

Genetically Engineered Crops

Do We Need Them?

Robert Wager
Vancouver Island University

Science vs Pseudo-science

The plural of anecdote is **NOT** data

Internet completely un-vetted information

Be wary of internet claims about GM crops and food

What is Agriculture

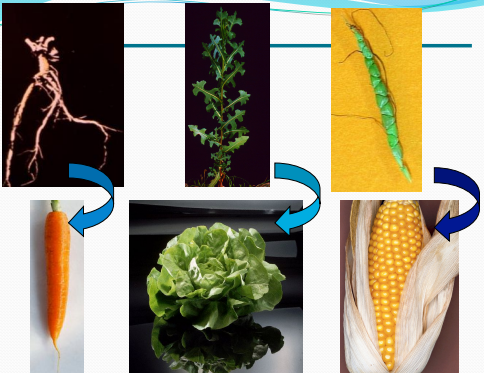
- There is nothing natural about agriculture
- Mankind has been manipulating the DNA of plants and animals for 10,000 years
- Only the methods used to change the DNA have changed over time
- All the changes to the DNA are to suit our needs not those of the plants or animals

Some crops never existed in nature



Einkorn x spelt Emmer x goat grass Bread wheat

www.mpiz-koeln.mpg.de/pr/garten/schau/Triticumaestivum/wh

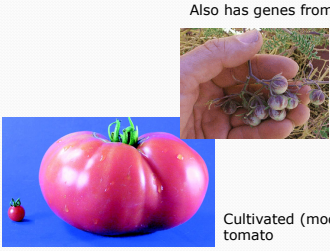


Top: Peggy Lemaux, John Heerde, Raul Coronado
Bottom: Corbis

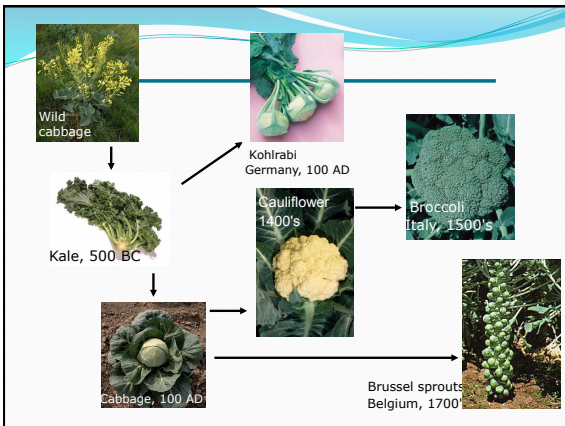
The starting misconception

The Myth of Natural Food

Also has genes from wild species



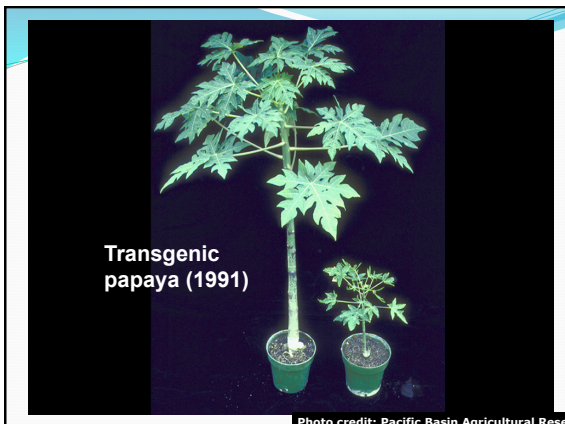
Ancestral tomato Cultivated (modified) tomato

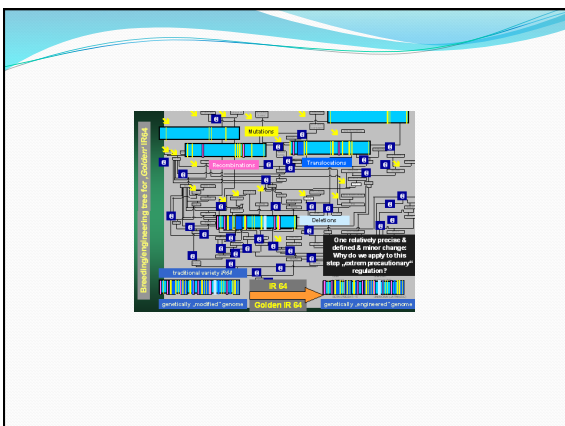


Conventional Breeding and GM Production

<ul style="list-style-type: none"> • <u>Conventional</u> • Mix thousands of genes and traits • Mutate unknown numbers of genes • Extreme inbreeding 	<ul style="list-style-type: none"> • <u>GM Production</u> • Add one or a few genes to a known genetic background • Add only one or a few traits
---	--

•All GM cultivars are scrutinized for 8-13 years before release to growers and up to \$100 million





Is GE Food Safe to Eat?

Global Scientific Opinion

- Moreover, the AAAS Board said, the World Health Organization, the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and “**every other respected organization that has examined the evidence has come to the same conclusion:** consuming foods containing ingredients derived from GM crops is **no riskier** than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques.” (2012)

WHO- 20 Questions about GMO's 2013

- “GM foods currently available on the international market have passed risk assessments and are **not likely to present risks for human health**. In addition, **no effects** on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved.”

