

Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 026" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/MedicalDevices>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 026. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: March 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5815 Filed 3-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0135]

Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding new FDA initiatives for ensuring the safety of foods and animal feed imported into the United States. The purpose of the public hearing is to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. In addition, there will be a separate discussion of FDA's efforts to gather information from regulators in other countries regarding the regulatory policies, practices, and programs they currently use to ensure the safety of foods and animal feed imported into their countries. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a 1-day public meeting to discuss implementation of the imports provisions found in the FDA Food Safety Modernization Act (FSMA).

DATES: *See* "How to Participate in the Hearing" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: *For questions about registration, to register orally, or to submit a notice of participation by mail, fax, or by e-mail:* Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott, suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, e-mail: ctreece@planningprofessionals.com.

For questions about the hearing, if special accommodations are needed due to a disability, to request onsite parking, or to submit the full text, comprehensive outline, or summary of an oral presentation: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1731, e-mail: Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Government and the food industry are pursuing proactive efforts to reduce the incidence of food borne illness. The President's Food Safety Working Group (FSWG) has recommended that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures designed to prevent problems before they occur (Ref. 1). The newly enacted FSMA (Pub. L. 111-353) also embodies the principle of prevention by requiring those who produce and import food to have systems of preventive controls in place and empowering FDA to hold them accountable to meet their new responsibilities.

FDA recognizes that to ensure the safety of imported foods and animal feed and fulfill its public health mission in a global age, it must embrace new approaches that take into account the entire supply chain and its complexity. Consistent with FSMA and the recommendation of the President's FSWG, FDA is focusing on preventing problems at appropriate points along the global food supply chain. This public hearing is an opportunity for the Agency to obtain views from interested persons concerning certain key aspects of these food safety initiatives: (1) International comparability assessments and (2) gathering information on the policies, practices, and programs used by foreign regulators to ensure the safety of imported foods and animal feed. The public hearing will be conducted in accordance with part 15 (21 CFR part 15), as described in the following paragraphs. (*See* "Notice of Hearing Under Part 15" in section III of this document.)

FDA's initiatives discussed at the 2-day public hearing align with and help support FSMA implementation. Day One of the hearing will open with a general discussion of FSMA from the perspectives of consumers, industry, legislators, and U.S. trading partners. Day Two will cover policies, practices, and programs used by foreign regulators to ensure the safety of imported foods and animal feed. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a 1-day public meeting to discuss implementation of the imports provisions found in title III of FSMA.

II. Topics for Discussion at the Hearing

A. Day One of Hearing: International Comparability Assessments

Under FDA's proposed model, FDA will consider the food safety system of a foreign country to be "comparable" to

the U.S. food safety system if, based on a complete assessment, FDA determines the foreign food safety system is: (1) Similar, though not identical, to the U.S. food safety system, (2) comprises elements that are analogous to those within the U.S. food safety system, and (3) a system for which FDA has determined provides the same level of public health protection as that of the United States. To help set regulatory priorities and improve the efficient use of FDA resources for import safety, FDA has developed a tool it proposes to use in assessing the overall food safety systems of other countries and comparing them to the U.S. food safety system. FDA will post the agenda prior to the hearing at <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm243781.htm>.

At this hearing, FDA will seek public comment on FDA's proposed comparability assessment process. In particular, FDA will be inviting the public to share its views on the following topic areas:

Comparability as a Tool

1. What are the perceived benefits and/or disadvantages to FDA's proposed comparability model?
2. What would be reasonable incentives for a country to participate in a comparability assessment?
3. What are the potential costs to the country undergoing a comparability determination and what would make the investment worthwhile?
4. Is there a more appropriate term for comparability? If so, what is the more appropriate term and why is it more appropriate?
5. How should comparability findings relate to the FSMA import safety provisions in title III (e.g., the importer verification and accredited third party provisions)?

Maintaining Comparability Status

1. For cases where a country's food safety system has been determined to be comparable: How often should FDA review assessments? Are there specific changes to a food safety system or regulatory system that should trigger a visit to the country?
2. Under what circumstances should comparability be revoked, and by what process?
3. What are reasonable expectations for ongoing communication, updating, and affirmation of a comparability determination?

Lessons Learned Through Equivalence

The Agency recognizes that comparability determinations represent

a novel construct, albeit there may be corollaries with certain equivalence determinations, such as those made by the United States Department of Agriculture's Food Safety and Inspection Service under its statutory authorities.

To gain insight from earlier work on equivalence and to inform efforts to assess comparability, FDA is requesting that countries share information on their experience with equivalence. FDA seeks information on the following issues:

1. What measures do other countries take to ensure transparency throughout the equivalence determination process?
2. What are the current practices in requesting translation of documents?
3. What are the perceived resource savings associated with finding a country equivalent?
4. Are cost benefit analyses available on equivalence determinations?
5. Have any equivalence determinations been reversed, and, if so, under what circumstances?
6. Are there data that demonstrate that equivalence determinations provide meaningful public health protections?

