**Science and politics in Indian GM crop regulation:**

**a u-turn down a blind alley**

**by**

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**Abstract**

There is a broad consensus that scientific evidence and expertise are necessary inputs to public policies for regulating technological risks, such as genetically modified (GM) crops, but there are heated debates about whether or not they can be sufficient. While many accept that science on its own may be insufficient, there have also been vigorous debates about how scientific considerations and policy considerations could and should be separated and integrated. This paper will analyse debates about the regulation of Bt Brinjal, the first GM food crop in India. This paper provides a characterisation of the evolution of the ways in which the Indian regulatory system has been officially represented, and then examines several features of the scientific debates about the safety of Bt Brinjal to benchmark the adequacy of those representations. The evidence adduced will be used to argue that nominally scientific discussions of the risks and safety of GM crops have in practice been based on unacknowledged and non-scientific assumptions, for example about what kinds of evidence should be deemed essential and/or sufficient for making regulatory decisions. The discussion concludes by suggesting some conditions under which such regulatory structures, institutions and processes could enhance both their scientific and democratic legitimacy.

Key words: Regulation, technological risks, science and policy

**Section 1: Introduction**

While scientific evidence and expertise are necessary for regulating technological risks, such as genetically modified (GM) crops, there have been heated debates about whether or not they are sufficient. If other types of considerations are also relevant, then which types of considerations might those be? And, how can they be differentiated from and/or coupled with scientific considerations? This chapter will outline several models in terms of which the role of science in technology policy-making has been conceptualised, and then use those resources to characterise the evolving controversy in India over the regulation of Bt Brinjal, which was the first GM food crops to be reviewed by Indian regulators. While numerous varieties of GM cotton have been cultivated in India, they are textiles and not foodstuffs, where issues such as consumer safety and choice are both more relevant and politically explosive.

Prior to October 2009, when the Minister of State for Environment and Forests (Jairam Ramesh) intervened in what had seemed a routine process, GM risk assessment deliberations had been portrayed officially and corporately as if purely scientific. The Indian government’s industrial policy was predicated on the assumption that India’s economic development should benefit from advances in science and technology; GM crops were approached through this lens. Ramesh initiated a series of open, public consultations across India, before announcing a moratorium on the introduction of Bt Brinjal on the grounds of inadequate scientific information on its long-term effects on the safety of humans and the environment. (The Hindu, 2010) The ministerial intervention in October 2009, along with the release of previously confidential documents following civil litigation under the Right to Information Act, revealed that the deliberations of the scientific advisors had not been purely scientific but rather that they were replete with unacknowledged non-scientific assumptions and judgements that were distinctly policy-sensitive. Those developments created the conditions in which those judgements and assumptions could be, and deservedly were, exposed and critically appraised. In the ministerial reshuffle in July 2011 Ramesh left the Ministry of Environment and Forests to become the Minister for Rural Development. Shortly after, a revised draft *Biotechnology Regulatory Authority of India Bill, 2011 (Bill No. 54 of 2011*) was published by the Ministry of Science and Technology and Earth Sciences, which endeavours (once again) to portray GM crop regulatory issues as if they were purely scientific. Optimists had hoped that Ramesh’s intervention would set a precedent and bring social engagement and transparency to future GM regulations. Yet, from the government’s perspective it appears that too little was learnt from the processes initiated or the information that emerged over the last two years.

**Section 2: Models of Science in risk policy-making**

A diverse range of competing models of the role of science in regulatory policy-making have been developed by scholars and policy analysts. (US NRC, 1983; US NRC, 1994, Oxera, 2000; CEC, 2002, Millstone, 2007) For the purposes of this discussion three contrasting models may suffice. In this context they are referred to as 1) the technocratic model, 2) the *Red Book* model and 3) the co-dynamic model. (van Zwanenberg & Millstone, 2005)

One very influential portrayal of the role of scientific expertise in policy-making emerged in 19th century France in the work of the positivists Saint-Simon and Comte. They portrayed scientific knowledge as if it was not just necessary but also sufficient for policy-making, and this model is often referred to as a ‘technocratic’ model. Technocratic models have often appealed to governments and ministers because they provide a narrative that may help them (at least to try) to depoliticise controversial policy issues. Those models also appeal to scientific expert advisors because it attributes a high status to their knowledge, expertise and influence. The conceptual structure of the technocratic model can be represented schematically in Figure 1.

