

The Precautionary Principle (PP)  
Requires to be Interpreted  
Critically and Pre-emptively for its  
Proper Application to the Unique  
Risks of GM crops

*“Man has lost the capacity to foresee and to forestall.  
He will end by destroying the earth”.*  
Albert Schweitzer

March - April 2015

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Lead Petitioner (Public Interest Writ (PIL) in India's Supreme Court)

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# Section 1

## Background & Overview

The Public Interest Writ Petition of 2005 (IA (CIVIL) No. 260/2005) filed in India's Supreme Court has as its main prayer, a conditional moratorium on the environmental release of any GMO and an appropriate ban in imports of viable seed and GM food and animal feed to ensure that India's crops, seeds and food chain are not contaminated by GMOs (genetically modified crops). In the 10 years since this PIL was filed, there have been several Orders from the Supreme Court (SC), including an interim ban (in 2006, barring open field trials and which was vacated the following year), recognising the need for caution and precaution, even at the significant level of an interim bar, in the regulation of GM crops; but the longer-term moratorium and specific bans which we continue to pursue, has eluded us. The court's Orders have included the requirement by the apex regulator to put all GMO bio-safety data in the public domain and to ensure there is NO CONTAMINATION. The latter Order it has to be said, did not go to its logical end to require how this regulatory mandate of the SC of "no contamination" must be achieved. Yet it is clear, that the central focus of the issue concerning GM crops is the imperative that there must be NO CONTAMINATION. This much the SC has recognised. But, the environmental release of GMOs through open field trials and commercialisation will eventually result without doubt, in contaminating the natural environment, (through sexually compatible crops and wild varieties) and India's foundation seed stock of considerable genetic diversity. This is because GMOs are living organisms. Contamination via pollen flow, insect mediated, by wind, seed dispersal etc. is a biological certainty. Beyond this, commingling and other forms of human error (virtually unavoidable as was found in Japan for example, where GMO (HT) rape was found growing along the dockside as a result of spillage from imported bales), are other sources of contamination for which there are several examples. Open field trials are a proven source of contamination (Bent Grass in the US, and Monsanto's HT wheat in Oregon)<sup>1</sup>, even from single trials as in Bayer Long-grain rice LL 601<sup>2</sup>. In India virtually all her food crops have been genetically engineered for open field testing with several thousand GMO trials having taken place in multiple locations around India in the last decade. These GMOs have not undergone requisite safety testing and are unsafe. No steps have been taken by the regulators to check for possible contamination despite specific SC Orders. On the other hand CSOs (civil society organisations) and NGOs have found clear cases of contamination from such trials. The critical issue is that GMO contamination is **irremediable and irreversible**. This means that the other connected CRITICALITY is the time factor. Open field trials present significant risk of contamination; and contamination as a result of a commercialised crop is certain. A decision related to the criticality of the 'timeliness' of a precautionary stand, which in the case of Bt brinjal extended to a moratorium on it, must therefore, be guided by these factors, as India will not get a second bite of the cherry. It was this recognition that was decisive in the indefinite moratorium on Bt brinjal ordered by India's erstwhile Minister (MoEF), Jairam Ramesh. He reversed the GEAC's approval for its commercialisation acknowledging that that this would lead to the irreversible contamination of India's domesticated and wild varieties of brinjal (India has the world's greatest diversity in brinjal).

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<sup>1</sup> SC evidence: Contamination through Gene-flow from trials of GM **Bent Grass** in the US occurred over distances exceeding 20 km. Oregon: In May 2013, unapproved GM Herbicide Tolerant wheat developed by Monsanto was discovered in a farmland in Eastern Oregon triggering bans on imports of US wheat into Japan and South Korea. It was last trialled eight years before in another distant location. In November 2014, Monsanto agreed to pay \$2.13 million into a settlement fund (<http://www.farming.co.uk/news/article/10642>).

<sup>2</sup> SC evidence: LL601 was a single field trial (2006) conducted in Louisiana State University, which exceeded mandated isolation distances and was conducted with rigour. Yet it contaminated US long-grain rice resulting in a shutdown of US exports of long-grain rice valued at billions of dollars. Bayer made a settlement on farmers of \$750 million.

## A. The evidence of four official reports before the Supreme Court

Unless however, the risks of GMOs are properly understood by the Supreme Court the PP cannot be interpreted integrally and correctly with respect to these novel organisms. Therefore, it is required of course that the Supreme Court (SC) is provided with the best science and INDEPENDENT science on GMOs to inform its processes of deliberation and interpretation of Constitutional Law. At its own initiative, the Court appointed a Technical Expert Committee (TEC) to advise it in this PIL, with a specific mandate on GMO risk assessment, the risks from GMO open field trials, and the sequencing of test protocols (in response to Petitioners' 'Prayers'). The final TEC report was submitted to the SC in June 2103 and awaits adjudication. Three other official reports (Ramesh, Bt brinjal; the Sopory Committee Report of the Ministry of Agriculture; and the Parliamentary Standing Committee report) have also been submitted in evidence. These four reports find a remarkable consensus in their conclusions. The Supreme Court's TEC is the fourth official report which exposes the lack of integrity, lack of independence (reflecting India's deeply conflicted Regulators and Government Ministries), and scientific expertise in assessing GMO risk. It is the third official expert report barring GM crops and their field trials singularly or collectively<sup>3</sup>.

Section 5 provides the up-dated science based on independent studies and analyses of empirical data of the two GM crops currently planted worldwide ie Bt and HT (herbicide tolerant) crops, which together represent over 99% of commercialised GM crops (ISAAA<sup>4</sup>).

## B. GMOs: how we might learn from history

There are in addition important pointers culled from a 100 years of the history of the impacts of products of innovation & technology. DDT, and Chlorofluorocarbons (CFCs) are two appropriate case studies used here to provide understanding and clarity on the precautionary principle, the levels of precaution that were necessitated eventually, and applied, from cautions to outright bans, the delays, the reasons why. Key to these lessons from history is the similarity and /or dis-similarity to GMOs. These critically inform the PP<sup>5</sup> in this matter, how it might be interpreted wisely for its' application to the unique risks presented by these novel GM organisms AND BEFORE GMO contamination confronts us with a fait accompli. In this respect, TIMELINESS is a criticality like no other technology has presented. At the point of commercial release of a GMO, if it has not already happened during open field trials, the door is opened to the permanent escape of transgenes<sup>6</sup> and inevitable contamination. The debate is presented in Section 4, under 'GMOS & THE PRECAUTIONARY PRINCIPLE INTERPRETED IN THE LIGHT OF 'CURRENT' SCIENTIFIC WARNINGS OF THEIR IMPACTS.

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GMOs are "UNNATURAL"<sup>7</sup> (because they are a laboratory technology and can only be made in a lab) and they have GLOBAL ramifications. For India especially, an agricultural economy and a global hotspot of biodiversity, their impacts are magnitudinal. They involve us in a big experiment in the idea that human agencies (even if rigorous, up-standing and zealous for the public good), can perform adequate risk assessment, which, it is expected, will deliver safety at every level/dimension of their impact on us — the environment, farming systems, preservation of biodiversity, human and animal safety. This is the immeasurable magnitude of GMO impacts and so we need to ensure that they will not cause irremediable and irreversible harm. We need to get it right.

<sup>3</sup> Aruna Rodrigues: The Hindu, Opinion 'Nip This in the Bud' of 12 August 2013. Also see section 5

<sup>4</sup> ISAAA (The International Service for the Acquisition of Agri-biotech Applications), 2014 estimates

<sup>5</sup> EEA: Late lessons from early warnings: Vol. I (2001): the Precautionary Principle 1896-2000 and Vol. II (2013), EEA (European Environment Agency); Rachael Carson: 'Silent Spring'

<sup>6</sup> GMO rape in Canada has eliminated Non-GM rape, (including organic rape) and permanently shut-down Canada's export markets for organic rape to the EU

<sup>7</sup> As defined by the WHO

## C. GMOs: India specifics

For India, the time factor for a decision on whether to allow open release is NOW, before GMO field trials of food crops become increasingly frequent and risky (for contamination) and before another crop beyond cotton is approved for commercialisation. Bt cotton is the only commercialised crop in India. In reality therefore, we do not face the pressure and competing urgency of public health & environmental harm vs economic stakes, even given that those

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economic stakes are essentially 'Industry'-dominated and 'Industry'-driven, based on patents and profits. This opposition obfuscates the debate and "puts the scientific process under enormous pressure" (EEA) exemplified by Bisphenol A, Polychlorinated Biphenyls (PCBs of Bhopal infamy), asbestos, tobacco, Thalidomide etc). However, such pressure is already sought to being exerted by no less than the PMO, (Prime Minister's Office) Government Ministries and Agencies like the IB (Intelligence Bureau), which has taken a public position of support for GMO outside its understanding, role and mandate, (which is the internal security of the Country), that opposition to GM crops, even through a Constitutional challenge in a Public Interest Writ or PIL

(public interest litigation) in the Supreme Court of India is anti-national! The Bt cotton story is hardly beneficial (Kranthi, Gutierrez, Gurian-Sherman, Tabashnik, DES data, the TEC report<sup>8</sup>). A case for the expansion of GM crops in India based on the experience of Bt cotton, that it has been a runaway success, (the official explanation in agreement with the 'Industry', and the basis for the approval of Bt brinjal), is not supportable. This is not the place for analyses of the performance of Bt cotton. (A brief overview is provided in Section 5: IV). The indisputable fact nevertheless, is that GM food crops are an entirely different proposition to Bt cotton (essentially an animal feed). This was clearly demonstrated in the case Bt brinjal: (a) in its independent scientific appraisal by leading international scientists; (b) the discovery that the self-assessed safety-dossier of Mahyco-Monsanto was fraudulent; (c) regulatory oversight virtually absent, and (d) finally, the subsequent and timely indefinite moratorium imposed on it. Bt brinjal is a stark reminder of how great the pressure is on India to open up its agriculture to the full -scale introduction of GM crops. It raises the urgency of the GMO issue to a state of virtual emergency.

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India's future to not merely survive but thrive will depend on how the PP is interpreted and applied to this technology in the light of history and warnings, which have always been 'current' from independent scientists of the hazards of GMOs and most importantly, with reference to the TEC reports, the Supreme Court's own Technical Expert Committee.

***March-April 2015***

<sup>8</sup> **Kranthi**: Need for Change (cotton statistics and news, 16 dec.2014); **Andrew Paul Gutierrez et al**: Indian Rain fed Cotton: Weather, Yields and Suicides; **Gurian Sherman**: <http://gmwatch.org/index.php/news/archive/2014/15828-gmo-industry-techno-fixes-for-bt-resistance-in-pests-are-counterproductive>; **Tabashnik et al**: <http://www.nature.com/nbt/journal/vaop/ncurrent/full/nbt.3099.html>; DES: Department of Economic & Statistics, Indian Ministry of Agriculture  
**TEC** (Technical Expert Committee) Final Report June 2013

# Section 2

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Lead Petitioner (Public Interest Writ (PIL) in India's Supreme Court)

## DDT & The Precautionary Principle<sup>9</sup>

*“The sedge is wither'd from the lake  
And no birds sing”.*

Keats

### Timelines:

- 1873: The DDT molecule was first synthesised
- 1939: **Paul Muller discovered the insecticidal property of DDT**
- 1945: available for civilian use
- 1948: Paul Muller wins the Nobel Prize for Medicine; mentions the first signs of resistance against DDT in flies
- 1950s-60s: Primary tool in the first global malaria eradication programme. (IRS –indoor residual spraying), DDT was used to spray wall and ceilings of houses and animal sheds of entire populations
- 1951: First reports of insecticide resistance to DDT
- 1962: Silent Spring published – impact of chemicals and DDT the focus
- 1970s: DDT banned in agriculture in many countries based on the increasing amount of data on environmental effects
- 2004: The Stockholm Convention on Persistent Organic Pollutants enforced, eliminating the production and use of DDT except for disease vector control where safe, effective and affordable alternatives are not available
- 2010: India in the only country that now produces DDT

**Source: EEA (European Environment Agency):** Late lessons from early warnings, Vol. II chapter 11

### Notes:

- With the publication of Silent Spring, US President John F. Kennedy responded by convening the Science Advisory Committee to investigate DDT, which thoroughly vindicated Silent Spring and its author RC. She is credited with the establishment of the US EPA (Environmental Protection Agency) and a heightened consciousness in the American Public of the need for the conservation of natural environments. DDT was banned in the US (domestic production and use, but not export) in 1972. In 1973, a collateral effect of Silent Spring was the enactment of the Endangered Species Act, *“easily the most the important conservation legislation”* in the US. Since the ban, and the Act, the birds came back – their success is the dramatic recovery of the bald eagle, brown pelican, peregrine falcon (and others), which were imperilled in the 50s & 60s, *“are now considered safe”* (Edward O. Wilson)
- From 1939 (the year DDT was discovered), it took **33 years** before the first responses in caution were affected. There were critical pieces of US legislation and the formation of a key institution of regulation (EPA). They were dramatic in their legislative impact, which led to the bar in caution being raised to the significant level of a Country Ban on domestic production (1972)
- It took another 32 years for the International community through the Stockholm Convention to enforce an international ban on DDT except for small quantities in vector control. Countries may continue to use DDT, in the quantity needed, provided that the guidelines and recommendations of the World Health Organization (WHO) and the Stockholm Convention are met. Any other current use of DDT is illegal.
- However, DDT is still in use almost 75 years later and we still live with its long-lasting effects

<sup>9</sup> EEA (European Environment Agency): Late lessons from early warnings Vol. II chapter 11; **Rachael Carson**: Silent Spring; **Linda Lear**: The life of the author of Silent Spring

## The relevance of DDT to the GMO debate

**Dichlorodiphenyltrichlorethane or DDT** is a particularly relevant case study for the GMO debate because 99% of GM crops planted out commercially worldwide, are either herbicide tolerant (HT) crops or Bt crops or a combination of both: these are pesticidal crops that internalise the pesticide (ref. Section 5). Glyphosate (the herbicide in HT crops), is ubiquitous; it is now found in food, even infant food through GM soy mixes, in drinking water, in streams via agricultural run-off, in human blood and urine. The ‘story’ of chemicals and DDT in *Silent Spring* by Rachael Carson has many parallels with the Biotech Industry and GMOs: their promotion by all and every means, big money, and the vilification of those who oppose them. In contrast to the official initial enquiry and interventions on DDT in the US, perhaps the most dangerous and insidious situation we face with GMOs today, is the spectacle of national governments and government institutions in several countries batting on behalf of the ‘Industry’ to promote GMOs, an issue of great criticality in India. GMOs have their genesis in the USA. Their regulation in India and many other countries has been significantly affected by the effective deregulation of GMOs in the US, the singular lack of oversight of the bio-safety of GM crops (ref. section 5.). This particular aspect is a marked departure from the record of the history of DDT in the US, where national Institutions of governance and legislation were created to study the science. They did so with a degree of objectivity, in response to the public consciousness sparked by *Silent Spring*, whose findings vindicated Carson. These were foremost in the corrective precautionary measures that were concluded and enforced for DDT nationally and internationally.

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## DDT: the debate unfolds

When DDT became available for civilian use in 1945, it was promoted as almost good enough to eat, which is the message that is delivered in this early advert.

Time Magazine, circa 1947



(Pennsylvania Salt Manufacturing Company)

There were only a few people who expressed second thoughts about this new ‘miracle’ compound. One was nature writer Edwin Way Teale, who warned, “A spray as indiscriminate as DDT --- Ninety percent of all insects are good, and if they are killed, things go out of kilter right away”. The other was Rachael Carson in *Silent Spring* (1962), about the environmental and health impacts of chemicals, with a focus on DDT. It meticulously described how DDT entered the food chain and accumulated in the fatty tissues of animals, including human beings, and caused cancer and genetic damage. A single application on a crop, she wrote, killed insects for weeks and months. Technology was moving ahead of science and on a faster trajectory than mankind’s sense of moral responsibility. She insisted that what science believed and technology made possible must first be judged for its safety and benefit to the “*whole stream of life*”. The pollution of the environment by the profligate use of toxic chemicals was the ultimate act of human hubris, a product of ignorance and greed. Like the rest of nature we are vulnerable to pesticides; we too are “*permeable*”. There are no “*thresholds*”, Industry’s guile response, or “*assimilative capacities*” that render pesticide poisons harmless. The negative effects of DDT were first reported on birds and declines in the populations of birds

of prey were observed in many places of the world and tied to eggshell thinning after bioaccumulation of DDT (ref: EEA: Bernes, 1998; Bernes and Lundgren 2009). *“The close association between humans and birds remains very apt. Representing the only two warm-blooded groups of life on Earth, mammals and birds share the same environments and threats”* (EEA).

The chemical industry in 1962 was a multimillion-dollar industry and one of the chief sources of American prosperity. IT WAS AN ERA DOMINATED BY INDUSTRY. They saw a threat to their right to make a dollar at whatever cost, in the same way that Monsanto in the 1990s didn't plan to lose \$1 dollar's worth of business to clean-up the drinking water of Anniston which they had knowingly poisoned with PCBs for decades and concealed.<sup>10</sup>. The Industry responded with a vicious attack on Carlson: She was a woman and hysterical. *“If man were to faithfully follow the teachings of Miss Carson,”* complained an executive of the American Cyanamid Company, *“we would return to the Dark Ages, and the insects and diseases and vermin would once again inherit the earth.”* Monsanto published and distributed 5,000 copies of a brochure parodying *Silent Spring* entitled **“The Desolate Year,”** relating the devastation and inconvenience of a world where famine, disease, and insects ran amuck because chemical pesticides had been banned. (NRDC - Natural Resources Defense Council).

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## Lessons and connecting threads

Little has changed. The 21st century is dominated by the chemical industry in an even more ominous way, concentrating seed power and insecticidal chemicals through GMOs. In the last two years, the agrichemical and food industries have mounted a public relations and political campaign of more than \$100 million, to support GM crops and the pesticides used with them and oppose labelling of GM food in the US (<http://t.co/EuhczWdB> & Gary Ruskin)<sup>11</sup>

- It is clear that there is a roadmap for the exit of DDT, but there is no timetable.
- With more than 10 % of bird species worldwide now threatened in one way or another, it is clear that we missed early warnings or failed to act on them.
- The public must decide which roads to travel, but can only do so if in full possession of the facts. *‘The obligation to endure gives us the right to know’* (Jean Rostand quoted by RC in *Silent Spring*). But those rights to know are not being met even now in the 21st C in a climate of even headier corporate hubris and corruption and its ability to make deep inroads into the corridors of political power and processes of governance. This is certainly true of India and the US in the specific matter of GMOs (ref. Section 5).
- The early warnings of resistance development in DDT were not viewed in any environmental light, but rather as an opportunity to develop new chemical pesticides to solve the problem, eerily prescient of the current FDA dismissal of the proven resistance and growing volumes of pesticides necessary with HT crops and the ensuing entrapment of farmers on a pesticide treadmill (Benbrook, Gurian-Sherman, Mortensen – see Section 5). Muller's

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<sup>10</sup> **Anniston:** An Alabama jury found that Monsanto Co. engaged in “outrageous” behaviour by releasing tons of PCBs into the city of Anniston and covering up its actions for decades (Washington Post 23 February 2002). Monsanto and its corporate successors were convicted on all six counts it considered: negligence, wantonness, suppression of the truth, nuisance, trespass and outrage. Under Alabama law, the rare claim of **outrage** typically requires conduct *“so outrageous in character and extreme in degree as to go beyond all possible bounds of decency so as to be regarded as atrocious and utterly intolerable in civilized society.”* Monsanto produced almost 99% of the PCBs (toxic polychlorinated biphenyls) for industrial use in the USA, before their ban in 1979. Fish in a creek were found with 7500 times the legal limit of PCBs, but according to Monsanto, *“there is little object in going to expensive extremes in limiting discharges.”* In 1975, a company study found that PCBs caused tumours in rats. They ordered its conclusion changed from “SLIGHTLY TUMORIGENIC” to “DOES NOT APPEAR TO BE CARCINOGENIC.” (Washington Post, 1 January 2001)

<sup>11</sup> USRTK January 2015

Nobel Prize presentation speech made no mention of potential environmental concerns from resistance to DDT, but rather the ‘persistence’ of DDT which was viewed positively. Today, this is one of the main environmental concerns. Early recommendations on how to use DDT were “*staggeringly indiscriminate*”, a description that fits perfectly, the manner in which HT crops invite indiscriminate and voluminous spraying without thought – indeed the Monsanto advice to farmers was to keep their nozzles wide open. Carlson’s closing comment in *Silent Spring* is a prophecy of the current times of the GMO era: “*The concepts and practices of applied entomology for the most part date from the Stone Age of science. It is our alarming misfortune that so primitive a science has armed itself with the most modern and terrible weapons, and that in turning them against the insects it has also turned them against the earth.*”

- Now, 50 years later, how modern and current many of the issues that she raised are. The issue of ‘mixture’ effects, referred to in the Stockholm Convention as ‘toxicant interactions’, pharmaceuticals and personal care products (PPCPs) is a major area of research. Scientific advances are finding ever more effects associated with chemicals in more and more biological systems; some effects such as endocrine disruption was barely understood at the time of Rachel Carson (EEC). Indeed, endocrine disruption does not form part of any risk assessment for GMOs anywhere, yet glyphosate is a teratogenic/ endocrine disruptor (Seralini, Carrasco<sup>12</sup>). This aspect is only now being probed by the FDA. It is a similar case with ‘synergistic’ effects of stacked genes in GMOs (Testbiotech; GeneWatch UK<sup>13</sup>), or with other pollutants (Sneff S<sup>14</sup>). Carson confronted us with the chemical contamination of the Globe, which every country has failed to stop (Edward O Wilson). Perhaps her most prophetic advice was: “*The most determined effort should be made to eliminate those carcinogens that now contaminate our food, our water supplies, and our atmosphere, because these provide the most dangerous type of contact — minute exposures, repeated over and over throughout the years.*”

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<sup>12</sup> Carrasco: Glyphosate-based herbicides produce teratogenic effects on vertebrates by impairing retinoic acid signalling: [http://www.gmwatch.org/index.php?option=com\\_content&view=article&id=12491](http://www.gmwatch.org/index.php?option=com_content&view=article&id=12491)

<sup>13</sup> TestBiotech & GeneWatch: Safety of Monsanto’s Synthetic-Toxin maize to be re-examined: <http://www.testbiotech.de/node/526>.

<sup>14</sup> Defining Autism with Dr Stephanie Seneff

# Section 3

Aruna Rodrigues

Lead Petitioner (Public Interest Writ (PIL) in India's Supreme Court)

## CFCs (Chlorofluorocarbons) & The Precautionary Principle<sup>15</sup>

The evidence which allows us to conclude, beyond reasonable doubt, that halocarbons are responsible for the damage to the ozone layer, is set out in a series of five reports prepared by the World Meteorological Organization (WMO) for the Parties to the United Nations Vienna Convention and Montreal Protocol (WMO, 1985, 1989, 1991, 1994 and 1999)<sup>16</sup>.

It has become conventional to regard **the late 1970s** as the time when damage to the ozone layer can be traced, when a level of **2.5 ppbv** (parts per billion by volume) of equivalent chlorine, was first reached. **In 1974** seminal papers by American scientists pointed out that CFCs WERE SO STABLE that they would eventually reach the stratosphere, that chlorine would be released there by

Photolysis, and that an ozone-destroying chain reaction would ensue, (Molina and Rowland, 1974; Cicerone et al, 1974). A vigorous debate followed, which was to continue for over a decade. A familiar pattern (to the later CBD 2-year cycle of negotiations on GMOs) of setting consensus and compromise before effectiveness, of negotiators consistently taking the view that it would be easier to get agreement at the next meeting, is perhaps the reason for the failure for decisive action on CFCs (EEA).

