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The Hon. Jairam Ramesh,
Minister of State (Independent Charge)
Ministry of Environment & Forests
Government of India
Paryavaran Bhawan, CGO Complex
Lodhi Road
New Delhi 110 003
INDIA

Re: Bt-brinjal

Dear Minister Ramesh,

Thank you for the opportunity to comment on the risk assessment of Bt brinjal for commercial use in India. I commend the ministry for delaying a final regulatory decision about Bt brinjal pending further review. I am a senior scientist for the science-based NGO, Union of Concerned Scientists in the United States, and a plant pathologist whose research included genetic engineering. I also worked for the U.S. Environmental Protection Agency, where I assessed the safety of genetically engineered crops and microorganisms, and served as an advisor to the U.S. Food and Drug Administration concerning the regulation of genetically engineered organisms. I am therefore qualified to review risk assessments of genetically engineered crops.

The purposes of this letter are to: address serious flaws in the EC-II report (*Report of the Expert Committee on Bt Brinjal Event EE-1*) on gene flow risks from Bt brinjal, and recommend steps necessary to correct the flaws and engender public confidence in the ministry's review. I do not consider here the potential for gene flow to reduce the genetic diversity of wild brinal relatives, nor the possible loss of genetically diverse and valuable Indian varieties (landraces) due to the adoption of Bt brinjal.

Based on my preliminary evaluation of the EC-II report, I find that its assessment of the risks of gene flow and possibility that, if gene flow occurred, environmental harm may result, is both flawed and incomplete. The conclusion of no risk is therefore invalid or at best premature. Several steps should be taken by the ministry to produce a valid risk assessment that reassures the public that the risks of genetically engineered crops are taken seriously.

Flaws in the EC-II risk assessment

Gene flow

The EC II report fails to adequately address gene flow in two major respects: the likelihood, first, that mating between brinjal and its wild relatives would occur in the environment, and second, that such matings would produce viable progeny.

I made several points and recommendations concerning gene flow risks in a previous paper (*Comments on Possible Consequences of Gene Flow from Bt Brinjal to Brinjal Wild Relatives in India, and the Inadequacy of the Current Risk Assessment*, April 15, 2009, attached, referred to here as "previous comments") that has since been considered by the EC-II. My previous

comments discussed environmental risk from gene flow, the potential for gene flow from Bt brinjal to related wild plant species, and an outline of the tests needed to determine risk from gene flow. The points made in my previous comments are based on scientific literature and expert consultation on gene flow and brinjal. These comments remain relevant to my assessment of the EC-II report.

At the time that I wrote my previous comments, the only assessments of gene flow from Bt brinjal evaluated by GEAC were several studies on pollination distances between brinjal plants. Such studies are typically done to determine adequate separation distances between genetically engineered crop fields and non-engineered plants to reduce the likelihood of gene flow during experimental field trials of engineered crops. This is not adequate for determining gene flow risk for commercialized crops because, as discussed at length by the U.S. National Research Council,[1] current containment methods—such as separation distances between the engineered crop and wild plants—generally cannot prevent gene flow after an engineered crop has been commercialized. This is why the other aspects of gene flow risk—outlined in my previous comments—need to be evaluated. None of these other aspects of gene flow risk were previously considered by the GEAC.

Recently, several additional studies concerning gene flow have been made public. These studies have been evaluated by the EC-II (page 56 of the EC-II report), which concluded that the concerns raised in my previous comments have been addressed, and no significant gene flow risk exists from Bt brinjal in India. Unfortunately, I have not had adequate time to thoroughly review these new studies, and my comments here must therefore be considered preliminary.

The following comments on the flawed gene flow assessment are based on my earlier comments and my preliminary assessment of the new studies. First, several of the new studies on the GEAC web site seem to show that mating between brinjal and at least one wild relative, *Solanum incanum*, can produce viable progeny. This suggests that such hybrids may also occur naturally through gene flow[2], and therefore contradicts the assessment of the EC-II. Because the successful production of viable progeny from mating between brinjal and *S. incanum* was accomplished without using extraordinary measures—that is, without highly artificial methods such as embryo rescue or protoplast fusion—these experiments suggest that viable crosses may occur in nature.

The artificial pollination of wild relatives of brinjal mentioned by EC-II appears to consist of hand-pollination methods that, while increasing the frequency of cross pollination, does not alter the fact that brinjal has been shown to cross pollinate without human assistance. Scientific literature and discussion with scientists who study brinjal and wild relatives that I cited in my previous comments, indicate that brinjal can successfully mate with *S. incanum* in the environment, and that their progeny are fertile.

It is therefore unclear why the EC-II concludes that gene flow cannot occur under natural conditions. This conclusion appears to be based on a single paper from 1979 by Rao, and observations that hybridization has not been reported. Differences between qualified scientists, on this or any issue, need to be resolved openly, rather than ignored—as seems to be the case in the EC-II report.

Although Rao's paper was useful for its time, reliance on a paper that predates more sensitive modern methods of determining gene flow in the wild—especially when more recent work contradicts this paper—is not adequate support for the unequivocal conclusions of the EC-II. More sensitive molecular methods, especially starting in the 1980s and 1990s, well after the Rao

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[1] National Research Council, 2004, *Biological Confinement of Genetically Engineered Organisms*; National Academies Press, Washington, DC.

