I Opening Remarks

Joint Committee (JC) Chairperson P. Brown welcomed everyone and called the meeting to order. R. Brooker read the antitrust statement. P. Brown announced the resignation of JC member Heather Arnold from Amway and the acceptance of Allison Zolnay also from Amway. Based on these changes, the current membership of the JC now consists of 8 industry representatives, 8 public health/regulatory representatives, and 8 members from the user category.

II Review of Agenda

P. Brown requested the group to review the October 2014 agenda for approval.  

Motion: S. Eisner motioned to accept the proposed agenda  
Seconded: J. Betz  
Objections: None  
Abstentions: None  
Vote by verbal affirmation: None apposed.  
Motion passed.

III Review of 2013 Meeting Summary

P. Brown asked if there were any additions or corrections to the November 2013 Joint Committee on Dietary Supplements meeting summary.  

Motion: M. McGuffin motioned to table the approval for further review.  
Seconded: J. Betz  
Objections: None  
Abstentions: None  
Vote by verbal affirmation: None apposed.  
Motion passed.

IV Purpose of JC and Membership Roles

R. Brooker gave a brief presentation on the purpose of the Joint Committee (JC) and the various roles of the membership types. The JC is the consensus body responsible for development and revision of their designated NSF/ANSI standard and the JC meeting is to discuss all issues that pertain to the scope of the standard. In order to recommend a change to the standard one must submit an issue paper for the JC to discuss and vote on.

There are two different ways a person can be active in the JC. The first is as a member and the second is as an observer. A JC member is an individual, representing a particular interest category, and capable of attending all scheduled meetings. The expectations of this person is to attend all scheduled meetings, vote on all ballots, participate in Task
Groups (TG), and to actively participate in committee discussions. An observer is an individual who has expressed interest in the work of one or more committee(s), and receives committee correspondence (agendas, minutes, etc.). They do not have the right to vote on committee ballots nor are they required to be at all scheduled meetings, but they can be assigned to a committee to work on an action item.

V Issue Paper versus Information Paper

R. Brooker presented on the difference between an issue paper and an information paper. An issue paper is a document that is used to suggest a change to the standard. They must be filled out on the current issue paper format (this is available on NOW) and turned in electronically to the Secretariat. The Secretariat will then pass the issue paper on the the JC Chairperson and he or she will decide if the issue can go straight to ballot or if it is something the JC must discuss.

An information paper is simply as it is stated, an informational document. This is also turned into the Secretariat electronically but it is not meant to initially incite change to the standard. For example this can be used when a new testing method is introduced in a publication and someone wants the JC to be aware of it.

M. McGuffin urged all members to submit issue papers and not just NSF. R. Brooker reminded that any member or observer can submit.

VI Task Group and Membership Updates

L. Thomas asked about balance if we add more people and R. Brooker said that we strive to have balance but know that it is rare to have exact balance. P. brown brought up activity and asking those who haven’t voted to be removed. J. Betz mentioned that there might be regulations that state the process for removing a member based on attendance and participation. R. Brooker is going to research this and will update the team at a later time.

The current task groups and task group membership was also reviewed and the following changes were requested.

**Action Items:**
1. Replace all K. Cox with J. Larson
2. AHP TG – R. Brooker contact R. Upton about recent activity of this group.
3. Herbal Safety – M. McGuffin would like to join the group.
4. Identity Task - P. Brown wants a meeting set up immediately. P. Brown doesn’t want to be chair. R. Brooker called for volunteers. P. Brown will chair this meeting but will ask then for a replacement. M. McGuffin and D. Harbaugh-Reynaud requested to join the TG.
5. Membership Task - P. Brown explained this was to help go over applications. K. Rimmer and J. Betz volunteered to be on the committee. P. Brown will set up meeting.
7. Pesticides – Change K. LeVanseler to Chairperson and add M. McGuffin to this group.
8. Public Agency – Disband this TG.
9. Targeted Verification – Disband this TG.
VII Current Ballot Status

A. 2011-1/2/3 (Issue 42) Rancidity

Discussion: R. Brooker gave an update on this ballot. The ballot was closed and passed on 5/16/14 with 100% of the voters voting affirmative. The public comment period opens 10/17/14 and will conclude on 11/16/14. The revised standard will be published by the end of the year.

