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SANA ACTIVITIES

SANA Notified Members of WAPF Comments to FDA and Working on Response
FDA staff for Office of Chief Counsel informed SANA of the impending submission of the Weston A. Price Foundation comments on the August 11, 2015 SNI letter to FDA regarding the validity for the soy protein and CHD health claim. SANA distributed the WAPF comments from November 9 (published online November 21) to SANA members and SNI members and has collaborated with Dr. Mark Messina in preparation of a response. The SNI response confirmed the strength of the evidence on soy protein and reduction of cholesterol and chronic heart disease (CHD) risk and referred to the 2015 Canadian as well as other country health claims for soy protein and CHD. A copy of the response will be available on the SANA Members Only section of website.

SANA Sends Letter to Congressional Appropriation Committee Leaders
SANA sent a letter to Committee leaders to raise objection to the language added to the House and Senate versions of the FY 2016 Agriculture Appropriations Bills that would restrict the scientific process used in development of the Dietary Guidelines. SANA has participated throughout the development process in submitting scientific research and several sets of oral and written comments to the 2015 Dietary Guidelines Advisory Committee (DGAC) and believes that the DGAC final report reflected many of the suggestions. A copy of the November 30 letter to Congress is available on the SANA Members Only section of website.

2016 Membership Renewals
Many SANA members have already renewed their membership in SANA for 2016. SANA staff will be sending out reminders this week regarding your renewal. We hope that you have found SANA working throughout 2016 to grow the sales of soyfoods and aggressively correcting misinformation and promoting the versatility and health benefits of soy based foods and beverages. Here is a link to the 2016 membership application.

Recently Added to soyfoods.org
- Vegan Friendly Thanksgiving
- European Food Safety Authority Says ‘No Evidence of Harm’ for Isoflavones
- Soy Protein Increases Muscle Strength
- Soy Shown to Reduce Inflammation for Men with Prostate Cancer
- Soyfoods for Healthy Bones on World Osteoporosis Day

Coming in December
- We will be releasing a press release that summarizes the top soy research of 2015, likely by December 8

Upcoming Meetings
- Executive Committee Conference Call, December 14, 1-3:00 PM EST

Loss of a Major Leader of the Soyfoods Industry
SANA staff sadly shares news of the death of Elmer Schettler, Founder and CEO of Devansoy who passed away November 16, 2015. Elmer always had the patience to answer any question with sage advice and was well respected as a leader in the soyfoods industry. He combined innovation and compassion with true integrity. As Deb Wycoff, current Devansoy CEO/COO, noted Elmer was “a true entrepreneur and free spirit, a leader and visionary, a good man. He loved the world of soy and the journey it allowed him to meet people from all across this industry. Please continue to remember Elmer’s family, Anne and his children, Steve, Renee and Sara along with their spouses in your thoughts and prayers.”
PUBLIC POLICY

FDA Requests Comments on Use of ‘Natural’ on Food Labels
Due to the changing landscape of food ingredients and production, the U.S. Food and Drug Administration (FDA) is asking the public to provide information and comments on the use of the term “natural” in the labeling of human food products. The FDA is specifically looking at questions such as: whether it is appropriate to define “natural”, if so, how it should be defined, and how should the agency determine appropriate use of the term on food labels. The FDA is taking this action in part because it received three Citizen Petitions asking that the agency define the term “natural” for use in food labeling and one asking that the agency prohibit the term “natural” on food labels.

FDA Has Taken Several Actions Related to Genetically Engineered Plants and Animals
First, the FDA has issued final guidance for manufacturers who wish to voluntarily label their foods as containing or not containing such ingredients. While genetic engineering is sometimes referred to as “genetic modification” producing “genetically modified organisms (GMOs),” FDA considers “genetic engineering” to be the more precise term. According to the FDA material, the agency is not aware of any valid scientific information showing that foods derived from genetically engineered plants, as a class of foods, differ from other foods in any meaningful way. GE foods don’t present greater safety concerns than foods developed by traditional plant breeding. For more information visit Labeling of Foods Derived from Genetically Engineered Plants.

Second, the FDA has denied petitions to consider requiring the labeling of genetically engineered foods. The FDA action comes as lawmakers are almost in agreement on legislation that would bar states from requiring GMO labeling on food products – Vermont is set to start GMO labeling in July – but may possibly require disclosures online and through smartphone codes.

