

Shri Jairam Ramesh
Minister, Environment and Forests
Ministry of Environment and Forests
New Delhi

December 1st 2009

Dear Shri Jairam Ramesh,

Sub: NO proof of safety established by the Indian Regulators of Bt cotton of Cry 1 AC protein regarding its impact on Animals that have grazed on /fed Bt Cotton:

Animals grazing in fields or being fed Bt cottonseed cake demonstrate potential and serious health problems. The potential for harm to humans from Bt brinjal, containing the same protein, and in the absence of any meaningful investigation of Bt cotton, is a risk that cannot be taken.

Submission to the honourable Minister, with a request to grant time to make a personal presentation of the case.

I wish to draw your attention to **Section V, Issue 8, pp 58-59** of the **“Report of the Expert Committee (EC-II) on Bt Brinjal event EE-1”**, wherein the committee refutes the need to conduct long-term studies for assessment of chronic toxicity and nutritional impact on mammals.

- i) The committee dismisses the above concern raised by eminent national and international scientists, citing instead extensive studies purported to have proved its safety, a history of safe use for human and animal that have consumed GM crops containing Cry1Ac protein, and that chronic toxicity studies are warranted only if any toxic effects are observed in acute or sub-chronic studies, which were not. They also state that the Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in the short term studies (Section VI, point 11, pp 63).
- ii) The Expert Committee Report in **table 2.2, point (i), on page 23**, records an additional condition stipulated by GEAC that *the food/feed safety assessment should include any possible foliage/shoot toxicity study on goats*. This condition was stipulated in view of the reports of sheep deaths in Andhra Pradesh due to grazing on Bt cotton fields. **However the GEAC subsequently reversed its decision and decided to dispense with the additional risk assessment test requirement on the grounds that**
 - a) *the reports of sheep deaths due to Bt cotton were unsubstantiated, and*
 - b) *that the newly adopted “Guidelines for the safety assessment of foods derived from GE plants , 2008”, do not require any food and feed safety assessment using goats as the model.*

i) I strongly contest the Expert Committee’s observations that Bt cotton has been proven safe for animals, which I wish to present before you based on the experiences of my organisation **Anthra- an organisation of women veterinary scientists**, which has been researching the impact of Bt cotton on livestock since the last 5-6 years.

ii) I draw your attention to how consistent and cumulative exposure to the Bt toxin has elicited a possible toxic / allergenic response in sheep, goats, cattle and buffalo populations in Andhra Pradesh and other states in India. Animals began to exhibit morbidity and mortality after continuous and cumulative exposure to Bt cotton (leaves, bolls, seeds, seed-cake), over successive years, with first reports of ill-health occurring in 2004-05, about 2 years after the commercial release of Bt cotton in India.

ii) I would also like to alert you to the total failure and inability of our existing public research institutions and National Regulatory Bodies (GEAC), to investigate/ test/ rigorously examine, prove or disprove these field observations, preferring to dismiss the reports as “unsubstantiated”, “exaggerated, and unscientific”, refusing to conduct a single field-based study and instead placing the onus of “proof” on shepherds, farmers and civil society groups who have reported the problem.

The argument that the latest guidelines do not require the suggested new risk assessments tests and hence have been dispensed with, negate and ignore the field realities where “non-target organisms” have been affected by the Bt toxin. On the contrary, these unique field experiences and observations, urgently invite new and additional specific regulatory and risk assessment protocols.

I confidently assert that the issues of safety are completely unresolved, evident as follows:

1) Field reports of toxic / allergenic reactions of animals exposed to Bt toxin in Bt cotton in Andhra Pradesh and other states: 2005-2009 and the complete failure of Public Research and Regulatory Bodies to investigate the same.

Between 2005 and 2009 Anthra has been closely investigating the reported morbidity and mortality observed in sheep and goat flocks, which have been grazed on harvested Bt cotton crop in Andhra Pradesh.

In the first 3 years, symptoms reported by shepherds, were confounded by the concurrent incidence of other contagious diseases such as peste-du petits ruminants (PPR) and blue tongue.

By 2008-09, due to in-situ presence of our veterinary scientists who continuously monitored the village flocks, which we ensured were vaccinated against all other possible preventable contagious diseases, we were able to narrow down and be precise about the specific morbidity exhibited by animals that grazed on harvested Bt cotton.

Morbidity selectively manifests itself symptomatically in animals by the 3rd of 4th day of consuming the Bt cotton as *nasal discharge, cough, respiratory distress, and occasional bloody urine and the absence of fever*. Mortality occurs in some animals, especially if untreated, not all animals.

Our field observations point towards a clear cumulative effect of the toxin on morbidity and mortality, with successive years of exposure/ grazing on the Bt cotton, eliciting what appears to be an allergenic immune response.

In Haryana, there is a strong correlation between feeding Bt cotton seeds and cotton seed cake to milch animals, and drop in milk yield and several reproductive disorders such as prolapse of uterus, premature birth of calves, increase in the incidence of abortions and decrease in conception rate. **These symptoms of reduced fertility correspond to results of reduced fertility in rats that were fed Bt Maize over four generations (Velimerov, A et al., 2008).**

2) Post mortem samples – Research institutes admit inability to test for Bt toxin; histo-pathological reports demonstrate lesions similar to those observed in rats fed on Bt maize (corn).

