ISIS Report

GM Food Nightmare Unfolding in the Regulatory Sham

Mae-Wan Ho[1], **Joe Cummins**[1,2] and **Peter Saunders**[1,3]
[1]Institute of Science in Society, PO Box 51885, London NW2 9DH, UK, www.i-sis.org.uk
[2]Department of Biology, University of Western Ontario, Canada
[3]Department of Mathematics, King's College, London WC2R 2LC, UK

Abstract
Our regulators are ignoring the precautionary principle, manipulating and corrupting science, sidestepping the law, and helping to promote GMOs in the face of massive public opposition and damning evidence piling up against the safety of GM food and feed

1. GM nightmare unfolds

Female rats whose diets were supplemented with genetically modified (GM) Roundup Ready soybeans gave birth to many severely stunted pups, with over half of the litter dead by three weeks, and the surviving pups were sterile [1]. This is the first investigation on the effects of unprocessed GM feed on reproductive function, foetal, and postnatal development, in an experiment lasting more than 90 days, a period set as adequate for food safety studies by the European Food Standards Authority (EFSA) [2], and the GM soya has been commercialised worldwide for food and feed since 1996.

These findings came from the laboratory of senior scientist Irina Ermakova at the Institute of Higher Nervous Activity and Neurophysiology of the Russian Academy of Sciences in Moscow. The results have been published in Russian [3-5], and in several conference proceedings in English [6-9].

These results are not an isolated case. They top a growing stack of evidence from all over the world, indicating that GM food and feed may be inherently hazardous to health (see Box 1).

Box 1
Accumulating evidence on the health hazards of GM food and feed

1. Between 2005 and 2006, scientists at the Russian Academy of Sciences reported that female rats fed glyphosate-tolerant GM soybeans produced excessive numbers of severely stunted pups and more than half of the litter dying within three weeks, while the surviving pups were completely sterile (main article).
2. Between 2004 and 2005, hundreds of farm workers and cotton handlers in Madhya Pradesh, India, suffered allergy symptoms from exposure to Bt cotton containing Cry1Ac or both Cry1Ac and Cry1Ab proteins [10].
3. Between 2005 and 2006, thousands of sheep died after grazing on Bt cotton crop residues in four villages in the Warangal district of Andhra Pradesh in India [11]. More deaths in sheep and cattle grazing on Bt cotton crop residues have been reported in 2007 [12], over 200 animals in the Adilabad district of Andhra Pradesh alone, according to the local Animal Husbandry Department.
4. In 2005, scientists at the Commonwealth Scientific and Industrial Research Organization in Canberra Australia tested a transgenic pea containing a normally harmless protein in bean (alpha-amylase inhibitor 1), and found it caused inflammation in the lungs of mice and provoked sensitivities to other proteins in the diet [13, 14].
5. From 2002 to 2005, scientists at the Universities of Urbino, Perugia and Pavia in Italy published reports indicating that GM-soya fed to young mice affected cells in the pancreas, liver and testes [15-19].

6. In 2003, villagers in the south of the Philippines suffered mysterious illnesses when a Monsanto Bt maize hybrid containing Cry1Ab protein came into flower; antibodies to the Cry1Ab protein were found in the villagers, there have been at least five unexplained deaths and some remain ill to this day [20].
7. In 2004, Monsanto's secret research dossier showed that rats fed MON863 GM maize containing Cry3Bb protein developed serious kidney and blood abnormalities [21] (see main text).
8. Between 2001 and 2002, a dozen cows died in Hesse Germany after eating Syngenta GM maize Bt176 containing Cry1Ab/Cry1Ac plus glufosinate-tolerance; and more in the herd had to be slaughtered from illnesses [22].
9. In 1998, Arpad Pusztai and colleagues formerly of the Rowett Institute in Scotland reported damage in every organ system of young rats fed GM potatoes containing snowdrop lectin, including a stomach lining twice as thick as controls [23].
10. Also in 1998, scientists in Egypt found similar effects in the gut of mice fed Bt potato containing a Cry1A protein [24].
11. The US Food and Drug Administration had data dating back to early 1990s showing that rats fed GM tomatoes with antisense gene to delay ripening had developed small holes in their stomach [23].
12. In 2002, Aventis company (later Bayer Cropscience) submitted data to UK regulators showing that chickens fed glufosinate-tolerant GM maize Chardon LL were twice as likely to die compared with controls [25].

