

Submission Cover Sheet

# Review of the Moratorium on GM Canola

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**Attachments Submitted with this Submission:**

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GM Canola Review Panel  
DPI, GPO Box 4440  
Melbourne VIC 3001

Dear Panel Member

**Executive Summary.** *The GM Moratorium needs to be extended until long-term, generational studies become part of the OGTR regulations for approval. GM has to be treated as an introduction of a self-reproducing chemical. Marketing and trade of Australian products will be severely affected once health and environment impacts of GM become quantified and public. GM investment will be wasted. Direct R&D to a productive and more sustainable biological agriculture for the health and wellbeing of citizens and environment.*

The following quote from the attached article shows that remaining GM-free is the best solution to avoiding economic problems later relating to health and environment:

“Rhetoric from Washington (repeated by Canberra’s CSIRO, OGTR, FSANZ *ed.*) since the early 1990s proclaims that genetically modified (GM) foods are no different from their natural counterparts that have existed for centuries. But this is a political, not a scientific assertion. Numerous scientists at the FDA consistently described these newly introduced gene-spliced foods as cause for concern. In addition to their potential to produce hard-to-detect allergies and nutritional problems, the scientists said that “The possibility of unexpected, accidental changes in genetically engineered plants” might produce “unexpected high concentrations of plant toxicants”. GM crops, they said, might have “Increased levels of known naturally occurring toxins, appearance of new, not previously identified toxins”, and an increased tendency to gather “toxic substances from the environment” such as “pesticides or heavy metals.” They recommended testing every GM food “before it enters the marketplace”. But the FDA was under orders from the first Bush White House to promote the biotechnology industry, and the political appointee in charge of agency policy was Monsanto’s former attorney—later their vice president. The FDA policy ignored the scientists’ warnings and allowed GM food crops onto the market without any required safety studies. From the few safety tests that have been conducted, the results are disturbing—lab animals fed GM diets show damage to virtually every system studied. Reports from farmers are even less encouraging—thousands of sick, sterile and dead animals are traced to GM feed.”

Australia seems to trust and follow the US food regulator in most issues while Europe is critical and independent even though the second biggest GM player, Bayer, hails from Germany.

Single genes are but a small part in the complex system of nature with its cyclical processes towards adaptation. Genes are interacting and switching on or off due to environmental circumstance. GM science is linear thinking at the cutting edge of new understanding. Each day we discover gene functions we didn’t know that we didn’t know. Danger for the future as it is always more expensive or impossible for society to solve problems arising from released technologies.

GM is a commercial venture needing markets in shortest possible time. Scientists involved work with the ‘substantial equivalent’ principle, which is not a scientific method as it is not the precise content in a volume but the nature of its packaging that is important. Federal regulators seem willing partners. GM is a short-term solution with long-term costs. Going with this unproven technology is fraud with dangers.

At the beginning, for example, scientists were telling us that avoiding neighbouring canola paddocks would be sufficient to avoid contamination of non-GM. However, segregation is impossible. For example, by 2003 27% of Canadian *registered* seed of non-GM canola varieties was already contaminated with GM.

There are no data available that show yields of the new GM against the best current varieties, only promises of higher yields. However, the GM genes are not related to yield, they are stacked on high yielding factors. Any yield increase can be achieved by breeding using markers, the useful component of gene technology, and by appropriate agronomy.

GM crops that can tolerate climatic and soil stresses such as drought, salinity and frosts? Increased nutritional value? Pharmaceuticals in crops? These promises have been made since the start of genetic engineering but only herbicide tolerance and insect resistance have been achieved and released. However, both are resulting in problems on farms with the arrival of resistant weeds, and new pests and diseases. Many weeds are now becoming resistant ten years after herbicide-tolerant GM crops were introduced. Insects will become resistant after, say, 20 years? What then? Fertility of farm animals is also already affected.

Herbicide tolerance was in 2006 accounting for 81% of overall GM crop acreage. Only in the first years after introduction is there a reduction in herbicide use. In subsequent years the weeds not killed by glyphosate become a problem, followed by glyphosate resistance in other weeds. Analysis of USDA data revealed increased pesticide use in the US by 60 million kilograms from 1996 to 2004. The 67 million kilograms of increased herbicide use off set by 7 million kilograms reduction in use of insecticide.

There is an alternative, and GM promises are increasingly being achieved with well-managed organic and biological crops on healthy, biological active soils. Dryland salinity paddocks are reclaimed to full production in just two years and yields are higher in droughts. Their higher mineral and nutritional contents give us required resistances through (slow) food. This research field is ignored here in Australia but gathers momentum in public funded science overseas. Biological farming is the transition from current as it allows use of some microbe-friendly fertilizers and herbicides as-need-be.

