



U.S. Pharmacopeia
The Standard of Quality™

**Food Additives Stakeholder Forum
Meeting 1 for 2005-2010
Friday, February 23, 2007
Bethesda North Marriott Hotel and Conference Center
North Bethesda, Maryland
Dr. Andrew G. Ebert, Chair**

FINAL Meeting Notes

Goals and Expected Outcomes

1. Provide a forum in which food additives stakeholders can meet and discuss challenges and opportunities to collaboratively and continuously improve *Food Chemicals Codex*.
2. Discuss the development of *FCC* standards.
3. Discuss the needs and issues of *FCC* constituencies for translation into future strategies.

See Appendix I for Attendee List

1. Opening, Welcome, and Call to Order

Dr. Ebert welcomed participants and called the Stakeholder Forum to order, noting that 22 stakeholder organizations were invited, and 13 responded, sending 19 representatives. Dr. Ebert conducted introductions of stakeholder organization representatives.

Dr. Williams thanked attendees and introduced USP staff members. He noted that USP has assembled a remarkable body of *FCC* volunteers, who are represented in both the Stakeholder Forum participants and the Food Additives Advisory Panel. The Panel is chaired by Ms. Joy Joseph from the Council of Experts Executive Committee. He indicated that the expected outcome of USP's combined activities is a new *FCC* that will be useful to manufacturers, food regulators, and the food science community. He noted that USP staff is privileged to work with stakeholder organization representatives to build the future *FCC* together.

Dr. Ebert said the Food Additives Stakeholder Forum's charge is "to provide information and advice to USP's CEO-EVP, staff, and Council of Experts standards-setting bodies for the Food Chemicals Codex." Stakeholder Forums operate in accordance with Chapter 3, Section 9 of the Bylaws of the USP Convention and Section 11 of the Rules and Procedures of the 2005-2010 Council of Experts. Key provisions include:

- Stakeholder Forums are formed to enable an exchange of information and perspectives between USP and the affected public, with the ultimate goal of improving USP standards and information
- Stakeholder Forum deliberations are advisory and are not binding in any way on the Council of Experts, its Expert Committees, or USP staff
- Stakeholder Forum and Project Team members serve as representatives of a particular interest group and/or company and not as representatives of USP
- Members of the Board of Trustees, Council of Experts, Expert Committees and Advisory Panel members may participate in Stakeholder Forum and Project Team discussions, but only as representatives of USP

Dr Ebert indicated that food additives have considerable public health and economic impact. They are legally marketed in the United States and elsewhere through a complicated and inter-related set of laws, regulations, and guidances. He noted that for reasons of security, trade, and advances in science, the availability and quality of food additives is expected to increase. Food additives standards have important consequences for food safety and processing. He indicated that the food manufacturing industry is a large and complex group of individual organizations and allied trade associations. The food industry is global so these bodies act nationally and internationally. Although historically *FCC* has been a US compendium, its horizon could be expanded internationally as a practical, science-based compendium. The advice of food manufacturers and their associations help provide

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consumers with safe, quality foods and food additives. He indicated that as many manufacturers and associations provide excipients for pharmaceutical dosage form manufacturers—and information to support monographs in USP's *National Formulary*—USP expects to benefit from this Stakeholder Forum in broader ways beyond the *FCC*.

Dr. Ebert indicated that an outcome of this Stakeholder Forum should be a full understanding by stakeholders of how USP staff will work on the *FCC* 6th edition, the stakeholders' role in this process, and their commitment to provide information, time and resources. Communication with other USP Stakeholder Forums will be encouraged.

Dr. Ebert introduced **Ms. Long**, who welcomed stakeholders. She acknowledged and thanked USP staff and *FCC* volunteer groups who met via telecon November 20, 2006 and January 24, 2007 to plan this Stakeholder Forum meeting. Ms. Long previewed the day's activities and the briefing book, which included a draft revised *FCC* monograph. She indicated that notes of the Stakeholder Forum will be distributed to attendees and posted on the USP website. USP has also created a special *FCC* website at www.usp.org/fcc.

Ms. Long indicated that there are four bodies within USP that are advancing the *FCC* at USP: 1) the Food Additives Advisory Panel (temporary), 2) the Food Additives Expert Committee (in process), 3) the Food Additives Stakeholder Forum, and 4) the Food Chemicals Codex Advisory Group. She indicated that elections are underway for Chair of the FA Expert Committee, and that Dr. Ebert is a nominee. (Subsequently, the USP Convention elected Dr. Ebert to this position). Expert Committee members will be elected in the spring of this year. She noted that the Food Additives Advisory Panel, chaired by Ms. Joy Joseph, is a temporary body until the Expert Committee is in place, and that many members of the former Food Chemicals Codex Committee are members of the Advisory Panel. The FA Stakeholder Forum will meet twice yearly. An *FCC* Advisory Group is forming.