K. LeVanseler stated that she doesn’t think that this ballot actually fixes the issue that was presented. She stated that there was an initial goal to create a list of oils that require rancidity testing since there are certain oils where rancidity is a primary concern. Then there was supposed to be a next step to look at moving rancidity testing to an obligation of the manufacturer. Currently NSF must request oil samples and have a manufacturer send a sample which may become degraded on shipment. She admitted that requiring manufacturers to test and show proof of testing is still difficult from an ANSI point of view because if the manufacturer does the testing their lab has to be a 17025 approved lab for us to accept that testing for certification. She concluded that this ballot allows us to focus on a set of oils but doesn’t allow for us to move the test requirement to an audit checklist which was one of the suggested goals. Because of that the task group needs to continue to work on this issue.

Motion: S. Eisner motioned to have another task group meeting.
Seconded: A. Ewing seconded and stated that she would set that up.
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
An email will be sent to the remainder of the JC to confirm vote since there was not quorum.

B. Issue 49 Section 5.3.1 (Metals)

A. Ewing commented that the group has not been active and she offered to take over as Chairperson. S. Eisner felt NSF was trying to drive the limit too low for practicality. She doesn’t think there is a need for the group to be moving forward. K. LeVanseler wanted the difference between the raw ingredient level and the finished product to be re-evaluated to make sure they are consistent. A. Ewing commented that she was not part of the initial task group but thought that the group may need to review the values again to ensure that the current values are reflective of the group’s discussions.

Action: R. Brooker will pull up the minutes and language from the last meeting. A. Ewing is going to look back and see where it left off. Remove A. Phelka from the TG and add A. Ewing, as Chairperson, as well as add M. McGuffin and D. Sullivan.

Motion: A. Ewing motion to reactivate the TG and have meeting.
Seconded: S. Eisner
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
An email will be sent to the remainder of the JC to confirm vote since there was not quorum.

C. DS-2013-2 (Issue 50) Protein Labeling
J. Travis presented on his issue paper regarding protein labeling and the concern that free amino acids may now considered towards protein level on the label; since the standard and regulations do not clearly address the subject. There was no task group formed initially and the issue went straight to ballot. The ballot received a few comments, two of which were from negative ballots. J. Travis commented that he had contacted each of the individuals who commented and presented his responses to the JC. He was open to the changes of the comments and would draft new language and send it forward to the JC.

S. Eisner said FDA requires that the digestibility score has to be taken into account on the label. J. Travis will come up with new language to the protein content in Section 5.6 and reballot. M. McGuffin stated that the FDA has proposed changes to its nutrition labeling regulation and that this issue is currently unresolved. He believes that the JC has proposed substantive changes to the regulation and suggested that the group should wait until the FDA has completed these regulation changes which should be released in 2015. S. Eisner disagreed and wants to move forward because the amino acid digestibility corrections are required at this time. D. Sullivan commented that if the standard is going to embrace this that there are 2 aspects to look at, the digestibility of the protein and the corrected amino acid score, and if you are looking at a new protein that has not been documented there is a bioassay that needs to be used and is complicated. He stated that this is no reason not to embrace it but it is difficult.

M. McGuffin wants a revision and to create a Protein Policy task group. He suggested that there are two AHPA members that would be useful for this task group and that he will contact them. J. Travis volunteered to chair the group with S. Eisner and D. Sullivan offering to be members.

Motion: M. McGuffin motioned to form a task group.  
Seconded: S. Eisner  
Objections: None  
Abstentions: None  
Vote by verbal affirmation: None opposed.  
An email will be sent to the remainder of the JC to confirm vote since there was not quorum.  

Action: M. McGuffin will contact industry members that have expertise in this area to sit on the TG.