## Figure 1: The Technocratic Model

**Facts**

**Policy decisions**

**Science**

This model implies that scientific facts can on their own be sufficient to determine policy decisions. Advocates of such technocratic approaches adopt remarkably optimistic assumptions about the progress, accuracy and adequacy of science. They assume that public administration by impartial experts could and should replace governance by those characterised by partiality, biases, ignorance or vested interests. The technocratic model of policy-making has often been encapsulated in the claim that policy should be based on, and only on ‘sound science’. In the USA from the 1950s to the late 1960s, and in much of Europe until the late 1990s, the dominant official narratives were technocratic. (Brickman et al 1985; Ezrahi 1990; Jasanoff 1990, van Zwanenberg & Millstone 2005) Technocratic narratives presuppose that the science and the relevant facts are socially and politically objective and neutral and that all relevant facts can readily be gathered.

An implication of this model is that responsibility for setting policy should be delegated to expert committees, and the responsibilities of elected ministers can be confined to recruiting the best experts and following their advice. Technocratic models and rhetoric are therefore potentially very vulnerable to criticisms that the evidential base and the understandings of experts are incomplete, unreliable or equivocal.

While technocratic narratives survived in Europe until at least the late 1990s, they became unsustainable in the USA during the late 1960s and early 1970s. This occurred in large part because of the passage of the US Freedom of Information Act, which revealed that often the science used to support policy was incomplete and uncertain. Consequently the US authorities needed an alternative model using a new vocabulary. Science-based risk appraisal and decision-making came to be portrayed in the USA as a two-stage process, the first of which is called ‘risk assessment’ and the second of which is known as ‘risk management’. The first of those two stages is typically portrayed as if purely scientific and the second as a policy-making stage at which non-scientific and often normative considerations, such as economic, social and political factors may be taken into account when making policy decisions. On this two-stage model, policy-makers (also known as ‘risk managers’) are informed and influenced by scientific advisors, but the scientific advisory bodies are portrayed as if entirely independent of policy, and of any and all non-scientific considerations. This model was outlined in an influential report from the US National Research Council (NRC) called *Risk Assessment in the Federal Government: Managing the Process*. (US NRC 1983) In what came to be known as the *Red Book* (given the colour of its cover) the NRC has been widely interpreted as asserting that science-based risk policy-making can and should be legitimate, but only if it is conducted in ways that ensures a proper separation of science from policy. The model is linear and uni-directional, and its structure can be represented schematically, as shown in Figure 2.

**Figure 2: The *Red Book* model**

**Scientific Economic, social**

**considerations political and technical**

**considerations**

**Risk**

**management**

**Risk**

**assessment**

This model, often supplemented with a third stage, termed ‘risk communication’, has been adopted by many powerful policy-making institutions; it became the new orthodoxy in the 1990s when it spread from the USA to multilateral bodies such as the OECD, the European Commission, to many EU Member States and to the World Trade Organisation.

**Critiquing the technocratic and *Red Book* models**

Despite their official popularity, science policy analysts and sociologists of scientific knowledge have long been critical of the Technocratic and *Red Book* models, and for two main reasons. Firstly, both presuppose that the available scientific knowledge is reliable and known (or knowable) with sufficient certainty, and that experts can readily reach a consensus. In practice, the available science is frequently incomplete, uncertain and equivocal, and the scientific community rarely speaks with one voice. Therefore, frequently different groups of scientists provide competing assessments of risks and of benefits, which may be equally scientific or at any rate plausible. In those circumstances, scientific considerations alone cannot determine policy decisions.

Secondly, it presupposes that scientific assessments of risks and/or benefits can be, and routinely are, developed in socially, politically and ethically neutral settings, and that scientific assessments can be and are constructed solely from scientific considerations. Numerous scholars have documented some of the most important ways in which social, economic, political and cultural considerations have influenced the agendas, deliberations and conclusions of official scientific advice on risk issues. (Levidow et al 1997; Jasanoff & Wynne 1998; Millstone et al 1999; Abraham 1993; Castleman & Ziem 1998; van Zwanenberg & Millstone 2000; Huff 2002) Jasanoff has been right to emphasise that while: “…pleas for maintaining a strict separation between science and politics continue to run like a leitmotif through the policy literature, the artificiality of this...can no longer be doubted. Studies of scientific advisors leave in tatters the notion that it is possible, in practice, to restrict the advisory process to technical issues or that the subjective values of scientists are irrelevant to decisionmaking.” (Jasanoff 1990 p 230) Accepting that premise entails abandoning both technocratic and *Red Book* models.

**A co-dynamic linear bi-directional model**

To avoid those difficulties, a new model has been developed. Like the two previous models it is linear, but unlike them its starting point is not a set of scientific facts but a set of normative judgements about what is important, and which policy aims and objectives are to be pursued. Secondly, though linear, it is characterised by reciprocal interactions; it is not uni-directional but bi-directional. This model is termed a ‘co-dynamic’ model, and its structure can be represented schematically, as shown in Figure 3.

