

**Senate Bill 510:**

1. **Dietary Supplements** that are regulated as foods and not drugs; that do not contain genetically modified components, or sourced from GMO materials; do not employ nanotechnology either in delivery, flavor enhancement, additives, etc; and are consistent with the organic standards are to separated from mainstream dietary supplements that employ nano drug technologies and source from GMO foods, be regulated under the AFSA.
2. AFSA has the mandate to review and evaluate the organic standards; the national list, etc to insure that it is not diluted contrary to the original intent of the Organic Production Act.
3. Synthetic components may not employ GMO, nano-scale or drug technologies such as for example “Senomyx \*. Synthetic components allowed via the national list in the organic standard must be labeled on products in order to achieve minimum safety requirements for participation in the standard safety regulations of the AFSA program.

Introduce an amendment to establish the Ancillary Food Safety Administration (AFSA) for the purpose of developing of an ancillary food safety system.

**Add the words “transitional or conversion” to section on organic.**

18“(E) in the case of production that is **transitional, conversion or**  
19**certified organic**, not include any requirements that  
20 conflict with or duplicate the requirements of the  
21 national organic program established under the  
22 Organic Foods Production Act of 1990 (7 U.S.C.  
23 6501 et seq.), while providing for public health  
24 protection consistent with the requirements of  
25 this Act.

**ADD: shall publish a notice**  
**establishing the Ancillary Food Safety Administration**

24 “(1) **IN GENERAL.**—Not later than 1 year after  
25 the date of enactment of the FDA Food Safety Mod26  
ernization Act, the Secretary, in coordination with 141  
1 the Secretary of Agriculture and representatives of  
2 State departments of agriculture (including with re3  
gard to the national organic program established  
4 under the Organic Foods Production Act of 1990 (7

5 U.S.C. 6501 et seq.)), **shall publish a notice to**  
**establish the Ancillary Food Safety Administration** and pro6  
posed rulemaking to establish science-based minimum  
7 standards for the safe production and harvesting of  
8 those types of fruits and vegetables that are raw agri9  
cultural commodities for which the Secretary has de10  
terminated that such standards minimize the risk of se11  
rious adverse health consequences or death.

“(3) **CONTENT.**—The proposed rulemaking under  
19 paragraph (1) shall—  
20 “(A) provide sufficient flexibility to be ap21  
plicable to various types of entities engaged in  
22 the production and harvesting of raw agricul23  
tural commodities, including small businesses  
24 and entities that sell directly to consumers, and

#### **S.510 DIETARY SUPPLEMENTS:**

**ADD: “Dietary supplements employing new nano-scale and drug technologies must be labeled and regulated”**

(f) *Dietary Supplements- Nothing in the amendments made by this section shall apply to any dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 379aa-1).*

d) *Rule of Construction- Nothing in this section shall be construed to affect the regulation of dietary supplements **unless employing nano or drug technologies of which case they must be labeled as such.** under the Dietary Supplement Health and Education Act of 1994 (Public Law 103-417).*

#### **S. 510 ADD Entire Section: ENGINEERED NANO MATERIALS: GENERALLY RECOGNIZED AS SAFE (GRAS)**

Components of food products and dietary supplements and nutraceuticals (drugs or vitamins in foods) employing nanotechnology may not be assigned GRAS status. **GENERALLY RECOGNIZED AS SAFE (GRAS)**

**Summary:** In the past GRAS has been assigned to components such as additives and flavorings based on scale (quantity). Because of new drug technologies (nano-scale technologies) scale (quantity) must no longer be the determining factor for GRAS. GRAS allows manufacturers to circumvent the FDA safety regulations and in many cases GRAS approval is determined by interested affiliate trade associations.

According to scientific opinion of *EFSA*'s Scientific Committee (SC), international approaches to risk assessment must be applied to engineered nano materials (ENM). But in practice due to lack of validated test methodologies make risk assessment of specific **nano** products very difficult.

According to SC, there are still some specific recommendations like investigating the interaction and stability of ENMs in food and feed, in the gastro-intestinal tract and in biological tissues, developing and validating routine methods to detect, characterise and quantify ENMs in food contact materials, food and feed and developing, improving and validating test methodologies to assess toxicity of ENMs (including reliability and relevance of test methods)

**\*NOTE SENOMYX example:**

Nestle, Coca Cola, Kraft, Campbell Soup, Cadbury-Schweppes and Ajinomoto use new drug and nano scale technologies to develop products such as "Senomyx" which has been given a GRAS status by FEMA (Flavor Enhancement Manufacturers Association) and thereby circumvents FDA regulations and studies.

It might be noted in uncovering coordinated strategies, that it was **the lobbyists for Altria, Kraft's majority owner, Abigail Blunt** succeeded in diluting the organic standard via covert legislative rider which without agricultural committee discussion overturned the hard fought and just decision and positive court ruling in the case of Arthur Harvey vs. Veneman, a case that safeguarded the organic standards under the 5% rule:

**Organic foods are governed by a federal law passed by Congress in 1990. It set strict standards for organic farming and manufacturing. But in November, an amendment (called a [rider](#)) was attached to another bill, which removed a key provision of the law.**

**The OTA (Organic Trade Association) rider removed the following clause from the organic law: "the substance [permitted to be used in manufacturing up to 5% of the total ingredients] ...is non-synthetic but is not organically produced"**

**The rider was attached to the agricultural appropriations bill by [lobbyists](#), without any discussion in the ag committees or elsewhere. This is possible when the majority leader simply decides to do it. It is to be noted that his wife is a lobbyist for Kraft Foods, a major organic manufacturer, researcher, developer in the nano technological field as it regards foods such as "senomyx" (see below)**

**The effect is to allow synthetic ingredients in manufacturing foods to be labeled organic. Prior to this change the words quoted above served as a**

**firewall for organic products, preventing the addition of synthetics. But now, only the discretion of USDA will determine which synthetics are used---mostly without being named on the labels.**

**\*Senomyx** has created novel flavors such as cold and creamy based on a rethinking of how taste buds perceive flavor. Using nano-scale assays, researchers have identified which individual cells on a given taste bud perceive a flavor. Each cell would recognize just one of the five main flavors — bitter, salty, sweet, sour, etc. Working within this conceptualization, the company has developed a library of flavors, including compounds called bitter blockers. **These specialized molecules trick the tongue of the consumer (drug the tongue) into thinking for example, it is eating sugar or salt but it is not.** Although this has application in the diet industries, etc, products employing new nano-scale drug technology and must be rigorously studied and clearly labeled for the consumers information. Currently as GRAS, products using this technology do not have to be labeled or simply labeled as a “flavor enhancer”.

Regards,

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*“It requires courage to utter truth; for the higher Truth lifts her voice, the louder will error scream, until its inarticulate sound is forever silenced in oblivion” ...Mary Baker Eddy, Christian Science*

*"Just Remember,  
when the weeding process takes place,  
you are the flowers."*

- Charlie Lutes