She also mentioned that USP is seeking two additional Scientific Liaisons to support *FCC* work. Project Teams with special topics of interest may also be formed to support Council of Experts' standards-setting activities for *Food Chemicals Codex*.

Ms. de Mars then talked about USP's governance. She reviewed Rules and Procedures for Stakeholder Forums. USP is a volunteer-driven organization. Its Convention is the governing body and meets every five years. USP has about 500 employees, and nearly 1,000 volunteers, the latter representing domestic and international academia, industry, government agencies, and associations. There are 58 independent Expert Committees, and an equal number of Advisory Panels participating in USP standards-setting processes. An amendment to USP's Bylaws formalized at the 2005 Convention created Stakeholder Forums as a vehicle to facilitate exchange of information between USP and affected public. Meetings are open to observers and notes are taken and posted to USP's website. USP Project Teams are designed to serve as advisory bodies under each Stakeholder Forum. They are formed as needed, and report their progress through Stakeholder Forums. Project Teams goals are to provide technical or scientific expertise on specific compendial topics. Formation may be recommended by Stakeholder Forums or Chair of Council of Experts (CoE). Members are appointed by the Chair with input from the CoE. Governing documents include: the Constitution and Bylaws, Code of Ethics and Policies, Rules of Business Practices, Rules and Procedures 2005-2010, Employee Handbook, and Quality Manual SOPs.

Discussion

USP's goal is to encourage broader adoption of the *FCC* because statutory reference for the *FCC* is not now the same as for the *USP-NF*.—such statutory recognition is a long-term *FCC* goal.



2. FCC's Future Direction

Dr. Williams spoke to the interrelationships of USP's four compendia: *US Pharmacopeia*, *National Formulary*, the *Food Chemicals Codex*, and the web-based *International Standards*. The first three compendia address standards for articles legally marketed within the United States, and *International Standards* addresses articles legally marketed outside of the U.S. Dr. Williams also explained the difference between official and authorized text. Official text encompasses the monographs and referenced General Chapters that is included in all four compendia. Authorized text includes non-referenced General Chapters, pending standards, and ancillary materials monographs. Dr. Williams then reviewed the USP staff structure that supports the work of the *FCC*, and the timeline for publishing the 6th Edition by February 2008. He acknowledged the speed at which the *FCC* effort has evolved and the progress that has been made since an agreement was signed with the Institute of Medicine (IOM) in August 2006. He mentioned the 1998 McKinsey study of USP, which recommended USP focus on its core business. The *FCC* speaks to USP's core activities and core customers, given USP's role in foods—dietary supplements—in DSHEA. The *FCC* 6th Edition will require assessing missing monographs and monographs needing updating, and working closely with manufacturers. Dr. Williams outlined key topics for the Stakeholder Forum including monograph acquisition, reference standards, legal recognition, and education.

Discussion

- A participant recommended against combining *National Formulary* and *FCC* into one volume.
- The “front matter” (General Notices) of *USP-NF* and *FCC* is very important. It includes valuable scientific and as process-related information and should be changed only with careful thought.
- Harmonization is important and has been challenging. International Pharmaceutical Excipients Council—Americas (IPEC) and International Food Additives Council (IFAC) provided assistance. “Concordance” is a possible solution, where USP could recognize other compendial procedures, e.g., from JECFA or other food additive compendia. The goal is to avoid time-consuming and costly duplicate testing that adds no value to consumer health protection.
- USP plans to generate comments on the *FCC* 6th Edition, with announcements in the coming months that web draft Requests for Revisions will appear
- *FCC* and *Pharmacopeial Forum* audiences differ in size and composition. Users of the *FCC* may not see that changes are coming and need to be made aware. Communication needs would be a good topic for consideration moving forward.
- USP might work closely with FDA legal counsel on any Congressional approaches.
- The success or failure of *FCC* will hinge on vigorous support from food additive manufacturers—the compendium will not be a success if manufacturers don't want to test to advanced standards and be in accord with USP's business model.

3. Regulatory Process for Food Additives and GRAS Ingredients

Dr. Folmer presented the structure of FDA Office of Food Additives and Safety—see PowerPoint presentation.

