assessment indicates what flexibility the agencies have in interpretation of such authority, and it seems to be considerable.

Transparency of the environmental assessment and the decision making process.

To the degree that there are ample opportunities to comment, workshops, stakeholder meetings, etc. , it is a transparent process. What is of concern is ‘the black hole’ phenomenon, whereby comments and input are solicited, and no iteration is forthcoming before implementation of a ‘final rule’. There should be a process of continual change, particularly in such a dynamic area.

Public involvement. We believe the agencies do a very good job in seeking and responding to the various publics that have interests in this area.

Interagency coordination. Coordination is still fragmented: the document refers to improvements in the offing between EPA and APHIS. More recently, on another Bt issue, it became apparent that there were problems in communication and coordination between EPA and FDA.

Confidential business information (CBI). Insofar as we can determine, and to our knowledge, CBI is handled appropriately. Some of the issues raised by concerned scientists and consumers can only be dealt with by examination in the public sector.

Comments on Sidebar No. II A Biocontrol using a virus (AcMNPV)

This case study is of an insect virus genetically modified with a scorpion toxin to more rapidly kill host insects. This biocontrol agent is still in small-scale field test stage.

Comprehensiveness and Rigor of Environmental Assessment-

The environment assessment seems very adequate. Information on the non-modified nuclear polyhedrosis viruses was used in making the determination. Perhaps more reference should be made to which Lymantrids are infected and which Lepodopterians were tested but not infected.

Comprehensiveness and Strength of Statutory Authority-

The relevant Federal agencies are given regulatory authority.

Transparency of the Environmental Assessment and the decision making process-

The whole process is open to the public with most documentation available to the public. However, data developed for the process should be more readily available for public viewing, except for that deemed confidential by the submitter based on confidential business needs.

Public Involvement

Procedures are in place for substantial public involvement.

Interagency Coordination

EPA, APHI, and DOI were involved. It should be that the Forest Service also be involved.

Confidential Business Information

This is routinely handled by the agencies in an acceptable manner.

Specific comments:

Pg 59

Paragraph 3

GVs and NPVs are not more complicated than other viruses, but different than many viruses. GVs and NPVs have adapted methods that permit them to complete their life cycle in their host, as do all viruses. This paragraph needs to delete language that implies that these virus have some unique inherent qualities that make them risky to use. Recommend:

GVs and NPVs are different than most viruses. Most know viruses exist as individual viral particles consisting of viral nucleic acid surrounded by a protein shell. By contrast, GVs and NPVs have a protein overcoat. For NPVs....

Pg 60

Paragraph 1

It is unequivocally stated further in the document the narrow host range and lack of persistence in the environment of these viruses. Thus, recommended the section beginning "The viruses..." be changed to: The viruses do not infect other organisms, including plants, beneficial insects, other wildlife, and do not persist in the environment.

Paragraph 5

Sentence beginning "Once ingested, the particles will find their way..." implies the viruses have an active means of movement, and additional sentence with "they take over" implies they have a schemed means to take over the insect. This is not true. Thus, make the following recommendation: Once ingested, the particles are taken up into cells of susceptible individuals. There, virus replication ensues to produce more infective virions within the occlusion body matrix.

Pg 61

Paragraph 1

There are a couple of inconsistencies in the statements provided. First the author(s) need to be consistent in the indication that the viruses are not stable in the environment, and that the host range is limited. Thus, recommend:

The virus is not stable on the plant surface, especially when exposed to sunlight and temperature extremes. Thus, the transfer of virus from deceased host to new living host is minimized compared to wild type virus as the AcMNPV/LqhlT2 does not persist in the environment.

What is the need for the phrase, "but does not show indications that the host range is enhanced or broadened"? The author(s) state the "host range is the same" in the next sentence. Recommend: The AcMNPV/LqhlT2 is modified to provide a quicker death to the target insect. Field test and laboratory....

Paragraph 2

First sentence is contradictory to the conclusion in the second sentence. Recommend:

If is not likely that the AcMNPV/LqhlT2 is able to proliferate and out compete wild type NPV since the behavioral changes in AcMNPV/LqhlT2 infected larvae are know contributing a sustained epizootic.

Comments on Case Study No. III Herbicide-Tolerant Soybean

This case study is of a genetically modified plant and a chemical herbicide already in Agricultural use. The case details how the plant was commercialized and how the chemical label was modified for this new use with maximum residue levels for consumption. An explanation of how the Coordinated Framework for Regulation of Biotechnology was reapplied with three agencies involved, USDA-APHIS, EPA, and FDA.

