Section 5

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

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

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"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.

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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[36]. 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)[37] 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[38] 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[39] 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.[40]

[36] SC evidence 2008: This collaboration with the Agricultural University of Dharwad (Karnataka), added to the serious conflict of interest on Indian soil.
[37]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.
[38] 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):
[39] GRAS: Generally Recognised as Safe given to foods that have long histories of safe use like vinegar.
[40] 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)[41]. GMO Myths and Truths is a comprehensive compilation of evidence of harm from Bt and HT crops.[42] 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[43]. 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)[44]. 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 conditions. Moreover, since lysine is a limiting nutrient in nature, cultivation and distribution of this maize could

[41] 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.

[42] 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."

[43] 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

[44] 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".

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[45].

*AMPA has not been investigated by regulators for health-safety[46].

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.

[45] T Bohn et al:Compositional difference in soybeans on the market: Glyphosate accumulates in RR GM Soybeans Food Chemistry 153 (2014) 207–215
[46] 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).

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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 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).

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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).

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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[47]) (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% to100% of rainwater and air samples (Chang et al 2011)), some foodstuffs and drinking water in many regions around

[47] 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".

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).

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).

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[48] 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)[49]
- **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 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).

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.

[48] Roundup Ready, Monsanto herbicide (Glyphosate)

[49] MSS: Task Force: Application of Agricultural biotechnology: Chapter 11. http://agricoop.nic.in/TaskForce/chep11.htm).

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[50], 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[51] 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.

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

[50] Prof Walter Pengue, an expert in agriculture and rural sustainable development (University of Buenos Aires)

[51] 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)[52]. 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.

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.

- "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.

[52] 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[53]. 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)

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

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[54] 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[54] 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[55]. 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).[56] A review published in 2013 (Samsel and Seneff, 2013[57]) 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.

[53] 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.
[54] Dr. Andres Carrasco, an embryologist and the former Director of the Molecular Embryology Laboratory at the University of Buenos Aires
[55] 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.
[56] International journal of environmental research and public health, 11(4), 4449-4527: http://www.mdpi.com/1660-4601/11/4/4449/htm
[57] 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[58]). 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.*

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.

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.

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

[58] Lancet Oncol 2015; Published Online March 20, 2015 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[59] (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[60] 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).

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. Pusztai and S.Bardocz)

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

[59] 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'.

[60] 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[61] 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[62] (xxxiv). This likewise raises anxiety with regard to approx. 1200,000 tonnes (2011estimates) of unlabelled Bt cotton-seed oil, which has contaminated our food-chain.[63]

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).

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).

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).

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).

[61] 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. Sygenta Corporation covered-up dozens of livestock deaths from Bt 176 corn (an animal feed). India has no ability to test for the Bt toxin

[62] Prof. Arpad Pusztai on Bt brinjal: Wednesday, 27 January 2010 20:08

[63] 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".*[64]

[64] 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.[65] [7]. 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-Monsnto).
- **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[66] 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

[65] Kumar.V (2011). Navsari Agricultural University, Gujarat. Bt Cotton : A Gujarat experience & issues
[66] 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%[67] 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[68]. 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[69])
- **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.

[67] 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.

[68] Pusztai, Andow, Heinemann, Schubert, Seralini, Gurian-Sherman, Carman, Gallagher: 2009-2010

[69] 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 m2) 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 [70] (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)

[70] 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[71] 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).

[71] 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[72] 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[73] : 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.

[72] Heineman et al: "A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assesment"

[73] 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)**[74] 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**[75]: '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.

[74] 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-
[75] 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[76] 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)[77]

> *"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[78]), 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[79]). Data from the

[76] Fiona Young et al: 'Endocrine disruption and cytooxicity 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

[77] http://www.un.org/millenniumgoals/2008highlevel/scanning/MDG_pga63_en.pdf;
Benbrook Charles: The First Sixteen Years: Environmental Sciences Europe, 2012.

[78] Seed Giants vs US farmers 2013 (see footnote 62)

[79] 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[80]), 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)[81]. 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)[82] 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[83]) 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[84] 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[85]).

'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

[80] Gray M (2010): ubs.acs.org/doi/abs/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

[81] 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

[82] **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

[83] **Nature**: http://www.nature.com/news/cross-bred-crops-get-fit-faster-1.15940?WT.ec_id=NATURE-20140918

[84] **http://www.ucsusa.org/**sites/default/files/legacy/assets/documents/food_and_agriculture/high-and-dry-report.pdf

[85] **Gurian-Sherman**: Plant Breeding vs. GMOs: Conventional Methods Lead the Way in Responding to Climate Change

superior. This rasies 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[86] 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[87] (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[88]). 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[89].) 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)[90]

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

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

[87] **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 [88] Hans Herren: recipient of the World food Prize

[89] Heinemann: 'Hungry for innovation: pathways from GM crops to agroecology' http://www.eea.europa.eu/publications/late-lessons-2 (Chapter 19).

[90] 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[91]) 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[92])Ii.

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.

[91] **Heinemann et al**: http://www.tandfonline.com/doi/full/10.1080/.U4embBYxHFI
[92] **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.

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.

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"* [93]. (Schubert: (liv)).

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.

[93]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 it 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).

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