Data generation, collection and utilization for establishing food standard Experience from Japan

Yukiko Yamada, Ph.D.

Participation

- Art. 3.4 of the SPS Agreement
  - Members shall play a full part, within the limits of their resources, in the … Codex Alimentarius Commission …, to promote … the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary … measures.
  - Participation is much more than being present

Why do you go to Codex meetings?

- To participate
  - To make Codex recommendations reflect your countries' situations
    - Need to provide comments and scientific/ technological information and make interventions
  - To contribute to the whole world
- To make friends from other countries
  - To share information as early as possible in the case of incidents
  - To be able to obtain information not on the Internet

For effective comments/interventions

- Comments
  - Based on the evidence/facts
    - Need for developing/collecting/analyzing data
    - Literature search is also important
  - In the food safety area, science-based
  - As clear and simple as possible (use tables, graphs and, if useful, photographs)
  - Be consistent with Codex basic recommendations, such as general standards
  - Be consistent within the country's comments

- Interventions
  - Be prepared
    - Read previous reports and working documents
    - Beforehand, think of all potential options
    - Think all possible questions and oppositions
    - Read and study other member's comments
  - At the session
    - Be clear and flexible
    - Be consistent
    - If possible, help the Chair, and support other members as appropriate
    - Speak on the agenda on the development of "Principles"
    - MAFF, JP, requires English qualification

Change of the Attitudes of MAFF Before 2001

- More interested in commodity standards than safety standards
  - Contributed in drafting the standards for canned oranges, chestnut pastes, and surimi
- For the safety standard, express oppositions without providing scientific information
  - Even the opinion did not get through, it was OK as long as the delegation continued to oppose (in particular, for Cd in rice, tried to block the discussion)
- Quiet, if no problems were foreseen

2001 and on

- Collect or develop data
- Provide the data after statistical analysis
- Express opinions in a scientific manner within the framework of risk analysis
- Contribute to the development of principles
- Intervene in discussions related to safety and to foods consumed significantly in Japan
- Participation in electronic working groups (not only to see what is going on but to provide data, information and opinions)
- Started preparing working papers for committees

Selection of Delegation Members (MAFF)

- As early as possible (before eWGs start)
- With sufficient and appropriate levels of
  - English
  - Scientific knowledge of related issues, e.g.
    - CCMAS: analytical methods and sampling
    - CCPR: pesticide residues, food classification
    - CCCF: chemistry and/or toxicology of contaminants and toxins, food producing/ processing methods
  - Capability to explain
  - Capability to think fast on site

Documents on Principles Related to Contaminants and Toxins

- Japan contributed in the development of
  - Working principles for risk analysis
  - Use of exposure assessment
  - General standard for contaminants and toxins in foods and feeds
- MAFF prepares a working documents on contaminants for CCCF every year in collaboration with the Netherlands

Developing Scientific Data Priorities for Surveillance (MAFF)

- Based on the prioritized hazards
- Important criteria
  - Availability of validated analytical method(s), which can also be used for enforcement
- Medium-term Plan for 5 years &
- Annual Plan
- Two categories
  - Priority A: must conduct surveillance in the specified period
  - Priority B: conduct surveillance if possible

Conducting Surveillance in MAFF

- Clear requirements included in the document for public tender
  - Internal quality assurance implemented in the laboratory
  - Participation in proficiency testing (same analyte, same or similar matrix)
  - Validated method for the analyte/matrix combinations
  - Accreditation, if available
- MAFF gives guidance on sampling
- Sometimes two steps, incl. preliminary one

Requirements

For the data provided by Japan to be used by JECFA:

- Sampling
  - Representative samples for Japan
  - Statistically sound number of samples "Codex General Guidelines on Sampling"(CAC/GL 50-2004)
- Analytical methods
  - Validated methods esp. for submission to Codex/JECFA
- Good laboratory management
  - Many recommendations from Codex

Sampling

- Representative of the population?
- Purpose of sampling
  - To know the average?
  - To know the violation rate?
- Characteristics of the population
  - Homogeneous
  - Heterogeneous

6 Dec. 2018, Y. Yamada, Ph.D. 13

Analytical Methods

- Validated?
  - Warrant similar results (whoever, wherever & whenever)
- Appropriate performance characteristics
  - Appropriately low limit of quantification (about 1/10 – 1/5 of ML)
  - Reproducibility
  - Selectivity, etc.

