UNION OF CONCERNED SCIENTISTS
COMMENTS TO THE ENVIRONMENTAL PROTECTION AGENCY
ON THE RENEWAL OF BT-CROP REGISTRATIONS
Docket OPP-00678B

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The Union of Concerned Scientists (UCS) is pleased to have the opportunity to comment on the Environmental Protection Agency's (EPA's) deliberations concerning requests to renew the registrations of several Bt crops. UCS is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective citizen advocacy to achieve practical environmental solutions.

BACKGROUND

Bt crops registered.
Since 1995, EPA has registered eight Bt crops as plant pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): six Bt corn, one Bt cotton, and one Bt potato (see Table). Each was genetically engineered to produce an insecticidal toxin from the naturally occurring soil bacterium *Bacillus thuringiensis* (Bt). The corn and cotton produce Bt toxins that kill Lepidopteran insects, that is, moths and butterflies. In corn, Lepidopteran pests include the European corn borer, corn earworm, and southwestern corn borer. In cotton, the major Lepidopteran pests are the cotton bollworm, pink bollworm, and tobacco budworm. Bt potato produces a toxin lethal to Coleopteran insects, or beetles, specifically, the Colorado potato beetle. Five companies registered the eight Bt crops (with two crops jointly registered by two companies).

Bt crops on the market.
Of the eight registered crops, four remain on the market today: Bt cotton and three Bt corn products, Mon 810, Bt 11, and Cry 1F. Syngenta and Dow/Mycogen allowed the registration for Event 176 to expire in April 2001. EPA has granted permission to sell existing 176 seed stocks through 2003. Earlier this year, Aventis requested cancellation of the StarLink registration and the registration of DBT 418 was canceled in late 2000. The registration for the Bt potato, not currently on the market, is permanent and will remain in force.

REGULATORY HISTORY

Expiring registrations.
Except for Bt potato, all Bt crops registrations are time limited (and conditioned on meeting resistance-management requirements) and were originally set to expire in

January or April 2001. As a result, companies wanting to keep their products on the market beyond January or April 2001 had to seek renewals of their Bt-crop registrations.

EPA's Bt-crop registration renewal process.
Recognizing that it was not prepared to make a decision on crop renewals in time for companies to prepare for the 2001 growing season, EPA announced in an August 9, 2000, *Federal Register* notice[1], an extension for the registrations of five Bt crops still on the market at that time—Bt cotton and Event 176, Bt 11, Mon 810, and StarLink Bt corn—until September 30, 2001. In that FR notice the agency announced its intention to conduct a comprehensive reassessment of the risks and benefits of Bt crops up for renewal, including "an open and transparent process that incorporates sound and current science, public involvement, and balanced decision making." [2]

Over the following months, EPA's renewal process unfolded as follows:

- September 2000: EPA released a document, *Biopesticides Registration Action Document: Preliminary Risks and Benefits Sections: Bacillus thuringiensis Plant-Pesticides*, providing the agency's preliminary assessment of the risks and benefits of the Bt crops up for renewal of registrations (hereinafter "Preliminary BRAD"). The agency requested public comment on the document.

- October 18-20, 2000: EPA held a three-day public meeting of the Scientific Advisory Panel (SAP) to evaluate the agency's assessment document and hear comments from the public.

- March 12, 2001: EPA released a report (hereinafter "March SAP Report") of the findings of the October SAP.[3]

- July 17, 2001: EPA announced the final steps in the renewal process leading to a decision on or before September 30, 2001.[4]

  The agency released and asked for public comment on a document entitled *Biopesticides Registration Action Document: Revised Risks and Benefits Sections: Bacillus thuringiensis Plant-Pesticides*[5] (hereinafter "Revised BRAD"). The document revised the September 2000 Preliminary BRAD. The Revised BRAD assessed three Bt crops up for renewal: Bt cotton and Mon 810 and Bt 11 Bt corn. Unlike the Preliminary BRAD, the Revised BRAD did not assess the risks and benefits of Event 176 Bt corn because the product's registration was allowed to expire in April 2001. Even though Bt potato was not the subject of the reassessment, the agency included information on that product in the Revised BRAD.

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[1] *Federal Register* 65:48701-05, 8/9/00.
[2] *Federal Register* 65:48704, 8/9/00.
[3] March SAP Report at www.epa.gov/scipoly/sap/2000/october/octoberfinal.pdf
[4] *Federal Register* 66:37227-29, 7/17/01.
[5] Revised BRAD at www.epa.gov/oppbppd1/biopesticides/otherdocs/bt_reassess/bt_crops_reassess.htm

EPA also sought public comment on a *Discussion Paper: Possible Options for Risk Mitigation for Bt Plant-Incorporated Protectants*[6] (hereinafter "Regulatory Options Paper").

New Bt-corn event belatedly added to renewal process.
In a September 5 *Federal Register* notice,[7] EPA officially announced that Cry 1F Bt corn would be reevaluated on the same schedule as Mon 810 and Bt 11 and that relevant reregistration decisions would apply to Cry 1F. The September 5 notice allowed comment on the Cry 1F *Biopesticides Registration Action Document* (BRAD)[8] until September 10.

Monarch research studies withheld from both EPA and the public.
On December 15, 1999, because of concerns raised by a May 1999 *Nature* article[9] showing that Bt-corn pollen killed monarch butterfly larvae under laboratory conditions, EPA issued a formal data call-in (DCI)[10] to industry. The monarch DCI required data on 23 issues relevant to determining the impacts of Bt corn on monarch and endangered butterflies. To generate the required data, industry and the US Department of Agriculture pooled funds and awarded research grants to several academic scientists. The results are to be published in the *Proceedings of the National Academies of Science* (PNAS).

Industry used information from the unpublished PNAS studies to prepare its response to the DCI (hereinafter "Industry Monarch DCI Response") but did not submit the studies to EPA. Rather, EPA relied on industry's interpretation of the unpublished PNAS studies. EPA is expected to make a decision on Bt-corn registrations before it has an opportunity to evaluate the monarch studies.

