

SUPREME COURT OF INDIA

NEW DELHI

DATED : 18<sup>th</sup> July, 2013

FROM : Assistant Registrar , PIL (Writ)

To

1. Mr.' Prashant Bhushan, Advocate, 301, New Lawyers Chamber .
2. Ms. Anil Katiyar, Advocate, Central Agency
3. Mr. A. P. Medh, Advocate, 22, Lawyers Chamber
4. Mrs. Sreekala G.K., Advocate, D-29, (FF), Gulmohar Park, New Delhi- 110049. "
5. Mrs. Anitha Shenoy, Advocate, 102, New Lawyers Chamber
6. Mr. Subramonium Prasad, Advocate, 104, Lawyers -Chamber

IN THE MATTER OF:

WRIT PETITION (CIVIL) NO. 260 OF 2005  
(Under Article 32 of the Constitution of India)

Aruna Rodrigues & Ors.etc ...Petitioners

Versus

Union of India, & Ors. etc ...Respondents

WITH

WRIT PETITION (CIVIL) NO.115 QF 2004  
(Under Article 32 of the Constitution of India)

AND

CONTEMPT PETITION ("CIVIL\*") NO.'295/2007

IN

WRIT .PETITION (CIVIL) NO. 260 OF 2005

Sir,

The Writ .Petition above' mentioned were listed before the Hon'ble Court' on 26.04.2013 when the Court was pleased to inter alia pass' the following order:

xx xx xx xx xx xx xx

As submitted by Mr. Paras Kuhad, learned Additional Solicitor General, let copies-of the Report be provided to the". Advo'cate-on-Record of the' respective parties;

xx xx xx xx xx xx xx"

Please find enclosed herewith, final report'dated 30.06.2013 alongwith Corrigendum dated 12.37.2013 sent by Technical Expert Committee(TEC)'.  
Yours faithfully,



12/07/13

The Registrar  
Supreme Court of India  
TilakMark  
New Delhi 110001

Subject: Corrigendum and Supplementary Material to the Final Report of the  
TEC viz. WP (Civil) No. 260 of 2005, Aruna Rodrigues vs. Union of India

Dear Sir,

Attached please find submission of Corrigendum and Supplementary Material comprising Response to the Affidavit. The material in the Response had been discussed at earlier meetings of the TEC and agreed upon by the members who have signed the report. Supporting letters from the members are attached.

It is kindly requested to release the Corrigendum and the Response to the Affidavit along with the Final Report sent earlier. The delay and inconvenience arising are highly regretted.

Thanking you,

Yours faithfully

Dr. Imran Siddiqi

On behalf of TEC

Corrigendum to the Final Report of the TEC viz. Writ Petition (Civil) No. 2600 of 2005, Aruna Rodrigues and Ors vs. Union of India

Words that are to be deleted in the originally submitted version are underlined and words inserted in the corrected version are also underlined:

1. page 17, line 4: "... we are not merely exposed by reared on food."  
Corrected: "...we are not merely exposed but reared on food."
  
2. page .18, lines 15-18: "If not possible (see Tor (c) below), they may be undertaken at a designated location that has been certified by the regulatory-agency under contained (restricted access) conditions i.e. those conditions under which confined field trials are to be performed (Tor d)."  
Corrected: "If not possible (see Tor (c) below), they may be undertaken outside greenhouse containment at a designated location that has been certified by the regulatory agency i.e. those conditions under which confined field trials are to be performed (TOR d)."
  
3. page 34, lines 26-27: "The inclusion of a vehicle control is ..."  
Corrected: "The comparison with a vehicle control is ..."
  
4. page 67, para 3, lines 6-8: "... the Norwegian system has an established commitment and experience in is one of the few that are attuned to considering socioeconomic issues..."  
Corrected: "... the Norwegian system has an established commitment and experience in capacity building in biosafety regulation and is one of the few that are attuned to considering socioeconomic issues ...".
  
