Submitted to the EPA, regarding

Plant-Incorporated Protectants; Potential Revisions to Current Production Regulations

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By

Jeffrey M. Smith
Executive Director
Institute for Responsible Technology
Fairfield, IA USA
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Introduction

The reason we are here today is because the 1992 White House chose to fast-track genetically modified (GM) foods and crops at the expense of science. Not wanting Congress to intervene and pass new laws that might slow down approvals through extensive testing and evaluation, they cobbled together a regulatory framework based on existing laws that were ill equipped to handle the harmful and unique risks of this new technology. As a result, the system is broken and public health and the environment are seriously at risk.

Ignoring safeguards in order to promote the biotech industry was particularly evident at the FDA in the early 1990s, when they created a new position for Michael Taylor, Monsanto's former attorney and later their vice president. Mr Taylor was in charge of crafting the FDA's GMO policy. Documents now public from a lawsuit reveal that the consensus among FDA scientists was that GM foods might promote allergies, toxins, new diseases and nutritional problems. They had urged superiors to require long-term safety studies. These warnings were ignored, even denied, and the FDA has no required safety testing.[1]

The narrow focus of today's docket threatens to perpetuate the legacy of regulatory jerry-rigging and shortcomings, by attempting to fix one broken area, while neglecting larger food safety issues. My presentation, therefore, responds to the docket's invitation to describe other unique characteristics of GM crops that need to be addressed, hoping to inspire fundamental change within and between agencies.

The information I am presenting is from my book, *Genetic Roulette*: *The Documented Health Risks of Genetically Engineered Foods,* published yesterday. *Genetic Roulette* was compiled with the input of more than 30 scientists over the last two years. The carefully referenced text demonstrates that the current generation of GM crops is not safe, that regulatory oversight is insufficient, that industry-funded studies are incompetent by intention and design, and that public health would be served by the immediate withdrawal of these high-risk foods.

Of the many recommendations in the book, I have selected 15 to present today, excerpted from my docket submission. With permission, I tend to favor laymen's terminology when possible, to help bring the technical issues to a wider audience.

1. **Revoke the now disproved assumptions that Bt-toxin is benign, destroyed during digestion, and non-active in humans and mammals**.

One maddening feature of GM crop regulations is that assumptions, not data, lay at its soft core. In the case of *Bt* crops, for example, the agency assumed that *Bt* toxin, used by organic farmers, had a history of safe use and could therefore be handled and consumed in GM crops without extensive safety testing. This assumption ignored the fact that:

- The *Bt*-toxin in crops is often thousands of times more concentrated than the spray version.[2]
- *Bt* in crops is usually produced in a molecular form that is more likely to provoke an immune or toxic response.[3]

- Natural *Bt* spray degrades quickly and can be washed off, [4] while crop incorporated toxins are consumed directly.
- Farm workers exposed to *Bt* elicited an antibody response.[5]
- Approximately 500 people who were exposed to *Bt* during aerial spraying for gypsy moths reported allergic-type reactions of the skin, eyes and upper respiratory tract.[6,7]

Notably, these were the identical symptoms reported by hundreds of farm workers in India due to handling Bt cotton. Employees at a cotton gin factory take antihistamines everyday to cope with the reactions that are linked only to the Bt varieties.

EPA assumed that Bt was destroyed during digestion and not interactive with the digestive tract of mammals. This ignored several mouse studies showing that:

- Ingested *Bt*-toxin provoked an immune response throughout the system, as well as in localized areas.[8]
- The immune response to *Bt*-toxin was "as potent as cholera toxin" and caused the immune system to become overly sensitive to formerly harmless compounds.[9]
- *Bt* exposure also induced antibody responses.[10]

Expert advisors to the EPA said that these mouse and farm worker studies "suggest that *Bt* proteins could act as antigenic and allergenic sources. . . . Only surveillance and clinical assessment of exposed individuals will confirm the allergenicity of *Bt* products."[11]

The results of the EPA's flawed allergy screening are disregarded by the agency

The EPA asks companies to compare the amino acid structure of their GM proteins to that of known allergens. Even though this method provides no guarantee of consumer protection, EPA appears to ignore even the red flags that these inadequate tests produce. In 1998, for example, an FDA researcher discovered that the *Bt* protein in Cry1Ab created in *Bt* corn shared a sequence of 9-12 amino acids with vitellogenin, an egg yolk allergen. The study concluded that "the similarity . . . might be sufficient to warrant additional evaluation."[12] No evaluation took place, and the EPA re-registered the corn variety in 2001 for an additional seven years.[13]