In addition to withholding the monarch studies from EPA and the public, industry also requested that EPA keep substantial amounts of information in the Industry Monarch DCI Response from the public on the grounds the material constituted confidential business information (CBI). On August 20, EPA posted a non-confidential version of the preface and executive summary of the Industry Monarch DCI Response at its web site.[11]

On August 30 at its web site[12] and in a September 5 *Federal Register* notice,[13] EPA announced an extension of the public comment period on the crop renewals to

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[6] Regulatory Options Paper at www.epa.gov/oppbppd1/biopesticides/otherdocs/bt_reassess/bt_crops_reassess.htm
[7] *Federal Register* 66:46457-58, 9/5/01.
[8] Cry 1F BRAD at www.epa.gov/oppbppd1/biopesticides/reds/brad_006481.pdf
[9] Losey, J.E. *et al*. 1999. Transgenic pollen harms monarch larvae. *Nature* 399: 214.
[10] EPA monarch data call-in at www.epa.gov/oppbppd1/biopesticides/otherdocs/bt_dci.htm
[11] Industry Monarch DCI Response: Preface and executive summary at www.epa.gov/oppbppd1/biopesticides/otherdocs/executive%20summary%20and%20preface.pdf
[12] www.epa.gov/oppbppd1/biopesticides/bt_reass_ext.htm
[13] *Federal Register* 66:46457-58, 9/5/01.

September 10 and noted that industry had agreed to allow the public to *read* the confidential portions of the Industry Monarch DCI Response information in 11 US cities under strict conditions,[14] including signing a confidentiality agreement with industry and agreeing not to communicate the information except in confidential comments to EPA. The CBI being made available did not include the text of the unpublished PNAS papers.

In response to EPA's request for comments on the revised BRAD and Regulatory Options Paper in the July 17 *Federal Register* notice UCS is submitting the analysis, conclusions, and recommendations below. Our comments focus on three areas: ecological risk, insect resistance management, and benefits. Our failure to mention, analyze, or offer recommendations on any other issues should not be interpreted as our agreement with the agency's position on those issues.

SUMMARY OF UCS FINDINGS

EPA analyzed the risks and benefits of the three Bt-crop varieties and concluded that they presented no unreasonable risk of adverse effects to human health and the environment and offered significant benefits through decreased costs to growers, increased yields, and decreased use of synthetic pesticides.[15] Although the agency found that Bt crops threaten the continued efficacy of the Bt toxin both in crops and sprays through resistance, it proposed to mitigate that loss by requiring resistance management plans in Bt corn and cotton.[16] EPA offered no preliminary decision on amending and/or extending the Bt-crop registrations nor did it propose any conditions, such as time limits and IRM and data requirements, that might be imposed on renewed registrations. Rather, the agency promised to consider both benefits and risks before making a decision in late September and asked for public comments on a range of regulatory options.[17]

UCS has reviewed the assessment provided by the agency of risks and benefits. Our analysis of EPA's assessment leads us to conclude that the assessment cannot support a finding of "no unreasonable adverse effects." We find that the revised BRAD failed to identify all the potential risks and did not properly evaluate already identified risks. At the same time, it ignored or failed to properly evaluate Bt-crop impacts that may reduce benefits. The failure of the assessment is reflective of the general flaws in EPA's program for assessing the risks and benefits of transgenic crops.

Because of the large acreage involved with Bt crops, any harm resulting from their use is potentially large in magnitude and irreversible. Society cannot be satisfied with a program that fails to devote sufficient resources to identifying and evaluating risks. Therefore, UCS recommends against amending or extending the Bt corn and cotton registrations until EPA establishes a strong, scientifically credible program capable of identifying and evaluating likely risks.

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[14] www.epa.gov/oppbppd1/biopesticides/otherdocs/bt_corn_monarch.htm
[15] Revised BRAD, pp. I-2 – I-5.
[16] Revised BRAD, p. I-4.
[17] Regulatory Options Paper, p. 1.

UCS's analysis of EPA's assessment of benefits leads us to conclude that the assessment correctly found pesticide-reduction benefits in the case of Bt cotton but did not provide a full and fair accounting of all the costs associated with this crop. Our analysis of the EPA assessment and other available data for Bt corn leads to a conclusion that the benefits of Bt corn are minimal at best.

Put in terms of the legal standard, until the agency presents a credible risk/benefit assessment, it cannot assure that the risks associated with Bt crops are not "unreasonable." This is obviously the case for Bt corn, where benefits are minimal. It is even the case for Bt cotton, where although benefits of pesticide reduction exist, they are likely to be limited by the emergence of resistance. Moreover, the loss of Bt will adversely impact not only users of transgenic crops but also organic and other farmers who use Bt sprays.

If the agency decides to renew the products, UCS recommends that the new registrations be subject to annual renewals and contingent on the generation of substantial new data on risks and benefits, including new data on impacts of Bt corn on monarchs. Because current resistance management plans are not sufficiently rigorous to prevent resistance to the Bt toxins, any renewed registrations must also be contingent on requirements for larger refuges placed near transgenic crops and effective resistance monitoring and remedial action plans. EPA must also develop an effective resistance-management compliance enforcement program.

UCS CONCLUSIONS AND ANALYSIS

I. EPA's assessment failed to identify, evaluate, and respond to the ecological risks of Bt crops.

Because it relied on a seriously flawed ecological risk assessment, EPA was able to reach a conclusion that Bt crops pose no unreasonable adverse effects on the environment. Had the agency followed the recommendations of its own SAP[18] and prepared a scientifically credible risk assessment, it would not have reached that conclusion.

At the most fundamental level, the agency wrongly persists in viewing the ecological risks of Bt crops through the lens of conventional pesticide toxicology.[19] Following a conventional pesticide paradigm of tiered testing of representative organisms potentially wastes agency and industry resources in analyzing risks which may be irrelevant to the impacts of pesticidal plants and, more importantly, may lead the agency to miss important, relevant risks—as in the case of Bt corn's threat to the monarch butterfly. EPA's own SAP has criticized the agency for failing to develop a risk assessment

[18] March SAP Report, pp. 34-59.
[19] See, for example, Obrycki, J.J., J.E. Losey, O.R. Taylor, and L.C.H. Jesse. 2001. Transgenic insecticidal corn: beyond insecticidal toxicity to ecological complexity. *BioScience* 51:353-61.

process tailored to pesticidal plants,[20] in which, for example, case-by-case exposure assessments would determine appropriate nontarget-organism tests.

In addition to this fundamental shortcoming, EPA's ecological risk assessment is flawed as a result of its failures to identify risks, incomplete analyses of risks, reliance on poor-quality risk studies, and biased evaluations of studies.

Appendix 1 of these comments, "Critique of EPA's Environmental Risk Assessment of Bt Crops" (hereinafter "Hilbeck/Meier Analysis"), prepared by Dr. Angelika Hilbeck and Matthias S. Meier, provides a detailed analysis of EPA's assessment. We highlight several major findings from that analysis below.

A. EPA failed to properly address risks to nontarget organisms, including monarch butterflies.

A close look at EPA's assessment of Bt-crop risks to nontargets reveals a number of serious flaws, including an incomplete analysis of risks to monarch butterflies, biased evaluation of studies on green lacewing risks, and uncritical acceptance of flawed studies on insect abundance.

