

**United Fresh Produce Association
Food Safety & Technology Council Meeting**

La Quinta Resort, La Quinta California
January 14, 2015

Draft Minutes

Council Members Present:

Bob Elliott, Sunkist Growers, Chair

Walt Armijo, Lighthouse FS&Q
Megan Arnold, C.H. Robinson Worldwide
Tony Banegas, Ready Pac Foods
Ed Beckman, Live Oak Farms
DeAnn Benesh, 3M Food Safety
Sally Blackman, CPMA
Mike Bledsoe, Village Farms
Jim Brennan, SmartWash Solutions
Jim Cranney, California Citrus Quality Council
Suresh Decosta, McDonald's
Harold Ewell, N2N Global
Ebrahim Firoozabady, Del Monte Fresh Produce
Lisa Fuentes, The Nunes Company
John Gurrisi, Chiquita Brands
John Headrick, Monsanto
Peter Hill, Alpine Fresh
Scott Horsfall, California LGMA
Refsnider Keith, Driscoll's
Beverly Kempf, Club Chef
Justin Kerr, Factor IV Solutions
Karan Khurana, Pulse Instruments
Cynthia Klein, Sun World International
Mahipal Kunduru, McDonald's
Tom Lovelace, McEntire Produce
Drew McDonald, Church Brothers
Bob Mills, The Harbinger Group
Gurmail Mudahar, Tanimura & Antle
Gail Murray, Disney Consumer Products
Courtney Parker, Chiquita Brands
Sean Picquelle, SP Food Safety Consulting
Bill Pool, Wegmans Food Markets
Jeanne Raede, Raede and Associates
Walter Ram, The Giumarra Companies
Keith Refsnider, Driscoll's
Joan Rosen, JC Rosen Resources
Aaron Schneider, Dole Fresh Vegetables
Gurjit Shergill, Taylor Farms
Marshall Sherman, Walter P. Rawl & Sons
Kim Snyder, Monterey Mushrooms
Stacy Stoltenberg, Dupont Qualicon
Susan Sahai, Subway - DRS
Trevor Suslow, UC Davis
Jon Wall, North Bay Produce

Tom Young, Young Appraisal & Consulting
Bob Ziel, McEntire Produce
Brian Zomorodi, Ready Pac Foods

United Fresh Staff:

David Durkin, OFW Law
David Gombas
Erin Grether

Guests:

Mustafa Bilgen, Dow Packaging
Carrie Carlson, Microsearch Laboratory
Joe Darden, Mastronardi Produce
Barry Eisenburg, BASF
Rudi Groppe,
Lauretta Johnson, Roka Bioscience
Lianna Kelly, Markon
Carson Ludwig, Gill's Onions
Susan Reimer Sifford, Darden
Rusbelinda Silva, Haliburton International Foods
Luciana Soler-Smith, Dole Fresh Vegetables
Mario Steta, Driscoll's
Karen Taylor, Noblis
Sterling Thomas, Noblis
Sharron Thomas, Fresh & Easy
Ruth Timme, FDA CFSAN
Mary Lou Tortorello, FDA CFSAN
Richard Walsh, Ecolab

Council Members Absent:

Stan Bailey, bioMerieux Industry, USA
Geri Barone, Professional Food Safety
Roger Becker, Gold Coast Packing Company
Mike Bentel, J & J Family of Farms
Rod Bernard, Southern Specialties
Ian Bessell, Birko
Sam Bierschwale, Lipman
Dan Botts, FFVA
Abram Bowman, Deerpoint Group
Barbara Braden, organicgirl
Jeffrey Brandenburg, The JSB Group
Preet Brar, Raley's Family of Fine Stores
Donna Lynn Browne, Naturipe Farms
Hap Carr, Titan Farms
Ed Casey, Ocean Spray Cranberries