VIII New Issues Affecting Standard 173

A. DS-2014-1 (Issue 51) Caffeine

J. Larson stated that NSF has adopted 150 mg per serving and 300 mg per day limits. P. Brown questioned where those limits came from. J. Larson explained that these limits are Health Canada’s restrictions and the 300 mg per day value was based on women of childbearing age, pregnant women and/or women who are breast feeding. J. Larson followed that by stating that since he wrote this issue paper the FDA has published a guideline of 400 mg per day.

M. McGuffin stated that AHPA states a limit of 200 mg per serving with not more than 3 to 4 servings per day and that CRN has a standard without a quantified limit. He would like to stay consistent with the limits already in place and suggested to have a 200 mg per serving limit and possible have a special suggestion for pregnant woman on the label. P. Brown stated that she would like to see 400 mg per serving since that is the FDA’s regulation for a healthy adult and that it is up to a pregnant woman to limit herself. M. McGuffin stated that Health Canada is 200 mg per serving and 400 mg per day unless
you are pregnant or are trying to become pregnant in which case it is 150 mg per serving and 300 mg per day. J. Larson agreed that those numbers are correct. S. Eisner suggested to ballot with 200 mg per serving and 400 mg per day. M. McGuffin opposed and asked J. Larson to create a TG and get more info to the group. J. Larson agreed and offered to be Chair with L. Thomas, S. Eisner, M. Charron, and A. Shao volunteering to sit on the TG. M. McGuffin requested that D. McKay, and Andrea Wong from CRN be contacted to participate on this TG.

Motion: M. McGuffin moved to created task group.
Seconded: S. Eisner
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
An email will be sent to the remainder of the JC to confirm vote since there was not quorum.

Action: M. McGuffin will contact D. McKay and Andrea Wong from CRN request that they participate on this TG.

B. DS-2014-2 (Issue 52) Ingredient Exclusions

A. Ewing stated that this the group has discussed in the past to prohibit certain product and ingredient types but there has been no list created. She would like to re-activate the Herbal Safety Review TG and rename it the Ingredient Review TG. This TG will develop a formal process to recommend and send to ballot the ingredient and/or product types that the JC would like to see excluded from the standard. This could be full exclusions or specific caveats such as allowing Yeba Mate but not smoked Yerba Mate. M. McGuffin questioned why safety was removed from the TG name.

S. Eisner wants the public to know what NSF doesn’t want to certify and why but then stated that publishing that NSF won’t certify certain products and/or ingredients will put a “black mark” on those products and could cause issues with insurance companies and other entities. L. Thomas clarified that a lot of this issue is coming from NSF’s sport group. The sport group will not certify products such as sexual enhancement and weight loss products. M. McGuffin said those examples were not about ingredients but were about claims. P. Brown agreed with M. McGuffin and that this issue is more about labeling and adulteration. She commented that she is not comfortable generating a list of exclusions based on the idea that NSF does not like them. She also stated that Health Canada has monographs which allow products to be under drugs and to state those claims. M. McGuffin stated that while he has some reservations there is a lot that he likes about creating this TG because there will be open discussion and ballots for each ingredient and product. He stated that he would add the wording “for recommending excluding” to the issue paper second bullet point. J. Betz would like to invite Carol Welch from the FDA to this task group. P. Brown stated that while she would welcome Carol Welch’s input she would not like her to be part of meetings because she does not want to give potentially damaging information regarding the industry to the FDA. M. McGuffin suggested that the JC might take the position that you can’t sell an ingredient but that perhaps you can’t sell it without an NDI note.

Betz said USP has a similar issue and that they have a subcommittee called the submissions committee which addresses whether or not something should be omitted. There was much more conversation about suggested names for this TG but in the interest of time L. Thomas suggested naming the TG at its first meeting. A. Ewing volunteered to be the Chair. J. Larson, M. McGuffin, L. Thomas, J. Travis, M. Charron, and D. Harbaugh Reynaud volunteered to join the committee. D. Harbaugh Reynaud
brought up groups of botanicals that can be grouped because of common adulterants and A. Ewing agreed and stated that it could be further discussed.

