Testimony on I-522, the legislative initiative to label genetically engineered seeds and food, before the House Agriculture and Natural Resources Committee, and the Technology and Economic Development Committee
Olympia, WA
By
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Dear House committee members,

Thank you for the opportunity to present testimony in support of I-522, the legislative initiative to label genetically engineered seeds and food. My name is Michael Hansen and I am a senior scientist at Consumers Union1[1] (CU), the policy and advocacy arm of Consumer Reports. I have worked on the issue of genetically engineered (GE) foods for more than 20 years and have been involved in the decisions/debate about these foods at the state, national and international levels.

There is global agreement that genetic engineering is different than conventional breeding and that safety assessments should be completed for all GE foods, including crops and animals, prior to marketing. The definition of genetic engineering used in I-522 is the same definition that has been used internationally and refers to *in* vitro nucleic acid technologies, which have developed in the last 40 years or so. Genetic engineering is a new technology. Humans have not been genetically engineering plants an animals for thousands of years as some might claim. With genetic engineering you can move cow genes into pigs, flounder gene into tomato, scorpion gene into corn, mouse gene into pigs, spider gene into goats, human genes into rice, barley, and safflower, and jellyfish genes into rabbits and dogs. All these examples of new life forms that have been created using GE could never be created using conventional breeding or even new techniques like irradiation breeding or mutation breeding. GE has also been used to move genes for resistance to the antibiotics kanamycin, streptomycin and amoxicillin into plants; again a feat that cannot be accomplished by conventional, mutation or irradiation breeding. Genetic engineering is a relatively new technology that raises unique safety issues and should be subject to mandatory premarket safety assessment for all GE foods.

The human safety problems that may arise from GE include introduction of new allergens or increased levels of naturally occurring allergens, of plant toxins, and changes in nutrition. There may also be unintended effects. Codex Alimentarius, the food safety standards organization of the United Nations, whose standards are referenced by the World Trade Organization, developed a number of documents, including a Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45, 2003); there are separate

[1] Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports, a non-profit, is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.

Guidelines for GE animals (CAC/GL 68, 2008) and GE microorganisms (CAC/GL 46, 2003), as well.[2] Many of our major trading partners, including the European Union, Japan, Korea and other Pacific Rim countries, do require mandatory premarket safety assessments.

The United States, however, unlike all other developed countries, does not require safety testing for genetically engineered (GE) plants (although it does require an assessment for GE animals). The US Food and Drug Administration's (FDA) original policy on GE (or GM, for genetically modified) plants, developed more than twenty years ago,[3] says that companies may go through a "voluntary safety consultation." But, in the end, FDA says it is up to the companies to determine safety of any GE food. To date, there have been some 94 "voluntary safety consultations."

The inadequacy of FDA's policy can be seen in the letter FDA sends to the company after completion of a "safety consultation." For example, the letter sent to Monsanto on September 25, 1996 about one of their first Bt-corn varieties, MON810, states, "Based on the safety and nutritional assessment you have conducted, **it is our understanding that Monsanto has concluded that corn grain and forage derived from the new variety are not materially different in composition, safety, or other relevant parameters from corn grain and forage currently on the market, and that they do not raise issues that would require premarket review or approval by FDA**" (**bold** added).[4]

The letters for all 94 "safety consultations" done since the first, for the Flavr Savr tomato, contain basically the same language. This clearly shows that the FDA has not made a conclusion about the safety for genetically engineered (GE) plants or the safety of the technology as a whole.

Just last June, the American Medical Association's House on Delegates voted to change its policy on "bioengineered" foods to one calling for "mandatory premarket systematic safety assessments": "**Our AMA supports mandatory pre-market systematic safety assessments of bioengineered foods** and encourages: (a) development and validation of additional techniques for the detection and/or assessment of unintended effects; (b) continued use of methods to detect substantive changes in nutrient or toxicant levels in bioengineered foods as part of a substantial equivalence evaluation; (c) development and use of alternative transformation technologies to avoid utilization of antibiotic resistance markers that code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic research in food allergenicity to support the development of improved methods for identifying potential allergens. The FDA is urged to remain alert to new data on the health consequences of bioengineered foods and update its regulatory policies accordingly"[5] **bold** added. Clearly, there are unanswered safety questions associated with GE plants.