2. Genetic modification and/or the artificial transgenic DNA to blame?

Many varieties of GM crops with different transgenes, fed/exposed to rats, mice, cows, sheep, chickens, or human beings, resulted in illnesses and deaths. The obvious suspect is the GM process and/or the artificial transgenic DNA used.

It is important to note that transgenic DNAs are constructs entirely new to evolution. The synthetic genes are considerably altered from their natural counterparts, combining copies of sequences from many different sources.

For example, MON863 maize is described on the AGBIOS Database as follows [26]: "The introduced DNA contained the modified cry3Bb1 gene from *B. thuringiensis* subsp. *kumamotoensis* under the control of the 4-AS1 promoter (CaMV 35S promoter with 4 repeats of an activating sequence), plus the 5' untranslated leader sequence of the wheat chlorophyll a/b binding protein (wt CAB leader) and the rice actin intron. The transcription termination sequence was provided from the 3' untranslated region of the wheat 17.3 kD heat shock protein (*tahsp17*). The modified cry3Bb1 gene encodes a protein of 653 amino acids whose amino acid sequence differs from that of the wild-type protein by the addition of an alanine residue at position 2 and by seven amino acid changes." The coding sequence for cry3Bb1 was also modified with numerous codon adjustments to compensate for codon bias in plants as opposed to bacteria.

There are 9 bits of DNA from different sources including the coding sequence, which has been substantially altered from the natural gene. The many homologies to different genomes including those of bacteria and viruses, the presence of recombination (fragmentation) hotspots such as the CaMV 35S promoter, and the general structural instability of transgenic DNA, are all factors that would greatly enhance horizontal gene transfer and recombination, the main route to creating new pathogens.

We have spelt out the potential dangers of the GM process in numerous publications (see Box 2) based on extensive reviews of the scientific literature, highlighting the hidden dangers arising from unintended horizontal transfer of transgenic DNA [27-36].

Box 2

Potential Hazards of GMOs

- Synthetic genes and gene products new to evolution could may be toxic for humans and other animals or provoke serious immune reactions
- The uncontrollable, imprecise process involved in making GMOs mutate and scramble genomes, and may generate unintended toxic and immunogenic products, these problems are exacerbated by the instability of the transgenic DNA
- Endogenous viruses that cause diseases may be activated by the transgenic process
- The synthetic genes in GMOs, including copies of genes from bacteria and viruses that cause disease as well as antibiotic resistance genes, may be transferred to other species via pollen, or by direct integration into other genomes in horizontal gene transfer
- Genetic modification is nothing if not facilitated and greatly enhanced horizontal gene transfer and recombination, the main route to creating disease-causing viruses and bacteria
- Transgenic DNA is designed to invade genomes, including those of animals and human beings, and its strong synthetic promoters may trigger cancer by activating cellular oncogenes
- Herbicide tolerant GM crops accumulate herbicide and herbicide residues that may be highly toxic to humans and animals as well as plants

3. "GM food is safe"?

Regulators have been assuring the public that "GM food is safe" because people have been eating GM food since its first release in 1994 and no one has been found to fall ill or die from it. However, there has been no labelling in countries like the United States where GM food and feed are most available, and many GM products are 'de-regulated' and hence not known or traceable as such. There has been no post-release monitoring, although research at the Centers for Disease Control suggested that food-related illnesses went up 2 to 10 fold in 1999 compared with a survey done just before GM food was commercially released in 1994 [37, 38]. GM food and feed may be linked to chronic illnesses such as autoimmune disease from bacterial DNA or indeed any novel transgenic DNA [39-42], slow viruses or cancer (see Box 2), which may be difficult to detect. Finally, animal feed accounts for up to half the world's harvest [43], so most of the GM produce so far has probably gone in animal feed after being processed for seed oil, corn starch and syrup, and increasingly, ethanol and biodiesel [44, 45]. Processing will remove or destroy at least some of the toxic metabolites, proteins and transgenic DNA. Thus, GM produce is seldom eaten directly by either animals or human beings so far, except in Argentina, with dire consequences for health [46]. In Argentina, GM soya has been promoted as a staple food, especially for the poor, which has no precedent in the world, and it is impossible to separate effects due to soya *per se*, from those due to GM soya, and further, those due to the toxic herbicide Roundup (see later) sprayed from the air, dousing people and their homes.

GM food is still being sent to Africa as 'food aid' after widespread rejection and protest [47], putting millions of the most hungry and vulnerable people at risk from the health hazards of GMOs, and threatening to contaminate their food supply for years to come.

