



**Commentary**  
***Food Chemicals Codex (FCC)***  
***Ninth Edition, Third Supplement***

**September 1, 2015**

In accordance with USP's provisionally-approved Rules and Procedures of the 2015-2020 Council of Experts (CoE Rules), and except as provided in Section 8.01(e) Immediate Standards, USP publishes proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum (FCCF)*, USP's journal for public notice and comment for *FCC*. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to official status or be republished in *FCCF* for further notice and comment, in accordance with the CoE Rules. In cases when proposals advance to official status without republication in the *FCCF*, a summary of comments received and the FIEC's responses are published on the *Commentary* section of the USP website at the time the revision is published.

The *Commentary* is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the FIEC's response to public comments. If there is a difference between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. In case of a dispute or question of interpretation, the language of the monograph text, alone and independent of the *Commentary* prevails.

For further information, contact:  
USP Executive Secretariat  
U.S. Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852-1790 USA  
[execsec@usp.org](mailto:execsec@usp.org)

**Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

**Monographs:**

- [Guar Gum](#)
- [Krill Oil](#)

**General Tests and Assays:**

- [Appendix XVII -- Food Fraud Mitigation Guidance](#)

**No Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

**Front Matter**

- General Provisions and Requirements

**General Test and Assays:**

- Coliforms
- E. Coli
- Enterococci
- Fluoride Limit Test
- Gellan Gum
- General Guidance for Food Ingredients
- Listeria
- Staphylococcus Aureus
- Salmonella

**Monographs:**

- Alginate-Konjac-Xanthan Polysaccharide Complex
- Ammonium Persulfate
- Bifidobacterium Animalis SSP. Lactis BI-07
- Bifidobacterium Animalis SSP. Lactis BI-04
- Bifidobacterium Animalis SSP. Lactis HN019
- Butyl Anthranilate
- Calcium L-Threonate
- Dextrin
- Lactobacillus Acidophilus LA-14
- Lactobacillus Acidophilus NCFM
- Lactobacillus Paracasei LPC-37
- Lactobacillus Rhamnosus HN001
- Rutin
- Sodium Phosphate, Monobasic
- Sodium Tripolyphosphate

**Monograph/Section(s):** Guar Gum/Multiple Sections  
**Expert Committee(s):** Monographs—Food Ingredients  
**No. of Commenters:** 2

### **Assay**

**Comment Summary #1:** The commenter recommended raising the galactomannans specification to NLT 75%, because it is the specification in the current European Commission Regulation and most guar gum today has a galactomannan content of about 80% based on their knowledge of guar composition in today's market.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

**Expert Committee-Initiated Change #1:** The equation for the percentage of galactose or mannose in this section was corrected to be:  $\text{Result} = (C_s/C_u) \times (r_u/r_s) \times 100$

### **Specific Tests/Protein**

**Comment Summary #2:** The commenter recommended changing the protein specification to NMT 6.0%, because the protein level of guar gum today is less than 6% and a protein level higher than 6.0% is an indication that the raw material is of lower quality, based on their knowledge of guar composition in today's market.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

**Monograph/Section(s):** Krill Oil/Identification  
**Expert Committee(s):** Monographs—Food Ingredients  
**No. of Commenters:** 3

**Comment Summary #1:** The commenter indicated that the proposed revision to raise the upper limit of stearidonic acid 18:4 n-3 in Krill Oil from 5.2% (w/w) to 5.7% (w/w) is not sufficient to cover the full range of stearidonic acid values exhibited by Krill Oil ingredients, because the fatty acid composition of krill is known to vary considerably by season. The commenter indicated that an upper limit of 7% (w/w) would be more appropriate and submitted limited data to support this limit.

**Response:** Comment incorporated.

**Comment Summary #2:** The commenter indicated that the proposed revisions to add limits for myristic acid, palmitic acid, and the ratio of palmitic:myristic acids is unnecessary since these values will vary considerably by season. They further indicated that adding any new fatty acid requirements to this table is problematic for manufacturers, due to the variable nature of the ingredient, and unnecessary given that Krill Oil is not sold based on the levels of any fatty acids other than

eicosapentaenoic acid (EPA) and docosohexaenoic acid (DHA). The commenter submitted data from multiple batches of krill oil as evidence of the variability of these fatty acid levels and the fact that not all production lots could meet the proposed limits for myristic and palmitic acid; however, the ratio specification could be met.

**Response:** Comment not incorporated. Sufficient data was not received to support the commenter's request to not add the proposed revisions to the monograph. This item may be considered in a future *FCC Forum*, if additional supporting data and information is provided.

**General Chapter/Section(s)** Appendix XVII: Guidance on Food Fraud Mitigation/Multiple Sections

**No. of Commenters:** 18

Note: Please also see the report from a Table-Top exercise hosted by USP in March 2015 to solicit feedback on Appendix XVII, which can be found at the end of this document (Attachment 1).

### **General Comments**

**Comment Summary #1:** The commenter suggested replacing the term "guidance" in the title of the appendix with "guidelines" to avoid confusion with Food and Drug Administration (FDA) issued guidance documents

**Response:** Comment not incorporated. The appendix is clearly presented as guidance from USP.

**Comment Summary #2:** The commenters suggested adding a section on how to operationalize this Guidance framework in an organization with many ingredients and suppliers.

**Response:** Comment incorporated. Text was added to the section *Lifecycle and Implementation* that includes strategies for implementing the guidance framework.

**Comment Summary #3:** The commenter suggested making the information resources referenced in the Guidance easier to use/find.

**Response:** Comment incorporated. *Table 6. Useful Information Resources* was added to the end of the Guidance in the section on *Information Resources*.

**Expert Committee-initiated Change #1:** The title of the Appendix was shortened and changed to emphasize the subject of the document: "Appendix XVII: ~~Guidance on~~ Food Fraud Mitigation Guidance."

**Expert Committee-initiated Change #2:** The first sentence in the Appendix was edited for clarity as follows, "This Appendix to the Food Chemicals Codex is intended to elaborate guidance frameworks and tools to assist users in the development of their own ~~personalized~~ preventive management system for food fraud."

**Comment Summary #4:** The commenter suggested adding emphasis to the *Audit Strategy* and *Supplier Relationship* sections on the effect of supplier and supply chain transparency on food fraud vulnerability.

**Response:** Comment incorporated. Text was added to the *Supply Chain* and *Supplier Relationship* sections to address comment.

**Comment Summary #5:** The commenter suggested that the supply chain level of the food component under assessment (e.g., raw material vs. processed component) and possibility that food components could be shipped through different regions than those where it was produced/grown may impact food fraud vulnerability assessments and should be addressed.

**Response:** Comment incorporated. Text was added to the *Supply Chain* section to address comment.

**Comment Summary #6:** The commenter suggested that additional example ingredient scenarios representing a range of food fraud vulnerability characteristics should be added to the guidance for training purposes, including those evaluated during the USP's Food Fraud Mitigation Table-Top Exercise (Attachment 1).