### Some key reasons why the CFC episode was not avoided - timelines

**The 1977 US Clean Air Act** explicitly states that '*no conclusive proof... but a reasonable expectation*' of harmful effects is sufficient to justify action (US EPA, 1987). This was in stark contrast to the 'wait and see' attitude adopted by industry. Du Pont, the world's first and largest producer of CFCs, had set this out in a full page in the *New York Times* (30 June 1975). It declared that: '*Should reputable evidence show that some fluorocarbons cause a health hazard through depletion of the ozone layer, we are prepared to stop production of the offending compounds.*' **It was to deny the existence of reputable evidence until 1986.** However, this does not answer the reason why the Government did not enforce the EPA Clean Air Act.

**1930 to 1948:** Recession and war restricted the growth of the CFC industry. Cumulative releases of CFC-12 and CFC-11 were only 25 and 5 kilotonnes respectively. The next two decades brought spectacular growth.

**1970:** By this decade the annual releases were 300 and 207 kilotonnes. People had been persuaded to buy CFCs and throw them away (aerosols). Industry's dream of 'wonder chemicals' was apparently coming true. It might reasonably have been asked whether such development was sustainable.

**1985<sup>17</sup>:** The report in 1985 of rapid and severe seasonal destruction of ozone over Antarctica was an outcome of systematic long-term measurements, begun solely for scientific exploration. It took everyone by surprise, including the authors. The accepted view was that the effects of CFCs should be seen first at high altitudes (30–50 km) in the tropics, and that any changes in the lower stratosphere in Polar regions would be very slow. It should also be noted that the ozone community was just completing the first of the WMO (World Meteorological Organisation) reports — an onerous task for authors and reviewers. The funding of long-term monitoring remains a serious problem. It

<sup>15</sup> EEA (European Environment Agency): Late Lessons from early Warnings: the PP 1896-2000, Report No 22 Chapter 7

<sup>16</sup> EEA: In the second half of the last century some **23 million metric tonnes of chlorofluorocarbons (CFCs)**, about 11 million tonnes of methyl chloroform, 2.5 million tonnes of carbon tetrachloride and 4 million tonnes of hydrofluorocarbon (HCFC-22) were released into the atmosphere. All of these halocarbons have atmospheric lifetimes, long enough for them to be transported to the stratosphere. The amount of chlorine in the stratosphere today is between six and seven times what it was in 1950. There is an 'ozone hole' over Antarctica from September to December each year.

<sup>17</sup> May 1985: That Ozone depletion over Antarctica much more severe than any prediction (*Natur*:(Farman et al., 1985) was confirmed by NASA in October 1985. In reporting the NASA results, the *Washington Post* gave the world the term 'ozone hole'.

is simply not practicable to provide open-ended funding at **the level needed to cope with uncovering a major environmental issue.**

**1987:** The Montreal Protocol was signed on 16 September 1987.

## Lessons and connecting threads

- i. Serious negotiations did not begin until severe depletion had occurred, and strong evidence found to link it with CFCs. The protracted, and frequently amended schedule for phase out of ODS (ozone depleting substances) suggests that, even at this stage, precautionary management of the environment was not uppermost in the minds of policy-makers.
- ii. “There can be little doubt that a conventional risk assessment, in say 1965, would have concluded that there were no known grounds for concern. It would have noted that CFCs were safe to handle, being chemically very inert, non-flammable, and having very low levels of toxicity. They were good heat insulators, and some were excellent solvents, mixing readily with a wide range of other organic substances”. What was not admitted however is that it was not known, what happens to CFCs when they are released into the atmosphere; “but no doubt, it would have been added that they had been released for more than 30 years with no apparent harm being done. There would probably have been a long list of recommendations for further research. In retrospect, it is easy to see that these should have included investigating the ultraviolet and infrared spectra of CFCs, measuring their atmospheric concentrations, and identifying their decomposition products. As it happens, there were hints of the risk to the ozone layer available (Weigert, 1907; Norrish and Neville, 1934 (10), if it had been recognised that atomic chlorine and fluorine might be released from CFCs in the upper atmosphere. But they would surely have been dismissed on the grounds that there would be at least 10 000 times more ozone than CFCs at the relevant altitudes”. (EEA)
- iii. Practices that appear to be reasonable when introduced (in this case when there were huge gaps in the understanding of atmospheric processes) may later (as understanding improves) be seen to be leading to a major global problem that can neither be avoided, nor rapidly alleviated. There is a deep-seated paradox here. Short-term safety appears to demand that synthetic chemicals in everyday use should be non-reactive. it has taken a long while for it to be realised that this means that they will be extremely persistent (EEA). It is clear that there were huge gaps in understanding CFCs.

These arguments are the classic ‘latency lacuna’ characteristic of long latent –period hazards: asbestos and DDT went from magic to malevolent like CFCs. In part, but only in part, their history reflects a parallel with GMOs. The magic of GMOs however, it must be clearly understood was a concoction, a myth from the start. This is the difference with the historical gaps in the understanding of CFCs. The warnings of harm from the process of genetically engineered plants/crops came from within the US FDA; they came before GMOs were commercially released in the US, but were comprehensively ignored and sidelined. This was systematic regulatory fraud perpetrated and perpetuated from the beginnings of the commercialisation of GMOs in 1992, in the US (the country that invented them). It was based on the unscientific theory of ‘substantial equivalence’ with Non-GM crops, giving GMOs GRAS (generally recognised as safe) status in the US. Therefore, there was no requirement for safety- testing, a matter that was left to the voluntary action of the crop developer (Schubert, Freese 2004; Druker [www.biointegrity.org](http://www.biointegrity.org); Supreme Court WP 2005). In this climate of self-referral diversionary tactics,

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the argument of the ‘absence of evidence of harm’ was and continues to be deliberately equated with ‘evidence of absence of harm’ with ‘deadly’ consequences for GMO safety-testing, regulation and agri policy in several countries both in the developed and developing world. The long-term argument of what harm might unfold over time is fully applicable to GMOs, which in any case are not subjected to long-term and life-time animal feeding studies by regulators anywhere, with the added twist that surprise is one inevitable outcome because of ‘unintended’ or unknown effects associated with GMOs. Furthermore, regulators rely on self-assessed company safety-dossiers or voluntary safety-disclosures as in the US, where cover-up and even fraud have been discovered when subjected to independent appraisal.<sup>18</sup> This massive conflict of interest puts the public at risk. The trust reposed in crop developers for self-assessment of safety-dossiers has a distinct note of the bizarre given 100 years of a dark history of crimes committed by Monsanto (DDT/Agent Orange/PCBs etc) and other biotech companies, including crimes for which Monsanto was convicted e.g. Anniston. Such policy has the serious outcome of cementing risk-assessment and policy in a perennial cycle of conflict of interest. Clearly this is unacceptable.

‘Unintended’ outcomes of the GMO conundrum demand that we recognise the nature and limitations of our knowledge of DNA (and RNA), which adds to the complexity of risk assessment. The huge and apparently insurmountable problem is of course the rot that has spread through the system in several countries because of severe conflicts of interest and the self-assessment processes by crop developers that regulators are committed to. In India, the inroads are cancerous, which necessitate serious litigation as the only remedy<sup>19</sup>. It is clear that like CFCs, there are also huge gaps in understanding the health and environmental consequences of open release with the additional burden that there is no commitment by the Indian regulators and relevant Ministries to uncovering the gaps.

***In India, the inroads are cancerous, which necessitate serious litigation as the only remedy<sup>19</sup>. It is clear that like CFCs, there are also huge gaps in understanding the health and environmental consequences of open release with the additional burden that there is no commitment by the Indian regulators and relevant Ministries to uncovering the gaps.***

- iv. In both cases, CFCs and GMOs, the technology has outpaced the science needed to assess the risks involved. Here again, because of the risks inherent in the technology of GE and other problems outlined above, the pressures, vilification and lack of resources faced by independent scientists in their research on GMOs are immense. Yet, despite these problems, independent and sound science is available; and it is raising alarms and warnings about this new and potent agricultural technology. If there is to be a solution for the public good including the protection of the environment from irreversible consequences, then these matters must be resolved. How that will be done will largely depend on in-country commitment to regulatory transparency at every stage. In the current prevailing climate of criminal conflict of interest in India, the mind-set is absent to recognise ignorance in the matter of GMOs and replace it with a real understanding of the science of GMOs and lessons learnt from the history of past errors and gaps in knowledge of the products of technology. In India the action that will bring about change is for conflict of interest in politicians and public servants administering policy, to be made a criminal offence. There are recent healthy legal interventions from High Courts and the SC on the corruption ensuing from conflicted positions within government in administering policy. Policy-makers must recognise, and rapidly that for GMOs, the time-factor or ‘TIMELINESS’ of a decision to stop their environmental release is a CRITICALITY: GMO contamination must be avoided as the prior objective of GM crop policy.
- v. One of the lessons should have been that NEITHER GOVERNMENTS NOR MULTINATIONAL COMPANIES HAVE A MANDATE FOR GLOBAL EXPERIMENTS. The CFC issue provides a stark warning (EEA). We appear to have ignored this lesson of history in the matter of GMOs.

<sup>18</sup> Profs. Seralini and Pusztai both confirmed that Monsanto’s safety dossier of Mons 863 corn was a cover-up, and demonstrated harm in the rat feeding studies. Bt brinjal in India was subjected to in-depth appraisal of the raw data of the Monsanto-Mahyco safety dossier (SC evidence and the appraisal process of Jairam Ramesh 2009-10), by several eminent international scientists, after the raw data was forced into the public domain by an Order of the SC and reluctantly complied with 16 months later (2008). There were both cover-up and undeniable fraud with virtually no regulatory oversight and Bt Brinjal was still approved by the apex Regulator the GEAC for commercial release (Oct. 2009); but subsequently stopped (Feb 2010) by the erstwhile Minister of the MoEF, (ministry of Environment & forests), Jairam Ramesh (UPA government); (ref. section 5 for details).

<sup>19</sup> The fuller treatment of these arguments is provided in Section 5.:

# Section 4

Aruna Rodrigues

Lead Petitioner (Public Interest Writ (PIL) in India's Supreme Court)

## GMOs & The Precautionary Principle Interpreted In The Light Of 'Current' Scientific Warnings Of Their Impacts

*"Within 10 years we will have a moderate to large-scale ecological or economic catastrophe, because there will be so many products being released."*

**Norman Ellstrand** (Prof. Ecological Geneticist, Univ. of California)

*"The ecosystem - you can always intervene and change something in it, but there's no way of knowing what all the downstream effects will be or how it might affect the environment. We have such a miserably poor understanding of how the organism develops from its DNA that I would be surprised if we don't get one rude shock after another."*

**Richard Lewontin** (Prof. of Genetics, Harvard Univ.)

- Prescriptive action requires knowledge of the facts surrounding a technology<sup>20</sup>, and also the politics. It further demands foresight and consideration of potential harm and uncertainty.

### Ultimately the Question is:

- Are there sufficient data/early warnings with regard to environmental, human and animal health impacts of GMOs to be concerned and that would warrant a level of action that raises the response from cautious and limited action (the SC Orders thus far have been in this category) to that of a moratorium and even a ban in the case of specific GM products as recommended by the SC-appointed TEC?

The answer is "yes". The discussion and reasons are as follows:

i. **GMO were approved fraudulently in the face of scientific warnings:** The warnings about GMOs were clear warnings right from the start, always 'current', not merely 'early' warnings. The technology is being promoted and rapidly deployed despite these 'current' warnings and scientific data to the contrary with *almost no thought whatsoever to its consequences* (Dr Suzanne Wuerthele)<sup>21</sup>. This is one aspect that distinguishes GMO technology from other hazardous technologies like CFCs and DDT, which were initially seen as almost magical in their effectiveness and benefits for the human race. The 'malevolence' of their impacts was revealed later. The distinction is important because in the case of GMOs, the 'TIMELINESS' of preventive action is a *criticality* we face globally as well as in each country, and no parallels come to mind in the history of technologies that can be cited to match this specific concern with GMOs, as we wrestle with the problem of certain irreversible GMO CONTAMINATION of our genetic diversity in seeds and food if they are deployed. The contamination of our seeds will change the structure of our food at the molecular level. Any harm or toxicity will

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<sup>20</sup> See Section 5

<sup>21</sup> **Suzanne Wuerthele:** EPA toxicologist

remain without the possibility of remediation or irreversibility. This is the outstanding issue and the unacceptable cost. We provide the analogy of Thalidomide. When thalidomide was banned, the tragic deformities ceased. It is so with all drugs. A harmful drug can be recalled. Remediation and reversibility are not options with GMOs. This is a potent agricultural technology of living modified organisms, which will reproduce themselves when released into the environment.

Their Introduction in the US, the country that invented them was skilfully contrived, with the full might of the White House *fostering* their commercialisation globally, through trade agreements, (which undermine national freedom to act independently on GMOs in food and agriculture), the WTO and diplomatic channels. Their introduction was a **political and economic decision**, which disregarded the overwhelming consensus of their own scientists who recognised the unique risks posed by GMOs (ref. Section 5 A). The 'sleight of hand' application of GRAS (Generally Recognised as safe) status to GMOs under US law led to the notion of 'Substantial Equivalence' (SE), which India has clung to and upholds right up to the present time. SE made it necessary to generate other myths in a series of self-endorsing and reinforcing claims, in order to underpin the premise of the safety of GMOs and legitimise the absence of regulatory oversight over GM crops in the US: (ref. Section 5 B: GMO Myths). These claims have been systematically overturned as scientifically untenable.

To this list, India has added her own home-grown myths. When confronted with indisputable evidence that GMOs in open field trials were not being subjected to appropriate protocols of safety-testing before release and were therefore, unsafe, the Union of India responded that field trials were necessary in order to conduct bio-safety tests! This curious and circular logic is only matched by the ability and it has to be said courage, of our regulators to make the claim in the first place. The second claim, in response to Petitioners' prayer for an injunction on field trials was that in this event all GMO research would stop and we would trail the world in GM crop technology to the detriment of Indian agriculture. By analogy, Western Europe has a de facto ban on growing GM crops. Yet its yields in the same (conventional) crop continue to grow, and to grow faster, than comparable crops that are GM in both Canada and the US (Heinemann et al 2014)<sup>22</sup>. The fact is that research of course would not stop and must be confined to secure laboratory conditions for the present. Yet, it is a sign of the times, that both these claims have been accepted by relevant Ministers in government. Open field trials have commenced, even large-scale, in mustard and corn, which hold real risk of GMO contamination.

ii. **Science, reason & ethics will not influence the government to change its GMO policy in India:** The problem this raises in respect of GMO policy is a peculiar and particularly serious one for India and her future. The endemic and proven conflict of interest drives GMO policy in India at the level of the PMO, ie GM crops are safe and are required for India's food security. Such is the official commitment to the wholesale introduction of GMOs into Indian agriculture that the IB (June 2014 document)<sup>23</sup> took the unlikely course of action to depart from its mandate of the internal security of India, to enter a debate it knows nothing of - to declare that opposition to GMOs is anti-national! Given Monsanto's monopoly ownership of around 90% of Bt cotton hybrids in less than 10 years of its introduction, (the only commercialised crop), this support of the potential foreign ownership of India's food production is astounding, as is the threat of tyrannising citizens who object to such an inherently anti-national policy as handing over India's food sovereignty into private hands and foreign corporations.

The profoundly disturbing point is also that under these circumstances, the debate is not and will not be, about the facts and science of GMOs, or its ethics, no matter how well we try to engage our government with the facts. The GEAC has also taken the regressive step of removing access to its website inviting a formal notice of Contempt of Court by Petitioners' Advocate Prashant Bhushan (2014). The intention is to keep the 'public in the dark' about GMOs, the food that they eat and make dissent difficult. Yet, 'the obligation to endure gives us the right to know', (a right under the Constitution of India). Therefore, and this is the distinction between GMOs and the history of CFCs - CFCs, were ultimately banned globally, though late, with individual country-action complying with that ban. On the other hand, we may not expect corrective public policy by regulators internationally, in the matter

<sup>22</sup> Heinemann, J. A., Massaro, M., Coray, D. S., Agapito-Tenfen, S. Z. & Wen, J. D. Sustainability and innovation in staple crop production in the US Midwest. *Int. J. Ag. Sustain.* 12, 71-88, doi:10.1080/14735903.2013.806408 (2014).

<sup>23</sup> Intelligence Bureau: DJBU-O. No. 28/01/2014(31)•1926-1941: SECRET IR/IS No. 002: 'Concerted efforts by select foreign funded NGOs to 'take down' Indian development projects'

of GMOs, to be driven by reason, ethics, and science. It is abundantly clear that such policy to safeguard India's public health and food security will only be delivered via a legal remedy, in the Supreme Court for a moratorium on the environmental release of any GM crop.

iii. **Experience of people:** They may anticipate the views of scientific experts by several years. This lesson from history in the cases of at least two products, Benzene and cigarettes, have not been learnt. In part, this is because the seriously conflicted regulators both in India and the West in support of the 'Industry' have rushed to neutralise every adverse report. Thousands of sheep died in India, grazing in Bt cotton fields. There have been similar problems of toxicity in animals reported from Germany, the US and the EU. Allergic reaction among cotton pickers is pretty well conclusive. The science of GMOs confirms it. No tests can guarantee that a GMO will not cause allergies. Although the World Health Organization recommends a protein screening protocol, the GM soy, corn, and papaya in our food supply fail those tests— because they have properties of known allergens.

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iv. **Unintended effects of the GE process & the 'latency lacuna':** In one sense GMOs fall outside the scope of

*“Given the fact that genetically modified plants are going to make proteins in different amounts and perhaps totally new proteins than their parental species, what are the potential outcomes? Direct toxicity may be rapidly detected once the product enters the market place, but carcinogenic activity or toxicity caused by interaction with other foods would take decades to detect, if ever”. (Schubert<sup>24</sup>).*

scientific risk assessment, given that surprise is one inevitable outcome of 'unintended effects' of the genetic engineering process. Long latent-period-hazards (the 'latency lacuna') are characteristic of GMOs (as they were of DDT) and particularly because it is an agricultural technology. The negative aspects of the 1st Green Revolution of the 1960s only became apparent decades later. We won't have the luxury of undoing any harm that GMOs may cause. “Given the fact that genetically modified plants are going to make proteins in different amounts and perhaps totally new proteins than their parental species, what are the potential outcomes? Direct toxicity may be rapidly detected once the product enters the market place, but carcinogenic activity or toxicity caused by interaction with other foods would take decades to detect, if ever”. (Schubert<sup>24</sup>).

What science learned later about the damaging effects of DDT and other pesticides was as follows. The highlighted text is what DDT and some GMOs have in common:

- **Disrupt the immune system**
- **Reduced Disease Resistance\***
- **Disrupt the endocrine system**
- Disrupt development of many systems
- **Birth Defects**
- **Reproductive Problems & Sterility**
- **Cause Cancer**
- Interfere with Higher Functions
- Cognition
- Memory
- Motor Coordination
- Behavioral & Emotional Problems
- **Gross ecological disruption**

\*herbicide effects

<sup>24</sup> Professor David Schubert, Cell Biologist, Cellular Neurobiology Lab, The Salk Institute For Biological Studies, San Diego, USA

v. **Neither governments nor multinational companies have a mandate for global experiments:** The CFC issue provides a stark warning (EEA). We appear to have ignored this lesson of history in the matter of GMOs. The parallel between CFCs and GMOs with regard to their global aspect for ruin is unique. For this reason, and supremely, the PP must be interpreted and deployed at the level of an international ban. *“It may not always be possible for a country to protect its nationals without relying upon other countries to meet their obligations to act according to the precautionary principle. This is a reciprocal obligation in the community of nations”* (Heinemann). GMOs cannot be ‘localised’; when harm is localised or non-spreading the *“potential danger for a miscalculation is bounded”* (Nassim Nicholas Taleb<sup>25</sup>). By contrast genetic contamination of non-GM crops and wild species through gene flow is certain and cannot be contained or reversed (rape and flaxseed in Canada, corn in Mexico, rice, wheat, and StarLink corn in the US, GM Cotton in India contaminating Non-GM cotton), as well as through human error, commingling, trading, spillages etc). Indeed, it is this global aspect of contamination that is the recognition and focus of the International protocols of the CBD for transboundary movement of GMOs cemented in the PP. When the potential impacts of damage are irreversible and unquantifiable as in GMOs, it raises the magnitude of the danger of a *“miscalculation to infinite”*. *“It is in this category of total ruin problems that the precautionary principle comes into play. A key difference between these types of risks is the statistical structure of their impact. The risk from genetically modified organisms is a potential for widespread impact on the ecosystem and widespread impact on human health. In other words, it is scale independent”* (N Taleb). Such impacts call for a fundamental change in the nature of decision-making, a fundamental shift in the interpretation of the precautionary principle that moves from caution and remediable action at this level, to a moratorium, and also selective bans (as required for example by India’s TEC). This demands a thorough understanding of what the risks are. Furthermore, how those threats are perceived will determine how the PP must be interpreted and then applied to these living modified organisms and it is information that is crucial to that determination.

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vi. **GM seed treatment and dying bees:** GM seeds and all Bt cotton seeds in India are treated with neonicotinoids to protect from insect pests other than that which is targeted by the Bt toxin (the bollworm). In recent years, it was noticed that bees were mysteriously dying in what is called ‘Colony Collapse Disorder’ (CCD). Some studies linked CCD to the widespread use of neonicotinoids, which are the most toxic of all insecticides to bees. Billions of bees were reported to have disappeared in Europe and America since 2006 because of CCD. Though many factors such as mobile towers, heavy metals, a microbe called Nosema, a mite called Varroa destructor, and a virus called Deformed Wing Virus (DWV) were implicated, the insecticide group ‘neonicotinoids’ was found to have the strongest effect on CCD. The scientific reports<sup>26</sup> showed that ‘neonicotinoids’ when used either as seed treatment or as foliar sprays are translocated into the tissues of the plant pollen and nectar which are collected by worker honey bees to build food reserves for the entire hive. Neonicotinoids kill bees at extremely low doses of 3-4 nano gram per bee, but when exposed to sub lethal doses, honey bees suffer from loss of orientation, lower productivity in worker bees and reduced queen’s brood production, memory loss, reduced immunity, impaired

<sup>25</sup> Black Swans: Nassim Nicholas Taleb et al - the Distinguished Professor of Risk Engineering at New York University. Co-authors: Raphael Douady at the Institute of Mathematics and Theoretical Physics in Paris and Yaneer Bar-Yam at the New England Complex Systems Institute in Cambridge. Ref: arxiv.org/abs/1410.5787 :

The Precautionary Principle (with Application to the Genetic Modification of organism: <https://medium.com/the-physics-arxiv-blog/genetically-modified-organisms-risk-global-ruin-says-black-swan-author-e8836fa7d78>; GMWatch, 29 October 2014 <http://www.gmwatch.org/index.php/news/archive/2014/15726>

<sup>26</sup> CCD: The moratorium in the EU was based on four important scientific studies published in Science (Penelope et al., 2012; Henry et al., 2012), Nature (Gill et al., 2012) and Bulletin of Insectology (Chensheng et al., 2012) and a review in 2013 by the European Food Standards Agency (EFSA) which identified “high acute risks” posed by the neonicotinoids for bees.

foraging and loss of track to return back to the hive. Employing the PP, the European Commission has adopted a proposal to restrict the use of three pesticides belonging to the neonicotinoid family (clothianidin, imidacloprid and thiametoxam) for seed treatment, soil application (granules) and foliar treatment on bee- attractive plants and cereals, for a period of two years from 1st December 2013 to be enforced by the 28 EU member countries. (i).

The impact of the decline in bees could cause an estimated loss of \$ 215 billion worth of global food production in 2005 (Gallai et al., 2009) (ii) and losses of \$138 Billion and \$334 billion in the agricultural sector and non-agricultural sectors, respectively (Bauer and Wing, 2010 (iii)).