5. page 69, lines 24-25: "... The completion of the risk assessment It needs to be pointed out..."  
Corrected: "... The completion of the risk assessment should be followed by preparation of an assessment report, duly signed and placed in the public domain. It needs to be pointed out..."
  
6. page 71, lines 3-5: "... exert a highly adverse impact over time on sustainable agriculture, rural livelihoods, and environment. The TEC finds them completely unsuitable in the Indian context."  
Corrected: "... exert a highly adverse impact on sustainable agriculture, rural livelihoods, and environment. The TEC finds them completely unsuitable in the Indian context and recommends that field trials and release of HT crops 'not be allowed in India.'"
  
7. page 71, lines 25-26: "It should be noted that has been advised ..."  
Corrected: " It should be noted that caution has been advised ..."

8. page 72, lines 19-21: 'The TEC therefore recommends that release of GM crops for which India is a centre of origin diversity should not be allowed.'

Corrected; "The TEC therefore recommends that field trials for commercial release (not research) of GM crops for which India is a centre of origin or diversity should not be allowed."

## Response of the TEC to the Affidavit

(with ref. to section 1-2, page 4, para 2 of the Final Report)

The Affidavit of the Union of India, filed by the DAC starts out with the overall premise that in order to achieve food security it is essential to increase food productivity and that in order to increase food productivity there is a need for GM crops. The affidavit then states that "... the 10 year moratorium on field trials of GM crops recommended by the TEC would mean a complete stop to agri-biotech research applications" and proceeds to list a set of consequences that such a ban would have. According to the affidavit the overall effect would be to set back progress in agricultural biotechnology in India to the point that it would be impossible to catch up and the damage would be irreversible. The affidavit then goes on to say that the interim report is scientifically flawed, lacks rigour, and has exceeded the mandate given by the Hon'ble Court. The affidavit further proceeds to state that the regulatory framework and processes in India are robust, and meet international standards. This is followed by a response to specific recommendations made by the TEC in the interim report and a discussion of the implications of the recommendations. The affidavit then concludes with a series of points making a case for the need to continue with field trials and reiterating concerns about the recommendations of the TEC.

The basis for the TEC's recommendations has been provided in the final report, and is briefly referred to here. The TEC found that a large number of applications in the Indian regulatory system were for Bt and HT including in food crops (Final Report, p10). This has implications for food security. The FAO definition of food security is "Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life". As discussed in the final report and summarized below, the TEC had concerns about the safety of Bt in food crops.

The major part of the case made in the affidavit rests on a misinterpretation of the TEC's recommendation by stating that the TEC had recommended a 10 year moratorium on GM crops. The fact is that the 10 year

moratorium was recommended only for Bt in food crops. The recommendation

Would not affect non-food crops such as cotton, castor, or rubber and other non-Bt transgenics in food crops, In Section 12B, the affidavit does correctly quote the interim report as recommending a ten year moratorium on Bt transgenics in food crops, however to the surprise of the TEC, this is mutated later in the affidavit to refer to GM crops in general! (Section 28), The intent of the TEC's recommendation was to not have commercial release of Bt food crops until their overall safety was established. This point has been further clarified in the Final Report where the recommendation is for a moratorium that is specifically directed towards commercial products and not research (consistent with the requirement for further research to address biosafety of Bt food crops). The time period for biosafety of Bt in food crops to be established has been left open in the final report. The recommendation of the TEC in the interim report (and in the final report) is for a limited class of transgenics and certainly not for all GM crops or transgenes. The larger case made in the affidavit that agricultural biotechnology as a whole in the country would be irreversibly set back is entirely without basis. The TEC would like to respectfully submit to the Hon'ble Court that none of the TEC's recommendations would place a block on research. A majority of the research involving gene identification and characterization takes place under contained conditions in the laboratory and greenhouse and it is only the later stages of testing and product development that require field trials. Field trials for noncommercial . research purposes would also not be affected by the recommendations of the TEC, thereby allowing advance in knowledge to occur freely. The restrictions recommended by the TEC are for a specific class of products that are directed for commercial release and which the TEC believes pose significant risks. On the other hand, if the future of agricultural biotechnology in India is seen by the DAC and Union of India to rest on the narrow foundation of Bt transgenics in food crops, then that itself is a cause for serious concern.

