

USHBC RESEARCH COMMITTEE  
MEETING MINUTES  
February 29, 2008

Chairman Dave Brazelton called the meeting of the USHBC Research Committee to order at 2:30 pm on Friday, February 29, 2008. Roll call showed committee members Parm Bains, Ryan Brown, Brian Caster, Adair Peterson, Amy Howell, Mike Mainland and Dave Trinka in attendance. Also attending the meeting, held at the Pan Pacific Hotel in Vancouver, British Columbia, were Rafael Manzoni (USDA AMS R&P) and USHBC staff members Leslie Wada, Mark Villata and Mary Nezbeth. Chairman Brazelton noted that, to allow for better use of time, the meeting agenda would be rearranged to allow for discussion of the FDA meeting and the Strategic Plan to take place after activity updates.

The first agenda item was an update on current Research Committee activities by Leslie Wada. Wada provided the following comments on currently funded research projects:

***“Novel Actions of Dietary Blueberry to Prevent Adipose Inflammation and Type 2 Diabetes”***

*Martin Obin- Tufts University*

Dr. Obin saw beneficial effects of blueberry feeding on insulin resistance at 8 weeks but the effect was lost at 12 weeks. The non-blueberry fed, obese mice did not gain as much weight as expected at 12 weeks, and therefore this may have contributed to the lack of difference with the blueberry-fed mice. Dr. Obin will be conducting further studies to evaluate this. His most recent findings show that gene expression data for two critical markers of adipose inflammation at early stages of insulin resistance showed a beneficial effect of blueberry feeding at the 8-week point. Both markers were reduced with blueberry and high fat feeding and not significantly greater than in low fat fed mice. He is also planning on looking at levels of anthocyanins in tissues with the cooperation of Dr. Milbury as they are both at Tufts.

***“Blueberry-Enriched Diets- Effect on Metabolic Syndrome in Rats”***

*S.F. Bolling and E.M Seymour- University of Michigan*

Dr. Bolling sent a six-month progress report showing that when Zucker obese rats were fed a high fat diet, they lost fat mass, abdominal fat and had lower plasma triglycerides when blueberries were added to the diet. However, when Zucker lean rats were fed the high fat diet, their weight and fat mass increased when blueberries were added to the diet. This finding, that normally lean animals eating a high fat diet to induce obesity do not receive protection with blueberries, is similar to the previously reported study by Ron Prior. The study will continue to look at these animals when fed a low fat diet as well as analyzing inflammatory markers.

***“Chronic Effects of Freeze-Dried Whole Blueberry Drink Consumption on Biomarkers of Lipid Peroxidation and Inflammation in Subjects with Metabolic Syndrome (MES)”***

*Arpita Basu- Oklahoma State University*

Dr. Basu has found it difficult to recruit subjects for her study. She has modified her study to allow the subjects to make fewer trips to the research center and will provide compensation more frequently with no change in overall amount. Two subjects have completed the study and one is currently enrolled. One subject liked the blueberry drink and requested more. She reported that she stayed healthy during the study, even though many around her had gotten sick. Project

completion will be later than originally planned. Chris Christian from the Strawberry Commission contacted Leslie Wada to ask about Dr. Basu, as they had been contacted to provide strawberry powder.

***"The Effect of Blueberry Extract to Enhance Insulin Sensitivity in Human Subjects- A Pilot Trial"***

*Dr. William Cefalu- Pennington Biomedical Research Center*

Dr. Cefalu at the Pennington Center has screened 8 subjects, two have qualified and one will be randomized soon. He made last minute changes to the IRB to allow for the cognitive studies that Don Ingram had added in conjunction with WBANA. We were not aware of this and the committee recommended that Wada contact Susan Davis and Dr. Cefalu to get more information.

***"Distribution of Anthocyanins in Tissues of Blueberry-Fed Pigs"***

*Paul E. Milbury- USDA HNRCA Boston*

*Willy Kalt- Agriculture and Agri-Food Canada, Nova Scotia*

Dr. Milbury has encountered equipment problems, so the remainder of his anthocyanin analysis is delayed. An extension to his contract is being processed.

***"Do Blueberries Improve Vision and Eye Health?"***

*Francois Tremblay- Dalhousie University, Halifax, Nova Scotia*

*Willy Kalt-Agriculture and Agri-Food Canada, Nova Scotia*

Dr. Kalt has completed screening of all of her subjects. After the first half she felt there was a beneficial effect with blueberries on adaptation after a bright light, however she doesn't see an effect after this second half. It is all speculative as she has not run any statistics yet.

***"A Systemic Study of the Synergistic Effects of Blueberry Phytochemicals Against Age-Related Macular Degeneration"***

*Jack N. Losso- Louisiana State University*

Dr. Losso has completed his study but we are awaiting his final report.

