To the Scientific Advisory Committee on Nutrition

Sept 1, 2014

RE: Consultation on the Draft report on Carbohydrates and Health

On behalf of Ocean Spray Cranberries, Inc. and our grower-owners, I submit these comments to the Scientific Advisory Committee on Nutrition in respect to their draft Report on Carbohydrates and Health.

The draft Report has been subdivided into sections dealing with specific health areas and sugars. Our representation is a summary of pertinent issues for cranberry, with naturally unpalatable taste that would prevent consumers from benefiting from the demonstrated health benefits without some sweetening. To take account of these health benefits, we request that evidence relating to cranberry be reviewed by SACN and weighed fairly against any negative connotations that could be implied by the carbohydrate content vital to allow cranberry products to be consumed by the average consumer. We hope that by making this comparison SACN would recognize that some fruits, such as cranberry, unpalatable in their natural state, need added sweeteners and that a section or at the very least, a commentary be added to the draft Report that addresses this specific issue.

Ocean Spray is an agricultural cooperative consisting of over 700 cranberry and grapefruit grower-owners in the United States, Canada and Chile, who have helped preserve the family farming way of life in rural areas of our country for generations. Founded in 1930, we have a long history of providing a wide variety of nutritious cranberry beverage and food products to consumers throughout the United States and the world. Our grower-owners are extremely proud of the history and heritage of cranberries and the nutritious products produced from the fruit grown on their farms.

While Ocean Spray supports efforts to improve the general health worldwide, we provide this comment to make clear the unique properties of cranberries. Their healthful properties were first recognized by Native Americans hundreds of years ago, and today's research confirms that cranberries are a nutrient-dense fruit that can deliver valuable health benefits to help consumers meet recommended fruit intake levels and maintain a healthy diet. Cranberries are rich in polyphenols, they provide well-documented urinary tract health benefits, and recent clinical research suggests that they also provide heart health properties.

<u>Cranberries Have the Capability to Improve Heart Health Due to the Rich Polyphenol Content.</u>

Randomized clinical trials support the fact that cranberry polyphenols are important bioactives in the diet for improving heart health, as reported by an international group of scientists and a recent roundtable in the UK.[1] Three recent randomized clinical studies, of at least 8 weeks long, support this conclusion. Dohadwala et al (2011) found that long term consumption (4 months) of low calorie

[1] Blumberg, et al., *Cranberries and their bioactive constituents in human health*, Adv. Nutr. 2013 Nov 6, 4(6):618-32; Gardner, *The health properties of cranberry juice*, Nutr. Bulletin, 2014, 39: 223–230.

cranberry juice in subjects with CAD significantly improved arterial stiffness.[2] Researchers at the United States Department of Agriculture (USDA)Human Nutrition Research Center show that healthy subjects drinking two servings of a light cranberry juice beverage (40 kcal) for 8 weeks in a controlled feeding trial have significantly reduced C - reactive protein and diastolic blood pressure while Basu et al (2011) showed that women with metabolic syndrome drinking light cranberry juice had significantly reduced oxidized LDL, malondialdehyde and 4-hydroxynonenal and a significant increase in plasma antioxidant capacity .[3] A review of NHANES data 2005-2008 show that cranberry juice consumers are more likely to have normal weight and significantly more likely to have lower waist-to-hip circumference and C-reactive protein, consistent with the clinical data.[4]

Cranberries Help Meet Fruit Recommendations

Cranberries can play an important role in helping consumers meet their recommended daily fruit needs. As a threshold matter, consumers should be encouraged to eat more fruit, an important food group, and for which most consumers do not meet their recommended intake. In the most recent Nutrition and Diet Survey published by Public Health England (PHE), only 30% of adults and 41% of older adults met the "5-a-day" recommendation. Additionally, boys and girls aged 11 to 18 years consumed on average 3.0 and 2.7 portions per day respectively. Only 10% of boys and 7% of girls in this age group met the "5-a-day" recommendation. Encouraging consumption of cranberry products can help achieve this goal: for example, dried cranberries contain at least 10% of the daily value of dietary fibre for US regulations and is a source of fiber according to the Nutrition and Health Claims Regulation 2006, as amended, where a claim that a food is a source of fibre, may be made where the product contains at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal; dried cranberries contain 5.5g fibre per 100g.