Coming to the question of whether the TEC recommendations exceed the mandate, the recommendations are derived from: (i) the TEC's conclusion



toxicity studies which the TEC has pointed out in the final report. This is being

Recognized as such based on recent work ([http://www.eufoodpolicy.com/cgi-bin/view article.pl?id=5590](http://www.eufoodpolicy.com/cgi-bin/view%20article.pl?id=5590)) and is also finding inclusion in risk assessments elsewhere (e.g. [http://qenok.no/wp-content/uploads/2013/03/H 75 Gen%C3%98k 19.04.13.pdf](http://qenok.no/wp-content/uploads/2013/03/H_75_Gen%C3%98k_19.04.13.pdf)) and should be included as one of the issues to be addressed in the testing process. The TEC is duty bound to bring this to the notice of the Hon'ble Court and make a specific recommendation to address this issue as desired by the Court, (ii) Given that a large number of applications are for Bt and HT in food crops, the implications of these need to be considered. The TEC disagrees with the interpretation implicit in the affidavit that 'tests' should be limited to narrow technical questions such as separation distances in field trials and protocols thereof. An important set of 'tests' that are missing from the considerations is an assessment of need, sustainability, and socioeconomic considerations taking into account available alternatives which has been pointed out in the final report. Given the significance of agriculture to Indian society, it is not out of place in the regulatory process to ask whether a GM product or technology such as for example HT is really needed in India and to assess what would be the impact and consequences of adoption, especially since the effects are likely to be large and potentially disruptive at various levels. This is unfortunately missing from the current evaluation process and needs to be included. When the TEC examined HT technologies as discussed in the final report, it came to the definite conclusion that these would not be appropriate for India and accordingly made a recommendation to the Hon'ble Court in the final report. Unfortunately the TEC is not able to accept the position of the DAC that the regulatory processes are robust, and reasons for this are provided in the final report in the section on study of the safety dossiers.

The affidavit also comments on specific recommendations of the TEC with regard to the conduct of field trials and related issues: Points 1 and 8. Specific sites for conducting field trials - The affidavit states that sites are selected in consultation with State Agricultural Universities and consent of the State Govt, and not fully left to the applicant. It also states that no site can be a pre-designated site and that the trials are monitored by the Central Compliance Committee. In point no. 8 of the response it is stated

that field trials are not permitted in farmers' field unless it

TEC comments: The TEC has serious concerns about choosing sites ' for GM trials from a wide range of possibilities and continues to recommend that field trials should be conducted in a limited number of locations and only on land that is publicly owned and permanently set aside for the purpose of GM crop trials. Conducting trials on land that is under private ownership (farmer or other third party) runs the risk of contamination taking place if the land is used later to grow another crop. Notwithstanding the assurances in the affidavit regarding monitoring, there have been reports in the media of field trials taking place in violation of the stipulated conditions and it would be advisable to avoid that to the extent possible. The TEC was informed in the course of discussions that the so-called long lease may not be all that long (possibly only three years). If this is correct, then the period is certainly not sufficient, as contamination can take place from leftover seed in the field for several years after use, notwithstanding all the measures that may be taken after harvesting to destroy the material. For example rodents and ants are capable of transporting seed several feet deep into the ground from where it can emerge later. Since the number of field trials at present is few, a beginning should be made to bring these into a publicly owned system that is under control of the regulator.

Point 2. Panel of scientists qualified in biosafety data to be engaged -

The affidavit recognizes that evaluation requires a team of multidisciplinary experts and states that such expertise is available within RCGM and DBT which have the necessary expertise to perform a thorough risk assessment. The affidavit also states that a roster of experts is under consideration in GEAC.