4. Evidence ignored and dismissed by regulators for decades

The list of evidence of GM hazards in Box 1 is by no means complete. In fact, evidence has been building up since the 1980s that should have halted the development or commercialisation of many, if not all GM crops [10], if the precautionary principle had been

applied. But our regulators were biased in favour of genetic modification from the first, and have systematically ignored and dismissed research findings that might harm the fledgling biotech industry [48]. We shall look at two examples, the immunogenicity and toxicity of Bt biopesticides and the horizontal transfer of transgenic DNA.

a. Immunogenicity and toxicity of Bt toxins

The Bt bacteria (*Bacillus thuriengensis*) and spores – the source of Cry proteins involved in many of the cases of fatalities and illnesses in Box 1 - were linked to allergic reactions [49] before the Cry proteins were widely incorporated into GM crops as 'biopesticide'. Bt crops were introduced first in the United States in 1996, and have expanded substantially in global area with little research on the toxicity or immunogenicity of the Cry proteins.

A research team in Cuba reported in 1999 that Cry1Ac is a powerful immunogen, and induced both systemic and mucosal antibody responses in mice similar to those obtained with the cholera toxin [50]. Contrary to the assumption that mammals do not have receptors for the protein, the team demonstrated that Cry1Ac binds to the inner surface of the mouse small intestine, especially to the brush border membranes, and induced a transient electrical hyper-polarization indicative of significant biological effect [51].

The synthetic transgenic Cry proteins may be worse than their natural counterparts. Green lacewings suffered significantly mortality and delayed development when fed an insect pest (lepidopteran) that had eaten GM maize containing transgenic Cry1Ab, but not when fed the same pest treated with much higher levels of the natural toxin [52, 53]. *All* Cry proteins in Bt crops have amino acid sequence similarities to known allergens [54-56], and are hence potential allergens until proven otherwise. Transgenic maize Cry1Ab survived digestion in pigs [57, 58], which would increase its immunogenic potential.

The immunogenic potential of all transgenic proteins is open to question since the demonstration that species-specific processing of proteins can turn a normally harmless bean protein into a powerful immunogenic when it was transferred to pea [13, 14]. The tests carried out to detect such reactions are still not required by regulatory agencies anywhere in the world.

b. Horizontal gene transfer happens

We have raised the issue of unintended horizontal transfer of transgenic DNA with our regulators repeatedly since the late 1990s [27, 59, 60] when they denied vehemently that it could happen, and assumed mistakenly that DNA would be rapidly broken down in all environments. We presented an extensive review in 1998 [31], documenting evidence that DNA persists in all environments and pointing out that transgenic DNA enhances and facilitates horizontal gene transfer for reasons stated above (Box 2). We called for a public enquiry, but to no avail.

In 1999-2000, we alerted our regulators to the hazards of the CaMV 35S promoter, which is in practically every commercial transgenic variety commercialised, calling for the GM crops to be withdrawn. The CaMV 35S promoter has a recombination (fragmentation) hotspot, which would enhance horizontal transfer of transgenic DNA and make transgenic DNA and transgenic lines unstable [32, 33]. Furthermore, contrary to the then common assumption that the promoter was only active in plants and plant-like organisms, it is in fact active in species across the living world, animal and human cells included [34], with the potential for activating dormant viruses and triggering cancer. Recently, the CaMV 35S promoter was demonstrated to be active in human enterocyte-like cells [61]. And evidence of transgenic instability has also emerged, with the CaMV 35S promoter representing a major breakpoint (see below).

By 1999, there was already evidence that horizontal transfer of transgenic DNA could occur, not only in the laboratory but also in the field [62]. Unfortunately, the researchers were far too cautious as scientists, and ended up *denying* the *prima facie* evidence that horizontal transfer of transgenic DNA had occurred [63], whereas a proper application of the precautionary principle would have made the researchers stress the possibility that it *had* occurred. It was a case of misplaced scientific caution displacing appropriate precaution necessary for protecting health and the environment.

Since then, evidence continued to accumulate [64]. Transfer of transgenic maize DNA antibiotic resistance marker could occur before the DNA was completely broken down, even when the breakdown was rapid, as in the sheep rumen or in silage. DNA breakdown was extremely slow in saliva, and hence the oral cavity would be a very important site for horizontal gene transfer [65].

High frequencies of horizontal transfer of transgenic plant DNA were demonstrated for soil bacteria, *Pseudomonas stutzeri* and *Acinetobacter* sp. when the transgenic plant DNA contained sequence homologies to the bacteria [66]. Again, the authors stressed that the transfer "strictly depends on homologous sequences", which could give the uninformed a false sense of assurance, forgetting that transgenic constructs often contain homologies to many different species of bacteria and viruses, and are therefore capable of engaging in high frequencies of horizontal gene transfer and recombination with all of them [64].