Fruit itself is a preferred means of delivering health benefits of the nutrients they contain. According to the IOM, evolving understanding of plant foods (such as cranberries) highlights three key takeaways: first, plant foods are compositionally complex; second, the health benefits of plant foods appear closely related to their compositional complexity, not to their individual components; and third, the levels of vitamins and minerals in foods do not necessarily correlate well with the other classes of beneficial components.[5] As the US Dietary Guidelines Advisory Committee (DGAC) 2010 has noted, "[fruits and vegetables] contain not only the essential vitamins and minerals that are often targeted in nutrient supplement pills, but also hundreds of naturally-occurring phytonutrients and other substances, including carotenoids, flavonoids, isoflavones, and protease inhibitors that may protect against cancer,

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[2] Dohadwala MM, Holbrook M, Hamburg NM, Shenouda SM, Chung WB, Titas M, Kluge MA, Wang N, Palmisano J, Milbury PE, Blumberg JB, Vita JA. Effects of cranberry juice consumption on vascular function in patients with coronary artery disease. Am J Clin Nutr. 2011 May;93(5):934-40

[3] Novotny, et al., *Low Calorie Cranberry Juice Reduces Risk Factors of Cardiovascular Disease in Adults*, Circulation, 2012, 126:21 Supplement A19732; Novotny, et al., *Low Calorie Cranberry Juice Lowers Blood Pressure in Healthy Adults*, Hypertension 2012, 60:3 Mtg Abstr. A299; Basu, et al., *Low-energy cranberry juice decreases lipid oxidation and increases plasma antioxidant capacity in women with metabolic syndrome*, Nutr Res. 2011 Mar, 31(3):190-6.

[4] Duffey, et al., *Adult cranberry beverage consumers have healthier macronutrient intakes and measures of body composition compared to non-consumers: National Health and Nutrition Examination Survey (NHANES) 2005-2008*, Nutrients, 2013 Dec 4; 5(12):4938-49.

[5] IOM (Institute of Medicine). 2007. *Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth*. Washington, DC: Nat'l Academies Press. at Box 2.1, p. 41.

heart disease, osteoporosis, and other chronic health conditions."[6] Critically, the US Institute Of Medicine (IOM) stated: "These points reinforce the need for nutrition standards to look beyond the criteria of nutrient upper limits (for sugars, fat, saturated fat, etc.), and to place at least equal emphasis on the health benefits of fruits, vegetables, and whole grains."[7] By focusing only on curtailing "sugar' without an accommodation that takes into account the positive impact that consumption of fruits like cranberries brings to the diet, global guidelines are not taking into account the importance of fruit phytonutrients to the consumers.

Cranberries Have Abundant Polyphenols, Including Unique Proanthocyanidins.

Research has shown that cranberry products have a wide range of positive nutritional benefits due to their high content of polyphenols, including their unique proanthocyanidins ("PACs"). PACs are a natural compound that reduces bacterial adhesion to cells, and may also positively impact gut and immune health.[8] In fact, cranberries contain the highest amount of polyphenols and PACs among commonly consumed fruits. (See Table 1 and Table 2).[9]

[6] 2010 DGAC at Section 2, Part D, p. 125.

[7] IOM, *supra* note 5.