GM technology is working on a symptom of our problems in agriculture. It does nothing on the cause, soil degradation, which will keep productivity on the edge and sliding down. We need to re-generate our soils, increase soil organic carbon content and active soil biology to achieve sustainable farming. Once soil carbon goes up with associated soil biology, then plants become resistant to insects and diseases under biological management.

GM science is not guiding us past pitfalls through use of appropriate risk. Risk is a principle calculated with numbers. However, such numbers don't exits for GM and risk is based on assumptions. Studies are being conducted with the aim of getting GM approved and scientists tend to design experiments to get the answers they want (I know the system from the inside). For example, only 30-90 day animal feeding studies and one to three-year environmental studies during GM introduction have been published. There is no published science giving us long-term, generational answers regarding the environmental and food safeties of GM crops.

So, who is in control of GM science? We need to determine for each GM introduction the cumulative, long-term impact in the environment on microbes and insects, the foundation of life on Earth. In humans and animals study the impact on health factors such as the condition of the liver, a main detoxifier for the body (see examples in attachment). This is an economic imperative. As long as these studies are not conducted, we should not release GM food crops as a precaution for incurring economic costs in the future.

Yours sincerely

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15 August 2007

**Attachment.** 'Genetically Modified Foods: Toxins and Reproductive Failures.'

## Genetically Modified Foods: Toxins and Reproductive Failures

By Jeffrey M. Smith – Institute for Responsible Technology

Rhetoric from Washington since the early 1990s proclaims that genetically modified (GM) foods are no different from their natural counterparts that have existed for centuries. But this is a political, not a scientific assertion. Numerous scientists at the FDA consistently described these newly introduced gene-spliced foods as cause for concern. In addition to their potential to produce hard-to-detect allergies and nutritional problems, the scientists said that “The possibility of unexpected, accidental changes in genetically engineered plants” might produce “unexpected high concentrations of plant toxicants.”<sup>[1]</sup> GM crops, they said, might have “Increased levels of known naturally occurring toxins, . . . appearance of new, not previously identified” toxins, and an increased tendency to gather “toxic substances from the environment” such as “pesticides or heavy metals.” They recommended testing every GM food “before it enters the marketplace.”<sup>[2]</sup> But the FDA was under orders from the first Bush White House to promote the biotechnology industry, and the political appointee in charge of agency policy was Monsanto’s former attorney—later their vice president. The FDA policy ignored the scientists’ warnings and allowed GM food crops onto the market without any required safety studies.

From the few safety tests that have been conducted, the results are disturbing—lab animals fed GM diets show damage to virtually every system studied. Reports from farmers are even less encouraging—thousands of sick, sterile and dead animals are traced to GM feed.<sup>[3]</sup>

### GM diet shows toxic reactions in digestive tract

The very first crop submitted to the FDA’s voluntary consultation process, the FlavrSavr tomato, showed evidence of toxins. Out of 20 female rats fed the GM tomato, 7 developed stomach lesions.<sup>[4]</sup> The director of FDA’s Office of Special Research Skills wrote that the tomatoes did not demonstrate a “reasonable certainty of no harm,”<sup>[5]</sup> which is their normal standard of safety. The Additives Evaluation Branch agreed that “unresolved questions still remain.”<sup>[6]</sup> The political appointees, however, did not require that the tomato be withdrawn.<sup>[\*]</sup>

According to Arpad Pusztai, PhD, one of the world’s leading experts in GM food safety assessments, the type of stomach lesions linked to the tomatoes “could lead to life-endangering hemorrhage, particularly in the elderly who use aspirin to prevent [blood clots].”<sup>[7]</sup> Pusztai believes that the digestive tract should be the first target of GM food risk assessment, because the gut is the first (and largest) point of contact with the foods; it can reveal various reactions to toxins. He was upset, however, that the research on the FlavrSavr never looked passed the stomach to the intestines. Other studies that did look found problems.

Mice were fed potatoes with an added bacterial gene, which produced an insecticide called Bt-toxin. Scientists analyzed the lower part of their small intestines (ileum) and found abnormal and damaged cells, as well as proliferative cell growth.<sup>[8]</sup> Rats fed potatoes engineered to produce a different type of insecticide (GNA lectin from the snowdrop plant) also showed proliferative cell growth in both the stomach and intestinal walls (see photo - [click here for larger image](#)).<sup>[9]</sup> Although the guts of rats fed GM peas were not examined for cell growth, the intestines were mysteriously heavier; possibly resulting from such growth.<sup>[10]</sup> Cell proliferation can be a precursor to cancer and is of special concern.

### GM diets cause liver damage

The state of the liver—a main detoxifier for the body—is another indicator of toxins.

