

附件四：各國專家專題簡報



Food Safety Policy

November, 2013
Ministry of Food and Drug Safety
IM Moo-hyeog



CONTENTS

- Introduction of MFDS
- Related Acts and Regulations
- Food Safety Control Policy

Introduction of MFDS

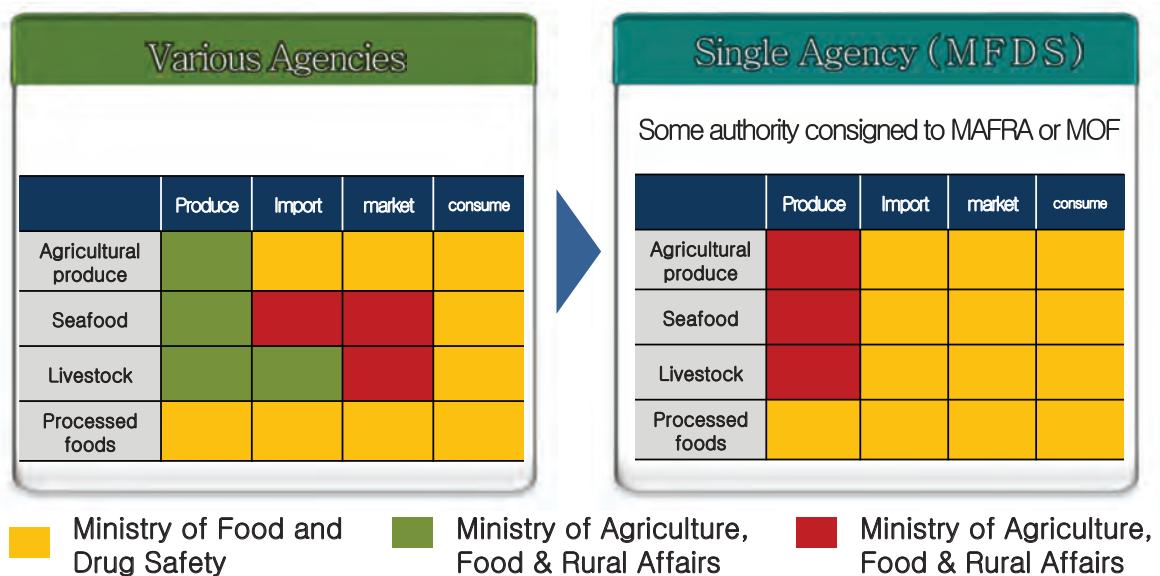
Ministry of Food and Drug Safety (MFDS)



History of MFDS

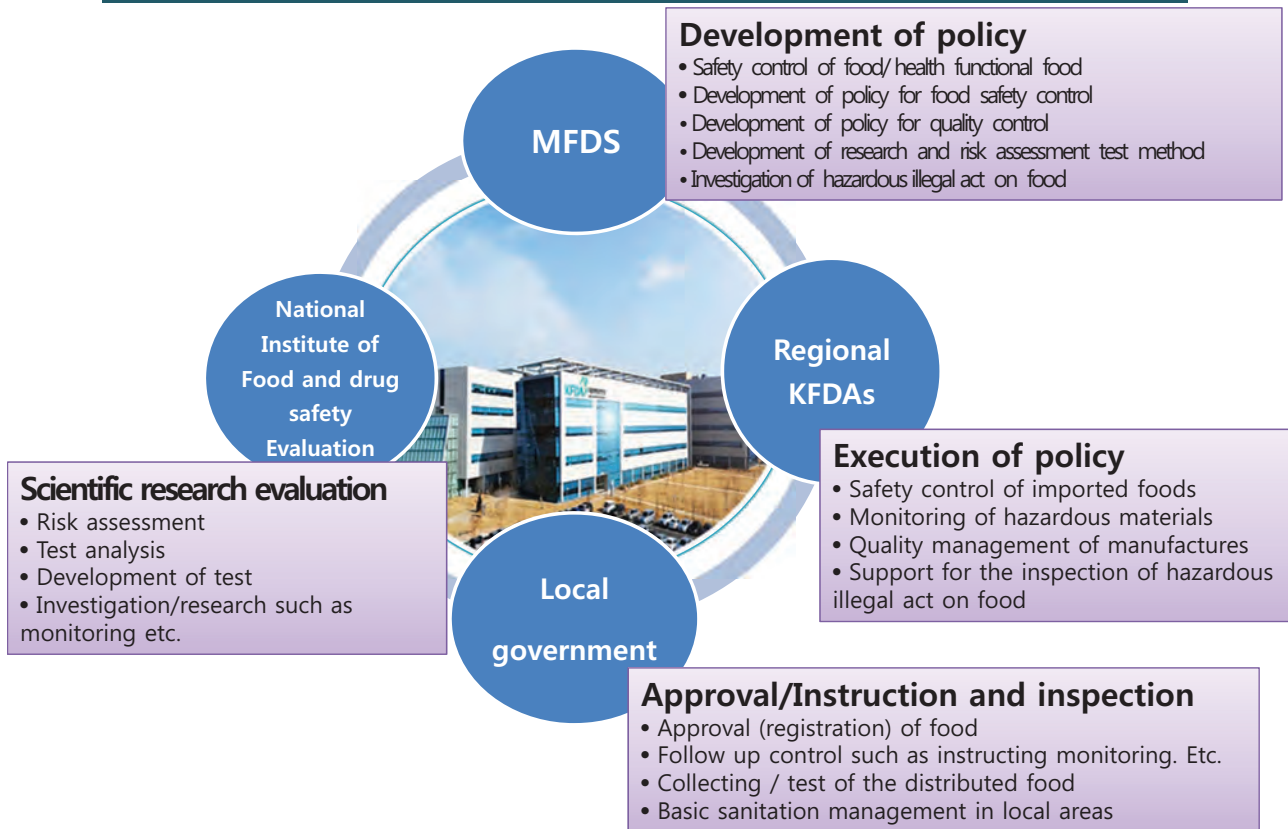
- Apr. 1996 : Established Korea Food and Drug Safety Headquarter under Ministry of health and welfare
- Feb. 1998 : The Korea Food and Drug Safety was raised to statues of administration
- Nov. 2010 : The KFDA relocated to Osong Health Technology Administration
- Mar. 2013 : The Ministry of Food and Drug Safety is restructured and expanded following consolidation of food management system which now includes agricultural, livestock fisheries products