[8] Nantz et al., *Consumption of cranberry polyphenols enhances human γδ-T cell proliferation and reduces the number of symptoms associated with colds and influenza: a randomized, placebo-controlled intervention study*, Nutr J. 2013 Dec 13; 12:161; Pierre JF et al. *Cranberry proanthocyanidins improve intestinal sIgA during elemental enteral nutrition*, JPEN J Parenter Enteral Nutr. 2014 Jan, 38(1):107-14, Zhang, L.; Ma, J.; Pan, K.; Go, V. L. W.; Chen, J.; You, W.-c., Efficacy of Cranberry juice on Helicobacter pylori infection: a double-lind, randomized placebo-controlled trial. Helicobacter 2005, 10, (2), 139-145., Shmuely, H.; Yahav, J.; Samra, Z.; Chodick, G.; Koren, R.; Niv, Y.; Ofek, I., Effect of cranberry juice on eradication of helicobacter pylori in patients treated with antibiotics and a proton pump inhibitor. Molecular Nutrition and Food Research 2007, 51, (6), 746-751; Gotteland, M., Andrews, M., Toledo, M., Munoz, L., Caceres, P., Anziani, A., Wittig, E., Speisky, H. & Salazar, G. (2008) Modulation of Helicobacter pylori colonization with cranberry juice and Lactobacillus johnsonii La1 in chidren. Nutrition, 24, 421-426.

[9] Table 1: Vinson, Su, Zubik, Bose, et al., *Phenol antioxidant quantity and quality in foods: fruits*, J. Agric. Food Chem., 2001 Nov, 49(11):5315-21; Table 2: Gu, et al., J. Nutr. 2004 Mar, 134(3):613-7.

Table 1: Polyphenol content of commonly consumed fruits.

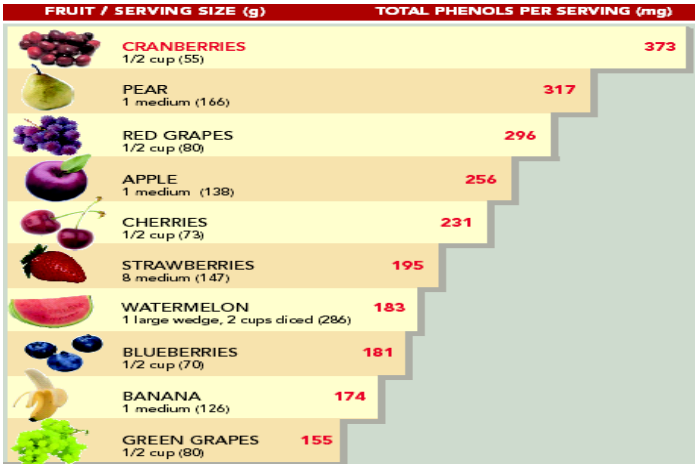
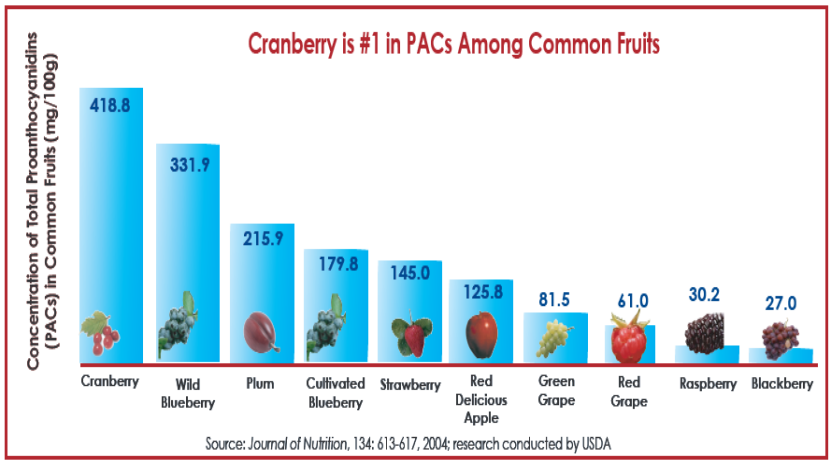


Table 2: Proanthocyanidin content of commonly consumed fruits.