**Response:** Comment not incorporated. The Expert Committee determined that the current examples were sufficient, but may consider future revisions to include additional examples.

**Comment Summary #7:** The commenter suggested adding page breaks between major sections of the Guidance to improve readability.

**Response:** Comment incorporated.

**Comment Summary #8:** The commenter suggested re-numbering steps 1+2, and 3 to be steps 3 and 4 respectively.

**Response:** Comment incorporated.

**Comment Summary #9:** The commenter suggested revising the vulnerability category descriptors in Table 1 and throughout the text to be clearer and mutually exclusive within vulnerability categories.

**Response:** Comment incorporated. Text edits were made to the Table 1 category descriptors.

**Comment Summary #10:** The commenter suggested clarifying that "vulnerable to adulteration" does not necessarily mean that adulteration is going to happen.

**Response:** Comment incorporated. The Text was edited in the *Terminology and Scope* section to address the comment.

**Comment Summary #11:** The commenter suggests that it is not practicable to develop one food fraud management system that will be applicable to all products and situations, as a one-size-fits-all approach is not practical for the industry. The commenter provided examples, including the variability within the food industry of processes, products, and ingredients that alter the susceptibility of the ingredients to EMA and the dynamic market driven nature of factors that drive EMA.

**Response:** Comment not incorporated. The Expert Committee determined that the Guidance sufficiently addresses the concerns described by the commenter.

**Comment Summary #12:** The commenter suggested in *Step 1* to separately group the factors related to raw materials inherent vulnerabilities and on which food fraud assessors (companies) will have no or little influence (Fraud History, Geopolitical Considerations, Economic Anomalies) from the factors which make the counter-balance and on which companies can actively act and put in place adequate mitigation measures (the remaining six factors in *Step 1*).

**Response:** Comment not incorporated. The Expert Committee determined that the current order of factors was sufficient, but may consider future revisions to the Appendix.

**Comment Summary #13:** The commenter suggested adding a section to emphasize the need for developing a cross-functional/disciplinary team within organizations to carry out the assessments in the Guidance.

**Response:** Comment incorporated. Text was added to the section on *Lifecycle and Implementation*.

**Comment Summary #14:** The commenter suggested adding to the Guidance a checklist of the type of documents and information that users should have available before using the tool, e.g. detailed audit reports, COAs, testing plans.

**Response:** Comment not incorporated. The Expert Committee determined that the current text was sufficient, but may consider future revisions.

**Comment Summary #15:** The commenter suggested revising Figure 1 to clarify the process and order as the current process was unclear. For example, one cannot determine if a mitigation strategy is effective without first implementing the strategy.

**Response:** Comment incorporated. A Figure 1 was revised to clarify the process.

### **Step 1: Supply Chain**

**Comment Summary #16:** The commenter suggested the following revision to text in this section, “In general theory, the scenario presenting the...”

**Response:** Comment incorporated.

### **Step 1: Audit Strategy**

**Comment Summary #17:** The commenter suggested revising the vulnerability category descriptors for this factor to provide more distinction between the medium-high and high categories.

**Response:** Comment incorporated. Changes to the text were made.

**Comment Summary #18:** The commenter suggested defining “adequacy of audit.”

**Response:** Comment not incorporated. The suggested change is beyond the scope of this Guidance document.

### **Step 1: Supplier Relationship**

**Comment Summary #19:** The commenter suggested that some possible supplier relationship scenarios (e.g. a supplier that is a cooperative) are not covered by the Guidance.

**Response:** Comment incorporated. The Expert Committee added language to clarify that understanding the legal structure of suppliers is a step that users will need to undertake.

**Comment #20:** The commenter suggested clarifying how to rank a new supplier when there is no history.

**Response:** Comment not incorporated. The Expert Committee determined that the text in this section was sufficient.

### **Step 1: History of Supplier Quality and Safety Issues**

**Comment #21:** The commenter suggested revising the title of this section to include information on the history of regulatory issues.

**Response:** Comment incorporated.

**Comment Summary #22:** The commenter suggested expanding the vulnerability category descriptors.

**Response:** Comment incorporated.

**Comment Summary #23:** To commenter suggested adding information on how to weigh quality versus safety issues when considering this factor.

**Response:** Comment not incorporated. The Expert Committee determined that this is beyond the scope of the Guidance, which is intended to be a qualitative tool, but may consider future revisions to address to suggestion.

**Comment Summary #24:** The commenter suggested revising the medium-high category descriptor to read, "Multiple persistent issues or some evidence of inadequate controls."

**Response:** Comment incorporated. The descriptor was edited to read, "Multiple persistent issues indicating lack of responsiveness to concerns; some evidence of inadequate controls."

**Expert Committee-initiated Change #3:** Formatting of "Salmonella Typhimurium" was corrected to "*Salmonella typhimurium*" in the PCA illustrative example.

**Expert Committee-initiated Change #4:** The reference to [www.imprex.us](http://www.imprex.us) as an information resource was removed because the site is not yet functional.

### **Step 1: Susceptibility of QA Methods and Specifications**

**Comment Summary #25:** The commenter suggested revising this section to reflect the possible use of non-targeted screening methods as part of raw material testing.

**Response:** Comment incorporated. The text and category descriptors for this entire section were revised to address this comment.

**Comment Summary #26:** The commenter suggested revising Figure 4 illustrations to look more like balances.

**Response:** Comment incorporated.

**Comment Summary #27:** The commenter suggested that the section indicates an unrealistic amount of testing required to achieve the low vulnerability category and that there may be only one or two critical tests.

**Response:** Comment not incorporated. The Guidance does not suggest specific numbers of tests, but rather focuses on how well the tests used characterize the ingredient and how useful the tests are for detecting adulteration.

**Comment Summary #28:** The commenter suggested that Table 2 needs to be clarified to explain that all tests would need to be run to achieve the listed vulnerability level. As proposed it gives the false appearance that running one individual test equates to qualifying for the vulnerability category.

**Response:** Comment incorporated. The text referencing Table 2 was revised to address the comment.

#### **Step 1: Testing Frequency**

**Comment Summary #29:** The commenter suggested providing more detailed definitions for the categories descriptors.

**Response:** Comment not incorporated. The Expert Committee determined that the current category descriptors are sufficient.

**Comment Summary #30:** The commenter suggested removing the term “independent” from this section with the rationale that the important factor is whether the lab is qualified/certified and trusted.

**Response:** Comment incorporated.

**Comment Summary #31:** The commenter suggested revising the following sentence, “This factor is intended to describe the vulnerability of ingredients to food fraud based on a lack of sufficient testing frequency.” to emphasize the important of evidence/risk-based testing.

**Response:** Comment incorporated.

**Comment Summary #32:** The commenter suggested re-wording the phrase “rolling the dice, with their dice” description in Table 3 with a clearer less colloquial example.