In India (ref. Section 4. p 46) seed companies treat Bt cotton seeds with a powerful insecticide called ‘Imidacloprid’ (family of neonics), which is translocated into seedlings to protect them for up to two months or more from sap-sucking insects. It is estimated that at least 1500 metric tonnes of neonicotinoid insecticides are used in India of which about 240 metric tonnes are used every year for seed treatment of Bt cotton. Undoubtedly this could be devastating bee populations thereby causing huge losses in biodiversity of agricultural crops and natural ecosystems. Though imidacloprid was registered in India in 1993, the usage was negligible until 2002 when Bt cotton was approved for commercial cultivation in India. An estimated 1000 metric tonnes are currently used every year on Bt cotton in the form of seed treatment and foliar sprays. Not much attention has been given to bees and CCD in India. It represents a significant gap. There is no post market monitoring of Bt cotton.

The practice of seed treatment is at odds with the *raison-detre* of Bt crops that they are intended to reduce insecticide use. But it fits well into the aim of adding extra value to the GM seed package for the ‘Industry’ and ensuring that farmers remain on a pesticide treadmill. CCD is a late discovery of a huge magnitude of harm associated with GM crops, (but not the technology of GE itself). CCD highlights the potential for serious unexpected harm. In this case, the death of pollinators and honey bees have such serious implications for European agriculture that the EU has thought fit to invoke the PP at the level of a ban.

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***“If the bee disappeared off the surface of the globe then man would only have four years of life left. No more bees, no more pollination, no more plants, no more animals, no more man.”***

**Albert Einstein**

vii. **RNA – dsRNA fall outside the radar of risk assessment:** Risk assessment protocols do not currently assess dsRNA (ref. Bt brinjal). The Heinemann et al study<sup>27</sup> establishes that *all GM crops should be evaluated for the presence of unintended dsRNA molecules*. That is, even crops not purposefully constructed to express these molecules like India’s Bt brinjal need to be evaluated for them, because they are a common by-product of the engineering process<sup>28</sup> (Ref Section 5. V). However, the first intentionally pesticidal GM crop trait based on RNA is before food safety regulators for approval to release as a food for humans or feed for animals.

What is illustrated here is that a new kind of pesticide product based on the active ingredient of dsRNA is the subject of both scientific uncertainty and regulatory uncertainty. As a pesticide, it clearly has the power to cause adverse ecological (and health) effects. As a contaminant in food or feed, the effects are uncertain. Taken together, the example illustrates a situation of scientific complexity, uncertainty or ignorance, the key trigger in Europe for invoking the precautionary principle.

<sup>27</sup> **Heineman J. A., Agapito-Tenfen, S. Z. & Carman, J. A.:** “A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments”. *Environ Int* **55**, 43-55,

<sup>28</sup> **Weld, R., Heinemann, J. & Eady, C. :** “Transient GFP expression in *Nicotiana plumbaginifolia* suspension cells: the role of gene silencing, cell death and T-DNA loss”. *Pl. Mol. Biol.* **45**, 377-385 (2001).

viii. **Court Decisions:** The recent **New Zealand High Court** decision (bibliography:58) is of singular importance for the risks we face from new kinds of GMO products because countries or companies may unilaterally decide that a product is not genetically modified. In doing so, notification to importing countries is no longer required (CBD norms). By rejecting the New Zealand Environmental Protection Authority determination that plants created by some new forms of genome editing were not genetically modified, the **COURT EFFECTIVELY ENFORCED THE PRECAUTIONARY PRINCIPLE BOTH DOMESTICALLY AND FOR OTHER COUNTRIES**. In essence, the New Zealand courts have acted to protect India's citizens too.

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In the **Philippines**, the **Judgment and Order of the Philippine Court of Appeals** imposed a prohibition on Bt brinjal, to protect the rights and safety of its citizens (CA-G.R. SP No 00013). The case illustrates the importance of sound appraisal processes in India being available to CSOs in other countries for use in legal interventions (ref. Section 5. V).

**Mexico: February 2015**<sup>29</sup>: there is an existing ban on the planting of GM Maize in Mexico, the 'cradle' of maize genetic diversity and civilisation. Conservation of native maize is necessary because it is the main source food and nutrition of the Mexican people and a cultural element of cohesion and social coordination. A string of 4 important court orders have upheld the ban, overturning Monsanto's challenge to end the ban.

ix. **The Precautionary Principle also points to alternative safer approaches.** In the **arena of agriculture**, and for India this is particularly vital. The evidence from several international agencies confirms the findings of the IAASTD Report. India is a signatory. It came to the conclusion that agricultural goals are not well served through the western innovation model. It delivers the message that simple solutions for complex problems - as they are being proposed with GMOs as the solutions to production problems of today and climate change impacts of tomorrow - are not credible (H Herren, Co-chair of the IAASTD). The IAASTD makes it clear that the road map for agriculture for the **next 50 years** must be through localised solutions, combining scientific research with traditional knowledge in partnership with farmers and consumers. The Report calls for a systematic redirection of investment, funding, research and policy focus toward these alternative technologies and the needs of small-farmers (Section 5. E).

*The lesson from the Climate Change (Cc) debates for GMOs is also the sheer scale of the disinformation regarding man-made contributions to Cc for decades. It has resulted in late and very late collective global action to drastically reduce CO2 emissions, the consequences of which will be much too serious for our planet. In like manner, we are being subjected to an incredible degree of dangerous untruths and disinformation with regard to GMOs. And we do not have the luxury of late action. The criticality of 'timeliness' so we are not presented with a fait accompli is an imperative. For India, that time for a decision on GMOs is now. We stand at the edge and must come off it.*

The lesson from the Climate Change (Cc) debates for GMOs is also the sheer scale of the disinformation regarding man-made contributions to Cc for decades. It has resulted in late and very late collective global action to drastically reduce CO2 emissions, the consequences of which will be much too serious for our planet. In like manner, we are being subjected to an incredible degree of dangerous untruths and disinformation with regard to GMOs. And we do not have the luxury of late action. The criticality of 'timeliness' so we are not presented with a fait accompli is an imperative. For India, that time for a decision on GMOs is now. We stand at the edge and must come off it.

The official spin is that both Bt cotton (the only commercialised crop) and Bt brinjal offer a sound basis to confidently launch into other products; the former based on 10 years of its 'superlative' performance and the latter on its sound biosafety dossier assessed by Mahyco-Monsanto. Both are untrue claims. The truth of Bt cotton is made

<sup>29</sup> <http://ejfood.blogspot.co.uk/2015/03/monsanto-in-mexico-four-february-court.html>

apparent by the Governments own statistics. Yield has stagnated at just over the 500kg/hectare level, barely higher than the pre-Bt era; insecticide use has gone up contrary to the *raison detre* given for Bt crops that insecticide use would go down; and all input costs have increased. (ref. Section 5 D IV - Bt cotton performance and V - The test case of Bt brinjal).

The climate of the times is the deception and fraud to misrepresent, and misinterpret studies and make erroneous claims about the benefits of GMOs (ref. Section 5. B). This is made possible by the enormous power and influence that biotechnology and chemical pesticide corporations wield over governments, regulators, media and academia. Bhopal and PCBs is the big festering sore that serves as a classic example of such power and our inability to successfully grapple with that disaster with justice and equity even after decades. For GMOs, it all started, as evidenced, in the USA with the approbation and active 'fostering' by the Whitehouse. The manoeuvre to demand scientific certainty of harm from GMOs is anti public-health, completely unjustified and dangerous. To illustrate the point, in the absence of good evidence that today's exposures to carcinogens are safe, it is wiser to apply the precautionary principle, and assume they are unsafe (EEA – late lessons from early warnings – the PP). Importantly, the precautionary principle as enshrined in India's Constitution, its precedence in Indian law and the CBD, does not only NOT require it, it articulates the reverse.

**In A.P. Pollution Control Board versus M.V. Nayudu [1999 (2) SCC 718]:**

*“The ‘uncertainty’ of scientific proof and its changing frontiers from time to time has led to great changes in environmental concepts during the period between the Stockholm Conference of 1972 and the Rio Conference of 1992. In Vellore Citizens' Welfare Forum v. Union of India 2 a three-Judge Bench of this Court referred to these changes, to the ‘precautionary principle’ and the new concept of ‘burden of proof’ in environmental matters. Kuldip Singh, J. after referring to the principles evolved in various international conferences and to the concept of ‘sustainable development’, stated that the precautionary principle, the polluter-pays principle and the special concept of onus of proof have now emerged and govern the law in our country too, as is clear from Articles 47, 48-A and 51-A( g ) of our Constitution and that, in fact, in the various environmental statutes, such as the Water Act, 1974 and other statutes, including the Environment (Protection) Act, 1986, these concepts are already implied. The learned Judge declared that these principles have now become part of our law. The relevant observations in the Vellore case 2 in this behalf read as follows: (SCC p. 660, para 14)*

*“In view of the above-mentioned constitutional and statutory provisions we have no hesitation in holding that the precautionary principle and the polluter-pays principle are part of the environmental law of the country*

*A basic shift in the approach to environmental protection occurred initially between 1972 and 1982. Earlier, the concept was based on the ‘assimilative capacity’ rule as revealed from Principle 6 of the Stockholm Declaration of the U.N. Conference on Human Environment, 1972. The said principle assumed that science could provide policy-makers with the information and means necessary to avoid encroaching upon the capacity of the environment to assimilate impacts and it presumed that relevant technical expertise would be available when environmental harm was predicted and there would be sufficient time to act in order to avoid such harm. But in the 11th Principle of the U.N. General Assembly Resolution on World Charter for Nature, 1982, the emphasis shifted to the ‘precautionary principle’, and this was reiterated in the **Rio Conference of 1992** in its Principle 15 which reads as follows:*

*“ Principle 15 .—In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for proposing cost-effective measures to prevent environmental degradation.”*

*In regard to the cause for the emergence of this principle, Charmian Barton, in the article earlier referred to in Vol. 22, Harv. Envtt. L. Rev. (1998), p. 509 at p. 547 says:*

*“There is nothing to prevent decision-makers from assessing the record and concluding that there is inadequate information on which to reach a determination. If it is not possible to make a decision with ‘some’ confidence, then it makes sense to err on the side of caution and prevent activities that may cause serious or irreversible harm. An informed decision can be made at a later stage when additional data is available or resources permit further research. To ensure that greater caution is taken in environmental management, implementation of the principle through judicial and legislative means is necessary.”*

*In other words, the inadequacies of science are the real basis that has led to the precautionary principle of 1982. It is based on the theory that it is better to err on the side of caution and prevent environmental harm which may indeed become irreversible.*

*The principle of precaution involves the anticipation of environmental harm and taking measures to avoid it or to choose the least environmentally harmful activity. It is based on scientific uncertainty. Environmental protection should not only aim at protecting health, property and economic interest but also protect the environment for its own sake. Precautionary duties must not only be triggered by the suspicion of concrete danger but also by (justified) concern or risk potential. The precautionary principle was recommended by the UNEP Governing Council (1989). The Bomako Convention also lowered the threshold at which scientific evidence might require action by not referring to “serious” or “irreversible” as adjectives qualifying harm. However, summing up the legal status of the precautionary principle, one commentator characterised the principle as still “evolving” for though it is accepted as part of the international customary law, “the consequences of its application in any potential situation will be influenced by the circumstances of each case”. ( See First Report of Dr Sreenivasa Rao Pemmaraju \* — Special Rapporteur, International Law Commission dated 3-4-1998, paras 61 to 72.)”*

It is clear from the above that we are not limited or restricted by the intent of the PP in Indian law, the CBD and in our Constitution, for its legitimate application to the uncertainties of science with respect to GMOs, a text-book case for its application. However, it is the interpretation of it for the level of caution that is required to protect India (and other countries) that must be decided and then applied. In this matter, it is therefore, necessary that the unique risks of GMOs are understood by the Supreme Court. To disentangle the truth in the prevailing climate of massive disinformation and cover-up is not easy, nor does such a situation aid the process of discernment and foresight that are required for such a decision, which is why the TEC report is central to the Supreme Court’s deliberations. No reliance may be placed on our institutions of agriculture, science and technology and regulators for sound, unbiased integral advice to the PM and his council of Ministers. It is difficult to surmise how systemic conflict of interest will be rooted out of our system, so that trust in the independence and integrity of our regulators is established. Monsanto’s influence is proven, its advice relied on, its self-assessed dossiers accepted for regulatory decisions on GMO bio-safety, as in the proven case of Bt brinjal.

***In this matter, it is therefore, necessary that the unique risks of GMOs are understood by the Supreme Court. To disentangle the truth in the prevailing climate of massive disinformation and cover-up is not easy, nor does such a situation aid the process of discernment and foresight that are required for such a decision, which is why the TEC report is central to the Supreme Court’s deliberations.***

There is one aspect that can be eliminated however. We are limited to one commercialised crop, Bt cotton. There isn’t therefore, a significant economic issue that masks the decision-making on this score.

### **To sum up the evidence:**

GMOs were first introduced in the US despite the warnings of their experts of their unique risks. The warnings were sidelined in order to usher-in and ‘foster’ the commercialisation of the GMO industry, based on a White House directive. There is strong scientific evidence of harm on several dimensions of the impacts of GMOs for animal and human health and for the environment. There are also serious uncertainties of what may emerge over the long term because of the unique problems presented by GMOs called ‘unintended effects’. There is the huge catastrophic dimension that has emerged unexpectedly in the last 5-7 years of bee deaths (CCD) that is still under scientific investigation, linked to GMO seed treatment using neonicotinoids. Are we to call a disaster of this magnitude collateral damage? There is the refusal thus far, by our Regulators to conduct INDEPENDENT rigorous risk assessment protocols, which must include long term and life-cycle feeding studies.

***There is the huge catastrophic dimension that has emerged unexpectedly in the last 5-7 years of bee deaths (CCD) that is still under scientific investigation, linked to GMO seed treatment using neonicotinoids. Are we to call a disaster of this magnitude collateral damage?***

There are new GMO products which will slip under the regulatory radar if it is represented that they are Non-GM

technology as was the case with genome-editing. The clarifying decision, of global benefit, came from the New Zealand High Court. In the Philippines, Bt brinjal subsequent to the Indian moratorium on it, was banned from release. In Mexico, a series of Court rulings has upheld the ban on GMO maize. RNA is not subjected to any kind of testing nor do GMOs get tested for endocrine disruption despite strong evidence that they are teratogenic and/endocrine disruptors (tragedies in Argentina of birth defects correlate with roundup and its formulations and glyphosate). And there is fraud by Monsanto, that they have known from the 1980s that roundup leads to birth defects. The unfolding process of serious harm is accelerating as highlighted by 3 unprecedented reports/peer reviewed studies in Feb-March 2015 itself (ref. viii of Section 5):

(i) **The IRAC ('International Agency for Research on Cancer') of the WHO**<sup>30</sup> has deemed glyphosate a "probable human carcinogenic" and "sufficiently demonstrated" for genotoxicity in animals, (Group 2A) and has rejected Monsanto's vociferous objections. A classification of 2A in cancer-causing potential for glyphosate of the IARC is its second highest categorisation. Two insecticides placed in the lower category (2B) in terms of cancer-causing potential are both in restricted use. Tetrachlorvinphos is banned in the European Union, but continues to be used in the US; while parathion has been severely restricted since the 1980s, and all authorized uses were cancelled in the European Union and USA by 2003. The US EPA follows a similar listing. It originally classified glyphosate as possibly carcinogenic to humans in 1985, but in 1991, changed the classification to non-carcinogenic. In 2013, the EPA raised the permissible limits of glyphosate contamination in farm-grown food and animal feed.

*A classification of 2A in cancer-causing potential for glyphosate of the IARC is its second highest categorisation. Two insecticides placed in the lower category (2B) in terms of cancer-causing potential are both in restricted use. Tetrachlorvinphos is banned in the European Union, but continues to be used in the US; while parathion has been severely restricted since the 1980s, and all authorized uses were cancelled in the European Union and USA by 2003.*

(ii) **Endocrine disruptor:** a study demonstrating Glyphosate is an endocrine disruptor in human cells at levels allowed in drinking water<sup>31</sup>

(iii) **Glyphosate and Bacterial resistance:** along with other herbicides glyphosate can promote antibiotic resistance in bacteria (Heinemann et al)<sup>32</sup>.

These data are alarming. The link with cancers and endocrine disruption in studies correlate with over a decade of epidemiological research in Argentina with regard to birth defects because of the 'soyaisation' of her agriculture. Several chronic diseases and GMOs demonstrate a positive correlation linked to the introduction of GM crops in the US. The ubiquitous presence of roundup, (in blood, in urine, irrigation run-offs into streams, the water supply), is also correlated with the introduction and increasing **use** of glyphosate (HT) crops.

<sup>30</sup> IARC: <http://uk.businessinsider.com/r-monsanto-weed-killer-can-probably-cause-cancer-world-health-organization-2015-3?r=US>: <http://us6.campaign-archive2.com/?u=29cbc7e6c21e0a8fd2a82aeb8&cid=d22866dc65&e=bee205d870>  
<http://www.bloomberg.com/news/articles/2015-03-20/who-classifies-monsanto-s-glyphosate-as-probably-carcinogenic>  
**Lancet Oncol** 2015 Published Online March 20, 2015: [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8)

TWN/Mae-Wan HO/Nancy Swanson: Scientists Back Up WHO's Classification of Glyphosate as "Probably Carcinogenic"

<sup>31</sup> Fiona Young et al: 'Endocrine disruption and cytotoxicity of glyphosate and roundup in human Jar cells in vitro'. Depart.of Medical biotechnology, South Australia.

<http://us6.campaign-archive1.com/?u=29cbc7e6c21e0a8fd2a82aeb8&cid=bea73886eb&e=bee205d870>

<sup>32</sup> Kurenbach, B., Marjoshi, D., Amabile-Cuevas, C. A., Ferguson, G. C., Godsoe, W., Gibson, P. & Heinemann, J. A.: "Sublethal exposure to commercial formulations of the herbicides dicamba, 2,4-dichlorophenoxyacetic acid, and dlyphosate cause changes in antibiotic susceptibility in Escherichia coli and Salmonella enterica serovar Typhimurium. mBio" 6, e00009-00015, doi:10.1128/mBio.00009-15 (2015).

The IRAC reappraisal of data from the 1980s with regard to Glyphosate is enormously troubling for its reinforcement of the question of FRAUD linked to both the US EPA and Monsanto. Research scientist Dr Anthony Samsel summarises those implications:

*“Monsanto’s Trade Secret studies of glyphosate show significant incidence of cell tumors of the testes and tumorigenic growth in multiple organs and tissues. They also show significant interstitial fibrosis of the kidney including effects in particular to the Pituitary gland, mammary glands, liver, and skin. Glyphosate has significant effects to the lungs indicative of chronic respiratory disease. **Glyphosate has an inverse dose response relationship**, (Section 5 -- ) and it appears that its effects are highly pH dependent. Both Monsanto and the EPA knew of the deleterious effects of this chemical in 1980 at the conclusion of their multiple long-term assessments, but the EPA hid the results of their findings as “trade secrets.” Monsanto has been lying and covering up the truth about glyphosate’s harmful effects on public health and the environment for decades. The increases in multiple chronic diseases, seen since its introduction into the food supply, continue to rise in step with its use. Monsanto’s Roundup glyphosate based herbicides have a ubiquitous presence as residues in the food supply directly associated with its crop use”.* **Source document:** ‘Monsanto knew of glyphosate / cancer link 35 years ago’: GM-Free Cymru Special Report 8th April 2015

And finally, farming based on ecological methods, using minimal amounts of herbicides and fertilizers and not using GM crop varieties, is more productive than industrial farming and more profitable than methods using GM varieties by 12 to 14 percent. Agroecology, Non-GE methods and plant breeding, including newer methods, continues to outperform genetic engineering in all regions, at much less cost per trait, but goes begging for funding at our universities. Based on these data, GM crops are therefore, irrelevant to rural households and national food security. However, they would contribute in significant measure to unsafe food and India’s food insecurity, health and development. *“A recent incident (Seralini study<sup>33</sup>) clearly shows how the GMO Industry is manipulating science to eliminate all negative information, THIS TIME JEOPARDING OUR ABILITY TO ASSESS THE SAETY OF OUR GLOBAL FOOD SUPPLY”.* (Schubert)

## **The SC-appointed Technical Expert Committee: Process & Findings**

A key requirement is for the Supreme Court of India, according to its own admission, to have access to independent sources of scientific advice on GMOs to aid its decision-making. In May 2012<sup>34</sup>, the SC appointed its TEC “primarily and substantially with reference to the Minutes (MoEF) dated 15 March 2011”, to provide the Court with an independent assessment outside and apart from Petitioners and Respondents alike on the matter of GM crops. The 6-member Committee comprised 3 nominees each of Petitioners & Respondents. One member, a nominee of the Union of India later declined to join. The Committee remained constituted and was directed by the SC to continue with 5 Members.

- Their first report submitted in Oct. 2012 was unanimous requiring a moratorium on all field trials. This unanimity among its 5 members included the Government’s nominees. At this point the MoA ‘insinuated’ a 6th member into the Committee, (and was so Ordered by the Court), to replace its missing nominee. Later upon a due diligence, it was found that Dr Paroda through his Trust and other Institutions promotes GMOs, lobbies for their introduction in India and is funded by Monsanto and the ‘Industry’ in his activities within India and abroad. This evidence is available in his own CV and conference documents/brochures. Thus, it is apparent that the MoA (Ministry of Agriculture) tried to subvert the independence and process of the SC’s own Technical Expert Committee (TEC), testimony to just how deeply conflicted, our GMO regulatory bodies are. The decision to engineer Bt into cotton hybrids, creating ‘value capture’ for Monsanto (ref. Section 5 IV.) was taken during his tenure as DG ICAR from 1994 – 2001.

<sup>33</sup> The journal **Food and Chemical Toxicology** (FCT) published a study that caused an international storm (Séralini, et al. 2012). The study, led by Prof Gilles-Eric Séralini of the University of Caen, France, suggested a Monsanto genetically modified (GM) maize, and the Roundup herbicide it is grown with, pose serious health risks. The two-year feeding study found that rats fed both suffered severe organ damage and increased rates of tumours and premature death. The study was retracted by the journal over a year later and after the paper had passed through the original peer review process and was published. The retraction drew wide condemnation from hundreds of scientists, who questioned the scientific integrity of the journal FCT and its obvious conflict of interest in this retraction.

<sup>34</sup> SC: 2012 STPL(Web) 294 SC 1: Aruna Rodrigues Vs. Union Of India

- The **Final Report** of the TEC submitted in June 2013 was also a unanimous 5-member Report. Dr Paroda submitted a separate Report.
- The TEC has recommended: (a) that all open field trials be stopped and a moratorium is placed on Bt food crops (emphasised, conditions attached); (b) HT crops should be barred; (c) GM Crops for which India is a centre of origin or diversity should also be banned.
- The TEC was also informed by the Secretary, DoA (Department of Agriculture) that it will not be possible to segregate GM from non-GM material during the overall process of collection, handling, and storage in India. This admission is startling given that denial of information/no labeling of GMO content is proscribed in India.