EPA also requires tests of the GM protein's stability by measuring how quickly the protein is broken down in test tubes with digestive enzymes and acid. These studies, however, do not accurately predict what happens inside the human gut[14] and cannot accurately distinguish between known allergens and non-allergens.[15,16] In addition, companies manipulate results by using a stronger pH and more enzymes to breakdown their protein more quickly. Monsanto, for example, "used 2000 times the amount of pepsin by weight recommended in the WHO/FAO protocol,"[17] and a pH of 1.2, rather than the recommended 2.0. The EPA's Science Advisory Panel also concurred that "The

normal population has a relative higher gastric value than the pH 1.2 or 1.5," and that using lower values does "not mimic the physiological state."[18]

[The *Bt* protein Cry1Ab,[19] found in Monsanto's Yield Guard and Syngenta's *Bt* 11 corn varieties, fails the WHO/FAO criteria. It is particularly resistant to digestion—nearly as stable as the *Bt* found in the unapproved corn variety StarLink. One test tube study reported that 10% of Cry1Ab survived for 1-2 hours.[20] At 2 hours, there were still protein fragments of substantial size—within the range considered typical of food allergens (15 kilodaltons). If the conditions used were those specified by the WHO/FAO, the protein would have lasted even longer. (By contrast, Monsanto used so much pepsin and acid that they reported over 90% degradation in just 2 minutes.) Animal studies demonstrated that "Cry1Ab protein is 92% indigestible in pigs."[21] Similarly, after calves were fed *Bt* 11, undigested Cry1Ab was found in the stomach, intestine and feces.

In addition, Cry1Ab was described as having "relatively significant thermostability … comparable to that of . . . Cry9C protein" found in StarLink corn. Although the study did not provide any additional measurements for Cry1AB, it did report that Cry9C protein was stable for 120 minutes at 90° C.[22] Here again, the EPA failed to collect the required heat stability data on Cry1Ab from Monsanto on its MON 810 corn variety.[23]]

2. Investigate evidence that links GM crops to thousands of sick, sterile and dead animals, and to allergic and toxic reactions in people worldwide.

In addition to the allergenic reactions above, *Bt*-toxin appears to have toxic effects. For example:

- A mouse study showed that *Bt* caused abnormal, damaged and excessive cell growth in the small intestine.[24]
- Monsanto's own 90-day feeding study on Mon 863 *Bt* corn demonstrated signs of toxicity in the liver and kidneys of rats.[25]
- In 2006, at least 71 Indian shepherds report that when their sheep grazed for 5-7 days on post-harvest *Bt* cotton fields by Monsanto, 25% of their herds perished. An estimated 10,000 sheep died. According to post mortems and investigations, preliminary evidence "strongly suggests that the sheep mortality was due to a toxin. . . . most probably *Bt*-toxin."[26] In 2007, the Indian Animal Husbandry department began investigating deaths among cattle that ate *Bt* crops as well.[27]
- A German farmer claims that *Bt* corn 176 from Syngenta was responsible for the deaths of 12 of his cows, while others became so sick they had to be killed.
- More than 20 farmers in North America report that pigs fed GM corn varieties had low conception rates, false pregnancies or gave birth to bags of water. Some also report sterility among cows and bulls.

3. Verify that the sequence of the transgene is what was intended and is stable.

Unintended changes in the transgene can create unintended changes in the protein

If a gene undergoes even a tiny point mutation of a single base pair, the protein it produces might be altered in its ability to trigger an immune or allergy response.[28] Transgene sequences, however, are regularly mutated during insertion. There is a point mutation in the Mon 863 transgene,[29] for example, and a major truncation in Mon 810. In the latter, only about 70% of the transgene made it into the corn genome with the stop signal lost entirely. As a result, when the plant creates a GM protein, two additional amino acids are created from the host corn, not the transgene.[30]

Syngenta's *Bt* 176 corn had mixed up and multiple transgenes.[31] Moreover, it was supposed to create the Cry1Ab form of *Bt*, but analysis "carried out both by French and Belgian government scientists" showed that the transgene had only a 65% similarity to Cry1Ab. Rather, it actually "showed 94% similarity with a synthetic construct of *crylAc* gene"—a different form of the toxin.[32] Syngenta's *Bt* 11 corn not only showed rearrangements, but also appeared to be contaminated with sequences from *Bt* 176.[33]

The transgene may be unstable, creating a variety of unknown proteins over time

The transgene sequence of several popular GM crop varieties were identified by European labs as different from the sequences registered by the companies. Many of the rearrangements appeared to be breaks in a known recombinant hotspot found in the inserted promoter (CaMV 35S0), which is prone to instability.[34] If the transgene changes over time, as this suggests, the amino acid sequences of the *Bt* toxin may change; EPA's safety assessments become largely irrelevant.