***"Mechanisms Involved in the Beneficial Effects of Blueberries on Neuronal Aging and Behavior"***

*Jim Joseph-USDA HNRCA Boston*

Dr. Joseph sent copies of recent articles he has published. The Linus Pauling Institute at Oregon State University has received a large grant to set up a research institute. Dr. Joseph applied for a position. Amy Howell suggested that we hold off our \$18,000 contribution towards his gait lab until we know where he will be working. Wada is to contact him and ask if he is planning on heading to the Linus Pauling Institute and if so, would Barbara Hale transfer to the Institute with him. We will also check to see which projects we currently have funded with him at the USDA lab at Tufts would be transferred with him to his new location.

***"Neuroprotective Effects of Highbush Blueberries"***

*Susan McGuire- Loyola University, Chicago*

Dr. McGuire has sent a report with results from various studies she has conducted recently. She was not able to find a beneficial effect with blueberries in her study and she has conducted several follow-up studies to try to determine the reason. In one case she felt the animals were not healthy. She also feels that the time point to initiate the stab wound may have changed. The committee

had considered providing interim funding, but as she has not submitted an official request it was suggested that she submit a proposal at the usual time this Fall. She has seen some interesting findings in a separate multiple sclerosis animal model and she may pursue that direction in her next proposal.

Upon the completion of her research project update, Wada then updated the committee on other actions to date. She reported that there have been no further developments with the National Institute of Standards and Technology blueberry standard as they lost a technician and just recently replaced him. She noted that a revised memorandum of agreement was submitted for Dr. Kalt's vision study extension and final signatures are expected shortly. Wada discussed the next berry health symposium that is now under the direction of the National Berry Crops Initiative (NBCI) and is planned for Monterey, California in June of 2009. The California Strawberry Commission will be hosting this event and assisting in its coordination. USHBC provided \$15,000 for the last conference and will most likely receive a request for this same about this May or June to fund the 2009 activity.

Mark Villata noted that the USHBC Finance Committee had added an additional \$100,000 to the Research Committee budget for 2008 bringing the budget total to \$387,500 (see Exhibit #1).

The second item of business was a USHBC/FDA meeting update and discussion of actions needed to develop a qualified health claim. Amy Howell summarized the meeting where representatives from the USHBC and USDA AMS met with representatives of the FDA to discuss language that is permitted in advertisements, publications or labels of blueberries. She noted that the FDA is selective about what types of research with blueberries can be used to support qualified health claims. There must be specific acceptable surrogate markers used when studying a condition (e.g. glucose levels for diabetes, LDL-cholesterol for heart disease) and not any marker will be acceptable. Only human clinical studies will be accepted. Any claim that the FDA will accept will be a general one that will include both highbush and lowbush, therefore the use of a mixture of both in studies may be advantageous. Even if a qualified health claim is not desired or achieved, these regulations would still be necessary for acceptable advertising and marketing messages. Brian Caster suggested that we consider these issues and alter our language in the next round of our RFP to request specific studies that will provide the needed information and that follow FDA guidelines and requirements.

The next agenda item was a discussion and prioritization of strategic goals assigned to the USHBC Research Committee in the updated 2007-2011 USHBC Strategic Plan and a discussion of an action plan to achieve the assigned goals. Chairman Brazelton led discussion on the strategic goals assigned to the Research Committee in the Strategic Plan. The current items listed are too specific and more general wording is necessary, as we do not know what areas of research will be fruitful. It was suggested that text similar to that from the minutes of the Dallas promotion meetings would be useful: "Direct research efforts to obtain a qualified health claim." He restated the need to conduct human trials in order to meet FDA requirements as well as the need to use a lowbush/highbush blueberry blend in future studies to meet the FDA goal that the project reflect blueberries as a category rather than specifically wild or cultivated. He noted that we would need to have some discussions with WBANA to determine their interest in any collaborative efforts.

Based on these requirements, the Research Committee modified their strategic goals as follows:

### Build Health Benefits Research

- Direct Research Efforts to Obtain a Qualified Health Claim
- Continue with Broad Research Efforts that will Support our Publicity Function and Identify New Areas of Opportunity

The assignment to "Support Food Safety Research" (Develop a sanitation step for berries) assigned to the Research Committee in the 2007-2011 strategic plan was discussed and it was the consensus of the committee that this function would be better addressed by the newly formed USHBC Food Safety Committee. Following discussion, a motion was made by Brian Caster that research efforts should be pointed in the direction of obtaining a qualified health claim and that food safety research should be directed to the USHBC Food Safety. Adair Peterson gave her second to the motion and the motion carried. Chairman Brazelton will make this recommendation to the Council at their meeting on Saturday.