- ***EPA did not identify or resolve the potentially significant role of toxic anther fragments in Bt-corn's impact on monarchs.[21]***

As noted above, EPA relied solely on industry's interpretation of several new monarch studies to conclude that Mon 810 and Bt 11 are not lethal to monarchs under field conditions. At the same time that it accepted, at face value, industry interpretations of unpublished studies, it virtually ignored an important peer-reviewed paper by Jesse and Obrycki,[22] which demonstrated that Bt corn was lethal to monarchs under field conditions.

The Jesse and Obrycki paper raised the possibility that monarchs may be killed by consuming fragments of Bt-corn anthers, the pollen-producing parts of the corn flower. By contrast, even though the Industry Monarch DCI Response acknowledged that anthers of Mon 810 and Bt 11 corn "contain considerably higher Cry protein concentrations than the pollen itself," industry considered anther fragments to be "study artifacts."[23] From what we have been able to learn, the soon-to-be-published monarch research used only pure pollen, not pollen with anther fragments, to determine the toxicity of Bt corn to monarchs. Depending on the extent to which monarch larvae are exposed to and consume the toxic anther fragments under field conditions, studies based on pure pollen may seriously underestimate the risks of Mon 810 and Bt 11 corn

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[20] March SAP Report, p. 43.
[21] Hilbeck/Meier Analysis, pp. 41-44.
[22] Jesse, L.C.H. and J.J. Obrycki. 2000. Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly. *Oecologia* 125:241-48.
[23] Industry Monarch DCI Response, executive summary and preface, p. 5.

to monarchs. The Revised BRAD does not mention toxic anther fragments; EPA apparently accepted industry's view of them as study artifacts.

- ***EPA failed to identify and address long-term risks of Bt corn to monarch butterflies.***

EPA's Revised BRAD focused on short-term or lethal effects of Bt-corn pollen on monarchs and did not evaluate the potential long-term impacts of the pollen and anther fragments. We know of no multi-year studies examining the impacts of Bt-corn flower parts on monarch reproduction, development, or migration.[24]

- ***EPA failed to properly assess Bt-corn risks to beneficial insect predators of European corn borer (green lacewings).[25]***

EPA's assessment of Bt-corn impacts on green lacewings, which are beneficial insect predators of European corn borers (ECB), illustrates the agency's general bias in the evaluation of studies. The agency accepted without criticism studies that reported no significant impacts of Bt corn on lacewings while it was overly critical, and occasionally misrepresented and misinterpreted, other studies showing potentially significant impacts of Bt corn on lacewings.

- ***EPA failed to identify serious weaknesses in studies of the impacts of Bt cotton and corn on the abundance of nontarget insects.***

Hilbeck and Meier[26] evaluated several studies which EPA used to conclude that Bt crops cause "minimal to undetectable to beneficial changes in the non-target insect populations."[27] The supporting studies had a number of flaws, including missing statistical analyses, small sample sizes, insufficient replication, and inappropriate experimental design. These flaws should have tempered the agency's sweeping conclusions on Bt-crop impacts on insect abundance.

- ***EPA failed to properly evaluate Bt-crop risks to other nontarget organisms.***

EPA ignored important studies showing Bt-toxin binding and immune response in mammals, improperly generalized results from one avian species, and accepted flawed tests of aquatic organisms and honeybees.[28]

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[24] Hilbeck/Meier Analysis, p. 44.
[25] Hilbeck/Meier Analysis, pp. 25-29
[26] Hilbeck/Meier Analysis, pp. 30-33.
[27] Revised BRAD, p. IIC63.
[28] Hilbeck/Meier Analysis, pp. 23-25.

B. EPA inadequately assessed the fate and effects of Bt toxins in soil communities.

Based on analysis of a number of different studies, EPA concluded that "sufficient evidence exists to suggest that adverse impacts of currently commercialized Bt Cry1Ab and Cry1Ac proteins in the soil are not likely...."[29] A closer look at the studies and EPA's analysis reveals significant shortcomings, including the agency's failure to: consider key findings on persistence of Bt toxin in soil, resolve conflicting lines of evidence, and critically evaluate the strengths and weaknesses of experimental approaches.[30]

C. EPA's assessment identified but failed to sufficiently mitigate the consequences of gene flow from Bt cotton to wild relatives.[31]

The agency identified five areas in the US and its territories and possessions where cultivated cotton may outcross to genetically compatible wild or feral species: southern Arizona, Hawaiian islands, southern Florida, U.S. Virgin Islands, and Puerto Rico. However, EPA appears to have imposed planting restrictions only in southern Florida and the Hawaiian Islands. Apparently native, wild cotton grows in areas of Arizona far from commercial cotton production.[32]

D. EPA's approval of Event 176 Bt corn in 1995, which is now known to be toxic to monarch butterflies under field conditions, is evidence of the agency's flawed risk assessment program.

According to the Industry Monarch DCI Response, Event 176 Bt-corn pollen kills monarch larvae "at Bt pollen densities typical of cornfields and cornfield edges."[33] EPA's original risk assessment of Event 176 Bt corn (as well as Mon 810 and Bt 11) failed to identify and consider the risk that toxic Bt-corn pollen might present to monarch butterfly larvae.

II. EPA correctly identified the risk of loss of efficacy of Bt insecticides to resistant insects but failed to adequately mitigate the risk through properly designed resistance management plans.

While we applaud EPA's acknowledgement that widespread planting of Bt crops threatens the usefulness of Bt insecticides and appreciate the agency's willingness to impose insect resistance management (IRM) plans, UCS remains concerned that the agency IRM requirements are too weak to prevent the evolution of resistance. Since the

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[29] Revised BRAD, p. IIC32.
[30] Hilbeck/Meier Analysis, pp. 15-21.
[31] Hilbeck/Meier Analysis 1, pp. 10-14.
[32] Revised BRAD, p. IIC10.
[33] Industry Monarch DCI Response, executive summary and preface, p. 5.

first approvals of Bt crops in the mid-1990's, UCS has urged EPA to defer commercial approval until strong, effective IRM plans are in place.

Appendix 2 of these comments, "New Science Shows that Current Bt-Corn and Cotton IRM Plans Will Not Significantly Delay Resistance to Bt-Based Pest Management Technologies" (hereinafter Benbrook IRM Analysis"), prepared by Dr. Charles Benbrook, provides a detailed analysis of EPA's assessment of IRM in Bt corn and cotton. We highlight several major findings of the Benbrook IRM Analysis below.

A. The Bt-corn IRM plans do not take into account that Mon 810 and Bt 11 produce a high dose against but one of the six corn pests affected by the Bt-corn hybrids.

