Dietary Supplements
Joint Committee Meeting

Tuesday, May 20, 2008

NSF International
Ann Arbor, MI
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<th>Time</th>
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<tr>
<td>9:00 am</td>
<td>Welcome</td>
<td>S. Eisner</td>
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<td>Introduction and new members</td>
<td>S. Eisner</td>
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<td>Anti-trust Statement</td>
<td>S. Kozanecki</td>
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<td>Review of Agenda</td>
<td>S. Eisner</td>
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<td>Review of Meeting Summary November 2007</td>
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<td>9:15 am</td>
<td>Old Business</td>
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<td>Review of Recent Passed Ballots</td>
<td>S. Kozanecki</td>
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<td>9:25 am</td>
<td>Review of Ballots needing Resolution</td>
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<td>• 173i20 – Fish Oil Contamination</td>
<td>S. Kozanecki</td>
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<td>• 173i18 – Allergen and “Free” Claims</td>
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<td>• 173i28 – Table 3 and 4 (Test Methods)</td>
<td>K. LeVanseler</td>
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<td>• 173i29 – QC Tables</td>
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<td>• 173i24 – Table 6A and 6B revisions</td>
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<td>10:00</td>
<td>• 173i26 – Regulated Metals</td>
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<td>AHP Monographs</td>
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<td>Standards Online Workspace Tutorial</td>
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<td>11:30 am</td>
<td>New Business</td>
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<td>Arsenic (DS-2008-2)</td>
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<td>12:00 – 1:00 pm LUNCH</td>
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<td>Aristolochic Acid (DS-2008-3)</td>
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<td>DEGs (DS-2008-4)</td>
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<td>Normative References (DS-2008-5)</td>
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<td>Heparin/Chondroitin Sulfate (DS-2008-1, Informational)</td>
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<td>Other Items</td>
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<td>Review of Action Items</td>
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<td>Next Meeting</td>
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3:15 – 4:00 pm Tour of NSF Facilities
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I OPENING REMARKS/REVIEW OF AGENDA

Joint Committee Vice-Chair Staci Eisner convened the meeting and welcomed the Joint Committee members and observers. Those participating via conference call announced themselves. Those present made brief self-introductions.

Sarah Kozanecki read the anti-trust agreement. All agreed.

S. Eisner reviewed the agenda with the participants.

**Motion:** Kerri Levanseler moved to approve the agenda as written. Roy Upton seconded.

**Vote:** All in favor.

*Motion passed. The agenda was approved as proposed.*

II REVIEW OF MARCH 2007 MEETING SUMMARY

S. Eisner asked for comments or corrections on the March 2007 draft meeting summary. They were provided for S. Kozanecki to include in the updated version.

**Motion:** Michael McGuffin moved to approve the summary with the corrections noted. Andrew Shao seconded.

**Vote:** All in favor.

*Motion passed. The meeting summary was approved.*

III REVIEW CURRENT BALLOTS

S. Kozanecki provided a brief update on the ballots.

**Issue 14 – GMPs for Raw Materials**

This ballot revised Section 8 (8.6.3) to require both identity testing and other testing of raw materials, including purity, strength, and composition as applicable. The third revision was balloted to the Joint Committee (JC) in April 2007 and to the Council of Public Health Consultants (CPHC) in August 2007. One comment was received and responded to by K. Levanseler. This change will be incorporated into next version of NSF/ANSI 173.

**Issue 23 – Allergen GMPs**

This ballot will incorporate language on the handling and storage of raw materials in an effort to reduce cross-contamination from allergens. It was the second revision, which included the addition of a definition of major food allergens and additional clarifications as discussed at the March 2007 JC meeting. It was then balloted and passed at the JC in April 2007 and at the CPHC in July 2007. This change was incorporated into NSF/ANSI 173-2006 Addendum.
Issue 25 – Formulation Requirements

This was a clarification of formulation requirements added for consistency and clarity. It passed at the JC in May 2007 (after some editorial comments were received and incorporated). The CPHC approved the ballot in July 2007 and it was incorporated into NSF/ANSI 173-2006 Addendum.

Issue 20 – Fish Oil Contamination

This language was proposed in March 2007 and incorporates testing requirements for potential contaminants in fish oil. It was balloted and several negatives were received. These were considered and incorporated into a second revision. This revision was scheduled to be balloted to the JC following the JC meeting.

