D.NO.1944/2005/SC/PIL

SUPREME COURT OF INDIA
NEW DELHI

Dated : 17th October, 2012

From : Assistant Registrar PIL (WRIT)

To :

1. Mr. Prashant Bhushan, Advocate,
   301, New Lawyers Chamber

2. Mr. S. Hariharan, Advocate
   24, Lawyers Chamber

3. Mr. Jitendra Mohan Sharma, Advocate,
   141, New Lawyers Chamber

4. Mr. A. P. Medh, Advocate,
   22, Lawyers Chamber

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   D-29, (FF), Gulmohar Park, New Delhi – 110049.

6. Ms. Kamini Jaiswal, Advocate,
   43, Lawyers Chamber

7. Mr. Subramanium Prasad,
   104, Lawyers Chamber

8. Mr. S.N. Terdal, Advocate,
   Central Agency

IN THE MATTER OF:

WRIT PETITION (CIVIL) NO. 260 OF 2005
(Under Article 32 of the Constitution of India)
WITH
WRIT PETITION (C) NO. 115 OF 2004
WITH
CONTEMPT PETITION (C) NO. 295 OF 2007
IN
WRIT PETITION (C) NO. 260 OF 2005

Aruna Rodrigues & Ors. etc. etc. .... Petitioners

Versus

Union of India & Ors. .... Respondents

Sir/Madam,

As per Hon'ble Court's Order dated 15.10.2012, I am directed to enclosed herewith a copy of the Interim Report dated 07.10.2012 received from Dr. Imran Siddiqui, the Member of the Technical Expert Committee.

This is for your information, compliance and necessary action.

Yours faithfully,

Assistant Registrar

Encl.: As above

pk/-

CONFIDENTIAL

Interim Report of the Technical Expert Committee

Background

In accordance with the Order of the Honourable Supreme Court of India dated May 10, 2012 on the Writ Petition (Civil) No. 260 of 2005 of Aruna Rodrigues Vs Union of India, a Technical Expert Committee (TEC) was constituted by the Honourable Supreme Court of India. The Honourable Supreme Court of India had also fixed seven Terms of Reference (TOR) for the TEC to examine and submit a report to the Honourable Supreme Court within three months with effect from 12th May 2012. The Honourable Supreme Court had also directed that in the event and for any reason whatsoever, the Committee is unable to submit its final report to the Court within the time stipulated in the Order, the Committee should instead submit its interim report within the same period to the Court on the following issues: "whether there should or should not be any ban, partial or otherwise, upon conducting of open field tests of the GMOs? In the event open field trials are permitted, what protocol should be followed and conditions, if any, that may be imposed by the Court for implementation of open field trials. "

The present report is an **interim report** submitted by TEC. The recommendations of this report were arrived at by consensus of all the five members of the TEC.

General Considerations

GM technology comes with the promise of a number of benefits as well as associated risks with regard to health and environmental safety. These risks need to be clearly recognized and addressed in order for GM products to gain societal acceptance and the potential benefits to be realized. Given the novelty of the technology and the issues of food safety as well as possibility of effects on and transgene spread to other organisms, it is important that safety

analysis also identifies areas of uncertainty and suggest strategies to address these uncertainties. India is a signatory to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity. Article 1 of the CPB incorporates reference to Principle 15 of the Rio Declaration (1992) on Environment and Development that states:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The objective of Article 1 is specified as under:

" *In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements"* (<https:bch.cdb.int/protocol/text/article.shtml?a=cpb-01>).

The Article 10.6 and 11.8 state:

"*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on conservation and sustainable use of biodiversity in the Party of import, taking into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of the LMO in question …, in order to avoid or minimize such potential adverse effects"* (https://bch.cdb.int/protocol/cpb_faq.shtml).