We have drawn attention to further evidence of the enhanced horizontal transfer of transgenic DNA in our submissions [67, 68] to the regulatory authorities in Hawaii objecting to an intended outdoor large-scale facility for transgenic strains of the alga, *Chlamydomonas reinhardtii* producing a range of pharmaceutical proteins. We pointed that DNA not only persists in all environments, but also that transformation by direct uptake of DNA is a major route of horizontal gene transfer among bacteria [69].

The close similarities (homologies) between the transformed plastid in transgenic *C. reinhardtii* and bacterial genomes is expected to greatly increase the frequency of horizontal gene transfer, by up to a billion-fold [70]; and furthermore, the horizontal transfer of non-homologous DNA occurs at relatively high frequencies when a homologous DNA 'anchor sequence' is present, which can be as short as 99bp. A review published in 2004 already listed at least 87 species of naturally transformable bacteria in the soil [71].

There is also evidence that transgenic DNA in food and feed may transfer into animal and human cells [72]. Several studies have documented the survival of DNA in food/feed throughout the intestinal tract in mice and pigs [57, 73, 74 and references therein], in the rumen of sheep [75], and in the rumen and duodenum of cattle [76], with varying degrees of sensitivities in PCR methods.

In the only feeding trial ever conducted in human volunteers [77], a single meal was taken containing GM soya with about 3×10^{12} copies of the soya genome. The complete 2 266 bp of the *epsps* transgene was recovered from the colostomy bag in six out of seven ileostomy subjects, though at highly variable levels, ranging from 10^{11} copies (3.7 %) in one subject to 105 copies in another. This is a strong indication that DNA is not rapidly broken down in the gastrointestinal tract, confirming earlier results from the same research group. In three of the seven ileostomy subjects, about 1 to 3 per million bacteria cultured from the contents of the colostomy bag were positive for the GM soya transgene, indicating that horizontal transfer of transgenic DNA had occurred, either before the single meal was taken, as claimed, or else as the result of the single GM soya meal, a possibility that cannot be ruled out [72]. Interestingly, no bacteria were found to have taken up non-transgenic soya DNA, which is consistent with our suggestion that transgenic DNA may be more successfully transferred for reasons given above.

No transgenic DNA was found in the faeces of any of 12 healthy volunteers tested. Either the remaining DNA has completely broken down by then as claimed by the researchers, *or else detectable fragments have all passed into the blood stream from the intestine* [72]. It is already known that food material can reach lymphocytes entering the intestinal wall directly, through Peyer's patches. And fragments of plant DNA were detected in cow's peripheral blood lymphocytes [78]. From the blood, the DNA can be transported to and taken up by tissue cells, and this has been known from experiments since the late 1990s. Transgenic DNA and viral DNA fed to mice ended up in cells of several tissues [79], and when fed to pregnant mice, the DNA crossed the placenta and entered the cells of the foetus and the newborn [80]. DNA from ingested food plants were also taken up into tissue cells [81].

Recent research has uncovered substantial amounts of DNA and RNA circulating in peripheral blood, which are actively secreted by living cells, and fully capable of transforming other cells [82, 83]. The nucleic acids appear to play a role in disease progression and metastasis of cancers. In plants too, foreign and endogenous nucleic acids circulate [84], apparently acting as intercellular messengers. There is a distinct possibility, therefore, that DNA from food could end up in peripheral blood and gain entry into cells [82].

c. Weight of evidence now undeniable but regulators helping to promote even more dangerous products

By now, the evidence against the safety of GM food and feed has accumulated to such an extent that the regulators should be answering a charge of criminal negligence at the very least in continuing their campaign of denial and misrepresentation, while failing to impose a ban on further releases of all GM crops until and unless they have been proven safe by thorough independent investigations [20]. Worse yet, the UK government has given the go-ahead for field trials of GM potatoes that are overwhelmingly rejected by consumers, all big food companies, and the British Retail Consortium [85]. The GM potatoes contain transgenes conferring broad-spectrum potato blight resistance, *Rpi-blb1* and *Rpi-blb2*. They code for proteins with a nucleotide-binding site consisting of leucine-rich repeats, known to be immunogenic in mammals. BASF Plant Science GmbH, the German company that created the GM potatoes, had carried out no safety tests, and was allowed to dismiss horizontal gene transfer by citing a single research paper that has been discredited long ago [29]. Despite the misleading title of the publication [86] that horizontal gene transfer from the transgenic potato "occurs, if at all, at an extremely low-frequency", the actual results showed quite the opposite. A high transfer frequency of 5.8×10^{-2} per recipient bacterium was demonstrated under optimum conditions. But the authors then proceeded to calculate an extremely low *theoretical* gene transfer frequency of 2.0×10^{-17} under extrapolated "natural conditions", *assuming that different factors acted independently*. The natural conditions, however, were largely unknown and unpredictable, and even by the authors' own admission, synergistic (multiplier) effects could not be ruled out.