What About European Science

- A Decade of EU-Funded GMO Research 2001-2010

Food Safety:

“The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than **500 independent research** groups, is that biotechnology, and in particular GMOs, are **not per se more risky** than e.g. conventional plant breeding technologies.”

German Academies of Science and Humanities GM Food Report 2009

- The report reaches the conclusion that in consuming food derived from GM plants approved in the EU and in the USA, **the risk is in no way higher** than in the consumption of food from conventionally grown plants. On the contrary, in some cases food from GM plants appears to be superior in respect to health.

Vancouver Coastal Health Authority Statement on GM crops to the Richmond City Council 2012

- “There is **no evidence** that Health Canada approved GE foods and food crops are any less safe for human health than non-GE varieties...There is **no public health reason** for a ban on genetically engineered trees, plants and crops as proposed by the resolution to Council.”

• April 26 2012 VCHA

- “**The overwhelming body of scientific evidence** continues to support the safety of NK603, genetically modified food and feed products in general, and glyphosate containing herbicides. However, whenever new information concerning the safety of an authorized product arises, this new data is carefully reviewed.”

- Heath Canada 2012
- <http://www.hc-sc.gc.ca/fn-an/gmf-agm/seralini-eng.php>

Is Organic Agriculture Threatened?

Canadian Organic Regulations

- “Organic practices and this standard cannot assure that organic products are entirely free of residues of substances prohibited by this standard and of other contaminants, since exposure to such compounds from the atmosphere, soil, ground water and other sources may be beyond the control of the operator. The practices permitted by this standard are designed to assure the least possible residues at the lowest possible levels...This standard is intended for certification and regulation to prevent deceptive practices in the marketplace. The **certification of a process, rather than a final product**, demands responsible action by all involved parties.”

- <http://www.spc.gc.ca/eng-c2gb/programme-program/normes-standards/Internet/fo-03-030-2008-eng.pdf>

IFOAM-Position on Genetic Engineering and Genetically Modified Organisms

- The potential of **GMO contamination does not** alter the traditional approach of certifying organic as a “**production method**” rather than an end-product guarantee.
- IFOAM does **not support** the introduction of de minimis thresholds for genetic contamination.
- Because of this, mandatory testing for genetic contamination **should not** be introduced for the verification of organic production.

National Organic Program-USDA

- “As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, **the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.**”

- www.ams.usda.gov/AMSv1.o/getfile?dDocName=STELDEV3004452

Organic Agriculture Not Threatened by GM Crops

- OSGTA v Monsanto NY State District Court 2012
>30,000 organic farmer plaintiffs
- **No evidence** of organic decertification for trace GM
- **No evidence** of Monsanto suing for trace amounts of GM in organic or conventional crops
- Case was dismissed <http://www.nysd.uscourts.gov/cases/show.php?db=special&id=156>

Is GE Crop technology Sustainable?

First Generation GE Crops

Herbicide tolerant

Insect resistant

Viral resistant

Mainly benefitting the farmer and the environment

National Academies of Science- Impact of Genetically Engineered Crops on Farm Sustainability in the US (2010)

- In general, the committee finds that genetic-engineering technology has produced **substantial net environmental and economic benefits** to U.S. farmers compared with non-GE crops in conventional agriculture.

-Generally, GE crops have **had fewer adverse effects** on the environment than non-GE crops produced conventionally.

-The adoption of HT crops complements conservation tillage practices, which **reduce the adverse effects** of tillage on soil and water quality.

-**Insecticide use has decreased** with the adoption of insect-resistant (Bt)crops.

What About European Science

A Decade of EU-Funded GMO Research 2001-2010

Environmental:

“Now, after 25 years of field trials **without evidence of harm**, fears continue to trigger the Precautionary Principle. But Europeans need to abandon this knowingly one-sided stance and strike a balance between the advantages and disadvantages of the technology on the basis of scientifically sound risk assessment analysis.”

Second Generation GMO's

Include direct benefits to the consumer:

- “Golden Rice” high in Beta Carotene
- High starch content potato, high protein potato
- Healthier Oil Plants with no trans-fats
- Iron enriched rice
- Fungal resistant crops
- Viral resistant crops
- In the future hypo-allergenic crops

Canadian Farms 2012

- Organic farms represent <2% of Canadian Farms
- Only 4% rise in organic farm operations 2006-2011
- 2012 saw 14% drop in major organic growing areas (Sask, Man)
- BC Farmer's market receipts up only 3% in 2012
- Non-GM regulations of organic food/feed are **self imposed by organic industry**. The 2% of the farming community should not dictate policy for the other 98% of the farming community?

• Data from Stats Canada 2012

European Organic Bean Sprout Disaster

Germany: Sprouts Did Cause Deadly E. Coli Outbreak (VIDEO)

AP/The Huffington Post

KIRSTEN GRIESHABER and DAVID RISING First

Posted: 06/10/11 09:41 AM ET Updated: 08/10/11 06:12 AM ET

- Over 50 people dead, 3400 people infected (with ~1000 having kidney damage for life)
- The word “organic” is no where in the article

“8 Easy Steps to Surviving an Organic Product Recall”

- 1) Know your customers
 - 2) Be One Step Ahead of Recall Announcements
 - 3) Have an Excellent Insurance Policy in Place
 - 4) Always Pull Questionable Products
 - 5) Understand How Voluntary Recalls Work
 - 6) *Communicate Clearly, Quickly and Honestly*
 - 7) Make the Recall Easy for Customers
 - 8) Choose Your **Public Relations** Team Wisely
- Where is the “investigate what went wrong and how can you prevent it from happening again” part?