4. Fully verify that GM proteins have the intended amino acid structure.

The agency fails to require that the GM protein is fully sequenced. The EPA's review of Cry1F corn, for example, states, "sequencing of 5 [amino acids] determined that the microbial and plant expressed protein maintained this sequence intact."[35] Identifying only 5 amino acids out of hundreds in a protein does not protect the public from possible harmful changes. In addition, independent scientists, wishing to present newly discovered data that might contradict these assumptions, are refused permission since it is common for scientists seeking permission to study a GM crop to have to pledge to the company that they will not sequence the protein.[36]

Studies on Roundup Ready soybeans showed that the NOS terminator failed to stop transcription; the resulting strand of RNA included sequences from DNA that were well beyond the transgene. The RNA was further processed into four variants, any one of which might produce unknown, untested proteins. The authors suggest that similar over-length RNA transcripts may be an overlooked, but commonplace occurrence in all crops that use this faulty NOS terminator.[37] It is used in many crops regulated by EPA.

5. Verify that GM proteins are folded properly, do not aggregate into harmful configurations, do not have dangerous molecular attachments, and are expressed within acceptable and safe levels under varied growing conditions.

Molecules added to GM proteins can make them dangerous

In 2005, when a pesticide producing GM pea was found to be potentially allergenic, the $2 million Australian project was canceled. If that pea had been subjected to only the EPA criteria used for such crops, it would have passed. The only reason its commercialization was halted was because they subjected it to advanced tests never used on approved GM foods. They blame an unexpected subtle change in added sugar chains for turning a harmless protein into a potentially deadly one.[38] The EPA testing regime allows use of substitute bacteria-derived proteins that would *never* catch such a change. Ironically, a Monsanto rep claimed that the GM pea incident showed that the regulatory system was working, but failed to mention that none of the company's approved products had been tested in the same way.

That same study also showed that when cooked, the built-in pesticide was sufficiently denatured to no longer be effective against its target insect, but it was *still* able to provoke an inflammatory reaction in mice. This overturns yet another assumption used to justify *Bt*-toxins in America's diet—that cooking corn will prevent allergic reactions.

GM proteins may become misfolded and promote disease

If the GM protein becomes folded incorrectly in its new plant environment, its effect on consumers might be dangerous. This is not checked by EPA methods.

[Sometimes, refolding can result in groups of proteins aggregating into shapes, called amyloid fibrils, with harmful consequences. These are involved with diseases such as Alzheimer's and Parkinson's. [39] "Studies indicate that any protein can adopt" the amyloid configuration[40] upon exposure to appropriate environmental conditions."[41] Consumption of GM crops with misfolded proteins could theoretically trigger diseases, since "hazardous aggregates of proteins survive digestion and are distributed throughout the human body." A difficulty in safety assessment of GM crops is that "exposure to some aggregated proteins in the amyloid form can take decades to produce an effect." [42]]

The amount of Bt expressed in crops varies wildly

Two reports released this year showed that the amount of *Bt* expressed in *Bt* crops was wildly erratic, varying as much as 100-fold in the same field.[43] EPA methods fail to account for this variation or the effect. Consider the experience in a Philippine village, where residents awoke one day to a "really pungent smell" emanating from the nearby cornfield. One person reported, "It was like we were breathing in pesticides."[44] When one person ventured into the field, his face swelled up and he had difficulty breathing. This started when the nearby *Bt* corn was pollinating. Villagers began experiencing skin, respiratory and intestinal symptoms and fever, starting with those living closest to the cornfield and then onto those further away. In total, 96 people got sick. In addition, nine horses, four water buffalos, and 37 chickens died soon after feeding on GM corn."[45] All 39 people who participated in blood tests showed an antibody response to *Bt*.[46] This

supports, but does not prove the link. However, when the same corn variety was planted in four other villages the next year, the symptoms returned there—again only during pollination time.