Megan Chedwick, Church Brothers	Sunny Luo, USDA ARS
Chris Christian, California Strawberry Comm.	Steven Lyon, Chick-fil-A
Cliff Coles, California Microbiological Consulting	Bridget Lyons, Taylor Farms
Gray Drohan, Junction Solutions	Tom Mack, Dole Fresh Vegetables
Amy Duda-Kinder, A. Duda & Sons	Amanda May, Paramount Citrus
Chris Dzuik, H-E-B	Donald Mayfield, Cabbage, Inc.
Thea Eubanks, organicgirl	Michael Menes, True Organic Products
Thomas Fenimore, GlobalG.A.P North America	Clarisa Molina, Ser-Ka Solutions
Steve Foster, Wholesale Produce Supply Co.	Bob Morrissey, National Watermelon Assoc.
Micah Fuson, Apio	Ernesto Nardone, N2N Global
Tom Gautreaux, Maxwell Chase Technologies	Jerry Noland, Safeway
Hank Giclas, Western Growers	Beth Oleson, GFVGA
Scott Grow, G.O. Fresh	Elis Owens, Birko
Laura Grunfelder, Northwest Hort. Council	Heena Patel, SCS Global Services
Valerie Hannig, The Oppenheimer Group	Chris Polito, Yum! Brands
Margaret Hardin, IEH Laboratories	Joshua Porbeni, Club Chef
Heidi Hau, Ecolab	Gale Prince, Your Food Safety Coach
Grace Ho, Misionero Vegetables	Eric Ritchie, McCain Foods USA
Joe Holt, Earthbound Farm	Jim Robbins, Wm. Bolthouse Farms
Bill Hurst, University of Georgia	Michael Roberson, Publix Super Markets
Michael Jantschke, Pro*Act	Mansour Samadpour, IEH Laboratories
Lance Jungmeyer, FPAA	Sam Schlagetter, Freshway Foods
Andy Kesler, Gray Dog Partners	Mark Seetin, U.S. Apple Association
Jeanna Kilmer, Silliker	Lori Tansey, Chiquita Brands
Ozgur Koc, Crunch Pak Sliced Apples	Hilary Thesmar, Food Marketing Institute
John Kolenski, The Kroger Company	Jim Topper, Neogen Corporation
Greg Komar, NSF Agriculture	Steve Tripp, Pacific International Marketing
Sharan Lanini, Chiquita Brands	Angela Valadez, Publix Super Markets
Jorge Leyva, MexBest	Tony Valenzuela, Naturipe Berry Growers
Jim Llano, Castle Rock Vineyards	Rich Varley, KiVar Chemical Technologies
	Matt Warren, Walter P. Rawl & Sons

I. Meeting Called to Order

Council Chair Bob Elliott welcomed the attendees and asked for self-introductions. The Council was reminded of the United Fresh antitrust guidelines. The Council approved the minutes of the September 2014 Council meeting without change. The agenda was approved without change, noting that the presenter for the AOAC Project on Field Sampling was unable to attend.

II. FDA Proposed Rules – United Fresh Comments

Gombas reminded the Council that FDA had already published seven proposed rules and two additional proposals in compliance with FSMA. The Council had previously been briefed on United Fresh comments submitted to all except the Supplementary Proposals to the two Preventive Controls rules, Produce Safety and Foreign Supplier Verification Programs, all published on September 29. The comment period for all four closed on December 15.

Gombas reviewed the key changes to the proposed rules and the comments submitted by the United Fresh working groups to each. He reminded the Council that all of the FDA proposals related to FSMA and the corresponding United Fresh comments are openly

accessible on the United Fresh website's [FSMA webpage](#). He also reviewed the expected timeframes for publication of the final rules and the years when each is expected to become enforceable. He also reminded the Council that FDA is expected to publish additional rules and guidance documents in compliance with FSMA, each of which will affect the produce industry and so will require working groups' assessments and comments to FDA.

III. Safe Food for Canadians Act Regulations

Sally Blackman reported that an expected CFIA update on the proposed requirements for Preventive Control Plans for produce had not occurred as planned, so there was no new information to report. She reminded the Council that key elements of the regulations are expected to include licensing of all operations selling produce in Canada (similar to FDA's requirement for facility registration, but also including farms (selling interprovincially) and non-resident importers), commodity specific food safety requirements, requirements for licensed operations (including farms) to have written Preventive Control Plans (exemption for small business with income less than \$30K) and for fruit and vegetable dealers to be members of a non-government entity (The Fruit and Vegetable Dispute Resolution Corporation) for dispute resolution, similar to USDA's PACA requirements. She noted that the non-resident importer licensing is proposed to be limited to operations from foreign countries recognized by CFIA as having a food safety system comparable to that of Canada and are importing food from that country into Canada (e.g., would not allow a U.S. importer to allow transshipments product from another country (unapproved or even approved) countries through the U.S. to Canada (directly or through the US). Blackman shared that comments submitted by CPMA to the proposals are available on the CPMA [website](#).

