



**Asia-Pacific
Economic Cooperation**

2015/SOM3/SCSC/FSCF/PTIN/RT/009

Perspectives of the United States Food and Drug Administration

Submitted by: United States



APEC
PHILIPPINES
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**Towards a Future of Prevention and Partnership:
Roundtable on Effective Industry / Regulator
Cooperation
Cebu, Philippines
24-25 August 2015**

 **U.S. Food and Drug Administration**
Protecting and Promoting Public Health www.fda.gov


Towards a Future of Prevention and Partnership: Roundtable
on Effective Industry/Regulator Cooperation

**Perspectives of the
U.S. Food and Drug Administration**

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APEC FSCF PTIN Workshop
Cebu, Philippines
Tuesday, August 25



 **U.S. Food and Drug Administration**
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Points to Cover

- Regulations Development Overview
- Case Study on Food Safety Modernization Act (FSMA) Regulations Development



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Regulations Development

- Administrative Procedure Act
 - Informal Rulemaking/ “Notice and Comment Rulemaking”
 - Public Meetings




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Case Study – FSMA

- Food Safety Modernization Act signed January 2011
- Listening sessions followed
- FDA then drafted proposed rules based on the new law, as well as input from public meetings and listening sessions
- FDA then published proposed rules for comment




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Case Study – FSMA

- Following the publication of the proposed rules, FDA:
 - Held proposal public meetings, listening sessions, industry roundtables, individual meetings
 - Drafted Supplemental rules
 - Published Supplemental Proposed Rules
- MORE Public meetings, listening sessions, industry roundtables, individual meetings were held after the publication of the Supplemental Proposed Rules



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Case Study – FSMA

- International Outreach
 - Participation in public events
 - Embassy Roundtables
 - Outreach by headquarters and FDA Foreign Posts, Foreign Agricultural Service Officers, Commercial Officers
- WTO notifications



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Case Study – FSMA

- What's next?
 - Extensive outreach!
- Thank you!

