

prescribed fee to get licence to sell medicines online. Such licence issued will be valid for three years. Online sales of tranquilisers, narcotic drugs, psychotropic substances and all habit forming medicines are banned. Premises of e-pharmacies is said to be inspected on a regular basis by a team of officers either from CDSCO or state licensing authorities, stated the draft. Moreover, registered e-pharmacies have to comply with provisions of Information Technology Act. Madras High Court on 17 December 2018 imposed a blanket ban on sale of medicines through e-pharmacies until the Central Government notifies rules on e-pharmacies¹³.

In the light of draft regulations on e-pharmacies, physicians, pharmacists and consumers should be trained alike on various aspects of functioning of e-pharmacies. There should be a strict vigilance with officers from both central and state licensing authorities visiting the premises of e-pharmacies to check authenticity of medicines sold and their storage conditions. Moreover, misuse and duplication of electronic prescriptions should be strictly monitored through available technologies. The CDSCO should play a pivotal role in governing e-pharmacies and should address the issues raised by Chemists and Druggists Associations.

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Genetic modification technology

The article by Datta *et al.*¹ (henceforth referred to as 17 authors) states that it deals with negative perceptions of genetic modification technology in general, as also discussed in a recent review by Kesavan and Swaminathan² (henceforth PCK–MSS paper). The latter publication provides concrete data and valid scientific references for most of the important statements, hence their criticisms are unfounded and invalid.

With reference to *Bt* and herbicide-tolerant crops, the 17 authors' paper does not provide either data or valid references to make claims about their biosafety. There is no food security without a solid foundation of food safety, and in particular for GMOs. In this regard, the United Nations Food and Agriculture Organization's (FAO) definition of *food security* is as follows: Food security

exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. Therefore, *Bt* brinjal was rightly not released for commercialization. *Bt* toxins were once considered to cause damage only to insect species having alkaline guts. It was therefore assumed that *Bt* toxins are safe for mammals, including humans. This is no longer true as has been explained in the PCK–MSS paper. The currently known mechanism of action of *Bt* toxins can certainly damage the intestines of humans and other mammals. This has been demonstrated in laboratory animals. The 17 authors' paper states that datasets on livestock from publicly available sources starting from 1983 and representing over 100 billion animals did not re-

veal unfavourable or perturbed trends in livestock health and productivity after introduction of GM crops. This is an untenable statement in view of the fact these billions of animals are not allowed to live their full lifespan and reproduce, since they are marked for slaughter for meat consumption within a few months of their birth. It is essential that real food safety assessment of genetically engineered foods must be tested over long periods of time, including descendants and their further descendants. It is well recognized that toxicity/cancer is chronic, not acute and requires long-term, multi-generational testing. Therefore, the reference cited by the 17 author's paper with respect to billions of animals is invalid.

The PCK–MSS paper has made reference to the biosafety dossiers of *Bt* brinjal. There was resistance despite a

Supreme Court directive, on the part of the developers of *Bt* brinjal to put the raw data in the public domain. Such resistance raises issues of transparency and possible deviations from scientific protocols. Eventually, when compliance was forced, these data analysed by a 5-member Technical Expert Committee appointed by the Supreme Court, as well as several eminent and independent international scientists confirmed our worst fears and proved to be a devastating commentary on our regulators. The conflict of interest in our regulators with regard to *Bt* brinjal appraisal has already been brought out by the two Parliamentary Standing Committees (PSCs) – the PSC of 2012–13, and the 301 PSC of Renuka Chowdhury. Despite these adverse remarks the Genetic Engineering Appraisal Committee (GEAC) could not/would not respond to the ‘can of worms’ exposed by the critical analyses of the raw data. It is therefore also unsurprising that the 17 authors who declared their work in GMOs, and the funding of it by ‘various agencies’ admitting to a conflict of interest in their article¹, similarly do not even mention these facts – they understandably deplore the moratorium on *Bt* brinjal. A democracy like India should be in a position to form scientific opinion based on factual and rigorous science and not rely on what another country chooses to do or not to do, but with a conflict of interest plaguing our regulatory and public science institutions, this will prove impossible.

The 17 authors’ paper states that ‘It is a fact that the report by Séralini on the toxicity of GMOs to experimental animals had to be withdrawn’¹. Yes, it was withdrawn and no, that withdrawal has been superseded and is untrue as of now. The fact is that Séralini *et al.*³ demonstrated the genotoxicity and tumorigenic activity of the herbicide glyphosate associated with HT transgenic crops, and it very much remains in the citable literature today. Details of that paper having been retracted and republished as such are as follows:

(1) Séralini *et al.*³ conducted long-term studies of two years, whereas most other studies conducted mainly by industry-supported scientists are terminated in 28 days, wherein no adverse effects of the herbicide develop in this very short period of time. However, in the studies by Séralini *et al.*³, which were much

longer (two years), the experimental rats revealed severe liver and kidney damage as well as increased rates of tumours and premature death. These findings did not please the industry. Nearly a year later, the then editor-in-chief of *Food and Chemical Toxicology*, A. Wallace Hayes retracted the paper from the journal on the unprecedented grounds that the findings on some of the end-points were ‘inconclusive’. The Committee on Publication Ethics (COPE) does not specify ‘inconclusiveness’ as one of the three reasons to retract a paper. Therefore, several hundred scientists worldwide criticized the retraction of the paper. One such scientist, viz. David Schubert (Salk Institute for Biological Studies, USA), wrote: ‘As a scientist, I can assure you that if this (inconclusiveness) were a valid reason for retracting a publication, a large fraction of the scientific literature would not exist’. Subsequently, it came to light that in order to retract Séralini’s paper, one of the scientists long associated with Monsanto was appointed as Associate Editor (Biotechnology) of the journal in 2013. The current position is that the same paper was republished in 2014 after further peer review; the paper is now citable⁴. In this regard, reference is made to an article in *Scientific American*⁵ describing how seed companies control GM crop research. The PCK–MSS paper refers to publications^{6,7} on the serious health hazards of development of pesticide-producing transgenic crops. It is therefore, unfortunate but not shocking that the 17 authors’ paper make a case for *Bt* brinjal and also herbicide-tolerant mustard hybrid DMH 11 based on implausible scientific argument.