4. Development of New FCC Monographs

Mr. Green explained why IPEC is involved in the *FCC* process—see PowerPoint presentation.

Discussion

Ingredients reviewed—but not approved—have always been a challenge for articles approved for use outside of the United States but not approved in the United States. Recently, JECFA stated that specifications are just one part of a full safety assessment for a food additive. It is presumed that a manufacturer has done the safety assessment.

- How should *FCC* handle Cyclamates and Sucralose? These are sweeteners approved and being used in various countries around the world.
- As a practical matter, manufacturers wishing to bring products into the US should convene a GRAS panel to ensure the product is safe for its intended use and meets specification criteria then present that to an *FCC* monograph panel for consideration.



- USP envisions a series of steps in monograph development. Following self-affirmation, USP would create a monograph, because the article has undergone GRAS self affirmation and is legally marketed. If the article is in the US market, it should be tested and inspected by the FDA. Another step to consider is if USP would ever rely on decisions from other standard setting authorities? It was noted the USP Board of Trustees would need to be consulted to allow monographs for food additives legally marketed outside of the US.
- The GRAS program is voluntary. A petitioner would inform the FDA after the petitioner has determined a substance is GRAS for its intended use. The manufacturer desires to receive a "no objection" letter from FDA. Customer demand can be a driving force in monograph development and a frequently published *FCC* containing monographs of interest can accelerate the regulatory process.
- USP Dietary Supplements Expert Committee makes safety judgments for dietary supplements legally marketed in the US—up to and including judgments that preclude USP from creating a monograph or verifying a specified ingredient/supplement.
- A revision proposal system similar to *Pharmacopeial Forum*, could provide a more robust change process, for example, interim revision announcements that allow for scientifically-justified quick changes
- USP will require substantial support from food additive/ingredient manufacturers to update and evolve *FCC* to be an advanced, science based food additive compendium.

5. Appropriate Analytical Methods

Ms. Sheehan provided a detailed outline of requirements for *FCC* monographs—see PowerPoint presentation.

Discussion

- Instrument-to-instrument variability and testing differences may cause apparent differences that may not truly exist. We need to consider tests being conducted on the same instruments using the same methods. USP's position is to use the best scientific approach to determine purity and identity.
- Another participant agreed, noting that some monographs were selected with certain IR or other analytical method peaks. Many standards are not pure and contain other constituents which may differ from one supplier to the next. We need to identify major peaks of concern and control testing to establish APIs that are 99% pure.
- An international perspective was presented: Identification tests are not necessarily used outside the United States. JEFCA tests are used in many countries. Sometimes JEFCA references *FCC*, which may reference USP tests.
- In some cases, it may not be critical to have an identification test for an article if an assay test follows. Conceptually, there is room to question identification tests in a food additive or ingredient.
- Could criteria be established for keeping old tests when adding new tests? Not for the less demanding tests, but for the more sensitive tests (heavy metals) it may be necessary and desirable e.g., for heavy metals
- A flexible approach should reside in the monograph.
- Spectra information could be posted on the website.
- In less developed countries less sophisticated tests are used. Simple methods exist for a reason, even if the United States doesn't intend to use them.
- A participant responded that it differs in the pharmaceutical/excipient realm. A chapter may be needed to outline what is necessary for foods, rather than for excipients. Clarify when an identification test is necessary. Do not overstep what has typically been done in food industry.
- How does JEFCA address the least sophisticated methods? When analyzing metals (arsenic, mercury), JEFCA monographs recommend atomic absorption. This is necessary because of the low limits established for contaminants. When possible, use simplest, least costly test methods that are adequate to assure fit for purpose.
- *FCC* timeline is rather bold—will everyone's input be ready for USP to review? The first comment period will occur through the USP website starting June 15, 2007. Comments could be emailed



to Ms. Sheehan (cxs@usp.org). The Food Additives Expert Committee will consider the comments and vote to accept or not accept them.

- A participant expressed concern that it will take at least two years for the food industry to become aware of these changes. The organizations represented in today's Stakeholder Forum need to help spread the word that changes lie ahead. USP sent out a press release to as many stakeholders as possible. When monographs become available for comments, USP will continue to communicate the coming changes to the industry.
- Are all the right associations represented at this Stakeholder Forum? USP needs a single point of contact so it can disseminate the information to them. USP also needs to communicate through *Food Technology*, *Food Chemical News*, and other trade press. Groups to be contacted could include the food science faculty and students (some pharmacy and medical school students are required to use the *USP-NF*.)
- A small communications team is needed. Dr. Ebert, Ms. Nabors, Mr. Shank and Ms. Becker volunteered. USP's Director of Corporate Communication, Laura Provan, will coordinate the effort.

