

## Pro-GMO Activism and Smears Masquerade as Journalism: From Seralini to Jairam Ramesh, Aruna Rodrigues Puts the Record Straight

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Asia-Pacific Research, June 17, 2018

Region: <u>South Asia</u> Theme: <u>Environment</u>, <u>Justice</u>

The Print is a Delhi-based, online news magazine that began operations in August 2017. On 9 June, it published a <u>short article</u> by **Sandya Ramesh** under the title 'EU study trashes anti-GM paper by French expert who **Jairam Ramesh** cited to ban Bt Brinjal'.

Sandhya Ramesh is a senior assistant editor (science) at The Print. Preceding the piece was the headline: 'EU investigation of the paper by Gilles-Éric Séralini comes as much-needed validation for scientists and farmers in India who have been pushing for GM crops.'

It set the tone for what followed: a careless and misleading attempt to rubbish the scientific research of **Professor Gilles-Éric Séralini** along with the decision in 2010 taken by Jairam Ramesh to stop the commercial cultivation of Bt brinjal. This would have been India's fist genetically modified (GM) food crop. Jairem Ramesh was at the time Minister of the Environment and Forests (MoEF).

Shortly after the publication of the piece, environmentalist Aruna Rodrigues submitted a substantive rebuttal for publication by The Print (possibly in two parts, given the length). However, given that outlet's lack of response (to date), Rodrigues has decided to publish her refutation elsewhere.

The reason Rodrigues decided to respond is because she says:

"Readers have the right to expect fair reporting and a decent jab at the truth."

Sandhya Ramesh's piece fell short on both counts.

Image on the right: File photo of Jairam Ramesh | Commons via The Print



Rodrigues accuses Sandhya Ramesh of dubbing anything that is a proper critique of GMOs based on 'independent' science (the distinction is important) as the work of 'anti-GMO' activists. She argues that a properly researched piece would have entailed weeks of serious research into the various studies carried out by Seralini and his team over the last decade as well as the reappraisal of Bt brinjal (October 2009 to February 2010) ordered by Jairam Ramesh.

Both are daunting tasks by any standard. Yet, Rodrigues notes that no one involved in these matters was even approached by Sandhya Ramesh or interviewed for a briefing. What we have instead is an astonishing telling of alternative 'facts':

"Yet, it would be hard to find, even with a magnifying glass, a semblance of a factual basis in reporting the facts. Instead, we have 'instant' journalism that connects several imaginary dots. This article is clearly an unabashed support of GMOs and Bt brinjal. The problem with this position at present, is that the science, socio-economics and perhaps the most clinching, the empirical evidence worldwide, do not support such a position."

Aside from the distortions and misrepresentations, something that is conveniently missing from Sandhya Ramesh's piece (and similar pieces by others over the years) is any discussion of the role of industry in fuelling the push for GM, whether in India or elsewhere. All we tend to hear are accusations about anti-GM 'activists' (aka 'luddites') with an 'agenda', which is little more than industry-driven spin designed to deflect attention from how the global agritech corporations have undermined democratic processes and subverted science through their massively funded lobbying campaigns and high-level political clout. Nothing is ever said about this which is revealing in itself, nor anything about the <u>small army</u> of groups and 'journalists' it uses to propagandize, smear and write hit pieces on its behalf.

Instead, we must turn to the likes of <u>Steven Druker</u> or **Aruna Rodrigues** herself to shed light on this. Indeed, Rodrigues points out that Monsanto and industry influence have penetrated regulators and Institutions, including Indian Regulators (amply documented in the Supreme Court over 12 years). It includes EFSA (European Food Safety Authority) in a long list of proven conflicts of interest and the US Environmental Protection Agency, which has known for 30 years that Monsanto's glyphosate is an endocrine disruptor that causes cancer! These matters are currently under investigation as a result of several law suits in the USA.

Presented below is Aruna Rodrigues' direct response to the Sandhya Ramesh piece.

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#### Aruna Rodrigues' rebuttal of Sandhya Ramesh's article in The Print

The Seralini study of 2012 with its reverberations is well documented. I will limit myself to a few points made by Sandya Ramesh (SR). Of course, irrespective of the debate on the Seralini study of 2012, it is improper to link it with the Seralini **critique** of the raw data of Bt brinjal in 2008-09, an assessment that was subsequently published in summary in 'NatureNews' 2009. This was not a study!