(2) The 17 authors’ paper also refers to *Bt* cotton and claims that India is now the largest producer of cotton, exceeding China and USA. This is a meaningless statement of the success of any technology as it refers to total production data of cotton and not yield/hectare. The PCK–MSS paper cites Kranthi⁸ and states that *Bt* cotton has failed to reduce the need for chemical pesticides and also to increase yield due to ineffective bollworm control or rising resistance. The core issue is stagnating productivity of *Bt* cotton (kilogram/hectare). Despite an enormous increase in the area under cotton cultivation, cotton yield has remained stagnant at around 500 kg/ha.

The 17 authors must surely be aware of the official strategy to transition from

Bt cotton to high density planting (HDS) with non-GM ‘Desi’ varieties of cotton, proving the hollowness of the claim of success of *Bt* cotton. The 17 authors’ paper is silent on the correlation between the failure of *Bt* cotton and farmer suicides – most suicides were by cotton farmers (reference cited in the PCK–MSS paper). The PCK–MSS paper also makes reference to the admission by the Union of India, in its counter affidavit in the Delhi High Court of the correlation between farmer suicides and failure of *Bt* cotton. It also refers to a paper which calls for adoption of integrated pest management (IPM) by *Bt* cotton farmers⁹. This plea comes after the report of pest resistance to Bollgard II.

Although, the author of this correspondence has not worked in cotton fields, he is of the view that growing ‘refuges’ to delay the onset of pest resistance and provide a longer life for *Bt* cotton is not quite feasible in the Indian situation involving very small holdings (about 1 ha or less) by millions of resource-poor small and marginal farmers. There are publications in the literature reporting that even when there is a large amount of land as in USA, a 20% ‘refuge’ is not very effective, or is effective only for a few years. In any case, the need for ‘refuge’ in an expensive technology such as *Bt* is like having a pair of bullock carts to pull a Mercedes.

(3) The 17 authors’ paper mentions that the herbicide glufosinate needs to be used only in the hybrid seed production plots. The authors admit that the resulting hybrids would be tolerant to the herbicide. Hence, it provides an opportunity for the farmers to apply the herbicide to transgenic mustard. The authors however do not mention this possibility of widespread usage of glufosinate in the farmers’ fields. The newspapers have been saturated with reports in the last several weeks of illegal HT cotton and even *Bt* brinjal being planted without much effective action being taken by the regulators either at the Centre or in the States. Glufosinate is at least as toxic as glyphosate and the latter has been declared as a ‘probable human carcinogen’ (IARC of the WHO). A recent paper after meta-analysis also confirms that glyphosate induces non-Hodgkin lymphoma¹⁰.

The PCK–MSS paper has also referred to the ‘selection pressure’ induced by HT transgenic technology and consequent emergence of ‘super weeds’ which are

not easy to control. In the Indian context 'super weeds' would pose insurmountable problems.

The PCK–MSS paper also reports that DMH 11 is inferior in yield when compared with non-GM hybrid DMH 1 and also some pure varieties. Non-GMO hybrid comparators were not used in the later BRL I and II field trials. The failure to do this makes the field testing of DMH 11 invalid. Despite lower yielding DMH 11, the President, NAAS in his letter (27 May 2017, NAAS/XIII.0/2017) to the Prime Minister of India has used an invalid basis of comparison that in field trials DMH 11 out-yielded the national and zonal checks by 20–30%. These are not hybrids. It is surely wrong to mislead our Prime Minister. There are other anomalies in that letter to which answers were sought by the present author. In particular, my letter dated 5 October 2017 to the then Secretary of NAAS (K. V. Prabhu) has not been answered even now.

This rejoinder to the 17 authors needs no further comment. GMO science and technology as practised seems to be analogous to 'science in a post-truth era'. A recent thought-provoking article¹¹ and several others¹² deal with a growing trend to destroy true science, which by definition, is based on absolute integrity. Those who preach that opposition to GM technology is anti-science and unscientific are seriously invited to consider if the opposite is instead true.

Finally, the reference to R. S. Paroda and his report to the Supreme Court mentioned in the paper¹ is highly inappropriate. It is a one-sided version and completely untrue. It is known that he was added as the sixth member to the Technical Expert Committee (appointed

by Honourable Supreme Court) of original 5 members after the submission of the interim report by the original 5 members. As former Director General of ICAR, he had an agenda unsupported by available scientific data and the literature. The present author would not like to elaborate on it any further in this paper.

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Response:

I do not find anything new in Kesavan's arguments. It would also be worthwhile to mention the article by Pental¹, which has also highlighted the flaws in Kesavan's arguments, here and earlier. When polarized positions have been taken, any amount of debate is not going to help. It is only obvious that India will not be able to sustain its growing population, given the dwindling availability of land, water and human resource, without resorting to plant-based technologies, including GM technology. We can move forward if the Government of India gives a go-ahead at least on a case-by-case basis.

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