*“The quality of information in several of the applications is far below what would be expected and required for rigorous evaluation by a regulatory body and is unlikely to meet international regulatory guidelines (pg 35) --- Based on the examination of the safety dossiers the TECc has found in unambiguous terms that at present, the regulatory system has major gaps and these will require rethinking, investment, and relearning to fix. A deeper understanding of the process of Risk Assessment is needed within the regulatory system for it to meet the needs of a proper biosafety evaluation”.* (Pg. 77) TEC Report

The TEC Report is itself corroborated by the independent findings of 3 other official reports of the Government of India. These are findings that are of course independent of and ‘outside’ Petitioners’ submissions. The four reports find common ground on the lack of integrity, scientific expertise in protocols of risk assessment, independence, even fraud in the GM regulator and our agri-institutions as the outcome of a pervasive conflict of interest, which makes sound and rigorous regulation of GMOs impossible. It is the 3<sup>rd</sup> official report barring GM crops’ field trials singly or collectively. This consensus is remarkable. The other 3 reports are: (a) The **‘Jairam Ramesh Report’** (Feb. 2010) imposing an indefinite moratorium on Bt brinjal, overturning the apex Regulator’s approval to commercialise it; (b) the **Sopory Committee Report** (Aug 2012) was an enquiry into the contamination of the so-called ‘desi’ Bt cotton (BNBt), with a Monsanto gene. It made this telling remark:

**Sopory Committee:** *“The Committee is of the view that there were indications, prior to commercial - release, that BNBt was contaminated with MON531”. The comment signifies that the very first step of the assessment of an ‘Event’, the molecular analyses, was not done”.*

***The TEC Report is itself corroborated by the independent findings of 3 other official reports of the Government of India. These are findings that are of course independent of and ‘outside’ Petitioners’ submissions. The four reports find common ground on the lack of integrity, scientific expertise in protocols of risk assessment, independence, even fraud in the GM regulator and our agri-institutions as the outcome of a pervasive conflict of interest, which makes sound and rigorous regulation of GMOs impossible. It is the 3<sup>rd</sup> official report barring GM crops’ field trials singly or collectively. This consensus is remarkable.***

And (c) the **Parliamentary Standing Committee (PSC) Report on GM crops:** (Aug. 2012 (37th Report) and 2013, (59th Report)).

*“The Government”s reply does not appreciate the ground realities mentioned by the Committee and does not inspire any degree of confidence in the Committee to change their well considered opinion on the subject. They, therefore, reiterate their earlier recommendation that further research and development on transgenics in agricultural crops should be done only in strict containment and field trials should not be undertaken till the Government puts in place all regulatory, monitoring, oversight, surveillance and other structures”.* **PSC 59th Report 2013** (emphasis added)

## The action & the caution

The collective evidence over 20 years of commercialised GM crops and their numerous ‘events’ released in open field trials points to systematic cover-up in conjunction with regulators in a number of countries. They include the US first and foremost, the EU, Argentina, Bangladesh and India among others. And the historical evidence of 100 years of hazardous technologies also demonstrates that GMOs are uniquely differentiated in key aspects from, for example, DDT and CFCs, which reinforce the need for collective precautionary action NOW because of their potential for global/widespread ecological disruption and impact on animal and human health.

We arguably, are faced with the most serious scientific fraud in the history of science and hazardous technologies. And the multi-dimensional impacts of GMOs are staggering and they are global. These translate into a biosecurity threat of global proportions, a threat by “Monsanto and chemical companies, who continue to destroy the biosphere” (Samsel A). Therefore, the Precautionary Principle must prevail at the level of every NATION and GLOBALLY ranging from national bans to a global moratorium on GM crops. With CFCs and in part, DDT the PP required a ban.

For India, it is the life and living of the Indian Nation which are hugely imperilled by GM crops: typified by her farming & seed diversity, her food, her ecology, her economic independence and her future health and prosperity. There will be no redemption. Other countries share a similar fate, indeed are actively playing out that awful fate like Argentina. It is required, based on the collective evidence, that the 5-Member TEC Report is fully implemented in India with its specified prohibitions along with an indefinite moratorium on GMO open field trials. The PP is required to be applied at this raised level of specified bans on pesticidal crops and crops of origin; and critically, to be implemented now in a ‘timeliness’, before any other GM crop is commercialised.

*We arguably, are faced with the most serious scientific fraud in the history of science and hazardous technologies. And the multi-dimensional impacts of GMOs are staggering and they are global. These translate into a biosecurity threat of global proportions, a threat by “Monsanto and chemical companies, who continue to destroy the biosphere” (Samsel A). Therefore, the Precautionary Principle must prevail at the level of every NATION and GLOBALLY ranging from national bans to a global moratorium on GM crops. With CFCs and in part, DDT the PP required a ban.*

*“The prospect of domination of the nation’s scholars by Federal employment, project allocations, and the power of money is ever present — and is gravely to be regarded. Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific technological elite”. Dwight D Eisenhower: US President, 1961 (Wikisource, 2012).*

# Section 5

Aruna Rodrigues

Lead Petitioner (Public Interest Writ (PIL) in India's Supreme Court)

## The Fraud Of GM Crops The Scientific Evidence

***“Ultimately, it is the food producer who is responsible for assuring safety”.***

FDA – Statement of Policy Foods derived from New Plant Varieties, 29 May 1992

***“Monsanto should not have to vouchsafe the safety of biotech food.***

***Our interest is in selling as much of it as possible. Assuring its safety is the  
FDA’s job”.***

Phillip Angell: Monsanto Director of Corporate Communications: (Pollan: NY Times Magazine 25 Oct. 1998)

No national laws allow toxins to be put into food. Cry proteins or Bt toxins as also herbicides with their other ‘ingredients’ that form the construct are pesticides and /or toxins or injurious. Indian Law is clear on this point:

*“Notwithstanding anything contained in sub-section (2) and sub-sections (1) and (3) of section 15, no variety of any genus or species which involves ‘any technology’ injurious to the life or health of human beings, animals or plants shall be registered under this Act. For the purposes of this subsection, the expression “any technology” includes genetic use restriction technology and terminator technology.” (Ref. Protection of Plant Varieties and Farmers’ Rights Act, 2001 section 29 (3)).*

Yet this is precisely what has transpired in the 20 years since GM crops have been commercialised and released in open field trials. Cry toxins are claimed by Monsanto to harm only pests with alkaline gut systems, an explanation that was accepted without scrutiny or the test of time in rigorous studies, and so accepted safe for animal and human consumption. The claim for the safety of glyphosate was similarly ingenuous: glyphosate is claimed and advertised as a safe herbicide, safe enough to eat, based on its ability to block the shikimate pathway involved in the production of aromatic amino acids in plants and bacteria. It has to be admitted that it takes a certain kind of mind to contrive to transform a toxin into something altogether benign and even ‘magical’ for the benefit of agriculture and the food security of the world. Indeed it would take a miracle to truly achieve such a metamorphosis. That ‘miracle’ is now fraying.

***Cry toxins are claimed by Monsanto to harm only pests with alkaline gut systems, an explanation that was accepted without scrutiny or the test of time in rigorous studies, and so accepted safe for animal and human consumption. The claim for the safety of glyphosate was similarly ingenuous: glyphosate is claimed and advertised as a safe herbicide, safe enough to eat, based on its ability to block the shikimate pathway involved in the production of aromatic amino acids in plants and bacteria.***

Bt and HT crops account for 99% of all GM crops planted worldwide, but essentially in 3 countries: the USA, Argentina and Brazil. India has one crop, Bt cotton. The promise of other traits, which are being promoted as the potential backbone of agriculture and answer to solutions to agricultural impacts from Climate Change (Cc) have not materialised.

Unfortunately, life and agriculture don't quite work in mythical ways at least not without Divine intervention. There is clear evidence of fraud, lies and cover-up. Monsanto and other biotechnology companies have been convicted for crimes committed against humanity. Notwithstanding these, GMOs would not have seen the light of day without the closest cooperation between national regulators and governments including India's. The genesis of the fraud however, starts in the USA and spread from there. This chapter is the evidence of that process; It forms part of the record of the Supreme Court of India in Affidavits over 10 years. It is also the evidence of the SC's-own Technical Expert Committee (TEC) appointed by it to advise it in this matter and 3 other official Government of India reports on GM crops.

## **A. GMOs: Their unique risks and genesis in the USA of the lack of regulatory oversight and why**

The warnings about the potential harm from GMOs have always been 'current', not merely 'early' warnings, which distinguish GMO technology from other hazardous or harmful technologies like DDT and CFCs which were initially thought to be incredibly beneficial. 'Current' warnings about GMOs were buried because the Industry led by Monsanto was able to co-opt the US Government into an on-going partnership to commercialise GM crops in agriculture. In the cases of CFCs and DDT for example, the dangers were not initially apparent. These technologies were thought to be 'magical' for their benefits to mankind. The malevolence of their impacts became visible later. One exception is tobacco, where the similarities in corruption (cover-up and fraud) are closely paralleled. (The tobacco Industry knew for well near 40 years that smoking caused lung cancer and covered-up this fact). Monsanto has known since the 80s that glyphosate is an endocrine disruptor/teratogenic or causes cancer.

The unique risks of GMOs are inherent to the technology and are:

- i. GMOs are unnatural, not just because they have been produced in the laboratory, but because they can only be made in the laboratory, creating organisms and in ways that have never existed in the course of 3.8 billion years of evolution. In other words, GM organisms do not stand the test or benefit from billions of years of natural selection
- ii. The technology breaks down species barrier by horizontal transfer of genes, not parent to parent. It involves recombining DNA, often from different organisms but not always, and inserting them into the genomes of target organisms to make GMOs (in the lab)
- iii. The intended gene is incorporated into the genome of a crop using a vector containing several other genetic elements, including as a minimum, promoters which may come from plant or plant viruses, transcription terminators, reporter genes and antibiotic resistant or herbicide resistant marker genes. Cells modified by these techniques pass the new genes and their traits on to their offspring.
- iv. GE however, is an imprecise technology as there is little control on where the new genetic construct will lodge within one or more of the target cell chromosomes
- v. although for GM health & food safety, the intended gene is very important, the potential effects of the whole construct, i.e. the other genes may contribute substantially to the overall effect
- vi. The protein produced from the gene of interest may interact in unpredictable ways including create new proteins
- vii. Scientists do not understand the mechanisms of GE-induced changes in gene expression in sufficient detail, or know what to expect, which confronts us with the inevitable surprise of 'unintended effects'. Unintended effects are common in all cases where GE techniques are used. Therefore, the risk of GMO can never be wholly assessed through risk assessment protocols, no matter how rigorous, nor their impacts mitigated with any certainty
- viii. A potent agricultural technology, it is being used to irrevocably change the fundamental molecular structure of the world's food and impact the biodiversity through un-recallable, self-replicating organisms

The regulatory record of the last 20 years of commercialised GM crops and their field trials demonstrates repeatedly that many risks posed by GM crops are masked, or covered-up, altered or ignored or not addressed at all through studies not done (allergenic and long term feeding studies for chronic toxicity), and the practise employed by regulators of accepting Industry-assessed biosafety dossiers whose studies have been conducted by the crop developer. It is an entirely corrupt cooperation, an unacceptable conflict of interest that dumps the public good but upholds the private interests of the Industry.

This is analogous to car manufacturers doing their own 'crash' tests. Is it likely that they will admit their cars failed the test?

### **What the USA contrived and served-up as an example to be followed by other countries**

If the US had not introduced GM crops, no other country would have. And GM foods would not have come onto the market if the facts about their unique risks had been acknowledged and if national laws in the US had been honoured (Druker S). Their introduction depended on a systematic cover-up and deliberate deception by both the biotech industry and the Government of the United States, to push a commercial agenda for spawning a multi-billion dollar industry for the United States in "violation of its own laws" based on the precautionary principle (Druker). The abrogation of the PP allowed the US to aggressively push GMOs worldwide through trade agreements, the WTO, diplomatic pressure and even active research assistance through the USDA (United States Department of Agriculture), with Monsanto and Cornell University to develop GM food crops for market introduction and commercialisation in third world countries as was the case with Bt brinjal in India<sup>36</sup>. For third World countries in particular, with their limited expertise in GMO risk assessment and limited resources, the US clearance of GE foods and crops for commercial release has given a flawed stamp of legitimacy and hoodwinked the public into believing that they are safe. India readily toed the US line. She entered into an agreement (the KIA)<sup>37</sup> that further and formally cemented the influence of US-style regulation of GMOs in India. This is evident from the borrowed 'assumptions' of 'Substantial Equivalence' (SE) of GMOs with conventional crops, being the starting point. There is in India a cavalier disregard of bio-safety during field testing and a worrying lack of concern on the issue of harm to health and potential GMO contamination from these trials. The gap between regulators and regulated is hardly apparent, the conflict of interest massive and proven.

US law has employed the Precautionary Principle since 1958, when Congress enacted an amendment to the Food, Drug and Cosmetic Act requiring that all new additives to food be proven safe in a pre-market assessment, prior to marketing. And Food and Drug Administration (FDA) regulations clearly define the standard of proof in practical, non-absolute terms, calling for demonstration of "*a reasonable certainty*" of no harm. Further, the approach that risks may always be offset by purported benefits, US food safety law forbids it, placing paramount concern on human health (Druker, iv).

For many years this precautionary law functioned well. But in **1992**, FDA administrators circumvented it in order to usher GM foods onto the market, in furtherance of their admitted agenda "to foster" Biotechnology (under a 'White House Directive') (Druker). David Kessler<sup>38</sup> described the agency's policy as "*consistent with the general biotechnology policy established by the Office of the President*". President George Bush senior put his Vice President, Dan Quale in charge of the anti-regulatory crusade on behalf of the biotech Industry. In doing so, they bowed to industry's desire and provided the legal sleight of hand remedy of GRAS<sup>39</sup> status, to avoid the extensive testing that would otherwise have been legally required to establish the safety of each GM food. GM foods were now claimed to be substantially equivalent (SE) to their conventional counterparts. They require no safety testing by the FDA and the FDA does not certify the safety of any GMO (v). They also disregarded the overwhelming consensus among their own scientists that such testing is necessary to screen for the unique risks posed by these novel products. When the experts at the FDA undertook an extensive examination of genetically engineered food, they readily recognized these risks and clearly reported them to their superiors. FDA microbiologist Dr. Louis Pribyl said, "*There is a profound difference between the types of 'unexpected effects' from traditional breeding and genetic engineering ....*" He added that "*several aspects of gene splicing . . . may be more hazardous . . .*" Many of the potential hazards are inherent in the GE process itself, which is not the case with traditional breeding. And they further ignored the fact that the first GM food (Flavr Tomato) had, according to the Agency failed to pass the safety testing to which its manufacturer voluntarily subjected it. These matters came to light when FDA files were subpoenaed during the course of the lawsuit filed by Steve Druker.<sup>40</sup>

<sup>36</sup> SC evidence 2008: This collaboration with the Agricultural University of Dharwad (Karnataka), added to the serious conflict of interest on Indian soil.

<sup>37</sup>KIA: 'The Indo-US Knowledge Initiative in Agriculture', (2006) to promote GM crops, had Monsanto on the Board from the US side. Though now lapsed, the forces it put into motion are all too visible.

<sup>38</sup> Kessler: Commissioner of Food & Drugs: "FDA Proposed Statement of Policy Clarifying the Regulation of Food Derived from Genetically Modified Plants--DECISION." Dated March 20, 1992 (IRT (Institute for responsible Technology):

<sup>39</sup> GRAS: Generally Recognised as Safe given to foods that have long histories of safe use like vinegar.

<sup>40</sup> SC evidence: WP 2005, Annexure P2.

## B. GMO Myths

The logical progression from the myth of SE necessitates the generation of several further myths to sustain this first claim of the safety of GMOs based on its extraordinary recognition of safety under GRAS (US). 20 years after the first GM crop (animal feed) was commercialised in the US the unscientific assumptions about the safety and presumed benefits of GM crops are being penned into Affidavits by the Indian Government in the Supreme Court in this PIL. In the wake of proven contamination in hundreds of GMO contamination events worldwide, the myth of 'co-existence' has been quietly dropped.

The grand unification of all myths finds its consolidation and expression in the ultimate statement that GM foods are an absolute requirement for food security and are required to feed the world; therefore, the target (of the biotech/seed and pesticide industries) is the food systems in the third world, the take-over of its agriculture through a wholesale shift to GMOs. India is a particular priority; the full range of her food crops have been and continue to be field tested in open trials, this despite the findings of the TEC in their 1st and 2nd reports (2012-2013), which are in the process of adjudication in the SC. This is testimony to the government of India's push for GMOs, the mindboggling value of the IP (intellectual Property) of such an enterprise and the conflict of interest that has all but scrubbed the line of separation between regulator and regulated, the public good being mortgaged.

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### Myths underpinning Industry & Regulators' (including Indian) claims of the health and environment safety of GMOs

- **Substantial Equivalence** (SE) to their conventional counterparts (or Non GM crops), thereby according general recognition of safety
- **Co-existence** between GM and Non-GM crops (effectively denying CONTAMINATION)
- **The Bt gene is only toxic to alkaline gut systems**, ie pests (boll worms), brinjal pests (shoot borer) and not to the mammalian digestive system, which is acidic
- **Long term testing for chronic toxicity** and allergenicity studies are not required. The Indian regulator does not require them.
- **Trillions of American meals** have been eaten with GMO content and no adverse effects have been demonstrated
- **GM crops require less chemicals**
- **Glyphosate is a safe herbicide** based on its ability to block the shikimate pathway involved in the production of aromatic amino acids in plants and bacteria. Its propensity to bind to soil and sediment means it will not leach into the water supply. It is also rapidly excreted from the body and therefore, risks of harm are negligible
- **RNA "is generally recognized as safe (GRAS)"** (crop developer's response when unexpected RNAs derived from mRNA were detected by independent researchers in one of the first significant commercial GM soybean varieties (vi))
- **"Genome editing" products by-pass regulation:**(RNA molecules also called siRNA, miRNA and microRNA, and cause 'silencing' effects such as RNAi (interference)); USDA approves Simplot potato (GE technology called RNAi (RNA interference))
- **GM crops are essential to feed the world**
- **Consensus** on GMO safety

One important vehicle to establishing these myths is through the claim by the 'Industry' that there is a '*consensus on GMO safety.*' The reality is somewhat different. There is a distinct divide between industry-sourced, influenced or funded studies (these include 'funded' academia), which find no problems in short-term 90 day feeding studies, or are dismissive of negative results as being statistically insignificant. Several country regulators including India require no long-term toxicity or allergenicity studies (though they are absolutely essential) and continue to rely on self-assessed safety-dossiers by crop developers thereby, aiding and abetting a dangerous and pernicious conflict of interest at the very beginnings of GMO scientific risk assessment. On the other hand, there is plenty of evidence

of harm from independent scientific studies including re-appraisals of Industry studies (SC evidence: 2005-2015: Mons 863 (Seralini, Pusztai); Bt brinjal reappraisal (India Event EE-1)<sup>41</sup>. GMO Myths and Truths is a comprehensive compilation of evidence of harm from Bt and HT crops.<sup>42</sup> Meta analyses done by the Industry have been successfully debunked as mostly cover-up, from which conclusions of safety cannot be drawn. A peer reviewed statement by 300 scientists and legal experts (vii) has stated that *“there is no scientific consensus on GMO safety”*. The statement says:

“Regarding the safety of GM crops and foods for human and animal health, the review also found that most studies concluding that GM foods were as safe and nutritious as those obtained by conventional breeding were “performed by biotechnology companies or associates, which are also responsible [for] commercializing these GM plants” ---

The Cartagena Protocol and Codex share a precautionary approach to GM crops and foods, in that they agree that genetic engineering differs from conventional breeding and that safety assessments should be required before GM organisms are used in food or released into the environment.

These agreements would never have been negotiated, and the implementation processes elaborating how such safety assessments should be conducted would not currently be happening, without widespread international recognition of the risks posed by GM crops and foods and the unresolved state of existing scientific understanding. (emphasis mine)

Concerns about risks are well-founded, as has been demonstrated by studies on some GM crops and foods that have shown adverse effects on animal health and non-target organisms. Many of these studies have, in fact, fed into the negotiation and/or implementation processes of the Cartagena Protocol and Codex<sup>43</sup>. We support the application of the Precautionary Principle with regard to the release and transboundary movement of GM crops and foods”. (emphasis added).

### **C. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD)**

The CPB is an international agreement which aims to ensure the safe handling, transport (safe transboundary movement) and use of living modified organisms (LMOs) resulting from **‘modern biotechnology’**, (when the genomes of organisms are transformed **through laboratory techniques**, including genetically engineered DNA (recombinant)) and their direct introduction into cells (see Protocol definition in foot note 44), that may have adverse effects on biological diversity, taking also into account risks to human health. It is rooted in the PP.

There is international consensus that the products of genetic engineering are not equivalent to their conventional counterparts. Many of the potential hazards are inherent in the GE process itself, and “are not techniques used in traditional breeding and selection” (CPB)<sup>44</sup>. This consensus is revealed in the community of nations that subscribe to the Convention (CBD) and its sub-treaty, the Cartagena Protocol on Bio-safety (CPB). This international treaty unites the majority of nations including India, (but not the US), and binds them in a collective undertaking to ensure the safe use of such biotechnologies, for impacts on health, the environment and SEC (socio-economic considerations). Consider the following example:

For instance, one can engineer maize to produce extremely high levels of the amino acid lysine. This does not occur in any plant that has ever existed on this planet and by way of some 4 billion years of historical observation (the history of life on Earth), would not arise by natural processes. There may be good things to come of such maize plants. However, because lysine is so reactive there may be unexpected food hazards that arise from this excess of lysine in the milieu of plant products that previously would not have mixed, especially under cooking or processing

<sup>41</sup> Bt brinjal reappraisal 2009-2010 (Ramesh appraisal process): Andow, Pusztai, Schubert, Heinemann, Swaminathan, Bhargava, Seralini, Carman, Cummins, Samuel, Gurian-Sherman, Gallagher and others; Ramesh Report (public domain) MoEF Feb.2010; SC evidence 2008-2010.

<sup>42</sup> GMO Myths and Truths, 2nd Edition 2014: Co authors Michael Antoniou and John Fagan: “An increasing number of studies are showing problems with GMOs and their associated pesticides, such as Roundup. There is evidence that Roundup, even at the low levels permitted in food and drinking water, could lead to serious effects on health over time, such as liver and kidney toxicity. Based on this evidence, it appears that the levels of exposure currently held as safe by regulators around the world are questionable.”

<sup>43</sup> CPB an international agreement came into force in 2003 and was ratified by 166 Countries including India but EXCLUDING the US; the UN Codex Alimentarius Commission has a membership of 160 nations including the US

<sup>44</sup> The Protocol (CPB): “‘Modern biotechnology’ means the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection”.

conditions. Moreover, since lysine is a limiting nutrient in nature, cultivation and distribution of this maize could have unexpected effects on pests. Is all this hypothetical? No. Monsanto tried to commercialise such a maize plant a few years ago and failed to consider all these very real possibilities. The obvious questions were ignored by regulators in the USA, Canada, Australia, New Zealand, Japan and South Korea. But the many different governments of Western and Eastern Europe (as well as regulators in Africa and elsewhere) raised these questions and asked for answers -- the response from Monsanto? They withdrew the product from production rather than affirm its safety during cooking and processing, (Heinemann).

It is therefore, surprising that despite this clarity, which leaves no room for the presumption of SE and the general safety of GM foods, the notion of SE continues to prevail and is relied upon by several regulators. It attests to the power of Monsanto and the Industry to wield influence and undermine safety regulation. The Indian regulators in their Affidavits before the SC, as well as the Ministry of Agriculture in their deposition before the SC-appointed Committee, the TEC, likewise base their interpretation of the general safety of GM foods in SE. This presumption is reflected at the level of the Prime Minister, Shri N Modi and before him Dr Manmohan Singh, calling GM foods safe; the route to higher yield in agriculture and food security. Opposition to this position is deemed uninformed, irrational and anti-national. It attests to the deep erosion of integrity in the processes of the regulation of GMOs in India and the flawed briefings given to the PMO (Prime Minister's Office).