<u>Cranberries' PACs Positively Impacts Urinary Tract Health & May Help Address Antibiotic Use Concerns.</u>

The unique PACs found in cranberry products provide significant health benefits in the areas of urinary tract health and antibiotic resistance. Bacterial adhesion to bladder cells is a factor in urinary tract infections ("UTIs"), necessary for infection to occur. *Urinary tract infections are the second most common bacterial infection* that results in more than 9.7 million physician visits annually in this country.[10] The recurrence rate of UTIs in women is up to 30%, and in children, the prevalence rate is

[10] *Medical Expenditure Panel Survey (MEPS)*, September 2012, Agency for Healthcare Res. and Quality, Rockville, MD, available at: http://www.ahrq.gov/research/data/meps/index.html.

about 7%, with a recurrent rate of about 12-30%. Chronic UTIs are also a serious problem. [11] In the United Kingdom, Urinary tract infections (UTIs) account for 1-3% of all GP consultations, For example, in April 2012 to March 2013: there were 281,296 finished consultant episodes and UTI admission to hospital. 1 in 3 women will have at least one UTI by age 24 years and 1 in 2 women are treated for at least one UTI during their life, troubling statistics discussed in a recent conference. [12] UTIs are recognized by WHO, and other bodies, as a significant public health challenge that should be addressed expeditiously due to their contribution to antibiotic resistance.[13] Against this backdrop, it is critical to recognize that consuming cranberry products helps improve urinary tract health, and reduces the risk of UTIs, by causing the bacteria that result in UTIs to become unable to adhere to bladder cell walls. The positive impact cranberries have on urinary tract health extends to women who suffer from recurrent UTIs.[14] Results from three recent pediatric trials support that consumption of cranberry-containing products protects against UTIs in children in addition to other at risk population.[15] Recent consensus reports and peer reviewed articles by several global health researchers confirm that cranberries can be important as a nutritional approach to help maintain urinary tract health.[16]

Prevention of UTIs via the improved urinary tract health associated with cranberry consumption also contributes positively to managing antibiotic resistance, which is likewise a public health concern, by helping to reduce antibiotic use.[17] A recent WHO Global Surveillance report on antimicrobial resistance recognized that very high rates of antibiotic resistance have been observed in bacteria that cause common community acquired infections associated with health-care and similar settings (e.g. urinary

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[11] Griebling, *Urologic diseases in America project: trends in resource use for urinary tract infections in women*, J. Urol. 2005 Apr; 173(4):1281-7; Greenhow, et al., *The changing epidemiology of serious bacterial infections in young infants*, Pediatr. Infect Dis. J. 2014 Jun, 33(6):595-9; Shim, et al., *The risk factors of recurrent urinary tract infection in infants with normal urinary systems*, Pediatr. Nephrol. 2009 Feb, 24(2):309-12; Nuutinen, et al., *Recurrence and follow-up after urinary tract infection under the age of 1 year*, Pediatr. Nephrol. 2001 Jan, 16(1):69-72.

[12] Gardner E. Cranberries: The Health Properties of Cranberries. *Nutrition Bulletin*, **39**, 223–230

[13] *Antimicrobial Resistance: Global report on surveillance 2014*, World Health Organization, April 2014, available at: http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf.

[14] Wang, et al., *Cranberry-containing products for prevention of urinary tract infections in susceptible populations: a systematic review and meta-analysis of randomized controlled trials*, Arch Intern. Med., 2012 Jul 9, 172(13):988-96.

[15] Salo, et al., *Cranberry juice for the prevention of recurrences of urinary tract infections in children: a randomized placebo-controlled trial*, Clin. Infect. Dis. 2012 Feb 1; 54(3):340-6; Afshar, et al., *Cranberry juice for the prevention of pediatric urinary tract infection: a randomized controlled trial*, J. Urol. 2012 Oct, 188(4 Suppl.):1584-7; Ferrara, et al., *Cranberry juice for the prevention of recurrent urinary tract infections: a randomized controlled trial in children*, Scand. J. Urol. Nephrol. 2009; 43(5):369-72.

[16] Blumberg, et al., *Cranberries and their bioactive constituents in human health*, Adv. Nutr. 2013 Nov 6, 4(6):618-32; Gardner, *The health properties of cranberry juice*, Nutr. Bulletin, 2014, 39: 223–230.