**Response:** Comment incorporated.

#### **Step 1: Fraud History**

**Expert Committee-initiated Change #5:** The text was edited to clarify the meaning of “substantiating evidence.”

**Expert Committee-initiated Change #6:** Vulnerability category text descriptors were edited to improve clarity.

#### **Step 1: Geopolitical Considerations**

**Comment Summary #33:** The commenter suggested adding a separate more detailed guidance to carry out this assessment that is more quantitative and weights certain factors.

**Response:** Comment not incorporated. The Expert Committee determined that the section is sufficient, but may consider this as a future enhancement to the Guidance.

**Comment Summary #34:** The commenter suggested revising this section, because some of the factors identified in this section pertain more to sustainability than to fraud.

**Response:** Comment not incorporated. The Expert Committee determined that the text is sufficient, because factors related to sustainability can lead to fraud vulnerabilities.

**Comment Summary #35:** The commenter suggested that the low Gross Domestic Product (GDP) should be removed from the section, because it does not necessarily mean a country would adulterate.

**Response:** Comment not incorporated. The Expert Committee determined that the text sufficiently addresses this point.

**Comment Summary #36:** The commenter suggested revising the text to improve consistency for the following terms, “single component,” “several components,” “one or more components”, “components”, “raw materials,” and “sub-ingredients.”

**Response:** Comment incorporated.

### **Step 1: Economic Anomalies**

**Comment Summary #37:** The commenter suggested adding a tutorial on how to pull pricing data to generate price history information.

**Response:** Comment incorporated. The section “Information Resources” was added to the end of the Guidance, which includes an example of how to pull pricing data from the USDA Global Agricultural Trade System Online “GATS” database.

**Comment Summary #38:** The commenter suggested adding more information on how to interpret price history.

**Response:** Comment incorporated.

**Comment Summary #39:** The commenter suggests adding additional text to clarify the meaning of the following phrase used to describe the high vulnerability category, “These can represent either broad industry acceptance of a type of fraud as being acceptable or the dissemination of a fraudulent ingredient broadly through complicated supply chains.”

**Response:** Comment incorporated.

**Expert Committee-initiated Change #7:** Text was added to Figure 7 to add copyright reprint permission information.

### **Step 2: Impact Assessment**

**Comment Summary #40:** The commenter suggested adding a definition of the phrase “public confidence in authority” to clarify if this was intended to mean public faith in authority to protect or to take action once something has occurred.

**Response:** Comment not incorporated. The Expert Committee determined that the text was sufficient.

**Comment Summary #41:** The commenter suggested adding additional information to allow easy incorporation of company policies related to weighting for this factor.

**Response:** Comment not incorporated. The Expert Committee determined that the text was sufficient.

### **Step 1 and 2**

**Comment Summary #42:** The commenter suggested adding additional information on the use of a numerical scoring system for steps 1 and 2 to facilitate their combined results in the Table 5 matrix and remove some subjectivity from the tool that would offer more credibility when presenting results of this Guidance to peers.

**Response:** Comment not incorporated. The Expert Committee determined that the suggestion falls outside the scope of the current Guidance, but may consider this a future revision.

**Comment Summary #43:** The commenter suggested adding to each box in Table 5 a numerical label to make the final score clear and easy to communicate.

**Response:** Comment incorporated.

**Comment Summary #44:** The commenter suggested adding more than three descriptive categories and related colors to Table 5, for example including another category called “New controls must be implemented” in the lower-right boxes.

**Response:** Comment not incorporated. The Expert Committee determined that the table is sufficient.

**Comment Summary #45:** The commenter suggested adding an orange cell representing an intermediate risk to the bottom row of Table 5 between the red cell (high risk) and green cell (low risk) based on the following reference: Cox, L.A. 2008. Risk Analysis 28(2): 497-512.

**Response:** Comment not incorporated. The Expert Committee determined that Table 5 was sufficient. In this situation it is not possible for the user to implement more control measures.

**Comment Summary #46:** The commenter suggested re-ordering rows in Table 1 and appearing in Figures 8-12 to correspond to the order of in text.

**Response:** Comment incorporated.



## **Report from USP's Food Fraud Mitigation Table-Top Exercise Held at USP Headquarters, Rockville, MD on Friday, March 13, 2015**

**Overview and Objectives:** To generate feedback on the utility and suggest improvements to USP's draft *Guidance on Food Fraud Mitigation*, USP's Food Ingredients Intentional Adulterants Expert Panel (FIIA EP) designed a tabletop exercise to simulate use of the tool. Scenarios for two food ingredients (stevia and ascorbic acid) were presented to two separate breakout groups of participants representing potential users of the tool from industry and regulatory agencies. Food manufacturers and suppliers used in the scenarios were fictional, "facts" used in the scenarios were hypothetical, but the information provided specific to the ingredients were based on actual information available. Facilitators led each breakout group through the process of using the draft USP tool to undertake a vulnerabilities characterization (steps 1, 2, and 1+2) of the ingredients presented in the scenarios. Participants were allowed to use any additional information resources available to them. Supplemental information compiled in advance of the exercise was made available to participants if requested. Each group reported the findings, observations, and comments for each scenario. A wrap-up discussion ended the exercise to further discuss, refine, and consolidate the comments and feedback to USP on the draft *Guidance*. The feedback collected as part of the table top exercise will be utilized by the FIIA EP to improve the USP *Guidance on Food Fraud Mitigation*.

### **General Comments and Suggestions**

- It was observed that in the absence of detailed information to inform assessments during the exercise, users typically used caution and chose the worst-case scenarios.
- Suggestion was made to make the information resource links easier to use/find in the guidance.
- Guidance users may need to consider the level of product or ingredient that one is using – raw material vs. processed. Expect this will be part of a company Foreign Supplier verification under FSMA. This impacts the assessment in that the Guidance user may not know actual source country. Items may be shipping through regions and not actually grown or manufactured there. Need to review actual level of detail needed as part of supply chain. Mitigation steps can impact this as well.
- Suggestion to use the table-top exercises as training in the Guidance or elsewhere, but to expand scenarios to include full range of final vulnerability results, i.e. some scenarios that result in green outcome and red outcome.
- Suggestion to insert page breaks so categories start at the top of the page in the published *Guidance*.
- It was suggested that another step, likelihood of occurrence, could be added to the USP Guidance as a step to initially discriminate low fraud likelihood ingredients from high ones.
- To facilitate the operationalization of this type of ingredient-by-ingredient system in organizations with many ingredients or ingredient-supplier combinations, it was suggested to add a guidance on potential pre-screening steps that could be added to reduce the total number of ingredients that would need a complete assessment as outlined in the Guidance. One general stumbling block for carrying out the assessments in Step 1 was confusion on how far back in the supply chain to go. Should the user only carry on the assessment on the supplier of the ingredient, what about the supplier to the ingredient supplier?

