



# A Regulators Perspective on U.S. Trade Policy Coordination



# Inter Ministerial Coordination: Components of a Comprehensive Trade Policy

Trade Policy Governance Through Inter-Ministerial Coordination by Leroy Saner states that the four relevant stakeholders in developing a unified national trade policy are:

1. Government ministries primarily responsible for trade policy-making and implementation;
2. Other relevant government ministries and agencies;
3. The private sector; and
4. Civil society organizations

This presentation will focus on how FDA works to shape trade policy as an “other relevant government ministry or agency”.

## Importance of Inter Ministerial Coordination

Inter ministerial coordination is required to ensure

- Public policy and trade positions reflect all of the diverse interests and values reflected in a central government.
- Trade obligations negotiated by the ministry responsible for trade policy can be feasibly and efficiently implemented by the regulatory authorities.
- The effectiveness of trade policies can be appropriately monitored, analyzed and evaluated.

## Inter Ministerial Coordination: One Government, Many Missions

In a 2003 OECD policy brief, the OECD noted that “As political sensitivity to certain issues rises in OECD countries, the degree of policy coherence tends to diminish. OECD taxpayers and consumers, as well as the people in developing countries will bear the costs of policy incoherence, whereas the benefits may flow to special interest groups.”

- “Working toward opening markets throughout the world to create new opportunities and higher living standards for families, farmers, manufacturers, workers, consumers and businesses.”
- “Ensure that all Americans are protected from significant risks to human health and the environment where they live and work”
- “To provide economic opportunity through innovation, helping rural America to thrive; to promote agriculture production that better nourishes Americans while also helping feed others throughout the world; and to preserve our Nation’s natural resources through conservation, improved watersheds, and healthy private working lands.”

## Inter Ministerial Coordination: One Government, Many Missions

- “Create the conditions for economic growth and opportunity.” “Expand the U.S. economy through increased exports and foreign direct investment that leads to more and better American jobs.”
- “Protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”
- “To foster, promote, and develop the welfare of the wage earners, job seekers, and retirees of the United States; improve working conditions; advance opportunities for profitable employment; and assure work-related benefits and rights.”

## OECD Mechanisms for Policy Co-Ordination:

In a 2009 follow-up to the OECD Policy Brief on Inter Ministerial Coordination for Development, the organization released a policy paper titled “Building Blocks for Policy Coherence for Development” which outlined these three mechanisms for coordinating policies between ministries:

- Ensure that informal working practices support effective communication between ministries.
- Establish formal mechanisms at sufficiently high levels of government for inter-ministerial co-ordination and policy arbitration, ensuring that mandates and responsibilities are clear and fully involve ministries beyond development and foreign affairs.
- Encourage and mandate the regulatory or development agencies to play a pro-active role in discussions about policy co-ordination.

In the United States, the formal mechanism for inter-ministerial coordination on trade policy is managed through our Trade Policy Staff Committee (TPSC) Process.

# TPSC Process

- The Trade Policy Staff Committee (TPSC), was established as part of the Trade Expansion Act of 1962 and is the principle staff-level mechanism for interagency decision making on U.S. trade policy.
- The TPSC is comprised of twenty-six different agencies with relevant environmental, economic, and foreign policy expertise.
- Within this framework FDA provides regulatory and technical expertise in order to shape trade policy text for FDA regulated products.
- On average, the TPSC inter-agency will clear, by consensus, 285 documents a year.
- The USTR Office of Policy Coordination distributes policy papers and negotiating documents to all agencies for review, under a specified timeframe.

# TPSC Process

- Within FDA we circulate any TPSC documents that could affect our operations, or our regulatory interests to subject matter experts so they can provide technical feedback.
- Our office, Public Health and Trade, reviews the technical feedback with a policy focus to strategically advance FDA's regulatory interests within the relevant trade context.
- If there is contradictory feedback from parts of the agency our office will act as an arbiter, and determine the best approach for the whole organization.
- After a policy or treaty text clears TPSC process, the document is subject to 4 days of Congressional review before it becomes official.
- If a document can not be cleared in the TPSC process it is elevated to the Trade Policy Review Group, which is comprised of deputy cabinet level officials. FDA is represented by the Deputy Secretary of Health and Human Services.
- If the TPRG can not come to a resolution on a specific issue then the issue is elevated to a principals meeting of Cabinet level officials.

## Informal Collaboration: Advantages

Informal cooperation between USTR and FDA is mutually beneficial for both organizations:

- USTR benefits from FDA's critical technical assistance when developing negotiating positions or comments for technical products.
- Both agencies have an opportunity to iteratively work through drafts of sensitive documents at the staff level, before a TPSC clearance needs to occur.
- FDA benefits by leveraging USTR's trade policy and negotiating expertise when implementing new regulations.
- FDA also actively participates in the interagency delegation for the WTO TBT Committee to ensure that the United States' public comments do not impede on the Agency's domestic policy priorities, and provides responses and follow up to any defensive concerns related to the Agency's regulatory oversight.

## Regulatory Planning and Review

- Regulatory agencies coordinate regulatory policy through an interagency clearance process as well.
- The process is outlined in Executive Order 12866 (1993) and gives the Office of Management and Budget (OMB) the responsibility of reviewing proposed rules to ensure
  - The regulator considered alternatives to the rulemaking and analysis of the rule's effects on society, both its benefits and costs
  - The regulation is consistent with other statutes and laws
  - The regulation is consistent with the United States trade obligations either under the WTO, or in free trade agreements.

# Questions?

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