**Motion:** S. Eisner motioned to move this conversation to the TG.
**Seconded:** J. Betz
**Objections:** None
**Abstentions:** None

*Vote by verbal affirmation:* None apposed.

An email will be sent to the remainder of the JC to confirm vote since there was not quorum.

C. DS-2014-3 (Issue 53) Pesticides

This issue paper was a joint effort between K. LeVanseler and A. Ewing. A. Ewing stated that there was a Pesticide TG that changed the standard to say “a broad pesticide screening shall be performed to confirm the absence of banned pesticides in botanical products.” The standard later states “banned pesticides are those listed in Annex 3 of the Rotterdam convention.” Given this information A. Ewing voiced that it is confusing that you would do a broad screen when only the Rotterdam convention pesticides are required for certification and the Rotterdam list only consists of ~33 pesticides. This brought up two concerns for her. The first being if the standard requires a broad screen then what is to be acceptable for the pesticides not on the Rotterdam convention? The second being that NSF and every other laboratory that she knows of is not able to do the full screening of the Rotterdam list.

K. LeVanseler commented that the Rotterdam list has a combination of four unique methods. There are some categories where a certain pesticide is not banned but a formulation that is highly concentrated is banned globally and a problem is that there is no way for testing what original formulation it came from. An example K. LeVanseler gave are things that are tin based and tin would not typically be done in a pesticide screen. Due to this she has found it to be a difficult requirement to assess from a practical nature.

A. Ewing suggested switching to the USP/EP list which is easier to test product to and it also has acceptability criteria. K. LeVanseler recounted that she and A. Ewing discussed this with the NSF lab techs; it was decided that if the standard had a list of pesticides they would at least have something to look at to state which pesticides to test.

D. Sullivan commented that he is in favor in getting rid of the Rotterdam list. He went on to say that he believes that the USP/EP list is different right now and that USP might be changing but that he is not sure what the time frame is for that. He also stated that those lists are very conservative. K. LeVanseler stated that one of issues we face is that companies use the USP/EP list and it passes but then fails with NSF because NSF’s restrictions are higher. S. Eisner mentioned that analytical testing has largely evolved since the law was originally passed we are now able to detect things that have no health or environmental relevance. She doesn’t want to put companies in the situation that they are against the law when pesticides are unavoidable and have no health or safety risk. A. Zolnay stated that she has found when importing these items into the United States that there is some disconnect with EPA banned substances and the USP/EP list. D. Sullivan added that items can pass the USP/EP list but if the product is shipped to Europe they test down to 10 parts per billion because those limits have been agreed to by the European Union. He agreed with S. Eisner that testing has become so precise that we can exclude many things so we need to be reasonable. S. Eisner said it is not a blanket number in Europe and that it is a more sophisticated approach. M. McGuffin said that it is specific for botanicals.
P. Brown agreed that there needs to be changes to the standard and would like the TG to meet to discuss. A. Ewing and M. Crocker asked to be added to the TG. S. Braden-McCann said that M. Hoard from ANS would also like to be on this TG.

**Motion:** S. Eisner motioned to move this conversation to the TG.

**Seconded:** A. Ewing

**Objections:** None

**Abstentions:** None

**Vote by verbal affirmation:** None apposed.

An email will be sent to the remainder of the JC to confirm vote since there was not quorum.

**Action:** K. LeVanseler will schedule a TG meeting.

**IX New Business**

**A. Global Retailers and Manufacturers Alliance (GRMA)**

**Discussion:** R. Brooker announced the start of a new group called the Global Retailers and Manufacturers Alliance (GRMA). This group was created to address the high cost of multiple audits done so that manufacturers can satisfy the requirements of multiple retailers and regulatory requirements. To date there have been 2 face-to-face stakeholder meetings that have consisted of 12 retailers and 19 manufacturers. In the last meeting which was held at the end of July the group divided into 4 product categories, dietary supplements, cosmetics, medical devices, and over the counter drugs. NSF has filled a Project Initiation Notification with ANSI for each product category and are currently creating committees on each. These standards will build off the foundational GMP requirements for each product category. Dietary supplements is unique within the 4 groups because it does already have an American National Standard for testing products but what GRMA is focusing on is the manufacturing process. It has not been determined yet whether the GRMA group will use NSF/ANSI 173 as a starting point or if it will create a separate new standard. The goal is to have a Standard that unifies both the manufacturers and retailers. It is a hope that the retailers will embrace NSF/ANSI 173 as a whole and we can take Section 8 and build off that. If anyone is interested in participating in this committee please contact R. Brooker.