<http://organic.about.com/od/retailchallenges/a/8-Easy-Steps-To-Surviving-An-Organic-Product-Recall.htm>

Choice

- **Non-GMO Project Verified Canola Oils From Viterra** 27-Feb-2013
- Viterra is the first canola oil processor verified by the Non-GMO Project.
- **All-Natural Canola Oil** from Viterra is manufactured using a double expeller-pressed process that maintains the natural nutritional value for food applications.
- Our relentless focus on quality, our unique relationship with Western Canadian canola growers and our superior logistical assets, ensure that we can deliver your exact oil requirements.
- **Viterra's Non-GMO canola oils** serve as a key ingredient in products such as cooking oils, snack foods, dressings, sauces, mayonnaise and food manufacturing.

European Law on GM Crop Ban

- France's highest administrative court this week struck down a government ban on the cultivation of the genetically modified (GM) corn variety known as MON 810 after finding that the French government had **failed to provide sufficient evidence that the GMO posed a particularly high level of risk for health and the environment** when it imposed the ban in 2008.
- The European Court of Justice released opinion that French ban on planting GM corn is illegal (Mar 2012)

Safety of Bt Proteins

Both the long history of safe use of *B. thuringiensis* and the acute oral toxicity data allow for a conclusion that these and other δ -endotoxins **pose negligible toxicity risk** to humans.

The overall safety record for Bt has been established in laboratory and field studies, which have looked at both formulated **Bt sprays [Organic] and specific Bt genes [GMO] in planta** (Betz *et al.*, 2000; Siegel, 2001; Federici, 2002).

(UN-OECD 2004)

FDA and GM crop Commercialization

- Voluntary consultation only for whole foods considered GRAS based on 1992 policy
- Very few Transgenic proteins GRAS- mandatory consultation.
- **Of 129 GE crops 129 have had FDA consultation.**
- Global evaluations include: FDA, USDA, EPA, Health Canada, FSANZ, EFSA, Korea FDA, Chinese Ministry of Agriculture, Japan Food Safety Commission etc.

ScientificBeekeeping.com

- Verdict on Bt crops: The specific Bt cry proteins used in GM crops were intentionally chosen to not cause harm to bees. There is **no evidence** to date that they do. On the other hand, Bt crops require less use of insecticides that are clearly toxic to bees [25].
- Verdict on GM crops in general: Allow me to quote from the USDA: *...there is **no correlation** between where GM crops are planted and the pattern of CCD incidents. Also, GM crops have been widely planted since the late 1990s, but CCD did not appear until 2006. In addition, CCD has been reported in countries that do not allow GM crops to be planted, such as Switzerland [33].*

<http://scientificbeekeeping.com/sick-bees-part-8e-colony-collapse-revisited-genetically-modified-plants/>

What is harming the bees?

Neonicotinoids and Bees

Varroa mites and Bees

Glyphosate(Roundup)

- Replaced herbicides with significantly higher EIQ's
- Patent expired.
- "Our review found **no evidence** of a consistent pattern of positive associations indicating a causal relationship between any disease and exposure to glyphosate."

Epidemiologic studies of glyphosate and non-cancer health outcomes: A review, Regulatory Toxicology and Pharmacology 63 (2012) 440-452

Indian Suicides and Bt Cotton

- Rural
 - Has 70% of population but only 13% of suicides
 - Rate dropped 13.6-10.3% past 5 years
 - Sikkim is mainly organic agriculture and has rate 30.3/100,00 (3x national average)
 - Punjab is intensive agriculture and has rate of 3.5/100,000 (1/3 national average)
 - Largest Bt cotton region with very low suicide rate (Gujarat)
 - Greater than 90% of all cotton in India is now Bt
 - India is world leader in cotton production

- Urban
 - Has 30% of population but 87% of suicides
 - Rate has increased 87-90% in past 5 years

Indian Suicides **not** due to Bt Cotton

• Data from Indian National Crime Bureau (www.ncrb.in)

Whole Foods: Totally Organic Produce

Produced with Ionizing Radiation Mutagenesis

THIS PRODUCT CONTAINS GENETICALLY MODIFIED ORGANISMS


THE LONG TERM SAFETY OF CONSUMING GMO PRODUCTS HAS NOT BEEN DETERMINED BY FEDERAL REGULATORY AGENCIES

- "How – and how quickly – can we move healthy, organic products from a 4.2% market niche, to the dominant force in American food and farming?"
- "The first step is to change our labeling laws.
 - -- Ronnie Cummins
 - <https://www.commondreams.org/view/2012/08/02-0>
- Published on Thursday, August 2, 2012 by Common Dreams

- "Personally, I believe GM foods must be banned entirely, but labeling is the most efficient way to achieve this"
 - - Dr. Joseph Mercola
 - <http://articles.mercola.com/sites/articles/archive/2012/02/29/new-vermont-gmo-labeling-policy-officially-introduced.aspx>

A product must be 95% organic to label as organic

- 1 organic seed in 100 does not make the batch organic.
- In fact, 95 of the 100 beans have to be organic before the batch can be labeled as organic.