#### The Seralini Study of 2012



Image on the left: Aruna Rodrigues (Source: firstpost.com)

The study was designed as a toxicological study, not as a carcinogenesis study. This is of great importance. Therefore, the tumour incidence and mortality results were reported, according to OECD guidelines for chronic toxicity studies, as secondary observations requiring follow-up using a study design intended to systematically assess carcinogenesis.

In November 2013, the editors of the journal *Food and Chemical Toxicology* (FCT) retracted Seralini's research paper, with implications for public, animal and ecosystem health against the desires of the authors. FCT created a new position, Associate Editor for Biotechnology, to which they appointed **Richard Goodman**, a past employee of Monsanto. The major agricultural biotechnology companies continue to fund his research at the University of Nebraska.

Goodman has been closely linked to the International Life Sciences Institute (ILSI), an industry-funded organization with a history of lobbying for industry-friendly risk assessment regulations for GM crops and pesticides. The World Health Organization (WHO) has barred ILSI from participating in WHO safety standards setting processes. The essence of the retractionnotice is as follows:

"A more in-depth look at the raw data revealed that no definitive conclusions can be reached with this small sample size regarding the role of either NK603 or glyphosate in regards to over-all mortality or tumor incidence —-"Ultimately, the results presented (while not incorrect) are inconclusive."

#### The question of inconclusive data

Schubert, Meyer, Hilbeck, Heinemann and others have pointed out, that if Wallace Hayes' (editor of FCT) reading of this recommendation were applied uniformly, most of the scientific literature would have to be retracted. It is the nature of research results that they are inconclusive. Regarding this, Portier et al ((2014) 'Inconclusive findings: now you see them, now you don't!' Environ Health Perspect 122(2):A36) state:

"To our knowledge, there is no precedent for 'inconclusive data' being a reason for retraction for Elsevier or other publishers, or elsewhere in the scientific literature. To single out this one study for retraction is almost certainly due to the controversy following its publication."

In January 2015, Hayes was replaced as senior editor at FCT and Goodman is no longer

listed as part of the FCT editorial board, but not before they were allowed by the FCT to do great damage to the cause of truth and science.

In June 2014, Seralini's paper was republished in the refereed journal *Environmental Sciences Europe* (ESEU).

#### The question of peer review

Seralini's paper was indeed peer reviewed by Food and Chemical Toxicology (FCT) as Reznick makes clear: "inconclusiveness, by itself, is not a sufficient reason for retracting an article..."

"How was a paper that the editors said did not meet the journal's scientific standards approved for publication in the first place?" The author concludes, "Journals that are reviewing studies with significant scientific and social implications should take special care to ensure that peer review is rigorous and fair."

And the reason why its republication in the ESEU (journal of *Environmental Sciences Europe*) was not peer reviewed, but instead the "role of the three reviewers that ESEU hired was to check that there had been no change in the scientific content of the paper," is clear from this: **Henner Hollert,** editor-in-chief of *ESEU*, is quoted as saying that this approach was taken because a scientific peer review "had already been conducted by Food and Chemical Toxicology, and had concluded there had been no fraud nor misrepresentation".

### EU funded EFSA (European Food Safety Authority) Study

On the other hand, this supposed recast of Seralini's study has not yet been peer reviewed and published, yet lobbyists have passed judgment that the findings disprove the Seralini study and do not support Seralini's demand for long-term studies on GMOs. The Julius Kühn-Institut, a federal research institution of the German Ministry of Agriculture, recommended that in light of the study results, the EU animal feeding trial requirement should be discontinued. This conclusion is a major misrepresentation and throws lumens of light on the regulatory agenda for GMOs. It is a large discussion in itself. I will confine myself to the following comments:

The first point to make is that the EU study was NOT a **replication** of the Seralini study, thus cannot be used to dismiss the findings of the latter. They used a different strain of rats; they used a different strain the KN603 Roundup tolerant GM maize; most crucially they did NOT use a Roundup/glyphosate alone comparison group.

The second point is that the full results have not been published, so it is impossible to judge whether there were or not any adverse effects in any of the feed groups. It is unscientific and out of order to announce study findings such as this <u>prior</u> to publication and without access to all the raw data for independent scientific scrutiny. We should wait.