TEC comments: The TEC does not accept that the risk assessment can be done by the members of RCGM/GEAC as this requires full time commitment and also specific training in biosafety and risk assessment, not merely area expertise in different areas of biology and agricultural sciences which RCGM/GEAC certainly has. In the Final Report, the TEC has recommended consultation with an established and internationally reputed

risk assessment body to develop a suitable framework for a regulatory system

That meets international standards. It is important that this is done so that the regulatory system actually meets international requirements rather than simply asserting that it does. The TEC is very clear that the present system does not meet international requirements and the evidence is before the Court in the Final Report.

Point 3. Conflict of interest - The affidavit states that this is outside the terms of reference (TOR) and goes on to provide general comments on various tasks performed under the ministries and departments of the Govt. It also states that it is important to associate experts who are involved in research and development of GM crops and that the GEAC has put in place a mechanism to avoid conflict of interest.

TEC comments: Although conflict of interest was not explicitly stated in the TOR, it was apparent, to the TEC that it was present in the structure of the regulatory system as stated in the interim report and may have a bearing on the evaluation process. Conflict of interest in the GEAC has also been noted in the Sopory Committee Report, 2012. Conflict of interest can exist at different levels: in the larger structure - if the goals of the department within which the regulatory body is located are connected to the matters that come before the regulatory body, then this can affect the decision making process; if the members of the regulatory body have an interest in activities and organizations that come before the regulatory body then that can also affect the process. The evolution and functioning of regulatory frameworks has been the subject of research, and mixing of industry/product development goals

- within the overall goals and responsibilities of the regulator have been advised against (Millstone, E. and van Zwanenberg, P. 2002. The evolution of food safety policy-making institutions in the UK, EU and Codex Alimentarius. Soc. Pol. Admin. 36, 593-609). In this regard, the association of experts who are involved in GM product development should be avoided. They can be consulted but it should be only with regard to specific issues or criteria as raised with regard to matters that come before the regulator.

Point 5. Broadening of expertise within the regulatory body - The affidavit states that the expertise available in the GEAC and procedures laid

down are adequate to evaluate the safety of GM crops.

TEC comments : The purpose of suggesting broadening of expertise was to bring in stakeholder participation, socioeconomic considerations, and assessment of impact the product/technology would be likely to have across the cross-section of Indian farmers. It is important that this is included within the overall dimensions of risk assessment. The risk assessment also needs to be more structured with the completion of the risk assessment culminating in a report.

Point 6. Ten year moratorium for field trials of Bt transgenics in food crops - The affidavit states that the recommendations lack scientific rationale, and the basis is not clear.

TEC comments: The rationale for the recommendation was that based on examination of the data, the TEC concluded that the health safety studies of Bt cotton and Bt brinjal did not establish their safety as has been discussed in the final report. There was also also the larger general question of the safety of Bt in food crops which would require more research including chronic toxicity studies to address. Unless this was done, further development of Bt transgenics in food crops for commercial release should not take place. This point has been further clarified in the recommendation in the final report wherein field trials for research purpose are allowed so that the research can be done to address this issue.

Point 7. Moratorium on field trials of HT crops until an independent evaluation of suitability in the Indian context had been done - The affidavit states that the recommendation of the TEC is based on unfounded perceptions.

TEC comments: For the purpose of the final report, the TEC has examined the benefits and risks associated with HT technology and come to the conclusion followed by a recommendation that the risks in terms of sustainability, environmental costs, and livelihood outweigh benefits and that the HT technology is not suitable in the Indian context and should not be allowed.

Point 9. Approval granted to Bt cotton events should be revisited - The affidavit states that TEC has recommended review of the Bt cotton approvals on the assumption that biosafety assessment was not adequate and post



release monitoring had been restricted to emergence of resistance (in the

Target organism) whereas effects on non-target organisms, soil fertility and performance under irrigated and un-irrigated areas had been ignored.

