







### CODEX@60



MRL Harmonization Workshop May 24-26, 2023

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U.S. Department of Agriculture





- What is Codex and why should you care?
- How does the U.S. Codex Program operate?
- How can you engage with Codex?
- What are the challenges and opportunities for Codex@60?



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# WHAT IS THE CODEX ALIMENTARIUS?

United Nations organization founded in 1963



Joint FAO/WHO Food Standards Program

Codex brings together food safety/consumer protection and trade interests, thereby strengthening both

### **CODEX MANDATE**



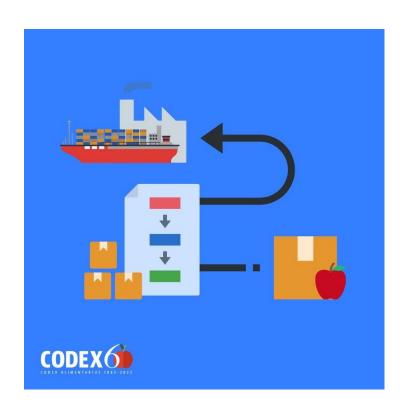
### Protect the health of consumers

 Science-based food safety and quality standards

### Ensure fair practices in the food trade

 Fosters harmonization of food standards worldwide

# CODEX STANDARDS AND TRADE AGREEMENTS



Trade agreements encourage harmonization and call for World Trade Organization (WTO) members to base their standards on international standards

Codex is recognized as *the* international standardssetting body for food safety

Countries that use Codex standards as their national standards enjoy a presumption of consistency with key trade obligations to base national measures on science and risk assessment

# IMPORTANT TO NATIONAL INTERESTS



As major agricultural importer: Codex enhances food safety and consumer protection

As major agricultural exporter: Codex maintains and expands market access for U.S. exports







Visit <a href="https://www.usda.gov/codex">https://www.usda.gov/codex</a> to learn more about Codex and food safety in the United States.



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### INCEPTION OF THE U.S. CODEX OFFICE



The United States was a founding member of the Codex Alimentarius Commission in 1963, but for decades there was no single point of contact for Codex in the United States

The U.S. Codex Office was formed on March 23, 1995, as a result of the Uruguay Round Agreements Act and the WTO SPS Agreement which entered into force on January 1, 1995

The Presidential Proclamation designated the Secretary of Agriculture as the official responsible for Codex

### THE U.S. CODEX OFFICE



Annual budget of ~\$4.9 million dollars

9 full time staff

38 delegates who are the technical experts from other agencies/departments

Governed by a Policy Committee that is made up of senior government officials, and a Technical Committee