6. FCC Monograph Redesign Project

Dr. Cecil presented the *FCC* redesign—see PowerPoint presentation.

Discussion

- Could USP offer a help-desk? USP explained that this is the role of USP liaisons, who each respond to about 10,000 inquiries per year.
- Another participant asked if USP will take note of small edits or more broad scientific edits? Both.
- USP may consider a "component" category different than "impurities". IPEC developed this to describe excipients; and can share this with USP. It might make sense to do something similar in *FCC*.
- USP likes the categorizing of types of monographs, especially the groupings presented by FDA.
- It is not the case with excipients that everything that is not an API is an impurity. The majority of food additives and excipients have multi-component aspects, similar to dietary ingredients.

7. A View of JECFA

Dr. Kuznesof announced he will retire from the FDA with a round of applause from participants for a job well done. He has enjoyed his association with Dr. Andy Ebert. He then presented a view of JECFA—see PowerPoint presentation.

JECFA's meeting sites alternate between Rome and Geneva. For further information, see:

- www.fao.org/ag/agn/jecfa/whatisnew_en.stm
- www.fao.org/ag/agn/jecfa/archive_en.stm
- www.codexalimentarius.net
- jecfa.ilsil.org/ : Summary of Evaluations

Discussion

- Why are flavors treated differently than food additives if they have already been deemed FEMA-GRAS? Since the late 1990s, JECFA has evaluated 150 to 200 new flavors annually using a new method with poundage data, toxicological and structural data. Most have been nominated by the US for evaluation by JECFA. The committee decides how many it can handle.
- JECFA and *FCC* specifications differ somewhat because the Europeans tend to include more information in some specifications

8. Harmonization with Other Compendia

Mr. Joy stated that while he represents International Chewing Gum Association (ICGA) at the Stakeholder Forum, his presentation is not an official ICGA presentation. He then spoke to harmonization opportunities—see PowerPoint presentation.



Discussion

- South Korea intends to harmonize its regulations and has a full structure in place to support harmonization. So does Taiwan. Reality check is that if *FCC* has been referenced, hopefully it is a current edition, if not, problems can arise
- Chinese Ministry of Health wants to harmonize but adoption is slow.
- If *FCC* block letters are used, it should imply the most recent edition is being used.
- The value of the food additives market is strong in the United States.

9. The 39th Codex Committee on Food Additives

Dr. Kuznesof mentioned the upcoming 39th Codex Committee on Food Additives (CCFAC)—meetings in Beijing in April—see PowerPoint presentation.

Dr. Auerbach presented selected *FCC* Chemistry issues for consideration by stakeholders. Harmonization efforts with other Compendia include *FCC/USP*, JEFCA/Codex Alimentarius, and EU/EFSA. There was a request to move away from the total heavy metals test for lead, as it was not sensitive enough. Recommendation is to require specific tests for the individual heavy metals.

There are issues of product identification e.g., Carrageenan versus Processed Eucheuma Seaweed (PES). A relaxation of specifications was proposed, and currently two JECFA monographs exist. Other issues include: Gum Arabic, Nisin, PGPR refractive index and instrumentation availability in developing countries.

Dr. Ebert and Ms. Long presented Stakeholder Forum hot topics, action items and next steps:

Hot Topics:

- General Notices
- International Harmonization
- Notice and Comment
- Official Status of *FCC*/Legal Recognition
- Articles Legally Marketed outside of the U.S. but not approved for use in the U.S..
- Delegation of Authority of a Monograph (FDA to USP or *FCC*)
- Updating Monographs
- Reference Standards
- Less Demanding Tests
- Communication (Industry, others)
- Marketing the Publication (Industry, Students)

Action Items

- USP to provide revised General Notices to the Food Additives Stakeholder Forum and Expert Committee for review
- Clear direction needed on articles not approved in U.S.
 - Apply concept of International Standards to *FCC* (where other stringent authorities approve a substance)?
 - Can be included in *FCC* Submission/Revision Guideline
- USP to consider formation of Project Teams on some of the hot topics
- Small group to brainstorm ideas for communicating to industry
 - Fred Shank
 - Lyn O'Brien Nabors
- USP to consider including in General Notices reference to use of the latest version of *FCC*

Redesign Comments

- Include full INS number (if available) assure includes item of commerce
- Impurities (concomitant components): Consider separate category in food additives monographs, e.g., "composition." (USP recommendation: place under SPECIFIC TESTS")



Next Steps

- Meeting of the small group on communications
- Frequency of meetings—for now, twice a year.
- Next meeting—summer 2007.