IV. IFSH – United Fresh Wash Water Validation Project Update

Dr. Mary Lou Tortorello, FDA CFSAN, provided an update on the joint project with the Institute of Food Safety and Health to develop a protocol/white paper that can be used to validate wash water systems, to comply with the requirement for process control validation expected in the final Preventive Controls rule. She provided a brief history of IFSH's efforts (the FS&T Council had decided to develop guidance on wash water validation in 2012, which merged with the IFSH project in 2013). Project participants include wash water experts from academia, FDA, CDC, USDA ARS and industry, including several Council members. The white paper, tentatively titled *Validating Antimicrobial Washes as Preventive Controls for Fresh-Cut Leafy Vegetables*, is intended to provide guidelines and practical advice to operations with wash systems, and will be published for broad distribution.

The paper will provide background information, including produce washing objectives, understanding cross-contamination, factors affecting antimicrobial effectiveness and maintaining antimicrobial effectiveness. The validation approach is modeled after historic approaches to thermal process validations. Current intent is to describe three options: a generic "Safe Harbor"; a non-challenge but facility-specific validation, such as might be established by a "process authority"; and a facility-specific inoculation study using the target pathogen or appropriate surrogate.

The group had met the previous day, and had struggled with the definition and description of the Safe Harbor approach. Based on research and literature review provided by Council member Yaguang "Sunny" Luo, the group had decided to focus on chlorine-based wash water systems and a "Critical Limit" of 10 ppm free chlorine; i.e., the minimum level of free chlorine that would reliably prevent cross-contamination from lettuce contaminated with up to 5 logs of pathogenic *E. coli*. The only Safe Harbor approach (i.e., independent of the

washing equipment being used) the group has been able to envision is for the operation to demonstrate the location of their equipment's "cold spot" – that is, the precise location where the free chlorine level is always lowest during operation – and to monitor continuously that the free chlorine level at that location does not fall below the 10 ppm Critical Limit during washing. The next option would be to validate the "worst case" levels of adjustable operating parameters (product:water ratio, turbidity, agitation, etc.) that would ensure the free chlorine level does not drop below 10 ppm in any part of the equipment wash water during operation. This option would also require learning the equipment's cold spot, but would not require routine monitoring of the chlorine level there. The third and most intensive option would be to inoculate lettuce with a surrogate at a level to mimic a 5 log challenge of the target pathogen, and demonstrate that cross-contamination is prevented when the equipment is run under worst case levels of the same adjustable operating parameters. For the second and third operations, post-validation monitoring and recordkeeping would involve ensuring the worst case levels are never exceeded during the wash process.

The group recognizes that the scope of the white paper – i.e., hypochlorous antimicrobial, leafy greens and pathogenic *E. coli* – and the 10 ppm minimum free chlorine level have a very narrow focus, but expects that the approach can be used by others to establish parallel validation protocols for other wash water systems.

Tortorello also described several related research efforts being performed by IFSH scientists, including a study of factors affecting risk of cross-contamination, being performed in scale-up systems from 50 ml benchtop equipment to the Biosafety level 3 (approved for work with human pathogens) pilot-scale flume that is unique to IFSH; a process analysis mathematical model to predict performance of wash water antimicrobials; development of a strategy for selection of appropriate non-pathogenic surrogates for validating systems; a comparison of indicator organisms that may be used instead of inoculation with surrogates; and an engineering study of in-line sensors for antimicrobial performance.

V. Whole Genome Sequencing

The presenter of last year's Science Symposium, Dr. Ruth Timme, FDA CFSAN, was invited to reprise her presentation on Whole Genome Sequencing (WGS) and FDA's Genome Trakr Project. She began by providing a perspective of FDA's food regulatory responsibilities: about 200,000 food facilities, over 300 ports of entry, 130,000 importers and over 11 million import lines per year. Domestically, there are over 2 million farms.