# U.S. DELEGATES AND ALTERNATE DELEGATES

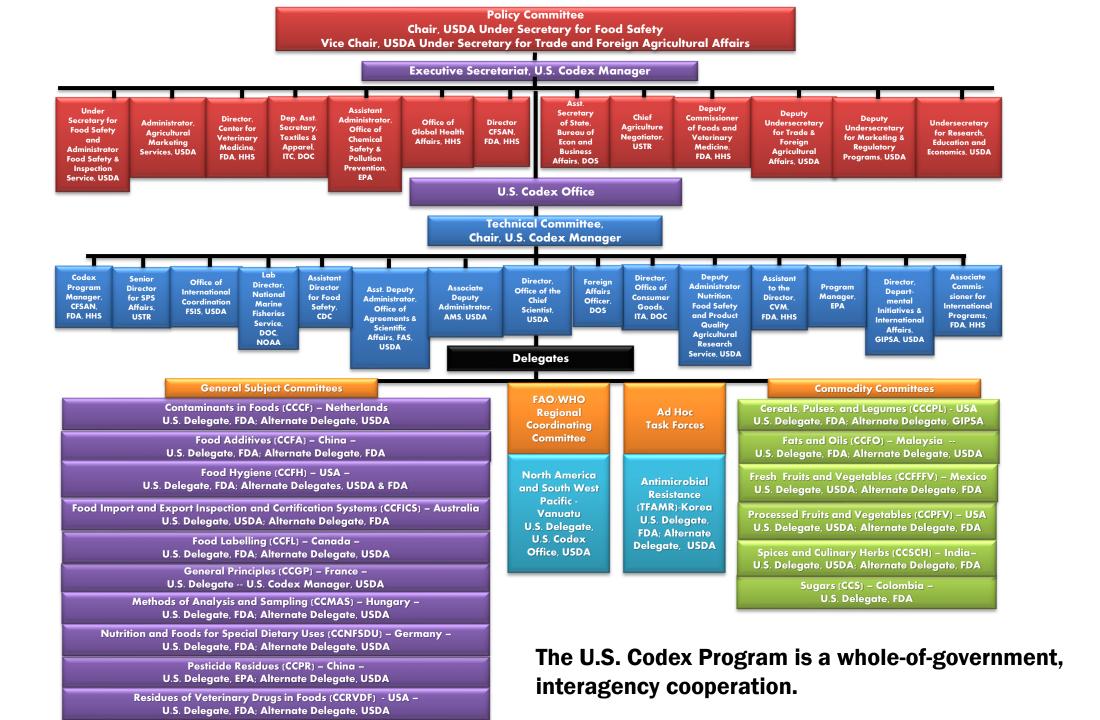


U.S. Environmental Protection Agency

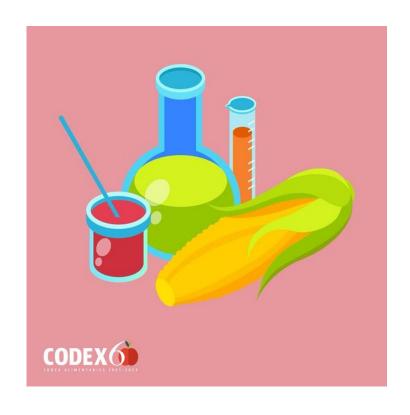
U.S. Food and Drug Administration

U.S. Department of Agriculture

National Oceanic and Atmospheric Administration



### U.S. PARTICIPATION IN CODEX WORK



Chairs several Codex committees (host country for CCFH, CCRVDF, CCPFV, CCCPL)

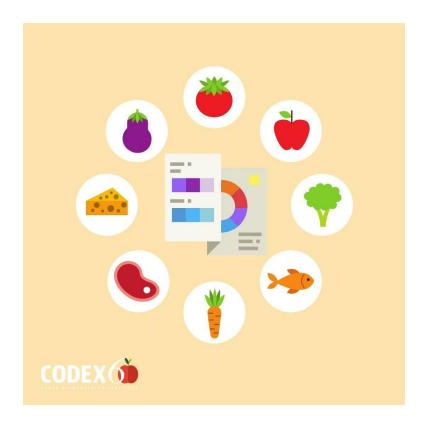
Participates in every Committee and Working Group

Provides experts to scientific advice bodies and supports reviews with data and financial resources

Supports effective developing country participation in Codex work

Seeks to establish policies and priorities to improve quality and timeliness of Codex standards

### **CODEX COLLOQUIA**



Informal discussions with other countries and regions

Routinely held with Africa (CCAFRICA) and Latin America and the Caribbean (CCLAC), aiming to increase engagement with Asia and the Near East

Often the U.S. position is adjusted to consider the concerns of our allies or to support the positions of our allies



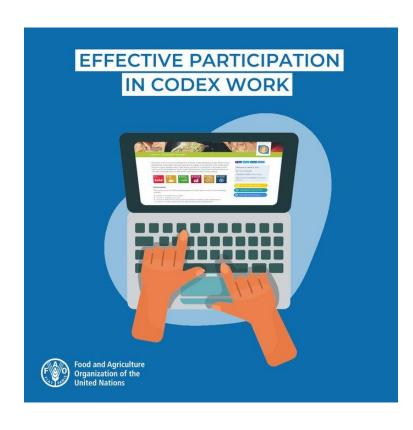
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### **INTERESTED PARTIES LIST**



- Each delegate maintains an interested parties list, which anyone can join
- Typically includes government agencies, consumer groups, and industry
- When documents are received from the Codex Secretariat, they are circulated to the interested parties list for comment, which is the beginning of U.S. position development
- Some of the lists contain 100+ people

