

**Testimony on H.112, a Bill to Require the Labeling of Genetically Engineered Food
Before the Senate Judiciary Committee
Montpelier, VT**

**By
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Thank you for the opportunity to present testimony on the constitutional and legal issues surrounding H.112, 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 senior scientist at Consumers Union¹ (CU), the policy and advocacy arm of Consumer Reports, whose headquarters is located in Yonkers, New York. 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.

The two major legal/constitutional questions associated with H.112 that I will discuss are: 1) is H.112 pre-empted by Federal Food Drug and Cosmetic Act (FFDCA)? 2) does H.112 violate the First Amendment?

Preemption

In a case involving warning labels on cigarettes (*Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 516 (1992)), the U.S. Supreme Court described the relevant 3-part test for determining whether Congress intended for a federal statute to preempt state law: “Congress’ intent may be explicitly stated in the statute’s language or implicitly contained in its structure and purpose. In the absence of an express congressional command, state law is pre-empted if the law actually conflicts with federal law, or is federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.”²

Let’s look at each of the 3 parts. First, Congressional intent (either implicit or explicit, also known as expressed preemption), does not apply to H.112 since the Federal Food Drug and Cosmetic Act (FFDCA), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) does not mention nor regulate the use of “genetic engineering.” The NLEA does contain an expression preemption provision, 21 U.S.C. §

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 *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 516 (1992) at: http://scholar.google.com/scholar_case?case=426636661616801210&hl=en&as_sdt=6&as_vis=1&oi=scholar

343-1, which prohibits states from enacting laws or regulations that are “not identical to the requirement(s)” of NLEA vis-à-vis labeling of: standard of identity; food sold under another name; imitation food; misleading containers; food in package form; prominence of information; standards of quality and fill of container; unidentified foods (e.g. foods without a definition or standard of identity); artificial flavoring, artificial coloring, and chemical preservatives; nutrition information; nutrition levels and health related claims; major food allergens; and nonmajor food allergens (see 21 U.S.C. § 343(b), (c), (d), (e), (f), (h), (i), (k), (q), (r), (w), (x); at § 343-1(a)(1)-(5). None of these expression preemptions apply to H.112, since NLEA does not regulate “genetic engineering.” For example, under the “standard of identity” provision, there is no problem since there is no federal standard of identify for “genetically engineered.”

Second, there is no implied conflict preemption, which would occur if it were “impossible for a private party to comply with both state and federal requirement.”³ Since neither FFDCA nor its enabling regulations concern the use of the term “genetically engineered,” there is no federal law for H.112 to conflict with.

Third, there is no implied field preemption, which occurs when “federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.” First, before the NLEA, the FFDCA had no express preemption provision. As a case involving Snapple beverage pointed out, “Health and safety issues have traditionally fallen within the province of state regulation. This is true of regulation of food and beverage labeling and branding.”⁴ In addition, the fact that NLEA has an express preemption provision demonstrates that Congress recognized the existence of state laws regulating the same field. Furthermore, NLEA explicitly states that it “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1] of the Federal Food, Drug, and Cosmetic Act.”⁵ Thus, H.112 is not preempted under principle of field preemption.

First Amendment

The First Amendment issue concerns whether H.112 ‘s requirement that foods that are “genetically engineered” or “produced with genetic engineering” must bear a short label statement violates the First Amendment. This constitutes compulsory speech in a commercial context. For the reasons cited below, we believe H.112’s compulsory labeling statement is constitutional under the First Amendment.

For required labels in a commercial speech context, the Courts have used the standard articulated in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). The *Zauderer* standard finds that laws requiring speech

³ *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990)

⁴ *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) At: http://www.gpo.gov/fdsys/pkg/USCOURTS-paed-2_12-cv-00874/pdf/USCOURTS-paed-2_12-cv-00874-0.pdf

⁵ Pub. L. No. 101-535, § 6(c)(1)

(e.g. labeling) are constitutional if two conditions are met. First, the compelled speech must convey purely factual information, and does not convey a viewpoint. Second, the compelled speech was support a legitimate government interest.

The label “genetically engineered” or “produced with genetic engineering” are factual statements. Opponents of H.112 may argue that the term “genetic engineering” conveys a viewpoint that “genetic engineering” is bad, but we disagree with this assertion. Furthermore the fact that H.112 also requires a contextual statement “the Food and Drug Administration does not consider foods produced from genetic engineering to be materially different from other foods” would effectively negate any implied negative connotations supposedly attached to the term “genetic engineering” and so would not convey a viewpoint about the supposed safety of such foods. Thus, the labels “genetically engineered” and “produced with genetic engineering,” along with the contextual statement constitutes a factual statement that does not convey a viewpoint.