B. Day One of Hearing: Update on Pilot: Comparability Review of New Zealand

The United States and New Zealand have several Cooperative Arrangements with each other relating to food safety. To facilitate the renewal of existing Arrangements between the United States and New Zealand, the New Zealand Food Safety Authority agreed to participate in a pilot comparability assessment using FDA's proposed model for international comparability assessment. An update on this comparability assessment process will be provided during the public hearing.

C. Day One of Hearing: Update on European Union (EU) Molluscan Bivalve Equivalence Determination With Comparability Component

During bilateral discussions early in 2010, the United States and the EU addressed issues related to possible approaches to equivalence assessments. During these discussions, it was noted that the *Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification systems (CAC/GL 53/2003)* (Ref. 2) provides guidance on equivalence determinations. It was determined that the comparability framework would allow FDA to apply the Codex concept to its equivalence determinations, by providing an objective basis for documenting the knowledge, experience, and confidence that can be used to underpin further equivalence

determinations. Currently, the United States and EU are in the process of conducting equivalence assessments of each other's systems for shellfish. An update on the United States and EU equivalence assessments of each other's systems for shellfish will be provided at the public hearing.

D. Day Two of Hearing: Policies, Practices, and Programs Used by Foreign Regulators To Ensure the Safety of Imported Foods and Animal Feed

FDA is interested in learning more about the policies, practices, and programs (including import and export certification programs) used by foreign regulators to ensure the safety of foods and animal feed imported into their countries and will engage directly with countries over the next several months to learn about their programs. Through these conversations with regulators from other countries, FDA is also interested in learning how countries measure the effectiveness of their import control and export certification activities. The information obtained from these conversations will allow FDA to explore using the innovation and improvements that are being adopted in other countries to improve the safety of imported food and animal feed products. For example, FDA seeks to better understand the control systems used by other countries for importation of ingredients used in processed food as well as the control systems for transshipment of products.

During Day Two of the public hearing, FDA will seek input from countries and international organizations that have undertaken activities to gather information on currently implemented import policies, practices, and programs, and to provide capacity building assistance in support of safe imports.

III. Notice of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15. The hearing will be conducted by a presiding officer, accompanied by FDA senior management and staff with relevant expertise.

Persons who wish to participate in the hearing (either by making an oral presentation or as a member of the audience) must file a notice of participation. (See table 1 and **FOR FURTHER INFORMATION CONTACT** of this document, and "How to Participate in the Hearing" in section IV of this document.) By delegation from the Commissioner (Staff Manual Guide 1410.21, section 1(G)(5)), the Assistant Commissioner for Policy has

determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. FDA requests that individuals and organizations with common interests consolidate their requests for oral presentations and request time for a joint presentation through a single representative. After reviewing the notices of participation and accompanying information, the Agency will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits, interested persons who attend the hearing but did not submit a notice of participation in advance may be permitted to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule and a list of participants will be placed on file at the Division of Dockets Management (see table 1 of this document) under the docket number listed in brackets in the heading of this notice. To ensure timely handling of any mailed notices of participation, presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement "Ensuring the Safety of Imported Foods and Animal Feed; Comparability of Food Safety Systems; Public Hearing Request for Comments." Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the

presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to the Agency's policy and procedures for electronic media coverage of public administrative proceedings in part 10, subpart C (21 CFR part 10, subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record Agency public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

Any persons requiring special accommodations to attend the hearing due to a disability should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearing specify that notices of participation be submitted electronically to an Agency Internet site,

to a contact person (outside of FDA) who will accept notices of participation by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as space permits). FDA is using these procedures for submitting notices of participation, rather than providing for the submission of notices of participation to the Division of Dockets Management, because the hearing is to be conducted within a short period of time and these procedures are more efficient. In addition, these procedures provide more flexibility to persons who wish to participate in the hearing than would be provided if participants were required to submit the notice of participation in writing to the Division of Dockets Management. By delegation from the Commissioner (Staff Manual Guide 1410.21, section 1(G)(5)), the Assistant Commissioner for Policy finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by the procedures listed in this notice rather than to the Division of Dockets Management.

IV. How To Participate in the Hearing

Advance registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis. Notices of participation may be submitted electronically (see table 1 of this document); FDA encourages the use of electronic means of advance registration. Notices of participation may also be submitted orally or by mail, fax, or e-mail (see **FOR FURTHER INFORMATION CONTACT**). See table 1 of this document for the dates by which notices of participation must be submitted. A single copy of any notice of participation is sufficient.

TABLE 1—INFORMATION ON PARTICIPATION IN THE HEARING AND ON SUBMITTING COMMENTS

	Date	Electronic address	Address (non-electronic)	Other information
Date of Hearing	March 30, 2011, 9 a.m. to 5 p.m. March 31, 2011, 9 a.m. to 1 p.m.	Harvey W. Wiley Building, First Floor Auditorium, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. Across the street from the College Park/University of Maryland Metro Station (Green Line).	Registration begins at 8:30 a.m.