SR is probably not aware of this. This matter is far from over. It also brings us to a revealing double standard in operation regarding GMO safety studies. It appears that it is a cardinal scientific sin to go public with such claims prior to peer-reviewed publication – but only if the message is that the GMO causes harm. If the message is that the GMO is safe, there's no problem with jumping the gun and going public with claims before the study has been

published.

It is moot to mention that the report of the International Agency for Research on Cancer (IARC) concluded that glyphosate is "**a probable human carcinogenic**" (Group 2A chemical) and California now labels the herbicide glyphosate in this way.

#### Bt brinjal and the Jairam Ramesh reassessment process

I provide a background to this debacle for a rounded understanding of the issues. ABSP II (Agricultural Biotechnology Support Projects), headquartered at Cornell University, USA, is funded by USAID and led by Cornell University. It teams up with Monsanto to promote and spread GM crops as was done with Bt brinjal in India.

The official remit of ABSP II (backed by **USAID)** is **to** "integrate GM into local food systems." Under this programme, Bt technology of the US seed multinational Monsanto was transferred to public sector institutes in India: TNAU, (Tamil Nadu Agricultural University), University of Agricultural Sciences and Dharwad, Indian Institute of Vegetable Research, Lucknow. These with Monsanto's Indian arm Mahyco are a part of the ABSP-II network.

Therefore, and clearly, at the first juncture India entangled itself with a major conflict of interest in the matter of Bt brinjal in particular and GMOs in general.

In the Supreme Court, an additional battle ensued. In early 2007, petitioners obtained a major Order in public interest that biosafety data must be in the public domain. When the regulators did not comply, a Contempt of Court Application was filed. Eventually, to cut a long story short, 16 months after the Order, respondents were forced into publishing the raw data of the self-assessed Monsanto Bt brinjal bio-safety dossier on the MoEF website on 16<sup>th</sup> Aug. 2008. At that point, I sent out an appeal to leading independent scientists worldwide to critique the raw data.

SR ascribes the Jairam Ramesh moratorium to his citing of a Seralini study in 2008. As clarified above, there was no study. Seralini undertook a critique of the raw data in 2008-09. However, according to SR, whether in 2012 or 2008-09, Seralini delivers junk science and the moratorium was similarly junk. This is the message.

However, the facts of the case cast a different light on his 2012 study. Notwithstanding these matters, Seralini was by no means the sole scientist involved, not even in the specific matter of the feeding studies and their assessment. (In this discipline a total of three scientists held in common that Monsanto's feeding studies presented several significant problems, which meant that Bt brinjal could not be judged safe). At least eight other scientists in key disciplines related to the science of GMOs, including advisors to the UN/CBD/FAO on GMO risk assessment protocols, also obliged.

Between September 2008 and February 2009, the developers' Bt brinjal biosafety dossier was examined and contested by international scientists. As lead petitioner, I challenged the GEAC in the Supreme Court on the basis of these appraisals of the developers' dossier.

EC II (Expert Committee II) was convened in February 2009 to answer criticisms, from international and Indian scientists, of the conclusions of safety based on the applicants' dossier, as well as concerns expressed from civil society. GEAC accepted the recommendation of EC II, in a hastily convened 'meeting' in October 2009, that Bt brinjal be

approved for commercial cultivation. The GEAC steadfastly maintained that it had sufficient information to evaluate the safety of Bt brinjal for both human health and environmental release and that the information provided to the regulator by Monsanto-Mahyco justified GEAC's high confidence that the product was safe for consumption and environmental release.

However, Jairam Ramesh, the then Minister for MoEF, following a nationwide outcry, intervened and instituted a review over the next 3½ months concluding in January 2010.

On 9 February 2010, as a result of the review including public hearings, J Ramesh announced a moratorium on the release of Bt brinjal. In coming to this decision, the Minister rejected GEAC's advice. After a careful consideration, the Minister concluded that:

"it is my duty to adopt a cautious, precautionary principle-based approach and impose a moratorium on the release of Bt-brinjal, till such time independent scientific studies establish, to the satisfaction of both the public and professionals, the safety of the product from the point of view of its long-term impact on human health and environment, including the **rich genetic wealth existing in brinjal** in our country" (emphasis mine).