It is all the more important now for regulators to take evidence seriously, as the biotech industry has been caught exaggerating the 'success' of GM crops in terms of the total area planted globally as opposition heightens worldwide [87], and GM crops are also proving disastrous for agriculture, as Roundup Ready resistant superweeds have emerged [88] and Bt cottons have failed disastrously in India, adding substantially to farmers' suicides [87], while Bt-resistant pests have evolved [89].

But the industry is aggressively pushing new generations of even more dangerous products, with help from the regulators.

Food crops are 'metabolically engineered' to overproduce single nutrients for 'health benefits', probiotic bacteria are genetically modified to serve the food industry and as vectors for gene therapy, and animals are genetically modified for a variety of purposes of which GM meat and milk will be by-products.

Many nutrients are known to be toxic in overdose [99], so food crops overproducing any single nutrient could be a public health hazard, and genetically modifying probiotic bacteria may turn them into pathogens pre-adapted to invade the gut, and should be strongly resisted if not banned [91, 92]. Foods derived from GM animals are likely to be contaminated with potent vaccines, immune regulators, growth hormones as well as nucleic acids, viruses and bacteria [93].

Genetically modifying animals are questionable in terms of animal welfare and ethics; that applies especially to cloned transgenic animals [94, 95]. But the United States Food and Drug Administration (FDA) and Department of Agriculture (USDA) have both presented cloned animals in a misleadingly positive light, implying that cloning by somatic cell nuclear transplant (SCNT) is no different from cloning by splitting embryos at the 2 or 4 cell stage. As is widely acknowledged [96], SCNT has an extremely low rate of success and causes massive suffering and death not just to cloned foetuses and calves, but also to the many surrogate mothers required.

In short, crucial evidence has been systematically ignored or dismissed by our regulators. As we shall make clear below, there is little or no protection for the public and the environment under the current regulatory regime that has no regard for the precautionary principle. Scientific data are routinely manipulated and science abused; regulators are colluding with industry to promote the products they are supposed to regulate, even to the extent of breaking the law.

5. Abusing science and the precautionary principle

a. The precautionary principle in Europe and the United Kingdom

Regulators in Europe are bound by law to operate on the precautionary principle as stated in the international Cartegena Protocol on Biosafety for genetically modified organisms (GMOs); and UK and the European Union have signed up to that, as have 137 other countries worldwide [97]. It is "taken into account" in the European Directive (2001/18/EC) for deliberate release into the environment of GMOs [98]

The European Commission (EC) Communication on the precautionary principle [99] made a strong statement: "the Commission considers that the precautionary principle is a general one which should in particular be taken into consideration in the fields of environmental protection and human, animal and plant health." It recognized that the precautionary principle has become "a full-fledged and general principle of international law", since it was written into the UN's Framework Convention of Climate Change, Convention on Biological Diversity, and in January 2000, Cartegena Protocol on Biosafety; it is also in the World Trade Organisation's Agreement on Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

UK's watchdog, the Food Standards Agency (FSA,) is advised by the Advisory Committee on Novel Foods and Processes (ACNFP), which advertises itself as "a nonstatutory independent body of scientific experts," even though the majority of its members, including the chair, have vested biotech interests as shareholders of companies, paid consultants or recipients of research grants [100].

The Food Standards Agency's Approach to Risk [101] states: "We will take a precautionary approach – that is, we will not always wait until we have proof of a potential

hazard to take action or issue advice. Such action will be taken on the best available evidence to protect public health. It will be reviewed if new evidence becomes available."

b. Manipulation of scientific evidence and abuse of science

In practice, however, the manipulation of scientific evidence and abuse of science have *prevented* the precautionary principle being ever invoked, let alone applied at the national or international level. The regulators have been operating on the *anti*-precautionary principle [102]. Not only do they require the public and genuinely independent scientists to prove there is hazard, they have persistently ignored all evidence of hazards submitted to them, and instead, continue to misinform the public by citing highly flawed studies that claim to find "no effect".