Second, in terms of the legitimate government interest, both prevention of consumer confusion and potential human health issues constitute a legitimate government interests. In 2013, the American Meat Institute sued the US Department of Agriculture over the final regulation requiring country-of-origin labeling (COOL) for meat products, claiming that this compelled speech violated their First Amendment rights. The D.C. District Court upheld COOL noting that the final regulation “was intended to address the possibility of consumer confusion regarding the origin of covered commodities.”⁶ Thus, prevention of consumer confusion is a compelling state interest. As with COOL, many consumers have stated that they want to know whether a food has been genetically engineered or not. A number of polls from 1995 to 2011 have found that between 70% and 95% of Americans polled supported mandatory labeling.⁷ Without such labeling, consumers may be confused as to whether the food product that are eating contains genetically engineered materials.

In 2008, the New York State Restaurant Association sued New York City Board of Health over the regulation that required restaurants to post calorie count information on their menus, claiming that this compelled speech violate the First Amendment. In 2009, the Second Circuit Court upheld the calorie statement because it was indisputably factual, and it furthers the State’s interest in mitigating obesity and, thus, protecting consumer health.⁸ Thus, potential impact on consumer health is a compelling state interest.

The state has a compelling state interest to require labeling because it will permit identification of any new allergenicity problems, especially problems caused by uncommon allergens, as well as unexpected toxins in genetically engineered food and thus protect consumer health.

⁶ Pg. 16 in *Am. Meat Inst. v. U.S. Dep’t of Agric.*, 13-CV-1033 KBJ, 2013 WL 4830778. At: <http://www.agri-pulse.com/uploaded/091113coolruling.pdf>

⁷ <http://gefoodlabels.org/gmo-labeling/polls-on-gmo-labeling/>

⁸ *New York State Rest. Ass’n v. New York City Bd. of Health*, 556 F.3d 134-136 (2d Cir. 2009) At: <http://www.citizen.org/documents/NYSRAOpinion.pdf>

There is broad recognition in the scientific community that genetic engineering can introduce new allergens or increase levels of naturally occurring allergens, increase plant toxins, and alter nutritional content in foods. There may also be unintended effects. Codex Alimentarius, the food safety standards organization of the United Nations, has developed a set of documents for assessing these risks.⁹

Dozens of countries follow the Codex protocols and require mandatory pre-market safety assessments of genetically engineered foods before they can be sold to consumers. Unlike other developed countries, however, the US does not require genetically engineered plants to be proven safe before they can go on the market. But even if all reasonable safety testing were required, certain individuals could still have unusual allergic responses that would not be detected in a good premarket safety assessment. Finally there can be unexpected effects--just as there are sometimes to pharmaceutical products-- despite extensive premarket testing.

If there are unexpected adverse health effects that happen as a result of GE, then labeling could serve as a risk management mechanism that would allow the state to identify and track such health problems if they arose. If a food with GE ingredients is not labeled as such, and that food causes an adverse health effect, such as an allergic reaction, there would be virtually no way to determine that the GE process was linked to the adverse health effect. For example, suppose a company decides to insert a synthetic gene, which codes for a modified protein, into tomatoes. 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. Patients would say that they ate tomatoes recently, but that they normally have no problem with tomatoes. Without labeling of the new type tomato, there would be no way to tie their response to the new modified protein.

Labeling will also give consumers an opportunity to avoid foods that may pose long-term health risks. Almost 300 scientists, physicians, academics, and experts from disciplines relevant to the scientific, legal, social and safety assessment aspects of genetically modified organisms have signed onto a statement that there is no consensus on the safety of GMOs.¹⁰ Clearly there are still unanswered questions about the safety of GE foods. I have included a discussion of the scientific evidence for long terms health effects in Appendix A of this testimony. We believe these questions also help constitute a compelling state interest.

⁹ 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

¹⁰ Statement: No scientific consensus on GMO safety. At: <http://www.ensser.org/increasing-public-information/no-scientific-consensus-on-gmo-safety/>

rbGH Case

Finally, Vermont is sensitive about the failure of the rbGH labeling law, which was overturned by the Second Circuit court in 1997. A three judge panel, in a 2 to 1 ruling, found that mere “consumer curiosity” was not a compelling state interest and so the mandated labeling of dairy products vis-à-vis treatment with rbGH was overturned.¹¹