L. Thomas added this is a GMP standard for GRMA and the only way that it could affect ANSI/NSF 173 is in Section 8. Currently Section 8 state that GMP must be followed and with the GRMA standard Section 8 could change to simply reference this new standard. While there might be some small changes L. Thomas explained that the goal is not to change the GMP audit too much from where it is now.

S. Eisner asked if it will differ from 21 CFR Part 111. L. Thomas answered that it will be 21 CFR Part 111 but with some additions. She also stated that Section 8 already has some increased requirements from 21 CFR Part 111. S. Eisner questioned “global” because there are different restrictions between countries and L. Thomas replied that this will just be for the United States.

K. LeVanseler asked if the GRMA standards will be applicable to the ingredient providers as well. L. Thomas stated that we already have some ingredient suppliers that are audited for GMP and we can have them under this new standard too if they would like to meet the requirements.

**B. NSF 229 Functional Food**
A. Ewing presented that NSF has a Functional Foods guideline that has been in use for many years and that it has recently been decided to create an ANSI standard. The current guideline is under revision and has been sent to a review committee to be approved. Once this committee approves this revision then the guideline will be used as a starting point to create a standard.

There was some confusion amongst the JC because there are members who are on both the review committee and this JC and they did not realize that they were receiving it as the review committee and not as the JC. A. Ewing cleared up this confusion and P. Brown volunteered to be on the review committee. A. Ewing explained that this is being presented to the group today to decide if this JC will oversee NSF 229 or if a new JC needs to be formed. R. Brooker updated the group that there was a Project Initiation Notification back in June. The PINs was published and the standard will be given the name NSF 229.

M. McGuffin questioned the term Functional Foods. R. Brooker opened the NSF guideline and read the Functional Foods definition which is "Foods in which the concentrations of one or more physiologically active food components or ingredients are satisfactorily demonstrated to enhance a healthful diet above and beyond basic nutrition functions to enhance the state of well-being and health have been manipulated or modified to enhance their contribution to a healthful diet above and beyond their basic nutritional functions and/or to reduce the risk of chronic disease."

S. Eisner questioned how much of this standard is about technical attributes or is it about how do you substantiate claims that are being made. L. Thomas replied that this program has been around for 10 or more years and NSF is simply looking to make this existing guideline into a standard. She went on to say the reason it was started was that customers were coming to NSF with products that were not dietary supplements but they wanted to have NSF certification and be able to have the NSF mark on their product. Some examples are protein bars and drinks that have a nutritional panel and therefore are not a dietary supplement. The way NSF treats these products is the same except for some of metals acceptance criteria.

L. Thomas explained that originally they were all audited to 21 CFR Part 111 but some of them were having difficulty meeting that because the requirements are very different for them. NSF developed a separate GMP audit for them that is closer to 21 CFR Part 110.

J. Betz questioned what types of claims are on the products labeled Functional Foods. J. Larson responded that the guideline is for those products that are similar to a dietary supplement but are not considered one and therefore the claims are very similar. J. Betz returned that the FDA says you can’t make a disease related claim on these products unless it has been approved by the FDA and that this program would be a way of bypassing the FDA’s rule making process for the approval of health claims. Certifying these claims would give consumers the confidence that they are following the law but they aren’t. J. Larson assured the JC that NSF does not approve health claims that have not been previously approved by the FDA. A. Ewing also commented that NSF will only certify a product to the guideline which states that content is tested; to make sure the product contains what it says that it contains and that it is not adulterated with metals and microbes.