The Precautionary Principle and potential for risk to the environment, biodiversity, and human health is thus clearly recognized by India and it is incumbent upon the national regulatory process to incorporate steps to ensure

that potential biosafety risks should be identified and minimized. It is the view of this Committee that such steps should be included from the conceptualization and design stage of a GM product right through its development, biosafety evaluation, and upto and **after its commercial release, including post-release monitoring.** In fact, a comprehensive assessment including a risk assessment should start from an assessment of need for the product/technology, and encompass a socio-economic analysis that includes the impact that the product would have on different sections of society and the economy. This is particularly important for GM foods given the novelty of the technology and the far reaching consequences that the cultivation and use of GM crops can have. As will be discussed below (Annexure I), it does not always follow that a particular technology will lead to a benefit for all users of the technology/product and others who are impacted. In the case of herbicide tolerance which was introduced to eliminate the need for manual weeding, the technology has been used mainly in scenarios where the farm size is very large (hundreds of acres). Its relevance to India where average farm size is much smaller (around 2.5 acres) has been seriously questioned. On the other hand introduction of Ht transgenics may also lead to health and environmental risk. Moreover, the use of herbicide tolerant crops would also take away a source of employment in rural areas for the weaker sections (mostly rural women); so it is not at all clear whether herbicide tolerant crops would benefit a broad spectrum of Indian farmers.

Given the broad range of possible products that GM can be used to create, biosafety issues need to be addressed on a casewise basis, taking into account, the transgene(s) being introduced, the crop, and the specific transgenic event, and the predominant traditional agricultural systems in India. Some of the issues involving health and environmental safety include the possibility of effects that may not be immediately apparent and require long term study, so it is important to recognize that safety analysis does not stop with approval for commercial release, and that post-release monitoring of environmental and/or health safety needs to be continued even after approval for commercial release. Post-release monitoring also provides valuable information that would have a bearing on longterm effects and sustainability of

a GM product and should be made mandatory. At the same time, it needs to be recognized that it is very difficult to guarantee that a product will **be entirely risk-free**. Biosafety evaluation would therefore need to assess risks, identify uncertainties, and balance potential benefits against possible risks to the health of consumers, nontarget organisms, and environment.

Response to the Terms of Reference (TOR)

The TEC held its first two meetings at MoEF, Paryavaram Bhavan, Delhi where the terms of reference, scope of work, and components of the task were discussed. The TEC also drew attention to the need for certain clarifications in the TOR as detailed in the minutes of the first meeting. As per the decisions taken in the first meeting, in accordance with the direction of the Hon'ble Supreme Court, invitations were sent to the petitioners, government of India respondents, and experts whose knowledge and experience were considered of relevance and importance by the TEC. This was followed by three meetings of two days each at the Centre for Cellular and Molecular Biology (CCMB)[1], Hyderabad where the TEC held deliberations and heard depositions from respondents and experts including petitioners, Government of India representatives, civil society groups, NGOs, representatives of industry, media persons of proven expertise, and farmers associations. A list of those deposing/submitting materials before the committee is provided as Annexure II, along with a list of submitted materials. In addition a number of respondents sent in written submissions. The members of the TEC then considered the submissions and information that had been collected, including consultations and discussions over the phone and by email. They then prepared their points and held two meetings over four days to discuss, and assemble the report in the light of their understanding and views. In view of the complexity of the issues and the number of factors involved, the TEC is of the view that a lot more time is required to arrive at a set of recommendations that addresses all the TORs in sufficient depth and detail.

[1] The choice of CCMB as venue was with the concurrence of MoEF and was based on the availability of facilities on site including guesthouse accommodation, and infrastructure support for holding meetings and extended discussions so as to enable the work of the TEC to be carried out in an efficient manner.

Therefore the committee opted to submit an interim report as directed by the Hon'ble Supreme Court.

For the purpose of the interim report, the TEC has considered those issues that relate to the conducting of field trials and food safety and exposure to the environment that have been raised by the petitioners. The TEC has also examined some of the biosafety data that is available from the GEAC website that provides an idea of the biosafety evaluation process, as one of the dimensions for making specific recommendations.

Biosafety and Field Trials

The process of making transgenic plants involves generating transgenics in the laboratory followed by growth of transgenic plants in the greenhouse where initial selection of promising candidate plants showing the desirable properties is carried out and those plants that show obvious defects are eliminated. However, to shortlist the transgenic plants for the best agronomic performance, a further round of selection called "event selection" needs to be performed. Event Selections are typically performed on families of small number of plants (of the order of a hundred or less), each family or line representing progeny/descendants of a single primary transgenic plant.