- Yet, all it takes is for 1 bean to be GM for all 100 to be considered GM by current labeling proposals




OSGTA v Monsanto Court Documents


- <http://www.nysd.uscourts.gov/cases/show.php?db=special&id=156>

American Medical Association 2012 Resolution on GM Food

- Our AMA recognizes the continuing validity of the three major conclusions contained in the 1987 National Academy of Sciences white paper "Introduction of Recombinant DNA-Engineered Organisms into the Environment." The three major conclusions are:
 - (a) There is **no evidence that unique hazards** exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms;
 - (b) The risks associated with the introduction of rDNA-engineered organisms **are the same** in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods;
 - (c) Assessment of the risk of introducing rDNA-engineered organisms into the environment **should be based on the nature of the organism** and the environment into which it is introduced, **not on the method** by which it was produced.)

Regulations

- GMO's are scrutinized to a far greater extent than conventional products
- No product is "Rushed to market"
- 8-13 years from initial production to arrival in the marketplace



*From Pandora's Picnic Basket
by Dr. A. McLughen

B.t. Protein in Maize

TABLE 2
Concentration of protein (microgram per gram of wet plant tissue) in various corn tissues and estimated grams of protein per acre of corn.

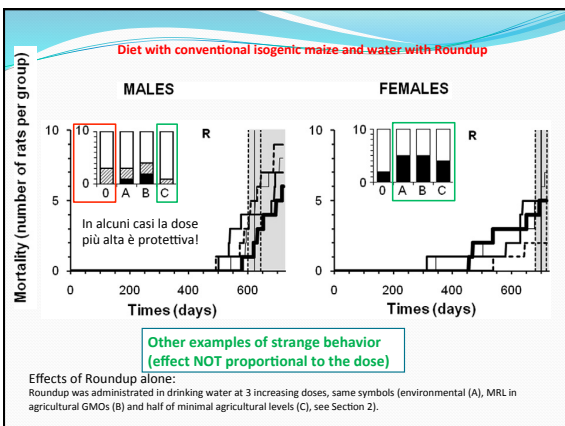
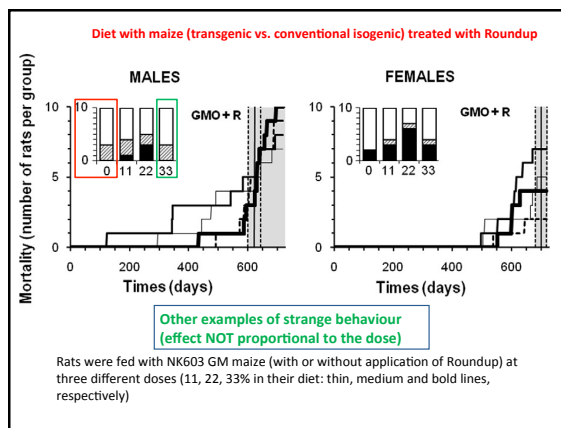
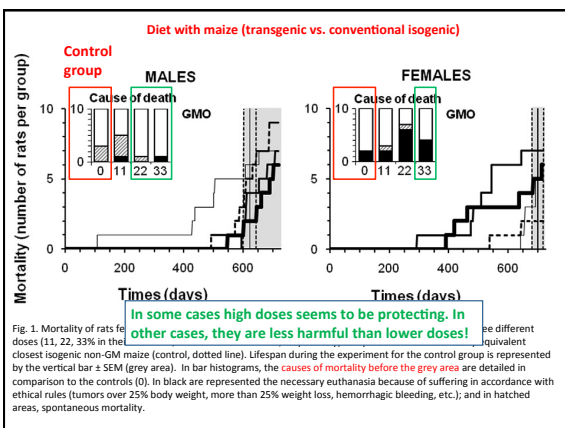
Registered Transgene	Whole Plant	Leaf	Roots	Pollen	Grain	Grams of insecticidal protein per acre
Bt CryIA (b)	3.65-4.65	7.93-10.34	NA	0.09	0.18-0.39	16.4-20.9
Bt CryIA (b)	0.6	4.4	<0.008 (A)	7.1	<0.005 (A)	2.7
Bt CryIA (c) (B)	0.22	0.10-0.26	0.03	NA	0.01	1.5
Bt Cry9C (B)	4.7	9.5	5.6	0.1	4	21.3
Bt spray (C)	NA	NA	NA	NA	NA	1.4
Bt spray (D)	NA	NA	NA	NA	NA	1.4

(A) Limit of detection for the Novartis transgene protein was roots, 0.008 µg protein per gram tissue and grain, 0.005 µg/g
(B) In the REED the data were expressed per unit of dry tissue weight; all values were adjusted to wet weight using a median wet weight transformation factor of 0.215 published for sweet corn. (See endnote 1B)
(C) Assumed a maximum rate of spray application of 0.81 kg/acre with a formulation containing 1.7% delta-endotoxin. (See endnote 1)
(D) Data not available.

