

Written testimony on SB 778, a Bill to Require Labeling of Genetically Engineered Food  
before the Maryland Senate Health Committee

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By

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Thank you for the opportunity to present testimony in support of SB1666, a bill that would require the labeling of food and food products derived from genetically engineered (GE) organisms. My name is Michael Hansen and I am a biologist at Consumers Union<sup>1</sup> (CU), the policy and advocacy arm of Consumer Reports, whose headquarters is located in Yonkers. I have worked on the issue of genetically engineered 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 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, has developed a set of documents on this topic.<sup>2</sup>

Unlike other developed countries, the US does not require genetically engineered plants to be proven safe before they can go on the market, despite significant safety concerns. A review of the scientific literature shows there are still open questions about the safety of genetically engineered foods, with independent studies finding some evidence of adverse effect, while other studies, often funded by industry or performed by industry-affiliated scientists, tend to find no safety problem.<sup>3</sup> But even if all reasonable safety testing were required, certain individuals could still have unusual allergic responses that would not be detected beforehand. Finally there can be unexpected effects--just as there are sometimes to pharmaceutical products, despite extensive premarket testing. For all these reasons, it is important to label genetically engineered food, so negative effects can be noticed and identified, and so consumers who simply want to avoid these new foods can do so if they wish.

The United States, however, unlike all other developed countries, does not require safety testing for GE plants (although it does require an assessment for GE animals). The US Food and

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<sup>1</sup> 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.

<sup>2</sup> CAC/GL 44, 2003; CAC/GL 45, 2003; CAC/GL 46, 2003; and CAC/GL 68, 2008 At: [http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en)

<sup>3</sup> Domingo JL and JG Bordonaba. 2011. A literature review on the safety assessment of genetically modified plants. *Environment International* 37: 734-742. At: <http://maurin.bnk.free.fr/Domingo%20et%20al.,%202011.pdf>

Drug Administration's (FDA) original policy on GE (or GM, for genetically modified) plants, developed in 1992,<sup>4</sup> states that GE is not different than conventional breeding so no safety assessments are required, but companies may go through a "voluntary safety consultation." The FDA makes no conclusions about the safety of the GE food, but says it is up to the companies to determine safety of any GE food. To date, there have been some 97 "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).<sup>5</sup>

The letters for all 99 "safety consultations" 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.

Since the 1992 Statement of Policy on genetically engineered food, FDA has admitted that its original policy was based on a false notion. In 2001, the FDA proposed requiring companies to notify the government at least 120 days before commercializing a transgenic plant variety. As part of that proposed rule, the FDA admits that insertional mutagenesis is a problem and suggests requiring data on each separate transformation event: "[B]ecause some rDNA-induced unintended changes are specific to a transformational event (e.g. those resulting from insertional mutagenesis), FDA believes that it needs to be provided with information about foods from all separate transformational events, even when the agency has been provided with information about foods from rDNA-modified plants with the same intended trait and has had no questions about such foods. *In contrast, the agency does not believe that it needs to receive information about foods from plants derived through narrow crosses [e.g. traditional breeding]*" italics added (FR 66(12), pg. 4711).<sup>6</sup> In other words, FDA has admitted that there is a difference between GE and traditional breeding and that companies should be required to submit data on safety of genetically engineered crops prior to market approval. In spite of this, FDA is still following the 1992 policy rather than the 2001 policy.

In June 2012, the American Medical Association's House on Delegates voted to change its policy on "bioengineered" foods to one that support mandatory pre-market safety assessment: **"Our AMA supports mandatory pre-market systematic safety assessments of**

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<sup>4</sup> 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/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>

<sup>5</sup> At: <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm161107.htm>

<sup>6</sup> Pg. 4711 in FDA. Premarket Notice Concerning Bioengineered Foods. *Federal Register* January 18, 2001. *Federal Register* Vol. 51(12): pp. 4706 – 4738. At:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096149.htm>

**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.”<sup>7</sup> **bold added.** This change in position is an implicit admission by the AMA that GE foods may have an adverse health impact.