Issue 22 – AER/Dietary Supplement Act

This language will require that manufacturers comply with new federal legislation on the reporting of adverse events from dietary supplements to the US FDA. It was discussed in March 2007, at which time some revisions were proposed. The second revision passed at the JC in September 2007 and was at ballot to the CPHC at the time of this meeting. Note: this ballot passed at the CPHC and will be incorporated into the next published version of NSF/ANSI 173.

Issue 24 – Table 6A and 6B

This issue, which includes a revised definition of "botanical ingredient" and adds a definition of “botanical ingredient extract” and “botanical ingredient non-extract,” was discussed at the March 2007 meeting. It was at ballot at the time of this meeting. Note: this ballot received one negative, which will need to be resolved before moving forward.

Issue 18 – Allergen and “Free” Claims

This issue, which seeks to establish requirements for allergen-free claims and establish a definition for “free” in terms of ppm, arose during the March 2006 meeting. After discussion at the March 2007 JC meeting, it was agreed that allergens should be addressed in NSF/ANSI 173 and the Standard should be revised to reference the FDA rule for gluten-free claims. For other claims, the Standard should reference the current best practice. Additionally, for the non-major food allergens, it was suggested that a thorough checklist be supplied for suppliers to ensure they have the proper documentation such as affidavits and random audits.

K. Levanseler explained that there needed to be some limits set for what qualifies as “free” for the purposes of verification of label claims. While all agree that there is no limit that can be set based on levels that trigger allergic reaction, there is a need for some practical limit since “free” claims are being observed. The original draft language for this issue suggested using the method reporting level as the limit. Stephen Dentali posited that the responsibility of label claim verification should fall on the manufacturer. Joseph Betz added that some verification with an analytical method would be valuable. K. Levanseler stated that it was not desirable for NSF to put the onus on the manufacturers for proof and described a scenario where the manufacturer had documentation to indicate that the material was free of an allergen, yet the testing indicated the presence of the allergen. NSF is concerned about the integrity and potential liabilities for NSF certification under this type of situation.

The group then discussed the FDA label requirements versus what is being seen on products in the marketplace as it relates to “free” claims.

Motion: R. Upton moved that the language state that an absence claim is not required to be proven, but rather supported by the testing. K. Levanseler seconded.

Discussion: K. Levanseler questioned how the language would achieve this. Vasilios Frankos suggested requiring documentation that raw materials do not come into contact with allergens. S. Eisner suggested that documentation should suffice from a manufacturer’s point. Proposed wording change to 2nd line in section 5.3.6 of the draft language was…”Raw materials and
finished products shall not contain specific proteins or other analyte(s) associated with the allergen at levels above the method detection limits.

**Vote:** All in favor.

*Motion passes. Language will be updated and re-balloted.*

**IV OLD BUSINESS**

**AHP Monographs**

R. Upton provided an update on the status of the AHP monographs. It was previously proposed that these go through the ANSI process. Therefore, the first (Goldenseal) was modified so that all of the compliance aspects were extracted. A subcommittee was chosen to review and make recommendations to the monograph. Just prior to the meeting, the technical difficulties (software incompatibilities) were resolved and the draft was made available. The Goldenseal monograph will soon be ready for subcommittee review.

**173i26 – Regulated Metals**

Clif McLeellan presented the ballot history for this issue, including the reason for balloting this change. He explained that the current requirements were established in 2003 based on international criteria and without any data indicating what levels to expect in the products. He stressed that the reduction that is proposed would have no impact on products already certified. As he walked through the proposed changes, he explained how the criteria were calculated, including the factor of the relative source contribution. C. McLeellan also addressed the negative comments that were received during the ballot period.

M. McGuffin stated that California “Prop 65” levels are in terms of μg/day, as are Health Canada’s and FDA’s. He suggested that NSF/ANSI 173 also use μg/day for consistency. C. McLeellan agreed that this was reasonable. He also added that clarification was needed to the term “per daily dose”. M. McGuffin also pointed out that most other standards specifically reference methyl mercury when addressing mercury levels. He suggested that NSF/ANSI 173 do the same. C. McLeellan agreed that it was appropriate to differentiate organic and inorganic. K. Levanseler suggested testing for total and leaving the option for speciating if the total mercury level was above the allowed.

