Whom So-ever It May Concern:

The Center for Food Safety is a non-profit, civil society organization based in Washington, DC, that supports sustainable agriculture and advocates for stringent, science-based standards in the assessment of novel, potentially hazardous food production technologies, such as genetic engineering. Since its founding in 1997, the Center has become one of the United States' leading independent authorities on genetically modified (GM) crops. We frequently engage the U.S. regulatory agencies with responsibility for agricultural biotechnology and strive to improve their regulations and performance, when necessary by litigation. Since 2006, the Center has won three US Federal District Court cases against the U.S. Dept. of Agriculture for failing to assess the environmental impacts of various GM crops prior to allowing their release into the environment (two) or unregulated commercial use (one). These decisions speak volumes about the laxity of the US regulatory regime.

As the executive director and science policy analyst of the Center for Food Safety, we are writing with regard to Dr. Pushpa Bhargava's recommendations for biosafety assessment protocols for GM crops in connection with the Supreme Court case involving the Indian government's Genetic Engineering Action Committee (GEAC). We have examined Dr. Bhargava's recommendations in the Application filed by Aruna Rodrigues, lead petitioner, in August 2008 (I.A. No. 25 of 2008 in the matter of Writ Petition (Civil) No. 260 of 2005), GEAC's counter affidavit to the same filed in September 2008, and the Petitioners' rejoinder affidavit.
In brief, we find Dr. Bhargava's biosafety assessment recommendations to be scientifically-grounded, consistent with those of many other leading independent scientists experienced in the relevant disciplines, and strongly protective of human health and the environment. In contrast, GEAC's minimalist regulatory standards are scientifically flawed, reflect the interests of the agricultural biotechnology industry in rapid rubber-stamp approval, and so are much less protective of human health and the environment.

Perhaps the most serious indictment of the cursory testing standards relied upon by GEAC, as expressed by its Secretary Dr. Ranjini Warrier in the counter affidavit, is the growing number of scientific studies showing that GM crops already approved according to these very standards have adverse environmental and, potentially at least, adverse human health impacts. The Austrian government recently released a meticulously executed long-term feeding study showing that a popular variety of GM corn reduces the fertility of mice. Mice that were fed this GM corn as 33% of their diet over a period of 20 weeks had fewer offspring and more females with no offspring in their third and fourth litters than mice fed a diet containing 33% of a highly similar, non-GM corn variety. These results support Dr. Bhargava's recommendation for long-term feeding trials with GM crops to examine their potential to interfere with reproduction or have other adverse, chronic effects. Long-term feeding studies
of this sort are not required in either the U.S. or the somewhat more stringent European Union regulatory system.

A 2008 Norwegian study found that small aquatic organisms known as Daphnia magna exhibited reduced performance, including reduced fertility, when fed a common variety of GE corn but not when fed conventional corn. In 2007, a US study found that consumption of GE corn debris slows the growth rate, and potentially the fertility, of small aquatic organisms known as caddisflies, versus those fed conventional corn. Since caddisflies are at the base of aquatic food webs, and the tested variety of GE corn is planted on millions of acres across the

Midwest, the scientists expressed concern that this GE corn may pose a long-term threat to the health of freshwater aquatic ecosystems.6 These results support Dr. Bhargava's call for ecological impact studies, especially impacts on aquatic organisms. U.S. GM crop testing standards practically ignore potential adverse impacts on aquatic organisms.

Dr. Warrier makes repeated reference to impressive-sounding "norms" or even "international norms" for GM crop testing that he maintains are followed by GEAC. However, these supposed "international norms" in fact represent a cursory set of inadequate tests that biotech companies have found it convenient to perform, and these tests fall far short of what international experts have recommended. Before we give a few examples, it is pertinent to note that the US regulatory system, which has become the model for India and the world in this regard, was designed chiefly by biotechnology companies, and in particular the Monsanto Company. An investigative article in the New York Times that explored the origins of the US regulatory system for GM crops in the late 1980s and early 1990s came to this startling conclusion:

"It was an outcome that would be repeated, again and again, through three administrations. What Monsanto wished for from Washington, Monsanto and, by extension, the biotechnology industry got. If the company's strategy demanded regulations, rules favored by the industry were adopted. And when the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing.

Even longtime Washington hands said that the control this nascent industry exerted over its own regulatory destiny through the Environmental Protection Agency, the Agriculture Department and ultimately the Food and Drug Administration was astonishing.

'In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do,' said Dr. Henry Miller, a senior research fellow at the Hoover Institution, who was responsible for biotechnology issues at the Food and Drug Administration from 1979 to 1994."

Thus, when Dr. Warrier says that the current testing norms for GM crops are based on "the combined wisdom of the world’s agricultural scientists," and criticizes Dr. Bhargava for "trashing" this "combined wisdom" with calls for “whimsical” tests, he is either ignorant of the true origin of GM crop testing regimes used in the world today, or conveniently ignoring it. Far from representing some consensus of independent agricultural scientists, as he states, the current norms for GM crop testing are largely a creation of biotech industry officers intent upon securing rapid approval for commercial use of their crops absent adequate testing for potential harm to the environment or human health. This is an extremely serious misrepresentation.