- Suggestion that additional example scenarios should be included in the Guidance that would cover a broad range of overall vulnerability categorizations from green to orange and red.
- Observation that without lab test results, users may make worst-case assumptions, which drive assumptions to the red; if more lab test data was available, it could drive assumptions toward the green.
- During this exercise and in other discussions, there were many areas in which descriptors should be improved.
- Some definitions did not match the scenario (e.g., an arrangement wherein a cooperative was the ingredient supplier did not appear in categories), so consider vetting them to reduce ambiguities in training
- Recommended clarifying that “vulnerable to adulteration” does not necessarily mean that adulteration is going to happen.

### ***Comments on Specific Aspects of the Draft Guidance***

- **Introduction**
  - Suggestion that an introductory statement should be added to address the need for cross functional teams to use the tool, i.e., geopolitical might need input from security and corporate affairs; scientific and non-scientific personnel; for impact assessment would involve functions which are public facing
  - Suggestion to add a checklist of the type of documents and information that users people should have available before using the tool, e.g. detailed audit reports, COAs, testing plans.
  - It was observed that without specifics, one is forced to consider worst case.
- **Step 1**
  - **Table 1**
    - Observation that Guidance users would like more text and content in the table itself, i.e., users are working primarily from the table and going to the text for reference
  - **Supply chain factor**
  - **Audit strategy factor**
    - Suggestion to expand the vulnerability category descriptors in table and text to provide better clarity, especially in the medium to medium-high categories (Supply chain descriptors were viewed as having an ideal amount of detail). As-is users found the Audit section definitions too short and subjective. New descriptors should include something about product vs. vendor; audit strength (robustness) vs. performance; what if a company supplier audit already includes EMA?
    - The audit strategy, geared toward auditing a direct supplier, could require that auditors expand to company requirements of audits back to an ingredient’s origin. Audit suppliers could make sure they have an audit program that captures adulteration.
    - Audit strategy review should look at good strategies, not at how the buyer or supplier arrived at their audit strategy.
    - Suggestion to define “adequacy of audit”
  - **Supplier relationship factor**
    - Need to clarify how to rank a new supplier when there is no history
    - The concept of transparency in the supplier relationship could be added to the tool.
  - **History of supplier quality and safety issues**
    - Suggestion to expand the vulnerability category descriptors.

- Suggestion to add history of regulatory compliance issues to the title of this section
  - Stumbling block was how to weigh quality versus safety issues? Should they carry the same weight?
  - Replace the semicolon with “or” in the definition of Medium-High in the “History of supplier quality & safety issues” row, so that it reads: Multiple persistent issues or some evidence of inadequate controls.
  - Recommend addressing safety aspect of the matrix and increased indication of safety issues. Should be more indication of the rankings by categories vs. just history of supplier quality.
  - Suggestion to clarify what is meant by “multiple persistent issues”. Otherwise this is very subjective
- **Susceptibility of QA methods and specifications**
    - What is the actual qualification of the lab? Need to link lab with the method. Not certain best location for lab.
    - Suggestion to have infographic specialist help to improve presentation of Figure 4.
    - Suggestion to add the concept of non-targeted adulteration detection schemes (screening -> confirmatory) to the section. As-is the guidance does not offer guidance on where this type of testing scheme fits in. Consider a combination of both a selective and nonselective approach as the lowest vulnerability.
    - Suggestion to add targeted analytical method(s) to the scheme. e.g. if someone is screening wheat gluten for melamine, this should decrease vulnerability somewhat.
    - Concern that Table 2 conveyed the wrong message the more testing is always better
    - Confusion on interpretation of Table 2. User did not understand which tests would be run to qualify for each vulnerability category.
    - Perhaps there is a balance to be found. If you leave the *Guidance* unchanged, companies will be pushed into performing more and more tests. However, running a test on all the other sweeteners may not make sense—it may be smarter to test for the three that you suspect.
    - Overall testing categories suggested an unrealistic amount of tests; there may be one or two critical tests.
  - **Testing frequency**
    - Suggestion to improve definitions used for the categories
    - It was observed that Table 3 seemed to be overlooked when users identified the vulnerability ranking for this factor, and may be necessary to pull this into the Table 1 or make Table 3 simpler.
    - Suggestion that labs may not need to be independent. Need lab that is qualified/validated/verified ex. ISO certified; term “trusted lab” may be more appropriate.
  - **Geopolitical considerations**
    - Suggestion to create a sub-tool to carry out this assessment that is more quantitative and weights certain factors
    - Should review the Global/Political factors. Some may be more pertinent to sustainability rather than EMA
    - Low Gross Domestic Product (GDP) does not necessarily mean a country would present a higher risk of adulteration.
    - Inconsistencies noted in descriptions of the origin and transit of “single component,” “several components,” and “one or more components.”
  - **Economic anomalies**

- Suggestion to provide a tutorial on how to pull pricing data (from USITC for example) to generate price history information.
- More guidance suggested on how to interpret price history.
- **Step 2**
  - **Table 4**
  - **Public health impact**
  - **Economic impact**
  - **Multipliers**
    - Need definition of Public Confidence in Authority. Not clear if this was public faith in authority to protect or to take action once they know something has occurred.
    - Should have form to allow easy incorporation of Company Rules for weighting
- **Step 1+2**
  - **Table 5**
    - Suggestion to allow the use of or the optional use of a numerical scoring system for steps 1 and 2 to facilitate their combined results in the Table 5 matrix. An example or guidance on how to do numerical scoring and consideration of weighting factors should be included. It was thought that this numerical approach would remove some subjectivity from the tool and would offer more credibility when presenting to others.
    - Suggestion to give each box in Table 5 a numerical label to make the final score clear and easy to communicate. A related suggestion was to use more than three descriptive categories and related colors, for example including a “New controls must be implemented” for lower-right boxes.
- **Step 3**
  - Suggestion to re-order rows in Table 8 to correspond to order in text.

# Appendix I – Agenda

*Friday, March 13, 2015*

**8:30 a.m. Registration & Coffee**

**9:00 a.m. USP Welcome & Opening Remarks**

*Dr. Gabriel Giancaspro, USP Vice President Foods, Dietary Supplements, and Herbal Medicines*

**9:10 a.m. Introduction to draft USP Food Fraud Mitigation Tool and Instructions for Exercise**

*Dr. Henry Chin & Ms. Susan Brown, Table-Top Facilitators and Members of USP's Expert Panel on Food Adulteration*

**9:40 a.m. Self-Introductions**

**9:50 a.m. Assignment to Breakout Groups A and B**

**10:00 a.m. Break**

**10:45 a.m. Groups Begin Work on 1<sup>st</sup> Ingredient Scenarios (Stevia)**

**11:30 a.m. Report Out on 1<sup>st</sup> Ingredient Scenarios (Stevia)**

**12:00 p.m. Lunch**

**12:45 p.m. Groups Begin Work on 2<sup>nd</sup> Ingredient Scenarios (Ascorbic Acid)**

**3:00 p.m. Report Out on 2<sup>nd</sup> Ingredient Scenarios (Ascorbic Acid)**

**4:00 p.m. General Comments on Tool and Wrap-Up**

*Dr. Jon DeVries, Chair USP Expert Panel on Food Adulteration*

**4:30 p.m. Adjourn**

## Appendix II – Attendee List

### **Panel Facilitators**

1. Susan Brown, USP Food Ingredients Intentional Adulterants Expert Panel Member
2. Henry Chin, USP Food Ingredients Intentional Adulterants Expert Panel Member