Scientists have been drawn effectively into a tightly closed loop of self-reinforcing "advocacy science" [103] that excludes not just counter scientific evidence but evidence from the real world (see Box 1), from the experience of farmers and consumers the scientists are supposed to serve. Advocacy science has but one goal: to smooth the passage of GM produce into the market, without regard for safety or moral, ethical concerns.

In the European Union (EU), scientific assessment on the safety of GM food products is done by the EFSA; and a 'positive opinion' from the EFSA would invariably result in commercial approval for the product. But EFSA's positive opinions have been challenged on scientific grounds [104, 105], and accusations of bias towards the biotech industry have come from both member states and civil society organisations. So much so that in April 2006, the EC decided to introduce improvements to EFSA's "scientific consistency and transparency of the decisions on GMOs" [106].

One particular study [107] cited by the ACNFP to dismiss Ermakova's findings [1] has been strongly challenged by scientists around the world [108]. It used processed soya, made from batches of soya harvested in the middle of two certain fields in South Dakota, and formulated into rat chow by a commercial company, which were fed to small number of mice (not rats). These are other peculiarities in experimental design made the study not only substantially different from that of Ermakova, but also completely unreplicable. The remarkable similarities in the composition of the GM and non GM diet - both supposed to contain 21.35 percent soya meal – were beyond belief. There were no standard deviations to the figures provided; 59 out of 78 were identical to 2 - 3 significant figures, and the rest differed so slightly that they would have been within standard errors. Could it be that the researchers have been feeding both groups the same diet? There was no evidence that the two diets were different, no PCR on the food samples were performed to ascertain that one was GM and the other non-GM.

Many other studies cited by the regulatory agencies that claim to show no effect are indeed highly misleading and/or seriously flawed. We give only two further examples here.

A paper claiming "absence of toxicity" of Bt-pollen to the black swallowtail butterfly under field conditions in the title [109] was faulted on experimental design, and actually demonstrated that Bt-pollen was highly toxic in laboratory experiments [110].

A study commissioned by the UK FSA claiming "no significant difference" between cows fed GM and non GM maize and soya diet, and failed to detect transgenic DNA in milk [76] was exposed to be practically worthless in experimental design and methodology [111]. Three cows were fed GM and three non-GM diets, on a peculiar "single reversal design with 4-wk periods", which meant that the groups of three cows alternated between GM and non-GM diets. The design should have generated 9 data points each for the GM and non-GM diets respectively from a small number of cows; it also guaranteed to balance out the effects of GM versus non-GM diets and is hence useless for determining differences between the two. In addition, the researchers made a blunder. Two of the cows in the non-GM group were

inadvertently fed on the GM-diet, so they ended up with 13 data points in the GM diet group and only 5 data points in the control non-GM diet group. Most serious of all, the PCR method for detecting transgenic DNA is so insensitive, and the sample of milk they used so small, that again, it would never succeed in detecting any transgenic DNA in milk.

The issue of transgenic DNA in milk has resurfaced. An unpublished study from the Weihenstephen Institute of Physiology and the Technical University of Munich showing that milk from cows on transgenic feed did indeed show positive signals for transgenic DNA. The unpublished study was done on milk collected from dairy cows in the farm in Hesse, Germany, where at least a dozen cows died after eating Syngenta's GM maize Bt 176 [22] (see Box 1). No autopsies were carried out on the cows, and this crucial study on transgenic DNA in milk dated 2000 remained under lock and key for more than three years before it was leaked to Greenpeace [112]. We can confirm the presence of transgenic DNA in the milk samples, in our own review of the evidence [113].

The EFSA's review of the evidence on the safety of GM food and feed [2] is selective and biased, citing all studies claiming to find no effect without comment, while excluding most of the evidence of serious adverse effects, practically the entire list in Box 1 except for items 5, 9 and 10, which are dismissed with irrelevant unsubstantiated criticisms. It omitted to mention the large volume of literature on the potential hazards of transgenic DNA in horizontal gene transfer (Box 2) and its successful detection in food and feed, and in tissues, cells, and milk of animals fed GM produce [72, 113], whenever the PCR detection methods were adequate to the task.

Studies that claimed GM feed had no adverse effects came mainly from biotech companies [114]; but even these were often contested by independent scientific review [104, 105]. In Monsanto's study on glyphosate tolerant maize NK603 which claimed no effect, Seralini and colleagues [114] found "more than 50 significant differences between GM fed and control rats". They further pointed out that glyphosate tolerant crops, which cover 87 percent of the global area of GM crops grown [115], are likely to be contaminated with toxic levels of glyphosate and Roundup (Monsanto's formulation) herbicide and metabolites. Gyphosate is indeed highly toxic to human placental cells and embryonic cells, Roundup even more so [114, 116, 117], and the herbicide is lethal to frogs [118].