Successful use of small refuges requires high toxin doses. Monsanto has developed data to verify, according to SAP guidelines, that Mon 810 produces a season-long high dose against ECB. The agency believes, though it does not have verified data to prove it, that Bt 11 also produces a high dose against ECB.[34] Neither produces a high dose against corn earworm or fall armyworm. Companies have not produced sufficient data to determine the level of toxin produced by Bt corn against other corn pests, including southern corn stalk borer, common stalk borer, and southwestern corn borer.

B. Current Bt-corn refuges are too small to prevent the evolution of resistance.

Refuges are needed to provide Bt-susceptible insects to mate with Bt-resistant ones from Bt fields to dilute resistance in the pest population. EPA currently requires a 20 percent refuge for Bt corn grown in northern non-cotton-growing regions and a 50 percent refuge in southern cotton-producing states. The northern refuge requirements are aimed at delaying resistance in ECB while the requirements in the south are directed at both ECB and corn earworm resistance. The agency allows refuges to be sprayed with insecticides only when pests reach economic thresholds. The agency does not monitor whether or not sprays are used only at economic threshold levels.

In contrast, two recent studies of corn IRM plans call for larger refuges. A report prepared for the biotechnology industry[35] recommended 20 percent unsprayed and 40 percent sprayed refuges for high-dose Bt corn (medium risk) grown in the North and 50 percent nonsprayed refuges in the South. A UCS report[36] called for a 25 percent unsprayed and 50 percent sprayed in noncotton-growing regions.

EPA has not required industry to submit data to determine appropriate refuge sizes to prevent the evolution of resistance in four other corn pests affected by Bt-corn hybrids:

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[34] Revised BRAD, p. IID35, Table D2.

[35] International Life Sciences Institute. 1999. *An Evaluation of Insect Resistance Management in Bt Field Corn: A Science-Based Framework for Risk Assessment and Risk Management*, Washington, D.C.

[36] Mellon, M. and J. Rissler, eds. 1998. *Now or Never: Serious New Plans to Save a Natural Pest Control*. Union of Concerned Scientists, Cambridge, Mass.

fall armyworm, southern corn stalk borer, common stalk borer, and southwestern corn borer.

C. Current refuges are too far from Bt-corn fields to ensure mating between resistant and susceptible ECB.[37]

Given that male ECB moths typically travel not much more than 0.1 miles in search of a mate, current refuge-placement requirements (within ½ mile of Bt-corn field in northern areas and within ¼ mile in southern areas where both corn and cotton are grown) may mean that substantial numbers of female moths surviving in a Bt field will not mate with susceptible males from the refuge.

D. Current Bt-corn refuge-management requirements are too lax.[38]

EPA acknowledges the value of refuges planted with varieties similar to the Bt varieties to provide susceptible insects in large numbers and at the same times as the resistant insects. Nevertheless, it does not require that the nonBt hybrid planted in refuges be similar in growing requirements and characteristics (e.g., planting and maturity dates; fertilizer, herbicide, and irrigation requirements) to the Bt hybrid.

E. Current Bt-cotton refuges are too small to prevent the evolution of cotton bollworm resistance.[39]

A high dose/refuge strategy is a cornerstone of IRM plans. Current Bt-cotton refuge sizes were established under the incorrect assumption that the crop produced a high dose against all three targeted pests: the cotton bollworm (CBW), tobacco budworm (TBW), and pink bollworm (PBW), when in reality Bt cotton produces only a moderate toxin dose against CBW. To the extent that a crop fails to produce a high dose, refuge size must be increased to produce the larger number of susceptible insects to mate with the expected larger population of resistant ones emanating from the moderate-dose fields. We agree with EPA's implicit acknowledgement that current Bt-cotton IRM plans must require substantially larger refuges to significantly delay resistance in CBW.[40]

F. Spraying of refuges is likely to undermine effectiveness of Bt-cotton IRM plans.[41]

The Revised BRAD summarized a number of studies showing that the spraying of refuges, particularly with the highly effective insecticides available today, can virtually eliminate susceptible adults moving from refuges to mate with resistant moths surviving

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[37] Benbrook IRM Analysis, p. 9.
[38] Benbrook IRM Analysis, p. 10.
[39] Benbrook IRM Analysis, pp. 11
[40] Revised BRAD, pp. IID61-IID103.
[41] Benbrook IRM Analysis, pp. 12-14.

in Bt-cotton fields.[42] Failure to change the rules governing the spraying of refuge acres may undermine cotton IRM plan efficacy.

G. Current refuges are too far from Bt-cotton fields to ensure mating between resistant and susceptible pests.[43]

The current cotton IRM plan allows most refuges to be planted within one linear mile of the edge of a Bt-cotton field, assuring that in some cases parts of the Bt field will be two miles or more from the refuge. Given that some target pests move just a fraction of a mile, the current separation distances are excessive and a major weakness in the IRM plan.

H. Weak monitoring, compliance, and remedial action provisions seriously undermine the effectiveness of the Bt-cotton and Bt-corn IRM plans.[44]

Monitoring, compliance, and remedial actions are critical to the success of IRM plans. The Benbrook IRM Analysis evaluates the monitoring, compliance, and remedial action provisions of the current corn and cotton IRM plans and finds them inadequate to the task of significantly delaying resistance. Among the shortcomings are inadequate sampling capacity for monitoring, insensitive monitoring techniques, inadequate grower compliance, lack of compliance enforcement capability, slow activation of remedial action plans, and inadequate remedial actions.

III. EPA failed to identify and address the risks associated with Bt crops containing two or more Bt genes.

The Revised BRAD does not identify or evaluate the risk and resistance management issues raised by "stacked Bt-gene" products, that is, crops producing two or more Bt genes. In the near future, it is likely that the currently registered Bt-corn and cotton genes will be combined with other Bt genes. For example, Monsanto has applications pending at EPA to register two new Bt genes: Cry2Ab against Lepidopterans in both corn and cotton and Cry3Bb targeted at corn rootworms. Monsanto has indicated its intentions to combine its currently approved Bt genes in corn and cotton with the Cry2Ab gene[45] and its Bt gene in corn with the Cry3Bb gene.[46]

Stacking two or more genes in crops raises many important concerns relative to impacts on expression levels, gene stability, food safety, environmental impacts, resistance management, and efficacy, none of which EPA addressed in the Revised BRAD. Among the many questions that need to be addresses are the following: Do mixtures of

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[42] Revised BRAD, p. IID72.
[43] Benbrook IRM Analysis, p. 12.
[44] Benbrook IRM Analysis, pp. 15-25
[45] Monsanto. 2000. Administrative materials in support of … the registration of … Cry2Ab insect control protein, as produced in corn … and cotton…. April 4, 2000, submission to EPA, p. 25.
[46] Monsanto. 2001. Insect resistance management for a transgenic corn rootworm control product. Submission to EPA, MRID 451845-01, p. 4.

toxins from a plant show the same heat stability and resistance to digestion as individual toxins? How much of each toxin is produced in various parts of the plants throughout the growing season? Is the total amount of toxin in a plant with stacked genes equivalent to the sum of each toxin produced when it alone is in a plant? What are the results of nontarget studies conducted with simultaneous exposure to a plant expressing two toxins? Might the stacked genes accelerate the evolution of resistance? What kinds of refuge strategies are needed to delay resistance in corn and cotton with stacked genes?