There is considerable evidence of potential health issue with GE foods. FDA is poised to approve a GE salmon, engineered to reach market weight in half the time of wild salmon. However, company data suggest that it may exhibit increased allergenicity.<sup>8</sup>

One big problem with safety assessments of GE plants is that there have been very few 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.<sup>9</sup> 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.<sup>10</sup> However, no animal tests are obligatory for any of the GE plants cultivated on a large scale in the US.

A second review article of animal feeding studies found “a certain equilibrium in the number of research groups suggesting, on the basis of their studies, that a number of varieties of GM products (mainly maize and soybeans) are as safe and nutritious as the respective conventional non-GM plant, and those raising still serious concerns, was observed. Moreover, it is worth mentioning that most of the studies demonstrating that GM foods are as nutritional and safe as those obtained by conventional breeding, have been performed by biotechnology companies or associates”.<sup>11</sup> A review of 94 health risk or nutritional assessment studies of GE foods found “a strong association was found between author affiliation to industry (professional conflict of interest) and study outcome”<sup>12</sup> in terms of health risk or nutritional assessment. Thus,

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<sup>7</sup> <http://www.ama-assn.org/resources/doc/yps/ref-comm-e-grid.pdf>

<sup>8</sup> Hansen, M. 2010. Submission to FDA’s Veterinary Medicine Advisory Committee meeting on safety assessment of AquAdvantage Salmon. <http://www.consumersunion.org/wp-content/uploads/2013/02/CU-comments-GE-salmon-0910.pdf>

<sup>9</sup> 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>

<sup>10</sup> Pg. 1 in IBID.

<sup>11</sup> Pg. 741 in Domingo JL and JG Bordonaba. 2011. A literature review on the safety assessment of genetically modified plants. *Environment International* 37: 734-742. At: <http://maurin.bnk.free.fr/Domingo%20et%20al.,%202011.pdf>

<sup>12</sup> Diels J, Cunha M, Manaia C, Sabugosa-Madeira B and M Silva. 2011. Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products. *Food Policy*, 36(2): 197-203. At: <http://www.sciencedirect.com/science/article/pii/S0306919210001302>

there is a lot of industry bias in much of the feeding and nutritional studies involving GE foods. More independent testing is clearly needed.

A long-term independent feeding study published in October, 2012 found that GE corn caused tumors and premature death.<sup>13</sup> The study, by Dr. Eric-Giles S eralini and colleagues was viciously attacked in the media by pro-GE and industry-affiliated scientists in what appear to have been an orchestrated campaign.<sup>14</sup>

The two main criticisms of the S eralini et al. study were that they used too few rat per group and that they used a strain of rat (Sprague Dawley, aka SD) that is prone to mammary tumors as they age. Both criticisms are off base. This study took blood and other biochemical measurements on 10 rats per group, the same number of rats that Monsanto took measurements on in their 90 day feeding study, which was published in the same journal eight years before the S eralini 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, S eralini 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 S eralini uses them, but ok when Monsanto and other biotech companies use them?

Both the French Food Safety Agency<sup>15</sup> (ANSES) and the European Food Safety Authority<sup>16</sup> (EFSA) have agreed with Dr. S eralini that such long-term safety assessment should be done on GE foods. Indeed, the ANSES report on the S eralini 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.”<sup>17</sup> 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.”<sup>18</sup> If the S eralini study is so flawed, why have ANSES and EFSA functionally agreed with its call for independently-funded long-term feeding studies on GE crops? On June 28, 2013 the European Commission announced they were spending 3 million

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<sup>13</sup> S eralini 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>

<sup>14</sup> Bardocz S, Clark A, Ewen S, Hansen, M, Heinemann J, Latham J, Pusztai A, Schubert D and A Wilson. 2012. S eralini and science: An open letter. *Independent Science News*. At:

<http://independentsciencenews.org/health/seralini-and-science-nk603-rat-study-roundup/>

<sup>15</sup> Reaction of ANSES (French Agency for food, environmental and occupational health and safety) to S eralini et al. study <http://www.anses.fr/Documents/PRES2012CPA20EN.pdf>

<sup>16</sup> Commission and EFSA agree need for two-year GMO feeding studies EU Food Policy, 17 December 2012 At: [http://www.eufoodpolicy.com/cgi-bin/view\\_article.pl?id=5590](http://www.eufoodpolicy.com/cgi-bin/view_article.pl?id=5590)

<sup>17</sup> ANSES, 2013. Op cit.