Tissue samples collected from post-mortems done on dead sheep and goat which died after grazing on Bt cotton, were sent to top research institutions of the country such as the Indian Veterinary Research Institute (IVRI) in 2008, with specific request that these be tested for Bt toxin. ***The IVRI reported their inability to test for Bt toxin (see annexure 1)***

Histo-pathological lesions in the kidney, liver and intestines of the post-mortemed sheep/goat, are similar to those recorded in Monsanto's own dossier of Mon 863, (Bt corn) of 90-day rat feeding studies, subsequently revealed by Pusztai on behalf of the German government and later, confirmed also by Seralini et al (2007) after many statistical studies (annexure 2.) The Company's hidden raw data were released in the public domain through a German Appeal Court decision (2005). Other studies by different researchers with rats fed Bt corn also revealed hepato-renal toxicity, and damage to liver and kidneys. (Kilic and Akay, 2008, Velimerov, A et al., 2008).

3) Deceptive “proof” of safety: serious scientific lapses in the investigation of animal morbidity

The so-called reports of safety, which GEAC has cited in its 82nd committee meeting, in January 2008, as having been received from the IVRI and Animal Husbandry department, AP (AHD), as evidence of “conclusive proof of safety”, which my organisation subsequently obtained through RTI, **un-ambiguously points to deception and serious scientific lapses.**

To illustrate: the IVRI when requested for its report of safety, responded stating that “*no studies have been done by them and that the Animal Nutrition Department of IVRI has not submitted any reports to the GEAC!*” (Annexure 3)

The GEAC's dossier of safety which they sent us, when we filed under RTI, included copies of 4 letters—one from the AHD, one from the IVRI, one from the Sri Venkateshwara Veterinary University (SVVU), AP and one from a Joint Director (AHD) of a district which never reported any sheep deaths. *Three of the four letters clearly state the need for further bio-safety studies.* (Annexure 4)

A subsequent RTI to IVRI, quoting their letter to the GEAC where they mention having conducted a Bt cotton feeding study on goats, resulted in IVRI sending copies of research protocol and methodology to test for HCN, glyphosate, alkaloids, nitrites and nitrates! They also sent a report of toxicity assessment of feeding Bt cottonseeds to rats; but no studies on goats, which is what I had specifically asked for! (Annexure 5)

Please note that there appears to be direct factual conflict between the letters from IVRI contained in annexure 3, annexure 4 and 5. One of these is simply not truthful. It is clear that the GEAC has based its conclusions regarding Bt cotton on untruthful statements by government agencies. We strongly object to the GEAC using the same untruthful “evidence” to justify the safety of Bt brinjal.

4) A safe toxin? Conflicting claims of “safe and tolerable levels of Bt toxin”

The other “proof of evidence of safety of Bt toxin”, sent to us by the GEAC, is a letter sent to the GEAC by the Director, Animal Husbandry Department (AHD), Andhra Pradesh, dated May 2007 (ref: No 3531/Epid/2006.dated 9/5/2007), wherein the director reports that (annexure 6)

“ The Bt protein levels detected in the samples of Bt cotton bolls and leaves sent for analysis was recorded as 5 µ/gm. This level is within the tolerable range which is said to be “5-10 µ/gm”.

This information was provided to the Director, AHD from the Department of Agriculture Biotechnology, Agriculture University, ANGRAU, AP, which had tested samples of Bt cotton plant (bolls and leaves), which were sent to them in connection with reports of death in sheep after grazing on Bt cotton in 2006.(ref: letter roc no: 14627/Epid/2006/, dated 20/9/2006).

5-10 µ/gm is equivalent to 5-10 ppm

The Bt protein content (of Bt brinjal) reported in the Expert Committees Report (**point 3.1.5**) describes the level of Bt protein (Cry1Ac protein) found in different parts of the crop to vary **between 5 to 47 ppm** in shoots and fruits.

For the sake of argument, if we are to go by the earlier submission of all institutions concerned (Agriculture university, cited by Animal Husbandry Department, cited by GEAC) that the reports of Bt toxin (Cry 1 AC protein) are safe and tolerable if they are between 5-10 ppm then it follows that the levels detected in Bt brinjal reported in the biosafety studies and Expert Committee Report, are not tolerable, as it is way above the supposed tolerable levels, which are cited as being safe for sheep!

This raises serious questions on supposed “tolerable” and safe levels of Bt toxin in plants. Who has decided on this supposed safe level for Bt toxin? What is the scientific evidence for safety? How can there be a safe level of “toxin” with a food product, when the very definition of a “toxin” indicates a poison, or something that is harmful?

The GEAC consistently referred to these Bt protein levels (as cited above) as proof of safety of Bt protein to animals, and the “evidence” that death in animals was due to Nitrate/ Nitrite / organophosphates/other diseases.