### **Participants**

3. Eyassu Abegaz, Ajinomoto
4. David Anthony, Elite Spice
5. Jason Bashura, PepsiCo
6. Marti Bergana, Abbott
7. Pablo Carrion, Nestlé-Purina
8. Cathy Dasenbrock, FDA
9. Matt Dofoo, Nestlé
10. Jeffrey Hurst, Hershey
11. Hendrik Perdana, Elite Spice
12. Joe Scimeca, Cargill
13. Tom Seipelt, Abbott
14. Tim Sonntag, National Seasoning Manufacturers Association
15. Christine Summers, Costco
16. Michelle You, CSM Bakery Products

### **Observer(s)**

17. Karen Everstine, National Center for Food Protection and Defense, University of Minnesota
18. Ryan Newkirk, FDA
19. Jon DeVries, Chair- USP Food Ingredients Intentional Adulterants Expert Panel

### **USP Staff**

20. Gabriel Giancaspro, Vice President – Foods, Dietary Supplements, Herbal Medicines
21. Jeffrey Moore, Senior Scientific Liaison, Food Standards
22. Lynette Nguyen, Expert Committee Manager
23. Doug Podolsky, Executive Secretariat Liaison
24. Shelby Thomson, Senior Global Development Manager

## Appendix III – Table Top Exercise Scenarios

### Stevia Scenario A

**Background:** Stevia is a low calorie sweetener that is obtained from the leaves of the stevia plant. Stevia plants can be cultivated in many countries. Due to the increasing popularity of stevia as a low calorie sweetener, production is increasing in many countries. Stevia is actually a complex mixture of steviol glycosides that are extracted and purified from the leaves of the stevia plant. Stevia leaves typically pass through 2-3 parties before receipt by a stevia processing company. Processing companies either extract crude steviol glycosides and purify to produce high-purity finished ingredients, or alternatively sell the crude extracts to another processor for purification into finished ingredients. Individual steviol glycosides have different organoleptic qualities. The contents and ratio of steviol glycosides can vary naturally due to species and geography. Manufacturers of ingredients often adjust the ratio of steviol glycosides through refining processes in order to meet the needs of the food developer. The sweetness intensity of stevia is approximately 300 times greater than the equivalent amount of sucrose. By comparison, the sweetness intensity of neotame, sucralose, saccharin, acesulfame K, aspartame, and cyclamate are 8,000, 600, 300, 200, 180, and 40 times that of sucrose, respectively. USP's Food Chemicals Codex has a monograph for stevia-derived sweeteners named *Steviol Glycosides*.

#### **Scenario:**

Big Brand Foods (BBF) is a food company with a Stevia-sweetened product line that is growing in sales and is poised for a breakout based upon increasing popularity with health conscious consumers. The product are targeted toward adults with an interest in all natural, organic ingredients and commands a price premium compared to other competitive products. BBF prides itself on its reputation for only working with suppliers who promote sustainable practices and requires its suppliers to adhere to a commitment to sustainability.

The Stevia-sweetened product line comprises about 15% of total sales for BBF, but is projected to grow to 30% in the next five years. Stevia is used as a sweetener in BBF products at a level of 600 mg/kg. BBF currently buys stevia primarily from Alpha Ingredients, but anticipates that additional suppliers will be used as their demand for Stevia grows. Currently Alpha Ingredients provides 80% of BBF's needs, while Model Ingredients (who is still being qualified) supplies 20%. Previous to buying stevia, BBF purchased other food ingredients from Alpha Ingredients. Stevia is the only product sold by Model Ingredients, which was only recently engaged as a supplier by BBF.

Alpha Ingredients sources stevia leaves from company owned plantations in China and Paraguay. The harvested leaves are dried locally, before they are bundled and sent to company owned factories for further processing. Leaves from China are processed in a factory in China, while leaves from Paraguay are sent to a factory in Puerto Rico for further processing. Refined stevia can be sourced from either factory. BBF contracts with Audits International to conduct audits of suppliers. Audits are usually performed every three years unless previous audits indicate a need for more frequent audits. BBF last audited Alpha Ingredients in 2012 at both facilities for GMP and HACCP. No deficiencies were found at the factory in China, but several deficiencies (mainly due to the age of the processing plant) were noted in Puerto Rico. Alpha Ingredients has agreed to address the deficiencies noted in the audits.

Model Ingredients sources stevia from farmer cooperatives in Brazil. Preliminary drying is done at a coop owned central facility in Brazil before the dried leaves are transported to a contractor for extraction and initial refining. The final refining of the crude powder is done at a new company-owned facility. BBF last audited Model Ingredients in 2013 using the same contractor as used for Alpha Ingredients. Some deficiencies were noted in the audit. These were attributed to inadequate knowledge about GMP (e.g., use of approved materials for food contact) and regulatory requirements in the United States.

BBF requires that stevia meet the Food Chemicals Codex specifications (95% steviol glycosides, see FCC monograph). BBF requires each lot to be accompanied by a Certificate of Analysis. Alpha Ingredients has internal analytical capabilities and supplies a COA from its own laboratory. Model Ingredients sends samples to a laboratory in the United States for analysis and COA.

As part of its quality assurance program, samples from each lot of finished product are evaluated organoleptically by BBF's QA team and samples are retained.

## **Stevia Scenario B**

**Background:** Stevia is a low calorie sweetener that is obtained from the leaves of the stevia plant. Stevia plants can be cultivated in many countries. Due to the increasing popularity of stevia as a low calorie sweetener, production is increasing in many countries. Stevia is actually a complex mixture of steviol glycosides that are extracted and purified from the leaves of the stevia plant. Stevia leaves typically pass through 2-3 parties before receipt by a stevia processing company. Processing companies either extract crude steviol glycosides and purify to produce high-purity finished ingredients, or alternatively sell the crude extracts to another processor for purification into finished ingredients. Individual steviol glycosides have different organoleptic qualities. The contents and ratio of steviol glycosides can vary naturally due to species and geography. Manufacturers of ingredients often adjust the ratio of steviol glycosides through refining processes in order to meet the needs of the food developer. The sweetness intensity of stevia is approximately 300 times greater than the equivalent amount of sucrose. By comparison, the sweetness intensity of neotame, sucralose, saccharin, acesulfame K, aspartame, and cyclamate are 8,000, 600, 300, 200, 180, and 40 times that of sucrose, respectively. USP's Food Chemicals Codex has a monograph for stevia-derived sweeteners named *Steviol Glycosides*.