M. McGuffin asked why there are levels for ingredients rather than raw materials. K. Levanseler stated that the concern is that a manufacturer will fail after encapsulating a raw material. On finished products, limits can be set in terms of daily dose. With raw materials though, some assumptions must be made in order to have a correlation to daily dose. She also clarified that the raw material limits are for the materials themselves, they do not take into account the amount of materials that a manufacturer of finished product could potentially use.

S. Dentali and C. McLeellan discussed putting use limits on raw materials. Kristen Holt clarified that if a raw material meets the Standard, the manufacturer should be able to calculate how much can be used in the finished product in order to meet the finished product requirements. V. Frankos stated that daily servings vary greatly, however, and that puts the burden on the manufacturer to determine what the appropriate level is for each supplier. R. Upton stated that this can be complicated. M. McGuffin suggested that since the scope of the Standard does not include raw materials, these limits be removed. However, K. Levanseler countered that the scope of the standard does include raw materials and in some finished products, the allowable level of the contaminant would be below the detection limit (e.g., PCBs and dioxins in fish oil). These cannot be tested at the finished product level. Therefore, she maintained that having levels for raw materials does add value.

**Lead**

S. Eisner questioned why the proposed lead level was below that allowable for bottled water. She added that since the contribution from supplements to daily lead intake is so minute, the lower level proposed is not beneficial and would only preclude otherwise good products from being certified. K. Levanseler stated that this issue was brought forward because many companies have been involved in the California
“Prop 65” issue. R. Upton argued that the limit should not be set based on one state’s requirements. In California, he argued, this is a labeling issue only. M. McGuffin disagreed and argued that when possible, levels should be lowered (he cited cadmium as an example). C. McLellan clarified that it was not the intent to base the level on that in “Prop 65”. When achievable, he argued, the levels should be reduced. R. Upton reiterated that there are many products that are not “good” from the herbal ingredient perspective that are able to meet the level because of fillers. He suggested making sure that the levels are based on what is attainable by sampling a broad sample of good quality products to support this change. C. McLellan argued that the toxicological data could not be considered in this case because there is no safe level of lead. Instead, the level is based upon a trigger point designated by the WHO.

C. McLellan explained that the changes were balloted, and there are negatives to address. S. Eisner suggested a tiered approach for products and a differentiation between synthetic versus animal- or mineral-derived products. M. McGuffin stated that he had data on botanicals for consideration in the new revision. C. McLellan stated that it would be helpful to see that data.

**Motion:** K. Levanseler moved to address lead in a separate ballot, and reballot this proposal for requirements for the other metals. Meanwhile, the data for lead should be reviewed. M. McGuffin seconded.

**Vote:** All in favor.

**Motion passes.**

**Mercury**

M. McGuffin stated that for mercury, there are 4-5 Prop 65 settlements that specify amounts permitted in products without labeling. There is also another reference to review that sets the limit for inorganic mercury at 3 μg/day and all other types at 0.3 μg/day. K. Levanseler responded that the proposal was simply to drop the limit 10-fold. It was suggested that the ballot be changed to include a limit for total mercury and a limit for inorganic mercury.

**Motion:** M. McGuffin moved to change the ballot on mercury to be a limit for total mercury and a separate limit for inorganic mercury. R. Upton seconded.

**Vote:** All in favor.

**Motion passed. C. McLellan was charged with developing language to be balloted.**

It was suggested that levels be specified that the are based on an assumed number of grams of consumption for ingredients.

**Cadmium**

M. McGuffin posed the question of whether the cadmium level should stay at 6 μg/day or be lowered to 4.1 μg/day. C. McLellan responded that one’s opinion on that matter would depend on their opinion of political reasons for the limit. Every other limit is health-based, which is why 6 μg/day was used here. M. McGuffin agreed that the limit should be left at 6 μg/day for that reason.

The group discussed whether the limit should consider the source of the product and what should be the basis. V. Frankos stated that if herbal products have naturally high levels, the limit on use should reflect that and final product should use less to keep lead levels down. S. Eisner stated that the industry does not make the assumption that herbal products do not have an added benefit. V. Frankos maintained that the level should be health-based. R. Upton emphasized that efficacy must also be considered. M. McGuffin pointed out that the GMP mandates that a Standard must be set for contaminants that cause a product to be “adulterated” – or to contain poisonous or deleterious levels of contaminants that render it injurious.
Exceptions to the Standard

Katherine Sharpless asked about exceptions. K. Levanseler stated that exceptions are precluded by the Standard. Sonya Agbessi asked if exceptions should be allowed if based on sound scientific evidence.