#### **D. Bt and HT (Herbicide Tolerant) Crops**

Bt Crops (which are genetically engineered to express an insecticidal toxin produced from genes of the Cry family) is a pesticidal crop which internalises the pesticide in the plant. THERE IS NO TRAIT FOR YIELD INCREASE. Herbicide Tolerant (HT) crops are engineered to tolerate application of broad spectrum weedicides and are also pesticidal crops. THEY SIMILARLY CONTAIN NO TRAIT FOR YIELD INCREASE. Both crops being pesticidal crops therefore, should be tested in the same way as pesticides (Seralini). In the case of HT crops, surfactants are used to get the active ingredient into the plant, which is engineered to withstand the herbicide so it doesn't die when sprayed. The pesticide/s cannot be washed off. The herbicide and surfactant are sprayed directly on the crops and significant quantities are then taken up into the plant. The weeds die – or used to! THEREFORE, THE FOOD CROP ITSELF CONTAINS THE HERBICIDE AS WELL AS A MIXTURE OF SURFACTANTS\*. Until the introduction of GM (HT) crops in 1996, herbicides were sprayed on fields before planting, and then only sparingly used around crops. 99% of GM crops planted worldwide comprise of these two varieties or a combination of them (stacked genes) and more than 80% of these are HT crops. US, Argentina (100% 'soyaisation') and Brazil have the highest acreages planted with Roundup Ready (RR) HT crops.

**\*Note:** A recent peer reviewed study (T Bohn 2013) found that Roundup Ready GM-soybeans sprayed during the growing season had taken up and accumulated glyphosate and AMPA\* at concentration levels of 0.4–8.8 and 0.7–10 mg/kg, respectively. In contrast, conventional and organic soybeans did not contain these chemicals. We thus document what has been considered as a working hypothesis for herbicide tolerant crops, i.e., that: "there is a theoretical possibility that also the level of residues of the herbicide and its metabolites may have increased" is actually happening (Kleter, Unsworth, & Harris, 2011) . Glyphosate is shown to be absorbed and translocated within the entire plant, and has been found in both leaf material and in the beans of glyphosate tolerant GM soy plants<sup>45</sup>.

**\*AMPA has not been investigated by regulators for health-safety<sup>46</sup>.**

#### **I. HT Crops: why they should be banned, as recommended by the SC's TEC**

##### **The empirical evidence from US crop data (USDA)**

**It was known from the start that HT crops would lead to accelerated resistance.**

<sup>45</sup> T Bohn et al: Compositional difference in soybeans on the market: Glyphosate accumulates in RR GM Soybeans Food Chemistry 153 (2014) 207–215

<sup>46</sup> AMPA: (aminomethyl phosphonic acid) is the breakdown product of glyphosate, the active ingredient in the herbicide roundup. It is found in most all drinking water in the US along with glyphosate.

**Resistance:** The US has the longest history of commercialised crops and reliable data of USDA crop statistics. HT corn, soy and cotton (animal feeds) were commercially planted in 1996. Ht corn and soy account for over 90% of area planted under these crops and cotton 73% (2012). About 50% of US cropland is planted to transgenic mainly HT followed by Bt. (viii). Monsanto's traits make up 93% of US soybeans, 88% of cotton and 86% of maize attesting to the resulting trend to monoculture, reduction in seed diversity, and consolidation of seed ownership through IP (intellectual property). In India Bt cotton virtually all of it Monsanto's, is currently more than 95% in some States, of area planted to cotton (Kranthi).

*Monsanto's traits make up 93% of US soybeans, 88% of cotton and 86% of maize attesting to the resulting trend to monoculture, reduction in seed diversity, and consolidation of seed ownership through IP (intellectual property). In India Bt cotton virtually all of it Monsanto's, is currently more than 95% in some States, of area planted to cotton (Kranthi)... the ability to spray a broad spectrum herbicide several times after a crop has emerged, controlling weeds competing with the crops but leaving the crop unharmed.*

Respected weed scientists (Van-Gessel 1996, Heap 1999, ISHRW 2012), warned that resistance was highly likely in the absence of disciplined resistance management plans. Herbicide tolerant technology would impose more severe selection pressure on weed populations because of the inherent and distinguishing attribute of HT crops – the ability to spray a broad spectrum herbicide several times after a crop has emerged, controlling weeds competing with the crops but leaving the crop unharmed. Heap went on to argue that glyphosate would need to be used in conjunction with MRM (Multiple Resistant Management) practices including non-chemical weed control methods (Heap 1999 and Benbrook et al 1996). The 1996 report by the US-based Consumers' Union stated that Ht crops are "custom-made" for accelerating resistance (Benbrook). Over-reliance has led to shifts in weed communities and the emergence of resistant weeds that have together, forced farmers to incrementally –

- Increase herbicide application rates (especially glyphosate),
- Spray more often, and
- Add new herbicides that work through an alternate mode-of-action into their spray programs.

Each of these responses has, and will continue to contribute to the steady rise in the volume of herbicides applied

*The treadmill for farmers is like a drug addiction: different herbicides to counter resistance and more herbicides as super weeds emerge. This is leading to the use of older, more toxic herbicides. The biotechnology-seed-pesticide industry's primary response to the spread of glyphosate-resistant weeds is development of new HT varieties resistant to multiple herbicides, including 2,4-D and dicamba which have now been approved by the FDA.*

per acre of HT corn, cotton, and soybeans (in the US). There are now two-dozen weeds resistant to glyphosate, the major herbicide used on HT crops, associated with the use of glyphosate on HT crops in the US and many of these are spreading rapidly. Millions of acres are infested with more than one glyphosate-resistant weed. In 2012 **61.2 million acres** of cropland were infested with resistant weeds, almost doubling from 2010 (Stratus research (ix)). The treadmill for farmers is like a drug addiction: different herbicides to counter resistance and more herbicides as super weeds emerge. This is leading to the use of older, more toxic herbicides. The biotechnology-seed-pesticide industry's primary response to the spread of glyphosate-resistant weeds is development of new HT varieties resistant to multiple herbicides, including 2,4-D and dicamba which have now been approved by the FDA. These older herbicides (3 of these with triazines are among the riskiest herbicides still in widespread use, 2,4-d, dicamba and paraquat), "pose markedly greater human health and environmental risks per acre

treated than glyphosate." Approval of corn tolerant to 2,4-D could lead to an additional **50% increase** in herbicide use per acre on 2,4-D HT corn (WSU; Gurian-Sherman) (x).

**Herbicide/Pesticide use:** The presence of Glyphosate resistant weeds drives up herbicide use by **25% to 50%**, and increases farmer-weed control costs by at least as much. HT crops have increased herbicide use by **527 million pounds over the 16-year period (1996-2011: Benbrook 2012)** (xi). The incremental increase per year has grown steadily from 1.5 million pounds in 1999, to 18 million five years later in 2003, and 79 million pounds in 2009.

The historical claim by Monsanto and other biotech companies has been, that GM crops require less chemicals (and this is true of their claim in India for Bt cotton and they put the same argument for Bt brinjal).

*The historical claim by Monsanto and other biotech companies has been, that GM crops require less chemicals (and this is true of their claim in India for Bt cotton and they put the same argument for Bt brinjal).*

But Monsanto moved in the opposite direction of proving its claim and the opposite of good stewardship and the sustainable use of glyphosate. It has actively argued, for example through advertisements to farmers, to keep the herbicide spray nozzles wide open rather than advocating practices that could have forestalled or reduced the rise of resistant weeds. Because of this, the company was taken to task by numerous weed scientists (Gurian-Sherman: (xii).

Based in part on the pesticide/seed industry's own analysis that both glyphosate and these other herbicides will be used together on engineered soybeans and corn, total herbicide use is projected to increase **more than twofold over the next decade**. Dicamba and 2, 4 – D are projected to increase **almost tenfold** (Gurian-Sherman) (xiii).

Six academic weed scientists had this to say:

*“are we as a discipline so committed to maintaining profits for the agrochemical industry that we cannot offer-up realistic long-term solutions to this glyphosate resistant weed problem?” (Harker: Weed Science April-June 2012).*

**No yield gain:** In the absence of traits for intrinsic yield gain, in the US, the data proves there has been no increase in performance yield either. Analysis of U.S. corn and soybean production over a 12 year period to 2008 reveals that conventional breeding and production methods are responsible for **86 to 100 percent of yield gain**, depending on the crop respectively, which means that the contribution of GM is negligible (Gurian-Sherman).

**Seed Costs:** The impact of rising herbicide use in these circumstances on farm income is grave and costs will continue to increase. US Company DowAgro, estimate a **100% increase** in **costs of weed control**. As far as seeds are concerned, the picture is similarly grim: soybean seed has gone from 14.80 per bushel in 1996 (year of (HT) RR soybeans) to 3 times of around \$53.20. In 25 years from 1975 through to 2000 soybean seed prices rose a modest 63%. **Over the next 10 years** as **RR soybeans** came to dominate the market, the prices rose an **additional 230%**. (Benbrook<sup>47</sup>) (xiv).

*The introduction of GE seeds and the rising cost of weed management, will result in the transfer to the biotechnology-seed-pesticide industry of between 15% and 30% of the farmers typical average long-run net income per acre. A transfer of this magnitude is of historical significance. It will strengthen the ability of the Industry to drive the direction of innovation and investment in supportive government and regulatory policies.*

Based on a continuation of recent US trends in corn and soybean yields, production costs and gross and net income, the introduction of GE seeds and the rising cost of weed management, will result in the transfer to the biotechnology-seed-pesticide industry of between 15% and 30% of the farmers typical average long-run net income per acre. A transfer of this magnitude is of historical significance. It will strengthen the ability of the Industry to drive the direction of innovation and investment in supportive government and regulatory policies. If GE seeds come to dominate the market the supply of non-GE seeds will decline and farmers will have a hard time finding non-GE versions of the highest yielding genetics suited to their soils and climate (Benbrook).

**Environmental impacts:** All herbicides can have negative impacts on non-target vegetation if they drift from the intended areas either as wind-dispersed particles or as vapours evaporating off of the application surface. In India the problem of herbicide drift is much more serious (discussed below). According to US authorities (AAPCO -- Association of American Pesticides Control Officers, 1999 & 2005), *“damage due to the drift of 2,4 D is already the most frequent reason for liability cases amongst neighbouring farmers”*. Glyphosate is now ubiquitous - in the soil, air, rainfall (60% to 100% of rainwater and air samples (Chang

<sup>47</sup> Benbrook: If these seed prices trends continue “sufficient dollars once earned and retained by farmers will be transferred to the biotechnology-seed-pesticide industry”. “Resistant weeds have and will continue to drive weed management costs upwards. – farmers could face tenuous economic conditions generating losses on a substantial portion of operations”.

et al 2011)), some foodstuffs and drinking water in many regions around the world. It has led to the Monarch Butterfly being endangered by drastically reducing milkweed populations. Landscapes dominated by dicamba and 2,4-D synthetic auxin-resistant crops may make it challenging to cultivate tomatoes, grapes, potatoes, and other horticultural crops with the threat of yield loss from drift.

Peterson and Hulting (2004) reported the risk to terrestrial plants by dicamba and 2,4-D as being 75 and 400 times greater than glyphosate, respectively. This trend would move us in the opposite direction of the reduced chemical inputs that scientists in sustainable agriculture have long advocated. (DA Mortensen).

A growing body of research has demonstrated that wild plant diversity in uncultivated, semi-natural habitat fragments interspersed among crop fields helps support ecosystem services valuable to agriculture, including pollination and biocontrol (Isaacs et al. 2009) (DAM). Studies show a number of novel adverse impacts on soil microbial communities, soli nutrient levels and bioavailability (Bennett et al 2004; devos et al 2008,; dewar 2003; Firbank et al 2003; Manay et al 2010, Marlander et al 2003; Peterson and Hulting 2004; Christoph Then).

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Resistant weeds can travel up to 122 km with wind speeds of just 17.5 km/hr and can move much farther in extreme weather events. A serious flood may disperse resistant weeds for hundreds of km, making low lying farmlands, reservoirs for further dispersal. (Benbrook: HT Crops in the EU: A Forecast of Impacts on Herbicide Use; Oct 2012).

#### NOTE

- The Indian regulators and MoA (Ministry of Agriculture) are promoting HT crops and field testing them and even allowing illegal HT cotton to proliferate. In several States beginning in Gujarat, over the last 6-7 years, illegal RR<sup>48</sup> cotton has been planted by farmers in large tracts of farmlands (GEAC Minutes of the 95th Meeting 2009, Agenda Item 6.2).
- “--such areas of biotechnological applications, which can reduce employment and impinge on the livelihood of rural families, should be avoided. Breeding for herbicide tolerance, for example, may have low priority on this account in several parts of India where there are large numbers of landless labour families. --- Biotech applications, which do not involve transgenics such as biopesticides, biofertilisers and bio-remediation agents, should be accorded high priority. They will help to enforce productivity in organic farming areas.” (MS Swaminathan, 2004)<sup>49</sup>

*Agroecological farming might also threaten the economic viability of genetic engineering. Development of an engineered crop trait is very expensive, about \$136 million on average (the total cost is estimated at around \$300 million) according to a recent industry report compared to \$1million for conventional breeding.*

- **Sustainable farming practises:** The problems resulting from this rising tide of resistance of weeds to herbicides and insects to Bt are serious. On the other hand, the best resistance management involves using long crop rotations, cover crops, mulches, and similar practices, along with minimal use of pesticides where needed. This greatly reduces pest numbers, is highly productive, and can be economically successful (Mortensen (DAM), Benbrook, Gurian-Sherman). Agroecological farming might also threaten the economic viability of genetic engineering. Development of an engineered crop trait is very expensive, about \$136 million on average (the total cost is estimated at around \$300 million) according to a recent industry report compared to \$1million for conventional breeding. That is one reason why most

GE crops so far are big-acreage row crops like corn, soybeans, and cotton. But the value of many of these traits would be greatly reduced when used in truly sustainable agroecological systems, because pest infestations would be much lower and cause much less damage. It would be hard for companies to charge farmers the very high

<sup>48</sup> Roundup Ready, Monsanto herbicide (Glyphosate)

<sup>49</sup> MSS: Task Force: Application of Agricultural biotechnology: Chapter 11. <http://agricoop.nic.in/TaskForce/chep11.htm>.

prices for seed as they do now, because they would have less value where pests are less of a problem. And without those high prices, it is unclear whether the companies could afford to develop these seeds. (Gurian –Sherman)(xv).

**Argentina:** The ‘soyaisation’ of agriculture in Argentina employing HT crops is 100%. Argentina is a grim picture of the heavy socio-economic and environmental cost (including super weeds), of its huge and premature experiment with GM soy. There are important lessons especially for India and other agri economies. Expansion of GM soy monoculture has damaged food security by displacing food crops. Soy production in the five years prior to 2005, displaced 4,600,000 hectares of land previously dedicated to other production systems such as dairy, fruit trees, horticulture, cattle, and grain. (Pengue<sup>50</sup>, W. 2005) (xvi).

ARGENTINA’S CHACO REGION is dominated by small-holder farmers, presenting an important case and model for India. As a result of the ‘soyaisation’ of Argentina’s agriculture, thousands of small- and medium-scale farmers have been forced out of the production system. In the **10 years**, to (around) 2005 the country lost its food sovereignty by concentrating on a few commodities for agro-export without value-addition. Poor people cannot afford a diverse diet any more. The protein basis of their meals has changed from high-quality meat proteins to soy protein. 20% of the children show signs of undernourishment. Landscape transformation in the rural sector is evident, and the appearance of glyphosate-tolerant weeds is becoming a common occurrence. Nutrient depletion, soil-structure degradation, potential desertification, and loss of species are some of the results of the overexploitation associated with the monoculture production of RR soybean. Migration from rural areas, concentration of agribusiness, loss of food diversity and food sovereignty are some of the socio-economic consequences. By 2003 to 2004 about 30% of the whole soybean area (at that time of 4.5 million hectares) was fertilised with mineral fertilisers. This shows a trend toward substantial depletion of nutrients in Argentinean soils, and if the trend continues, nutrients will be totally extracted in 50 years (Ventimiglia; 2003; Pengue2005 (xvii).

*As a result of the ‘soyaisation’ of Argentina’s agriculture, thousands of small- and medium-scale farmers have been forced out of the production system. In the 10 years, to (around) 2005 the country lost its food sovereignty by concentrating on a few commodities for agro-export without value-addition. Poor people cannot afford a diverse diet any more... Nutrient depletion, soil-structure degradation, potential desertification, and loss of species are some of the results of the overexploitation associated with the monoculture production of RR soybean. Migration from rural areas, concentration of agribusiness, loss of food diversity and food sovereignty are some of the socio-economic consequences.*

- **Classical Breeding and Monsanto admissions:** The myth of how rapidly genetic engineering can produce a commercial GMO compared to breeding is not even believed by the largest genetic engineering company in the world. Dr Robert Reiter, a molecular biologist and VP Biotechnology at Monsanto said in New Zealand (Heinemann: ‘Hope not Hype’) that: “*Conventional crop breeding requires a 7 – 8 year cycle, compared to 10 – 15 years from inception to development for genetically modified crops...*”. “It’s significantly cheaper and with a different regulatory requirement, and let’s face it, a different public perception,” (Stark – Monsanto); “Genetic transformation can only be used to introduce one segment of novel genetic material to a variety at a time, but biotech tools can be used to enhance a host of existing traits. It’s a numbers game and ultimately non-transformation [ie non-GM] biotech offers the greatest potential.”

## II HT Crops: Health Impacts: Evidence from Independent science

*Glyphosate is a powerful chelating agent. Its ability to bind to metals allows glyphosate-metal complexes to persist in the soil for decades*

Glyphosate<sup>51</sup> is a powerful chelating agent. Its ability to bind to metals allows glyphosate-metal complexes to persist in the soil for decades (Huber 2012 (xviii)). This chelating property has also led to the hypothesis that the glyphosate-metal complexes are the cause of a fatal chronic kidney disease epidemic ravaging Central America, and Sri Lanka (xix). Ubiquitous Glyphosate and its degradation product amino-methyl-phosphonic acid (AMPA) has been detected in air, rain, ground water, surface water, sea water and soil. The chemical is accumulating in our environment (xx). Monsanto patented glyphosate as an herbicide in 1970 and has marketed the chemical as Roundup since 1974. Glyphosate is now the world’s most widely used herbicide.

<sup>50</sup> Prof Walter Pengue, an expert in agriculture and rural sustainable development (University of Buenos Aires)

<sup>51</sup> Dr Jeff Ritterman: compilation of studies showing harm from Glyphosate: ‘The case for banning glyphosate’, 23 feb. 2015 (Truthout); <http://www.truth-out.org/news/item/29244-will-richmond-reject-roundup-the-case-for-banning-glyphosate>

Monsanto has claimed (based on a number of assumptions, including the lack of the Shikimate pathway in vertebrates (EPSP synthase) that Glyphosate is safe and has advertised it aggressively as boon for farmers for weed control. Monsanto claims (website):

“Glyphosate binds tightly to most types of soil so it is not available for uptake by roots of nearby plants. It works by disrupting a plant enzyme involved in the production of amino acids that are essential to plant growth. THE ENZYME, EPSP SYNTHASE, is not present in humans or animals, contributing to the low risk to human health from the use of glyphosate according to label directions.” (xxi)

However, a body of research is demonstrating serious concern. In 2012, a rare long term, 2-year rat feeding study was conducted with GM maize and Roundup (Seralini)<sup>52</sup>. Of the findings, Seralini says, the study showed severe liver and kidney deficiencies and hormonal disturbances, such as breast tumours, AT LOW LEVELS OF ROUNDUP THAT ARE BELOW THOSE PERMITTED IN DRINKING WATER IN THE EU. Similar effects were observed from the long-term consumption of Roundup-tolerant GM maize. No tumours were detected BEFORE 9 months attesting to the insufficiency of current 90-day protocols followed by the Industry and regulators. Seralini says that these are due to residues of Roundup and to the specific genetic modification of this maize. The formulations of roundup, as well as roundup-tolerant GMOs should therefore be considered endocrine (hormone) disruptors and should be re-evaluated for safety by the health authorities, using long-term exposure periods to ensure the real protection of public health.

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- “Biochemical analyses confirmed very significant chronic kidney deficiencies, for all treatments and both sexes; 76% of the altered parameters were kidney-related
- In treated males, liver congestions and necrosis were 2.5 to 5.5 times higher Marked and severe nephropathies were also generally 1.3 to 2.3 times greater
- In females, all treatment groups showed a two- to threefold increase in mortality, and deaths were earlier
- This difference was also evident in three male groups fed with GM maize
- All results were hormone- and sex-dependent, and the pathological profiles were comparable
- Females developed large mammary tumours more frequently and before controls
- the pituitary was the second most disabled organ
- the sex hormonal balance was modified by consumption of GM maize and Roundup treatments
- Males presented up to four times more large palpable tumours starting 600 days earlier than in the control group, in which only one tumour was noted
- These results may be explained by not only the **NON-LINEAR ENDOCRINE**-disrupting effects of Roundup, but also by the over-expression of the EPSPS TRANSGENE or other mutational effects in the GM maize and their metabolic consequences
- Our findings imply that long-term (2 year) feeding trials need to be conducted to thoroughly evaluate the safety of GM foods and pesticides in their full commercial formulations”.

The Seralini study was very bad news for Monsanto. The response from Monsanto and the Industry was immediate, vociferous and nasty. The original study, published in Food and Chemical Toxicology (FCT) in September 2012, was controversially withdrawn when Monsanto intervened with the editorial board before the retraction by FCT. A former Monsanto scientist, Dr. Richard Goodman, was brought into the journal as biotechnology editor. The study has been republished by Environmental Sciences Europe. The republished version contains extra material addressing criticisms of the original publication.

<sup>52</sup> Seralini et al: Republished study: Long-term toxicity of a Roundup herbicide and a Roundup-tolerant GM maize: Environmental Sciences Europe 2014, 26:14: <http://www.enveurope.com/content/26/1/14>

## Glyphosate and Birth defects

However, several other independent studies also report similar findings to the Seralini study including the huge hazard of Roundup being an endocrine disruptor<sup>53</sup>. One of the earliest studies was done in 1979-1981, under the auspices of the United Nations Environmental Program, the International Labour Organisation and the World Health Organisation. Rats exposed to low levels of the herbicide developed testicular cancer. A larger dose did not produce the cancer. Unfortunately, at the time of the experiment, it was not understood that certain substances have more potent effects at lower doses than at higher doses. The evaluators dismissed the results (xxii)

In 2004, researchers from the National Scientific Research Center in France exposed sea urchin embryos to glyphosate. The herbicide caused significant errors in cell division. The scientists commented that these abnormalities are hallmarks of cancer and delivered a particularly chilling warning: the concentration of glyphosate needed to cause these errors was 500 to 4000 times lower than the dose to which humans may be exposed by aerial spraying or handling of the herbicide (xxiii).

**Argentina** is experiencing an alarming increase in birth-defects and cancers correlated with the massive shift to Glyphosate/Roundup GM soy, after a decade (1995-96 to 2005) of intensive and extensive RR spraying reinforcing findings that Glyphosate is an endocrine disruptor (xxiv).

*The late Dr. Andreas Carrasco<sup>54</sup> of Argentina in ground-breaking research on the hazards of Roundup and glyphosate, identified the mechanism through which glyphosate exercises its birth-defect-causing toxicity, as the retinoic acid signalling pathway (xxv).*

The late Dr. Andreas Carrasco<sup>54</sup> of Argentina in ground-breaking research on the hazards of Roundup and glyphosate, identified the mechanism through which glyphosate exercises its birth-defect-causing toxicity, as the *retinoic acid signalling pathway* (xxv). Dr. Carrasco suspected that glyphosate caused an abnormal hyperactivity in the Vitamin A pathway, which is present in all vertebrates from the very earliest stages of embryonic development. It turns on certain genes and turns off others (xxvi). Any disturbance of the Vitamin A pathway can result in birth defects<sup>55</sup>. Since this pathway is present in all vertebrates, it follows that glyphosate has the capacity to cause birth defects in fish,

birds, amphibians, reptiles, and mammals.