Monsanto's study on MON 863 maize turned up many adverse effects [21] that were dismissed by both Monsanto and EFSA as "biologically insignificant." Monsanto, supported by EFSA, kept the study from public scrutiny under a false claim of confidential business information until a German court order a year later forced Monsanto to release the full report. Preliminary analysis by Seralini and colleagues [119] revealed serious flaws in the study at every stage, from experimental design, to data collection, analysis, and reporting. The GM fed group was compared, not just to the group fed the non-GM isogenic line as it should have been, but also to five more 'control' groups fed other non-GM varieties. This had the effect of increasing the range of variation and making the treatment group of animals too small, thereby considerably decreasing the sensitivity of the test. The results were analysed with the wrong statistical tests, and despite having compared many variables, the correct standard statistical tools (multivariate and principal component analyses) were not used. Instead, in comparing one variable at a time, the researchers failed to note significant trends in body weight differences between experimental and control animals. Statistically significant differences that nevertheless turned up were then all dismissed as biologically insignificant; and EFSA agreed, and gave MON 863 maize a 'positive opinion'. It is an absolute travesty that the health of people and planet is hanging on such gross distortion and corruption of science, aided and abetted by our regulators.

Regulators that sidestep the law to protect the industry

The UK FSA website contains the following description of genetic modification under "GM food" [120]:

"But whereas traditional methods involve mixing thousands of genes, genetic modification allows just one individual gene, or a small number of genes, to be inserted into a plant, animal or micro-organism (such as bacteria), to change it in a pre-determined way. Through genetic modification, genes can also be 'switched' on or off to change the way a plant or animal develops."

The description implies a level of precision and control in the process of genetic modification that flies in the face of extensive evidence indicating that the very opposite is the case, especially for plants and animals.

It is now generally accepted that the genetic modification process is uncontrollable, unreliable and unpredictable, and far from precise. It damages the natural genetic material of the organism, resulting in many unpredictable, unintended effects in the few "successes", including gross abnormalities that you can see, and metabolic changes that you can't [27, 28, 36].

A transgenic line is essentially derived from a single cell that has taken up and integrated the transgenic DNA into its genome, so the properties of the transgenic line will depend on where and in what form in the genome the insert(s) landed, and the collateral damages done to the genome, which will differ from one event to another. That is why the EU directive [98] requires event-specific characterization of the transgenic insert(s), which also provides a method for detecting transgenic contamination of non-GM produce, an increasingly frequent occurrence, involving transgenic lines that have not even been approved for commercial release.

And when that happens, as with the recent GM rice contamination, regulators came to the rescue on both sides of the Atlantic. The USDA proposed to deregulate the illegal rice to make it effectively legal, considering it as safe as a 'similar' variety that has been approved [121], making a mockery of event-specific characterisation required by European law. The EFSA, while admitting that the available data were "not sufficient to allow the safety of LLRICE601 to be assessed", nevertheless considered that "the consumption of imported long grain rice containing trace levels of LLRICE 601 is not likely to pose an imminent safety concern to humans or animal" [122].

UK's FSA and ACNFP were even more obliging. Based on an incomplete dossier supplied by Bayer CropScience, they consulted two scientists, who also decided there was no "imminent" safety concern (note the qualifier "imminent"). The FSA even told retailers in a memo later leaked to the press that there was no need to check whether any of the rice they were selling was tainted; which was against the law. It was only when Friends of the Earth threatened to take the FSA to court that FSA backed down [122].

There is yet another way in which our regulators have seriously sidestepped, if not broken the law. The EU Directive for deliberate release not only requires event-specific characterisation of the transgenic line, it also requires evidence of genetic stability of the insert (s) [98, p.30].

For years, we had warned that the transgenic lines were unstable, not only in the silencing of the transgenes in later generations, but also in the structural instability of the GM inserts that tend to break, rearrange, delete, or insert elsewhere in the genome. That would effectively transform the transgenic line into something else that could be unsafe, *and* impossible to trace [123]. It would also make the transgenic line illegal in European law.

And yet, when it was discovered that the GM inserts of five out of five commercially approved transgenic varieties had rearranged since characterised by the company [124], a clear sign of genetic instability [125], and the illegality pointed out to the EFSA [126],

neither the EFSA nor the European Commission had seen fit to withdraw commercial approval from those transgenic lines. The CaMV 35S promoter was indeed identified as a frequent break point [124], as we had predicted [32].