If the GEAC says the Bt protein is Cry1AC, then by their own admission, the level is not tolerable in Brinjal. If they admit the protein in Bt cotton and Bt brinjal are different, then the whole Bt Brinjal report is wrong because Mahyco is treating the chimeric protein as if it were Cry1AC, which is re-iterated by the Expert Committee in their report.

5) Deception/Cover-up by the GEAC: Absence of a rigorous protocol to test for the presence or absence of Bt toxin / Bt antibodies in sick animals/ dead animals results in its automatic omission from reported results. This has been presented as evidence of proof of safety.

It is a serious matter that in the name of scientific enquiry, we have instead, clear evidence of deception and fraud on the part of all the regulatory bodies in India, to pass off the non-testing of a toxin, and hence its “non- detection”, as evidence of proof of safety.

What we have is (a) No tests to assess immune responses to the Bt toxin/ presence of Bt toxin, but (b) nevertheless, the unfounded claim of a “negative result of having not detected Bt toxin” which is passed off as proof of safety. It is scientifically untenable that without performing any tests, its absence is cited as evidence that the toxin is safe.

This circular argument of “safety” is the basis on which the GEAC claims that reports of animal deaths are “unsubstantiated”, and reversed its decision to carry out further risk assessment tests on goats, as cited earlier in this letter (page1).

6) Bt toxin detected in rumen liquor and liver malfunctions detected in sheep fed on Bt cotton: 2007 study by State Veterinary University, Andhra Pradesh

In 2007, the Sri Venkateshwara Veterinary University, Andhra Pradesh initiated a season-long study on Bt cotton and sheep (annexure 7). ***The investigations were able to detect the presence of Bt toxin in the rumen liquor of the sheep, indicating that Bt insecticide is not really digested by the sheep (annexure 7, Table 6).***

This seriously contradicts the Expert Committees report (Section VI, point 11, pp 63) that “*. Cry1Ac protein has shown to be rapidly degraded (in 30 seconds) in simulated digestive fluids and thus is not detectable even in the short term studies.*”

The Expert Committee in their report makes the above statement without any supporting scientific peer reviewed reference. We need to know the scientific evidence in the literature for this statement.

There are other aspects in the Universities study findings that warrant further investigation, no matter that they have been dismissed as unimportant by the department, which conducted the research:

- i) The presence of higher toxic heavy metals in Bt plants (842.25 ppm of lead in Bt cotton as compared to 134.62 ppm of lead in non-Bt cotton after 45 days), which is 6.25 times higher after 45 days, as compared to the non-Bt cotton.
- ii) The liver marker AST which is known to increase after hepato-cellular injury, as the author of the experiment indicates, is increased in the protocol by 37% in Bt treated sheep in comparison to the untreated group of sheep fed on regular cotton, by the second month.

Then, C. (2009) in a recent article, reviewed published peer-reviewed literature, which showed that several extrinsic factors (such as enzymes, environmental stress, non-pathogenic microorganisms and infectious disease) and synergisms can impact the efficacy and selectivity of Bt toxins. The author concludes that risk assessment of genetically engineered plants should put into question the general assumption of a high selectivity and a linear dose-response relationship in the toxicity of Bt protein. Efficacy and selectivity can be influenced by synergism, which can provoke unexpected and undesired effects in non-target organisms. These findings suggest that systematic research be promoted on synergism between Bt toxin and potential extrinsic factors that could impact the spectrum of susceptible organisms.

It is evident from the above that there is much to worry about. There are obvious lies and a host of contradictions within the “safety” parameters being presented to us citizens.

Most worrying is that there is total failure and reluctance on the part of any public research institution to respond to problems, and carry out rigorous investigations. No formal regulatory guidelines and protocols exist which can respond to these emerging field conditions.

In our experience with animals, every institute that claimed the safety of the Bt Cotton plant absolved themselves of any responsibility towards conducting stringent and rigorous scientific research, to examine the field realities. The official cover-up and fraud are unacceptable and must be investigated. The implications for India are as serious as it can get.

I request you to kindly grant me personal time, to present this documentation in line with your commitment in your press release on consulting with a range of stakeholders before the government takes a final decision on granting permission for the commercial cultivation of Bt Brinjal.

Yours sincerely



Sagari R Ramdas
Director, Anthra

Encl: Annexure 1- Report from IVRI regarding inability to test for Bt toxin
Annexure 2: Seralini's Paper
Annexure 3: RTI obtained from IVRI- stating that Animal Nutrition Dept has conducted no studies on Bt cotton
Annexure 4: RTI obtained from GEAC- their submission of "proof of safety of Bt cotton"
Annexure 5: RTI from IVRI – "protocols for testing HCN, et. al"
Annexure 6: Letter from Dept AHD, AP to Dept of Agriculture summarising tests conducted on Bt cotton and safety of toxins.
Annexure 7: "Studies on the toxicity of Bt cotton plants incorporated in the feed of small ruminants". Project Report. Sri Venkateshara Veterinary University, Tirupati
Annexure 8: Bt cotton and livestock. Paper presented by Dr Sagari R Ramdas, July 2009

cc: Dr Ranjini Warriar, Member Secretary, GEAC, MOEF

References

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