Further evidence corroborates that Roundup, even at the low levels permitted in food and drinking water, could lead to serious effects on health over time, such as liver and kidney toxicity (xxvii). A meta-analysis has confirmed a link between exposure to glyphosate herbicides such as Roundup and non-Hodgkin's lymphoma, a type of blood cancer (Schinasi, L., & Leon, M. E. (2014).<sup>56</sup> A review published in 2013 (Samsel and Seneff, 2013<sup>57</sup>) hypothesized a mechanism by which glyphosate herbicides could be contributing to modern human diseases that are on the increase worldwide. The authors focused especially on celiac disease and gluten intolerance, but also drew potential links between glyphosate toxicity and a broader range of diseases, such as ADHD (attention deficit hyperactivity disorder), autism, Alzheimer's disease, infertility, birth defects, and cancer. The review cited Glyphosate's known ability to disrupt gut bacteria and to suppress the activity of the **cytochrome P450 (CYP)** family of enzymes, which play an important role in detoxifying harmful chemicals. The authors concluded that glyphosate enhances the damaging effects of other food-borne chemical residues and environmental toxins.

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<sup>53</sup> An endocrine disruptor is a chemical that can mimic or block a hormone. Because hormones work as chemical messengers at very low doses, even a minute dose of an endocrine disrupter can lead to serious illness.

<sup>54</sup> Dr. Andres Carrasco, an embryologist and the former Director of the Molecular Embryology Laboratory at the University of Buenos Aires

<sup>55</sup> It is because of the enhanced risk of birth defects that pregnant women are advised not to take any Vitamin A (retinoic acid) containing medications.

<sup>56</sup> International journal of environmental research and public health, 11(4), 4449-4527: <http://www.mdpi.com/1660-4601/11/4/4449/htm>

<sup>57</sup> Samsel and Seneff: Entropy 2013, 15(4), 1416-1463; doi:10.3390/e15041416

**Epidemiology – cancer IARC (WHO):** Scientists from the International Agency for Research on Cancer (IARC, of the WHO that promotes cancer research), have analyzed studies spanning almost three decades. The agency views cancers as linked, directly or indirectly, to environmental factors. They have found a positive association between organo-phosphorus herbicides, like glyphosate, and non-Hodgkin's lymphoma. The B cell lymphoma sub-type was strongly associated with glyphosate exposure (xxviii).

In March, 2015, 17 experts from 11 countries met at the International Agency for Research on Cancer (IARC, Lyon, France) to assess the carcinogenicity of the organophosphate pesticides tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate (the Lancet<sup>58</sup>). The meeting followed almost a year of review and preparation, including a comprehensive review of the latest available scientific evidence. The experts were selected on the basis of their expertise and most importantly, *the absence of real or apparent conflicts of interest.*

The results were announced on 20 March 2015. The IRAC has deemed glyphosate a “probable human carcinogenic” and “sufficiently demonstrated” for genotoxicity in animals, (Group 2A) and has rejected Monsanto's vociferous objections. A classification of 2A in cancer-causing potential for glyphosate of the IARC is its second highest categorisation. Two insecticides placed in the lower category (2B) in terms of cancer-causing potential are both in restricted use. Tetrachlorvinphos is banned in the European Union, but continues to be used in the US; while parathion has been severely restricted since the 1980s, and all authorised uses were cancelled in the European Union and USA by 2003.

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The US EPA follows a similar listing. It originally classified glyphosate as possibly carcinogenic to humans in 1985, but in 1991, changed the classification to non-carcinogenic. In 2013, the EPA raised the permissible limits of glyphosate contamination in farm-grown food and animal feed (xxix).

The IRAC reappraisal of data from the 1980s with regard to Glyphosate is enormously troubling for its reinforcement of the question of FRAUD linked to both the US EPA and Monsanto. Research scientist Dr Anthony Samsel summarises those implications:

*“Monsanto's Trade Secret studies of glyphosate show significant incidence of cell tumors of the testes and tumorigenic growth in multiple organs and tissues. They also show significant interstitial fibrosis of the kidney including effects in particular to the Pituitary gland, mammary glands, liver, and skin. Glyphosate has significant effects to the lungs indicative of chronic respiratory disease. **Glyphosate has an inverse dose response relationship**, (Section 5 -- ) and it appears that its effects are highly pH dependent. Both Monsanto and the EPA knew of the deleterious effects of this chemical in 1980 at the conclusion of their multiple long-term assessments, but the EPA hid the results of their findings as “trade secrets.” Monsanto has been lying and covering up the truth about glyphosate's harmful effects on public health and the environment for decades. The increases in multiple chronic diseases, seen since its introduction into the food supply, continue to rise in step with its use. Monsanto's Roundup glyphosate based herbicides have a ubiquitous presence as residues in the food supply directly associated with its crop use”. **Source document:** ‘Monsanto knew of glyphosate / cancer link 35 years ago’: GM-Free Cymru Special Report 8th April 2015*

<sup>58</sup> Lancet Oncol 2015; Published Online March 20, 2015 [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8)

## **Monsanto fraud: divergence of regulatory decisions from scientific evidence (xxx)**

This peer reviewed paper<sup>59</sup> (Antoniou et al 2012) (also published as ‘Roundup and Birth Defects: Is the Public Being Kept in the Dark?’ (xxxi)), makes the astounding claim that there is collusion between Monsanto and EU regulators over the safety of RR and Glyphosate and this is a divergence from scientific evidence resulting in a serious public health risk. It reveals that Monsanto has known since the 1980s that glyphosate in high doses causes malformations in experimental animals; since 1993, the company has been aware that even middle and low doses can cause these birth defects. These abnormalities include absent kidneys and lungs, enlarged hearts, extra ribs, and missing and abnormally formed bones of the limbs, ribs, sternum, spine and skull. It calls for an immediate withdrawal of Roundup and glyphosate from the European Union until a thorough scientific evaluation is done on the herbicide. The report says:

*Monsanto has known since the 1980s that glyphosate in high doses causes malformations in experimental animals; since 1993, the company has been aware that even middle and low doses can cause these birth defects. These abnormalities include absent kidneys and lungs, enlarged hearts, extra ribs, and missing and abnormally formed bones of the limbs, ribs, sternum, spine and skull.*

“The public has been kept in the dark by industry and regulators about the ability of glyphosate and Roundup to cause malformations. In addition, the work of independent scientists who have drawn attention to the herbicide’s teratogenic<sup>60</sup> effects has been ignored, denigrated or dismissed. These actions on the part of industry and regulators have endangered public health.”

*To be noted is the history of regulatory complicity with the biotech Industry, with its origins in the US, and the virtual deregulation of GMOs in that country. The Indian regulatory record is completely dismal, with an endemic conflict of interest firmly established within the regulators and concerned Ministries. Also to be noted is that fraud and cover-up are ingrained in Monsanto’s approach to profit-making.*

To be noted is the history of regulatory complicity with the biotech Industry, with its origins in the US, and the virtual deregulation of GMOs in that country. The Indian regulatory record is completely dismal, with an endemic conflict of interest firmly established within the regulators and concerned Ministries. Also to be noted is that fraud and cover-up are ingrained in Monsanto’s approach to profit-making. This is true of many biotech corporations, as well as the chemical Industry. The poisoning of the water-supply of the residents of Anniston is a particularly glaring and telling example of Monsanto’s functioning, for which Monsanto was convicted in a court of law.

### **III. Bt Crops: The toxicity of Bt genes: evidence from independent science**

#### **➤ The TEC recommends an indefinite moratorium on open field trials, especially Bt food crops**

The Indian regulators in line with the position taken by Monsanto have consistently refused to let-go of their dogma that Bt toxins are lethal only to alkaline gut systems. This premise is untrue with growing evidence of its toxicity and allergenicity to animal and humans. The claim is used to justify the reasons for open field trials in Bt food crops and therefore, the question of its validity could not be more important (see Bt brinjal below).

Bt toxins function by binding to the surface of cells in the guts of insects and killing them. There is increasing evidence that Bt toxins also bind to mammalian cells in the stomach (Vazquez-Padron) and intestine and cause inflammation that will lead to cancer in people. The claimed exclusiveness of the specificity of Bt toxin-binding to the insect gut can therefore, no longer be maintained, as there is credible

*The claimed exclusiveness of the specificity of Bt toxin-binding to the insect gut can therefore, no longer be maintained, as there is credible scientific evidence that some Bt toxins will also bind to the gut of mammalian species (A. Puztai and S.Bardocz)*

<sup>59</sup> M Antoniou, MEM Habib2 CV Howard, RC Jennings, C Leifert, RO Nodari, CJ Robinson, and J Fagan: ‘Teratogenic Effects of Glyphosate-Based Herbicides: Divergence of Regulatory Decisions from Scientific Evidence’.

<sup>60</sup> A teratogen is any agent that can disturb the development of an embryo or a foetus. The term stems from the Greek teras, meaning monster).

scientific evidence that some Bt toxins will also bind to the gut of mammalian species (A. Pusztai and S. Bardocz) (xxxii). The capacity of various A-B toxin-lectins, including *Bacillus thuringiensis* (Bt) Cry1Ac protoxin to stimulate and modulate both the systemic and mucosal immune systems is now firmly established (xxxiii).

Immune responses<sup>61</sup> were reported in farm workers after exposure to *Bacillus thuringiensis* pesticides (Environmental Health Perspectives 107, 575-582). Reproductive Technology (2011) published a study (Leblanc) which showed that Cry1Ab toxin was detected in 93% and 80% of maternal and foetal blood samples, respectively, and in 69% of tested blood samples from non-pregnant women, raising concerns about this toxin in insect-resistant GM crops (a) that these toxins may survive digestion and therefore, may not be effectively eliminated in humans and (b) there may be a high risk of exposure through consumption of contaminated meat (stealth foods) (Pusztai<sup>62</sup> (xxxiv)). This likewise raises anxiety with regard to approx. 1200,000 tonnes (2011 estimates) of unlabelled Bt cotton-seed oil, which has contaminated our food-chain.<sup>63</sup>

**Mons 863:** The MON 863 study was a reappraisal of Monsanto's safety dossier. Contrary to Monsanto's claim that this event is safe, it revealed that rats fed on transgenically expressed Bt toxin in maize caused kidney and liver problems in addition to interfering with the normal growth of young rats (Seralini et al. 2007). Bt toxin expressed in potatoes caused major changes in the small intestine of mice (Fares, N.H. and El-Sayed, A.K. (1998); there were fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes (Natural Toxins 6, 219-233).

The evidence for the survival of the Bt toxins in the digestive tract and internal organs is clear-cut. Thus, it is expected that the situation with Bt brinjal will not be different. Accordingly, all the already described potentially harmful effects on consumers of the Bt toxins can also be expected to occur with Bt brinjal. As their release into the environment is an irreversible act, sanctioning such large scale field trials would be highly irresponsible (Pusztai).

It is 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 investigator's bias”* (Schubert: submission to Minister J Ramesh (MoEF) dated 18 November, 2009). He says: there are at least four mechanisms by which the introduction of the Bt toxin gene into plant genome can cause harm. These include (1) the random insertion of the Bt gene into the plant DNA and the resulting unintended consequences, (2) alterations in crop metabolism by the Bt protein that results in new, equally unintended and potentially toxic products, (3) the direct toxicity of the Bt protein, and (4) an immune response elicited by the Bt protein. There are scientifically documented examples of all four toxic mechanisms for bt crops. In support of the human data, when animals are exposed to Bt toxins, the toxin also acts as a potent immunogen, eliciting responses from both the blood and gut-based immune systems. based upon these data, the us environmental protection agency (epa) recommended extensive safety testing of Bt crops for this trait, but due to the lack of required safety testing for GE food crops in the US, this was never done. (Schubert).

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These include (1) the random insertion of the Bt gene into the plant DNA and the resulting unintended consequences, (2) alterations in crop metabolism by the Bt protein that results in new, equally unintended and potentially toxic products, (3) the direct toxicity of the Bt protein, and (4) an immune response elicited by the Bt protein. There are scientifically documented examples of all four toxic mechanisms for bt crops. In support of the human data, when animals are exposed to Bt toxins, the toxin also acts as a potent immunogen, eliciting responses from both the blood and gut-based immune systems. based upon these data, the us environmental protection agency (epa) recommended extensive safety testing of Bt crops for this trait, but due to the lack of required safety testing for GE food crops in the US, this was never done. (Schubert).

The long-accepted version of Cry toxicity is not the actual mechanism. 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* (Heinemann, Bt brinjal genomic assessment).

<sup>61</sup> In India In 2006, thousands of sheep and goats died in Andhra Pradesh (AP) as a result of grazing their animals in harvested Bt cotton fields. These were never investigated by the Regulators (ascertained through an RTI): Sagari Ramdas: review process of J Ramesh dated 1 December 2009: 'No proof of safety of Bt toxin impact on Animals' (Annexure IV of Ramesh's Report on Bt Brinjal on the MoEF website). Allergenicity in humans is attested and reported from several States. Animal deaths attributed to the Bt toxin, and among other symptoms, decreasing milk yield, are not novel – only reported from India. Syngenta Corporation covered-up dozens of livestock deaths from Bt 176 corn (an animal feed). India has no ability to test for the Bt toxin

<sup>62</sup> Prof. Arpad Pusztai on Bt brinjal: Wednesday, 27 January 2010 20:08

<sup>63</sup> Parliamentary Standing Committee Report on GM crops: 'Prospects and effects': Aug 2012

#### IV. Bt Cotton performance in India

Bt cotton was approved in 2002 for commercial cultivation in central and south India, and in 2005 in north India. By 2011, the market share of Bt cotton was more than 92%. Bt cotton is the only commercialised crop in the Country. Its 'superlative' performance as claimed by the regulators and in every government report, has been the official justification for the expansion planned for the wholesale introduction of GM crops into Indian agriculture, as a result of which, thousands of open field trials have been conducted for several years in virtually all of India's food crops and approval was given for the commercialisation of Bt brinjal in Oct 2009, (overturned by Jairam Ramesh). The onward progression has been to GM Crops being the answer to India's food security because of proven high yields of Bt cotton. These claims are wrong. It is therefore, of the utmost importance for India's future that the performance of Bt cotton is clarified and the reality recognised.

Given that the short time -frame under review is a scant ten years, (in reality less because in the first two years the market-share of Bt cotton was negligible), we don't need to cut butter with a chain saw in the manner of complicated analyses, but apply a commonsense approach. The analyses is based on official government data by the Department of Economics and Statistics (DES) and the Cotton Advisory Board (CAB). We take 2004 -2011 as the Bt era when the market share of Bt C was around 6% and 92% respectively. A brief analysis is provided below:

- **Yield** is stagnating at around 500 kg/hectare over these 9 years, according to the Government's official data of the Cotton Advisory Board (Textile Ministry) and the Department of Economics and Statistics (DES: Ministry of Agriculture). In the starting year of the Bt-era (2004), yield was around 400 kg lint/hectare rising to round 500 kg lint/hectare. Data of the Ministry of Agriculture show that the increase in yield is clearly associated with increase in chemical inputs, irrigation and increase in the area under hybrid cotton. According to Gruere and Sun (IFPRI) (xxxv), yield increase is being wrongly attributed to the technology of Bt alone. The use of India's best hybrids in Bt cotton, (hybrid area went up from 40% in 2002 to 95% by 2011 in Central and South India and from 0% in 2004 to 95% by 2011 in north India), increase in fertilisers and insecticides also contributed to the increase in yield. India is the only country that has introduced Bt in hybrids, forcing the farmer to buy seed year after year. In every other country, the Bt gene is engineered into varieties.
- **Insecticide use (Rs/hectare) has increased (volume data are at present not available):** The essential selling point of Bt technology is to decrease the use of insecticides. This has not happened. During 2004-2011, it has gone up from Rs 1540 to Rs 2430 (rounded-up). The bollworm incidence has in fact been low in the decade under review (AICCIP All India Coordinated Cotton Improvement Programme). Significant infestation by secondary pests, in common with the experience in other countries growing Bt crops have forced up insecticide use.
- **Fertilisers (kg/hectare) use doubled:** For the same period, fertiliser use has increased from Rs 112/hectare to 222/hectare.
- **Seed cost (Rs/hectare) doubled:** The increase is quite dramatic from Rs 1795 in 2004 to Rs 3595 in 2011 (rounded up).
- **Area planted (million hectares):** The one statistic that did go up significantly was the area planted under Bt. C. For the same period (2004-11) it is around 36%. The area under cotton increased from 9.2 million hectares in 2008 to 12.95 million hectares in 2014. However, when confronted by the Parliamentary Standing Committee (PSC) on the displacement of food crops this would have caused *"thus jeopardizing the country's food security to that extent"*, [5]the response from the MoA (Ministry of Agriculture) was that there had been no expansion ---- *"the total acreage under cotton crop remained almost same all these years. The area under cotton crop in India was 8.9 million hectares during 1997-98 and 9.2 million hectares during 2008-09. The productivity increased from 302 kg/ha in 1997-98 to 591 kg/ha in 2008-09. Therefore, there has been no negative effect of cultivation of Bt cotton on the food security in the country"*. This response is enlightening indeed of the degree of manipulation and fantasy to support the mirage of Bt cotton. The PSC went on to state:

*"Also, due to the popularity of Bt. Cotton, countless number of traditional varieties of cotton has been wiped out. The same fate would have befallen our traditional varieties of brinjal had the moratorium not been placed on the commercialisation of Bt. Brinjal. Taking a very serious note of this matter, the Committee had recommended that an in-depth probe may be carried out to track the decision-making involved in the commercial release of Bt. Cotton right from the initial stage"*.<sup>64</sup>

<sup>64</sup> PSC: Report no 59 Committee on Agriculture 2013-14: Cultivation of GM crops – Prospects and Effect. Action taken by the Govt (37th Report 2011-12): Recommendation para 6.146

## Note:

- In Gujarat for example, where the highest yield is recorded of all States, 0.6 to 0.7 million hectares of new land was planted with Bt cotton (previously under groundnut), irrigated by a 100,000 new check dams (Kranti.K, 2011). In Gujarat, **65% irrigated cotton area contributes 84%** and **35 % un-irrigated** area contributes **16%** of the state's cotton production. The average productivity in irrigated area is 689 lint kg/ha whereas that in un-irrigated is a mere 247 kg.<sup>65</sup> [Z]. The national figure for irrigated farm-land is 33%.
- **Honey Bees: Colony Collapse Disorder caused by Bt cotton seeds:** An insecticide called imidacloprid (Gaucho) of the 'neonicotinoid' insecticide group is used at 10 gm per hectare as sprays and 10 gm per Kg Bt cotton seeds per hectare. All Bt cotton seeds are mandatorily treated with Gaucho in India (Kranthi K, 2011). Non-Bt varieties are not treated with this chemical because they are generally resistant to sap-sucking insects. Imidacloprid is translocated into cotton flowers, pollen and nectar and is carried by honey bees to their hives to feed young larvae. The insecticide is most toxic to honey bees at a median lethal dose of 5 nano grams per bee (Thakur, IARI, 2015) ( xxxvi). Thus 10 gm of Imidacloprid can kill one billion bees. Bayer claims that the insecticide has a long residual life of more than two months when used as seed treatment and sprays. Every year more than 240,000 kg of imidacloprid is used as seed treatment of Bt cotton seeds in India (at 10 gm per kg seed; 2 kg seed per hectare for 12 million hectares).

It is estimated that there is a several fold increase in Gaucho sprayed on the Bt cotton crop. Studies have been initiated only recently in India (Thakur 2015) on the colony collapse disorder after the EU banned the use of the neonicotinoid group of insecticides on 1st December 2013 in 28 countries of Europe.

- The government should have done a post market monitoring (PMM) of Bt cotton to monitor Bt cotton,) and its socio-economic impacts. Bee deaths (CCD) may have become apparent if they had done so. Furthermore, isogenic lines of non-Bt cotton should have been grown side-by-side to determine the contribution of Bt cotton to performance yield, separating the yield attributable to hybrid vigour. There is a void in these matters. The serious aspect is that the regulators and Ministers still make the claim in the SC (clearly perjurious) and to Parliament of the runaway success of Bt cotton. They then went one step further: much more seriously, they were willing to risk the country with the introduction of Bt brinjal. This is still the plan, and to enlarge it to cover virtually all our food crops, The flawed basis is two-fold: the dubious performance of Bt cotton and the claim of the safety of Bt brinjal (based on its self-assessed dossier by Mahyco-Monsanto).
- **Value capture:** Bt cotton was introduced into India's hybrids, not varieties, the only country to do so, forcing our farmers to buy seeds each year and allocate the yield from hybrid vigour to Bt Cotton instead (Ramasundaram, 2014) (xxxvii). This 'VALUE CAPTURE' for Monsanto, which was contrived and approved by our own government mortgaging the public interest has ensured that in a short 10 years, 95% of cotton seeds in the form of Bt cotton are owned by Monsanto. The damage to India's organic cotton market and status is significant. India is the largest organic cotton producer/exporter in the world. It is Monsanto now that decides which of 1000 Bt cotton hybrids should be planted, where and when by our farmers, a role that the MoA has absconded or been eliminated from. The Royalties accruing to Monsanto that have been expatriated are approximately Rs 4800 Crores in 12 years, (excluding other profit mark-ups). What will this figure be if GMOs and propriety seeds flood our farms in Bt hybrids as is the plan and without Biosafety assessment and regulation? The PSC is quite right in calling for a high level enquiry into these matters.
- **Resistance:** In 2010, Monsanto reported that the pink bollworm had developed resistance to Bt cotton in India. Dhurua and Gujar (2011) (xxxviii) from IARI Delhi confirmed the resistance report. Bt resistance was also confirmed for the first time in the US, which has the longest history of any country under GM crop cultivation and because, a 20% 'refuge' policy to manage resistance is mandated by law. 'Refuges' of the Non-GM plant (surrounding the GM crop) ensures non-resistant adult insects can survive to breed with resistant ones so that the resistance gene does not become dominant. Such is its seriousness in the US that 22 academic corn experts have sent a strong message of caution<sup>66</sup> in a letter dated March 5 2012 to the Environmental Protection Agency telling regulators they are worried about long-term corn production prospects *because of the failure of the genetic modifications in corn aimed at protection from rootworm*. Unlike the US, India has no effective policy to manage

<sup>65</sup> Kumar.V (2011). Navsari Agricultural University, Gujarat. Bt Cotton : A Gujarat experience & issues

<sup>66</sup> <http://in.reuters.com/article/2012/03/09/us-monsanto-corn-idINBRE82815Z20120309>

resistance; we cannot mandate that our farmers with their small farm-size maintain 20%<sup>67</sup> refuges leave alone 50%. This was the earlier recommended refuge in the US. It was reduced to 20% to accommodate Monsanto, ) given its ability to bring pressure on US regulatory agencies, in this case, the EPA) and which is “likely the reason for the development of resistance”).