**Figure 3: a co-dynamic model**

**Socio-**

**economic**

**and political**

**factors**

**Scientific**

**factors**

**Technical, economic,**

**social**

**and political factors**

**Framing**

**assumptions:**

**aka**

**‘**

**Risk Assessment**

**Policy**

**’**

**Risk management**

**policy-making**

**Expert**

**Risk**

**Assessment**

**reciprocal communication**

This model assumes that science-based technology policy-making depends on both expert scientific assessments and on non-scientific considerations, but instead of portraying expert risk assessments as if they occurred in a policy-free space, the model represents those scientific deliberations as ‘sandwiched between’ two sets of judgements. On the one hand, there is a set of up-stream judgements that provide key assumptions about what is to be assessed and the questions to which scientific answers are expected, and on the other a set of down-stream evaluative judgements about what actions are appropriate in the light of those answers, including comparisons with alternative courses of action and the distribution and acceptability of the associated costs and benefits.

There is evidence indicating that the reasons why different groups of scientific risk assessors reach different conclusions about the risks from GM crops is not because they are providing competing interpretations of agreed and shared bodies of evidence, but because they have asked and answered different questions, and have therefore reviewed different data sets; in other words they have adopted conflicting risk assessment policies. (Millstone et al, 2008)

**Operationalising a co-dynamic approach**

While co-dynamic analyses have become increasingly accepted amongst science policy scholars and sociologists of scientific knowledge, public policy institutions have been far slower in understanding the implications of co-dynamic analyses, or they have understood them but have been reluctant to accept some or all of their implications.

In the food safety regulatory field, it has been the Codex Alimentarius Commission (or CAC) that has been in the vanguard. The CAC was jointly established in 1963 by the Member States of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO); it sets food safety standards for internationally traded food products. Until 1994 Codex standards were merely advisory, with no statutory force. Since the establishment of the World Trade Organisation in 1995, Codex standards have been adopted as food safety benchmarks below which importing countries can lawfully exclude products. Individual Codex Member States may set higher standards than those adopted by Codex, but if challenged at a WTO Dispute, they would need to justify those standards as ‘based on a scientific risk assessment’ and as not as discriminatory trade barrier to prevent or inhibit imports. (WTO, 1998)

Since 1995, with the enhanced role of Codex standards within the WTO regime, regulatory convergence and divergence has become increasingly important and problematic. Codex has struggled to set agreed common standards given the differences amongst the competing standards of Member States. Under those conditions, and given the collisions amongst the risk assessments and regulatory standards of competing Codex and WTO member states, it is unsurprising that explicit attention has been given by Codex to up-stream framing assumptions that contribute to the construction of competing risk assessments. Codex is the first major public policy institution explicitly to acknowledge that scientists’ assessments of food safety risks are framed by prior up-stream framing assumptions, which Codex has termed ‘risk assessment policy’.

The Codex Alimentarius Commission has characterised ‘**Risk Assessment Policy’** in the following terms:

* Determination of risk assessment policy should be included as a specific component of risk management.
* Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
* The mandate given by risk managers to risk assessors should be as clear as possible.
* Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options. (CAC 2003, Appendix IV paras. 13-16)

The introduction of those provisions in the early years of the 21st century represented an important innovation. Codex introduced a novel obligation on its risk management committees to articulate risk assessment policies, though several Codex Committee have been struggling with that challenge. (Millstone, 2009) The implications of these developments may be quite profound although their significance is not yet widely appreciated. Their importance has been hugely reinforced by the fact that at the July 2007 plenary meeting of the Codex Alimentarius Commission, a text on the ***Working Principles for Risk Analysis for Food Safety for Application by Governments*** was formally adopted. (CAC, 2007, p. 9 paras 56-60) Under the provisions of that agreement, all Codex Member States, including India, have accepted the obligation for their domestic risk managers to provide their risk assessors with explicit risk assessment policies prior to the start of the deliberations of those risk assessors.

Whether Codex Member States realise it or not, they have, at least implicitly acknowledged that scientific representations of risks and/or benefits cannot be fully separated from policy considerations, though their separate contributions can and should be duly acknowledged and legitimated. On the other hand, few Codex Member States are fully implementing the commitments they made. (Millstone, 2009)

In this context, it is important to note that while Ramesh, in his role as India’s Environment Minister, deemed the GEAC’s risk assessment policy to be inadequate, the Indian government has never yet indicated what alternative policy it would deem appropriate.