We believe that Vermont lost this case because the state failed to argue that milk from rbGH-treated cows differed from milk from untreated cows in ways that raised safety issues, thereby creating a compelling state interest. We saw the opposite outcome, affirming voluntary rbGH labeling, in a case in Ohio. Ohio issued regulations that prohibited the labeling of milk from rbGH-treated cows as “rbGH-free,” supposedly because there were no compositional differences between milk from rbGH-treated cows and milk from untreated cows. The International Dairy Foods Association (IDFA) and the Organic Trade Association (OTA) sued the state of Ohio to allow the labels. In 2010, the Sixth District Court found for IDFA and OTA, saying that there were, indeed, differences between milk from rbGH-treated cows and untreated cows and that such differences could have an impact on health and nutrition. The decision in favor of labeling stated, “As detailed by the amici parties seeking to strike down the Rule, the use of rbST in milk production has been shown to elevate the levels of insulin-like growth factor 1 (IGF-1), a naturally-occurring hormone that in high levels is linked to several types of cancers, among other things. The amici also point to certain studies indicating that rbST use induces an unnatural period of milk production during a cow’s “negative energy phase.” According to these studies, milk produced during this stage is considered to be low quality due to its increased fat content and its decreased level of proteins. The amici further note that milk from treated cows contains higher somatic cell counts, which makes the milk turn sour more quickly and is another indicator of poor milk quality. This evidence precludes us from agreeing with the [lower] district court’s conclusion that there is no compositional difference between the two types of milk.”¹² Thus the legality of rbGH labeling was affirmed.

Conclusion

For the reasons stated above, we believe that H.112 would not be preempted by the FFDCFA. Furthermore, H.112 would not violate the First Amendment, as the compelled speech is purely factual and furthers a legitimate state interest.

¹¹ *IDFA v. Amestoy* 92 F.3d 67 (1996). At:

http://www.public.iastate.edu/~jwcwolf/Papers/IDFA_Amestoy.pdf

¹² *IDFA v. Boggs* Nos. 09-3515, 09-3526 (6th Cir. Sept. 30, 2010) At:

<http://www.ca6.uscourts.gov/opinions.pdf/10a0322p-06.pdf>

APPENDIX A: STUDIES SUGGESTING LONG TERM HEALTH RISKS FOR GE FOODS

Animal safety tests are obligatory for any of the GE plants cultivated on a large scale in the US. However some animal feeding studies have been undertaken.

A carefully designed meta-analysis was done of 19 published studies involving mammals fed GE corn or soy.¹³ 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.¹⁴

A second review article of animal feeding studies states: “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”.¹⁵

According to a review of 94 health risk or nutritional assessment studies of GE foods, “a strong association was found between author affiliation to industry (professional conflict of interest (COI)) and study outcome”¹⁶ in terms of health risk or nutritional assessment. This study found that of 41 papers with a professional conflict of interest (defined as at least one author working for industry), all 41 found no problem with GE food. Of 51 papers without a profession COI, 39 found no health risk while 12 found adverse health impacts. This difference—41 to 0 versus 39 to 12—is highly statistically significant and shows that if there is a single industry author on a paper it will not find any health risks of GE food; only studies done independently of industry have a chance of finding an adverse effect.

¹³ 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>

¹⁴ Pg. 1 in IBID.

¹⁵ 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>

¹⁶ 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>

A long-term independent feeding study published in October, 2012 found that GE corn were associated with tumors and premature death.¹⁷ The study, by Dr. Eric-Giles Séralini and colleagues was viciously attacked in the media by pro-GE and industry-affiliated scientists in what appear to have been an orchestrated campaign.¹⁸

The two main criticisms of the Séralini et al. study were that they used too few rats 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 a 90 day feeding study, which was published in the same journal eight years before the Séralini study, and was used to affirm the safety of GE foods. If ten rats is too small a sample size to demonstrate health problems, how can ten rats be 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.

Both the French Food Safety Agency¹⁹ (ANSES) and the European Food Safety Authority²⁰ (EFSA) have agreed with Dr. Séralini that 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.”²¹ At an EFSA board meeting in December, the “there was agreement that long-term studies were needed and it was now just a question of how to fund them.”²² On June 28, 2013 the European Commission announced they were spending 3 million Euros to fund a two-year carcinogenicity study on the same GE corn variety (NK603) that Dr. Séralini and colleagues used.²³

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

¹⁷ 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>

¹⁸ 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/>

¹⁹ 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>

²⁰ 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

²¹ ANSES, 2013. Op cit.

²² 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

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http://ec.europa.eu/research/participants/portal/page/portal/FP7:efp7_SESSION_ID=HqWqRkJXfQg25hfLY6P6XthpWS6y8STyrJnpPlhZgM6clLy2pTL1!259407533?callIdentifier=FP7-KBBE-2013-FEEDTRIALS&specificProgram=COOPERATION#wlp_call_FP7

(while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for *Food and Chemical Toxicology*.”²⁴ The Editor-in-Chief also 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.²⁵ None of these reasons apply to the Séralini et al. study. This was a highly controversial decision. More than 150 scientists have signed a statement condemning the retraction of the article as an attack on scientific integrity and demanding that the journal reinstate the study.²⁶ 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.”²⁷

²⁴ 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>

²⁵ Committee on Publication Ethics. 2009. Retraction Guidelines. At: <http://publicationethics.org/files/retraction%20guidelines.pdf>

²⁶ At: <http://www.endsciencensorship.org/>

²⁷ 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>