### **PUBLIC MEETINGS**



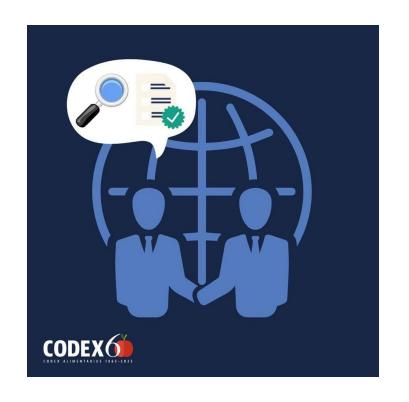
~1 month prior to every Codex committee meeting there is a U.S. Public Meeting

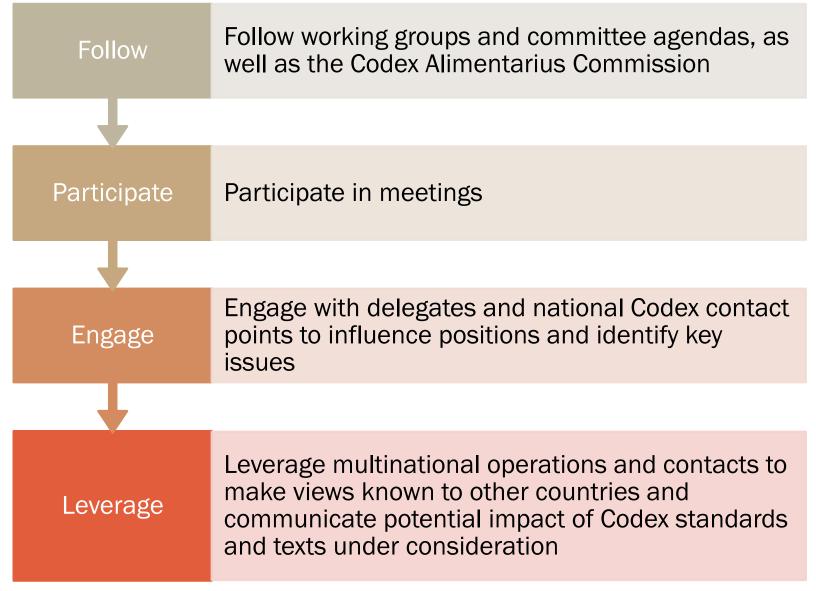
Open to everyone, and even some foreign representatives attend

The delegate presents the draft U.S. positions for the upcoming Codex committee and solicits input

People can submit written comments on the draft U.S. positions

# HOW TO WORK EFFECTIVELY WITH CODEX









Visit <a href="www.usda.gov/codex">www.usda.gov/codex</a> to sign up for the Codex News, a bi-weekly electronic newsletter

Email us at: <a href="mailto:uscodex@usda.gov">uscodex@usda.gov</a>



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### CROSS-CUTTING AND EMERGING ISSUES



- Defending the scientific basis of Codex decision-making (e.g., MRLs for veterinary drugs)
- Consideration of environmental factors and sustainability issues in Codex (e.g., pesticide MRLs)
- Coordination of Codex scientific advice with other WHO bodies (e.g., food additives)

### CODEX DECISION MAKING



While Codex standards are global, delegates will make interventions based on factors specific to their country or region

Science is the great equalizer as it is applicable to everyone (i.e., is it safe or not)

Codex makes decisions based on consensus (or, where necessary, via voting)