Some of the respondents who deposed before the committee have indicated that event selections cannot be performed in the greenhouse as performance in field conditions can be quite different from that in the greenhouse. The TEC in its own deliberations learnt that in other cases, event selections have been done under contained conditions in the greenhouse. The TEC is therefore of the view that event selections should be performed under contained conditions in the greenhouse (specially designed) as far as possible. The TEC recommends some basic laboratory-based tests relating to toxicity and allergenicity (e.g. Ames test, micronucleus test for genotoxicity, allergenicity screening) should be carried out on the selected events while they are in contained conditions in the greenhouse. In case the developer finds that event selection cannot be done in the greenhouse under contained

conditions, they should apply to the regulator giving specific reasons why the tests cannot be done in the greenhouse. In this case the preliminary laboratory-based biosafety tests would need to be done on all the material that is proposed to be subjected to event selection, while it is still under containment (i.e. prior to performing event selections outside greenhouse containment). In any case, the event selections should not be done on leased land or in farmer's fields, or in areas that are in close proximity to farmer's fields. Event selections should only be **done at a designated location**, which has been certified by the regulatory agency. Once the events have been selected, biosafety and toxicity studies on the selected events should be carried out.

With regard to the sequence of testing for biosafety, the TEC has been informed that the "Guidance Document for Information/Data Generation and Documentation for Safety Assessment of Regulated Genetically Engineered (GE) Plants" is what is operationally being followed for the last approximately four years. This is a draft document that is still under discussion in GEAC, outlining the biosafety tests and the sequence in which these are to be carried out. The document as it stands does not direct the applicant to conduct any *experimental* biosafety tests on the transgenic plant *before* the Biosafety Research Level I and II (BRLI/BRLII) field trials. The studies required to be done before BRLI/BRLII relate to descriptions of the genetically engineered plant, the biology of the non-transgenic host plant, the genetic modifications and how the genetic modifications were introduced into the organism, an assessment of possible toxicity and allergenicity based on theoretical considerations, and an experimental confirmation that the new trait is stable and inherited over successive generations. All experimental biosafety information is to be obtained either in parallel or during the course of BRLI and BRLII trials. Thus, there is nothing in the present guidelines that requires any experimental biosafety tests to be carried out before the start of field trials. This is a serious weakness in the present guidelines.

The TEC is of the view that some basic information on biosafety is required before field trials and that it is necessary to carry out some tests for biosafety before the BRLI trials. These should cover food safety and toxicity

tests on rodents (rats) and include sub-chronic feeding studies. The TEC also recommends that those studies listed in the guidance document under checklist 12 (Molecular Characterization of the Genetically Engineered Plant), checklist 13 (Assessment of Possible toxicity – Proteins), and checklist 14 (Assessment of Possible Allergenicity) should be done prior to BRLI. Material to be used for sub-chronic feeding studies may be grown under the same conditions as Event Selection trials. Taken together, the results of these studies should provide preliminary information with regard to food safety and toxicity of the transgenic plant.

Although longterm feeding studies are not part of the current set of tests, the TEC is **of the view that both longterm and intergeneration feeding studies in small animals (e.g. rodents) should be included in the set of tests.** The need for this is highlighted by the fact that food is something that is consumed throughout the lifetime of individuals, and longterm studies are, therefore, essential for determining safety including at **different stages of development starting from conception to end of the life cycle.** The early stages of development and reproductive phases are particularly sensitive and it is quite possible that some risks may come to light only in long-term studies and therefore the TEC is of the view that the inclusion of these tests is justified. Longterm and and intergeneration studies may be done after the start of BRLI.

A second point of concern is the process of choosing a site for conducting BRLI/BRLII trials. The TEC notes that in the Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants (2008), the site selection is left entirely to the applicant (Permitted Party) whose responsibility it is "to ensure compliance with all of the terms and conditions for authorization of a confined field trial" (p10, Section 7). According to the Guidelines, the applicant is also allowed to subcontract the testing to another party. **The TEC is of the view that the policy of delegating responsibility by leaving the choice of site selection to the applicant and also allowing the work to be subcontracted is contrary to the basic safety requirements and is most likely to lead to**

violation of the conditions of safety. Both practices should be halted immediately. The regulator should designate a certain number of sites in ICAR institutes or State Agricultural Universities where the required conditions of isolation are established and certify that these are the sites for BRLI/BRLII trials. Sites in the company's premises may also be considered for certification for trials. These designated sites should be used only for growing GM plants and **not** the non-GM crops so as to avoid contamination of non-GM by GM seeds. In any case BRLI/BRLII trials should **not** be conducted in farmer's fields and this practice should be immediately stopped including those trials that have been already approved.