Was this a case of unstable *Bt* corn on steroids? Tests of the suspect corn did reveal wide variations in *Bt* expression levels, with a 64-fold difference as well as measurements above and outside the limits of detection.[47]

6. Identify all unintended compositional changes due to the GM transformation process and test their possible interactions with the plant-made GM toxin under varied growing conditions.

EPA must consider interactions with the plant produced toxin

EPA assumptions fail to address how natural or man-made substances might interact with the plant produced toxin and impact health. University of Wisconsin scientists, for example, accidentally discovered that *Bt*-toxin becomes more deadly to insects when mixed with very small amounts of a naturally occurring antibiotic (zwittermicin A—a byproduct of bacteria).[48] Tests have not been conducted to determine if the enhanced toxicity is also more dangerous to animals or humans.

Thorough safety assessments should take into consideration the interactions between the toxin and compounds produced within the plant. There up to 5000 natural products found in a single plant. Moreover, GM crops undergo massive collateral damage in the GM transformation process, which can change the levels of these compounds or introduce new ones.

- Mutations usually occur near the insertion site.[49]
- Insertions commonly end up disrupting known gene sequences.[50]
- Growing a crop from tissue culture can create hundreds or thousands of mutations throughout the DNA, creating differences in an estimated 2%-4% of the DNA, according to two studies.[51,52]
- One study demonstrated that up to 5% of the genes tested changed their levels of RNA expression when a single gene was inserted.[53]
- The location of the transgene insertion may, according to the FDA, lead to "higher levels of toxins than normal, or lower levels of a significant nutrient."[54]
- The promoter sequence inserted into plant to switch on the transgene may also inadvertently permanently turn on a native plant gene.

Unpredicted changes in the genome sequence and functioning can lead to novel or altered levels of plant compounds. We know of numerous changes to nutrient and toxin levels in GM crops, both experimental and commercialized, which may of themselves cause harm to consumers and the environment.

For example, the stems of *Bt* corn varieties MON 810 and *Bt* 11[55] (as well as Roundup Ready soybeans) have markedly increased levels of lignin (by 20%).[56] Lignin is produced through a complex series of steps, which also create other important plant constituents. Since lignin has increased, the amount of other related compounds in its

biosynthetic pathway may have also changed. These include "rotenone, a plant-produced insecticide that may cause Parkinson's disease."[57] Should the EPA ignore changes in the levels of this compound just because the FDA does? I hope not. I strongly urge the EPA to take responsibility for addressing the impact of these changes, even though it has traditionally been the FDA that has officially abdicated that responsibility.

Even if the EPA continues to overlook the direct impacts of altered compounds, it *must* take these into account when assessing their interaction with the plant-produced toxin. Thus, EPA should usher in the use of modern detection methods to analyze the full changes in the RNA, protein and metabolic profiles of GM crops, rather than allowing companies to use obsolete and insensitive technologies to characterize their creations.

At this point, however, the agency even overlooks interactions between GM proteins produced from two or more different transgenes inserted into the same crop. To treat two separate pesticides produced in the same corn variety as fully independent and non-interactive is to extend reductionism science into even more dangerous territory.

Many environmental factors are overlooked by regulators

Environmental factors have a huge impact on gene expression, and yet assessments are regularly made based on a narrow range of conditions. Several experts and organizations agree that "environmental influences" on GM crops "need more attention."[58] In fact, not only will transgene expression vary greatly, but the impact of some mutations might not become apparent until the crop is grown under the specific conditions that normally trigger the gene.

7. Study the long lasting effects generated by self-propagating genetic pollution, stable Bt deposits in the soil, transfer of transgenes into soil bacteria, and the persistence of Bt in cotton or other products.

Another critical feature of toxin producing GM crops is the longevity of the effect.

If Indian farm workers are having allergic reactions to *Bt* cotton, how long is the *Bt* toxin in the fiber active? Might it be active in tampons or diapers? What about bandages? If *Bt*-toxin in bandages delayed the healing of wounds of diabetics, it might lead to amputation.

Longevity also includes the self-propagating genetic pollution that is inevitable with transfer of traits to non-GM crops and wild relatives. As long as studies do not take into account the long-term and expanding nature of GM crops, they will fail to address their unique threat to health and environment.

