Testimony on I-522, the legislative initiative to label genetically engineered seeds and food, before the Senate Agriculture, Water and Rural Economic Development Committee, Olympia, WA

By
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Dear Senators,

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 Union[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.

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 human safety problems that may arise 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, 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 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. Unlike all other developed countries, the US Food and Drug Administration (FDA) does not require safety testing for genetically engineered (GE) plants (although it does require an assessment for GE animals). The FDA's original policy on GE (or GM, for genetically modified) plants, developed more than twenty years ago,[3] says that companies may go

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[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 .*

[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

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 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]. Clearly, there are unanswered safety questions associated with 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 have criticized FDA's health assessment[6] and its environmental assessment[7] as grossly inadequate.

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[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

[6] Hansen, M. 2010. Submission to FDA 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

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 foods 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 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 kidneys and livers which could be 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. Although the study was attacked as being of poor quality, it turns out that 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, ANSES report on this 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."[12] 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."[13]

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 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

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

[13] 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

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 GE 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 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 corn as the source of the problem (the person would have to obtain and eat the offending 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 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.[14] A number of polls from 1995 to 2011 have found that between 70% and 95% of Americans polled supported mandatory labeling.[15] 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.[16] 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.[17]

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

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