[2] Ellstrand, N. 2003. *Dangerous Liaisons: When Cultivated Plants Mate with their Wild Relatives*. Johns Hopkins University Press, Baltimore, MD. See for example p. 59.

paper, have often shown that gene flow occurs in the wild in other species, despite earlier belief that gene flow to wild relatives was not common.[3]

Undocumented observations, mentioned by EC-II, also cannot substitute for careful experimental analyses. Hybrids may not always be observed or be distinct enough to be noticed in the field.

The EC II has also not adequately considered gene flow to *S. insanum.* Perhaps this is because some classify *S. insanum* as a subspecies of brinjal rather than a separate species. But even if that is the case, the ability of *S. insanum* to survive and spread on its own in non-agricultural environments strongly suggests that it should be evaluated. This is especially so because it has been reported to be a weed of brinjal, and is often found near brinjal fields which would allow gene flow to occur.

Evaluation of the Possibility that the Bt Gene could Spread in Wild Brinjal Relatives, and Cause Harm

Insects that feed on weeds and other wild plants may reduce the fitness of those plants and possibly their ability to compete and spread in the environment. Conversely, the plants may spread more aggressively in the environment if these insects are prevented from feeding on the plants. If this occurs, these plants may displace other plants species or become more aggressive weeds.

The EC-II improperly concluded that insects that can be controlled by the Bt gene are not prevalent on wild relatives of brinjal, and therefore gene flow would not increase weediness or other environmental harm. In addition, the report failed to adequately assess potential selective advantage whether or not insects turned out to be prevalent.

The report provides no support for the assertion that Bt-susceptible insect pests are not prevalent (not defined by the EC-II) on brinjal wild relatives—in particular *S. incanum* and *S. insanum.* No scientific references are provided, for example, that survey the insect pests found on brinjal wild relatives. Furthermore, I could find no research by the developers of Bt brinjal on this issue. Perhaps there are no data or existing data have not been disclosed. Lack of disclosure of whatever sources or information that the EC-II relied upon to conclude that insects are not prevalent on brinjal wild relatives is also contrary to accepted scientific practice because it does not allow review of the data—which is a fundamental tenant of sound science.

Prevalence of insects often varies considerably over time and at different locations, so there needs to be a number of such observations to determine prevalence over time and space. And even if not prevalent, a selective advantage favoring gene flow may still occur. This usually must be determined by careful experimentation, as has been done in other cases,[4] rather than by simple observation. Population genetic theory shows that even low positive selection advantage which may occur with low or variable presence of insects, will lead to the spread of a gene over time.[5]

Recommendations

Given the shortcomings of the risk assessment, I offer four recommendations below, which, if followed, would substantially strengthen the EC-II report and improve the public's confidence in the ministry's oversight of GMO crops.

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[3] Ellstrand, N. 2003. *Dangerous Liaisons*, see for example chapter 7.

[4] See, for example, Snow AA et al. 2003. A Bt transgene reduces herbivory and enhances fecundity in wild sunflowers. *Ecological Applications,* Vol.13:279-186.

[5] See, for example, Haygood et al. 2004. Population genetics of transgene containment. *Ecology Letters* , Vol. 7, Issue 3, pages 213-220. These authors use moderate selection in their equations. Lower selection—for example as may occur from low prevalence of insects—would produce similar gene flow results, only more slowly.

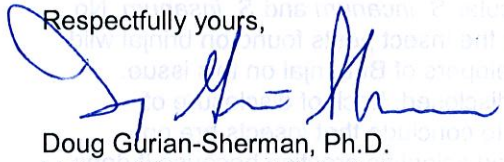
First, to produce a valid assessment of gene flow risks, additional testing should be performed along the lines that I recommended in the last section of my previous comments. The details of those tests would need to be determined.

Second, if there is any basis for the EC-II conclusion that insect pests are not prevalent on brinjal wild relatives, and that insects that feed upon wild brinjal relatives—prevalent of not—do not increase the fitness of those plants, those data should be made public.

Third, I recommend that your Ministry consult with independent, internationally respected scientists who are experts on gene flow or brinjal and its wild relatives. Gene flow experts include Allison Snow at the Ohio State University, Norman Ellstrand at the University of California at Riverside, and Paul Gepts at the University of California at Davis. These scientists have been advisors to U.S. regulators of GMO crops and other governments and have served on U.S. National Academy of Sciences panels evaluating gene flow issues. Experts on brinjal and its wild relatives include, for example, Dr. Marie-Christine Daunay of INRA in France and Dr. J. L. Karihaloo at the CGIAR in New Dehli.

Finally, the Ministry should allow additional time for non-government scientists to thoroughly evaluate the new data recently added to the Ministry web site. You have taken admirable steps toward making the risk assessment of Bt brinjal a more transparent process that, if completed, could provide the public with improved confidence in the conclusions of the Ministry. Truncating this process, on the other hand, could have the opposite effect. The issue of Bt brinjal is sufficiently important that a reasonable postponement of a final decision in the interest of safety and confidence in the evaluation process is warranted.

Respectfully yours,



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