Older approaches to differentiating microorganisms include serotyping and Pulsed-Field Gel Electrophoresis (PFGE), both of which have limits in discrimination. In the past 6 years, DNA sequencing has undergone a huge paradigm shift, becoming much faster, cheaper, and easier to collect the sequence of an entire bacterial genome. With WGS, 3-5 million data points are collected for each isolate, and has the added advantage that genomes can be analyzed in their evolutionary context. That is, WGS is accurate enough to detect single nucleotide polymorphisms (SNPs) and genomic mutations are rare enough that isolates with only a few SNP differences can be geographically linked. WGS analysis is also comparable in time to conventional PFGE techniques, each pathway taking about seven days. More than two dozen laboratories in the U.S. and elsewhere are contributing sequences to a database maintained by the National Center for Biotechnology Information (NCBI), a part of the National Institutes of Health. For example, the Salmonella database now includes genomic sequences from 65 countries, 45 U.S. states, all 5 Salmonella subspecies and over 400 serovars of *Salmonella enterica* from the past 25 years.

Timme suggested that WGS offers multiple advantages to the produce industry:

- WGS can speed an outbreak investigation, notifying companies faster so that they can get contaminated product out of consumers' hands sooner, reducing the public health risk and the damage that comes from prolonged media scrutiny.
- Outbreaks can falsely implicate a large swath of the distribution chain. WGS can pinpoint a specific source, exonerating the remaining network supply chain.
- Operations can distinguish between endemic (entrenched) vs. ingredient or transient contamination.

More information about FDA's Genome Trakr Project and WGS is available here:

<http://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/default.htm#Intro>

In response to a question, Timme provided updated information about the ongoing listeriosis outbreak linked to caramel apples. She reported that FDA and California Department of Public Health had conducted a joint investigation of Bidart Bros, the alleged source of the apples, and that several food contact swabs were positive for *Listeria monocytogenes* strains indistinguishable by PFGE from the outbreak strains. All of the clinical and environmental isolates were undergoing WGS.

VI. Whole Genome Sequencing for Foodborne Pathogen Traceback: Pilot Project

Karen Taylor and Dr. Sterling Thomas, Noblis, described a volunteer pilot project they are leading to collect WGS data for the NCBI sequence database (see above). Taylor described Noblis as a nonprofit science, technology, and strategy organization with over 1000 employees, based in Virginia. She described the pilot as a 3-4 month duration project, beginning now, where participation may be anonymous or open. Participants send their isolates to Noblis for WGS analysis with an option to submit anonymized final sequences and metadata (information about the isolate) to NCBI. She said that data generated under the project would be protected by standard customer-laboratory relationship. Noblis believes operations will find value in participating in a low-cost, low-risk, rapid way to try out a new technology and to partner with Noblis to sequence and analyze their own pathogen samples, e.g., in-plant or product isolates that an operation wants to determine if they are from a common source or unrelated transients. Thomas described Noblis' BioVelocity tool as an even faster genome analysis platform. Anyone wanting more information about Noblis or the pilot project, including benefits to participants, should contact Taylor (karen.taylor@noblis.org; 703-610-2875) or Thomas (sterling.thomas@noblis.org; 703-610-1682).

VII. Council Priorities

Elliot reminded the Council that, in September, we had brainstormed new objectives and that several ideas had seemed to have broad support:

- Develop a scientific rationale to support a non-zero tolerance for *Listeria monocytogenes* on raw agricultural commodities that do not support growth.
- Development of tools to support industry under FSMA regulations, e.g.:
 - Sanitation and sanitary design education for in-field, packinghouse, etc.
 - Process validation procedures for produce
 - Risk mitigations for water use in field
 - Transportation risks from field to Packhouse
- Follow and develop recommendations, as appropriate, on emerging issues; e.g., biotechnology and GMOs.

Elliott described the non-zero tolerance as likely the most important potential objective, but recognized that the on-going listeriosis outbreak linked to apples would delay this until information from the FDA investigation is available. Meanwhile, we should plan on bringing outside experts (e.g., Dr. Martin Weidmann, Cornell Univ; Dr. Mickey Parish, FDA) to Chicago to brief the Council on *Listeria* and the potential for a non-zero tolerance. Trevor Suslow suggested that, instead of trying to remove the zero tolerance for all *L. monocytogenes*, we focus on having FDA react to only certain subtypes.