Additional discussion on qualified health claims and human feeding trials followed. Amy Howell mentioned ways to consider relatively less expensive human studies such as conducting research in other countries, however different populations and cultures could result in findings that may be different than those of North American subjects. Another option could be to consider using less expensive research sites. For example, she noted that research centers at locations such as Duke and the University of Michigan might be more expensive than research centers at a location such as Walter Reed Hospital.

The question of WBANA's interest in pursuing qualified health claims was addressed to Neri Vautour, Executive Director of WBANA Canada who was attending today's meeting. Vautour felt that health claims were not a major discussion point with his members, but that he sees the benefit of working with the cultivated group in research efforts where possible.

Amy Howell noted that she felt that the USHBC should not be left behind if other groups are moving quickly to developing qualified health claims. Dave Trinka raised the question if we are required by FDA to include both highbush and lowbush in our projects and Brian Caster asked about requirements for different species. Howell stated species is not an issue and noted that as an example the FDA would not require information on each individual apple variety in considering a claim for apples. It was suggested that further clarification is needed to be sure we are up to speed in how the FDA would handle the lowbush/highbush blueberry question.

Given the change in strategic direction recommended by the Committee, and the action plan to work toward a qualified health claim, Ryan Brown moved, with a second from Mike Mainland, that the USHBC initiate discussions with WBANA Maine and Canada to explore working together on a qualified health claim for blueberries. It was noted that Ruth Lowenberg has been approached by WBANA to work on a joint press release on Willy Kalt's recently published work. It was agreed that she could move ahead on this.

The second action item will be to revise the USHBC RFP packet, to be distributed this Fall, to reflect the updated strategic direction of the Research Committee, FDA requirements, our

emphasis on clinical studies and research conducted at centers of excellence. (The RFP packet with revised language will be reviewed at the next meeting )

Action item three would be to continue to pursue current areas of opportunity Dave Trinka moved to accept these action plans. His motion was given a second by Ryan Brown and the motion carried

The final agenda item was a discussion of possible additional studies or projects for 2008. Amy Howell shared a proposal for a drug interaction study by Dr. David Greenblatt from Tufts University to look at the interaction between blueberry juice and drug metabolizing enzymes in humans. The direct cost for this project is \$92,000 and with the indirect costs requested by Tufts would total approximately \$101,200. It was noted that he would not publish study results without USHBC permission and that In vitro assays would not be acceptable. There was discussion about the high cost of this project and whether other groups, such as Welch's or the Strawberry Commission have done similar research. Howell noted the effect this issue had recently on the cranberry industry and how important this research could be. Given the unique aspects of this research, it was decided that Chairman Brazelton request direction from the Council at their Saturday meeting.

The committee discussed blueberry placebo development. Amy Howell had followed up on some leads and discussed this possible project with Tara McHugh at the USDA Lab in Albany, California. The USDA Lab does not have a pasteurization facility but would be able to develop a frozen drink that they can prepare on site, however they cannot accommodate large volumes. Howell noted she would like the USDA Lab to develop a placebo that has thickness without adding fiber. It was noted that they also have a small animal facility and could run a 30 subject pilot study. It was decided that more discussion and follow up is needed on this project. Leslie Wada will assist in discussion with this USDA Lab that is located very near to her office in the Bay Area.

The committee discussed the effort to develop a blueberry study matrix and database. Wada noted that she is continuing to explore this area and has found a possible software source that may meet Committee needs. She will continue to explore this software option and will get back to the Committee with a recommendation shortly.

The Committee discussed the current inventory of blueberry powder and concluded that the current amount in storage is sufficient to meet this year's needs. It was decided that additional Rubel and Tifblue blueberries (approximately 4,000 pounds total) be purchased from the 2008 crop in addition to our normal purchase for our frozen blueberry bank so that blueberries are available for possible freeze drying in 2009.

There being no further business Dave Trinka moved, with a second from Mike Mainland, to adjourn the meeting. The motion carried and the meeting was adjourned at 5:30pm

# EXHIBIT #1

## USHBC 2008 RESEARCH BUDGET

Approved As of February 2008

<i>ACTIVITY</i>	<i>2008 Budget</i>
<i>Research Projects:</i>	
<i>Continuing Projects-</i>	
USDA HNRCA (Joseph)	\$26,000
<i>New Project Commitments-</i>	
Vision Study Extension (Kalt)	\$39,394
Gait Lab (Joseph)	\$18,000
<i>Sub Total Research Projects</i>	<i>\$83,394</i>
Research Administration	\$26,000
Blueberry Research Bank	\$28,000
Blueberry Researcher Travel	\$5,000
Sponsorships	\$2,500
Reserve	\$242,606
<b>Budget Total</b>	<b>\$387,500</b>
<i>Additional Options for 2008:</i>	
<i>Blueberry Drug Interaction Research</i>	
<i>Blueberry Placebo Development</i>	
<i>Blueberry Study Matrix and Data Base</i>	