IV. EPA's benefits assessment overstated the benefits and ignored important costs of Bt crops.

EPA's benefits assessment painted a rosy picture of Bt crops—concluding that "significant benefits accrue to growers, the public, and the environment" from these products.[47] The agency achieved this favorable view through questionable assumptions and estimates and selective use of information that incorrectly inflated benefits and ignored significant costs that would reduce benefits. Appendix 3 of these comments, "EPA Continues to Overstate the Benefits of Bt Crops and Ignores Important Costs" (hereinafter "Benbrook Benefits Analysis"), prepared by Dr. Charles Benbrook, provides a detailed analysis of EPA's benefits assessment of Bt corn and cotton. We highlight several major findings of the Benbrook Benefits Analysis below.

A. The Revised BRAD exacerbated the shortcomings of the initial benefits assessment and failed to take into account the recommendations from the agency's own SAP to correct major deficiencies.[48]

The March SAP report, which offered a scathing criticism of the Preliminary BRAD benefits assessment, called the agency to task for a number of shortcomings, including failure to explain methods and assumptions; use of questionable methodology, assumptions, and estimates; incorrect interpretations; overly narrow view of total benefits; and inadequate data on costs of IRM compliance.[49] The Revised BRAD failed to correct deficiencies identified by the SAP (e.g., failure to explain methods and assumptions) and even exacerbated some of them (e.g., failure to take into account costs that might reduce benefits, questionable methodology and estimates).

B. EPA correctly acknowledged that Bt corn does not reduce insecticide use.[50]

The agency correctly backed away from its earlier stance on the pesticide-reduction benefits of Bt corn and now concurs that Bt corn is not likely to significantly affect overall corn insecticide use.

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[47] Revised BRAD, p. I-5.
[48] Benbrook Benefits Analysis, pp. 1-3.
[49] March SAP Report, pp. 64-71.
[50] Benbrook Benefits Analysis, pp. 3-4.

C. EPA erroneously concluded that yield increases are a major benefit of Bt corn.[51]

Yield increases attributable to Bt corn are quite variable and highly dependent on ECB pressure, which is notoriously uneven and unpredictable. ECB reach economic threshold levels typically in only one of four to eight years. Most years, growers do not experience significant ECB pressure.

EPA's conclusion of Bt-corn yield increases depended, in part, on a highly questionable assumption of a 5.4-bushel/acre yield differential between Bt and conventional corn under low ECB pressure. In fact, a careful look at the literature on Bt-corn production shows very little or no impact on yield under low pest pressure. Taking the analysis one step further, recent research, for example, from Purdue University, University of Illinois, and Iowa State University, which EPA failed to include in its analysis, points toward little or no economic return to growers on their investment in Bt-corn varieties.[52]

D. EPA's claim that Bt corn reduces mycotoxin contamination was not substantiated.[53]

The Revised BRAD relied on simplistic and unsubstantiated assumptions and selected data to project annual benefits of $16 to $348 million for Bt corn's putative capacity to reduce mycotoxin[54] contamination of corn. According to EPA, Bt corn is less likely to be damaged by insects, thereby reducing the points of entry for mycotoxin-producing fungi into corn tissue. EPA's superficial analysis avoided consideration of the complex interactions among insects, fungi, host plant, and environmental conditions that affect mycotoxin levels and ignored data which, for example, showed higher mycotoxin concentration in Mon 810 than the nonBt hybrid under drought stress.[55]

E. EPA ignored the cost of lost export markets due to the presence of Bt corn.[56]

Since the introduction of Bt corn in 1996, the US corn industry has lost foreign markets because of its inability to segregate and label Bt corn. Many European and other countries refuse to import corn shipments contaminated with Bt-corn varieties unapproved for their internal markets. As a result, for example, US corn exports to the European Union decreased from $190 million in 1997 to $6 million in 1999.[57] EPA's

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[51] Benbrook Benefits Analysis, pp. 4-8.
[52] Benbrook Benefits Analysis, pp. 7-8.
[53] Benbrook Benefits Analysis, pp. 11-12.
[54] Mycotoxins are toxic and carcinogenic compounds produced by particular kinds of fungi, some of which grow on crops like corn and peanuts.
[55] Benbrook Benefits Analysis, pp. 11-12.
[56] Benbrook Benefits Analysis, p. 9.
[57] US Department of Agriculture, Economic Research Service. 2001. *Economic Issues in Agricultural Biotechnology*, p. 33.

benefits assessment should account for the extent to which Mon 810 and Bt 11 are unapproved in US export markets and thereby contribute to loss of markets.

F. EPA ignored the costs of crop contamination to conventional and organic corn growers and other segments of the food-production system.[58]

The Revised BRAD failed to consider the substantial costs to growers and others in the US food chain as a result of the contamination of conventional and organic corn supplies by Bt corn. Because of strict standards, organic corn contaminated with Bt genes cannot be sold as an organic product—costing the producer important price premiums.[59] As an example, assuming two percent of US corn acres are organic, an average harvest is 120 bushels per acre, and $0.50 per bushel is an organic price premium, the potential lost income to organic corn farmers is nearly $90 million annually. If the sector continues to grow as it well may now that organic livestock standards require organic feed, it could account for five percent of corn acres within a decade. The loss of the organic premium could then approach $220 million, close to EPA's current upper-bound estimate of net grower benefits from the planting of *Bt* corn.[60]

Growers of conventional corn also stand to lose important export markets and premium prices when their harvest is contaminated with engineered seeds. In addition, organic and conventional growers, grain marketers and shippers, and food-processing companies may incur significant new costs in order to test their crops for Bt contaminants. Finally, seed companies and sellers could incur substantial costs developing and implementing strategies for protecting at least a portion of the US seed-corn supply from Bt-gene contamination.