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[2] At: http://www.codexalimentarius.net/web/standard_list.do?lang=en

[3] Pg. 22991 in FDA. Statement of Policy: Foods Derived From New Plant Varieties, May 29, 1992, *Federal Register* vol. 57, No. 104. At: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm

[4] At: http://www.fda.gov/Food/Biotechnology/Submissions/ucm161107.htm

[5] http://www.ama-assn.org/resources/doc/yps/ref-comm-e-grid.pdf

Unlike GE plants, FDA does require safety assessments for GE animals. A GE salmon, called AquAdvantage Salmon (AAS), is most of the way toward approval. This GE salmon is engineered to grow to market size in half the time of the non-GE salmon. However, numerous experts, including Consumers Union,[6] have criticized FDA's health assessment and its environmental assessment[7] as grossly inadequate.

On the health side, we have serious concerns that the GE salmon may have increased allergy-causing potential. A study using sera from people allergic to Atlantic salmon showed a highly statistically significant increase in allergenic potency of the engineered salmon compared to the non-GE salmon.[8] Yet, FDA chose to disregard this finding, concluding from data on just six fish, that there are no allergy concerns. This is not scientifically defensible.

One big problem with safety assessments of GE plants is that there have been virtually no long-term animal feeding studies, with most feeding studies being of 90 days or shorter. A carefully designed meta-analysis was done of 19 published studies involving mammals fed GE corn or soy.[9] The meta-analysis also included the raw data from all the published studies that could be found as well as a number of 90-daylong feeding studies that were obtained as a result of court action or official requests. The meta-analysis highlighted damage in the kidney, liver and bone marrow, which could be potential indicators for the onset of chronic diseases.[10] However, no animal tests are obligatory for any of the GMOs cultivated on a large scale in the US.

Last fall, a study was published that was the first long-term (e.g. 2 years) feeding study which involved rats fed Roundup-resistant corn (NK 603).[11] The study found that females rats fed the GE corn died 2-3 times more quickly, and developed mammary tumors more often than controls who ate non-GE corn, while male rats fed the GE corn have liver and kidney problems at higher rate than controls, and more large tumors than rats fed non-GE corn. This study, by Dr. Giles-Eric Séralini received a lot of media attention. The study was viciously attacked in the media by pro-GE and industry-affiliated scientists in what appears to have been an orchestrated campaign.[12] The two main criticisms were that they used too few rat per group and that they used a strain of rat (Sprague Dawley) that is prone to mammary tumors as they age. Both criticisms are off base. The Séralini et al. study took measurements on 10 rats per group, the same number of rats that Monsanto took measurements on in their 90 day feeding study, which

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[6] Hansen, M. 2010. Submission to FDA's Veterinary Medicine Advisory Committee meeting on safety assessment of AquAdvantage Salmon. http://www.consumersunion.org/pdf/CU-comments-GE-salmon-0910.pdf

[7] LeVaux, A. 2013. A risk scientist comments on AquAdvantage Salmon. February 13, 2013. At: http://www.flashinthepan.net/?p=999

[8] See Hansen, 2010. Op cit.

[9] Séralini, G-E, Mesnage, R., Clair, E., Gress, S., de Vendômois, JS and D. Cellier. 2011. Genetically modified crops safety assessments: present limits and possible improvements. *Environmental Sciences Europe*, 23: 10. At: http://www.enveurope.com/content/pdf/2190-4715-23-10.pdf

[10] Pg. 1 in IBID.

[11] Séralini et al. 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and Chemical Toxicology*, 50: 4221-4231. http://www.sciencedirect.com/science/article/pii/S0278691512005637

[12] Bardocz S, Clark A, Ewen S, Hansen, M, Heinemann J, Latham J, Pusztai A, Schubert D and A Wilson. 2012. Séralini and science: An open letter. *Independent Science News*. At: http://independentsciencenews.org/health/seralini-and-science-nk603-rat-study-roundup/

was published in the same journal eight years before the Séralini study. If ten rats is too small a sample size to demonstrate health problems, how come ten rats is a sufficient sample size to demonstrate no safety concerns? As for the strain of rat use, Séralini used the same strain (Sprague Dawley) that was used in the Monsanto feeding study. In addition, the same strain of rat was used in a Monsanto-sponsored two-year feeding study of rats fed glyphosate as part of a reregistration process in Europe. Why is use of SD rats bad when Séralini uses them, but ok when Monsanto and other biotech companies use them?