**Motion:** Allison McCutcheon moved to incorporate language into 173, which would allow exceptions to the standard if supported by sound scientific evidence. M. McGuffin seconded.

**Discussion:** C. McLellan stated that this would be difficult to implement. K. Holt stated that her preference is that the JC specify when exemptions are allowed so that NSF does not have the burden of determining what level of evidence is sufficient.

K. Levanseler suggested submitting an issue paper to address this. C. McLellan clarified that it should address the Standard and stay away from certification issues.

**Amendment:** S. Eisner suggested that the motion be revised to recommend further development of the exemptions. A. McCutcheon and M. McGuffin accepted the amendment.

**Vote:** All in favor.

*Motion passes. A. McCutcheon was charged with bringing this forward as an issue paper.*

**Table 3 Test Methods (DS-2007-3)**

K. Levanseler stated that the content of tables 3 and 4 has not been reviewed or evaluated since the release of the first version of the standard in 2001. Therefore, she suggested that this be done in order to expand and update them to more accurately reflect the test methods currently in use for products and ingredients being evaluated. She agreed to make the tables available electronically and asked for feedback.

**V NEW BUSINESS**

**Arsenic (DS-2007-9)**

C. McLellan presented his issue to the JC. He described the different types of arsenics and explained that currently only total arsenic is addressed in the Standard. He explained that there is a lot of data on arsenic; it is a known human carcinogen with many non-carcinogenic health effects as well. The inorganic form is either As(III) or As(V). He explained that the current EPA limit is based on a well-accepted Taiwanese drinking water study where dose was linked to health effects. The results showed that a 20-μg/L dose would increase the cancer risk by 1/1000 people. It uses a simple logarithmic function to determine the other risks. Therefore, C. McLellan requested that the JC ballot the level at the proposed 2 μg/day.

Michael Rowley summarized his issue with arsenic in his product. He stated that the product his company makes is mined with naturally occurring arsenic. He stated that the issue surrounding arsenic is complex. The NRC suggests that within a certain range, arsenic is nutritional. It has also been used medicinally at much higher levels than are found in dietary supplements. Further, dissolution studies at the USP showed no accumulation in rats. He recommended that the limit be changed to address the different types of arsenic and be based on the current understanding of arsenic toxicity.

M. Rowley answered some questions about the toxicology study done for Sierra Mountain Minerals. R. Upton suggested having the study published, as that would give it more credibility. C. McLellan stated that NSF would not give a published document more credence. His questions were regarding the conclusions of the study. S. Eisner stated that there are two questions to answer: 1) what the arsenic limit should be, and 2) how to address exceptions to the rule. The second question has already been discussed pertaining to cadmium. She directed the group to focus on discussing the former question, and also to ask whether organic and inorganic arsenic should be differentiated in the Standard. S. Eisner recommended the same approach as with mercury – that the total should be measured and if above the limit, speciate to determine the levels of inorganic and organic.
M. McGuffin asked whether C. McLellan’s recommendation was based on arsenic in shellfish. C. McLellan confirmed that it was only based on the IRIS database for inorganic arsenic. However, there is clearly a documented difference between the organic and inorganic types, which is supported by epidemiological evidence.

**Motion:** V. Frankos moved to differentiate organic from inorganic arsenic. M. McGuffin seconded.

**Discussion:** C. McLellan stated that he was in agreement with the proposal. M. Rowley clarified that the numbers proposed were based on a literature review. K. Levanseler questioned whether the rat data was appropriate from a toxicological standpoint.

**Vote:** All in favor.

*Motion passed.*

**Motion:** M. McGuffin moved to ballot the change to set the limit for inorganic arsenic at 2 μg/day. K. Levanseler seconded.

**Discussion:** It was mentioned that “Prop 65” proposed 0.1 μg/day a few years ago but now there is no proposal for a limit on arsenic. M. McGuffin stated that the 0.2 μg/day in this proposal was from 10% of the 20 μg/day that EPA claims is consumed. C. McLellan confirmed that the range given by the EPA was 2-20 μg.

**Vote:** All in favor.

*Motion passed.*

K. Levanseler answered a question regarding methodology for determining arsenic concentrations, stating that differentiation would require chromatography separation, with ICP/MS for detection.