G. EPA properly attributed reduction in synthetic insecticide use to Bt cotton.[61]

While we might disagree with some of the details of EPA's assessment of Bt cotton's influence on insecticide use in cotton-growing regions, we agree with the agency's conclusion that Bt cotton has reduced the overall use of synthetic pesticides for control of bollworms and budworm in cotton. The effect of Bt cotton varies widely from state to state. For example, Arizona, a high adopter of Bt cotton, has shown a remarkable decline in bollworm/budworm sprays—down from 397,000 pounds in 1995 to 2,000 pounds in 2000. By contrast, farmers in another high-adoption state, Alabama, almost doubled their use of bollworm/budworm sprays from 1997 to 2000 despite over 60 percent of their acres planted to Bt cotton.

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[58] Benbrook Benefits Analysis, pp. 9-10.
[59] See, for example, Genetic drift: organic industry threatened by GMOs. *The Organic Report*, June 2001.
[60] Benbrook Benefits Analysis, p. 10.
[61] Benbrook Benefits Analysis, pp. 12-14.

H. EPA ignored the cost of compliance with IRM plans in both the Bt-corn and Bt-cotton benefits assessments.[62]

EPA's benefits assessment failed to consider costs to farmers of complying with IRM plans, including the costs of planting and maintaining refuges and collecting and shipping insects to monitor for resistance. For example, if one sample were tested for each thousand acres of Bt corn planted and 25 million acres are grown annually and each sample costs $300 for collecting, shipping, and testing, the annual testing costs would be $7.5 million for Bt corn alone. This essential product stewardship activity is an unavoidable cost if resistance is to be managed and should be counted as a direct cost of using Bt crops**.**

I. EPA ignored the cost of the potential loss of Bt sprays to organic and conventional growers in both the Bt-corn and Bt-cotton benefits assessments.

The Revised BRAD did not consider the costs that might be incurred by both organic and conventional growers if Bt toxins lost their efficacy due to pest resistance. Those costs could be substantial given the growth in the organic sector and the increasing reliance of conventional farmers on Bt sprays when synthetics no longer work or are taken off the market. According to a survey conducted by the Organic Farming Research Foundation, organic growers use Bt sprays more than any other purchased product to manage insect pests.[63] Over 50 percent of the survey respondents reported using Bt sprays—18 percent frequently or regularly, 27 percent occasionally, and 12 percent rarely or as a last resort.

In addition, many conventional growers now rely on Bt sprays, particularly when faced with the loss of synthetic pesticides. For example, Glades Crop Care, Inc., the largest crop consulting company in Florida, reports that Bt sprays are the most-used biopesticide among tomato growers, particularly for armyworms and pinworms. A 1997-8 survey showed that nearly 90 percent of the spring and 77 percent of the fall tomato acreage was treated at least once with Bt sprays. [64]

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[62] Benbrook Benefits Analysis, pp. 8 and 15.
[63] Walz, E. 1999. Final results of the Third Biennial National Organic Farmers' Survey, Organic Farming Research Foundation, Santa Cruz, Calif.
[64] Glades Crop Care, Inc. at http://gladescropcare.com/PMAP_report.html, pp. 144, 147, 172.

UCS RECOMMENDATIONS

I. UCS recommends that EPA not renew, amend, or extend the registrations of Bt corn and cotton because the agency's assessment does not support a finding of "no unreasonable adverse effects."

For the reasons detailed above, we conclude that EPA's Revised BRAD does not support a finding of "no unreasonable adverse effects" of Bt crops. In our view, the Revised BRAD did not identify all the potential risks of Bt crops and did not properly evaluate the risks already identified. *In particular, it appears that the agency has yet to resolve the threat of Bt corn to monarch butterflies.* At the same time, it ignored or failed to properly evaluate Bt-crop impacts that may reduce benefits. Until the agency establishes a strong program for evaluating pesticidal plants and conducts a scientifically credible risk/benefit assessment which will support a finding of no unreasonable adverse effects, it should not renew, amend, or extend the expiring registrations of Bt corn and cotton.

II. If EPA decides to renew, amend, or extend Bt corn and cotton registrations, UCS recommends that EPA limit the registrations to one year and condition them on the generation of new data, monitoring of monarch butterflies, and implementation of strong resistance management plans.

A. EPA should limit renewals, amendments, or extensions to one year to allow for rapid response to the emergence of resistance and new risk research.

It is reasonable to expect that resistant insects could emerge in the coming growing season, particularly in pests for which a high dose/refuge strategy has not been implemented. Moreover, scientists are developing new, relevant risk data which may call for changes in IRM plans, ecological monitoring, or restrictions to protect human health and the environment. To enable effective responses to rapidly changing circumstances, for example, new data on impacts on monarchs, EPA must be able to change registration conditions quickly. The agency has the most leverage to modify permit conditions during registration and renewal processes. Renewal on a yearly basis would give EPA opportunity to modify registration conditions before each growing season.

B. EPA should condition registrations on requirements to generate substantial new data to fill the significant gaps in the agency's risk/benefit assessment and strengthen IRM plans.

Even a cursory reading of the Revised BRAD reveals a host of serious data gaps in the agency's risk/benefit assessment and IRM plans. The agency itself has identified and is

asking for public comment on the need for new studies in a number of areas.[65] We concur with the EPA's implicit acknowledgement of the need for additional research and urge the agency to require at least the following:

- Field studies to determine whether monarch larvae potentially obtain lethal doses of Bt toxin from Bt 11 and Mon 810 anther fragments
- Field studies on the long-term risks of Bt corn to monarch butterflies
- Substantial additional product characterization data for all Bt crops [66]
- Toxin expression data for all Bt crops obtained under standardized protocols in all types of plant tissues throughout growing seasons to allow comparisons among and between toxin levels
- Data from studies conducted under standardized protocols to determine the fate of Bt corn and cotton toxins in the soil under a range of conditions found in agroecosystems
- Studies on the biology, genetics, migration of all pests affected by Bt corn and cotton to enhance the modeling of resistance in those pests
- Modeling of potential remedial action strategies to determine their effectiveness
- Research to develop more sensitive monitoring methods, such as the F_2 screen.

C. EPA should condition registrations on the requirement to monitor for adverse effects of Bt corn on monarchs.

Properly designed ecological monitoring programs can serve as early warning systems of emerging adverse effects. In the case of Bt crops, this capacity may be particularly important for protecting valuable resources, like monarch butterflies, where risks have yet to be resolved. As noted above, field studies have not yet resolved the potential impacts of Bt corn on monarchs. Until it is definitively established that Bt corn is neither a short- or long-term threat to monarchs, EPA, with the advice of its SAP, should require companies to establish a program for monitoring the potential adverse effects of Bt corn on monarchs.[67]

D. EPA should condition the registrations on compliance with provisions of strengthened IRM plans.

We applaud the agency's acknowledgement that IRM plans are necessary to mitigate the risk of resistance to Bt toxins and its willingness to condition permits on compliance with IRM plans. However, as our comments above and the appended Benbrook IRM analysis argue, the agency must substantially strengthen IRM requirements if the goal of preventing resistance is to be achieved. In light of the substantial gaps in scientists' understanding of pests and resistance and the inability, as a result, to confidently design effective resistance management plans, EPA should adopt conservative IRM plans to enhance the probability of success. A conservative

[65] Regulatory Options Paper, pp. 2-5.
[66] Including data in the six areas identified in the Regulatory Options Paper, pp. 2-3.
[67] Hilbeck/Meier Analysis, pp. 50-52.

approach, for example, would mean that the agency errs on the side of larger, not smaller refuges, and on the side of closer, not distant, refuges.