Both the French Food Safety Agency (ANSES) and the European Food Safety Authority (EFSA) have concluded that such long-term safety assessment should be done on GE foods. Indeed, the ANSES report on the Séralini study notes, "ANSES recommends initiating studies and research on the long-term effects of GMOs in combination with plant protection products … [and] calls for public funding on the national and European level to enable large-scale studies and research for consolidating knowledge of insufficiently documented health risks."[13] At a meeting in December, the "EFSA board meeting on Thursday last week there was agreement that long-term studies were needed and it was now just a question of how to fund them."[14] If the Séralini study is so flawed, why have ANSES and EFSA functionally agreed with its call for independently-funded long-term feeding studies on GE crops?

In addition to FDA not requiring any premarket safety testing, there is virtually no independent safety testing of these crops in the US due to intellectual property right problems. When farmers buy GE seed in the US, they invariably must sign a product stewardship agreement which forbids them from giving such seeds to researchers.[15] In addition, researchers must get permission from the biotech companies before they can do research, the result is a paucity of independent research. Scientists have even been threatened with legal action if they revealed information obtained via freedom-of-information.[16] In early 2009 26 public sector scientists in the US took the unprecedented step of writing to the US Environmental Protection Agency (EPA) protesting that "as a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology."[17] As a result, the editors of Scientific American published a perspective stating that "we also believe food safety and environmental protection depend on making plant products available to regular scientific scrutiny. Agricultural technology companies should therefore immediately remove the restriction on research from their end-user agreements." We concur and believe that only truly independent safety tests will give us an answer about the safety of GE foods. In the meantime, it's crucial that GE foods be labeled, so that if people experience negative effects, they and their doctors can identify them.

Consumers Union has long favored labeling of all GE foods on health grounds, as well as giving consumers choice over what they eat. Given the scientific uncertainties about the potential

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[13] Reaction of ANSES (French Agency for food, environmental and occupational health and safety) to Séralini et al. study http://www.anses.fr/Documents/PRES2012CPA20EN.pdf

[14] Commission and EFSA agree need for two-year GMO feeding studies. EU Food Policy, 17 December 2012 http://www.eufoodpolicy.com/cgi-bin/view_article.pl?id=5590

[15] Waltz, E. 2009. Under wraps. Nature Biotechnology, 27(10): 880-882. At: http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf

[16] IBID

[17] http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research

health impacts of GE foods, it is essential to label GE plants and animals so as to be able to track any potential adverse human health or nutritional impacts. It will be very difficult for FDA or a doctor to identify the source of any unforeseen problem if they have no idea what foods a person is eating. For example, suppose a company decides to insert a synthetic gene, which codes for a modified protein, into corn and decides not to notify the FDA for currently acceptable reasons (i.e. the company thinks that the modification was "minor"). Suppose that the novel protein causes a strong but delayed (say by 24 hours) allergic reaction (e.g. serious rash, upset stomach, or anaphylactic shock) in some relatively small subset of the population. To start with, doctors would have an extremely difficult time identifying the source of the problem.
If the offending GE corn variety is not very prevalent (i.e. does not have a large market share), then the regular allergy test, making a list of all foods eaten in the last 24 hours, might not uncover the GE corn as the source of the problem (the person would have to obtain and eat the offending GE corn variety a second time and get the same reaction). It might well take large numbers of people being adversely affected and having the offending GE corn variety be a large share of the market before there would be any hope of figuring out that a problem even existed.

Finally, at least 62 countries, which together include more than half the world's population, (including all European Union, China, India, Japan, Korea, Australia, Russia, Brazil and South Africa), require labeling of GE foods.[18] A number of polls from 1995 to 2011 have found that between 70% and 95% of Americans polled supported mandatory labeling.[19] A 2008 Consumers Union nationwide poll found that 95 percent of respondents said they thought food from genetically engineered animals should be labeled, and 78 percent strongly agreed with this.[20] A ballot initiative last November in California (Prop 37) lost by just 51% to 49%, despite an advertising blitz in which industry outspent consumer and environmental groups by over five to one. Recent polling of those who voted no on Prop 37 showed that 20% actually favor GE labeling, but were convinced by the industry ads that this initiative was poorly worded or too weak.[21]

For all these reasons, CU strongly supports I-522.

[18] See http://www.centerforfoodsafety.org/ge-map/
[19] http://gefoodlabels.org/gmo-labeling/polls-on-gmo-labeling/
[20] At: http://www.greenerchoices.org/pdf/foodpoll2008.pdf
[21] http://gefoodlabels.org/2013/01/10/post-prop-37-poll-shows-strong-public-support-for-future-ge-food-labeling/