The three models of the role of science in policy set out above will be used in the next section to analyse debates about the appraisal of Bt Brinjal in India, including the key question of the extent to which the Indian authorities have engaged explicitly with GM food crop risk assessment policies.

**Section 3: The scientific and policy debates about Bt Brinjal in India**

Many varieties of Brinjal are cultivated and consumed in India; Brinjal is a type of vegetable that is known in Europe and the USA as an aubergine. In May 2008 an Indian-based corporation called the Maharashtra Hybrid Seed Company (or Mahyco) applied to the Indian government for consent for the commercial release of Bt Brinjal seeds, by reference to an 8-volume dossier of information submitted to the Department of Biotechnology. Data in the dossier related to some of the potential risks from, and safety of Mahyco’s GM variety of Brinjal (Bt Brinjal), which the firm had modified so that it expressed a bacterial insecticide known as [*Bacillus thuringiensis*](http://en.wikipedia.org/wiki/Bacillus_thuringiensis) (or Bt), making the crop resistant to a pest known as the ‘fruit and shoot borer’ or *leucibodes orbonalis*. The new variety had been developed by Mahyco in collaboration with the agrochemical company Monsanto. The dossier was submitted to and reviewed by a committee of scientists called the Genetic Engineering Approval Committee (or GEAC). In October 2009 the GEAC cleared Bt Brinjal for commercial release.

Before that release could take place, the Ministry of Environment and Forests published GEAC’s report inviting comments. Those comments were extensive and informed by the disclosure in August 2008 of much of the underlying data, following the intervention of critics of GM crops and adjudications by the Chief Information Commissioner and the Indian Supreme Court. (Gupta, 2011) Prior to the disclosure of those documents and the data they revealed, the Indian system had been portrayed by Mahyco, by GEAC and by the Indian government in traditional orthodox technocratic terms, as if only scientific considerations had contributed to regulatory deliberations or decision-making. The impact of the disclosure of the contents of the Bt Brinjal dossier in India had a similar effect to that accomplished by the introduction of Freedom of Information in the USA - it torpedoed the technocratic model below the waterline.

The dossier was scrutinised, analysed and critiqued by several authoritative and influential scholars, and the following discussion draws both on the text of the dossier and several scholarly critiques. (Seralini, 2009; Carmen, 2010) By revealing that the available science was at best incomplete and at worst equivocal and chronically uncertain, and that numerous non-scientific considerations contributed to GEAC’s deliberations and decisions, the evidence deprived technocratic and *Red Book* narratives of whatever limited plausibility they might previously have enjoyed in relation to India’s science-based risk management system.

Even though Mahyco’s dossier ran to eight volumes, it does not follow that the underlying data sets were substantial or adequate. The dossier covered a range of topics, though just two main types of possible risks were discussed. Firstly, it commented on possible risks to human health, either directly from consuming Bt Brinjal or indirectly from consuming animal products from livestock fed on crop residues from Bt Brinjal plants. Secondly, it commented on possible environmental risks to flora and fauna from cultivating this Bt Brinjal. A third set of possible risks, namely those arising as economic or social consequences of commercialising Mahyco’s Bt Brinjal were not addressed in the dossier, despite their importance to many of Mahyco’s potential customers and consumers. Wynne has recently summarised some of the most controversial aspects of debates about the putative socio-economic consequences of commercialising GM crop technologies. He explains that a key axis of contestation concerns arguments that GM technologies “…exacerbate[s] already-unsustainable high-input industrialised farming and concentrates ownership and control of key resources of the global food-chain in private corporations, while also shaping innovation in their interests… damages the social distribution of production, control, and access to food, especially for the most desperately needy.” (Wynne, 2012) In this context it is not possible comprehensively to review all of those categories of potential risks; instead the discussion will focus just on the first of those sets, namely food safety risks to consumers, on the understanding that the pattern that emerges is characteristic of debates about all three types of risks.

One set of preparatory remarks may be helpful. Before the use of a new chemical can be authorised for use as for example a pharmaceutical, a pesticide or a food additive the set of tests that will be required routinely include a so-called chronic toxicity test. The test is ‘chronic’ in the sense of requiring repeated daily dosing with the test compound for all or most of the life time of a sample of laboratory animals. Mice in labs regularly live for ~18 months, while for rats average lifetimes are ~30 months. A standardised chronic rodent feeding study is considered sub-standard if fewer than 400 animals are used. The most commonly encountered chronic toxicity protocols use 50 male and 50 female animals, at each of three dosing levels (low, medium and high), plus one counterpart control set, making a total of 400. Not only should these be repeat-dose studies, protocols require that a broad set of anatomical, physiological, biochemical and histopathological parameters should be monitored. As the following section explains, Mahyco’s tests on Bt-Brinjal fell a very long way short of those conventional benchmarks.