## V. The test-case of Bt brinjal Event EE-1

When the raw data of the Indian Bt brinjal self-assessed dossier by Mahyco-Monsanto was forced into the public domain by a SC Order, lead petitioner appealed for an appraisal of the dossier. Several leading international scientists responded, who also submitted reports to Jairam Ramesh in his review process<sup>68</sup>. The Bt brinjal Dossier did not inspire confidence, after it had been scrutinised by eminent independent global scientists. The erstwhile Minister MoEF, Jairam Ramesh imposed an indefinite moratorium on Bt brinjal in February 2010, calling for independent testing and scientific risk assessment that would be acceptable to citizens and scientists alike (xxxix). Bt brinjal is the ONLY dossier in the public domain. Its reappraisal reveals the appalling lack of sound risk assessment protocols for GM crops in India & for untested GMOs being released into the environment in open field trials (OFT). Individually and collectively, the appraisals indicate minimal regulatory oversight of this self-assessed biosafety-dossier of Mahyco-Monsanto, and serious cover-up amounting to FRAUD, of studies said to be done, but were not done. Briefly:

- **Bt brinjal is a fusion or “chimeric” gene** (Cry 1Ac/Ab) as stated in the Dossier, but this was not known to the Regulators till it was highlighted by Seralini. Thereafter, it was announced by the Regulators that in any case, the difference was only 1 amino acid at the claimed identity of 99.4% with Cry 1Ac. As Heinemann was to point out (2012), the question of a difference of 1 was never on record. The difference of 7 is “consistent with the original description by Monsanto, 1997”. At “**94% identity** there could be a difference of up to **70 different amino acids**. To conclude that a novel protein is likely to be of no safety concern because of even as few differences as 7 amino acids, is not a research-based conclusion. Changes of single amino acids can significantly alter the characteristics of proteins (a fact that underpins the field of directed evolution). The critical and fundamental characterisation of the event was not completed, usually because of assumption-based reasoning. When such fundamental misunderstandings of the basic tools of the procedure were demonstrated by the developer, seemingly went unchallenged by the regulator, it was very difficult to accept assurances that the other procedures in the evaluation of Bt brinjal could be trusted. (Heinemann, 2012<sup>69</sup>)
- **Heinemann:** He asserts Mahyco has failed at the first, elementary step of the safety study, analysing the insertion: “*I HAVE NEVER SEEN LESS PROFESSIONALISM IN THE PRESENTATION AND QUALITY ASSURANCE OF MOLECULAR DATA THAN IN THIS STUDY*”. He criticises Mahyco for “*working from a discredited model of Cry toxicity*”), testing to below acceptable standards and for inappropriate and invalid test methods. (Seralini and Carman made similar observations in their appraisal of the animal feeding studies of the Mahyco dossier); Mahyco has provided no information whatsoever on novel RNAs. This is a significant omission. Monsanto states on pg 93 that “*it is unlikely that seed or other brinjal tissues would enter aquatic habitats*”. This has been proved wrong. Bt corn residues and pollen were found to concentrate in streams and have a significant effect on aquatic organisms in the US Midwest; 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 (see III above). 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.

<sup>67</sup> Dr. K Kranthi: 10 years of Bt cotton in India in 3 parts of 1 May 2011: in Part III he says: “The tobacco caterpillar, *Spodoptera litura*, resurfaced as a problem again as predicted, because of the low toxicity of the Cry1Ac toxin on the species. Bollworms started reappearing on Bt cotton. In February 2010, Monsanto, India declared that pink bollworm had developed resistance to Cry1Ac and that only Bollgard-II would be effective thereafter. Resistance monitoring studies at CICR showed that the American bollworm *Helicoverpa armigera* was also showing incipient tolerance in some parts of India. The area under Bt cotton has reached above 90% in many parts of the country but farmers are not following the recommended refugia practices. The intensive Bt cultivation and the noncompliance of refugia is likely to hasten resistance development. The concern needs to be addressed on priority before it is too late.

<sup>68</sup> Pusztai, Andow, Heinemann, Schubert, Seralini, Gurian-Sherman, Carman, Gallagher: 2009-2010

<sup>69</sup> Heinemann: Bt brinjal reappraisal of Monsanto’s dossier

- **Seralini:** “Bt brinjal cannot be considered as ‘safe’. It is known anyway that NATURAL BT TOXINS HAVE NEVER BEEN AUTHORISED FOR MAMMALIAN CONSUMPTION. Artificial ones should not be either, before a more serious assessment. Significant effects in comparison with controls are also noticed with other GMOs tolerant to Roundup, and in total with at least four GMOs for which these kinds of tests have been done. These resemble classical side effects of pesticides in toxicology; and these have also been observed for MON810 maize producing a related insecticide which is present in part in the Bt brinjal, Cry1Ab”.---“The agreement for Bt brinjal release into the environment, for food, feed or cultures, may present a serious risk for human and animal health and the release should be forbidden”.
- **Andow: The scope and adequacy of the GEAC environmental risk assessment -**

*“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”.*

**“The evolution of resistance in BFSB** (brinjal fruit and shoot borer) 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;

**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. Many of the experiments submitted by Mahyco in the Dossier provide little relevant information about the potential impact of Bt brinjal on species in India and do not assess any real concern in India.

**The soil studies** were not designed to evaluating effects on soil health, brinjal productivity, or the productivity of other crops grown by brinjal farmers, which are the real concerns for Indian farmers. Instead, they measure microbial populations, which have little relevance for assessing these real concerns.

Insecticide use can be reduced substantially using integrated pest management (IPM). Useful alternative production systems for control of BFSB are being tested, actively used, and promoted in India: IPM, traditional pest management, organic production and other locally-derived methods that reduce costs associated with external inputs.

**EE-1 Bt brinjal is proposed as a hybrid, and is unlikely to fit well in the small-scale production systems** relying on open-pollinated varieties (OPVs) of brinjal. For small-scale resource-poor farmers brinjal is *critical for creating economic security*. *Farmers are expected to retain only 10% of the increase in profitability from Bt brinjal*, but are expected to retain *63% of the increase from brinjal IPM*. **Nearly all brinjal farmers in India are small-scale resource-poor farmers**, who farm <1ha for all of their crops (DES 2008). They grow brinjal in small (~65 m<sup>2</sup>) plots, and sell to local village and town markets. For these farmers, brinjal production is essential for their overall economic security and well-being (APEDA 2009).

**Andow lists some 37 studies of which perhaps 1 has been conducted and reported to a satisfactory level by Monsanto.**

## **Lessons & Connecting Threads - HT & Bt crops**

**i. Bt brinjal:** The Bt brinjal dossier was fraudulent, and should have been withdrawn from the regulatory record as requested on several occasions. It invites an enquiry as recommended by the PSC <sup>70</sup> (see below), on the decision to approve its commercialisation. Furthermore, the failure to withdraw the dossier has had consequences for both Bangladesh, a country with little or no bio-safety experience with GMOs -- Mahyco-Monsanto were able to use a ‘current’ and valid dossier to recommend the commercialisation of Bt brinjal in that country. The consequences for India are very serious. A porous border with Bangladesh means that unsafe Bt brinjal threatens India’s brinjal diversity and food security and is a significant bio-security risk because of potential contamination. Both countries have fallen short of their commitments under the ‘Protocol’ (CBP of the CBD)

<sup>70</sup> PSC recommendations to Parliament on GM crops, 9 august 2012.

**“On Bt Brinjal approval decision by GEAC-** The Committee recommends 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 by a team of eminent independent scientists and environmentalists”. [PSC Para 2.79]

In the Philippines, the international appraisal of India’s Bt Brinjal was to great effect for regional and global biosecurity. The Judgment and Order of the Philippine Court of Appeals has imposed a prohibition on Bt brinjal, to protect the rights and safety of its citizens ( CA-G.R. SP No 00013).

As provided for in Section 16, Article II of the Philippine Constitution, “--- *there is no compelling reason that would warrant a reversal or modification of this Court’s May 17 2013 decision. -- it is not true that the requirements for the issuance of a writ of kalikasan and a writ of mandamus have not been met in the case at bench. The fact is that such requirements have actually been met*”. --- *“It would be well to reiterate what has been stated by us in our decision that the right of the Filipino people to a “balanced and healthful ecology” is actually a compound right. It is a conjunct of two rights namely, (1) the right to a balanced ecology and (2) the right to a healthful ecology. The right to a balanced ecology is the right to live in an ecosystem that functions naturally --- on the other hand the right to a healthful ecology is the right to not suffer acute or chronic harm resulting from alterations of natural ecological dynamics.– Both of the aforementioned conjunct rights must be affirmed and held true – and no one is denied – so the entire constitutional guarantee is affirmed and held true. Consequently, the testing or introduction of Bt talong into the Philippines, by its nature and intent is a grave and present danger to (and an assault on) the filipinos’ constitutional right to a balanced ecology ----. --- the whole constitutional right of our people (as legally and logically construed) is violated”*.

(A Writ of Kalikasan is a legal remedy under Philippine law which provides for the protection of one’s right to “a balanced and healthful ecology in accord with the rhythm and harmony of nature,”).

**ii.** The appraisal and conclusions of the Bt brinjal dossier by leading independent scientists is an important test-case and warning for India. It demonstrates the abject and systemic failure in the matter of the governance and risk assessment of GMOs, as much because of a cavalier disregard for safety concerns, a pernicious conflict of interest, as well as a lack of integrity and expertise. The combination of these factors will be lethal for India without intervention.

**iii.** Open field trials of Bt brinjal including large scale trials, were systematically carried out before all the ‘planned’ safety testing was conducted. If this is the state of affairs with Bt brinjal, the only crop whose self-assessed dossier was put in the public domain and which was thereafter and exceptionally, subjected to expert re-appraisal, then the vacuum in regulation and risk assessment with regard to all other crops which have been field-tested over the last ten years and which continue to be tested even as the TEC Report is under adjudication, is a clear indication of the bankruptcy in intent and execution of regulatory oversight.

**iv. External, independent corroboration of the need to stop GMO field trials:** Four external OFFICIAL Reports<sup>71</sup> independently arrive at conclusions of collusion, fraud, serious regulatory lapses, lack of oversight and expertise. 3 of these reports recommend a specific moratorium as with the Ramesh Report on Bt brinjal, or unanimously require comprehensive moratoriums on all open field trials (PSC and TEC). The TEC, which is the SC’s own expert committee goes further in requiring a BAN on HT crop and crops for which India is a Centre of Origin like brinjal. These official reports present a remarkable consensus. They importantly provide external and independent corroboration of the standpoint of civil society organisations on GMOs.

The importance of the Sopory Committee Report cannot be overstated. It was initiated by the ICAR (Indian Council of Agricultural Research, India’s apex agri institution), because of the infringement of Monsanto’s IP, (Intellectual Property), its gene being found in so-called ‘Desi’ BN Bt cotton (Desi means indigenous gene).

<sup>71</sup> 4 Independent Official Reports – see also Section 1: The Jairam Ramesh Report (Feb. 2010); The Sopory Committee Report (Aug. 2012); The PSC Report (Aug. 2012 and its follow-up, 2013); and the TEC Report (June 2013).

That contamination occurred well BEFORE Desi BN Bt cotton was approved demonstrating, like in Bt brinjal, that there was no regulatory oversight at the very start, ie of the molecular analyses of the Event. On the other hand however, it was not thought necessary in the case of Bt brinjal, to require the most serious investigation at the highest level as recommended by the Parliamentary Committee Report on the corrupt process that led to its approval. Monsanto's IP being breached carries more weight than the public good.

**v. RNA – dsRNA fall outside the radar of risk assessment:** Risk assessment protocols do not currently assess dsRNA (ref. Bt brinjal). The Heinemann study<sup>72</sup> establishes that *all GM crops should be evaluated for the presence of unintended dsRNA molecules*. That is, even crops not purposefully constructed to express these molecules like India's Bt brinjal, need to be evaluated for them, because they are a common by-product of the engineering process.

However, the first (xl) intentionally pesticidal GM crop trait based on RNA is before food safety regulators for approval to release as a food for humans or feed for animals. It is anticipated that other products incorporating dsRNA into sprays or other kinds of delivery vehicles will also be developed as herbicides and insecticides. Pesticidal activity is based on what are called double-stranded (ds)RNA molecules. These molecules influence the expression of genes. While we are most familiar with the ability of dsRNA molecules to either ramp down or prevent translation of a messenger RNA (mRNA) into a protein, dsRNA can also up-regulate some genes and can interfere with RNA that is not mRNA (xli).

The Codex Alimentarius guidance draws special attention to the characterisation of novel RNAs, stating: "Information should be provided on any expressed substances in the recombinant-DNA plant; this should include: A) the gene product(s) (e.g. a protein or an untranslated RNA)" paragraph 32 of (xlii).

However, this Codex recommendation is rarely if ever applied. When unexpected RNAs derived from mRNA were detected by independent researchers in one of the first significant commercial GM soybean varieties (xliii), the concern raised was that it may be used to create different forms of protein rather than the RNA being a risk per se. In response, the developer of the GM soy said that RNA "is generally recognized as safe (GRAS)", and thus "the presence of...secondary RNA transcripts themselves raises no safety concern" p. 5 (xliv).

Likewise, the Office of the Gene Technology Regulator in Australia does not consider RNA as a source of risk to people, making no distinction for dsRNA (Heinemann, ft note 57). A similar position has been taken by Food Standards Australia/New Zealand the bilateral food safety authority (Heinemann ft note 57).

In contrast, the US Environmental Protection Agency (EPA) recently concluded a large-scale evaluation of dsRNA-based pesticide products and whether or not existing risk assessment frameworks were sufficient to evaluate them for safety. The answer, succinctly, was 'no'.

The EPA evaluation involved a standing group of scientists taking both written and oral submissions from scientists and other interested persons from around the world. "Overall, the Panel agreed with the concerns raised by the EPA regarding the inadequacies of the current environmental fate and non-target effects testing frameworks for dsRNA PIPs [plant incorporated protectant] and exogenously applied dsRNA products ---". (see endnote (b)33).

What is illustrated here briefly is that a new kind of pesticide product based on the active ingredient of dsRNA is the subject of both scientific uncertainty and regulatory uncertainty. As a pesticide, it clearly has the power to cause adverse ecological effects. As a contaminant in food or feed, the effects are uncertain. Taken together, the example illustrates a situation of scientific complexity, uncertainty or ignorance, the key trigger in Europe for invoking the precautionary principle.

**vi. High Court Decision, New Zealand<sup>73</sup>** : the recent High Court decision in New Zealand demonstrates, countries or companies may unilaterally decide that a product is not genetically modified. In doing so, notification to importing countries would then no longer be required (CBD). By rejecting the New Zealand Environmental Protection Authorities determination that plants created by some new forms of genome editing **were not genetically modified**, the COURT EFFECTIVELY ENFORCED THE PRECAUTIONARY PRINCIPLE BOTH DOMESTICALLY AND FOR OTHER COUNTRIES.

<sup>72</sup> Heineman et al: "A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessment"

<sup>73</sup> High court NZ: CIV 2013-485-877 [2014] NZHC 1067: The sustainability council of NZ Trust vs The environmental Protection Agency (may 2014)

**vii. Dose (ref. HT crops):** Several scientists among them Carrasco, Seralini and Vandenberg state, (based on their findings of glyphosate and other chemicals), that toxic effects are not dose-related; specifically, “a safe dose determined from high doses does not guarantee safety at lower, untested doses that may be closer to current human exposures”, (Vandenberg: xlv). In other words, there is no linear relationship between chemicals and their effects, especially in endocrine disrupters and bioaccumulation in cells, and glyphosate falls into this category. Carson (Rachael) similarly argued, that many decades ago that the human body was “permeable” -- levels of exposure could not be controlled and scientists could not accurately predict the long term effects of bioaccumulation in the cells or the impact of a mixture of chemicals on human health. She categorically rejected the notion proposed by Industry that there were human “thresholds” for such poisons, as well as its corollary that the human body had “assimilative capacities” that rendered the poisons harmless (Linda Lear on Carson). Laura Vandenberg states:

*“a safe dose determined from high doses does not guarantee safety at lower, untested doses that may be closer to current human exposures”, (Vandenberg: xlv). In other words, there is no linear relationship between chemicals and their effects, especially in endocrine disrupters and bioaccumulation in cells, and glyphosate falls into this category.*

*“Although scientific inquiry is a dynamic give-and-take among researchers with different opinions and viewpoints, the so-called controversies surrounding low-dose effects and NMDR (Nonmonotonic Dose Responses) curves should be put to rest, given that they now affect public health decisions... These phenomena have been demonstrated time and again for a sufficient number of endocrine-related endpoints, and they no longer merit being considered ‘controversial’ topics.”*

**viii. Accelerating evidence of health hazards of GMOs:** In February-March 2015 there have been a series of peer reviewed studies demonstrating serious harm to health. Three of these concern Monsanto’s Roundup, the ubiquitous weed-killer on the planet. The huge concerns of over a decade, linking roundup formulations and glyphosate in epidemiological studies with cancers, and birth defects (teratogenic effects and endocrine disruption) in Argentina, are underpinned by at least two of these studies. They raise a red flag on the use of HT crops.

- **WHO (IARC):** 20 March 2015: (see Epidemiology – cancer IARC (WHO, pg 64): the ‘**International Agency for Research on Cancer (IARC)**’<sup>74</sup> finds evidence that Monsanto’s Glyphosate may cause non-Hodgkin Lymphoma – “Evaluation of five organophosphate insecticides and herbicides,” the herbicide glyphosate (the major component in Monsanto’s Roundup) “has been classified as probably carcinogenic to humans.”
- **Heinemann et al: 24 March 2015**<sup>75</sup>: ‘Exposure to Herbicides can Cause Change in Bacterial Response to Antibiotics’: Sub-lethal exposure to the herbicides dicamba, 2,4-D and glyphosate (the world’s most-used herbicide) can induce a multiple-antibiotic resistance phenotype in potential pathogens (can cause bacteria to change their response to clinically-relevant antibiotics). The effect occurs upon simultaneous exposure to antibiotics and is faster than the lethal effect of antibiotics. But the researchers also saw increased susceptibility or no effect.

The magnitude of the induced response may undermine antibiotic therapy and substantially increase the probability of spontaneous mutation to higher levels of resistance. The combination of high use of both herbicides and antibiotics in proximity to farm animals and important insects, such as honeybees, might also compromise their therapeutic effects and drive greater use of antibiotics. To address the crisis of antibiotic resistance requires broadening our view of environmental contributors to the evolution of resistance.

<sup>74</sup> IARC: <http://uk.businessinsider.com/r-monsanto-weed-killer-can-probably-cause-cancer-world-health-organization-2015-3?r=US>  
<http://www.bloomberg.com/news/articles/2015-03-20/who-classifies-monsanto-s-glyphosate-as-probably-carcinogenic->

<sup>75</sup> Heinemann et al: <http://mbio.asm.org/content/6/2/e00009-15>

- **Roundup is an endocrine disruptor** in human cells at levels allowed in drinking water<sup>76</sup> 10 Feb. 2015.  
The TEC recommends a ban on HT crops. The evidence shuts the door for their use. It would be difficult to argue that greater harm will accrue if they are not used.

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## E. Are GMOs a needed part of the solution to feed India and the world and in sustainable agricultural solutions?

*“The essential purpose of food, which is to nourish people, has been subordinated to the economic aims of a handful of multinational corporations that monopolize all aspects of food production, from seeds to major distribution chains, and they have been the prime beneficiaries of the world crisis.”*

Miguel d’Escoto Brockman - President of the General Assembly of the United Nations (2008)<sup>77</sup>

*“Agroecology mimics nature not industrial processes. It replaces the external inputs like fertilizer with knowledge of how a combination of plants, trees and animals can enhance productivity of the land. Yields went up 214% in 44 projects in 20 countries in sub-Saharan Africa using agroecological farming techniques over a period of 3 to 10 years... far more than any GM crop has ever done.”*

Olivier De Schutter, UN Special Rapporteur: Right to Food

The Government of India through the Ministry of Agriculture (MoA) has formally stated its commitment to GM crops in an Affidavit in the SC in 2012, that *“GM Crops are needed to meet India’s food security”*. Given the proven serious conflict of interest in our Regulators, public sector institutions of agriculture, and the DBT (Department of Biotechnology) of the Ministry of Science and Technology (MoS&T) this statement is unsurprising, but nevertheless flags the mindset that is able to completely discount the sheer weight of evidence against Bt and HT crops, (neither of which are engineered for yield gain as a trait), and which represent 99% of current commercialised GM crops planted worldwide (ISAAA). This raises justified alarm at the dim prospect emanating from the government for corrective national policy. The empirical evidence of crop data on yield drag, resistant pests, super weeds, increased herbicide and pesticide use, (26 percent more chemicals per acre were used on GE crops than on non-GE crops in the US - USDA data<sup>78</sup>), rising seed and farmer costs and greater use of fertilisers is clear. The US Department of Agriculture’s Review of 10 years of GM crop cultivation in the States, which has the longest history of GM crops, has concluded:

*“Currently available GM crops do not increase the yield potential... In fact, yield may even decrease if the varieties used to carry the herbicide tolerant or insect-resistant genes are not the highest yielding cultivars... Perhaps the biggest issue raised by these results is how to explain the rapid adoption of GE crops when farm financial impacts appear to be mixed or even negative.”* USDA

In India, Monsanto owns 95% of cotton seeds (all of it hybrid Bt) also signifying the decrease in seed diversity. Official data from DES shows that yield has stagnated, but insecticide and fertiliser use, and seed costs have all risen during the Bt cotton era, not come down (see D IV. Bt cotton performance in India).

Monsanto, DuPont, and Syngenta—now control 53 percent of the global commercial seed market. 86% of corn, 88% of cotton, and 93% of soybeans farmed in the U.S. are now genetically-engineered (GE) varieties, making the option of farming non-GE crops increasingly difficult (Centre for Food Safety CFS) Report 2013<sup>79</sup>). Data from the

<sup>76</sup> Fiona Young et al: ‘Endocrine disruption and cytotoxicity of glyphosate and roundup in human Jar cells in vitro’. Depart.of Medical biotechnology, South Australia.

<http://us6.campaign-archive1.com/?u=29cbc7e6c21e0a8fd2a82aeb8&id=bea73886eb&e=bee205d870>

<sup>77</sup> [http://www.un.org/millenniumgoals/2008highlevel/scanning/MDG\\_pga63\\_en.pdf](http://www.un.org/millenniumgoals/2008highlevel/scanning/MDG_pga63_en.pdf);

Benbrook Charles: The First Sixteen Years: Environmental Sciences Europe, 2012.

<sup>78</sup> Seed Giants vs US farmers 2013 (see footnote 62)

<sup>79</sup> Seed Giants vs US farmers:

<http://salsa3.salsalabs.com/dia/track.jsp?v=2&c=hg1TzbrVrst9uR9KhZ4m4UyW%2BtxYPUJk>

US corn belt state of Illinois suggest that it has become harder for farmers to obtain high-quality non-GM varieties of corn seed (Gray 2010<sup>80</sup>), with 40% saying they could not find such varieties. On the other hand, comparisons between European countries that do not grow GM crops, and with less penetration and control from GM seed companies, have higher genetic diversity as measured by numbers of crop varieties (Hilbeck et al. 2013)<sup>81</sup>. Genetic diversity is critically important for continuing improvement of crops and to respond to climate change of new crop pests. Reports by crop geneticists and breeders also point to decreasing genetic diversity of crops in the US where genetic engineering and transnational corporate control is dominant (S&B, 2014)<sup>82</sup> The advent of GM crops has become the gateway to controlling seed germplasm, and this is threatening the genetic diversity of crops.

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**Failed Promises:** Claims that genetic engineering produce new and desirable traits, and do so more quickly than conventional breeding, are false. In the 1970s and 1980s the promise was that genetic engineering (GE) would increase nitrogen fixation in plants. More than 30 years of research later, no genetic engineer makes this claim anymore. The science journal *Nature* (Sept. 2014<sup>83</sup>) has reported that CONVENTIONAL BREEDING SUBSTANTIALLY OUT-PERFORMS GENETIC ENGINEERING FOR SEVERAL VERY IMPORTANT TRAITS -- drought tolerance and the ability to increase nitrogen fixation in plants more efficiently. It points out: “*Transgenic techniques, which target one gene at a time, have not been as quick [as conventional breeding] to manipulate [drought tolerance].*” Conventional seeds have been shown to improve yields by as much as 30 percent as compared to Monsanto’s drought tolerant seeds, which provide only about 5 or 6 percent yield increase<sup>84</sup> in the U.S., and only under moderate drought conditions. When considering the geographic limits where this trait may be applicable in the US, according to USDA, the net yield benefit in a typical year would be only about 1 percent (High and Dry, (ref footnote 5).