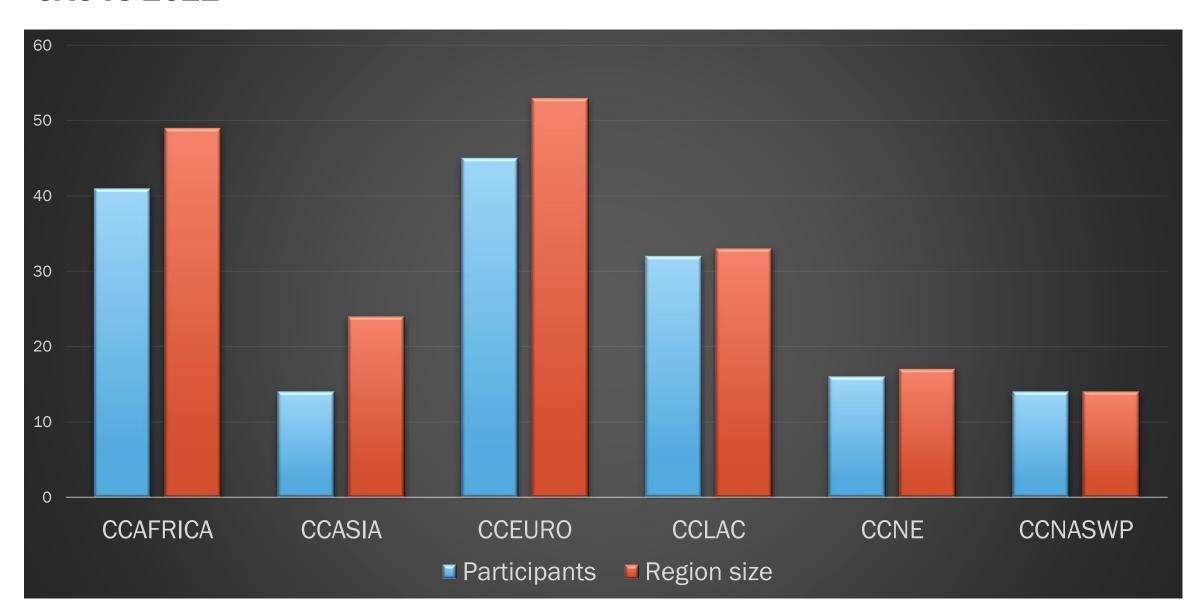
Decisions are generally driven by those physically in the room