**Assessing food safety**

A starting point for an attempt to estimate the consumer health and/or environmental impact of Bt Brinjal involves a chemical and biological characterisation of the product. The Mahyco dossier did include data from some rather limited chemical analyses, along with assertions that they were sufficient to establish ‘substantial equivalence’ to non-GM Brinjal counterparts, concluding that Bt Brinjal can safety be consumed. The dossier also provided data from some limited biological and toxicological studies, to supplement the chemical analytical data. (Mahyco, 2008, Vol 1 Ch 7) The dossier revealed however that those analyses of chemical composition were conducted on just three samples of Bt Brinjal and three samples on non-Bt Brinjal. (Mahyco, 2008, Vol 1 Section 7.2, p 104) The parameters included in those chemical analyses did not, however, include data on either amino acids or fatty acids, or levels of enzymes. Data reporting levels of intended protein additions and unintended modifications were also conspicuously absent. Seralini highlighted the fact that even the slender data set indicated that the dietary calories available from Bt Brinjal were some 15% below the average levels for the non-GM Brinjal. (Seralini 2009) The text of the dossier discounts those differences as insignificant, and characterised Bt Brinjal as unproblematically safe.

The dossier did contain some data on how Bt Brinjal might be digested, and the GEAC considered those data. The data were, however, derived only from experimental models contained in laboratory equipment (so called *in vitro* studies), while data from the digestive systems of living organisms (so called *in vivo* studies) were also conspicuous by their absence. GEAC treated the *in vitro* data as sufficient. As Carmen has argued, however, “Such [*in vitro*] studies are notorious for providing false assurances about the digestibility of GM DNA and proteins. For example, such studies often use unrealistically high levels of stomach acid and digestive enzymes. The level of acid in a human stomach moves towards neutral once food enters it. The only real way to determine how quickly GM DNA and protein are digested is to do experiments in animals or humans.” (Carmen, 2010) If such studies had been conducted they were not reported.

Data that had some bearing, albeit indirectly, on the possible allergenicity of Bt Brinjal were included in the dossier; notwithstanding their limitations GEAC deemed them sufficient. Mahyco conducted a paper-based analysis, which assumed that the GM Bt protein would split into smaller familiar segments and they compared those segments with selected databases of known allergens. Mahyco did not however consider possible allergenic effects of unintended proteins. The paper exercise was supplemented with data from a skin irritation test and a mucous membrane test using vaginal tissue in rabbits. For both of those studies, only three rabbits were included in each treatment group, and they only received single doses, after which they were monitored for just 72 hours, and the results compared to nine control animals. The almost vanishingly small number of animals tested could barely provide an adequate model of effects on a larger population of rabbits, let alone a vastly greater and more diverse group of human consumers. Nonetheless GEAC accepted the data as reassuring and sufficient.

Data from acute toxicity studies in mice were reported by Mahyco and reviewed and accepted by GEAC even though those data were obtained from a test that was not conducted with the specific protein that is expressed in Mahyco’s Bt Brinjal, which supposedly was being assessed. Their Bt Brinjal contains a chimeric Cry1A protein (Ccry1A) but a different protein (i.e. Cry1Ac) was used in Mahyco’s study. Furthermore only 10 mice per dose group were used, and the only data submitted reported body weight and food intake; apparently tissue samples were taken but not analysed, or at any rate no analyses were included in Mahyco’s dossier. Nonetheless, GEAC deemed those few data sufficient and reassuring.

Data from an acute toxicity study on rats were included, but for that study only five rats per gender per dose group were used, and the animals were exposed only to single doses, and they were monitored for just 14 days. Nonetheless, those data suggested that male rats fed GM brinjal had a concentration of AST (a liver function enzyme) that was 48% and 63% higher than the rats fed non-GM Brinjal. The GEAC discounted the apparent evidence of toxicity, and deemed the data sufficient and reassuring.

A study was conducted with lactating cows fed on plant material from Bt Brinjal. The data from that study suggested that the cows fed GM brinjal produced significantly more milk after 6 weeks, approximately 14% more, suggesting that the GM feed had acted like a lactation-enhancing hormone. The GEAC discounted that possibility, but otherwise deemed the data sufficient.

A sub-chronic (i.e. 90-day) feeding study was conducted with goats, but only six goats per sex per dose, eating a diet containing Bt Brinjal. The results indicated that those fed Bt Brinjal-derived material consumed significantly less hay in week 11 when compared to those fed a non-Bt diet. The authors did not interpret that difference as problematic. Moreover the dossier suggested that the feeding trial consisted of six males and three females, but provided no explanation for the disappearance or exclusion of data from the three missing females. Those results were nonetheless deemed sufficient and acceptably reassuring by the GEAC.