Examination of biosafety data

In order to examine the tests that have been done and how biosafety issues have been addressed as part of the evaluation process leading to approval, the TEC examined the toxicology data on Bt transgenic cotton hybrids that have been approved for commercial release. The approved material for which data is publicly available (igmoris.nic.in) comprises six different Bt hybrid cotton events.

The TEC found several instances where the number of samples was less than the prescribed minimum value resulting in a reduction in the quality and sensitivity of the test (e.g. Mahyco Cry1Ac (HD73) vol 1: p161-173: Tables-17-42). In other cases, there were significant differences in biological indicators such as blood cell parameters (WBC and RBC counts), tissue and organ health and integrity, and milk yield between Bt and control samples. Small but consistent changes in some bio-indicators were discernable and which appear not to have received due attention for possible impact. It is necessary to point out that even small but consistent and apparently insignificant changes in a set of indicators, if observed repeatedly in different but related experimental situations, become important and these would require further testing. Some of the problematic issues that the TEC found are similar to those that have been pointed out in the case of Bt-brinjal by others, including international experts, and which contributed to the declaration of a

moratorium on Bt-brinjal. The TEC is of the considered view that taken together these findings point to serious weaknesses in the review of safety data by the regulator. The TEC also noted that the mode of feeding of a powder that has not been characterized, by gavage does not reflect the human mode of consumption of brinjal.

Post-release monitoring

A further issue which requires serious attention is the fact that a broad-based post-release monitoring of Bt cotton does not appear to have been carried out. Given that the technology is novel and represents the first introduction of a GM crop in India, this should have been undertaken from the beginning. Based on the information the TEC was able to get related to post-release monitoring, there has been only limited post-release studies with regard to the emergence of resistance and secondary/new pests whereas other factors such as effects on non-target organisms, soil microflora, fertility, and performance under irrigated vs non-irrigated conditions have not been extensively studied. This is an important requirement which has not been addressed so far.

Strengthening the Evaluation Process

In considering the areas where the evaluation process needs to be strengthened, the TEC has identified three major factors that require attention:

Apparent lack of qualified full-time personnel in the regulatory bodies

A basic question that can be asked is "Who in the regulatory bodies (GEAC and RCGM) undertakes the detailed scrutiny of the data in the safety dossiers?" RCGM and GEAC, the two committees responsible for review and safety evaluation consist of about 30 members each and the TEC has been informed that the examination of the applications is done primarily by the members. The members are from various public sector institutions, universities, and government departments. Almost all of them have other

primary responsibilities and are expected to be able to devote only a small fraction of their time to the matters that come before the GEAC/RCGM. The only member who may be working full-time for the GEAC is its Secretary, who is from the MoEF. The Secretary is supported by 1-2 officers whose role is mostly to provide administrative support to process applications and material that comes before the committee. The same is the case with the RCGM. Overall there is limited expertise in biosafety science and the capacity to critically evaluate the safety data being submitted by the applicants/developers. Given the voluminous amount and diverse nature of material that comes before these bodies, the TEC is not convinced that the regulatory bodies in their present form are in a position to rigorously evaluate and interpret all aspects of the data that comes before them. If this is indeed the case, and the applications are receiving only limited scrutiny, then the effectiveness of the entire evaluation process is called into question.

While a great deal of effort has been invested by DBT/MoEF in organizing and preparing documents and procedures for safety testing, including guideline documents, listing of tests and how to conduct them, formats etc., the actual operational mechanisms appear weak. Many of the responsibilities (including for field trials) seem to have been delegated or left to the applicant, and there seems to be very limited mechanisms and overall capacity to ensure compliance and accountability. The impression of the TEC is that the evaluation process has a pipeline which lays down a set of procedures and steps but is short on substance and requisite rigour.

The regulatory body would need a dedicated team of scientists who are well qualified in the science of biosafety, environmental impact, and socio-economic aspects to scrutinize and take responsibility for examining the safety data and dossiers. The examination process should ensure **with accountability**: (i) that the data are of a sufficient scientific standard and (ii) that the data are analyzed rigorously so as to determine whether or not they establish the biosafety. The examiners should sign and certify that the data have been examined and point out the deficiencies if any. This should not be left in an informal way to the committee whose members cannot be

reasonably expected to scrutinize all the data at the necessary level of detail. The committee's job would be to provide additional inputs and oversight to the evaluation process.