[17] *Medical Expenditure Panel Survey (MEPS)*, September 2012, Agency for Healthcare Res. and Quality, Rockville, MD, available at: http://www.ahrq.gov/research/data/meps/index.html. .

tract infection, pneumonia) in all WHO regions.[18] The high proportion of resistance reported for *E. coli* and *K. pneumoniae* to third generation cephalosporins, which are used to treat urinary tract and blood stream infections, means that treatment of severe infections that are likely to be caused by these bacteria must rely on carbapenems, the last-resort to treat severe community and hospital acquired infections. The Center for Disease Control published a similar antibiotic resistance report in July 2013, which noted that UTIs are the second most common infection leading to an antibiotic prescription in nursing homes, at nearly 33%.[19]

Additionally, the US FDA's list of qualifying resistant pathogens of public health concern, which it promulgated just two months ago (June 5, 2014) includes *Enterobacteriaceae* (e.g., *Klebsiella pneumoniae*), *Enterococcus* species, and *Helicobacter pylori* among those pathogens that pose particular risk of antibiotic resistance.[20] Importantly, these are pathogens that have been found to be impacted by cranberry compounds.[21] Thus, whereas treatment of UTIs with antibiotics has the potential to contribute to the problem of antibiotic resistance, maintenance of a healthy urinary tract through consuming cranberry products can mitigate growing resistance of those pathogens to antibiotics by reducing our population's reliance on those antibiotics used to treat UTIs. Facilitating the consumption of cranberry products capable of delivering the benefits of a healthy urinary tract should be encouraged wherever possible.

Despite The Need to Be Sweetened, Cranberries Are Nutrient Dense

Yet, cranberries (unlike grapes, apples and oranges) are naturally low in sugar, giving them a distinctively tart, astringent and even unpalatable taste as shown by the sugar (brix)-to-acid ratio in Table 2 below. As such, consumers enjoy the benefits of cranberry products that are sweetened to a level that is lower than (low calorie with non-nutritive) or at similar levels with, endogenously present sugar in comparable fruit juices and dried fruit products (See Table 3 and Table 4). This sweetening for palatability does not diminish the healthful properties of cranberry products, a fact that has been acknowledged by USDA [22]

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[18] *Antimicrobial Resistance: Global report on surveillance 2014*, World Health Organization, April 2014, available at: http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf.

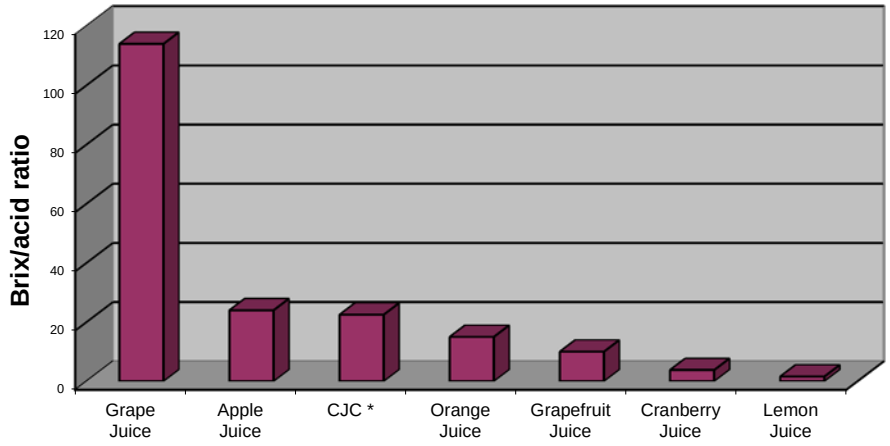
[19] Benoit, et al., *Factors Associated with Antimicrobial Use in Nursing Homes: A Multilevel Model*, J. Am. Geriatr. Soc. 2008 Nov, 56(11):2039-44.

[20] *Establishing a List of Qualifying Pathogens Under the Food and Drug Administration Safety and Innovation Act*, 79 FR 32464, 21 CFR Part 317, Docket No. FDA-2012-N-1037, June 5, 2014.

[21] Gupta, et al., *Inhibition of adherence of multi-drug resistant E. coli by proanthocyanidin*, Urol. Res. 2012 Apr, 40(2):143-50; Shmuely, et al., *Cranberry components for the therapy of infectious disease*, Curr. Opin. Biotech. 2012 Apr, 23(2):148-52.