**GMPs (DS-2007-8)**

Ed Wyszumiala reviewed the issue paper he submitted that recommended replacing much of section 8 of the Standard with a reference to the recently published 21 CFR § 111. He explained that when section 8 was first balloted for inclusion in the Standard, it was presumed that when the federal regulation was published, it would replace this section.

R. Upton stated that the current GMP requirement in 21 CFR § 111 does not require lot numbers, with which he disagreed. M. McGuffin agreed and stated that the lot number should be required to be disclosed on the finished product.

M. McGuffin pointed out that the three parts of section 8 that are proposed to be retained in the Standard are shelf life dating, handling/storage, and complaint files. He stated that complaint files are incorporated into 21 CFR § 111 so should be removed. E. Wyszumiala agreed. He also stated that after review, he would also propose that the shelf-life section be removed. J. Betz stated that the GMP outlines a minimum requirement; however, the JC has the opportunity to raise the bar. He suggested that if additional requirements add value, they should be maintained in the Standard. After some discussion, it was agreed that shelf life could be removed. K. Holt pointed out that the Standard is raising the bar with the addition of handling/storage requirements, lot numbers, and complaint files. V. Frankos clarified that the FDA requirement is that there is some means of designating batches, but it is not limited to lot numbers.

**Motion:** R. Upton moved to require lot numbers to be on the finished product package. M. McGuffin seconded.

**Vote:** All in favor (V. Frankos abstained).

*Motion passed.*
The Committee then discussed the proposed implementation date. E. Wyszumiala stated that the proposal is that this would become effective when the regulation becomes effective, January 1, 2008. However, companies will have until June 2008 to comply. S. Eisner argued that this was not a feasible compliance date for all manufacturers.

**Motion:** M. McGuffin moved that an implementation date be incorporated into the Standard specifying a date by which products shall comply with 21 CFR § 111.

**Discussion:** S. Kozanecki clarified that the Standard cannot (in the normative sections) include any references to implementation dates. K. Levanseler suggested that a footnote could be included to specify a specific date, however. E. Wyszumiala pointed out that section 8 is consistent with 21 CFR § 111; therefore the implementation date is not an issue. K. Holt stated that the Standard references the regulation, and in NSF’s certification policies an implementation date would be specified.

**M. McGuffin withdrew his motion.**

**Motion:** M. McGuffin moved to ballot the proposed substitution of section 8. K. Levanseler seconded.

**Discussion:** S. Eisner stated that she disagrees with the FDA’s justification and would not vote in favor of this change. M. McGuffin stated that this change would go above the regulation to also make ingredient suppliers comply with 21 CFR § 111. K. Levanseler suggested that the language could be changed such that for ingredients, the current section 8 requirements would remain. K. Holt indicated that auditing to two sets of GMP requirements would be difficult to manage and execute. V. Frankos spoke from the perspective of the FDA. He stated that the qualification aspect is what is important. Since ingredients assist finished products in meeting the final standard, compliance of the ingredients makes them more attractive to manufacturers. The group continued discussing whether the GMPs should apply to ingredient suppliers, and agreed that they should not.

M. McGuffin argued that the requirement for complaint files does not need to remain. Those present agreed. M. McGuffin also posited that the proposed section on handling/storage was also unnecessary. K. Levanseler stated that this section was viewed as unique from 21 CFR § 111 since it previously specified for aflatoxin testing, however, the wording was in the process of being changed per Issue 14. The newly accepted language should be reviewed against 21 CFR § 111 to determine if the requirements are over and above the regulations.

The group discussed keeping section 8 to the reference to 21 CFR § 111 plus a lot number requirement.

**Vote:** All in favor.

*Motion passed.*

E. Wyszumiala suggested that the bioterrorism and AER sections (both currently in section 8) should also remain.

**Motion:** M. McGuffin moved to reestablish the current section 8.9 (bioterrorism section). Jo Ann Peterson seconded.

**Vote:** All in favor.

*Motion passed. All language changes will be balloted.*

**DEGs (DS-2007-7)**

K. Levanseler explained that DEG has been found as a contaminant in glycerin and asked whether the JC felt that the Standard should require testing for DEG if glycerin is an ingredient in the product. V. Frankos stated that the opinion of the EPA is that DEG should be tested for where glycerin is present. M.
McGuffin suggested taking care not to require both ingredient and finished product testing. He also suggested citing the FDA test method. J. Betz expressed concern that, since adulterants evolve, one may end up testing for dozens of possible contaminants after some years. Therefore, he suggested that perhaps the burden should be to establish a product’s purity. R. Upton echoed this concern, stating that one incident of contamination should not mandate testing; the question remains, however, at what point a test should be required for a potential contaminant.