Lastly, the FDA approved the first genetically modified animal - AquAdvantage Salmon –for human consumption. FDA states that the salmon “contains an rDNA construct that is composed of the growth hormone gene from Chinook salmon under the control of a promoter (a sequence of DNA that turns on the expression of a gene) from ocean pout (another type of fish). The salmon can only be raised in contained hatchery tanks in two facilities in Canada and Panama.

FDA Releases Proposed Rule to Establish ‘Gluten-Free’ Labeling Compliance Requirements for Fermented, Hydrolyzed and Distilled Foods
On November 17, 2015, the FDA released a proposed rule to establish requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, and bear the “gluten-free” claim, such as yogurt, sauerkraut, pickles, cheese, green olives, vinegar, and FDA regulated beers. In 2013, the FDA issued the gluten-free final rule, which addressed the uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods in terms of intact gluten. FDA has issued this proposed rule to provide alternative means for the agency to verify compliance, based on records that are made and kept by the manufacturer. The FDA is accepting public comments beginning Wednesday, November 18. To electronically submit comments to the docket, visit here.

FDA Issues Guidance on Fortification of Foods
In response to questions and comments on fortification of foods with essential nutrients, the U.S. Food and Drug Administration republished its 1980 fortification policy (with no changes) and provided new guidance, Questions and Answers on FDA’s Fortification Policy. In summary, it states that “adding nutrients to specific foods is an effective way of maintaining and improving the overall nutritional quality of the food supply. However, indiscriminate fortification of foods could result in over- or under fortification in consumer diets
and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims on certain foods.”

**IOM Issued New Report on WIC Food Package Improvements**

The IOM’s Committee to Review WIC Food Packages issued a [second report](#) that presents the evidence, analyses, and framework that will be applied to develop the final report (phase II), which will recommend any changes to WIC food package. This report does include soy along with nuts and seeds in recommended food groups. Comparing the 2005 to the 2015 Dietary Guideline recommendations, the WIC package would need to increase the nut seeds and soy food group from 2 ounces/week for 1000 kcal intake to 5 ounce equivalents/week for 2200 kcal intake. Soymilk and tofu are included with discussions of dairy. Also 95% of WIC agencies allowed soymilk, whereas 63% of agencies permitted tofu as part of WIC food packages.

**MARKET NEWS**

**EFSA Finds Glyphosate Unlikely to Cause Cancer**

The European Food Safety Authority (EFSA) [announced](#) that it had finalized the re-assessment of glyphosate, a chemical that is widely used in pesticides including Monsanto’s Roundup. The report concludes that glyphosate is unlikely to pose a carcinogenic hazard to humans, and proposes a new safety measure that would tighten the control of glyphosate residues in food. A peer review expert group made up of EFSA scientists risk assessment representatives from European Union (EU) Member States has set a maximum safe daily dose of 0.5 mg per kg of body weight – the first time such an exposure threshold has been applied to the chemical. EFSA scientists said their study differed from International Agency for Research on Cancer’s (IARC), which classified glyphosate as probably carcinogenic, in that it only looked at glyphosate, whereas IARC had assessed groups of related chemicals. They said the toxic effects could be related to reactions with “other constituents or ‘co-formulants’”. This conclusion will influence the European Commission in deciding whether or not to retain the substance on the European Union’s list of approved active substances, allowing its continued use in pesticides.

**RESEARCH**

**Advances in Nutrition Looks at Differences in Plant Protein Versus Animal Protein**

A scientific review in Advances in Nutrition looked at the different effects plant protein versus animal protein have on heart health. In the review "Plant Protein and Animal Proteins: Do They Differentially Affect Cardiovascular Disease Risk?" the authors found numerous studies evaluating the health benefits of each kind of protein; however, they discovered it is difficult to determine the role of a particular plant or animal protein on cardiovascular disease risk. Protein food sources contain a broad array of non-protein compounds, vary in preparation and processing methods, and when people consume a high protein diet, it typically lowers the consumption of other foods and nutrients, these factors also affect cardiovascular disease risk factors, making it difficult to make general statements about plant proteins versus animal proteins. Considering all of these complexities, the authors believe broad statements about plant or animal protein consumption may not be possible and recommended addition studies to further our understanding of the complexities of plant versus animal protein.