[22] Interim Final Rule, *National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy Hunger-Free Kids Act of 2010*, Federal Register, Vol. 78 No. 125, June 28, 2013 ("USDA Nutrition Standards").

Table 3: Brix-to-acid ratios of common fruit juices.[23]



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Adding a modest amount of sugar to cranberry products does not diminish the health benefits of the cranberry that those products deliver, as shown by the high polyphenol content of cranberry juice in comparison to other fruit juices. This is not only true for cranberry juice cocktail (See Table 4A), but also dried cranberries, which contain more polyphenols per serving than raisins (See Table 4B). In fact, a majority of peer-reviewed studies that the health benefits of cranberries referenced in this Comment were conducted using sweetened cranberry products.

Table 4A: Nutritional Profile of cranberry juice cocktail to comparable 100% Juices.[24]

Juice	**Calories per 240 ml**	**% Calories from added sugar**	**Total Sugar (g)**	**Polyphenols (uM)**
Cranberry Juice Cocktail	110	88	28	81
100% apple	112	0	28	65
100% white grape	156	0	39	14
100% orange juice	90	0	22	20

[23] Table 3 adapted from: Leahy, Roderick, Brilliant, et al., *The Cranberry – Promising Health Benefits, Old and New*, Nutr. Today 2001 at 36(5):254-265 and Ocean Spray laboratory data. Note: "CJC" means cranberry juice cocktail.

[24] Adapted from Mullen, et al., *Evaluation of Phenolic Compounds in Commercial Fruit Juices and Fruit Drinks*, J. Agric. Food Chem. 2007, 55 (8), p. 3148–3157; Vinson JA, Su X, Zubik L, Bose P. Phenol antioxidant quantity and quality in foods: fruits. J Agric Food Chem. 2001 Nov;49(11):5315-21.

Table 4B: Nutritional Profile of dried cranberries to comparable dried fruit.

Dried Fruit	**Calories per 40 g (1/4 cup)**	**% Calories from added sugar**	**Total Sugar (g)**	**Fiber (g)**	**Polyphenols (mg)**
Dried Cranberries	130	92%	26-29	3	177
Raisins	130	0%	26-29	2	150

The US DGAC concluded in 2010 that the best use of added sugar is to increase the palatability of nutrient-dense foods.[25] As FDA acknowledges in their Proposed Rule, "small amounts of added-sugars can increase the palatability of nutrient-dense foods," and that such foods are "appropriate in a balanced diet."[26] Sweetened cranberry products achieve this goal. In June 2013, USDA promulgated new "Nutrition Standards for All Foods Sold in School" in connection with its responsibilities for the National School Lunch Program and School Breakfast Program ("School Nutrition Standards").[27] USDA's School Nutrition Standards establish guidelines for foods that may be sold as "competitive foods" in our nation's school cafeterias and vending machines before and after school, including a cap on the amount of sugar that may be in such products. Importantly, in its School Nutrition Standards, USDA recognized that cranberry products should be available to school children. The standard approved by USDA requires that food items have 35% or less of their weight derived from total sugars to be sold in schools, with a general restriction on foods with added sugars. However, USDA created a specific exemption to the standard:

> "Dried whole fruits, or pieces, with nutritive sweeteners that are required for processing and/or palatability purposes (i.e. cranberries, tart cherries, or blueberries) are exempt from the sugar standard."[28]

In exempting dried cranberries from the School Nutrition Standards, USDA recognized that encouraging the consumption of this unique fruit, with all its attendant health benefits, would serve the public good. Concerns regarding sugar content should not outweigh the overall health profile of the food, and in recognizing this fact, USDA correctly determined that cranberry products should not be unfairly penalized simply because they require sugar to achieve palatability.

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[25] U.S. Department of Agriculture and U.S. Department of Health and Human Services.(DGAC) (2010) "*Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*", 7th Ed. Washington DC: U.S. Government Printing Office. p 46.