Bt toxin is excreted from GM crop roots and binds with clay in the soil, remaining stable for months or years. Further, the *Bt* producing gene might be picked up and expressed by the DNA of soil bacteria, causing an unaccounted for source of continuous *Bt* production in the environment.

8. Find out if Bt genes transfer to gut bacteria, converting our intestinal flora into living pesticide factories.

DNA fed to mice was found to "persist in fragmented form in the gastrointestinal tract, penetrate the intestinal wall, and reach the nuclei of leukocytes, spleen and liver cells."[59] When pregnant mice were fed DNA, it was also found in several organs of the offspring, including their brains. The transfer of *Bt* producing genes could theoretically alter human DNA as well.

While horizontal gene transfer between plants and animals is considered rare, it is common between bacteria. The transgenes inserted into GM crops, however, dismantle most of the barriers of gene transfer from plant into bacterial DNA.[60] The *Bt* transgene is from bacteria, is short, without introns in the coding sections, and comes with its own promoter to switch it on.

The only published human feeding study ever conducted verified that parts of the transgene, including the promoter, transferred from Roundup Ready GM soybeans into human gut bacteria in a stable manner. The fact that the bacteria also survived Roundup's active ingredient, glyphosate, strongly suggests that it was functioning. This means that years after US citizens decide to stop eating GM corn chips, their own gut bacteria may continue to produce *Bt*-toxin within their intestines.

9. Extend safety assessments to include impacts of herbicide residues and their breakdown products within herbicide tolerant crops, including studies on endocrine disruption.

GM crops might bioaccumulate pesticides from the environment

FDA scientists warned that GM crops might gather "toxic substances from the environment" such as "pesticides or heavy metals"[61] and yet neither the FDA nor the EPA evaluate such a possibility.

We do know of breakdown products from glyphosate (AMPA) and glufosinate (NAG) in Roundup Ready and Liberty Link crops designed to survive applications of these herbicides. But the amounts and effects of these have not been carefully evaluated. Further, NAG is known to re-toxify in the gut of mammals, depositing small amounts of glufosinate herbicide into the organs.[62,63,64] These small amounts may operate as endocrine disruptors in the consuming animal or human.

Recent research demonstrates that Roundup has effects on human placental cells at 10,000 times less than the concentration sold in stores[65] and is active at less than the residues "in discussion to be authorized in GMO feed in the United States."[66]

By 2004, farmers used an estimated 86% more herbicide on GM soy fields compared to non-GM.[67] Higher levels of herbicide residue in GM soy might cause health problems.

Certainly the EPA should investigate any studies on Roundup Ready soybeans that show adverse reactions, in case it is the herbicide that caused the problem. Feeding studies on GM soybeans led to altered DNA gene expression, misshapen cells, increased metabolic activity and changed enzyme production in key organs in mice and rabbits. [68,69,70,71,72,73] Young sperm cells were altered, [74] DNA expression in embryos was affected, [75] and the offspring of mother rats fed GM soy had a five-fold increase in infant mortality, along

with reduced size[76] and apparent reproductive problems. It is unclear if any of these results are from the GM transformation or the herbicide.

It is noteworthy that when a UK study revealed that soy allergies skyrocketed by 50% soon after GM soy was introduced there,[77] the symptoms linked to soy consumption included many that are associated with glyphosate exposure. [The allergy study identified irritable bowel syndrome, digestion problems, chronic fatigue, headaches, lethargy, and skin complaints, including acne and eczema, all related to soy consumption. Symptoms of glyphosate exposure include nausea, headaches, lethargy, skin rashes, and burning or itchy skin. It is also possible that glyphosate's breakdown product AMPA, which accumulates in GM soybeans after each spray, might contribute to allergies.]

In another study on herbicide-tolerant Liberty Link corn, twice the number of chickens died, compared to those fed commercial non-GMO feed.[78] Rats fed Roundup Ready canola had substantially heavier livers.[79]

10. Test viral proteins from virus-resistant plants to see if they are toxic or suppress viral defenses in humans and animals.

Viral proteins produced in disease-resistant crops may increase viral infections in humans.

Viral genes inserted into disease-resistant crops produce "viral" proteins. More than 100 studies have shown that viral proteins can promote infections by related and unrelated viruses.[80] (Nearly every type of virus protein has this ability: viral coat proteins,[81] viral movement proteins, [82] viral replicase proteins,[83] viral proteins involved in overcoming host defenses[84] and miscellaneous viral proteins.[85]") Since important viral defense mechanisms in plants (such as gene silencing) are very similar in humans, proteins that work in plants may also disable human defenses. Some GM crops are designed to produce viral proteins in every cell, exposing us to unprecedented levels. This could weaken our resistance to viral infections, particularly in the gut, where viral proteins circulate after a meal.

