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Mr. Jairam Ramesh
Minister, Environment and Forests,
Government of India

Re: Bt-brinjal Part One

Dear Minister Ramesh

It is my pleasure to respond to your request of 7 November 2009 for my views on the Monsanto-Mahyco application to approve open cultivation of Bt-brinjal for use as food. As you know, I was one of a number of independent scientists who read and critiqued the scientific information provided by the developer in its case to demonstrate that the genetically engineered Bt-brinjal posed no safety concerns for human health or the environment. I came to the conclusion that the molecular data, and some related analyses, were too poorly conducted to make a definitive claim that this product is safe.

Since that time, the official Indian advisory body, GEAC, has ruled that the science provided by the company does satisfy them that Bt-brinjal is safe. I have only just learned, however, that new evidence in support of the claim of safety has become available. All or some of this evidence was gathered after the dossier was made publicly available in August of 2008. The new data was posted for viewing only days ago. I have been unable to review the new data to determine if they adequately address the concerns I raised previously. To do so properly, I will need additional time. Considering the volume of new data posted, I hope that you will extend your period of review until March of 2010.

Therefore, if you would permit me, I would prefer to respond to your request in two parts. In this letter, I will describe how I came to my present views on agriculture and my involvement in assessing other genetically engineered crops and the outcome of those assessments. This I believe to be important information because it is related to how I prioritise my assessment of the testing of Bt-brinjal, which will be the focus of my next letter.

Traits such as Bt (insect tolerance in general) and HT (herbicide tolerance in general, often RR for roundup ready) suit particular agroecosystems and philosophies of industrial

agriculture. That is perhaps why, even according to industry figures, 67% of all commercialised genetically engineered crops are grown in only 2 countries, the United States and Argentina, and 80% in just 3 countries including Brazil. India, which the industry describes as a GE megacountry, produces only 6% of the world's GE crops and only uses 4% of its agricultural land for GE. The industry figures are contested and may overstate the amount of GE produced outside of the US and Argentina, making the concentration of GE crops in just a few agroecosystems even more telling.

As I discuss in my book *Hope not Hype*, only two countries on this planet have gambled with GE on more than 35% of their agricultural land. Those two countries are Argentina and Paraguay (and decidedly *not* the United States). They have over two-thirds of their agricultural land in GE production. Alongside the change to GE production has been an increase in "food insecurity" and "very low food security" as measured by the UN Food and Agriculture Organisation (see Box 7.2 of *Hope not Hype*).

Since India's only genetically engineered crop at this time is cotton, it is worth considering how GE cotton varieties in the US, where they have been in production the longest, are doing. Interestingly, the latest studies do not vindicate the claim that the crops are reliably increasing yield or financial returns (this is discussed and fully referenced in detail in Chapter 5 of *Hope not Hype*). The latest research shows that over time profits follow yield, but there is no consistent yield increase with GE cotton. There is year-to-year variation, with good yield years promoted by those who sell GE cotton seeds.

There are many reasons beyond safety to consider whether GE crops are the right kind of biotechnology for your country. These were considered methodically and holistically by the single largest research exercise on global agriculture in history conducted with funding from multiple UN agencies and the World Bank. This report, published in January as *Agriculture at a Crossroads*, was produced under the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD). It involved around 400 researchers and twice the number of peer-reviewers. Built on the IPCC model, it underwent two rounds of open international peer-review and was ratified overwhelmingly at the intergovernmental plenary in April 2008.

The "IAASTD report" came to the conclusion that 'business as usual' will inevitably result in food and fuel needs exceeding global ability to meet them. However, this isn't a food shortage problem. The problem historically and presently is caused by social barriers and because of the model of agriculture for which most GE products are designed. In fact, more GE is more

‘business as usual’. Some hunger in the future will probably be due to production limitations, but again mainly because of conspicuous consumption in wealthy countries, loss of land and fertility in both developed and developing countries (because of use of fossil-fuel dependent fertilizers), and poor policy decisions on water and biomass use. Unless the problem of “feeding the world” is considered holistically, inappropriate technologies that are not sustainable will be proposed as stop-gap solutions and that would not address the major causes of shortage.

