United States of America
National Coordination Procedures, Transparency, WTO Notifications and Capacity Building

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<table>
<thead>
<tr>
<th>Treaty of Versailles, Article 18</th>
<th>Customs Convention</th>
<th>United States Administrative Procedures Act</th>
<th>GATT Article X</th>
<th>WTO Agreement and Covered Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1919</td>
<td>1923</td>
<td>1946</td>
<td>1947</td>
<td>1995</td>
</tr>
</tbody>
</table>
United States
Administrative Procedures Act (APA) of 1946
• Governs administrative procedures for all U.S. federal agencies
• Notice and comment rulemaking solicits input from the public
• Public is informed of agency procedures and rules
• Fosters an administrative culture of transparency
• The APA is the legal framework that supports U.S. notifications to the WTO
WTO Agreements

• Transparency Provisions
  – Article X of the GATT
  – Article 7 of the Agreement on the Application of Sanitary and Phytosanitary Measures
  – Article III of the General Agreement on Trade in Services
  – Article 12 of the Customs Valuation Agreement
  – Article 63 of the Agreement on Trade-Related Aspects of Intellectual Property Rights
United States
Interagency Trade Policy Mechanism
• Trade Expansion Act of 1962 – created the interagency trade policy mechanism
  – Two Processes:
    1) Trade Policy Review Group (TPRG) and
    2) Trade Policy Staff Committee (TPSC)
• Uruguay Round Agreements Act (1994)
  Implementing Uruguay Round Agreements into U.S. Law
Office of Information and Regulatory Affairs (OIRA)

- Established by Congress in 1980 Paperwork Reduction Act (44 U.S.C. Chapter 35)
- Part of Office of Management and Budget (OMB) within Executive Office of the President
- Reviews draft proposed and final regulations under Executive Order 12866
- OIRA consults with relevant agencies & departments in EO 12866 reviews
- Reviews for consistency with international obligations
Transparency in Development and Implementation of Regulations

• Consistency with the APA requirements
• Interagency Review and Comment
• Public Notice and Comment Period – Proposed Rule on public docket (Regulations.gov)
• Notification to the WTO
• Review of public comments submitted to public docket
• Agency Review
• Public Notice and Comment Period -- Final Rule
How FDA develops regulations

**Development of policy through Rulemaking or Guidance**

Amendments enacted into law

For example, Federal Food, Drug, and Cosmetic Act

As Amended <date>

Steps for Notice and Comment

Title 21 of the Code of Federal Regulations

Guidance for Industry www.fda.gov
Potential steps for development of a regulation

1. Developing a rule
   - Law
   - Citizen Petition
   - Judicial decisions
   - Agency priority-setting.

2. Advance Notice of Proposed Rulemaking
   - Opportunity to ask questions, seek relevant information
   - Comments reviewed to decide a course of action

3. Notice of Proposed Rulemaking
   - Presents agency’s thinking and tentative conclusions on a regulation
   - Seeks comments on proposal
   - Comments reviewed to decide a course of action

4. Final Rule
   - Presents agency’s conclusions on a regulation
   - Responds to comments on proposal
   - Indicates an effective date

Note: At each step the agency can decide to proceed, not to proceed, or consider a new course of action.
Public Outreach

- FDA undertakes significant public outreach on new rules, policies and activities.
- Public hearings, information (listening) sessions and public meetings are held across the United States.
- FDA hosted several webinars with trading partners on the Food Safety Modernization Act (FSMA) and made the rules available in several languages.
Stakeholder comments

• FDA establishes a docket for the Proposed Rule public comment (www.regulations.gov)

• FDA receives thousands of comments for some rules
  – 71,388 (Preventive Controls for Human Food)
  – 39,887 (Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption)
  – 289,653 (Revision of the Nutrition and Supplement Facts Labels)

• For Final Rules, FDA publishes responses to significant comments received and the rationale for the course of action taken
Comments are considered before issuing Final Rule

- Preventive Controls for Human Food
  - Many comments argued for increased flexibility in application of preventive controls
    - FDA provided flexibility by clarifying that preventive control management components (monitoring, corrective actions/corrections and verification activities) depend on the role of the preventive control in the facility’s food safety system and the nature of the preventive control
  - From other comments received:
    - FDA provided for use of “exception records” (in which a record is made only when a deviation occurs) for monitoring preventive controls where appropriate
    - FDA provided for the reanalysis of an applicable portion of the food safety plan rather than the complete food safety plan in certain circumstances
WTO NOTIFICATIONS

• FDA notifies:

➢ Proposed and Final Rules
  • FDA meets WTO obligation to provide a minimum of 60 days for comment
  • Proposed and Final Rules typically have 60-90 days or longer for interested parties to submit comments
Coordination and comments

• FDA coordinates with the U.S. National Notification Authority to ensure timely notification of the measure to the WTO
• WTO members may submit comments through the docket (instructions given in the notification) that will be reviewed and considered with all other stakeholder comments
U.S. FDA Supports Transparency Efforts Through Partnerships

- Standards and Trade Development Facility (STDF)
- Asia Pacific Economic Cooperation (APEC)
- Food and Agriculture Organization (FAO)
- World Health Organization (WHO)
- Global Food Safety Partnership (GFSP)