Types of GM Products

- **Canada:** 15 Maize, 11 Canola, 5 Cotton, 4 Potato, 3 Tomato, 4 Squash, 1 Flax, 4 Soya, 1 Wheat, 1 Sugar beet
- **USA:** 12 Maize, 7 Canola, 6 Tomato, 5 Cotton, 4 Potato, 3 Soya, 2 Sugar Beet, and 1 Squash, Papaya, Flax, Chicory and Cantaloupe
- **UK:** 5 Canola, 3 Tomato, 1 Maize, 1 Soya

• Seralini



Health Canada response to Seralini paper

Following a review of the published data, scientists from Health Canada and the Canadian Food Inspection Agency (CFIA) have identified **significant shortcomings in the study design, implementation and reporting**. The methodology used was inadequately described, the full data set was not presented, and the data that was reported was not presented in a transparent manner. Furthermore, the **statistical methods used by the authors to analyze the data were judged to be inappropriate**. These limitations make the validity of the study results difficult to determine...The **overwhelming body of scientific evidence continues to support the safety of NK603, genetically modified food and feed products in general, and glyphosate containing herbicides**.

However, whenever new information concerning the safety of an authorized product arises, this **new data is carefully reviewed**. Should any risks of concern be identified from the consumption of NK603 or exposure to glyphosate, Health Canada and the CFIA will take appropriate action.

- <http://www.hc-sc.gc.ca/fn-an/gmf-agm/seralini-eng.php>
- **Third time** Seralini et al has been caught publishing pseudo-science.

European Food Safety Authority statement on Seralini et al 2012

- On 19 September 2012, Seralini et al. published online in the scientific journal Food and Chemical Toxicology a publication describing a 2-year feeding study in rats investigating the health effects of genetically modified (GM) maize NK603 with and without Roundup WeatherMAX® and Roundup® GT Plus alone (both are glyphosate-containing plant protection products). EFSA was requested by the European Commission to review this publication and to identify whether clarifications are needed from the authors. EFSA notes that the Seralini et al. (2012) study has unclear objectives and is inadequately reported in the publication, **with many key details of the design, conduct and analysis being omitted**. Without such details it is impossible to give weight to the results. Conclusions cannot be drawn on the difference in tumour incidence between the treatment groups on the basis of the design, the analysis and the results as reported in the Seralini et al. (2012) publication. In particular, Seralini et al. (2012) draw conclusions on the incidence of tumours based on 30 rats per treatment per sex which is an insufficient number of animals to distinguish between specific treatment effects and chance occurrences of tumours in rats. **Considering that the study as reported in the Seralini et al. (2012) publication is of inadequate design, analysis and reporting, EFSA finds that it is of insufficient scientific quality for safety assessment.** Therefore EFSA, concludes that the Seralini et al. study as reported in the 2012 publication does not impact the ongoing re-evaluation of glyphosate, and does not see a need to reopen the existing safety evaluation of maize NK603 and its related stacks. **EFSA will give the authors of the Seralini et al. (2012) publication the opportunity to provide further information on their study to EFSA.**
 - © European Food Safety Authority, 2012
 - Seralini refused to give omitted raw data to the EFSA.

Partial List of World Food Safety Authorities that are critical about Seralini et al 2012

- Health Canada
- Canadian Food Inspection Agency
- European Food Safety Authority
- Food Standards Australia New Zealand
- German Federal Institute of Risk Assessment
- German Federal Office of Consumer Protection and Food Safety
- France- ANSES (Agency for Food, Environmental, and Occupational Health and Safety)
- France- HCB (High Council for Biotechnology)
- Six Academies of Science (France)
- Denmark- DTU National Food Institute
- Netherlands- Bureau for Risk Assessment (Netherlands Food and Consumer Product Safety Authority)
- Brazil- CTNBio (Brazilian National Technical Commission on Biosafety)
- Belgium- BAC (Biotechnology Advisory Council)
- Romania (Food Safety Authority)
- Belgium- VIB (Life Sciences Institute)
- French Society of Toxicological Pathologists (SFPT)
- European Federation of Biotechnology
- AFBV (French Association for Biotechnology Vegetables)
- ABNE (African Biosafety Network of Expertise)
- ACB (African Center for Biosafety)
- European Society of Toxicological Pathology

Global Science Complaints about Seralini et al 2012

- Over 700 Scientists signed petition demanding Seralini release data
- 17 LITTE of FCT complaints about the Seralini et al 2012 publication
- European Society of Toxicological Pathology:

“We would like to finish our commentary with a question: what is the scientific rationale that led the journal reviewers and the editorial board of Food and Chemical Toxicology to accept this article for publication.”