### **Scenario:**

Healthy Foods is a specialty food company with a supplement like product that is sweetened with a proprietary formulation of steviol glycosides. The product is marketed primarily to young women as a low calorie alternative to a full calorie product. The concentration of steviol glycosides in the low calorie product is 600 mg/kg. These two products comprise approximately 30 and 70% respectively of the sales of Healthy Foods.

Healthy Foods currently gets its stevia from only one supplier, Specialty Ingredients. Specialty Ingredients worked closely with Healthy Foods to develop the proprietary formulation of steviol glycosides that is used by Healthy Foods. Specialty Ingredients owns the intellectual property associated with this formulation of steviol glycosides.

Specialty Ingredients buys crude stevia extracts from various sources and does further processing using proprietary methods to obtain the formulation that is provided to Healthy Foods. Specialty Ingredients's processing plant is located in India. Specialty Ingredients confirms that each batch of stevia meets internal specifications by on-line analysis of the distribution of steviol glycosides and provides a COA to accompany each batch.

Healthy Foods contracts with an audit firm to audit Specialty Ingredients. Specialty Ingredients was audited as part of the qualification process in 2012. Healthy Foods does not require re-auditing of approved suppliers. During the 2012 audit, some GMP deficiencies were noted, but were addressed prior to full approval of Specialty Ingredients. Specialty Ingredients is a new food ingredient supplier entering the business in 2010 as a supplier of proprietary stevia formulations.

As part of its quality program, Healthy Foods pulls samples from every batch of finished product. These are evaluated organoleptically prior to release. Retained samples are subjected to analysis to confirm select parameters of product composition (nutrients and sweetener profile).

# Ascorbic Acid Scenario A

**Background:** Ascorbic Acid is a multipurpose food ingredient. In addition to its use as a nutrient, ascorbic acid is also used in foods as an anti-oxidant and acidity regulator. While it can be sourced from plants, most of the ascorbic acid that is sold for food use is manufactured synthetically. There are two commercial processes for manufacturing ascorbic acid. One is a traditional chemical process, while the newer one is based upon fermentation using genetically modified bacteria. About 80% of the ascorbic acid is produced in China, although Canada and the Netherlands are also significant sources of U.S. imports even though the only western producer of ascorbic acid is in Scotland. USP has a monograph for ascorbic acid. There have been several instances of price fixing of ascorbic acid; the most recent resulted in a \$162 million fine for two Chinese manufacturers, North China Pharmaceutical Group, and Heibei Welcome Pharmaceutical Company. One of the arguments in defense of the companies and supported by Chinese Ministry of Commerce was that they were required by law to coordinate export prices and volumes.

## **Scenario:**

Food manufacturer, Felix Foods, uses ascorbic acid as an antioxidant in several lines of processed meat products. The products containing added ascorbic acid comprise about 50% of the total sales of FF. As an antioxidant, ascorbic acid is added to products at levels ranging from 10-40 mg/100 g. FF does not source ascorbic acid as a single ingredient, but rather purchases several premixes which contain the required amount of ascorbic acid plus other ingredients that are used in the product. Ascorbic acid is part of a premix containing other ingredients.

The premixes are sourced from several suppliers because each supplier provides a product that is somewhat unique from their competitors. Some suppliers claim that their premixes are more effective as an antioxidant, or that ascorbic acid is more stable in their formulations.

Alpha Ingredients is based in the Netherlands and is basically a blender who purchases the ingredients in their premix from various suppliers globally. Alpha Ingredients does not have either an internal source for ingredients nor do they use “dedicated” suppliers, however they currently use a local supplier for ascorbic acid

Beta Ingredients is based in Puerto Rico and is part of a corporation that has an ascorbic acid manufacturing plant in China. For their premixes, Beta Ingredients sources ascorbic acid from the plant in China and other ingredients either from internal sources or from “partner” companies.

Gamma Ingredients is based in China and sources ascorbic acid from “partner” companies in China. Alpha and Gamma Ingredients have been mentioned in FDA Import Alerts. Alpha had an incident where certain lots of premixes contained an unapproved color. Gamma had an incident where a premix was mislabeled.

The competition between Alpha, Beta, and Gamma is based not only on price, but also on product performance. One of the performance attributes that is very important to FF is the ability of the premix to contribute to maintaining the desirable appearance of the product.

FF has conducted a HACCP analysis of their premixes, which came to the conclusion that the premixes present minimal food safety hazard. As such, FF only requires that their premix suppliers maintain documentation showing the satisfactory completion of a food safety audit by a recognized provider. FF requires that their supplier provide a Certificate of Identity (COI) for each batch of premix. The COI attests that the batch meets the ingredient composition established for the premix and that the ingredients are food grade.

The relationship between FF and their suppliers of premix is very fluid. The choice of supplier is determined by 1) price, 2) availability, and 3) premix attributes. While FF has a history with Alpha Ingredients, this relationship is not close. Beta and Gamma Ingredients have become suppliers to FF since 2012.

Products containing the premix are evaluated organoleptically prior to release. These products do not make a nutrient content claim for ascorbic acid.

## **Ascorbic Acid Scenario B**

**Background:** Ascorbic Acid is a multipurpose food ingredient. In addition to its use as a nutrient, ascorbic acid is also used in foods as an anti-oxidant and acidity regulator. While it can be sourced from plants, most of the ascorbic acid that is sold for food use is manufactured synthetically. There are two commercial processes for manufacturing ascorbic acid. One is a traditional chemical process, while the newer one is based upon fermentation using genetically modified bacteria. About 80% of the ascorbic acid is produced in China, although Canada and the Netherlands are also significant sources of U.S. imports even though the only western producer of ascorbic acid is in Scotland. USP has a monograph for ascorbic acid. There have been several instances of price fixing of ascorbic acid, the most recent resulted in a \$162 million fine for two Chinese manufacturers, North China Pharmaceutical Group and Heibei Welcome Pharmaceutical company. One of the arguments in defense of the companies and supported by Chinese Ministry of Commerce was that they were required by law to coordinate export prices and volumes.

### **Scenario:**

Food manufacturer, Great Brands, has several beverages that are fortified with ascorbic acid. The ascorbic acid content of these beverages is between 30 and 50 mg/100g. Children are large consumers of these fortified beverages.

GB purchases food grade ascorbic acid from Number One Ingredients. Number One is a company based in China that manufactures ascorbic acid and other chemicals that are used in foods, pharmaceuticals, and personal care products. Number One provides ingredients capable of meeting various specifications depending upon the needs of the purchaser.

GB has a program that “qualifies” all new suppliers and then schedules regular audits at approved suppliers. Number One was qualified by GB in 2006, and has been audited by GB in 2009 and 2012. The only deficiencies noted by the auditor relate to lapses in food security, e.g., unsecured access to areas where finished products are stored. Number One has addressed the deficiency by storing finished products in a secured area with limited access.

Number One provides a COA with each batch of ascorbic acid. The COA documents that the batch meets the specifications established in the Food Chemicals Codex.