Data from a 3 month long (or sub-chronic) feeding study on rats were included in Mahyco’s dossier, but only 10 rats per gender per dose were used, and only very few data were reported, especially histological data, i.e. data reporting the detailed conditions of particular types of cells. The initial sample of rats was unusually varied; the body weights of some groups varied by as much as 31%. Since there were only 10 rats per group, the intra-group variation could have easily masked any evidence of effects as between different groups. Those data were nonetheless deemed acceptable and sufficient by the GEAC.

Several other possible categories of putative toxicological risks were not covered by the reported studies. In particular, there is no evidence of studies conducted to explore whether the use of antibiotic marker genes, which were deliberately introduced into the Bt Brinjal, might provoke resistance to therapeutically important antibiotics, in particular to kanamycin. The GEAC failed to comment critically on that omission. There were, moreover, no data from studies designed to investigate reproductive toxicity, genotoxicity or carcinogenicity, although they are routinely required for studies of chemicals deliberately added to human diets, even if they are to be used at low levels. Once more, the absence of such data was not discussed in the GEAC report.

In these circumstances it is readily understandable why Seralini highlighted the tactics repeatedly adopted by Mahyco and the GEAC when discounting evidence that appeared to indicate positive signs of adverse effects. Seralini argued that the potentially significant differences were repeated deemed to be “…not biologically meaningful…” by both Mahyco and the GEAC. (Seralini 2010 p. 14) The judgments to discount such findings were superficially legitimated by the deployment of several un-scientific devices, which included:

1. …comparison with several unnecessary ‘reference’ groups of animals, including in some cases animals that had eaten a different type of Brinjal to that which had been genetically modified (i.e. not a sister line but different lines of Brinjal).
2. The control or reference group was in some cases six times larger than the GMO treated group (in some instances the historical data of the laboratory conducting the experiment served also as references in some files).
3. For some…effects, the differences in the effects on males and females were interpreted as indicating that the differences were not linked to the GM treatment.
4. For some apparently significant effects, the fact that they were only evident during some weeks of the experiment were cited as ground to discount any possible biological significance. Mahyco suggested that unless those differences were evident during the entire duration of the experiment they could be discounted.
5. Some apparently adverse effects were discounted because there was no simple linear correlation with the dose level, as if all toxic effects exhibit linear monotonic dose-effect relationships.

While such tactics have been encountered in other contexts that is not sufficient to confer on them scientific legitimacy.

**Section 4: Summary and analysis**

The foregoing discussion of the assessment of the risks posed by GM Bt Brinjal has focussed relatively narrowly on issues of food safety, understood as a concern with consumer health. It has not provided a review of corresponding evidence, questions or debates in relation to possible impacts of cultivating Bt Brinjal on the environment, let alone the social and economic consequences of cultivating Mahyco’s Bt Brinjal in India. While the discussion of food safety has been quite broad, it has not been comprehensive, let alone exhaustive. Nonetheless a clear set of patterns has emerged. Very similar patterns can be discerned in relation to environmental and socio-economic risks, but the scope of this paper cannot extend to a detailed discussion of those topics.

The patterns that emerged in the Indian Bt Brinjal saga show that the deliberations and conclusions of Mahyco’s portrayal of the putative risks to consumer health from its Bt Brinjal were profoundly influenced by a broad range of non-scientific (risk assessment policy) assumptions concerning how the scientific questions should be framed, about how much (or rather how little) evidence might be deemed sufficient, and about how those evidential fragments could be interpreted. Furthermore it is clear that those assumptions were shared by, and implicitly endorsed by, the GEAC.

In other words, what was represented by Mahyco and the GEAC as if it was a purely science-based technocratic policy-making system was in reality an exemplification of a co-dynamic system, because the presence, characteristics and influence of a set of prior non-scientific framing assumptions determined Mahyco’s ‘risk assessment’ of its own product and GEAC’s endorsement of Mahyco’s judgements and conclusions. The evidence indicates that Mahyco and the GEAC both repeatedly made non-scientific judgements that consistently favoured Mahyco and that they were relentlessly optimistic about the safety of Bt Brinjal and relentless sceptical about any possible risks. So despite their adoption of technocratic narrative, Mahyco and SEAC’s portrayal of the putative risks of Bt Brinjal can be most comfortably accommodated in a co-dynamic model, which reveals much that Mahyco and the GEAC chose to conceal.