It is to be noted because of its implications that on the morning of the 9<sup>th</sup> Feb. 2010, **Nina Federoff**, Scientific Advisor to the US Secy. of State went on TV to advise the Indian Government that Bt brinjal was good for India! Tie this in with ABSP II (above). This is the extent of the domination sought to be exercised by the US on India, a country where GM crops are virtually deregulated.

It is pertinent to focus on the assessment, albeit as briefly as possible, of key international scientists with regard to their appraisal of the Bt brinjal dossier. In doing so, let me emphasise at the very start that GMO contamination of the environment and of Non- GMO crops, is the OUTSTANDING concern because it is irreversible. For India, a country with a rich genetic diversity, including that it is a centre of origin/diversity of several crops species, the concern is particularly acute. India is the world's centre of brinjal diversity. It is now accepted that with a commercialised GM crop, contamination is a certainty.

**Dr MS Swaminathan** needs no introduction. He informed JR Ramesh that if Bt brinjal were commercialised, brinjal in India would be contaminated, and that we had an enviable diversity in brinjal.

#### **Prof Schubert: Salk Institute, USA:**

"It is logically false to claim that because there is no evidence of illness following the introduction of a GE product, therefore the product is safe to eat. In fact, perhaps my major concern with the introduction of any GE food is that even if it did cause an illness, it would not be detected because of the lack of epidemiological studies and the technical limitations for detecting such an illness. For example, to detect an epidemic of a disease, an incidence of at least of two-fold above the background rate of the disease is required. Therefore, if Bt brinjal were to cause a disease like Parkinson's which has an incidence of about 20 new cases per year per 100,000 people, then in India 200,000 new cases per year would have to be diagnosed and tabulated in order to identify a significant increase, and there would still be no way to associate the disease directly with a Bt crop. In addition, many

environmentally caused diseases take many decades of exposure to develop symptoms. Clearly, once Bt brinjal is commercially released, there will be no way to monitor adverse health effects caused by the product."

And there are "at least four mechanisms by which the introduction of the Bt toxin gene into the brinjal genome can cause harm. – There are scientifically documented examples of all four toxic mechanisms for Bt crops. – It should be emphasised that the majority of this material has been published in peer-reviewed journals and reproduced in more than one laboratory therefore, ruling out the possibility of an individual investigators bias. —my conclusion – Bt brinjal is not worth the risk and that it would be a profound disservice to India if Bt brinjal were allowed to enter her food supply."

#### **Prof Jack Heinemann: University of Canterbury, NZ:**

"The claim made by Mahyco is that the safety of Bt proteins (such as Cry1Ac) "is attributed to the mode of action and specificity." These claims are made on page 93 (section 6.3) of the Toxicology and allergenicity studies vol 1 and elsewhere. The long-accepted version of Cry toxicity is not the actual mechanism. Thus, the range of organisms that will find Cry toxic may not be predicted from knowledge based on toxicity screening of the Cry proteins alone. The toxin is necessary but not sufficient for killing. It appears that the Cry toxins permeabilize the gut epithelium and this creates an opportunity for commensal bacteria to cause septicaemia. In the context of cry-expressing (Bt) plants, there is the possibility of exposing a vast new array of gut ecosystems, because the variety of insects and the variety of microbes inhabiting them is very large. The new model of how Cry toxins kill raises issues of uncertainty surrounding effects on non-target animals. As Mahyco does not cite the literature on the new model, it is unlikely that their thinking and therefore their experimental design was influenced by the latest research on Cry toxin activities. Since current understanding of how insects die after ingesting Cry proteins differs from Mahyco's expressed understanding, there are safety concerns that they have not addressed.

In my opinion, the studies summarised here and the few more covered in detail in the Appendix would not be of sufficient standard to publish in any peer-reviewed journal much less to satisfy the scientific community that a proper molecular and microbiological characterisation of this genetically modified plant had been done."