6 Dec. 2018, Y. Yamada, Ph.D. 14

Analytical Results

- Submission must be on the fixed format prepared by MAFF
  - Name, address & contact person of the laboratory
  - Analyte(s) and matrices
  - Sample (receiving date & condition, and storage condition)
    - Require analysis within a few days after receiving samples
    - If stored frozen more than 2 months, require storage stability study
    - Require replicate sample to be stored

6 Dec. 2018, Y. Yamada, Ph.D. 15

- Sample preparation procedure
- Analytical method and its SOP
- Validation of the method (how & matrix)
- Limits of detection and quantification (how they were determined)
- Calibration curve (standard reagent, its purity & identification, preparation, etc.)
- Recoveries (method and results)
- Uncertainty (method and results)
- Analytical results

6 Dec. 2018, Y. Yamada, Ph.D. 16

- Information on the laboratory
  - Internal quality assurance
  - Participation in proficiency testing
    - Analyte/matrix
    - Result
  - Accreditation against ISO 17025
- Sampling

6 Dec. 2018, Y. Yamada, Ph.D. 17

Evaluation of Results

- Receive all necessary information
- Check the values
- Statistical analysis, including drawing histograms
- Preliminary exposure estimation
  - Deterministic estimation
  - Probabilistic estimation using modelling
- Determination of safety
- Development of a code of practice, as necessary
- Preparation of a press release

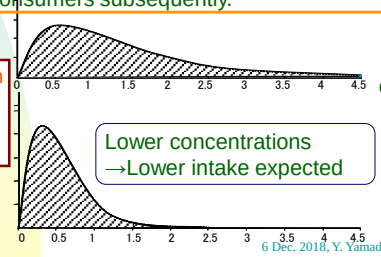
6 Dec. 2018, Y. Yamada, Ph.D. 18

Codes of Practice to Prevent and/or Reduce Contamination

Effect of COP on Reduction of Concentrations

- More effective, efficient and economical to control at production stage than inspection of final products for compliance.
- Shift of distribution to lower concentration will decrease intake by consumers subsequently.

Implementation of new production method



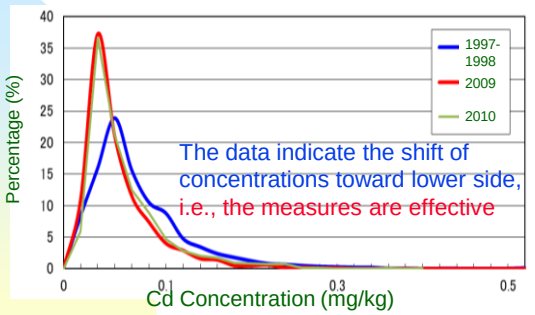
6 Dec. 2018, Y. Yamada, Ph.D. 20

Codex Codes of Practice

- Falls under the responsibility of MAFF in Japan
- Collected scientific data
- Contacted the relevant industry for inputs
- Japan contributed in the development of the following
  - Prevention and Reduction of Arsenic Contamination in Rice (chair of eWG)
  - Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes
  - Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products That Contain Acid-HVPs

6 Dec. 2018, Y. Yamada, Ph.D. 21

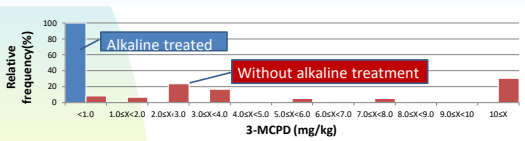
Effect of Risk Management Measure on Cd in Rice in Japan (1997-1998, 2009 & 2010)



6 Dec. 2018, Y. Yamada, Ph.D. 22

3-MCPD in Vegetable Protein Hydrolysate

Veg. protein hydrolysate	No.	<LOQ	3-MCPD (mg/kg)			
			Min.	Median	Max.	Mean
Alkaline treated	179	0	0.004	0.050	0.30	0.056
Not alkaline treated	59	0	0.010	3.2	57	10



- With or without alkaline treatment makes significant difference in 3-MCPD concentrations
- Alkaline treatment breaks down 3-MCPD

6 Dec. 2018, Y. Yamada, Ph.D. 23

Maximum Levels (MLs) for Contaminants

Codex General Standard on Contaminants and Toxins in Food and Feed

Criteria for the Establishment of MLs in Foods

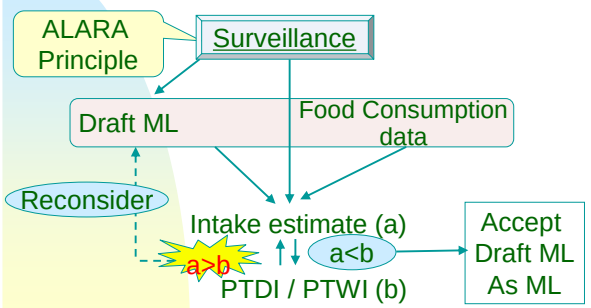
- Only for those contaminants that present a significant risk to public health
- Only for those foods that are significant for the total exposure of the consumer to the contaminant
- As low as reasonably achievable (ALARA) Principle