**Clinical Inquiry: Does high dietary soy intake affect a woman's risk of primary or recurrent breast cancer?**

A recent [clinical inquiry](#) from University of Washington doctors sought to answer the question: Does high dietary soy intake affect a woman's risk of primary or recurrent breast cancer? Through the peer review process, it was determined that high dietary soy intake does not affect the risk of primary breast cancer and that high intake of soyfoods has a favorable affect in decreasing the risk of cancer recurrence. Compared

**The effect of a dietary portfolio compared to a DASH-type diet on blood pressure**

In addition to lowering blood cholesterol, after 24 weeks, Dr. Jenkins Portfolio diet that includes, soy protein, viscous fibers and nuts has been shown to reduce systolic, diastolic and mean arterial blood pressure by 2.1 mm Hg, 1.8 mm Hg and 1.9 mm Hg, respectively compared to the control of a DASH-type diet. Interestingly, blood pressure reductions were small at 12 weeks and only reached significance at 24 weeks. *Nutr Metab Cardiovasc Dis.* 2015 Nov 6. [Epub ahead of print]

**Phytoestrogen consumption and risk for cognitive decline and dementia: With consideration of thyroid status and other possible mediators**

A recent [review](#) assessed the relationship between phytoestrogens interacting with estrogen receptors in the brain and the potential effect on cognition. Though research findings in this area are inconsistent, possible mediators were identified to explain discrepant findings and for consideration in future research. Evidence suggests that inter-individual variants that can affect phytoestrogen bioavailability (and thus cognitive outcome) include age and ability to breakdown ingested phytoestrogens into their bioactive metabolites. Other variants to consider include type of soy product, dosage, frequency of dietary intake and type of cognitive test used. *J Steroid Biochem Mol Biol.* 2015 Nov 1. [Epub ahead of print]

**Isoflavone and Soyfood Intake and Colorectal Cancer Risk: A Case-Control Study in Korea**

Researchers used a semi-quantitative food frequency questionnaire to assess the impact of usual diet on colorectal cancer risk in a case-control study of 901 colorectal cancer cases and 2669 controls from the National Cancer Center, Korea. Isoflavone intake was measured from five soyfoods: legumes (black soybeans and green peas), tofu, soymilk, sprouts, and fermented soy paste. A high intake of total soyfoods, compared to their counterparts with the lowest intake quartiles in men and women, was associated with a lower risk for colorectal cancer in men and women, though the middle quartiles of soyfoods intake were associated with an elevated risk. In contrast, a high intake of fermented soy paste was associated with an elevated risk for colorectal cancer in men. The reduced risk for the highest intake groups persisted for distal colon cancer in men and rectal cancer in women. The association between soyfood intake and colorectal cancer risk was more prominent among post-menopausal women than pre-menopausal women. *PLoS One.* 2015 Nov 17;10(11):e0143228.

**NEGATIVE**

**Soy-Based Infant Formula Feeding and Ultrasound-Detected Uterine Fibroids among Young African-American Women with No Prior Clinical Diagnosis of Fibroids**

Researchers at the NIH National Institute of Environmental Health Sciences are engaged in an ongoing cohort study, The Study of Environment, Lifestyle & Fibroids (SELF), of 1,553 African-American women participants aged 23-34 years to evaluate the relationship between infant soy formula feeding and ultrasound-detected fibroids. Baseline questionnaire on soy formula feeding during infancy was obtained and ultrasound screening detected fibroids ≥0.5 cm in diameter in 345 women. Among those with fibroids, the size was compared between soy formula-exposed and unexposed women using multivariable linear regression. There was no observed association between soy formula feeding and fibroid prevalence; nor were exposed women with fibroids more likely to have ≥2 tumors than unexposed women with fibroids. On average, soy formula feeding was associated with a 32% increase in the diameter of the largest fibroid and a 127% increase in total tumor volume. The authors note that their observation that women fed soy formula as infants have larger fibroids than unexposed women further supports the persistent effects of early life phytoestrogen exposure on the uterus. *Environ Health Perspect.* 2015 Nov 13. [Epub ahead of print]