Comprehensive and Rigor of Environmental Assessment-

Many aspects of the total situation were considered by the agencies. Since the transgene included portions of genetic material from a plant virus, the genetically modified soybean was considered for its potential as a plant pathogen. The safe history of these regulatory sequences in transgenic plants was considered. Sustainable agriculture was recognized by the agency for its soil conservation and it was properly noted that the product would enhance use of this technology in agriculture. It was encouraging to note that experiences of conventional soybean breeding programs were used in making some of the determinations. In re-registration of the chemical much of the original information on chemical toxicity was reviewed and additional data were required for the new registration on soybeans. In general the environmental assessment seemed thorough and complete.

Comprehensiveness and Strength of Statutory Authority-

The authority of the various agencies is clearly spelled out in this case study. All aspects of this situation seem to be covered by the various agencies.

Transparency of the Environmental Assessment and Decision Making Process-

This appears adequate, based on experience.

Public Involvement-

Procedures are in place for substantial public involvement.

Interagency Coordination-

The improved coordination among agencies that is discussed in this case study is welcome. The proposed ad hoc interagency work group would allow concurrent review by more than one agency and allow data gaps to be spotted more rapidly, thus speeding the total process. The agencies are encouraged to develop specific coordination measures and to make them standard procedures.

Confidential Business Information-

This is routinely and well handled.

Specific Comments:

Page 20

Petitions for determination of non-regulated status.

Paragraph 2 of section:

Assessment questions are referred to as Appendix C. In the version I have there are questions labeled as Appendix B; are these the questions?

Page 21

Paragraph 5

The agency also needs to consider that development of weed resistance would result in additional research for the development of classes in herbicides that are more environmentally benign.

Paragraph 6

I am concerned about the basis for the expressed need for more information about the environmental effects of gene transfer to other plants. It has been clearly stated in the document that this is not an issue in regards to herbicide resistance in soybean. This expressed need seems to be more directed at the process of developing an engineered GMO rather than at the product. Why should the author(s) think there would be any more environmental effect on gene transfer from an engineered GMO soybean line than one produced by conventional breeding?

Page 34

Appendix B (should be C?, re: page 20, paragraph 2)

1. Phenotypic expression

If the intent of these criteria is to determine the "phenotypic expression of the transgenic plant relative to its nearest nontransgenic counterpart and/or range of cultivated types" then it is recommend that a set of criteria be established by professional soybean breeder. They will have the greatest knowledge on the parameters used to differentiate new lines because germplasm and cultivar releases are published on a regular basis on the then currently accepted criteria. It appears that these questions are being raised to investigate the process of the new characteristic rather than the characteristic itself.

2. Potential nontarget affects

2.6 Unclear what "altered seed morphology" refers to in regards to animals.

3. Growing the Transgenic Plant

3.1.3 Unclear as to the intent of this question. Most crop plants in North America are not in their "normal" geographical area based on the germplasm from which they were developed. Hence, what is the need for question 3.1.3.1

3.1.4 Unclear why this is relevant as most crop plants are grown outside the usual "managed ecosystem for the species."

Comments on Case Study V. Bioremediation using Poplar Trees

Since this is a prospective study, based as yet only on laboratory and greenhouse studies, the case study is presented as to what is expected to take place in oversight and regulation of field trials.

Comprehensiveness and rigor of environmental assessment. This analysis appears adequate, and is based on prior experience with poplar trees, expert input and the scientific literature. The case is well made as to the rationale of using poplar for the purpose of bioremediation.

Comprehensiveness and strength of statutory authority. In general, this seems clear. However, it would appear that EPA would have primary jurisdiction over the trees, not APHIS, based on the characteristics to be imparted, namely detoxification of TCE, a significant and toxic chemical that is widespread in soil and water. It is not clear why the trees could not be considered ultimately for deregulated status, if all conditions for introduction are met. Trees not encountering TCE would presumably have the same characteristics as the unmodified trees, and it is recognized that destruction before flowering would be required to minimize gene flow. This situation thus does not appear different in kind than that for commercially grown transgenic plants.

While dissemination of tree material by animals is considered, there is no mention of potential consumption of young trees. It may not be feasible to confine the trees and keep all animals away, such as deer. The question is whether wildlife consuming the quantity of TCE and its intermediates would be adversely affected. Further, insects are mentioned as being unaffected in key properties of growth rate and fecundity, but this appears to be only in unpublished work.

Transparency of the EA and the Decision Making Process. This appears adequate, based on prior experience. However, it is not clear why a sample release notification letter is in reference to potato. It would seem that either one could have been constructed for trees or comments made in reference to trees.

Public Involvement.

Procedures are in place to allow for substantial public involvement.

Interagency Coordination. Since poplar trees presumably would be interest to the DOI, it should be considered as an interested party.

CBI. No specific mention is made. However, to our knowledge, this is routinely and well handled.

Overall, the American Phytopathological Society believes the current process adequately addresses the issues of concern, principally gene flow, chemical intermediates and disposal. If the applicants can be encouraged to construct plants in which the gene is not expressed in reproductive parts, it would be an even more desirable plant tool. In principle, such technology is currently available.