TABLE 1—INFORMATION ON PARTICIPATION IN THE HEARING AND ON SUBMITTING COMMENTS—Continued

	Date	Electronic address	Address (non-electronic)	Other information
Advance Registration.	By March 21, 2011.	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm243781.htm .	FDA encourages the use of electronic registration, if possible. ¹ .	Registration to attend the hearing will also be accepted onsite on the day of the hearing, as space permits. Registration information may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to disability.	By March 21, 2011.	Juanita Yates, 301–436–1731, email: juanita.yates@fda.hhs.gov .	
Make a request for onsite parking.	By March 23, 2011.	Juanita Yates (see previous row in the fourth column of this table).	
Make a request for oral presentations.	By March 14, 2011.	Requests made on the day of the hearing to make an oral presentation may be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information.
Provide a brief description of the oral presentation and any written material for the presentation.	By March 23, 2011.	Juanita Yates, 301–436–1731, email: juanita.yates@fda.hhs.gov .	Written material associated with an oral presentation may be posted without change to http://www.regulations.gov .
Submit written comments.	Submit comments by June 30, 2011.	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	FAX: 301–827–6870, Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane rm. 1061, Rockville, MD 20852.	All comments must include the Agency name and the docket number found in brackets in the heading of this document. All comments received may be posted without change to http://www.regulations.gov , including any personal information provided. FDA encourages the submission of electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see the “Request for Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

¹ Registrations or requests to make an oral presentation may be submitted by mail, fax, e-mail, or telephone by providing registration information (including name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available)) (see **FOR FURTHER INFORMATION CONTACT**).

The notice of participation must include the participant’s name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If the participant wishes to request an opportunity to make an oral presentation during the open public comment period of the hearing, their notice of participation also must include the title of their presentation, the sponsor of the oral presentation (e.g., the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations must be limited to the questions and subject matter identified in this document.

Under § 15.20(c), if an opportunity to make an oral presentation is requested,

the presentation must be submitted (either as the full text of the presentation, or as a comprehensive outline or summary). This may be done by e-mail or in writing. See table 1 of this document for the dates by which a presentation must be submitted. See table 1 and **FOR FURTHER INFORMATION CONTACT** of this document for information on where to send a presentation.

Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of oral presentations, FDA may need to limit the time allotted for each oral presentation (e.g., 5 minutes each). Depending on the content of the

presentations, the time allotted for oral presentations may vary. The Agency requests that interested persons and groups having similar interests consolidate their requests for oral presentation and present them through a single representative. If special accommodations are needed due to a disability, please inform the Agency (see table 1 and **FOR FURTHER INFORMATION CONTACT** of this document).

FDA will also accept registration onsite; however, space is limited. Onsite registration will be accepted on a first-come, first-served basis and will be closed when the maximum seating capacity is reached. Requests for an opportunity to make a presentation from individuals or organizations that did not register in advance to make an oral

presentation may be granted if time permits.

Persons who registered in advance for the hearing should check in at the onsite registration desk between 8:30 a.m. and 9 a.m. Persons who wish to register onsite on the day of the hearing should do so at the registration desk between 8:30 a.m. and 9 a.m. FDA encourages all participants to attend the entire hearing.

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (*see* table 1 of this document) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

VII. References

The following references are on display at the Division of Dockets Management (*see* Transcripts), between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the following Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. President's Food Safety Working Group findings, <http://www.foodsafetyworkinggroup.gov/ContentKeyFindings/HomeKeyFindings.htm>.
2. Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification systems (CAC/GL 53/2003): http://www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5943 Filed 3-10-11; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this public meeting in the Orlando, FL, area is to engage in a dialogue about issues of importance to FDA's Center for Devices and Radiological Health (CDRH) and to members of the public, including the medical device industry, health care professionals, patients, and consumers.

Date and Time: The public meeting will be held on May 5, 2011, from 8 a.m. to 12 noon EST.

Location: The public meeting will be held at the Sheraton Orlando Downtown Hotel, 400 West Livingston St., Orlando, FL 32801. Attendees requiring sleeping rooms should call 401-843-6664 and request the group rate for the "Food & Drug Administration Town Hall Meeting" room block. The meeting will not be videotaped or Web cast.

Contact: Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4320, Silver Spring, MD 20993, 301-796-5718, e-mail: heather.howell@fda.hhs.gov.

Registration and Requests for Oral Presentations: If you wish to attend the public meeting, you must register online at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm244462.htm>. Persons without Internet access may call Heather Howell at 301-796-5718 to register for the meeting.

Provide complete contact information for each attendee, including name, title, company or organization, address, email, and telephone and fax number.

Registration requests must be received by 5 p.m. EST on Friday, April 22, 2011.

If you wish to make an oral presentation during any of the sessions at the meeting (*see* section II of this document), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. EST.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661 or susan.monahan@fda.hhs.gov, at least 7 days in advance of the meeting.

Comments: FDA is holding this public meeting to share information and discuss issues of importance to the public, including the medical device industry, health care professionals, patients, and consumers.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

In 2010, CDRH held three Town Hall meetings in Minneapolis, MN, Boston, MA, and Los Angeles, CA, to provide the public with a new venue to discuss issues of interest with the Center. Any member of the public was invited to provide comments to or ask questions of CDRH participants. We received positive feedback on these meetings and