[26] FDA Proposed Rule 2014: Revision of the Nutrition and Supplement Facts Label at 11905.

[27] USDA National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010; Interim Final Rule at 39077, 39086.

[28] Id.

The European Union has also recognized the need for special treatment of unique cranberries to overcome their tart and astringent taste. Council Directive 2001/112/EC of 20 December 2001, as amended, relating to fruit juices and certain similar products intended for human consumption (Annex IV) specifies a category of fruit nectar made from "fruits with acidic juice unpalatable in the natural state," including cranberries.[29] Pursuant to this EU Directive, for a product containing at least 30% cranberries (by volume of the finished product) may contain added sugar and still be labelled a "fruit nectar." This Directive by the EU appropriately recognizes that cranberries and other naturally tart, nutrient-dense fruits require sweetening for palatability so consumers can increase their recommended daily fruit intake and enjoy the many health benefits of the cranberry.

While the term 'sugars' refers to monosaccharides and disaccharides, various terms are used to define the types of sugars described in dietary recommendations, with definitions ranging from 'added sugar ' (FDA) to 'non milk extrinsic sugar' (UK), to 'free sugar' (WHO). As described in Chapter 6 (pg 105) of the SACN report, intake of sugars or individual sugars is not associated with the incidence of type 2 diabetes mellitus, glycaemia, insulinaemia or insulin resistance, and although a greater risk of developing type 2 diabetes mellitus is associated with the consumption of sugars-sweetened beverages in cohort studies, there is insufficient data to form firm conclusions with regard to sugars-sweetened beverage intake. As noted above, despite the need to be sweetened, cranberry juice is a not nutrient poor beverage and provides a rich source of polyphenols to support heart health. The 2010 DGAC report notes that "the body's response to sugars does not depend on whether they are naturally present in food or added to foods."[30] That same report found that randomized clinical trials show that added sugars are not different from other calories in increasing energy intake or body weight.[31]

Simply put, our bodies do not distinguish between naturally-occurring sugar and added sugar; and the body's conversion of sugar to energy is indifferent with regard to the source of that sugar. One is not preferable to the other, and efforts to treat them differently is concerning.[32] FDA in their proposed rule on nutrition labeling concluded that the intake of "added sugars" does not relate to any chronic disease or health condition.[33] The US FDA notes that:

> "U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease … neither the 2010 DGA nor the IOM macronutrient report concluded that added sugars consumption from all dietary sources, in itself, increases obesity. In fact, the 2010 DGA states that added sugars do not contribute to weight gain more than any other source of calories."[34]

Other authorities are in accord. The results of a large meta-analysis commissioned by the World Health Organization to examine a link between "added sugar" and body weight, selecting 30 of over 7900

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[29] Council Directive 2001/112/EC of 20 December 2001 at 61 and Annex 4.

[30] DGAC 2010 Report

[31] Id.

[32] As FDA acknowledges, there is a "lack of a physiological distinction between added and naturally occurring sugars," and no "analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product.

[33] FDA Proposed Rule 2014: Revision of the Nutrition and Supplement Facts Label at 11904.

[34] Id.

randomized clinical trials and 38 of over 9400 cohort trials concluded that the overall quality of the available evidence for changes in body weight in relation to both increasing and decreasing “added sugars” intake in adults was considered to be “moderate to low.”

In conclusion, we urge the SACN to recognize the importance of cranberry products despite their need to be sweetened as they contribute varied, unique health benefits supporting urinary tract, heart health and other benefits which may help address other public health issues. We support the continuing inclusion of fruit juices as important sources of fruit servings and not a source of empty calories. Fruits and fruit products, especially polyphenol rich fruits like cranberries can help increase fruit intake in the population. Cranberries, uniquely abundant in Type A Proanthocyanidins, have additional benefits that address public health concerns such as preventing urinary tract infections, mitigating the problem of antibiotic resistance, and helping to promote heart health – and can be part of a healthy balanced diets.

Thank you for your consideration of our comments,

Sincerely,

Geoffrey Woolford,
VP R&D and Corporate Quality
Ocean Spray Cranberries, Inc