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Transparency in Food Safety Rulemaking

Submitted by: United States



**Second Expert Meeting on Trade
Facilitation Through an APEC Framework
on Food Safety Modernisation
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Transparency in Food Safety Rulemaking



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Points to Cover



- 1) Need and basis for transparency
- 2) Stakeholders and types of inputs
- 3) Transparency in Action: Focus on new food safety modernization regulations
- 4) Rulemaking Process: Core Concepts and Recommendations

Basis for Transparency

- Administrative Procedure Act of 1946 requires federal agencies and to:
 - Keep the public informed of their organization, procedures and rules;
 - Provide for public participation in the rulemaking process (e.g., public commenting)
 - Establish uniform standards for conducting formal rulemaking and adjudication;
 - Define the scope of judicial review

The Administrative Procedure Act



- Protects against “capricious and arbitrary” measures
- Supports appropriate separation of authorities of legislative, judicial, and executive branches of government
- Assures public inputs, official record keeping and standard procedures

Stakeholders and Types of Inputs

- Most of our rulemaking is called “notice and comment” rulemaking
- A variety of private and public stakeholders provide comments (e.g., small and large businesses, consumer groups, academia, trading partners)
- We receive data, information on the practicality of our proposed rules, experience

Focus on Food Safety and the Food Safety Modernization Act (FSMA)

- FSMA updated how the U.S. Food and Drug Administration (FDA) regulates food safety
- FDA regulates all foods consumed in the United States except for meats, poultry, processed egg products and catfish
- Other key agencies involved in food safety are USDA/FSIS, and CDC

Focus on Food Safety and the Food Safety Modernization Act (FSMA)

- **FDA followed the “notice and comment” rulemaking process**
 - Listening sessions
 - FDA drafted proposed rules based on the new law, as well as input from public meetings and listening sessions
 - FDA published proposed rules for comment
 - Followed with a second round of listening sessions
 - Comments were considered and changes integrated into proposed rules
 - Final Rules were published/listening continues
 - Guidance developed
- **WTO notification (s)**

Stakeholder Impact

- Examples of changes from the Preventive Controls proposal(s) based on stakeholder inputs include:
 - Farm definition (e.g., packing and holding of own and other's raw agricultural commodities)
 - Definition of holding
 - Definition of very small business
 - Hazard analysis and preventive controls
 - Product testing and environmental monitoring
 - Supplier program

Rulemaking Process: Core Concepts



CONSULTATION

- Enhances quality of regulations and facilitates their implementation
- Mitigates trade impact and spreads awareness to constituents
- Helps to avoid unnecessary regulation and minimizes the resources required for effective enforcement

RECOMMENDATION: Engage early and standardize processes.

Rulemaking Process: Core Concepts



COMMUNICATION

- Creates a credible, consistent, and positive environment
- Transparency → accountability → quality
- Builds and indicates mutual respect

RECOMMENDATION: Identify and maintain clarity of key points of contact and build strong relationships.

Rulemaking Process: Core Concepts



COLLABORATION

- Provides varied perspectives, increased information dissemination, and insight into trade implications
- Results in recognition of the importance of managing scarce resources
- Consistent collaboration drives priority alignment

RECOMMENDATION: Commit to building cross-sectoral relationships. It takes time!

Rulemaking Process: Core Concepts



COORDINATION and CAPACITY BUILDING

- Public Private Partnerships will facilitate the “closing of the gap” between developed and developing economies in the APEC region
- Modernized food safety systems → fewer outbreaks → improved trade flow

RECOMMENDATIONS:

- ✓ Establish interface between private and public sectors on regulation development. Standardize coordination contact points and processes.
- ✓ Consider international standards and regulatory coherence/alignment.
- ✓ Identify capacity building needs and link them to outcomes or a results framework.

The U.S. Rulemaking Process

<https://www.youtube.com/watch?v=NGc1SUedEr0#>

Thank you!

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