S. Eisner commented that her hesitation is around the word “Functional Foods” and suggested that changing the name may help this issue. J. Betz stated that in NSF’s definition of a functional food “…are satisfactorily demonstrated to enhance a healthful diet…” and that the FDA are the only ones allowed to make the determination if it is satisfactorily demonstrated and they do it through the rule making process. S. Eisner pointed out that there is a different provision in the law that allows you to make claims that aren’t approved by the FDA for dietary supplements. A. Ewing acknowledged that
and added that there is a statement in the dietary supplement standard that indicates that certification does not ensure compliance with regulatory requirements and questioned why that couldn’t be added to a functional food standard.

L. Thomas stated that it is obvious that there is a need for the program and that it needs to be a separate JC. She went on to state that NSF has found functional foods that are not meeting their claims and some that contain banned substances, and therefore this standard is needed in the industry.

**Motion:** J. Betz motioned that this JC not oversee NSF 229.

**Seconded:** S. Eisner

**In Favor:** K. Rimmer, A. Zolnay, M. McGuffin, M. Bradley, A. Ewing, and J. Betz

**Objections:** D. Sullivan and A. Shao

**Abstentions:** M. Rettinger, M. Charron, D. MacKay, and S. Eisner

*An email will be sent to the remainder of the JC to confirm vote since there was not quorum.*

**C. Other New Business**

P. Brown opened the meeting to anyone who would like to discuss new business. M. Rettinger commented that she is happy that NSF is willing to look at the needs of the DS industry. She suggested the creation of a task group to look at herbal medicine specifically the use of cannabis. She stated that currently these companies do not know what they need to test against. P. Brown was in favor of looking into this and creating a group to discuss it because she sees that the industry has been changing.

L. Thomas stated that NSF’s CEO has publically stated that NSF will not be addressing medical marijuana.

**X Committee Administrative Issues**

**2014 Meeting Summary**

A lot of task group meetings will be scheduled within the next three months. P. Brown stated that she would like to increase the membership and activity from its members. The 2015 meeting date will continue to be part of Supply Side West. There were some requests to have it later in the day but due to an AHPA meeting in the afternoon a few people would not be able to make an afternoon meeting. Late Saturday was also given as an option. R. Brooker will set up a January teleconference.

**ADJOURN**

S. Eisner motioned to adjourn the meeting; Betz seconded.

**Vote:** All in favor. Meeting adjourned.
Meeting Participants

Joint Committee Members

Chairperson, Paula Brown (British Columbia Institute of Technology)
Joseph Betz (National Institute of Health)
Michael Bradley (Perrigo_ via phone
Martin Charron (Health Canada) - via phone
Staci Eisner (Cortex Scientific Botanicals)
Angela Ewing (NSF)
Michael McGuffin (American Herbal Products Association)

Douglas McKay (Council for Responsible Nutrition) – via phone
Mitzi Rettinger (Cerilliant Corporation)
Kate Rimmer (National Institute of Standards and Technology) – via phone
Andrew Shao (Herbalife) – via phone
Darryl Sullivan (Covance Inc.)
Allison Zolnay (Amway) – via phone

Proxies

Troy Rhonemus – proxy for Frank Jaksch (Chromadex)

Joint Committee Members not in attendance

Wendy Applequist (Missouri Botanical Garden)
Gregory Cumberford (Bent Creek Institute, Inc.)
John Fitzloff (University of Illinois at Chicago)
James Gormley (Gormley NPI Consulting)
Harry Rice (GOED)
Sidney Sudberg (Akemists Labs)
Susan Ulery (Assure Consulting, dba Select Quality LLC)
Roy Upton (American Herbal Pharmacopoeia)
Vicki Whitsitt (Natural Products Association)
Anthony Windust (National Research Council – Canada)

Observers

Danica Harbough Reynaud (Authen Technologies LLC)
Mary Crocker (Juice Plus)
Janice Wilson (AHPA)

NSF International Staff

Soncea Braden-McCann
Jacob Larson
Kerri LeVanseler
Lisa Thomas
John Travis – via phone
David Trosin