The co-dynamic model cannot yet be comprehensively applied to this saga, but only because (at the time of writing – May 2013) no decision has yet been taken by the Indian authorities to either definitively license or ban Mahyco’s Bt Brinjal. In the absence of a risk management policy decision, other than an interim decision to delay, it would be premature to conclude that the ‘down-stream’ right-hand-end part of Figure 3 fully applies. Nonetheless, the evidence adduced above has shown that Mahyco’s risks assessment and GEAC’s acceptance of Mahyco’s conclusion cannot be comprehended within the resources provided by either a technocratic (cf Fig 1) or a *Red Book* (cf Fig 2) model; they can only be understood as exemplifying at least the centre and left-hand-end of Figure 3.

**Political developments since October 2009**

As Gupta has argued, changes in the regulatory framework in India for GM crops: “…have been stimulated by socioeconomic concerns relating to foreign dependence, social need and economic gain (or lack thereof) from transgenic crops…” (Gupta, 2011, p 737) In particular, when the Minister of State at the Ministry of Environment and Forests (Ramesh), announced in October 2009 that the GEAC’s judgements and advice on Bt Brinjal were not being accepted, and that further studies and more data would be required before any regulatory decision could be made, his decision could be understood as a repudiation of the technocratic model. His policy judgement clearly indicated that he took the view that too few endpoints and putative risks had been studied or assessed, and that, for those that had been investigated, too few data had been gathered from samples that were too small. Instead, Ramesh initiated a process of public consultation that, amongst other things, addressed issues such as: 1) how wide or narrow the scope of any adequate ‘risk assessment’ should be, and 2) how extensive and comprehensive should the requisite studies be? What never emerged from the Indian government was a definitive statement of its risk assessment policy for GM foods and crops. Mahyco was, in effect, told that its risk assessment policies and data sets had been insufficient, but the Indian government did not provide any indication of what might eventually be deemed necessary and sufficient. While this paper has highlighted how limited the testing had been and how few data were available, neither this paper nor this author is recommending what should be deemed necessary and/or sufficient in India. It is intrinsic to the analysis provided here that responsibility for judging how much data of which sorts will be necessary for Indian policy-making purposes is a matter for which Indian ministers should take responsibility, and for which they should be democratically accountable. It is not for a British academic to tell the Indian government or Parliament what it should require and accept. On the other hand, it would be reasonable to assume that if the Indian government set its requirements significantly below those set for the European Union, Indian exporters of GM crops might have considerable difficulties gaining access to the EU’s single market.

The tactics adopted by the Indian government since the summer of 2011have however been bizarre and perverse. Instead of abandoning the pretence of trying to operate a purely technocratic regime and embracing a more sophisticated and realistic understanding of science-based risk policy-making, the Indian government attempted to turn back the clock and to re-impose a technocratic structure, procedure and narrative. Once however ‘Pandora’s box’ has been opened, it is not clear that an attempt to re-impose a technocratic orthodoxy can be sustained.

At the end of July 2011 a draft BRAI Bill (Bill No. 54 of 2011) was published by the Ministry of Science and Technology and Earth Sciences. The Bill is a remarkable document; because it is drafted in a way that suggests either that no lessons whatsoever had been learnt from the Bt Brinjal or that too many (cynical) lessons had been internalised by the authorities. Some explanatory light on those developments may be cast by Gupta’s comment that: “… the regulatory system has sought a balance of authority between concerned governmental actors, with the central axis of conflict being between a proactive Department of Biotechnology under the Ministry of Science and Technology, which aggressively promotes development and adoption of transgenic crops, and a more precautionary Ministry of Environment and Forests.” (Gupta, 2011, p 737)

At the time of writing the position is that, while the Bill was tabled in the summer of 2011, the procedure to debate, amend and decide the Bill has been stalled. The Bill has not been withdrawn, but neither has it progressed, although there was a plan to re-table the Bill in April 2013. What matters however in this context is its text rather than its legislative progress. According to Saldanha & Rao: “…The proposed Bill makes no effort at all to wholistically address a variety of concerns associated with the high risks involved in biotechnology. In fact as a legislative effort it brazenly, controversially and questionably proclaims it as a ‘Bill to promote the safe use of modern biotechnology’.” (Saldanha & Rao, 2011, p1) The centrepiece of the legislation is the creation of a body to be called the **Biotechnology Regulatory Authority of India** (or BRAI). This institution is portrayed in the Bill in narrowly technocratic terms; it is to be staffed only by scientists, who are to be chosen and managed by a committee of bureaucrats working under the Cabinet Secretary, with no Parliamentary or democratic oversight or accountability. (BRAI Bill, 2011, Ch. 2) Moreover, most of the operational details concerning how risk assessments will be scoped, framed and conducted have been left open-ended and un-resolved, as have details of how policy decisions are to be reached; the processes by which they might be decided remain obscure and consequently unaccountable.