# Prof David Andow: Dept of Entomology: University of Minnesota: Distinguished McKnight University Professor:

Andow is an acknowledged international expert on the environmental risks of GE crop plants: In his assessment of Bt brinjal Event EE 1, 'The scope and adequacy of the GEAC environmental risk assessment' he raises critical issues. I address three because of their added relevance to our Bt cotton experience and its now admitted widespread failure. Bt brinjal was of course patterned on Bt cotton with 2 Cry toxins:

"The GEAC set too narrow a scope for environmental risk assessment (ERA) of hybrid Bt brinjal, and it is because of this overly narrow scope that the EC-II is not an adequate ERA". -- "most of the possible environmental risks of Bt brinjal have not been adequately evaluated; this includes risks to local varieties of brinjal and wild relatives, risks to biological diversity, and risk of resistance evolution in BFSB" (brinjal fruit and shoot borer). **India is the centre of the** 

world's biological diversity in brinjal with over 2500 varieties grown in the country and as many as 29 wild species. Some local varieties have significant religious and cultural value." (This year the variety 'Mattu Gulla' was given GIS status – AR).

"The EE-1 transgene may be a second-rate Bt brinjal product. Efficacy of EE-1 is low. It provides only 73% control of BFSB in the MST (multi-site trials) field trials (Dossier vol. 6). Given these considerations, it seems clear that the applicant has invested little in the development of a useful Bt brinjal product for India. Indeed, an inflammatory characterisation of the process so far would be a case of "transgene dumping."

**Resistance:** "Any major pest control practice will select for resistant individuals in the target pest population. If enough individuals become resistant, the control fails, the pest becomes abundant and crop yields decline. The evolution of resistance to Bt crops is a real risk and is treated as such throughout the world and the evolution of resistance in BFSB to overcome Bt brinjal is a real risk that must be managed. EC-II does not acknowledge this risk and the Dossier does not propose effective means to manage it. Event EE-1 Bt brinjal poses several unique challenges because the likelihood of resistance evolving **quickly is high**. Without any management of resistance evolution, **Bt brinjal is projected to fail in 4-12 years."** 

The Parliamentary Standing Committee on Agriculture, 2012, in its report on the 'Cultivation of GM Crops —' made the following comment on Bt brinjal:

"The Committee have been highly disconcerted to know about the confession of the Co-Chairman of Genetic Engineering Appraisal Committee (Prof. Arjula Reddy) that the tests asked for by Dr. P.M. Bhargava, the Supreme Court nominee on GEAC for assessing Bt. brinjal were not carried out and even the tests undertaken were performed badly and that he (Prof. Arjula Reddy) had been under tremendous pressure as he was getting calls from industry, GEAC and the Minister to approve Bt. brinjal. Convinced that these developments are not merely slippages due to oversight or human error but indicative of collusion of a worst kind, they have recommended a thorough probe into the Bt. brinjal matter from the beginning up to the imposing of moratorium on its commercialization by the then Minister of Environment and Forests (I/C) on 9 February, 2010 —." (Recommendation - Para No. 2.79)

I also reproduce the PSC scathing comment upholding the evidence of conflict of interest in our Institutions of governance of GMOs. A Constitutional Bench has ruled that is now permissible to submit reports of the PSCs as evidence in Court.

"Noting with concern the grossly inadequate and antiquated regulatory mechanism for assessment and approval of transgenics in food crops; **the serious conflict of interest** of various stakeholders involved in the regulatory mechanism; the **total lack of post commercialization, monitoring and surveillance**, the Committee have felt that in such a situation what the Country needs is not a bio-technology regulatory legislation but an all- encompassing umbrella legislation on bio-safety which is focused on ensuring the bio-safety, biodiversity, human and livestock health, environmental protection and which specifically describes the extent to which bio-technology, including modern bio-technology, fits in the scheme of things, without compromising with the safety of any of the elements mentioned above. —" (Recommendation - Para No. 3.47 & 3.48)

Jairam Ramesh's moratorium on Bt brinjal was curiously prescient and Andow's warning that Bt brinjal would fail in four to 10 years was spot on in the light of the subsequent escalating failures of Bt cotton in various states as a result of rising pink bollworm (PBW) resistance to cry toxins in Bt cotton. Desperate and high levels of pesticide use by farmers to try and save their crop, rising farmer deaths from pesticide poisoning and suicides are the tragic and unforgiveable fallout of faulty regulatory decisions surrounding Bt cotton. Eventually, the Central Govt. in early 2016 was forced to admit in the Delhi High Court that Bt cotton was a victim of pest resistance to Bt toxins, which is a "natural phenomenon". And so we come full circle — QED

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