### CODEX MEMBERSHIP

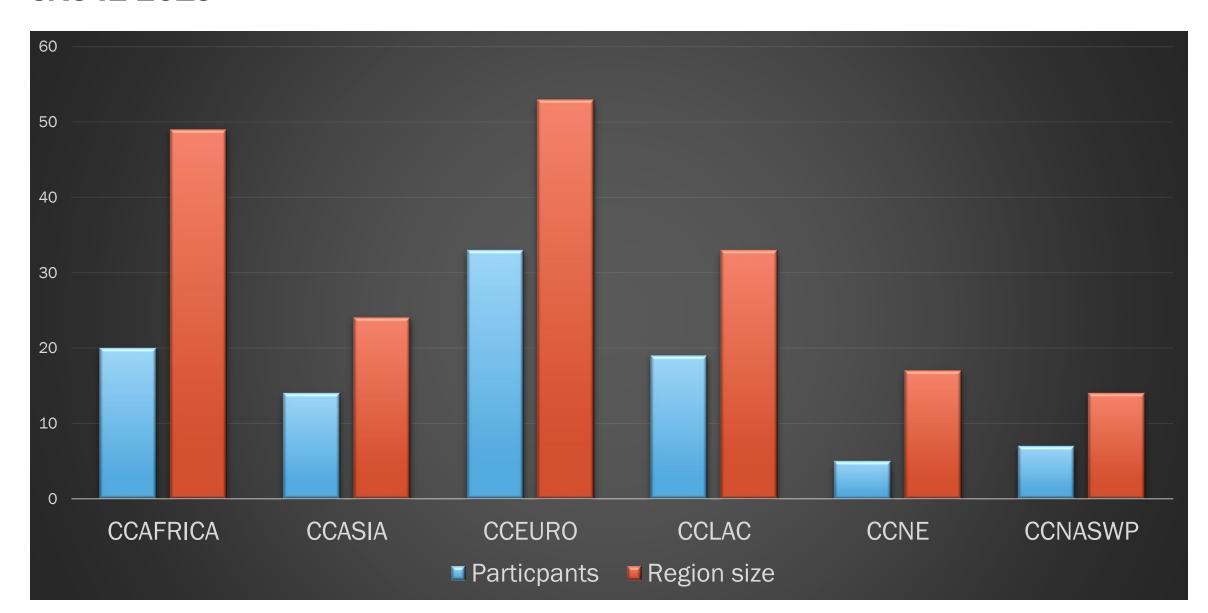




### CAC45 2022



### CAC42 2019



# FOR CODEX TO FUNCTION AS A GLOBAL STANDARDSETTING BODY...



CODEX
ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

All members must actively participate

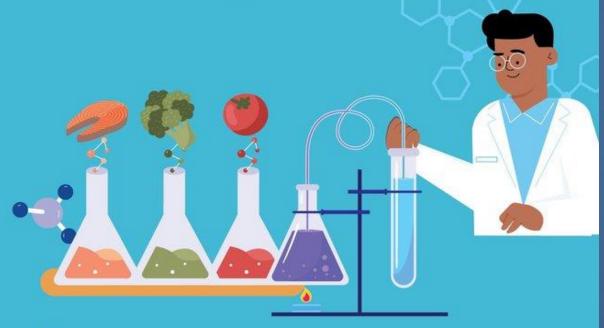
Consider global interests and practices

Focus on food safety and not cultural issues

Respect the independent risk assessors (JECFA, JEMRA, JMPR and JEMNU)

Food safety is everyone's business

Sound science underpins food safety







Thank you! Questions?

### **Additional Slides**

### Codex Committee on Pesticide Residues (CCPR)

- CCPR established in 1966 and currently hosted by China
- Meets on annual basis and attended by 80+ countries and many external organizations
- Establishes evaluation process for establishing maximum limits for pesticide residues on food and animal feed in international trade
  - ✓ Approved Good Agricultural Practices (GAPs) (e.g., labeled use rate, re-entry interval, target crop)
  - ✓ Anticipated residues reflected in supervised field trials
  - ✓ Risk assessment of dietary exposure



### **Codex Nomination & Evaluation Process**

### Roadmap for Obtaining Codex MRL

### National Registration Sponsor obtains national registration of pesticide for

agricultural use



Nomination Request Sponsor submits nomination to U.S. Delegation to request scheduling of Codex review

#### General Timeline

	CY2020			CY2021				CY2022				CY2023			
			1		2		3	4	4	4			5	6	
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

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CCPR

CCPR Schedule/Priority List CCPR confirms nomination information and schedules for JMPR scientific review

#### **JMPR Data Call**

JMPR issues data call and sponsor submits toxicology and field residue data



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### JMPR Scientific Review JMPR conducts scientific assessment and makes MRL recommendations



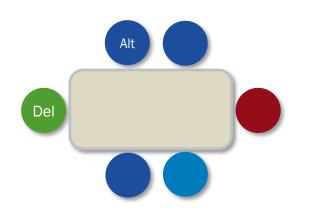
CCPR Meeting
CCPR Advances MRL
Recommendations to
CAC



Codex Standard
CAC establishes MRL
standard in Codex
Alimentarius

Source: Aaron Niman, U.S. Delegate to CCPR

### U.S. Government Delegation to CCPR



- U.S. Delegate (Del)
- U.S. Alt. Delegate (Alt)
- USDA Codex Office Rep
- USDA/FAS
- FDA
- IR-4 (Classifications)

Aaron Niman, EPA/OPP

Alex Domesle, USDA/FSIS

Marie Maratos, USDA/US Codex Office

Barakat Mahmoud, USDA/FAS

Sara McGrath, FDA/CFSAN

Bill Barney, IR-4







### U.S. Delegation Role in Advocating for U.S. Stakeholders

Stakeholder Engagement
Engage U.S. and International
Stakeholder

U.S. CCPR Direction Setting
Participate in CCPR working
group projects throughout
calendar year

CCPR Plenary Leadership
Advance U.S. interests and
strategic priorities during plenary

### **U.S. CCPR Interest Group**



- Managed by U.S. Delegation and used to engage with U.S. stakeholders
- Includes 60+ representatives from Federal Agencies and Non-Government organizations, including trade associations, growers, and registrants













#### Areas of Interest & Engagement

### MRL Nomination & Evaluation Process

- MRL Nominations
- Data Call Notifications
- Concern Forms

### Stakeholder Input on CCPR Activities

- Electronic Working Groups
- Circular Letters
- Position Papers

### Strategic Planning

- Near/long-term strategic priorities
- Strengthen harmonization
- Expand capacity and improve efficiency of CCPR/JMPR

### **Key U.S. Activities for CCPR**

#### Stakeholder Engagement

Lead U.S. CCPR Interest Group Meetings and Minutes

Lead U.S. CCPR Public Meeting

Lead International Meeting (QUADs, CCLAC, etc)