As part of its quality program, GB organoleptically evaluates each production lot and performs some basic product quality testing. To determine whether fortified products are staying in compliance with FDA regulations for nutritional labeling, a small number of retained samples are tested for declared nutrients each year.

## **Almond Milk Scenario A (extra scenario not used)**

**Background:** Almond milk is a beverage in its simplest form consists of water and finely ground almonds. It does not contain cholesterol, lactose, or animal products making it popular with segments of the population who have intolerances to cow's milk as well as vegans or vegetarians. In 2011, almond milk sales increased by 79% and in 2013 surpassed soymilk as the most popular plant based milk. Almonds are high in many nutrients including vitamin E, magnesium, iron, and calcium. These do transition over to the milk. Processing can impact the actual transition. Almond milk is lower in protein than cow's milk. Regulatory standards of identity have not been established for almond milk. Processing can be either directly by soaking almonds in water and then blending or by diluting almond paste with water. Almond paste may or may not contain sweeteners and other additives. There may or may not be a filtration step depending on the process. The flavor of basic almond milk is very bland. The composition of almond milk can vary depending upon the recipe and process that is followed by the manufacturer. Products are typically fortified with sugars, thickeners, and flavors to increase consumer acceptance. Additional background on almond milk is appended.

### **Scenario:**

Ben's Wholesome Beverage Company is located in California and has been producing almond milk for 30 years. It is a family owned business. They process the milk directly from almonds which they source locally (California is a major producer of almonds). Their market until recently has been to regional health food stores. Their overall flavor, lack of artificial sweeteners and low sugar content has gained the product line wide acceptance. They have recently begun to require Certificates of Analysis, which include compliance to Food Chemical Codex specifications for all additives.

Ben Smith, the founder of the company, recently passed away at the age of 95. Due to anticipated expenses to comply with the changing food regulatory environment and lack of capacity to expand into other markets, his family has decided to sell the business.

Big Brand Foods (BBF) tendered an offer which was accepted. It was agreed that the current staff would continue in place for 12 months.

BBF acquired the business principally for the formulas and the Brand name. They recognize the quality of the products and see this as a solid addition to their beverage product line. They have budgeted a 15% ROI.

They want to expand beyond the current 3 state distribution to a national one. This will require increased capacity. BBF has a solid quality and regulatory organization. Their supplier on boarding process is strong and considered extremely comprehensive based on third party audits. They have a strong internal group familiar with sourcing globally especially from China. The staff includes a number of members who are fluent in Chinese, French, Spanish and Polish in addition to English.

In order to meet their expansion plans, BBF has tentatively laid out the following plans for the next 18 months.

- In order to increase production capacity and meet current regulatory standards for GMPs they plan to move processing to a BBF facility that currently handles other beverages. This facility currently handles dairy and fruit juices, producing shelf stable thermally processed products.
- Also to increase production capability they need to locate additional suppliers for raw almonds. For the next 18 months, they will continue to buy from local suppliers, but they anticipate needing additional suppliers in the near future. The highest quality almonds are used in the whole nut business, so BBF anticipates needing to source raw almonds or almond paste from secondary sources including foreign markets.
- The almond milk currently produced by Ben's Wholesome Beverage is pasteurized and requires refrigeration. In order to expand distribution, BBF intends to thermally process the product to make it shelf stable.

As part of their due diligence prior to the purchase of Ben's Wholesome, BBF identified that a number of manufacturing and quality practices at Ben's did not meet BBF standards. These included lack of audit standards and lack of a HACCP plan. However, BBF staff committed to addressing the gaps within 60 days after purchase.

## **Almond Milk Scenario B (extra scenario not used)**

**Background:** Almond milk in its simplest form consists of water and finely ground almonds. It does not contain cholesterol, lactose, or animal products making it popular with segments of the population who have intolerances to cow's milk as well as vegans or vegetarians. In 2011, almond milk sales increased by 79% and in 2013 surpassed soymilk as the most popular plant based milk. Almonds are high in many nutrients including vitamin E, magnesium, iron, and calcium. These do transition over to the milk. Processing can impact the actual transition. Almond milk is lower in protein than cow's milk. Regulatory standards of identity have not been established for almond milk. Processing can be either directly by soaking almonds in water and then blending or by diluting almond paste with water. Almond paste may or may not contain sweeteners and other additives. There may or may not be a filtration step depending on the process. The flavor of basic almond milk is very bland. The composition of almond milk can vary depending upon the recipe and process that is followed by the manufacturer. Products are typically fortified with sugars, thickeners, and flavors to increase consumer acceptance. Additional background on almond milk is appended.

### **Scenario:**

Healthy Beverage to Go (HBG) has been in business for 5 years. It was started by Max Smith and currently employs 20 (FTE). They buy bulk plant based milks and fill into individual serving containers. Almond milk constitutes 65 % of the products they sell. The almond milk product they sell include on package claims including that it is "Free of: Dairy, Soy, Lactose, Cholesterol, Peanuts, Casein, Gluten, Eggs, Saturated Fat, and MSG" that it is "Made in a peanut free facility" and "Is made from almonds that were not genetically engineered"

The material has the following ingredient statement.

Ingredients: Almond milk (filtered water, almonds), pure cane sugar, contains less than 2% of the following (vitamin A, vitamin E, vitamin D2, vitamin B2, vitamin B12, zinc sulfate, calcium carbonate), natural vanilla flavor with other natural flavors.

The flavor blend was developed for HGB and is proprietary to them. Two years ago, Max has made the formula available to his currently supplier. This allowed him to remove some mixing tanks from his site.

Their primary market is schools. Until recently, they only serviced 1 district but due to their superior customer service and competitive price, they were awarded the contract for 2 additional districts. This will double the volume through the plant. To handle the new business, Max reduced the space for holding the bulk milk, added a new filling line, and expanded the finished product storage.

Max was able to reduce the bulk storage due to agreements with his suppliers. They hold the equivalent of one day's filling on their site. They ship to his site twice a day. This allows him to keep one shift's input on his site. The plant runs 2 shifts – Sunday through Thursday.

The sites providing milk to HBG and the actual products had to be inspected tested and approved prior to HBG being awarded the school contracts. No testing is conducted by HBG.

The supplier of almond milk, Good Plant Co., produces and stores all their products at a single site. A recent earthquake resulted in significant damage to the facility. The local health department has declared the facility unacceptable for food production. They have been granted permission to ship products in sealed containers stored in their outbound warehouse, however they cannot produce any additional products. The release of their raw material is still under review. Repairs and health department approval to restart is estimated to be 3 months.

Max estimates that he has only three weeks inventory between unfilled and finished product before he will start shorting customers. If he cannot satisfy the schools, he would lose 40% of his annual revenue. There is also the risk that if another supplier steps in he will not have the opportunity to re-bid on the business for 2 years.

