Life cycle of a Codex MRLs

Workshop on Global MRL Harmonization Initiative
Alexandria, Egypt, 30 March- 2 April 2009

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1. Codex Alimentarius: what it is and how it works
2. How Codex Pesticide MRLs are developed
3. Criteria for MRL priorities
4. Life span of Codex MRLs
5. Conclusions
1. Codex Alimentarius: what it is and how it works
Codex Alimentarius Commission:

Established in 1961-1962 by FAO and WHO to implement the Joint FAO/WHO Food Standards Programme
Director-General of FAO
Dr Jacques Diouf

Dr Margaret Chan
Director-General
World Health Organization
Codex is located inside FAO.
Codex Alimentarius: what it is

- Latin, meaning *Food Law or Code*.
- Collection of internationally adopted food standards, guidelines, codes of practice and other recommendations.
Codex Alimentarius

- To protect the health of consumers
- To ensure fair practices in the food trade
- To coordinate all food standards work
How Codex works and how Codex Standards are established

Codex Alimentarius Commission
  Executive Committee
  General Committees (10)
  Commodity Committees and Task Forces
    Active Committees (5)
    ad hoc Task Forces (1)
    Committees adjourned (6)
  Secretariat
  Regional Committees (6)
The only Worldwide Intergovernmental Food Standards Organization consisting of:

- 180 Member countries and one Member Organization (EC)

Observers:
- United nations organizations
- International Scientific Organizations;
- Consumer organizations;
- Food Industry and Trade
Executive Committee (CCEXEC)

- Chairs and vice-chairs of the CAC
- Coordinators from Regions
- 7 members elected by the CAC on a geographic basis
- Not more than one delegate from any one country shall be a member of the Executive Committee

Between CAC sessions CCEXEC acts as executive organ of the CAC:
- makes proposals to the CAC regarding general orientation;
- strategic planning;
- programming of the work of the CAC;
- study special problem;
- assist the CAC in the management of the CAC programme of standards development, namely by conducting a critical review of proposals to undertake new work and monitoring the progress of standards development;
- report to the Commission
General Subject Committees

- General Principles (*France*)
- Food Additives (*China*)
- Contaminants in Foods (*Netherlands*)
- Food Labelling (*Canada*)
- Food Hygiene (*USA*)
- **Pesticide Residues** (*China*)
- Methods of Analysis and Sampling (*Hungary*)
- Food Import and Export Inspection and Certification Systems (*Australia*)
- Residues of Veterinary Drugs in Foods (*USA*)
- Nutrition and Foods for Special Dietary Uses (*Germany*)
Commodity Committees and Task Forces

- Milk and Milk Products (New Zealand)
- Fish and Fishery Products (Norway)
- Fats and Oils (Malaysia)
- Fresh Fruits and Vegetables (Mexico)
- Processed Fruits and Vegetables (USA)
- Natural Mineral Waters (Switzerland, not active)
- Sugars (UK, not active)
- Cereals, Pulses and Legumes (US, not active)
- Meat Hygiene (New Zealand, not active)

- Cocoa Products and Chocolate (Switzerland, not active)

Task Force

- Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (Republic of Korea)
Codex Secretariat

1. Administrative and technical support to the work of the Commission
2. Keeps the link with the Codex Contact Points inside a country
Codex outputs:

- **293 Standards for commodities** – fruits, vegetables, cereals, pulses, legumes, meat, fish, milk, fats, oils, sugars, cocoa and products of all these. Foods for special dietary uses, irradiated foods, mineral water, Food labelling, claims, nutrition labelling etc, including:
  - More than 2000 MRLs for 234 pesticides
  - 25 Guideline Limits for Contaminants
  - 54 Veterinary drugs
  - Around 800 food additives

- **66 Codes of Practice** – Recommended Code of Practice - General principles of food hygiene; Hygienic practice for milk and milk products, Transport of foods in bulk, Good animal feeding etc

- **69 Guidelines** – Guidelines for the Use of Flavourings, organically produced foods, on sampling, Guideline for the Validation of Food Safety Control Measures, etc

- **Other texts** – Codex Classification of Foods and Animal Feeds, General principles for addition of essential nutrients to foods, etc
Scientific input to the CAC and CCPR comes from:

- Independent FAO/WHO Expert Committees:
  - Joint Meetings on Pesticide Residues (JMPR) – serves CCPR;
  - Joint Expert Committee on Food Additives (JECFA) – serves CCFA, CCRVDF
  - Joint meetings on microbiological risk assessment (JEMRA) – serves CCFH
- Ad Hoc Expert Consultations
2. How Codex Pesticide MRLs are developed
Pesticide

**Pesticide** means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.
Pesticide Residue means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.
Codex Maximum Limit for Pesticide Residues (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.
Good Agricultural Practice in the Use of Pesticides (GAP)

Good Agricultural Practice in the Use of Pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

- Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

- Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.
Codex Committee on Pesticide Residues (CCPR)

- establishes maximum limits for pesticide residues in specific food and feed items;
- prepares priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);
- considers methods of sampling and analysis for the determination of pesticide residues in food and feed;
- considers other matters in relation to the safety of food and feed containing pesticide residues; and
- to establishes maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.
Basis for the work of Codex Committee on Pesticide Residues (CCPR)

- General decisions of the Commission
- Strategic Plan of the Commission for 2008-2013;
- Terms of reference for the CCPR;
- Risk Analysis Principles Applied by the CCPR (under revision);
- Criteria for the Prioritization Process of Compounds for Evaluation by JMPR;
- Codex General Criteria for the Establishment of Work Priorities
Codex Alimentarius
- its scientific basis -