#### B. U.S. CCPR Direction Setting

U.S. Comment on Electronic Working Group (EWGs)

Chair of Classification EWG

Chair of Enhancements to CCPR/JMPR

U.S. Nominations for CCPR Schedule/Priority List

U.S. Comment on Circular Letters (CLs)

CCPR Concern Forms

#### CCPR Plenary Leadership

Draft U.S. Position Paper

U.S. Delegates Report on Outcomes of CCPR

Draft U.S. CCPR Position for CAC-42

3-4 meetings per CCPR cycle

2 meetings per CCPR cycle

1 all-day meeting + email/teleconferences

5 EWGs \* ~2 review rounds

**EWG Discussion Paper + Lead Plenary** 

**EWG Discussion Paper + Lead Plenary** 

Review/compile U.S. nominations

Review/compile U.S. comments

Review/compile U.S. comments

1 report

1 report

1 report

### CCPR and COVID-19

- Covid-19 pandemic introduced major challenges to Codex MRL setting process
  - ! Postponement of CCPR-52 in 2020
  - ! Virtual meetings in 2021 and 2022
  - ! JMPR unable to meeting in-person until 2022



- However, Codex was also able to adapt and meet virtually to advance its core work. Now that
   Codex has resumed in-person meetings, we can build on this experience and enhance the CCPR.
- U.S. Delegation is also leading work to identify opportunities to enhance the CCPR/JMPR

### **CCPR Electronic Working Group**

### **Enhancement of the Operational Procedures of CCPR and JMPR**

- Established by CCPR-53 in response to stakeholder concerns
  - ! CLI discussion paper and stakeholder workshops
  - ! Growing backlog of evaluations due to Covid-19 pandemic
  - ! Need to enhance system to meet future demand
- Chaired by the United States and Co-Chaired by Costa Rica, France, Germany, and Uganda
- Progress to date
  - ✓ Nov-2022: Developed circular letter requesting information on need to enhance CCPR and opportunities and challenges
  - ✓ Feb-2023: Received 26 pages of comments in response from 18 stakeholders
  - ✓ Mar-2023: Developed discussion paper that has been well accepted by Codex Members and
    Observers
  - ☐ Will be further discussed at CCPR and used to set the stage for future plans....

### **CCPR Electronic Working Group**

### **Enhancement of the Operational Procedures of CCPR and JMPR**

#### **Discussion Paper Key Findings**

- There was general consensus that there is a need to enhance the operational procedures of CCPR and JMPR to address concerns related to both JMPR current workload and future demand for compounds evaluations.
- Commenters highlighted:
  - JMPR is essential for the independent international evaluation of pesticide residues
  - growing workload due to disruptions from the Covid 19 pandemic,
  - increasing complexity of assessments, and
  - growing number of existing compounds that qualify for periodic review.

#### **Areas of Interest**

#### **Opportunities for Enhancement**

- Data Sponsor Dossier and Electronic Data Submission
- o CCPR Processes and Procedures
- o JMPR Evaluation Process and Procedures
- JMPR Organizational Structure, Staffing and Resources
- Other Areas of Enhancement

### **Opportunities for Major Reform**

- Use of National Reviews and Data
- Alternative Peer Review Models

### **CCPR Electronic Working Group**

### **Enhancement of the Operational Procedures of CCPR and JMPR**

#### **Discussion Paper Recommendations**

- 1. There was consensus that there is a need to enhance the operational procedures of CCPR and JMPR to address concerns related to both JMPR's current workload and future demand for compounds evaluations. CCPR will transmit the EWG discussion paper and supporting CL2022/75-PR comments to JMPR for consideration at JMPR's 2023 Regular Meeting. Based on consideration of this information, along with other supporting information, JMPR should identify initial priorities for enhancing its operational procedures and report back to CCPR55 on its recommendations and specific areas that will require guidance from CCPR.
- 2. Based on consultation with the CCPR and JMPR Secretariats, as well as FAO/WHO, CCPR and JMPR should identify an appropriate approach to:
  - (i) identify potential priorities for enhancement and major structural reforms and
  - (ii)develop a roadmap for implementing both enhancements and major structural reforms.

Potential approaches could include commissioning an independent third-party organization to conduct an organizational assessment or working through an existing Codex advisory body or committee.