I was a lead author on Chapter 6 of the global report, and of the biotechnology section of the Synthesis Report. This latter role was why I was invited to represent the authors at the intergovernmental plenary at which the report was adopted. In addition to that role, I have been a biotechnology advisor to multiple government agencies in New Zealand, and agencies of the US and Norwegian governments. I am listed by the United Nations as a biosafety expert and serve on the Ad Hoc Technical Experts Group to the Secretariat of the Convention on Biodiversity. I publish in the international peer-reviewed literature including such journals as *Science*, *Nature*, *Nature Biotechnology* and *Trends in Biotechnology* and have an active laboratory with three PhD students (with more on the way), a postdoctoral scholar and an honours student.

I am also the director of a research centre that voluntarily participates in the consultation in our country over the use of GE crops as human food. Our food regulator, Food Standards Australia New Zealand, is the competent authority for both Australia and New Zealand. They invite opinion, particularly scientific opinion, on applications for amending our food code to include GE crops on a case by case basis. I have reviewed three applications in great detail, and four applications to date. Two applications for which I submitted comments were withdrawn by the applicant (both ostensibly for commercial reasons, but there are reasons to doubt that, at least for the second application).

Both applications that were ultimately withdrawn were from Monsanto. The first was for a modified wheat plant in 2004.The most recent withdrawal was of Monsanto’s high lysine maize LY038. This is the most interesting case. My colleagues and I found over a hundred scientific flaws in the data. Nonetheless, the application was approved in several jurisdictions, including Australia/New Zealand, despite these problems. However, many of those flaws, and the most significant ones, were not considered permissible by many European countries or the European Food Safety Authority (EFSA), which refused to approve the maize unless the key problems with the scientific dossier were addressed with new experiments and the results still supported approval. Instead of investing the small increment of money necessary to produce

this science, Monsanto instead stopped all commercial development of LY038. Since we estimate that Monsanto had by this time invested nearly US$1 billion in development, marketing and processing facilities, and by its own admission expected that this product would produce a revenue stream of US$1 billion/year, a few hundred thousand dollars of new scientific tests was to us an unlikely reason for withdrawing the product.

I relate this story for two reasons. The first is to let you know that I am not naïve to what it takes to make a quality dossier for an application to approve a GE plant and determine that it is safe for human health and the environment. I have been doing this analysis for some time, and been found to be in agreement at least with some competent authorities. Strikingly, the major defect in the LY038 dossier was the use of the wrong comparator. They used another GE variety against Codex Alimentarius and EU rules. Some jurisdictions went to great lengths to excuse this fundamental flaw, but others held their ground. I could not find the comparator even mentioned in the brinjal safety studies that I took special note of, much less a sense that the studies consistently used the appropriate comparator.

Second is to say that while India can have whatever standards it wishes for deciding on GE foods, other countries may close the door if proper and thorough safety testing has not been done. The LY038 application is instructive here. The Bt-brinjal dossier I viewed in August 2008 is, in my opinion, nowhere near the sophistication and quality of the LY038 dossier, and that dossier was still unacceptable to Europe. Many of the Bt-brinjal experiments, at least as described, would not satisfy Codex Alimentarius guidelines as applied by careful regulators. Does India want a reputation for low standards in food? Does it want to put its exports at risk? If the answers to these questions are ‘no’, then I would encourage you to set the standard with Bt-brinjal that you would like the industry to meet now and in the future for any GE crop.

It is easier for industry to meet high government standards communicated clearly at the start than it is for government to raise industry standards later.

It is for me a serious error to assume that those with an interest in product development can also be biosafety scientists. The extensive network of funding for research for the purposes of advancing commercial agendas includes many in academia, so it is no longer valid to simply choose researchers from universities and call them independent. A truly world-leading strategy would be to maintain a distance between the regulator and the technology, and to certainly remove any consideration of trade from the regulator’s brief. India could achieve this by supporting independent laboratories and researchers committed to public and environmental safety at both the basic research level and in review of technological

applications. As we are witnessing by the accumulation of research results from a small and widely spread independent research community, the truth ultimately comes out. The challenge will be for political leaders such as yourself to ensure that the truth comes out before any undetected harms of new technologies.

With best wishes,

Prof. Jack Heinemann
24 November 2009