Time and again, Dr. Warrier dismisses legitimate tests recommended by Dr. Bhargava, invariably adopting the position of biotech companies rather than the views of independent scientists. The "surrogate" protein issue is a case in point. Biotech companies invariably fail to extract the foreign proteins (e.g. Bt insecticidal proteins in Bt cotton and other Bt crops) actually produced in their GM crops for use in testing. Instead, they generate “surrogate” versions of these proteins in transgenic bacterial hosts, which often differ in important respects from the GM plant-produced protein, but are easily and cheaply obtained. A prestigious U.S. National Academy of Sciences committee that conducted an exhaustive review of Bt crops stated: “Tests should preferably be conducted with the protein as produced

in the plant." A surrogate protein is not permissible unless it is first demonstrated to be equivalent to the plant-expressed protein based on clear, scientifically justifiable criteria:

"The EPA should provide clear, scientifically justifiable criteria for establishing biochemical and functional equivalency when registrants request permission to test non plant-expressed proteins in lieu of plant-expressed proteins."

Contrary to Dr. Warrier, then, leading independent agricultural scientists have recommended preferential use of "the protein as produced in the plant," not bacterial surrogate protein, for use in testing. The NAS committee urged the U.S. Environmental Protection Agency to issue clear, scientifically justifiable criteria for establishing equivalency if a company wished to use a "non-plant expressed" (i.e. "surrogate") protein for testing purposes. A group of independent scientific advisers to the EPA recommended such "test substance equivalence" criteria to the EPA, but the EPA has refused to adopt them. The toxicity and allergenicity assessments of Bt crops currently on the market (in some cases for a decade or more) employed surrogate proteins that did NOT meet these criteria. This regulatory failure means that currently approved Bt crops may be posing risks to humans and non-target organisms that were missed due to lax and faulty testing procedures. Freese (2003) provides a fuller discussion of the "surrogate protein" issue as well as other inadequacies in testing practices for GM crops.

Finally, we note that Dr. Warrier's objection that sufficient quantities of GM plant-produced protein cannot be extracted from plant tissue mirrors precisely the excuse invariably provided by biotech companies. While more expensive than use of surrogate proteins, it is indeed possible to extract sufficient quantities of protein for testing purposes. In any case, needed tests should not be neglected on the mere basis of cost considerations.

Dr. Warrier dismisses DNA fingerprinting, proteomics and similar tests recommended by Dr. Bhargava in terms that further reveal his and GEAC's scientific incompetence as well as their strong bias in favor of the biotechnology industry:

"The scientific opinion does not consider most of them [i.e. tests recommended by Dr. Bhargava] as essential or remotely relevant. He wants genomic and proteomic data which costs enormously in both time and money. The genomics and proteomics data vary with several different situations such as the time of taking the sample and the age of the source. Dr. Bhargava knows fully well that it would be near impossible to implement his prescription and so no GE product will be commercialized."

DNA fingerprinting and proteomics belong to a class of "profiling" techniques that have indeed been recommended for GM crop assessments by leading independent scientists, as discussed below. As so often, Dr. Warrier construes "[t]he scientific opinion" narrowly to mean those scientific opinions favored by the biotechnology industry and its adherents.

The need for such techniques derives from the high rate of "insertional mutagenesis" associated with genetic engineering. That is, the genetic engineering process itself causes random and in some cases large-scale mutations in crop genomes, regardless of what gene is being inserted. These mutations give rise to a higher potential for generating unintended and potentially adverse human health and environmental effects than conventional breeding methods. Current testing regimes are based on a "targeted approach" that is ill-suited to

detect the unpredictable changes that occur in GM crops. According to leading European GM crop safety scientists, with this "targeted approach:"

"…unexpected changes are merely identified by chance. The targeted approach has severe limitations with respect to unknown anti-nutrients and natural toxins…"

These same experts recommend profiling techniques, such as those recommended by Dr. Bhargava, as well as metabolic profiling, because they offer a means to test for dozens or hundreds of compounds at once to detect GM-induced elevations in the levels of naturally occurring, low-level plant toxins or antinutrients, as well as potentially hazardous novel compounds not found in conventional crops. We note that these techniques would be a useful accompaniment to long-term feeding trials. They provide a good means of pinpointing the chemical basis of adverse effects found in such trials, such as the reduced fertility found by Austrian scientists in mice fed GM corn in the study cited above.

These same European experts support molecular characterization studies to determine the precise site of insertion of the foreign gene in the plant genome, as well as any mutations to flanking regions, as also recommended by Dr. Bhargava:

"Location and characterization of the place(s) of insertion are the most direct approaches to predicting and identifying possible occurrence of (un-)intended effects due to transgene insertion in recipient plant DNA. Data for transgene flanking regions will give leads for further analysis, in the case of a transgene insertion within or in the proximity of an endogenous [i.e. plant] gene."