- ***EPA should require larger refuges placed closer to, or embedded within, Bt fields to ensure adequate mating between susceptible and resistant insects.***

Current refuge requirements in Bt cotton are dangerously small, the legacy of an early industry/EPA hope that Bt cotton produced a high dose against the CBW. Now that EPA and industry acknowledge Bt cotton's moderate CBW dose, EPA should mandate larger refuges. Bt-cotton IRM plans should require either a 50-percent sprayed refuge within one-half mile of the edge of Bt-cotton fields or a 17 percent unsprayed embedded refuge. [68]

Bt-corn refuges must also be increased to ensure adequate supplies of susceptible moths. We urge EPA to require 25 percent unsprayed or 50 percent sprayed refuges for Bt corn grown in noncotton-producing regions and 50 percent nonsprayed refuges in cotton-growing regions.[69] While infield strip refuges are preferable, growers who choose separate refuges should ensure that all parts of a field planted to Bt-corn are within 0.1 miles of the refuge.

In addition, EPA should mandate that refuges and Bt fields be planted with agronomically similar varieties and treated similarly (except when spraying is allowed in certain refuges) to ensure that susceptible and resistant insects develop and emerge synchronously.

- ***EPA should require companies to develop detailed, effective monitoring programs and implement them no later than the 2003 growing season.***

The agency's SAP concluded that "it did not have detailed information on the current monitoring programs" and therefore, could not comment on their adequacy.[70] It is distressing that six years into commercialization and the agency apparently was unable to provide the SAP with sufficient detail to permit a scientific review of the adequacy of monitoring efforts.

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[68] Gould, F. and B. Tabashnik. 1998. Bt-cotton resistance management, pp. 67-105 *in* Mellon, M. and J. Rissler, eds. *Now or Never: Serious New Plans to Save a Natural Pest Control*. Union of Concerned Scientists, Cambridge, Mass.

[69] International Life Sciences Institute. 1999. *An Evaluation of Insect Resistance Management in Bt Field Corn: A Science-Based Framework for Risk Assessment and Risk Management*, Washington, D.C.; Andow, D. and W. Hutchinson. 1998. Bt-corn resistance management, pp. 107-35 *in* Mellon, M. and J. Rissler, eds. *Now or Never: Serious New Plans to Save a Natural Pest Control*. Union of Concerned Scientists, Cambridge, Mass.

[70] March SAP Report, p. 25.

EPA should move immediately to convene an SAP to advise the agency on how best to use existing methods, six years of research and field experience, and new information[71] to develop and implement, no later than the 2003 growing season, sensitive, effective monitoring methods capable of detecting resistance in time to allow successful remediation.

- ***EPA should require companies to be ready to deploy detailed, effective remedial action plans by the 2003 growing season.***

As we noted with the monitoring programs above, EPA has, for the most part, failed to put in place effective remedial action plans. For example, the March SAP report notes that "[i]n one case … a detailed plan was in place …" and that "for CBW and TBW, there were no remedial action plans," [72] indicating that only Arizona had developed a remedial action plan—to deal with the emergence of resistance in the pink bollworm.

EPA should move quickly to require companies to develop and be ready to implement effective remedial action plans for all pests affected by Bt corn and cotton in the event resistance emerges. EPA must establish strict conditions under which resistance must be confirmed quickly, followed by decisive action. For example, one member of the SAP suggested the possibility that some plans could require as much as a two-year delay between determining resistance frequency and implementing remedial action. Another SAP member suggested action might need to be implemented within a week to assure eradication.[73] Unless EPA is careful to ensure that delays do not occur, remedial action plans could be doomed to failure.

- ***EPA should establish a program for independently verifying and enforcing compliance with IRM plans.***

We note again that EPA has had six years to put a needed program in place—in this case, a compliance and enforcement program—but thus far has not done so. Currently, the agency must rely solely on industry-conducted surveys to estimate compliance with refuge strategies. And as far as we know, EPA is ill-prepared to take action against those who fail to comply with the conditions of Bt-crop registrations.

EPA must put in place procedures to ensure compliance. For example, the agency should consider a requirement that independent verification of compliance with IRM plan components be carried out on a regional basis and that significant penalties be imposed on companies in any region where compliance falls below a target level.

The agency should also make the results of compliance monitoring surveys and lists of noncompliant growers and companies publicly available.

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[71] See, for example, Gahan, L.J., F. Gould, and D.G. Heckel. 2001. Identification of a gene associated with Bt resistance in *Heliothis virescens*. *Science* 293: 857-60, 8/3/01.
[72] March SAP Report, p. 27.
[73] March SAP Report, pp. 27-28.

E. Until it has addressed the risk and resistance management implications of stacked Bt genes, EPA should condition the registrations on the requirement that no other Bt genes be added to commercial varieties of Bt cotton and Mon 810 and Bt 11 Bt corn.

As noted above, EPA has not identified or evaluated the risk and resistance issues raised by stacked Bt genes. Until it addresses these concerns and develops a policy, informed by public input, on the registration of stacked-gene products, EPA should prevent companies from selling any crops containing two or more Bt genes.

F. EPA should condition the Bt-cotton registration on requirements that prevent planting in Hawaii, Puerto Rico, southern Florida, and the US Virgin Islands.

As noted above, EPA acted to mitigate the risk of pollen flow from Bt cotton to wild or feral cotton by excluding planting in southern Florida and limiting planting in Hawaii. We urge EPA to prevent the planting of Bt cotton—both at commercial scale and in field trials—in all areas where wild relatives occur, including southern Florida, Hawaii, Puerto Rico, and the US Virgin Islands.

III. For future renewals or new registrations of Bt crops, UCS recommends that EPA commit to a transparent process that fully discloses health and safety data to the public in a timely fashion and provides for full public participation.