## Appendix IV – Reports from Break-Outs

### Group A (Stevia Scenario A)

- **Step 1 Contributing Factors**
  - Supply chain, high vulnerability
  - Audit strategy, medium vulnerability, given current definitions; but the group felt the audit strategy should be expanded
  - Supplier relationship, high vulnerability; group saw this as a worst-case scenario
  - History of supplier quality and safety issues, high vulnerability, due to model; lots of gaps and unknowns
  - Testing frequency, medium-high vulnerability; group felt there was too much reliance on Certificate of Analysis (CoA) and organoleptic testing
  - Susceptibility of Quality Assurance (QA) methods and specifications, medium vulnerability
  - Geopolitical considerations, high vulnerability; but the group noted that the contribution to vulnerability descriptions should be consistent
  - Fraud history, medium-high vulnerability; but the group suggested the option of medium-high-to-high
  - Economic anomalies, medium vulnerability; but the group suggested the option of medium-to-medium-high
- **Step 2 Impact Evaluation Matrix**
  - Food safety, low-to-moderate vulnerability
  - Economic impact, high vulnerability; the group noted that even one event would be risky
  - Focused consumption, low vulnerability
  - Nutritional sufficiency, low vulnerability
  - Public confidence, high vulnerability
- **Step 1 + 2 Vulnerability Characterization Matrix**
  - Low public health/high economic, moderate-high (new controls strongly recommended)

### Challenges to carry out assessment

- Adding details about companies (e.g., company size, international recognition) would help users make vulnerability assessments.
- “Vertically integrated” does not necessarily mean there is no risk, but the group made that assumption.
- The *Guidance* may have been developed with single supplier in mind, but that is rarely the case in the real world; integrating risk assessments of two suppliers in the scenario was challenging.
- When there are two suppliers, the group graded on the worst-case scenario. However, suppliers would not want a worst-case supplier driving their control requirements, especially if they do not need to do all of those controls.

### Group B (Stevia Scenario B)

- **Step 1: Contributing Factors Assessment**
  - Supply Chain, medium-high vulnerability, testing not significant; company-specialty ingredients are only 5 years old
  - Audit Strategy, medium vulnerability, with no established program, suggesting that changes are needed

- Supplier Relationship, medium vulnerability, with Good Manufacturing Practices (GMP) deficiency, and assuming no U.S. testing equivalency
  - History of supplier quality and safety issues, medium vulnerability, with unspecified GMP issues; assuming a straight forward corrected action is needed
  - Testing frequency, medium-high vulnerability, CoA not clear, and no certificate for testing program; assuming low rigor of testing cases for adulteration
  - Susceptibility of QA methods and specifications, medium vulnerability and then changed to medium-high vulnerability, methods not detailed, no heavy metal analysis; CoA concern
  - Geopolitical consideration, high vulnerability, assuming only raw materials are sourced locally in India and question about supplier knowledge; India ranked 36 out of 100 with civil unrest, terrorism, and GDP down
  - Fraud history, medium-high vulnerability, assuming more fraud reports
  - Economic anomalies, high vulnerability; high cost of Stevia
- **Step 2: Impact Evaluation**
    - Food safety, low vulnerability
    - Economic impact, high vulnerability, portfolio limited
    - Focused Consumption, low vulnerability, though target was young women
    - Nutritional Sufficiency, low vulnerability
    - Public confidence, medium-high vulnerability, assuming that stevia is in many products industry wide
- **Step 1 + 2 Vulnerability Characterization Matrix**
    - Moderate-high (new controls strongly recommended)
    - Group recommended a method to distinguished the boxes, especially those in red
    - Perhaps give a value to boxes
    - Change “recommended” to “must be implemented” for the bottom right four boxes

#### **Challenges to carry out assessment**

- High priority item: Need to see the audit
- Need to understand the entire supply chain—origin important

#### **a. Group A (Ascorbic Acid Scenario A)**

- **Step 1: Contributing Factors**
  - Supply chain, high vulnerability, in open market and multiple ingredients besides ascorbic acid, indirectly sourced.
  - Audit Strategy, high vulnerability, no specific requirements for audit, but warrants verification. (Clarification: This was an evaluation of current practice without considering the rationale of the current process against these definitions.)
  - Supplier Relationship, high vulnerability, relationship is either new or not close.
  - History of supplier quality and safety issues, medium-high vulnerability, with potentially serious, unapproved colors or mislabeling. Regulatory

issues but no history of fraud. (Should food safety quality include regulatory considerations?)

- Testing frequency, high vulnerability, no testing done
- Susceptibility of QA methods and specifications, high vulnerability, no testing done on the premix, but finished product is evaluated.
- Geopolitical consideration, high vulnerability, with multiple ingredients and possible mixing of identity.
- Fraud history, low vulnerability, with possible over supply. No detected or reported fraud in USP database, but take press reports into consideration.
- Economic anomalies, medium-low vulnerability with isolated unexplained anomalies.

- **Step 2: Impact Evaluation**

- Food safety, “light green” vulnerability with lack of controls noted. Compliance risk, but possibly low food safety risk for adulterants of concern from food safety standpoint. Hazard Analysis & Critical Control Points may not detect long-term safety issues of worrisome unknown-unknowns. Real-world functionality driving adulteration? Economic Impact, bright orange vulnerability, 50% of volume. Impact would be large with direct and indirect costs. Substitution would affect taste—or performance of the product
- Focused Consumption, low vulnerability, with no focused consumption
- Nutritional Sufficiency, low vulnerability with no focused consumption
- Public confidence, dark or light green vulnerability, noting vulnerable if few options are available and possible quality control issue

- **Step 1+2**

- Red (new controls strongly recommended) with a composite far to the right. Consider whether adulteration is possible or probable. Different Grade substitution? Ascorbic acid has some risk but blended item is more concerning.

**Challenges to carry out assessment**

- Due to the design of the exercise, it was difficult to assess the premix.
- Would rather the tool err on conservative side and say vulnerability “might be an issue” rather than that “it is not an issue.”

**b. Group B (Ascorbic Acid Scenario B)**

- **Step 1: Contributing Factors Assessment**

- Supply chain, medium, not vertically integrated (thus not low risk) and 90% controlled by China
- Audit strategy, medium, with an assumption that the company is knowledgeable because it has its own auditor. The group assumed that because of the depth of audit, food security had been discussed. However, audit strategy could be improved (written that it was only done when vulnerable).
- Supplier Relationship, low vulnerability
- History of supplier quality and safety issues, medium-high, with an assumption of repeat offenses written on audit.
- Testing frequency, medium-high, with assumption that CoA contains all FCC required testing.

- Susceptibility of QA methods and specs, medium-high, noting that only a small quantity retained for testing, and assuming that the lab might not have been audited.
- Geopolitical considerations, medium-high
- Fraud History, low
- Economic anomalies: medium-low
  
- **Step 2: Impact Evaluation**
  - Food safety, low
  - Economic impact, low
  - Focused consumption, medium high, noting that kids might be picky eaters
  - Nutritional sufficiency, moderate
  - Public confidence, medium-high
  
- **Step 1+2**
  - New controls should be considered (row 3, col 3)