Need for removing conflicts of interest

For the regulatory process as a whole to have public confidence (this is a must on something as fundamental as food safety), it is important for the regulatory structure to be free of conflict of interest. The fact that a major regulatory arm, the RCGM is located within DBT is at variance with this requirement, given that DBT's mandate is to promote and support biotechnology and the development of biotechnological products including GM crops. The location of RCGM within DBT significantly compromises the regulatory process and this is independent of how good a job RCGM may in fact be doing. It is neither in the interests of the regulatory body nor DBT for the latter to be associated with the regulatory process. Whereas RCGM can continue to be involved in evaluation of applications for research projects, when it comes to product development, RCGM should not have a role. The regulatory body for GM products should be located entirely outside of the DBT, and a suggestion is that it could be either in the MoEF or Ministry of Health and Family Welfare or both (environmental and health safety respectively). It is also important that members of the regulatory bodies should not have any interests, explicit or implicit, in the development/promotion of transgenic products that would be deployed commercially.

Broadening perspectives and increasing inclusiveness of stakeholders with regard to decision making on GM products

GM food impinges on agriculture and society in very many ways and the regulatory and decision-making process has to include representation by a larger set of stakeholders from an early stage itself in order to: (i) identify scope of issues and address these in a way that meets the concerns of all stakeholders; (ii) build trust, (iii) achieve an understanding of the advantages and limitations so as to maximize benefits and minimize negative fallouts to stakeholders. If this is not done, then the process has a high likelihood to fail

as appears to have happened. In a country such as India where the number of stakeholders connected to agriculture is large, it would be highly appropriate to have wider representation in the regulatory body (GEAC) so as to include agricultural economists, sociologists, members of civil society, farmers representatives, representatives of organizations working on agriculture and farmer-related issues, besides technical experts in toxicology, cell and molecular biology, ecology, and plant breeding (see Annexure I for an example on possible impact of GM on export related issues).

Recommendations of the TEC

(a) General:

The TEC deliberated on a number of issues related to the field trials and regulatory processes. All the members of the TEC unanimously felt that the present regulatory system and protocol for conducting the field trials was unsatisfactory and inadequate, requiring major changes, restructuring, and strengthening. These include removal of conflict of interest as discussed earlier (page 11), designation and certification of specific sites for conducting field trials, and access to a panel (in the short term), along with development of a secretariat (in the long term) of qualified scientists for scrutinizing and analyzing the safety data. There was also a need to include some basic laboratory based toxicity and allergenicity tests under contained (greenhouse or laboratory) conditions before the GMO is released for field trials in containment. Furthermore, **additional toxicity tests comprising longterm and intergenerational studies should be added to the existing requirement which stops at sub-chronic studies.**

Finally, the TEC draws attention to the fact that the Cartagena Protocol to which India is a signatory, recognizes the crucial importance of biodiversity and in taking all steps to preserve it as a longterm resource. If the rate at which GM cotton has proliferated in India is any indication of things to come, then it is highly likely that the introduction of transgenics in crops for which India is a centre of origin or a centre of biodiversity will contaminate the biodiversity and this should not be allowed to happen.

(b) Specific:

1. Given the findings of the TEC that there have been several cases of ignoring problematic aspects of the data in the safety dossiers, all biosafety data for applications in process as well as those that have been approved for release will need to be reexamined by scientists who are qualified in biosafety science and experienced in evaluation of biosafety dossiers for transgenic plants. If necessary, this should be done by international experts who have the necessary experience.

2. Longterm and intergenerational studies in rodents need to be added to the tests and performed for all products whether already approved or yet to be approved.

3. Acute and sub-chronic feeding studies for all applications including those in progress should be completed before BRLI, as also molecular analysis and allergenicity tests. If these studies indicate potential risks of any kind, the GM event should be rejected outright to save time, resources and contamination.

4. Genome-wide expression analysis in the toxicity studies of the test organism (e.g. rodent) that is being exposed helps to identify changes in biomarkers that are indicative of toxicity. This is an important test to be included as biomarkers are sensitive indicators and are capable of revealing changes before visible symptoms appear.

5. The regulator needs to designate and certify a defined number of sites in different parts of the country to be used for BRLI/BRLII trials. All BRLI/BRLII field trials should be carried out only at these sites. These sites should be used only for growing GM plants and not the non-GM material. Trials should not be conducted in farmer's fields. This also applies to those trials for which permission may have previously been given by the regulator.