For much of the Bt-crop renewal process, the agency fulfilled a commitment which it announced a little more than a year ago when the process began:[74]

> It is EPA's goal to assure that we continue to make our regulatory process and decisions within a sound and transparent process framework and that *we are fully informed by the most recent and scientifically sound information*. The Agency will *assure a transparent and interactive review process for its decisions and will make every effort to involve all of our stakeholders*—the manufactures, the growers, and the public—to provide the public with confidence in EPA's regulatory decisions and provide U.S. farmers with the tools they need to continue to produce a safe and healthy food supply. (emphasis added)

In the final three months of the year-long process, EPA retreated from its commitment. In its handling of studies on the impacts of Bt-corn pollen on monarchs, EPA failed to keep its promises to: provide a transparent process, include all stakeholders, and take advantage of the most recent and scientifically sound science.

As noted above, the agency is moving ahead with a decision on the Bt-crops *before* it evaluates the monarch research—the very research undertaken in response to the agency's own data call-in. Access to the studies was also denied to the public. Yet, the

[74] *Federal Register* 65:48701-05, 8/9/00.

potential threat to monarchs raised more controversy and concern than any other ecological risk identified thus far for any genetically engineered crop.

The denial of access to these unpublished studies is a result of mismatches in timing between the issuance of the EPA decision and the publication of the papers in a peer-reviewed journal. The scientists who conducted the studies and wrote the reports submitted them to PNAS, which is withholding them pending publication, despite a July 24 request from USDA and EPA urging the journal to expedite public access.[75] Industry has been privy to the information because it supported some of the research.

To expedite its review and meet an arbitrary decision deadline, EPA chose to forgo an analysis of the studies—" the most recent and scientifically sound information" on Bt corn and monarchs—and relied instead on industry's interpretation of the data. Relying solely on industry's interpretation of such critical data is unacceptable.

By taking this course rather than delaying its decision, EPA turned a transparent process into an opaque one, excluded the public—and quite amazingly, even managed to exclude itself from review of critical risk data.

For future decisions on Bt crops, UCS recommends that EPA establish and implement policies and procedures that guarantee a transparent process, timely public—and agency—access to health and safety data, and full and equal participation of *all* stakeholders in the deliberations.

IV. UCS recommends that EPA begin immediately to develop a new risk/benefit assessment program for Bt crops.

In our view, EPA's Bt-crop assessment program is on the wrong track. The agency must put aside its commitment to the conventional pesticide paradigm and its general bias in favor of pesticidal crops, take advantage of its experience thus far with Bt crops, call on the SAP and other scientists for advice, and begin building a scientifically credible assessment program tailored to transgenic pesticidal plants.

Crafting a strong program is a big task and far beyond the scope of these comments. However, the Hilbeck/Meier Analysis offers a broad outline of one piece of the risk assessment puzzle—the evaluation of ecological risks.

[75] Letter from Floyd Horn, USDA Agricultural Research Service, and Marcia Mulkey, EPA Office of Pesticide Programs, to John Malloy, PNAS, July 24, 2001.

Applied to Bt crops, such an assessment would consist of six steps: [76]

- Characterizing the transgenic plant
- Determining modes of input and fate of transgenic plants and their novel proteins in the ecosystem
- Identifying exposure and impact pathways and affected organisms
- Selecting relevant non-target organisms according to certain criteria
- Developing testable hypotheses
- Developing appropriate testing protocols.

V. EPA erred in approving Event 176 Bt corn and should remove all Event 176 seed corn from the market immediately.

According to the Revised BRAD, the registration for Event 176 Bt corn lapsed in April 2001.[77] However, even though the agency now knows that Event 176 is toxic to monarch butterflies, it is allowing existing stocks of the seeds to be used through the 2003 growing season. Because of its threat to monarchs, we urge EPA to reverse that decision and not allow any Event 176 seeds to planted in 2002 and beyond.

VI. EPA should defer any decision on Cry 1F Bt corn until after it extends the five-day official public-comment period to 45 days to allow full public participation in the regulatory process.

As noted above, EPA officially allowed a five-day public comment period on the Cry 1F BRAD. EPA erred in its failure to provide a reasonable opportunity for public participation in the renewal process for Cry 1F corn. We urge the agency to publish a *Federal Register* notice immediately allowing a 45-day period for the public to fully evaluate and comment on the Cry1F BRAD before the agency makes a decision.

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[76] Hilbeck/Meier Analysis, pp. 4-7; the assessment was developed at a recent international conference on the risks of Bt rice; IOBC Global Working Group on Transgenic Organisms in IPM and Biocontrol, Newsletter No. 2, June 2001 (appended to Hilbeck/Meier Analysis); for a similar proposal for a risk assessment framework, see also Obrycki, J.J., J.E. Losey, O.R. Taylor, and L.C.H. Jesse. 2001. Transgenic insecticidal corn: beyond insecticidal toxicity to ecological complexity. *BioScience* 51: 353-61.

[77] Revised BRAD, p. I-5.

TABLE: BT CROPS REGISTERED BY EPA – 1995-2001

BT TOXIN	CROP	PESTS	PRODUCT NAME(S)	COMPANY	REGISTRATION	RENEWAL STATUS
Cry1A(c)	*Cotton*	*Lepidopteran pests—cotton bollworm, pink bollworm, tobacco budworm*	*BollGard®*	*Monsanto*	*1995 2001 expiration*	*Renewal requested*
Cry 1A(b)	*Corn*	*Lepidopteran pests**	*Bt 11 YieldGard® Attribute™*	*Syngenta*	*1996 field corn 1998 sweet corn 2001 expiration*	*Renewal requested*
Cry 1A(b)	*Corn*	*Lepidopteran pests**	*Mon 810 Yieldgard®*	*Monsanto*	*1996 2001 expiration*	*Renewal requested*
Cry 1F	*Corn*	*Lepidopteran pests**	*Cry 1F Herculex I®*	*Pioneer Dow/ Mycogen*	*2001 2001 expiration*	*Renewal requested*
Cry 3A	Potato	Beetle pest—Colorado potato beetle	New Leaf®	Monsanto	1995	No expiration; no renewal required; not on market as of 2001
Cry 1A(b)	Corn	Lepidopteran pests*	Event 176 NatureGard® KnockOut®	Syngenta Dow/ Mycogen	1995 field corn 1998 popcorn 2001 expiration	Companies withdrawing product; no renewal requested; existing stocks used through 2003
Cry 1A(c)	Corn	Lepidopteran pests*	DBT 418	Monsanto/ DeKalb	1997 2001 expiration	Registration voluntarily canceled; no renewal requested
Cry9C	Corn	Lepidopteran pests*	StarLink™	Aventis	1998 nonfood uses 2001 expiration	Registration voluntarily canceled; product withdrawn; no renewal requested

*Lepidopteran pests of corn include European corn borer, corn earworm, fall armyworm, southwestern corn borer, southern corn stalk borer, and common stalk borer.