We do not know how many other transgenic lines have proven unstable that continue to be given positive opinion and approval for the market. The lack of transparency, and the increasing tendency to misuse business confidentiality has kept information crucial for risk assessment and risk management out of the public domain.

US courts rule GM crop field-tests and releases illegal

There have been three recent court cases involving field-testing and approval of GM crops in the United States. In all three cases, the courts ruled against USDA for failing to carry out proper environmental impact assessment, making the original releases illegal.

The first case was on drug-producing GM crops. A federal district judge in Hawaii ruled in August 2006 that the USDA violated the Endangered Species Act as well as the National Environmental Policy Act in allowing drug-producing GM crops to be cultivated throughout Hawaii, and failing to conduct even preliminary investigations on environmental impact prior to the approval of planting. The case was heard in US District Court in Hawaii. The plaintiffs were the Center for Food Safety, KAHEA (The Hawaiian Environmental Alliance), Friends of the Earth, and the Pesticide Action Network, North America. The defendants were the US Secretary of Agriculture and administrators of the USDA.

From 2001 to 2003, four companies, ProdiGene, Monsanto, Hawaii Agriculture Research Center (HARC), and Garst Seed, were allowed to plant corn and sugarcane genetically modified to produce experimental pharmaceutical products such as vaccines, hormones, cancer fighting agents and other proteins that are still under development and hence not yet approved.

The plaintiffs argued that USDA/APHIS broke the law in issuing these permits. Because these crops produce pharmaceutical products that are still at the experimental stage of development, their effect on Hawaii's ecosystem (especially Hawaii's 329 endangered and threatened species) is unclear. The experimental crops could cross-pollinate with existing food crops, and contaminate the food supply. Animals feeding on the crops would also become unwitting carriers of experimental pharmaceutical products, causing even more widespread dissemination of these experimental drugs.

The court concluded that APHIS' issuance of four permits was "arbitrary and capricious" and "an unequivocal violation of a clear congressional mandate" [127].

The second ruling was even more significant. A case was filed in Federal Court Washington DC against the trials of GM creeping bentgrass by the Center for Food Safety, Klamath-Siskiyou Wildlands Center, and other individuals and organizations in 2003. In February 2007, the court gave a decision that broadly affects field trials of all GM crops. Federal district judge Harold Kennedy ruled that the USDA must halt approval of all new field trials until more rigorous environmental reviews are conducted. USDA's past approval of GM herbicide-tolerant creeping bent grass led to widespread dispersal of pollen from the GM grass, and USDA's approval of bent grass trials was ruled illegal [128].

The third decision was on a case filed in Northern California by the Center for Food Safety, environment activists, seed producers and farmers. A Federal Court ruled (February 2007) that Monsanto's Roundup Ready alfalfa had been approved for commercial release illegally because there had been no Environment Impact Statement. [129]. According to Center for Food Safety, The decision may prevent this season's sales and planting of Monsanto's GM alfalfa and future submissions of other GM crops for commercial deregulation.

In all three cases, USDA was found to have flouted the law and disregarded health and environmental concerns in their approvals of the GM crops. The failure to identify the locations and the exact nature of GM crops being tested must also be addressed along with the frivolous use of Confidential Business Information designations to conceal crucial information for safety evaluation and the persistent regulatory bias towards the uncritical acceptance of GM crops.

At the recent Franco-British Council conference on Risk Management and Government Policy [130], David Gee, Project Manager of the European Environment Agency (EEA) talked about some of the case histories documented in the excellent EEA Report, *Late Lessons from Early Warnings* [131] which covers fisheries, radiation, benzene, asbestos, polychlorinated biphenyls (PCBs), halocarbons, diethylstilboestrol (DES), antibiotics as growth promoters, sulphur dioxide, chemical contamination in the Great Lakes, tributyltin (TCB) antifoulants, hormones as growth promoters and BSE. We were struck at how GM food/feed looks so much like a replay of government policies in these cases, in the "misplaced science, and the wrong kind of science" dominating decision-making, with devastating consequences.

Former UK Minister for the Environment Michael Meacher told a public conference on Science, Medicine and the Law that we need independent science and scientists who take the precautionary principle seriously, and called for sweeping changes in science funding and scientific advice to the government [132]. That applies all the more so to the regulatory agencies entrusted with the task of protecting the environment, human, animal and plant health, in which they have singularly failed so far.

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