TEC comments: The TEC had recommended review of the data, but had not asked for a review of the approval. Nor had it said in the recommendations that approvals should be revisited because of lack of post-release monitoring and effect on non-target organisms. The purpose of an independent review would be to arrive at a better understanding of the basis of approval given the problems that the TEC had come across. Point 10.

**Post Release Surveillance**■- The affidavit states that the recommendation of the TEC with regard to post release monitoring is misplaced in the context of guidance for field trials. The affidavit submits that in India, no case specific parameters (for carrying out post release monitoring) have been prescribed as "results ... in other countries did not indicate the need to continue monitoring of non-target organisms ..." The affidavit also states that there has been no evidence of any observed decline in productivity and production in the cotton-wheat rotations in India.

TEC comments: It is not correct to dismiss the need for a thorough post-release monitoring based on reference to studies done in other parts of the world. After all, the Indian environment and non-target organisms are different from those elsewhere. The fact is that the significance of such studies was ignored and an opportunity to get important information on the environmental consequences of the first GM crop to be released in India was missed. The affidavit does not acknowledge the poor performance of Bt-cotton hybrids in rainfed regions which could have been identified by post release monitoring.

The affidavit then goes on to discuss alleged implications of the interim report, again based on the incorrect representation that the 10 year moratorium on Bt food crops field trials that the interim report recommended

extends to all GM crops.

Final report - regarding

pschauhan <[pschauhan1939@gmail.com](mailto:pschauhan1939@gmail.com)>

Fri, Jul 12, 2013 at 2:33 PM

To: imran Siddiqi <[imransiddi@gmail.com](mailto:imransiddi@gmail.com)>

To,  
The Hon'ble Supreme Court of India,  
New Delhi.

Subject: Corrigendum and Supplementary material to the Final Report of the Technical Expert Committee (TEC) appointed by the Hon'ble Supreme Court in the matter of Writ Petition (Civil) No.260 (2005) of Aruna Rodrigues vs. Union of India - in agreement with

Sir,

Subsequent to the submission of the final report on the 30 June 2013, a corrigendum to the Report and supplementary material as a response to the Affidavit, Union of India, which has been thoroughly discussed amongst the Members is being submitted. I have gone through both and fully agree with the contents there in.

With regards .  
Faithfully yours

PSChauhan  
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Nerul (West),Navi Mumbai - 400706  
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(no subject)

PC Kesavan-MSSRF <[pckesavan@mssrf.res.in](mailto:pckesavan@mssrf.res.in)>

Fri, Jul 12, 2013 at 4:39 PM

To: Imran Siddiqi <[imransiddi@gmail.com](mailto:imransiddi@gmail.com)>

Prof. P. C. Kesavan

Member, Technical Expert Committee (TEC)

To

The Honourable Supreme Court

Dear Sir,

**Subject:** Corrigendum and Supplementary material to the Final Report of the Technical Expert Committee (TEC) appointed by the Honourable Supreme Court in the matter of Writ Petition (Civil) No.260 (2005) of Aruna Rodrigues vs. Union of India.

Subsequent to the submission of the final report on the 30<sup>th</sup> June 2013, a corrigendum and supplementary material comprising Response of the TEC to the affidavit filed by the Ministry of Agriculture, Union of India are being submitted to the Honourable Supreme Court. I have gone through these and fully agree with these.

Thanking you

Yours faithfully

P.C. Kesavan

Prof. P. C. KESAVAN

Emeritus Professor, IGNOU, New Delhi &  
Distinguished. Fellow

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my agreement

**P S Ramakrishnan** <[psr@mail.jnu.ac.in](mailto:psr@mail.jnu.ac.in)>

Thu, Jul 11, 2013 at 5:16 PM

To: Imran Siddiqi <[imransiddi@gmail.com](mailto:imransiddi@gmail.com)>

The Honorable Supreme Court of India, New Delhi

Dear Sirs:

Subsequent to our submitting the final report, on 30th June, 2013, there has been a requirement of a corrigendum and supplementary material to be submitted. I agree to the contents of this.

Yours truly

P.S. Ramakrishnan