- Rats fed the GNA lectin potatoes described above had smaller and partially atrophied livers.<sup>[11]</sup>
- Rats fed Monsanto’s Mon 863 corn, engineered to produce Bt-toxin, had liver lesions and other indications of toxicity.<sup>[12]</sup>
- Rabbits fed GM soy showed altered enzyme production in their livers as well as higher metabolic activity.<sup>[13]</sup>
- The livers of rats fed Roundup Ready canola were 12%–16% heavier, possibly due to liver disease or inflammation.<sup>[14]</sup>
- And microscopic analysis of the livers of mice fed Roundup Ready soybeans revealed altered gene expression and structural and functional changes.<sup>[15]</sup> Many of these changes reversed after the mice diet was switched to non-GM soy, indicating that GM soy was the culprit. The findings, according to molecular geneticist Michael Antoniou, PhD, “are not random and must reflect some ‘insult’ on the liver by the GM soy.” Antoniou, who does human gene therapy research in King’s College London, said that although the long-term consequences of the GM soy diet are not known, it “could lead to liver damage and consequently general toxemia.”<sup>[16]</sup>

## Higher death rates and organ damage

Some studies showed higher death rates in GM-fed animals. In the FlavrSavr tomato study, for example, *a note in the appendix* indicated that 7 of 40 rats died within two weeks and were replaced.[17] In another study, chickens fed the herbicide tolerant “Liberty Link” corn died at twice the rate of those fed natural corn.[18] But in these two industry-funded studies, the deaths were dismissed without adequate explanation or follow-up.

In addition, the cells in the pancreas of mice fed Roundup Ready soy had profound changes and produced significantly less digestive enzymes;[19] in rats fed a GM potato, the pancreas was enlarged.[20] In various analyses of kidneys, GM-fed animals showed lesions, toxicity, altered enzyme production or inflammation. Enzyme production in the hearts of mice was altered by GM soy.[21] And GM potatoes caused slower growth in the brain of rats.[22]

## Reproductive failures and infant mortality

In both mice and rats fed Roundup Ready soybeans, their testicles showed dramatic changes. In rats, the organs were dark blue instead of pink (see photo - [click here for larger image](#)).[23] In mice, young sperm cells were altered.[24] Embryos of GM soy-fed mice also showed temporary changes in their DNA function, compared to those whose parents were fed non-GM soy.[25]

More dramatic results were discovered by a leading scientist at the Russian National Academy of sciences. Female rats were fed GM soy, starting two weeks before they were mated.

- Over a series of three experiments, 51.6 percent of the offspring from the GM-fed group died within the first three weeks, compared to 10 percent from the non-GM soy group, and 8.1 percent for non-soy controls.
- R20;High pup mortality was characteristic of every litter from mothers fed the GM soy flour.R21;[26]
- The average size and weight of the GM-fed offspring was quite a bit smaller.[27]
- In a preliminary study, the GM-fed offspring were unable to conceive.[28]

After the three feeding trials, the supplier of rat food used at the Russian laboratory began using GM soy in their formulation. Since all the rats housed at the facility were now eating GM soy, no non-GM fed controls were available for subsequent GM feeding trials; follow-up studies were canceled. *After two months on the GM soy diet, however, the infant mortality rate of rats throughout the facility had skyrocketed to 55.3 percent (99 of 179).*[29]

## Farmers report livestock sterility and deaths

About two dozen farmers reported that thousands of their pigs had reproductive problems when fed certain varieties of Bt corn. Pigs were sterile, had false pregnancies, or gave birth to bags of water. Some cows and bulls also became sterile. Bt corn was also implicated by farmers in the deaths of cows, horses, water buffaloes, and chickens. [30]

When Indian shepherds let their sheep graze continuously on Bt cotton plants, within 5-7 days, one out of four sheep died. There was an estimated 10,000 sheep deaths in the region in 2006, with more reported in 2007. Post mortems on the sheep showed severe irritation and black patches in both intestines and liver (as well as enlarged bile ducts). Investigators said preliminary evidence “strongly suggests that the sheep mortality was due to a toxin. . . . most probably Bt-toxin.”[31]

## Dangerous denial

The warnings of the FDA scientists appear to have come true. But we were not supposed to know about their concerns. The agency’s internal memos were only made public due to a lawsuit. Instead, we were supposed to believe the official FDA policy, claiming that the agency is not aware of information showing that GM foods are meaningfully different. This statement, crafted by political appointees, directly contradicts the scientific consensus at the FDA.