Viral proteins may be toxic

In addition, viral proteins are often toxic to their hosts. They attack fundamental processes, such as the cycle by which a cell divides and the mechanism for creating proteins from RNA.[86] If these were damaged in human beings, it could have serious health consequences and may cause disease. (Disrupting the cell cycle, for example, can lead to cancer.)

11. Verify that regulatory RNA created in disease-resistant plants or other GM crops will not impact gene regulation in humans or animals.

Virus-resistant GM crops are engineered to create large quantities of small regulatory double stranded RNA. We now understand that regulatory RNA can influence gene expression, even in future generations. With the new body of research emerging about the impact and importance of RNA, a proper safety assessment should look at this for both disease-resistant crops and GM crops in general.

12. Investigate whether GM crops may play a contributory role in Colony Collapse Disorder among bees, and look closely at the insecticides used in seed dressing, especially those highly concentrated varieties designed for refuge areas in Bt crop fields.

The Colony Collapse Disorder (CCD) is a growing catastrophe that must be mentioned here. Is it due primarily to GM crops? Unlikely. Regions where the disorder is found include those with very few GM acres planted. But GM crops theoretically could lead to such an unpredicted nightmare. In fact, they may be contributing to CCD. Preliminary studies have already demonstrated that bees' immune systems were weakened after pollinating certain GM fields and that transgenes from Liberty Link corn transferred into the gut microorganisms within the bees.

One major candidate for causing CCD is neonicotinoid insecticides used in seed dressing. The widespread application of the neonicotinoids are highly toxic to bees at very low concentrations. French beekeepers noticed that imidacloprid affected the bee's orientation and ability to return to the hive. Italian scientists found that sub lethal doses of imidacloprid in laboratory and field experiment decreased flight activity and olfactory discrimination, and olfactory learning performance was impaired.

It is noteworthy that companies sell seeds specifically designed for *Bt* refuge areas with a five-fold concentration of the time-released neonicotinoid insecticides. This might certainly impact bee health and may explain the particularly high rate of bee losses in the US. It is also important to note that the bee disorder is not being reported much among organic beekeepers, supporting the notion that agricultural chemicals and GM crops may be contributors.

13. Meticulously explore possible effects on the developing fetus and children.

Children and newborns are most at risk

Embryo development may be highly sensitive to changes in the diet due to GM foods, but almost no intergenerational feeding studies have been conducted. Furthermore, not only will nutritional imbalances and metabolic disturbances affect infant health, they can even influence gene expression "and may even be transmitted to the next generation."[87]

Children are more susceptible to potential problems. They are three to four times more prone to allergies than adults and "are at highest risk of death from food allergy."[88] One reason for this sensitivity, according to the EPA, is that "An immature gut or permeable mucosal epithelium is more likely to allow a higher degree of macromolecular transport and access to the immune system than the intact barrier of a normal mature gut. . . . The

immune system must also be of sufficient maturity. . . . Both systems appear to be functioning optimally by age three to five."[89] This makes children particularly vulnerable to the enormous variability of *Bt*-toxin expression. And according to the Royal Society of Canada, "The potentially widespread use of GM food products as food additives and staple foods, including use in baby foods, may lead to earlier introduction of these novel proteins to susceptible infants either directly or via the presence of the maternally ingested proteins in breast milk."[90]

Children can react to much smaller doses of toxins than adults. Exposure to hormones or endocrine disruptors may also severely affect normal development. But if GM foods are creating problems, according to biologist David Schubert of the Salk Institute, "we will probably never know because the cause will not be traceable and many diseases take a very long time to develop."[91]

14. Replace studies by biotech companies with rigorous independent research.

A close examination of the design and reporting of safety assessment funded by biotech companies has revealed clear methods used to avoid finding problems. I refer you to the 43 pages of part 3 in my book *Genetic Roulette*, detailing how these corporations have got bad science down to a science.

15. Employ long-term, inter-generational whole food animal studies, evaluate plant-produced proteins, use animal models for allergy testing and protein stability, and fully utilize the new tools of science to characterize the genome, RNA, proteins and plant made compounds, under varied conditions.