The Bill proposes that the BRAI body will have responsibility for all regulatory decisions, rather than merely for providing scientific advice to policy-makers. The Bill proposes that scientists, and scientists alone, should decide to authorise biotechnological crops, with ministerial responsibilities confined to appointing scientists to the BRAI and ensuring that BRAI’s decisions are implemented. Members of the BRAI, and especially those named as Chief Regulatory Officers, must undertake to keep the data, by reference to which they reach their decisions, confidential and secret. (BRAI, 2011, Ch V, para 21.5, and para 28(1)) The BRAI may release some of the data, but only if it is satisfied that: “…the public interest outweighs the disclosure of commercially confidential information…” (BRAI, 2011,Ch. V, para 28(2)) That suggests that the BRAI will decide its own risk assessment policy, to which the BRAI Bill makes no direct reference. It could mean that policy decisions will masquerade as if they were scientific and un-contestable, when in practice they will be non-scientific and potentially very controversial.

The draft Bill endeavours however to restrict controversy, by the inclusion of Clause 62, to the effect that: “If a person, in connection with the requirement or direction under this Act, provides any information or produces any document that the person knows is false or misleading, he shall be punishable with imprisonment for a term which may extend to three months and also with fine which may extend to five lakh rupees.” (i.e. about US $10,000) The implications of this clause are, predictably, controversial but critics of the Bill and of the government’s enthusiasm for GM crops interpret that clause as designed to muzzle or silence the critics. The fact that the Bill stipulates that neither the civil courts nor the individual Indian states will have any say in any of these matters is also highly controversial. The draft Bill also assigns no roles or responsibilities to independent scientific laboratories, as if science and scientists can be relied upon to ‘speak with one voice’ and as if commercial and corporate science could be relied upon to be sufficient and reliable.

The disclosures about Mahyco’s dossier on Bt Brinjal and GEAC’s interpretation of that dossier revealed that the available scientific evidence is far from complete, comprehensive, unequivocal, certain or decisive. They also showed that the choices that Mahyco and GEAC had made, concerning the scope and adequacy of microscopic quantities of data, had been relentlessly optimistic and forgiving. Since the widespread outrage these revelations sparked in India, it is hard to imagine a re-constructed technocratic system of the sort envisaged by the 2011 BRAI draft Bill, being seen to have any scientific or democratic legitimacy; that is why the sub-title of this chapter is ‘: a U-turn down a blind alley’. (Gupta, 2011)

The foregoing discussion suggests that if a new regulatory regime for GM crops is to be constructed in India that might deliver both scientific and democratic legitimacy, it will need to be structured in a way that explicitly corresponds to a co-dynamic model, or something rather similar to it, rather than doing so covertly. Heineman has, for example, recently published a set of proposals that would contribute significantly to complying with that requirement. (Heineman, 2012) His recommendations include: “The regulatory review process should begin with the participation of all stakeholders, from industry (not just the applicant’s industry), civil society and government and seek a consensus endorsement in the scope and nature of the risk assessment. The stakeholder engagement should not begin with an evaluation of the outcome of a risk assessment. A scientific risk assessment should be based on scientific information that is available for review and verifiable (through independent testing) by qualified scientists who have reliable career independence from the commercial incentives pervading both public and private research.” In other words, Ministers should consult relevant stakeholder groups, and then take responsibility for setting risk assessment policies for GM crops in India, and expert advisors should be accountable for acting in accordance with that policy guidance. Given moreover that in August 2012, a technical expert panel appointed by the Indian Supreme Court recommended a 10-year moratorium on all field trials of GM food crops; the prospects for the rapid adoption of the BRAI Bill seem remote.

Since October 2009 events and disclosures in India have not only undermined the plausibility of technocratic regimes, they have also cut the ground from underneath a regime resembling a *Red Book* model. If a sufficient proportion of policy stakeholders recognise that scientific assessments of technological risks are invariably framed by prior up-stream assumptions, for example about what is to be counted as a risk and how much of which kinds of evidence can be deemed as variously necessary and/or sufficient for policy decisions then both technocratic and *Red Book* regimes become unsustainable - they lose a minimum requirement for their superficial appearance of legitimacy. As can be seen in many of the other chapters in this book on public health, pollution, natural hazards and civil nuclear power plants there is a growing need for a general re-appraisal of science-based technological risk management regimes; to turn these inside out and bring to the surface buried policy judgements and assumptions for debate.

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