Nearly every independent animal feeding safety study on GM foods shows adverse or unexplained effects. But we were not supposed to know about these problems either—the biotech industry works overtime to try to hide them. Industry studies described above, for example, are neither peer-reviewed nor published. It took lawsuits to make two of them available. And adverse findings by independent scientists are often suppressed, ignored, or denied. Moreover, researchers that discover problems from GM foods have been fired, stripped of responsibilities, deprived of tenure, and even threatened. The myth that GM crops are the same safe food we have always eaten continues to circulate.

With the overwhelming evidence of problems since their introduction in 1996, however, it is likely that GM foods are contributing to the deterioration of health in the United States. Without human clinical trials or post-marketing surveillance, we can't tell which worsening health statistic may be due to these foods. But we also can't afford to wait until we find out. GM foods must be removed from our diet immediately. Fortunately, more and more people are making healthy non-GM choices for themselves and their family. To learn which foods are genetically modified and how to protect yourself, visit [www.GeneticRoulette.com](http://www.GeneticRoulette.com).

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[\*] Calgene had submitted data on two lines of GM tomatoes, both using the same inserted gene. They voluntarily elected to market only the variety that was not associated with the lesions. This was *not* required by the FDA, which did not block approvals on the lesion-associated variety. The FlavrSavr tomato has since been taken off the market. After the FlavrSavr, no other biotech company has submitted such detailed data to the FDA. And the superficial summaries they *do* present to the agency are dismissed by critics as woefully inadequate to judge safety.

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[1] Edwin J. Mathews, Ph.D., in a memorandum to the Toxicology Section of the Biotechnology Working Group. Subject: Analysis of the Major Plant Toxicants. Dated October 28, 1991

[2] Division of Food Chemistry and Technology and Division of Contaminants Chemistry, "Points to Consider for Safety Evaluation of Genetically Modified Foods: Supplemental Information," November 1, 1991, [www.biointegrity.org](http://www.biointegrity.org)

[3] Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, Yes! Books, Fairfield, IA USA 2007

[4] Department of Veterinary Medicine, FDA, correspondence June 16, 1993. As quoted in Fred A. Hines, Memo to Dr. Linda Kahl. "Flavr Savr Tomato: . . . Pathology Branch's Evaluation of Rats with Stomach Lesions From Three Four-Week Oral (Gavage) Toxicity Studies . . . and an Expert Panel's Report," Alliance for Bio-Integrity (June 16, 1993) <http://www.biointegrity.org/FDAdocs/17/view1.html>

[5] Robert J. Scheuplein, Memo to the FDA Biotechnology Coordinator and others, "Response to Calgene Amended Petition," Alliance for Bio-Integrity (October 27, 1993) [www.biointegrity.org](http://www.biointegrity.org)

[6] Carl B. Johnson to Linda Kahl and others, "Flavr Savr™ Tomato: Significance of Pending DHEE Question," Alliance for Bio-Integrity (December 7, 1993) [www.biointegrity.org](http://www.biointegrity.org)

[7] Arpad Pusztai, "Genetically Modified Foods: Are They a Risk to Human/Animal Health?" June 2001 Action Bioscience [www.actionbioscience.org/biotech/pusztai.html](http://www.actionbioscience.org/biotech/pusztai.html)

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[10] Arpad Pusztai, "Facts Behind the GM Pea Controversy: Epigenetics, Transgenic Plants & Risk Assessment," *Proceedings of the Conference, December 1st 2005* (Frankfurtam Main, Germany: Literaturhaus, 2005).

[11] Arpad Pusztai, "Can science give us the tools for recognizing possible health risks of GM food," *Nutrition and Health*, 2002, Vol 16 Pp 73-84.

[12] John M. Burns, "13-Week Dietary Subchronic Comparison Study with MON 863 Corn in Rats Preceded by a 1-Week Baseline Food Consumption Determination with PMI Certified Rodent Diet #5002," December 17, 2002 [www.monsanto.com/monsanto/content/sci\\_tech/prod\\_safety/fullratstudy.pdf](http://www.monsanto.com/monsanto/content/sci_tech/prod_safety/fullratstudy.pdf)

[13] R. Tudisco, P. Lombardi, F. Bovera, D. d'Angelo, M. I. Cutrignelli, V. Mastellone, V. Terzi, L. Avallone, F. Infascelli, "Genetically Modified Soya Bean in Rabbit Feeding: Detection of DNA Fragments and Evaluation of Metabolic Effects by Enzymatic Analysis," *Animal Science* 82 (2006): 193–199.

[14] Comments to ANZFA about Applications A346, A362 and A363 from the Food Legislation and Regulation Advisory Group (FLRAG) of the Public Health Association of Australia (PHAA) on behalf of the PHAA, "Food produced from glyphosate-tolerant canola line GT73," [www.iher.org.au/](http://www.iher.org.au/)

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