European Food Safety Authority Report on Previous Seralini publications

- The EFSA GMO Panel has considered the paper by de Vendômois et al. (2009, A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health, *International Journal of Biological Sciences*, 5: 796-797), a statistical reanalysis of data from three 90-day rat feeding studies already assessed by the GMO Panel (EFSA, 2009a,b; EFSA 2009a,b; EFSA 2009b,c). The GMO Panel
- concludes that the authors' claims, regarding new side effects indicating kidney and liver toxicity, are not supported by the data provided in their paper. **There is no new information** that would lead it to reconsider its previous opinions on the three maize events MON80, MON863 and NK603, which
- concluded that there were no indications of adverse effects for human, animal health and the environment.
- The GMO Panel notes that general of its fundamental statistical criticisms (EFSA, 2009a,b) of the authors' earlier study (Seralini et al., 2007) of maize MON863 are also applicable to the new paper by de Vendômois et al. The significant differences highlighted by de Vendômois et al. have all been considered previously by the GMO Panel in its previous opinions on the three maize events MON80, MON863 and NK603.
- The study by de Vendômois et al. provides no new evidence of toxic effects.**

<http://www.efsa.europa.eu/en/events/event/gm100127.htm>

• GMO Myths and Truths

Reference Analysis of GMO Myths and Truths

- “Even natural Bt toxin has been found to have negative health effects. In farm workers, exposure to Bt sprays was found to lead to allergic skin sensitization and immune responses. (84)” GMT pg.51
- Reference 84 says: “**did not find** significant reaction to a preparation of Bt protein in the group of workers that exhibits an immune response to whole B. thuringiensis... **no allergy or clinical symptoms** were ever seen”

Reference Analysis of GMO Myths and Truths

- “One type of Bt toxin killed human cells at the dose of 100 parts per million. The findings showed that GM Bt toxin does affect humans, contrary to claims from the GM lobby and regulators.(83)” GMT pg. 51
- Reference 83 is the **completely discredited** Seralini et al
- Toxic effects on the small intestine, liver, kidney, spleen, and pancreas(12,14) **Seralini et al**
- Reduced weight gain **Seralini et al**

Reference Analysis of GMO Myths and Truths

- “A study on cows found that Bt toxins from GM maize MON810 were not completely broken down in the digestive tract.(99)” GMT pg. 52
- Reference 99 states: “In comparison with total protein in feed, the relative amount of Cry1Ab protein in feces is markedly reduced indicating that Cry1Ab protein is **not more stable** than other proteins in feed”

Reference Analysis of GMO Myths and Truths

- “A study simulating human digestion found that the Bt toxin protein was highly resistant to being broken down in realistic stomach acidity conditions and still produced an immune response.(100)” GMT pg.52
- Reference 100 states: “**It is unlikely** that such low doses of Cry1Ab fragments would induce a mucosal response in humans”

Reference Analysis of GMO Myths and Truths

- “But independent scientists disagree. A 2003 review states that compared with conventional breeding, GM has a “*greater potential to introduce novel proteins into the food supply*” and increase the likelihood of allergic reactions.(103)” GMT pg. 53
- Reference 103 actually states: “Although theoretically **any plant-breeding technique can modify the allergenicity of foods**, biotechnology has a greater potential to introduce novel proteins into the food supply, and thus has been subjected to closer scrutiny by regulators.”

Allergenicity

- “Notwithstanding the limits of current technology, a GM food which has undergone a thorough, scientifically valid evaluation process for allergenicity, with negative results, should be considered at low risk to provoke or induce allergic responses and could possibly be **even safer** than a non-GM novel or exotic food which has not been subjected to the same scrutiny”
- Royal Society of Canada-2000

Reference Analysis of GMO Myths and Truths

- “The seriousness of CDC’s error in using E. coli- rather than maize-derived Cry9C protein is graphically illustrated by the study on GM peas containing an insecticidal protein from beans (4)” GMT pg. 50
- Reference 4 states: “we examined the gastrointestinal tract of pea and transgenic pea-fed mice and **observed no histological abnormalities** in either group...**we do not know** the frequency at which the structure and immunogenicity of transgenic expressed proteins occurs or **whether this is unique to transgenic** expressed alpha A1 amylase.”

Reference Analysis of GMO Myths and Truths

- “Glyphosate, AMPA, and especially the commercial formulation Roundup have been found to be toxic, in some cases at extremely low levels.^{13,14,15} GMT pg.65
- This statement references Seralini *et al.* The EFSA examined the Seralini so-called research; they completely dismissed it: **“Considering that the study as reported in the Seralini *et al* (2012) publication is of inadequate design, analysis and reporting, EFSA finds that it is of insufficient scientific quality for safety assessment.”**

Rebuttal to a review of Dona and Arvanitoyannis 2009

- An examination of the search criteria reveals that **the word safety was not included** in the search parameters.
- Changing the search parameters to “*GM food safety*” found 419 hits in pubmed.
The authors incorrectly concluded:
“studies focused on demonstrating the health safety of GM foods remain very limited”
because they intentionally avoided all such literature.