<sup>18</sup> 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](http://www.eufoodpolicy.com/cgi-bin/view_article.pl?id=5590)

Euros to fund a two-year carcinogenicity study on the same GE corn variety (NK603) that Dr. Séralini and colleagues used.<sup>19</sup>

In November, 2013, the Editor-in-Chief of *Food and Chemical Toxicology* (FCT), announced the retraction of the Séralini et al. study, noting that “the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for *Food and Chemical Toxicology*.”<sup>20</sup> The Editor-in-chief also clearly stated that he “found no evidence of fraud or intentional misrepresentation of the data.” The Committee on Publication Ethics (COPE) guidelines for retracting articles list four reasons for retraction: scientific misconduct/honest error, prior publication, plagiarism, or unethical research.<sup>21</sup> None of these reasons apply to the Séralini et al. study, yet Elsevier, publisher of FCT and member of COPE, decided to retract the study. More than 150 scientists have signed a statement condemning the retraction of the article as an attack on scientific integrity and demanding that FCT reinstate the study.<sup>22</sup> The NIH-associated publication, *Environmental Health Perspectives* also recently published an editorial that concluded, “Efforts to suppress scientific findings, or the appearance of such, erode the scientific integrity upon which the public trust relies. .... We feel the decision to retract a published scientific work by an editor, against the desires of the authors, because it is “inconclusive” based on a *post hoc* analysis represents a dangerous erosion of the underpinnings of the peer-review process, and Elsevier should carefully reconsider this decision.”<sup>23</sup>

In addition, 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.<sup>24</sup> 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.”<sup>25</sup> 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

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[http://ec.europa.eu/research/participants/portal/page/call\\_FP7:efp7\\_SESSION\\_ID=HqWqRkJXfQg25hfLY6P6XthpWS6y8STyrJnpPlhZgM6clLy2pTL1!259407533?callIdentifier=FP7-KBBE-2013-FEEDTRIALS&specificProgram=COOPERATION#wlp\\_call\\_FP7](http://ec.europa.eu/research/participants/portal/page/call_FP7:efp7_SESSION_ID=HqWqRkJXfQg25hfLY6P6XthpWS6y8STyrJnpPlhZgM6clLy2pTL1!259407533?callIdentifier=FP7-KBBE-2013-FEEDTRIALS&specificProgram=COOPERATION#wlp_call_FP7)

<sup>20</sup> FCT (Food and Chemical Toxicology). 2013. Retraction notice to “Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize” [Food Chem. Toxicol. 50 (2012) 4221–4231]. At: <http://www.sciencedirect.com/science/article/pii/S0278691513008090>

<sup>21</sup> Committee on Publication Ethics. 2009. Retraction Guidelines. At: <http://publicationethics.org/files/retraction%20guidelines.pdf>

<sup>22</sup> At: <http://www.endsciencensorship.org/>

<sup>23</sup> Pg. A36 in Portier CJ, Goldman LR and BR Goldstein. 2014. Inconclusive findings: now you see them, now you don't! *Environmental Health Perspectives*, 122(2): A36. At: <http://ehp.niehs.nih.gov/wp-content/uploads/122/2/ehp.1408106.pdf>

<sup>24</sup> Waltz, E. 2009. Under wraps. *Nature Biotechnology*, 27(10): 880-882. At: [http://www.emilywaltz.com/Biotech\\_crop\\_research\\_restrictions\\_Oct\\_2009.pdf](http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf)

<sup>25</sup> <http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research>

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.

Because of these safety questions raised by the long-term feeding studies, because of the allergy issues, and because consumers have a basic right to know that they are eating, CU supports labeling of GE food. 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.<sup>26</sup> A number of polls from 1995 to 2011 have found that between 70% and 95% of Americans polled supported mandatory labeling.<sup>27</sup> Such labeling is important because consumers have a right to choose the foods they eat and to avoid any unintended health effects.

Bottom line, CU supports mandatory labeling of GE foods and so supports SB 778.

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<sup>26</sup> See <http://www.centerforfoodsafety.org/ge-map/>

<sup>27</sup> <http://gefoodlabels.org/gmo-labeling/polls-on-gmo-labeling/>