- Codex CCPR - Risk management

- FAO/WHO Expert Bodies - Risk assessment
  - JECFA – food additives, veterinary drug residues, contaminants in food
  - JMPR – pesticide residues in food
  - JEMRA – microbiological hazards in food
  - ad hoc Expert Consultations

Liaison & Separation
Pesticide residues

- **Step 1:** decision of the CAC on the pesticide/commodity combination or on the specific text
- **Step 2:** JMPR evaluation (when available) or text when available
- **Step 3:** Secretariat sends the outcome of JMPR evaluation or text for comments
- **Step 4:** Consideration at the CCPR
- **Step 5:** Approval by the Commission
- **Step 6:** Secretariat sends for comments MRL or text
- **Step 7:** Consideration at the CCPR
- **Step 8:** Approval as Codex MRL by the Commission
- **Step 5/8:** Recommendation of the CCPR to the CAC with recommendation to omit Steps 6 and 7
Establishment of MRLs – CCPR Policy

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES
(Adopted by the 30th Session of the CAC in 2007)

• Scope
• Roles of CCPR and JMPR in Risk Analysis
• Interaction between CCPR and JMPR
• Role of the CCPR
• Role of JMPR

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR
Establishment of MRLs – CCPR Policy

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

Procedure for proposing pesticides for Codex Priority List
MRLs for Commodities of Animal Origin
MRLs for Processed or Ready-to-eat Foods or Feeds
MRLs for spices
MRLs for fat-soluble pesticides
Establishment of MRLs
Utilization of Steps 5/8 for elaboration of MRLs
Establishment of EMRLs
Periodic Review Procedure
Deleting Codex MRLs
MRLs AND METHODS OF ANALYSIS
Codex MRLs development

– CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation i.e. when ADI is established.

– CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

– When establishing its MRLs, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR’s risk assessment and recommended maximum residue levels and specify its reasons for doing so.
Codex MRLs development (2)

- JMPR performs risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate;

- JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.
Codex MRLs

Codex MRLs– a valuable source of harmonized values that are:

- Based on sound science
- Developed by international consensus
- Recognized by international agreements (WTO SPS)
- Contributes to global harmonization
3. Criteria for MRL priorities
General Criteria

Criteria for Inclusion of Compounds on the Priority List

Before a pesticide can be considered for the Priority List it:

- must be registered for use in a member country;
- must be available for use as a commercial product;
- must not have been already accepted for consideration; and
- must give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.
CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be established

– The commodity for which the establishment of a Codex MRL or EMRL is sought should be such that it may form a component in international trade. A higher priority will be given to commodities that represent a significant proportion of the diet.

– Note: Before proposing a pesticide/commodity for prioritization, it is recommended that governments check if the pesticide is already in the Codex system. Pesticide/commodity combinations that are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion at each Session of the Codex Committee on Pesticide Residues. Consult the document of the latest session to see whether or not a given pesticide has already been considered.
CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

2. Criteria for Prioritisation
   – 2.1 New Chemicals

When prioritizing new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

– If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);

– The date when the chemical was nominated for evaluation;

– Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;

– The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and

– Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.
CRITERIA FOR THE PRIORITIZATION PROCESS OF COMPOUNDS FOR EVALUATION BY JMPR

2.2 Periodic Re-Evaluation
– When prioritizing chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:
– If the intake and/or toxicity profile indicate some level of public health concern;
– Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
– The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – Not Yet Scheduled;
– The date that data will be submitted;
– Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
– If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
– The availability of current labels arising from recent national re-evaluations.
4. Life span of Codex MRLs

Due to intellectual property rights, Codex MRLs for new chemicals are limited normally to 15 years; then chemical is reviewed and based on JMPR evaluation an MRL is reviewed: new MRL is proposed and old is deleted (according to data submitted; CCPR is considering on how to proceed with MRLs for which new data were not submitted to JMPR for evaluation.
4. Life span of Codex MRLs

Most of Codex MRLs has a life span between 10 and 18 years; On exceptional cases it might be a bit longer, if there is commitment from member governments to provide data.

Some “Old” (from 1991) MRLs for:
- bromide ion (i.e. broccoli, lettuce head)
- methomyl (asparagus, cabbages, head, lettuce, head)
- cypermethrins (alfa, zeta) (berries and other small fruits)
- fenvalerate (Brussels sprouts, kale, kiwi)
- permethrin (Wheat brann, unprocessed etc)
4. Life span of Codex MRLs

- A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.

- A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary with a copy for consideration by the Committee. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
5. Conclusions

- Codex Alimentarius forms a considerable source of globally harmonized information (definitions, Maximum Residue Limits (MRLs)) which governments (food control agencies / bodies) can use now, saving on that substantial amount of human and financial resources.
Welcome

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

NEWS

Welcome to New Codex Member

It is with great pleasure that we welcome Djibouti as a member of the Codex Alimentarius Commission (Region: Africa). This brings the membership of the Commission to 181 members (180 member countries and one member organisation).

New! FAO/WHO Codex E-Learning Course - now available in Spanish

The course explains the organization, management and procedures of the Codex Alimentarius Commission (CAC) and its subsidiary bodies.
Resources for trainers in Spanish

Codex Newsletter

The first issue of Codex Newsletter has been released and sent to all Codex members. A web version is available here.

CAC31 REPORT

The report of the 31st Session of the Codex Alimentarius Commission is now available in: English, French, Spanish, Arabic and Chinese.
Thank you very much for your kind attention and I wish you all the best and success!