Keeping all these in view, the TEC is unanimously of the view that all field trials should be stopped until the following conditions have been met as discussed above:

i) Specific sites for conducting field trials have been designated and certified and sufficient mechanisms for monitoring the trials put in place.

ii) A panel of scientists, qualified in evaluation of the biosafety data of Genetically modified crops has been engaged for scrutiny and analyses of the safety data.

iii) Conflict of interest in the regulatory body has been removed as discussed above.

iv) The requirement for preliminary biosafety tests prior to field trials including sub-chronic toxicity in small animals has been included.

6. Outsourcing/subcontracting of field trials should be banned.

7. Assessment of need should be carried out for products/technologies and involve analysis by scientists, agricultural economists, sociologists, farmers' representatives and agriculture department officials.

8. Representation on regulatory bodies should be expanded as discussed above.

In addition the TEC recommends the following with regard to certain classes of products:

9. Based on the current overall status of food safety evaluation of Bt transgenics including the data on Bt cotton and Bt brinjal examined by the TEC and in accordance with the precautionary principle, the TEC recommends a ten year moratorium on field trials of Bt transgenics in all food crops (those used directly for human consumption).

The TEC is of the view that a period of ten years is a reasonable length of time for restructuring and operationalization of a strengthened regulatory regime, developing a cadre of experts in areas of relevance to food safety evaluation, environmental impact assessment etc. It is also expected that during this time additional data should emerge relating to post-release monitoring, and longterm toxicity tests as proposed above. The issue may be reappraised at that time.

10. In view of the concerns bearing on health, environmental, and socioeconomic considerations, the TEC recommends a moratorium on field trials of herbicide tolerant (Ht) crops until an independent committee comprising of experts and stakeholders has examined and assessed the potential impact of Ht-technology and its suitability in the Indian context.

11. India is a signatory to the Cartagena Protocol which recognizes the crucial importance of biodiversity as a longterm resource. The TEC accordingly recommends a ban on field trials of transgenics in those crops for which India is a centre of origin or a centre of diversity, as transgenics can contaminate and adversely affect the biodiversity.

The above comprises the interim report of the TEC relating to the conduct of field trials and the conditions to be imposed. The TEC has also felt it necessary to comment on the regulatory process as a whole since that is an overarching issue that also bears on the field trials and their evaluation. The remaining TORs will be addressed in the final report.

Dr. P.S. Chauhan

Member

Prof. P.C. Kesavan

Member

Prof. P.S. Ramakrishnan

Member

Dr Imran Siddiqi,

Member

Dr. B. Sivakumar

Member

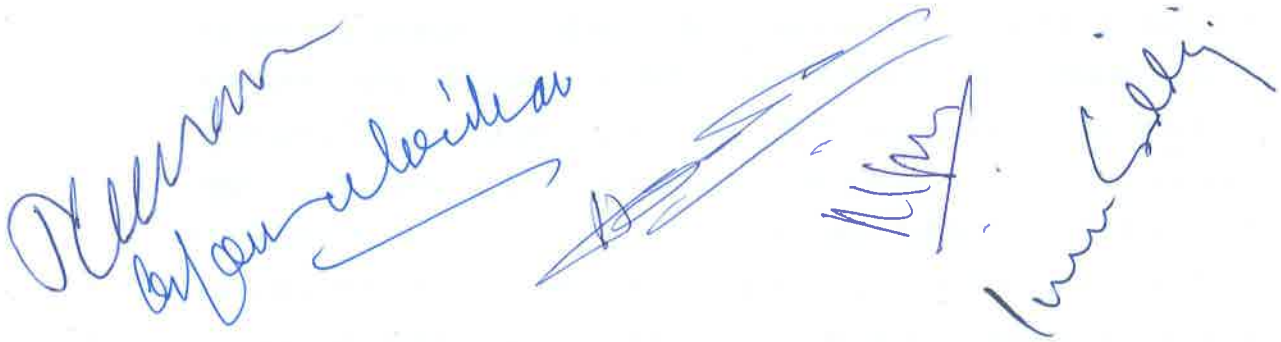
Oct 7th, 2012

Annexure I -- Need, Socioeconomic Assessment , and Post Release Monitoring

Need and socioeconomic assessment is a critical thing that needs to be done at a preliminary stage, well before the product has been developed. The regulatory body must anticipate the possible impact a product can have on society and particularly the farmer, rather than being driven purely by general technical considerations and adopting a laissez faire approach, assuming that a successful technology will also lead to a successful product that will benefit society as a whole. Examples of questions that need to be asked include: In what product context is the technology to be developed and used? Whom will it benefit and to what extent? Whom will it not benefit? Is it likely to pose a risk or hazard to a section of farmers or society? What is the extent of that risk and can it be avoided? Some of these factors also need to be examined through post-release monitoring which provides important information on environmental and societal impact of usage of the GMO. Post release monitoring has been almost completely absent.