Rebuttal to a review of Dona and Arvanitoyannis 2009

- This paper, published recently in “Critical Reviews in Food Science and Nutrition” by the internationally well known editorial house Taylor & Francis, needs to be critically commented for a multitude of reasons:
- In a first overview, the reader will find a lot of mostly unconfirmed concerns about the safety of foods derived from GM crops, the citations are extremely filtered in a way to depict a negative picture on GM crops, and the review authors seem to lack proper knowledge about the field of food safety as a whole.
- They also publish numerous paragraphs as their own writings, whereas they are just taken by copy-paste from other publications, and worse: those placatory passages are selected from papers with a negative bias and with notorious contents, which have been rebutted recently and for the majority even some years ago. Most of those rebuttals are written by the best authorities in the field, well publicized and easily obtainable in the internet or in libraries from the best peer reviewed journals.
- Thus Dona et al. give the uninformed reader the wrong picture, as if the food safety situation in 2008 would still be precarious. This is simply not the case and in summary this is a blatant example of scientific distortion of the overall picture in this field of scientific research on food safety.
- <http://www.ask-force.org/web/AF-7-Dona-rebuttal/AF-7-Dona-2012016-opensource.pdf>

Mice Fertility Study Retracted.

- Austria withdraws study on the long-term consequences of GM maize
- (26 March 2010) Austria has withdrawn a study on long-term feeding trials with mice that was published in November 2008. The study had caused quite a public stir since some of the mice that were fed with genetically modified maize gave birth to fewer offspring. The media and gene technology critics had interpreted the result as evidence of a reduced fertility caused by GM maize.
- The Austrian government had already announced in a meeting of the ‘Standing Committee for the Food Chain and Animal Health’ at the EU commission in October 2009 that the scientists commissioned to do the study had not managed to present a ‘satisfactory statistical evaluation’ of the data. In addition, the Austrian Ministries that had commissioned the study no longer expected to receive such an evaluation.

Union of the German Academies of Science and Humanities: Are there hazards for the consumer when eating food from genetically modified plants?

- **Abstract**
- On the basis of existing scientific literature this report examines the potential risks for people who consume products of genetically modified (GM) plants. Taken into account are toxicity, the potential of causing cancer and food allergies, and the effects of consuming foreign DNA, including the DNA of antibiotic resistance genes.
- The report reaches the conclusion that in consuming food derived from GM plants approved in the EU and in the USA, **the risk is in no way higher** than in the consumption of food from conventionally grown plants. On the contrary, in some cases food from GM plants **appears to be superior in respect to health.**

Review Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: Chelsea Snell, et al.

- **abstract**
- The aim of this systematic review was to collect data concerning the effects of diets containing GM maize, potato, soybean, rice, or triticale on animal health. **We examined 12 long-term studies (of more than 90 days, up to 2 years in duration) and 12 multigenerational studies (from 2 to 5 generations).** We referenced the 90-day studies on GM feed for which long-term or multigenerational study data were available. Many parameters have been examined using biochemical analyses, histological examination of specific organs, hematology and the detection of transgenic DNA. The statistical findings and methods have been considered from each study. **Results from all the 24 studies do not suggest any health hazards and, in general, there were no statistically significant differences within parameters observed.** However, some small differences were observed, though these fell within the normal variation range of the considered parameter and thus had no biological or toxicological significance. If required, a 90-day feeding study performed in rodents, according to the OECD Test Guideline, is generally considered sufficient in order to evaluate the health effects of GM feed. The studies reviewed present evidence to show that GM plants are nutritionally equivalent to their non-GM counterparts and can be safely used in food and feed.
- Food and Chemical Toxicology 50 (2012) 1134–1148

Effects of genetically modified T2A-1 rice on faecal microflora of rats during 90 day supplementation

- **Abstract**

Many animal studies have been performed on products with the *Bacillus thuringiensis* insecticidal toxin-encoding gene (Bt products), but less have focused on its effects on intestinal micro-flora owing to difficulties in culturing. This 90 day study was designed to assess unintended effects of genetically modified T2A-1 rice (GMR) on selected intestinal bacteria (*Lactobacillus* group, *Bifidobacterium* genus, *Escherichia coli* subgroup, *Enterococcus* genus and *Clostridium perfringens*) of rats by the real-time polymerase chain reaction (PCR) method.

- **CONCLUSION:**

No adverse effects on the numbers of specific bacteria in rat feces were observed as a result of GMR feeding.

Evaluation of genetically engineered crops using transcriptomic, proteomics and metabolomic profiling techniques

- **Abstract**

Transcriptomic, proteomic, and metabolomic profiling techniques have been increasingly applied to the analysis of genetically engineered (GE) crop plants with regard to their food safety and nutritional equivalence. This literature survey is based on 44 recent "omic" comparisons between GE and non-GE crop lines with or without deliberate modification of metabolic pathway... Transgenesis **has less impact** on the expression of genomes or on protein and metabolite levels than conventional breeding or plant (non-directed) mutagenesis when comparison is available... From a scientific point of view, these observations indicate that the current regulatory burden on GE crops should be lowered.