Elliott reviewed other potential objectives arising from the brainstorming session, including updating guidance for what to do when FDA knocks on the door. David Durkin agreed to draft an update to that guidance for the Council's review prior to the Chicago meeting. He also suggested sending the Council his article on *Photography and the Protection of Trade Secrets*.

Suresh DeCosta recommended the Council work on more hands-on guidance on how to use and execute sanitation programs, in the same way that we developed the *Listeria* guidelines. Walter Ram added that targeted information on grower/packhouse equipment design needs, for users and manufacturers, would be of value. Harold Ewell suggested engaging the IAFP Sanitary Design Professional Development Group in this project. Justin Kerr suggested that we develop some one-page briefing materials, like the American Meat Institute's "Top 10 for Sanitary Design". He also suggested we develop materials on unconventional cleaning procedures for packing operations, and he described a novel approach to verifying performance of sanitation programs using RFID.

Tom Lovelace recommended that we develop and deliver regional workshops on preparing for the FSMA rules. Bill Pool suggested developing a simple explanation of FDA's water testing requirements for growers.

Finally, it was suggested that we engage the United Fresh Produce Marketing & Merchandising Council for advice on how to get our information out to those who are not part of our Council.

VIII. Preventive Controls Plan for Fresh-Cut

Gombas reported that the Food Safety Preventive Controls Alliance (FSPCA) being coordinated by IFSH was nearing completion of their training curriculum for "qualified individuals" under the proposed Preventive Controls rules. A subgroup of the FSPCA is developing example Preventive Controls Plans to be used in training. Gombas had offered that the FS&T Council could develop one or two such plans for fresh-cut products for use in the Alliance training. He showed several excerpts of a plan being drafted by the FSPCA subgroup, as an example of the level of detail being considered, noting that the subgroup intends to include "optional" information, not just what is required by the rule. He suggested that the Council consider developing two plans: one for a typical fresh-cut bagged leafy greens salad, and one for a manual-cut fruit-in-clam-shell product. He also suggested that such plans would be a valuable addition to the *Food Safety Guidelines for the Fresh-cut Industry*. He asked for a volunteer group to develop or adopt one or more Preventive Controls rule-compliant plans for this purpose. Jim Cranney recommended that United Fresh hire a consultant to develop such a plan and circulate it to the Council for acceptance/recommendations.

IX. Learning Center topics

Erin Grether reviewed the Fresh Tech Learning Center topics from 2013 and 2014, and asked for recommendations/requests for 2015 topics. Suggestions offered at the meeting:

- A session, in layman's terms, on the role of WGS and other genetic tools in outbreak investigations, and how they may help the specificity of a recall or advisory, and help consumers understand what's safe. FDA's Eric Brown was suggested as a speaker.
- The updated manual on what operations should do during an FDA inspection, with David Durkin as the speaker.
- A hands-on, practical session on what's available in sanitation procedures and tools, with Justin Kerr and Joe Stout as potential speakers.
- A session on wash water validation, if the IFSH white paper is ready.
- With the final Produce Safety and Preventive Controls rule expected later this year, it was suggested that we have a session on "FSMA tools" – what's new that will be expected at packinghouse and fresh-cut operations, in particular what capital expenses.
- How the industry should work with researchers in a way that benefits both
- Social accountability – what are buyers requiring? What are suppliers doing? Is there potential for harmonization?
- How UAVs/drones are being used in food safety.
- Futurists (e.g., the Steinbeck Innovation Center): what's coming and how will "big data" be used
- Successful worker training examples and how to verify training effectiveness (perhaps tied in with the sanitation session)
- The Produce Safety Alliance final curriculum and training plans
- The FPAA project on children's education in the fields – keeping families together
- Food defense for the produce industry

X. What Have You Heard?

A regular agenda item, Council members shared information that may be of general interest.

- Bob Ziel described McEntire Produce's new flumeless wash system for leafy greens, [Simply Clean](#), and showed a short video about the system from their website.
- There was a brief discussion regarding Council members' reaction to the Mexico labor "news" series. Several shared they considered the story slanted with a prejudicial intent. Gombas shared that this was on the Board agenda the next day.

XI. Next Meeting

The next scheduled meeting of the Council will be Monday, June 8, 2015 in Chicago, immediately preceding the United Fresh 2015 show. Times and specific location will be shared with the Council when known.

Having reached the end of the agenda, the meeting was adjourned.