As with drought tolerance, conventional breeding is making inroads with nitrogen use efficiency (NUE)—21 varieties with improvements of about 1 tonne per hectare in trials (in much of Sub Saharan Africa, this would amount to about 20 to 50 percent yield increase or more), with GE traits “at least 10 years away,” says *Nature*. In developed countries, improved NUE is important because inefficient fertilizer use is the main culprit in over 400 coastal dead zones (EPA xlvi), where it is harming fisheries. It is also the main contributor of the potent global warming gas, nitrous oxide, but there are no successful GM NUE traits in developed countries or anywhere else, despite at least 15 years of research efforts. (Source document: Gurian-Sherman<sup>85</sup>).

*‘Failure to Yield’* (Gurian-Sherman) considered the technology’s potential role in increasing food production, based on peer-reviewed scientific research literature, in addition to evaluating genetic engineering’s potential over the next few decades. The report does not discount the possibility of genetic engineering eventually contributing to increase crop yields. It does, however, suggest that it MAKES LITTLE SENSE TO SUPPORT GENETIC ENGINEERING AT THE EXPENSE OF TECHNOLOGIES THAT HAVE PROVEN TO SUBSTANTIALLY INCREASE YIELDS, ESPECIALLY IN MANY DEVELOPING COUNTRIES. THE REPORT FOUND YIELD INCREASES CONTRIBUTED BY BT CORN IN THE US TO BE MUCH LOWER THAN YIELD INCREASES BASED ON BREEDING OR OTHER METHODS. Most research on GM crops in developed countries agrees that the yield contribution of these crops is small. This work shows that when GM is compared to other agricultural technologies, as occurs in developed countries, those other technologies and methods are greatly

<sup>80</sup> Gray M (2010): [ubs.acs.org/doi/abs/10.1021/jf102673s](https://doi.org/10.1021/jf102673s): Relevance of Traditional Integrated Pest Management (IPM) Strategies for Commercial Corn Producers in a Transgenic Agroecosystem: A Bygone Era? *J. Ag Food Chem*

<sup>81</sup> Hilbek (2013): ‘proceedings of the 2014 summit on seeds and breeds for 21st century agriculture: Washington, DC March 5-7, 2014. Edited by Bill Tracy and Michael Sligh. <http://rafiusa.org/docs/2014SummitProceedings.pdf>

<sup>82</sup> **Seeds & Breeds:** proceedings of the 2014 summit on seeds and breeds for 21st century agriculture, Washington, DC, March 5-7, 2014. Edited by Bill Tracy and Michael Sligh. <http://rafiusa.org/docs/2014SummitProceedings.pdf>

<sup>83</sup> **Nature:** [http://www.nature.com/news/cross-bred-crops-get-fit-faster-1.15940?WT.ec\\_id=NATURE-20140918](http://www.nature.com/news/cross-bred-crops-get-fit-faster-1.15940?WT.ec_id=NATURE-20140918)

<sup>84</sup> [http://www.ucsusa.org/sites/default/files/legacy/assets/documents/food\\_and\\_agriculture/high-and-dry-report.pdf](http://www.ucsusa.org/sites/default/files/legacy/assets/documents/food_and_agriculture/high-and-dry-report.pdf)

<sup>85</sup> **Gurian-Sherman:** Plant Breeding vs. GMOs: Conventional Methods Lead the Way in Responding to Climate Change

superior. This raises questions about why developing countries like India would choose to import or develop GM rather than those other methods. In addition, recent studies have shown that organic and similar farming methods that minimize the use of pesticides and synthetic fertilisers can more than double crop yields at little cost to poor farmers in such developing regions as Sub-Saharan Africa. “Traditional breeding outperforms genetic engineering hands down.” (Gurian-Sherman).

Goodman<sup>86</sup> estimates that conventional breeding typically costs about a million dollars per trait, compared to hundreds of millions for genetic engineering. An industry-supported report puts the average cost at \$136 million per GE trait, with the large majority of the cost going to research and development and the like, not regulatory expenses. (Source document: Gurian-Sherman<sup>87</sup> (xlvii). Neither is genetic engineering quicker at delivering traits than conventional breeding. Even Monsanto does not believe this. Dr Robert Reiter, a molecular biologist and VP Biotechnology at Monsanto said in New Zealand (Heinemann: Hope not Hype) that: “Conventional crop breeding requires a 7 – 8 year cycle, compared to 10 – 15 years from inception to development for genetically modified crops...”. “It’s significantly cheaper and with a different regulatory requirement, and let’s face it, a different public perception,” (Stark – Monsanto); “Genetic transformation can only be used to introduce one segment of novel genetic material to a variety at a time, but biotech tools can be used to enhance a host of existing traits. It’s a numbers game and ultimately non-transformation [ie non-GM] biotech offers the greatest potential.” (Farmers Weekly, quoting Monsanto’s global head of plant breeding).

**Consensus of opinion by International Agencies & The IAASTD Report:** the UN, FAO, WWI (World Watch Institute), the UNCTAD etc, state that the solution to food and nutritional security is through agro-ecological sustainable models of agriculture, and confirm the findings of the **IAASTD Report**, (The International Assessment of Agricultural Knowledge, Science and Technology for Development, 2008). The IAASTD, to which INDIA is a signatory, is 4 year study commissioned by the UN and the World Bank, by over 400 scientists, and is agriculture’s equivalent to the IPCC Report on Climate Change. It came to the conclusion that agricultural goals are not well served through the western innovation model. It delivers the message that simple solutions for complex problems - as they are being proposed with GMOs as the solutions to production problems of today and climate change impacts of tomorrow - are not credible (H Herren, Co-chair of the IAASTD<sup>88</sup>). The IAASTD makes it clear that the road map for agriculture for the **next 50 years** must be through localised solutions, combining scientific research with traditional knowledge in partnership with farmers and consumers. The Report calls for a systematic redirection of investment, funding, research and policy focus toward these alternative technologies, infrastructure like roads and food storage, and the needs of small-farmers. Food security will follow not only from producing more food, but how we produce and consume it (IAASTD, 2009c).

**Genetically modified crops and agroecological methods** are two examples of innovation outputs and strategies that have very different outcomes in the way we produced food (Heinemann<sup>89</sup>.) The former is driven by production goals and short-term profit maximisation incentives. GM crops developed thus far are economically profitable within a system of high-input industrialised monoculture that is largely unsustainable in its reliance on external, non-renewable inputs. In such systems, economies of scale allow the farmer to outweigh the higher costs of production of such farming practices. Industrial agricultural practices on average require 10 calories of exogenous energy for every 1 calorie of food produced (Giampietro, 1993; UNEP, 2011). (Heinemann)<sup>90</sup>

The highest yielding varieties of GM crops are so because of ongoing and intensive genotype improvement through traditional breeding, rather than through the development of genetically engineered traits (Gurian-Sherman, 2009). Even in the most mature GM agroecosystems, such as cotton plantations in the US south, GM-farmers have not enjoyed a net economic benefit for adopting these plants compared to other high yield varieties (Jost, 2008). The high rent of patent-protected seeds is an upfront cost to farmers who may not realise a benefit from the trait each

<sup>86</sup> **Major Goodman:** North Carolina State University, corn geneticist and member of the National Academy of Sciences: [www.ncsu.edu/experts/search/expertise/Genetics](http://www.ncsu.edu/experts/search/expertise/Genetics)

<sup>87</sup> **Gurian-Sherman:** Plant Breeding vs. GMOs: Conventional Methods Lead the Way in Responding to Climate Change: [https://www.google.co.in/search?sourceid=navclient&ie=UTF-8&rlz=1T4GGLD\\_enIN317&q=Plant+Breeding+vs.+GMOs%3a+Conventional+Methods+Lead+the+Way+in+Responding+to+Climate+Change](https://www.google.co.in/search?sourceid=navclient&ie=UTF-8&rlz=1T4GGLD_enIN317&q=Plant+Breeding+vs.+GMOs%3a+Conventional+Methods+Lead+the+Way+in+Responding+to+Climate+Change) <sup>88</sup> Hans Herren: recipient of the World food Prize

<sup>89</sup> Heinemann: ‘Hungry for innovation: pathways from GM crops to agroecology’ <http://www.eea.europa.eu/publications/late-lessons-2> (Chapter 19).

<sup>90</sup> Heinemann: <http://www.eea.europa.eu/publications/late-lessons-2> (Chapter 19).

year, or would have to purchase other inputs, such as expensive agrochemicals, to gain any benefit. Here again, especially for poor farmers, those initial costs can be too high (Delmer, 2005). (463).

**Area planed to GM crops:** Despite more than 30 years of research and development and nearly 20 years of commercialisation of GM crops, surprisingly only two traits have been significant in the marketplace — herbicide tolerance and insecticide production. And they are grown at scale only in a small number of countries. Industry-derived figures (James, 2011) report a large number of global hectares under GM cultivation, but when examined by country indicate an uneven global commitment to GM crops. The five countries **USA, Brazil, Argentina, India and Canada** account for **91 %** of the global GM crop production, with the next five largest GM-cultivating countries accounting for another 8 %, leaving a total of 1 % of all GM acreage produced annually among just seven other countries. These figures correspond to just 3 % of the world's agricultural land (Heinemann – see note 69).

**Subsidies on GM crops:** they commonly benefit from subsidies, such as maize, soy and cotton in the US (Pechlaner, 2010). These subsidies in developed countries undermine the market for these crops in developing countries. 'The average support to agricultural producers in the major developed countries as percentage of gross value of farm receipts was at 30 % for the period 2003–2005, representing an amount of almost USD 1 billion per day (OECD, 2006). These developed-country agricultural policies cost developing countries about USD 17 BILLION PER YEAR — A COST EQUIVALENT TO FIVE TIMES THE RECENT LEVELS OF ODA [OFFICIAL DEVELOPMENT ASSISTANCE] TO AGRICULTURE' (Hoffman).

**IP:** Leading international institutions have dismissed prevailing IP instruments as agents of constructive economic or food security change in developing countries at least at their stage of development (WHO, 2005; WorldBank, 2007). The patenting of germplasm is concentrating IP rights-based control of the seed supply under a very small number of multinational corporations. For example, the UK Parliament says that: 'The use of patents on genes is controversial. There are concerns that in countries where GM technology is widespread in agriculture, seed companies may have reduced incentives to develop conventional varieties, as the market for these varieties is reduced, and they tend to have weaker IP rights than the patents usually used with GM crops. The presence of patents may also limit public-sector research in some areas' (POST, 2011). ( pg 472)

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**The evidence for agroecological farming:** The focus on farmers is a viable alternative and moral imperative to the focus on genotypes. As the UN FAO have argued, '75 % of the additional food we need over the next decades could be met by bringing the production levels of the world's low-yield farmers up to 80 % of what high-yield farmers get from comparable land' (Molden, 2007). This suggests that the future of sustainable, low impact agriculture is one in which products and methods are developed at landscape rather than global or even national levels. In this way we agree that 'there is a need to invest in science and practice which gives farmers a combination of the best possible seeds and breeds and their management in local ecological contexts' (Pretty, 2011).

*The focus on farmers is a viable alternative and moral imperative to the focus on genotypes... In this way we agree that 'there is a need to invest in science and practice which gives farmers a combination of the best possible seeds and breeds and their management in local ecological contexts' (Pretty, 2011).*

- International projects to initiate organic and sustainable agriculture have shown excellent overall results. UNEP-UNCTAD reported an average crop yield increase of 116% for organic and near organic projects involving more than 1.9 million African farmers on roughly 2 million hectares of cultivated land within the 114 cases analysed. The benefits were not just in yield — improvements in natural, social and economic capital associated within these farming systems led to an array of benefits that have increased food security.
- Another synthesis study investigated the increases in productivity since the implementation of 286 sustainable

agriculture initiatives from the FAO, which covered 37 million hectares in 57 countries (Pretty, 2008). They found increased productivity on 12.6 million farms with an average crop increase of 79 %, and a rise in key environmental services.

- The most comprehensive meta-analysis to date comparing organic productivity with the most productive industrial farming methods, and using improved statistical analysis, found that contrary to previous work which claimed that organic had 20 to 30 percent lower productivity, ecologically-based organic methods had only slightly lower yields (8 to 9 percent) (L.C. Ponisio et al. 2014(xlviii). The authors noted that it is remarkable that organic methods produce only slightly less than industrial methods given that overwhelmingly greater research funding of industrial methods for many decades. Those that believe that science can make a difference in farming productivity should note that with comparable research funding, it would be unlikely that organic would not be as or more productive than industrial farming.

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Long-term farm scale research at one of the premiere agricultural universities in the US has found that farming based on ecological methods, using minimal amounts of herbicides and fertilizers and not using GM crop varieties, is more productive than industrial and more profitable than methods using GM varieties by 12 to 14 percent (Davis et al., Gomes et al.) (xlix)

## **SUMMATION: Are GM crops a needed part of the solution to feed the world**

- The IAASTD is the equivalent in agriculture of what the IPCC is to Cc (Climate Change), and was sponsored by the World Bank and several UN agencies, and endorsed by over 50 countries. As with the IPCC, it was an international, multi-year effort that involved about 400 scientists and other scholars. Human intervention in climate change is not now seriously questioned. Neither should the IAASTD report, a roadmap for agriculture for the next 50 years, which sets out the choices which require to be made by nations such as India for food security. GMOs are not one of them. Every UN Agency since the IAASTD report was published (in 2008), has affirmed its conclusions. It has also done so through the results of its several projects, (as above). India is a signatory to the IAASTD. But the IAASTD roadmap doesn't get a mention in the government's agriculture road-map and budget or the SC.
- Research on many major crops over the past 20 years such as wheat and its relatives has shown that current widely grown crop varieties use only a small fraction of available genetic potential. The so-called "yield plateau" of the last several decades in some crops is more likely due to complacency and reduced funding after the green revolution. We have not scratched the surface of the genetic potential of crop species.
- While breeding continues to meet important challenges for traits like improving drought tolerance, improving nitrogen fertiliser efficiency, or increasing yield, genetic engineering has contributed little or nothing. And in recent years there has been significant development through conventional breeding of many drought tolerant varieties of corn, cassava, rice, wheat, millet, and sorghum.
- A massive comparative study of the North American (especially GM crops) and Western European (no GM crops) agriculture systems that covered over **50 years of data (I)** found that Western Europe without GM was both out-producing North America in absolute terms and in the ability to increase yield per year, while significantly reducing pesticide use compared to North America (Heinemann et al 2014<sup>91</sup>) The best yielding and most-affordable crops to feed the world are Non-GMO crops in small-holder agri-ecological farming systems (UN/FAO/IAASTD<sup>92</sup>)i.

*Human intervention in climate change is not now seriously questioned. Neither should the IAASTD report, a roadmap for agriculture for the next 50 years, which sets out the choices which require to be made by nations such as India for food security. GMOs are not one of them. Every UN Agency since the IAASTD report was published (in 2008), has affirmed its conclusions.*

<sup>91</sup> **Heinemann et al:** <http://www.tandfonline.com/doi/full/10.1080/U4embBYxHFI>

<sup>92</sup> **IAASTD:** The international Assessment of Agricultural Knowledge Science & Technology for Development

- Rotations, largely abandoned by industrial agriculture, typically increase yields by 20 or 30 percent. Water holding capacity of soil can be improved, and susceptibility to drought lessened, by planting cover crops that increase soil organic matter. Such methods can greatly reduce water pollution from nitrogen and the need for pesticides.
- Given India's agrarian structure and smallholder farming, GM crops, which promote monoculture, will drive millions off the land in a massive rural exodus into urban shanty towns with disastrous public health consequences. (For more references on the value of small farms: (Iii)). This has been the pattern in Argentina (Iiii) with the GM 'soyaisation' of the economy.
- Food security also means 'safe' food which, on present indications of Bt and HT technology, genetic engineering is unable to ensure and deliver. Since 'co-existence' is impossible, what this means is that GMO contamination of India's foundational seed stock will change the molecular structure of our food for all time (Schubert). Any toxicity from GMOs will be retained and will render our food poisonous without the possibility of remediation. Change at the molecular level also excludes the possibility of labelling for GMO content. Therefore, epidemiological studies will be impossible. The long-term impact on the health of the nation in the form of allergies and potential cancers as an on-going possibility is a nightmare scenario.

## Conclusions

Prescriptive action requires knowledge of the facts surrounding a technology, and also the politics. It further demands foresight and consideration of potential harm and uncertainty. 20 years into the commercialisation of GMOs and their open field trials, a clear picture has emerged and it's not pretty.

GMO were approved fraudulently in the face of scientific warnings: the warnings about GMOs were clear warnings right from the start, always 'current', not merely 'early' warnings. These early warnings have been confirmed and reinforced through independent studies; this despite great difficulties faced by scientists, which include 'persecution', and sackings, nothing short. This is the collective evidence over 20 years of commercialised GM crops and their numerous 'events' released in open field trials. The systematic cover-up of safety concerns in conjunction with regulators in a number of countries includes the US first and foremost, the EU, Argentina, Bangladesh and India among others.

And the historical evidence of 100 years of hazardous technologies also demonstrates that GMOs are uniquely differentiated in key aspects. This is one aspect that distinguishes GMO technology from other hazardous technologies like CFCs and DDT for example. Both were initially seen as almost magical in their effectiveness and benefits for the human race. The 'malevolence' of their impacts was revealed later. The distinction is important because in the case of GMOs, the 'malevolence' was acknowledged by scientists from the start. The so called 'magic' of this technology promoted as a technocratic fix for every agricultural malady was concocted in a series of self-reinforcing 'myths' that have unravelled. Furthermore, 'TIMELINESS' of preventive action is a criticality we face globally as well as in each country, and no parallels come to mind in the history of technologies that can be cited to match this specific concern with GMOs, as we wrestle with the problem of certain irreversible GMO CONTAMINATION of our genetic diversity in seeds and food if they are deployed. Therefore, the need is for collective precautionary action NOW because of their potential for global/widespread ecological disruption and impact on animal and human health.

Seed treatment required for Bt cotton and other GM crops also disproves the claim that the GM crops reduce the pesticide load in agriculture. Increases in seed treatments despite Bt is, in part, because genetically modified crops have become part of, and have facilitated, our current unsustainable industrial agriculture system that aggravates pest problems. The further lesson to be learned is that seed treatment has also led to a fall out of enormous magnitude, the significant and dangerous decline in honey bees (and pollinators) because of CCD. Are we to call a disaster of this magnitude collateral damage?

The problems of GE remain:

- GMO contamination is certain with a commercialised crop and is irreversible. Therefore, co-existence between GM and Non-GM crops is not possible. On its own, this effectively eliminates GMOs from being a solution for food security and of course safe food.
- The high economic concentration of the seed industry, facilitated by gene patents
- current uses of the technology also seem to encourage the expansion of industrial monoculture farming, with all its problems -- and most of the pipeline for GMOs is more of the same—herbicide resistant and Bt crops that will exacerbate pesticide use. The Bt cotton experience in India is proving this true.
- The health and environmental safety issues are not subsiding. They are increasing.

Pointedly, GE is not NEEDED. It does not offer solutions for food security, food sovereignty, reduction of scarce-resource-use, or reduction of pollution from agriculture (climate change and dead zones). But agroecology, breeding and smallholder farming are meeting these challenges and will increase their potential to do so with the right investments and incentives. But, GE is cornering scarce resources, which are finite. Money invested in GE is an ‘opportunity cost’ lost to agroecology and breeding.

Meanwhile, Non-GE methods and plant breeding, including newer methods, continue to outperform genetic engineering in all regions, at much less cost per trait, but goes begging for funding at our universities. Based on these data, GM crops are therefore, irrelevant to rural households and national food security. However, they would contribute in significant measure to unsafe food and India’s food insecurity, health and development. *“A recent incident clearly shows how the GMO Industry is manipulating science to eliminate all negative information, this time jeopardising our ability to assess the safety of our global food supply”*<sup>93</sup>. (Schubert: (liv)).

***Pointedly, GE is not NEEDED... Non-GE methods and plant breeding, including newer methods, continue to outperform genetic engineering in all regions, at much less cost per trait, but goes begging for funding at our universities. Based on these data, GM crops are therefore, irrelevant to rural households and national food security. However, they would contribute in significant measure to unsafe food and India’s food insecurity, health and development.***

It is falsely argued that in the US two decades of GM food (mainly produced for biofuel or animal feeds composed of corn, soy and cotton), have not resulted in any health problems. Foods are not labelled for GM content in the US. In the absence of labelling even if any GE food did cause an illness, it would not be detected because of the lack of epidemiological studies and even then, there would be no way to associate the disease directly with a Bt/Ht crop. Many environmentally-linked diseases take many decades of exposure to develop symptoms (lv). This is the kind of light-weight argument proffered by our Regulators to justify the safety of GM foods.

Despite the serious evidence of harm from the very few long term studies that have been conducted, Regulators everywhere have studiously ignored the absolute need for these studies, which are vital to reveal long term toxicity and cancers that are not apparent in short 90-day feeding studies. The recent IRAC (of the WHO) conclusion that Glyphosate is a ‘probable human carcinogenic’ must set the seal on business as usual with regard to GMO risk assessment to include endocrine disruption, and GMO technology that slips under the radar of risk assessment like ds RNA. The IRAC findings implicate the US EPA; and reinforce the accusation that Monsanto has known since the 80s that Glyphosate causes cancer or is an endocrine disruptor.

On the other hand, Monsanto’s dark history of crimes against humanity is all of a pattern with cover-up and fraud in order to profiteer at the expense of society. Monsanto knowingly poisoned the water supply of Anniston with PCBs because it was unwilling to forgo \$’1 worth of business to keep the township’s water-supply safe from contamination. It was convicted.

<sup>93</sup>This is a reference to the Serallni study originally published in Food and Chemical Toxicology (FCT) in September 2012. It was controversially withdrawn when Monsanto intervened with the editorial board before the retraction by FCT. A former Monsanto scientist, Dr. Richard Goodman, was brought into the journal as biotechnology editor.

Why on earth would Monsanto then disclose harm from its GMO products revealed in its self-assessed dossiers? Is it expected to disclose that its products are harmful? IT DOES NOT. Bt brinjal and Mon 863 among other examples of self-assessed dossiers, prove that Monsanto is at least predictably characteristic.

### **The more important Q of government is:**

Why is there this astonishing expectation from Regulators and the Indian Regulators in particular along with the political establishment that Monsanto will tell the truth? Self-assessment also indicates the acceptance of conflict of interest in the regulatory process. That of course is unacceptable.

### **The action & the caution**

- We arguably, are faced with the most serious scientific fraud in the history of science and hazardous technologies. The multi-dimensional impacts of GMOs are staggering and they are global. These translate into a biosecurity threat of global proportions, a threat by *“Monsanto and chemical companies, who continue to destroy the biosphere”* (Samsel A).
- Therefore, the Precautionary Principle requires to be interpreted critically and pre-emptively for its proper application to the unique risks of GM crops. It must prevail at the level of every NATION and GLOBALLY ranging from national bans to a global moratorium on GM crops. With CFCs and in part, DDT the Precautionary Principle required a ban.
- For India, it is required, based on the collective evidence, that the 5-Member TEC Report is fully implemented with its specified prohibitions along with an indefinite moratorium on GMO open field trials and on Bt crops specifically. The PP is required to be applied at this raised level of specified bans on pesticidal crops and crops of origin; and critically, to be implemented now in a ‘timeliness’, before any other GM crop is commercialised.

“The prospect of domination of the nation’s scholars by Federal employment, project allocations, and the power of money is ever present — and is gravely to be regarded. Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific technological elite”. Dwight D Eisenhower: US President, 1961 (Wikisource, 2012).

**March - April 2015**

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