NB: Establishing ML = Need for enforcement & compliance test

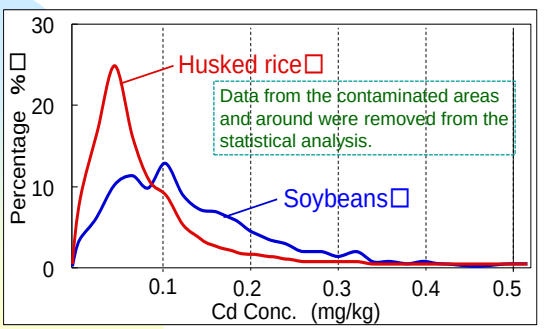
Application of the ALARA Principle

- As Low as Reasonably Achievable
- MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods which are produced with current adequate technological methods to avoid undue disruptions of food production
- Precondition:
  - Protection of the health of consumers
  - Appropriate production/manufacturing to avoid contamination

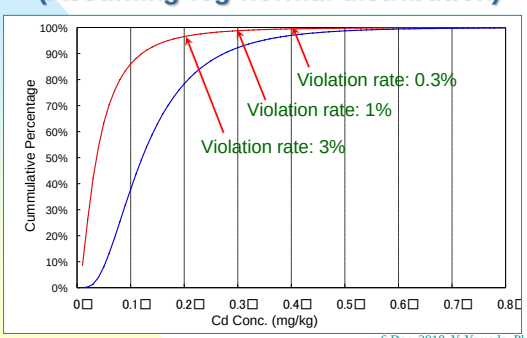
Establishment of Maximum Levels



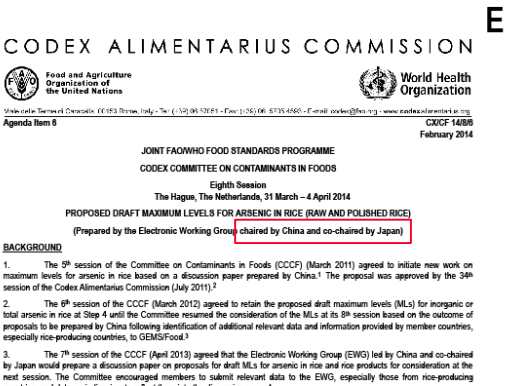
Distribution of Cd concentrations



Cumulative Distribution of Cd Concnetrations (Assuming log normal distribution)



Example: iAs in polished rice



E

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Agenda Item 6

CX/CF 14/8/6

February 2014

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eighth Session

The Hague, The Netherlands, 31 March – 4 April 2014

PROPOSED DRAFT MAXIMUM LEVELS FOR ARSENIC IN RICE (RAW AND POLISHED RICE)

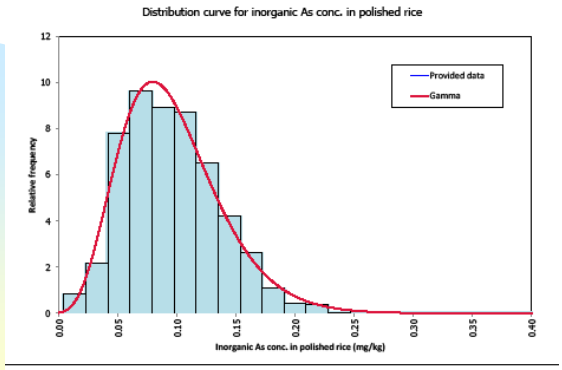
(Prepared by the Electronic Working Group chaired by China and co-chaired by Japan)

BACKGROUND

1. The 5th session of the Committee on Contaminants in Foods (CCCF) (March 2011) agreed to initiate new work on maximum levels for arsenic in rice based on a discussion paper prepared by China.[1] The proposal was approved by the 34th session of the Codex Alimentarius Commission (July 2011).[2]

2. The 6th session of the CCCF (March 2012) agreed to retain the proposed draft maximum levels (MLs) for inorganic or total arsenic in rice at Step 4 until the Committee resumed the consideration of the MLs at its 8th session based on the outcome of proposals to be prepared by China following identification of additional relevant data and information provided by member countries, especially rice-producing countries, to GEMS/Food.[3]

3. The 7th session of the CCCF (April 2013) agreed that the Electronic Working Group (EWG) led by China and co-chaired by Japan would prepare a discussion paper on proposals for draft MLs for arsenic in rice and rice products for consideration at the next session. The Committee encouraged members to submit relevant data to the EWG, especially those from rice-producing



ML proposals for iAs in polished rice

ML Proposal (mg/kg)	Percentage >ML proposal	Mean (mg/kg)
No ML	-	0.096
0.1	41	0.061
0.2	2.0	0.092
0.3	0.0	0.096

Too high!
Appropriate
Useless
Effective

*Each mean was calculated for deterministic exposure assessment from the distribution model with excluding range above a given ML proposal in the model.

Thank you for your attention!