Dr. Warrier exhibits inordinate concern for the costs of such testing procedures, once again placing the biotechnology industry's financial interests above safety.

We could provide further examples supporting the legitimacy of Dr. Bhargava's recommended tests, and the specious reasoning and scientifically flawed arguments put forward by Dr. Warrier in support of GEAC's minimalist regulatory framework, but feel those described above should serve to make our point.

We will close by examining Dr. Warrier's blanket statement that: "....regulatory authorities have concluded that there is no evidence of harm for each of the currently approved transgenic crops."

As discussed above, the regulatory framework in the U.S. , which has served as the model for India and the world, has been profoundly shaped by the biotechnology industry to serve its interests in rapid, rubber-stamp approval. The sampling of studies discussed above suggesting adverse impacts from GM crops approved by those regulatory authorities casts strong doubts on the adequacy of this regulatory framework, as do the three US Federal District Court decisions against our USDA for failure to properly assess GM crops cited at the outset. Finally, the many improvements to regulation of GM crops urged by independent scientists have gone largely ignored.

Yet even if one ignores the dissenting data and assumes for the sake of argument "no evidence of harm" from approved GM crops, one must ask whether "no evidence" means that appropriately conducted studies have found no harm, or simply that appropriate studies have not been conducted. A U.S. National Academy of Sciences committee criticized ambiguous

claims such as Dr. Warrier's in its scathing critique of the U.S. Dept. of Agriculture's performance at regulating GM crops in the U.S. Noting that commercially approved GM crops are not, but should be, monitored for adverse effects not detectable at the small field-trial stage, the committee called such "no evidence" claims "non-scientific," noting that: "...any effects that might have occurred could not have been detected. The absence of evidence of an effect is not evidence of absence of an effect."

For all of these reasons, the Center for Food Safety respectfully urges the Supreme Court of India to rule positively on the testing recommendations outlined by Petitioners and Dr. Bhargava. This course of action would best ensure that any GM crop approved for field testing or commercial use would not harm India's citizens, livestock, or environment. While it would take time to properly establish the necessary testing procedures and protocols, we believe that a moratorium to accomplish this would be time well spent.

Respectfully yours,
Andrew Kimbrell, Executive Director
Center for Food Safety
Bill Freese, Science Policy Analyst
Center for Food Safety

1. See: http://www.centerforfoodsafety.org/pubs/Three%20Case%20Victory%20Summary%202-20-07.pdf .

2. Velmirov, A, Binter, C and J. Zentek (2008). "Biological effects of transgenic maize NK603 x MON810 fed in long term reproduction studies in mice," Federal Ministry for Health, Families and Youth, Government of Austria, October 2008.

3. Bohn, T., Primicerio, R., Hessen, D.O. and T. Traavik (2008). "Reduced fitness of Daphnia magna fed a Bt transgenic maize variety," Archives of Environmental Contamination and Toxicology, published online March 18, 2003.

4. Rosi-Marshall, EJ et al (2007). "Toxins in transgenic crop byproducts may affect headwater stream ecosystems," Proceedings of the National Academy of Sciences 104(41): 16204-16208.

5. Eichenwald, K., G. Kolata and M. Petersen (2001). "Biotechnology Food: From the Lab to a Debacle," The New York Times, January 25, 2001.

6. "Genetically Modified Pest-Protected Plants: Science and Regulation," Committee on Genetically Modified Pest-Protected Plants, National Research Council, National Academy of Sciences, 2000, p. 65, see: http://books.nap.edu/catalog/9795.html . For similar recommendations, and examples of immunologic differences between nearly identical proteins, see: "The StarLink Affair," Friends of the Earth, July 2001, sections 9.2 to 9.4, at www.foe.org/safefood/starlink.pdf.

7. "Mammalian Toxicity Assessment Guidelines for Protein Plant Pesticides," EPA's Scientific Advisory Panel, SAP Report No. 2000-03B, Sept. 28, 2000, p. 14. http://www.epa.gov/scipoly/sap/2000/june/finbtmamtox.pdf.

8. Freese, B. (2001), “A Critique of the EPA’s Decision to Reregister Bt Crops and an Examination of the Potential Allergenicity of Bt Proteins,” adapted from comments of Friends of the Earth to the EPA, Dec. 9, 2001. Available at: www.foe.org/safefood/comments.pdf .

9. Freese, B. (2003). “Genetically engineered crop health impacts evaluation – GAPS analysis,” Friends of the Earth, Washington, DC, USA . http://www.foe.org/safefood/gapseval.pdf .

10. Wilson, AK, Latham, JR and RA Steinbrecher (2006). “Transformation-induced mutations in transgenic plants: Analysis and biosafety implications,” Biotechnology and Genetic Engineering Reviews, Vol 23, Dec. 2006, 209-234.

Center for Food Safety
660 Pennsylvania Ave., SE , Suite 302, Washington, DC 20003
(202) 547-9359 -- fax (202) 547-9429
2601 Mission St., Suite 803, San Francisco, CA 94129
(415) 826-2770 -- fax (415) 826-0570
www.centerforfoodsafety.org