- **Plant Physiology Preview. Published on February 24, 2011**

Next-generation protein-rich potato expressing the seed protein gene AmA1 is a result of proteome rebalancing in transgenic tuber

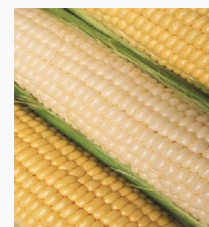
- **Abstract**

Protein deficiency is the most crucial factor that affects physical growth and development and that increases morbidity and mortality especially in developing countries. Efforts have been made to improve protein quality and quantity in crop plants but with limited success. Here, we report the development of transgenic potatoes with **enhanced nutritive value** by tuber-specific expression of a seed protein, AmA1 (Amaranth Albumin 1), in seven genotypic backgrounds suitable for cultivation in different agro-climatic regions. Analyses of the transgenic tubers revealed up to 60% increase in total protein content. In addition, the concentrations of several essential amino acids were increased significantly in transgenic tubers, which are otherwise limited in potato. Moreover, the transgenics also exhibited enhanced photosynthetic activity with a concomitant increase in total biomass. These results are striking because this genetic manipulation also resulted in a moderate increase in tuber yield. The comparative protein profiling suggests that the proteome rebalancing might cause increased protein content in transgenic tubers. Furthermore, the data on field performance and safety evaluation indicate that the transgenic potatoes are suitable for commercial cultivation. In vitro and in vivo studies on experimental animals demonstrate that the transgenic tubers are also safe for human consumption. Altogether, these results emphasize that the expression of AmA1 is a potential strategy for the nutritional improvement of food crops.

This work was supported by the Department of Science and Technology, Department of Biotechnology, Ministry of Science and Technology, the Government of India, and the National Institute of Plant Genome Research, India.
PNAS | October 12, 2010 | vol. 107 | no. 41 | 17533-17538



Teosinte



Modern corn

Global Problem with Aluminum

- Aluminum one of most abundant minerals
- Over 2 billion acres affected, 30% of all arable land, mostly in sub tropical and tropical areas.
- Again, traditional breeding has almost no success
- Biotechnology will help address this issue

Global Problem with Salt

- Each year 25 million acres are lost to salt
- in 30 years 10% of all arable land
- Traditional breeding has almost no success
- Biotechnology has isolated genes from mangroves and sea-dune grasses resulting in salt tolerant crops.

Yield Data

Developed World

- Positive yield studies- 36
- Neutral yield studies- 18
- Negative yield studies- 7

Developing World

- Positive yield studies- 88
- Neutral yield studies- 13
- Negative yield studies- 6

• Nature Biotechnology Vol8 no 4, p339

EFSA Quotes

- Many feeding trials have been reported testing GM maize, potatoes, rice, soybeans and tomatoes on rats or mice for prolonged periods, and parameters such as body weight, feed consumption, blood chemistry, organ weights, histopathology etc have been measured. The food and feed under investigation were derived from GM plants with improved agronomic characteristics like herbicide tolerance and/or insect resistance. The majority of these experiments did not indicate clinical effects or histopathological abnormalities in organs or tissues of exposed animals. These studies can be used to assist the safety evaluation of GM plant derived food and feed and to reach conclusions on whether they can be considered as safe as their conventional counterpart. **In some cases adverse effects were noted, which are difficult to interpret due to shortcomings in the studies.**

EFSA Quotes

- Based on studies with a range of chemical compounds, it can be concluded that a **90-day study shows a relatively large capacity in terms of measurable toxicological endpoints to detect potential toxicological effects.**
- Laboratory animal feeding studies of **90-days duration appear to be sufficient to pick up adverse effects of compounds** that would also give adverse effects after chronic exposure, and therefore in general, chronic toxicity testing of GM food and feed does not seem to generate additional valuable information to the safety assessment.
- Many subchronic feeding studies in rodents have been conducted over the past 15 years on food and feed derived from GM plants developed so far. **Those studies which were well designed and followed internationally accepted protocols did not reveal indications of adverse effects.** The results obtained from the testing of GM food and feed in rodents indicate that large safety margins can be established between the levels of animal exposure and the estimated human daily intakes without adverse effects.

Review

Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials (2008)

- Considerations for safety and nutritional assessment of GM food and feed
- In silico and in vitro methods
- Laboratory animal models for toxicity testing of single substances
- Laboratory animal models for the safety and nutritional assessment of whole GM food and feed
- Target animal models for the nutritional and safety assessment of GM feed
- Standards for test sample preparation, test materials, diet formulation and analysis.
- Formulation of test and control diets
- Types of diets used for target animal studies
- Data collection, analysis and interpretation in the hazard characterisation procedure.
- Strategies for the safety and nutritional assessment of GM plant derived food and feed
- **Conclusions and recommendations** S98
- 7.1. The comparative approach to safety and nutritional testing of food and feed derived from GM plants S98
- 7.2. Experience from testing of non-GM and GM whole foods S98
- 7.3. In silico and in vitro tools available for safety and nutritional testing of GM plant derived food and feed S99
- 7.4. Testing of defined single substances from GM plant derived food and feed in in vivo studies S99
- 7.5. Testing of whole GM plant derived food and feed in animal feeding studies S99
- 7.6. Importance of a structured approach for development of data for the pre-market safety and nutritional testing of
 - GM plant derived food and feed S61

EFSA Guidelines for Risk Assessment of Food and Feed from GM Plants (2011)

- Principles of Risk Assessment (4 subcategories)
- Molecular Characterization (2 subcategories)
- Comparative Assessment (5 subcategories)
- Toxicological Assessment (5 subcategories)
- Allergenicity Assessment (3 subcategories)
- Nutritional Assessment (2 subcategories)
- Exposure Assessment
- Risk Characterization