**Motion:** K. Levanseler moved that NSF review the FDA recommended method before submitting the language with the revision citing the method for ballot. R. Upton seconded.

**Amendment:** M. McGuffin proposed a friendly amendment that the proposal be reworded to minimize redundancy. K. Levanseler agreed to the amendment.

**Vote:** All in favor.

**Motion passed. Language will be reviewed and balloted.**

**Melamine (DS-2007-6)**

K. Levanseler introduced the information paper on melamine. The question that is posed is whether NSF should test for melamine (independently from GMPs) as part of certification of finished products. It is a contaminant of concern in amino acids. The group discussed this and agreed that it made sense if it is warranted by the formula review. V. Frankos stated that the FDA is requiring all products to be tested for melamine. J. Betz suggested that it was not a problem as long as it was not applicable to ingredients.

One suggestion was that the testing be based on geographic location of the manufacturer. S. Eisner posited that if the product is sold in the U. S., this testing would be redundant (since the FDA is requiring the test); however, if it sold outside of the U. S., it may be warranted. K. Levanseler clarified with V. Frankos that products manufactured entirely outside of the U. S. and imported are not tested. V. Frankos confirmed that they are not. E. Wyszumiala pointed out that it might be necessary to go further into the supply chain to ingredient brokers.

Jason Lilly pointed out that this is just the contaminant of concern now because of recent findings of contamination, but it could be any number of things in years to come.

The group discussed the analytical methods for amino acid content. It was suggested that a suite of methods might be necessary. There was some agreement that total amino acid could be used to determine the total protein.

**VI ADJOURNMENT**

**Next meeting**

S. Kozanecki agreed to find a suitable date for the next meeting, to be held at NSF world headquarters in Ann Arbor, MI via email correspondence with the Committee.

**Motion:** M. McGuffin moved to adjourn. R. Upton seconded.

**The meeting adjourned at 5:15 pm.**
**Joint Committee Members in Attendance**

Steven Dentali – AHPA  
Staci Eisner – Cortex Scientific  
John Fitzloff – University of Illinois at Chicago (via conference call)  
Vasilios Frankos – FDA Division of Dietary Supplements  
L. Wendell Haymon – Nutricia  
Frank Jaksch – Chromadex  
Kerri Levanseler – NSF International  
Jason Lilly – Neogen  
Anita Mishra – AOAC (via conference call)  
Alison McCutcheon – University of British Columbia (via conference call)  
Michael McGuffin – AHPA  
Jo Ann Peterson – National Enzyme Company  
Andrew Shao – Council for Responsible Nutrition  
Katherine Sharpless – NIST (via conference call)  
Roy Upton – American Herbal Pharmacopoeia

**Observers Attendance**

Sonja Agbessi – Health Canada (via conference call)  
Joseph Betz – National Institutes of Health  
Barry Brown – MeriCal  
Paula Brown – BCIT  
Puri David – Nutrilite (via conference call)  
Daniel Fabricant – NPA  
Kristen Holt – NSF International  
Amber King – NSF International  
Clif McLellan – NSF International  
Bob Rathbone – AOAC (via conference call)  
Michael Rowley – Sierra Mountain Minerals  
Ed Wyszumiala – NSF International

**Joint Committee Members NOT in Attendance**

Heather Arnold – Nutrilite (via conference call)  
Michael Bradley – Perrigo of South Carolina  
Roger Clemens – USC School of Pharmacy  
Mary Hardy – David Geffen School of Medicine at UCLA  
Helmi Hussien – Health Canada  
Len Monheit  
Jim Roza – Source One Global Partners  
Leila Saldanha – NutriQ LLC  
Wyn Snow – Dietary Supplement Quality Initiative  
Edward Steele – EAS Consulting Group  
Sidney Sudberg – Alkemists Pharmaceuticals  
Darryl Sullivan – Covance, Inc.  
Chirag Varaiya – Jarrow Industries  
Victoria Whitsitt – NPA  
Anthony Windust – National Research Council Canada