A certificate of appreciation was presented to Dr. Ebert for his service as Chair. Mr. Christopher C. DeMerlis, representing the International Pharmaceutical Excipients Council (IPEC), was asked to chair of the next Food Additives Stakeholder Forum, and he accepted. Dr. Williams thanked everyone for their participation.

The Food Additives Stakeholder Forum adjourned at 4:00 p.m.



Appendix I: Attendee List

Stakeholders	Organization	Representing*
1. Eunice Cuirle	FMC BioPolymers	IFAC
2. Christopher C. DeMerlis	Colorcon	IFAC
3. Andrew G. Ebert, Ph.D.	International Food Additives Council	IFAC
4. Wendy Florence	Procter and Gamble	CHPA
5. Richard Green	CP Kelco	IPEC
6. David Joy	Keller and Heckman LLP	ICGA
7. Russell Kemp	Innophos, Inc.	IFAC
8. Sarah Kraak-Ripple Chr.	Hansen, Inc.	IFAC
9. Paul M. Kuznesof, Ph.D.	FDA CFSAN	FDA CFSAN
10. Lyn O'Brien Nabors	International Food Additives Council	IFAC
11. Kenneth T. Paydon	National Enzyme Company	ETA
12. Frederick Razzaghi	Consumer Healthcare Products Association	CHPA
13. Susan H. Rodgers	Novozymes North America	ETA
14. David R. Schoneker	Colorcon	IPEC
15. Fred R. Shank, Ph.D.	Institute of Food Technologists	IFT
16. Jennifer W. Snyder	Corn Refiners Association	CRA

*Appendix II – Organizational acronyms

Food Additives Ad hoc Advisory Panel

17. Joy A. Joseph, Chair, Consultant
18. Michael H. Auerbach, Ph.D. Danisco USA Inc.
19. Joseph F. Borzelleca, Ph.D., Medical College of Virginia
20. Grady W. Chism III, Ph.D., Indiana University Purdue
21. Jonathan DeVries, Ph.D., General Mills, Inc.
22. Daniel E. Folmer, Ph.D., FDA Center for Food Safety and Nutrition (FDA Liaison)
23. Lori L. Klopff, Ph.D., ICL Performance Products LP
24. Suzanne Nielsen, Ph.D., Purdue University, Department of Food Science
25. Pamela J. White, Ph.D., Iowa State University

Observers

26. Theresa Gibson, Cytex
27. Karrie S. Hawbaker, Environics Communications
28. Scott C. Messner, Abbott

USP Staff

29. Tristan Alexander, Meeting Planner
30. Margaret A. Becker, Vice President, Publications
31. Shona O. Bramble, Production Coordinator, Publications Department
32. Jennifer A. Brown, Senior Copywriter, Marketing
33. Todd L. Cecil, Ph.D., Vice President, Standards Development
34. Susan S. de Mars, J.D., Chief Legal Officer
35. John T. Fowler, Chief Business Officer
36. Kathy L. Flanagan, Director, Publication Marketing and Product Development
37. Norissa Giangola, M.B.A., USP Consultant, FCC Product Leader
38. Joyce Hawkins, Coordinator, Meeting Services
39. Helen L. Kharab, Manager, Stakeholder and Organizational Affairs, VOA
40. Angela G. Long, Vice President, Volunteer and Organizational Affairs
41. Ruth K. Miller, J.D., Counsel
42. Jennifer R. Payette, M.B.A., Director, Stakeholder and Organizational Affairs, VOA
43. Sheilah S. Rowe, Project Manager, Volunteer and Organizational Affairs
44. Catherine Sheehan, Director, Excipients, Food Chemicals Codex
45. Roger L. Williams, M.D., Executive Vice President and Chief Executive Officer



Appendix II Organizational Acronyms

Acronym	Organization
CHPA	Consumer Healthcare Products Association
CRA	Corn Refiners Association
ETA	Enzyme Technical Association
FDA CFSAN	US Food and Drug Administration Center for Food Safety and Applied Nutrition
ICGA	International Chewing Gum Association
IFAC	International Food Additives Council
IFT	Institute of Food Technologists
IPEC	International Pharmaceutical Excipients Council