The EPA needs to be the consumers' champion

If your answer to any of these recommendations is that it is "Not my job," than this is a problem that should be investigated above all others. The strange malady of passing on the responsibility to others has befallen too many regulatory agencies in regards to GMOs. And when it is traced back to see who is ultimately providing assurances, it often turns out to be the biotech companies offering assumptions that promote profits.

As our consumer and environmental champions, abandon out-dated assumption-based regulations in favor of independently derived reliable data.

Please regulate GMOs as if our lives depended on it. Our food security is at risk.

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[1] See www.biointegrity.org for the FDA memos made public by lawsuit spearheaded by the Alliance for Biointegrity

[2]US EPA, "Biopesticides Registration Action Document (BRAD)—*Bacillus thuringiensis* Plant-Incorporated Protectants: Insect Resistance Management," EPA BRAD (2001e) (October 15, 2001): IID2; http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/4-irm.pdf The high concentration is by design, in order to limit pest resistance.

[3] See for example, A. Dutton, H. Klein, J. Romeis, and F. Bigler, "Uptake of *Bt*-toxin by herbivores feeding on transgenic maize and consequences for the predator *Chrysoperia carnea*," *Ecological Entomology* 27 (2002): 441–7; and J. Romeis, A. Dutton, and F. Bigler, "*Bacillus thuringiensis* toxin (Cry1Ab) has no

direct effect on larvae of the green lacewing *Chrysoperla carnea* (Stephens) (Neuroptera: Chrysopidae)," *Journal of Insect Physiology* 50, no. 2–3 (2004): 175–183.

[4] "BT: An Alternative to Chemical Pesticides," Environmental Protection Division, Ministry of Environment, Government of British Columbia, Canada, http://www.env.gov.bc.ca/epd/epdpa/ipmp/fact_sheets/BTfacts.htm; and C. M. Ignoffo, and C. Garcial, "UV-photoinactivation of cells and spores of *Bacillus thuringiensis* and effects of peroxidase on inactivation," *Environmental Entomology* 7 (1978): 270–272

[5] I.L. Bernstein et al, "Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides," *Environmental Health Perspectives* 107, no. 7(1999), 575–582; see also M.A. Noble, P.D. Riben, and G. J. Cook, "Microbiological and epidemiological surveillance program to monitor the health effects of Foray 48B BTK spray" (Vancouver, B.C.: Ministry of Forests, Province of British Columbi, Sep. 30, 1992).

[6] Washington State Department of Health, "Report of health surveillance activities: Asian gypsy moth control program," (Olympia, WA: Washington State Dept. of Health, 1993).

[7] M. Green, et al., "Public health implications of the microbial pesticide *Bacillus thuringiensis*: An epidemiological study, Oregon, 1985-86," *Amer. J. Public Health* 80, no. 7(1990): 848–852.
For more information on all these points above, see Jeffrey M. Smith, *Genetic Roulette*: *The Documented Health Risks of Genetically Engineered Foods*, Yes! Books, Fairfield, IA USA, 2007

[8] Vazquez et al, "Intragastric and intraperitoneal administration of Cry1Ac protoxin from *Bacillus thuringiensis* induces systemic and mucosal antibody responses in mice," *Life Sciences*, 64, no. 21 (1999): 1897–1912; Vazquez et al, "Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from *Bacillus thuringiensis* HD 73 in mice," *Brazilian Journal of Medical and Biological Research* 33 (2000): 147–155.

[9] Vazquez et al, "*Bacillus thuringiensis* Cry1Ac protoxin is a potent systemic and mucosal adjuvant," *Scandanavian Journal of Immunology* 49 (1999): 578–584. See also Vazquez-Padron et al., 147 (2000b).

[10] L. Moreno-Fierros, N. Garcia, R. Lopez-Revilla, R. I. Vazquez-Padron, "Intranasal, rectal and intraperitoneal immunization with protoxin Cry1Ac from *Bacillus thuringiensis* induces compartmentalized serum, intestinal, vaginal, and pulmonary immune responses in Balb/c mice," *Microbes and Infection* 2 (2000): 885–90.

[11] EPA Scientific Advisory Panel, "*Bt* Plant-Pesticides Risk and Benefits Assessments," March 12, 2001: 76. Available at:
http://www.epa.gov/scipoly/sap/2000/october/octoberfinal.pdf

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