There have been reports that Bt cotton hybrids currently deployed (in India all Bt cotton so far has been been deployed as hybrids and not as straight varieties) are not suitable for rainfed (non-irrigated) areas which are scarce in water as the projected high yield is highly sensitive to the availability of water. In rainfed areas if rainfall has been low and the soil is dry by late season when boll setting takes place, then yield can be greatly reduced. Coupled to the high input costs for Bt hybrids, including seed and fertilizer, and large fluctuation in yield in rainfed areas, this can result in putting the farmer at greater risk. This has been considered an important contributing factor to farmer distress and suicides. Has this been considered at all in the decision making process on regulation? The TEC's understanding is it probably has not and yet it can have such a major impact. Post-release monitoring of the performance of Bt-cotton (the first GM crop to be released in India) has not been done under different conditions which could have revealed some of these factors.

Another factor is the possibility of contamination of non-GM food by GM food. In India given the small plot size and relative lack of control in harvesting, storage, transport, it is likely that such contamination would be high. Organic farmers whose products need to be certified as being free of chemicals/pesticides and non-GMO would be particularly strongly affected. In 2011-12 India was the largest exporter of rice in the world. If we assume that contamination will be high, how will it affect the non-GM product. In case of e.g. export of Basmati and non-Basmati rice, what will happen? If the rice is contaminated with GM rice, then essentially India stands to lose the entire European market. The total value of rice export from India worldwide is about Rs. 14,000 cr. (2011-12 data). If the value is small and much less than projected benefits, that is one thing, but if it is high then it could do grave damage. To the best of the TEC's knowledge this possibility has not been considered by regulatory bodies when allowing development of transgenic rice in India which is presently in full swing and there are several applications before GEAC. Is there a mechanism for compensation of the farmer whose product is affected, and who would pay the compensation? To the best of the TEC's knowledge there are no statutory mechanisms in place to address these issues.



Annexure II – List of Respondents and Submissions

1.	Ms. Aruna Rodrigues:	Slides and written submission
2.	Dr. G.V. Ramanjaneyulu (CSA):	Slides and written submission
3.	Ms Kavitha Kuruganthi:	Slides and written submission
4.	Dr. Sagari Ramdas (ANTHRA):	Slides and written submission
5.	Dr. Ramesh V. Sonti (member, GEAC):	Written submission
6.	Dr. Pushpa M. Bhargava:	Written submission
7.	Mr. Rajesh Krishnan (Greenpeace):	Slides
8.	Dr. Usha Barwale and team (Mahyco):	Slides and written submission
9.	Mr. Raju Kapoor and team (National Seeds Assocn. of India):	Slides and written submission
10.	Dr. K.K. Narayanan (Metahelix):	Slides
11.	Dr. Ranjini Warrier (GEAC):	Written submissions
12.	Dr. Balasubramanian (TNAU):	Slides
13.	Dr. N. Seetharama (ABLE):	Slides and written submissions
14.	Dr S.R. Rao (DBT):	Slides and written submission
15.	Prof. Deepak Pental (Univ of Delhi):	Slides
16.	Prof. Swapan Datta (ICAR):	Slides
17.	Dr. O.P. Govila (DoA):	Slides
18.	Mr. K. Nageswara Rao:	Written submission
19.	Mr. P. Sainath:	Print material and visual media
20.	Mr. P.V. Satheesh (Deccan Dev Soc):	Media and written submission
21.	Prof. Asis Datta:	Written submission
22.	Dr. Vandana Shiva:	Written submission
23.	Dr. Suman Sahai:	Written submission

24. Dr. R.R. Hanchinal (UAS Dharwad): Written submission

25. Prof. Jack Heinemann: Written submission

26. Dr. Doug Gurian-Sherman: Written submission

27. Dr. David Andow: Written submission

28. Dr. Keshav Kranthi (CICR): Written submission

29. Dr. V.S. Vijayan (Salim Ali Foundation) Written submission

30. Department of Agriculture Written submission

31. Mr. P. Chengal Reddy (CIFA) Written submission