Integration of Food Safety Authorities

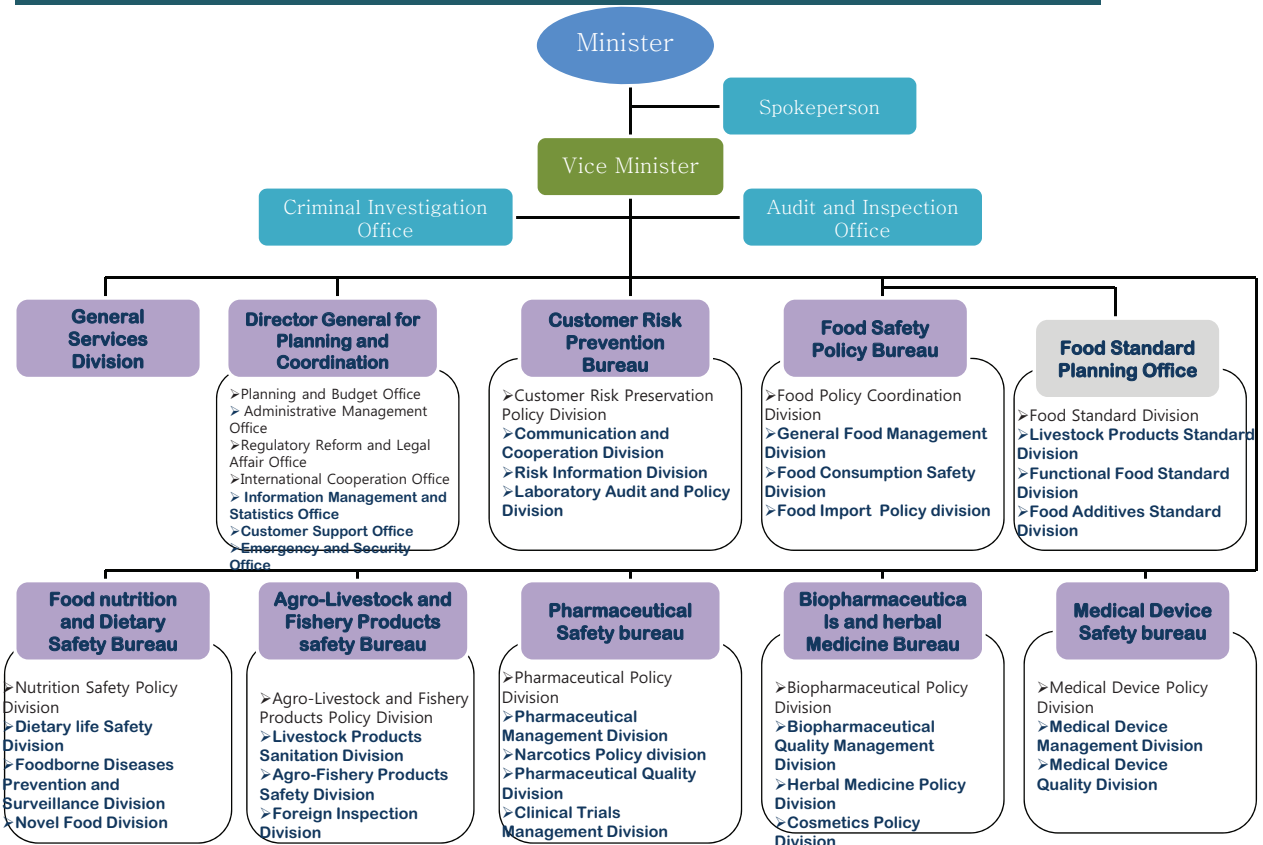


MFDS cooperates with MAFRA and MOF.
 Consigned authorities can be cross-checked by interagency activities.

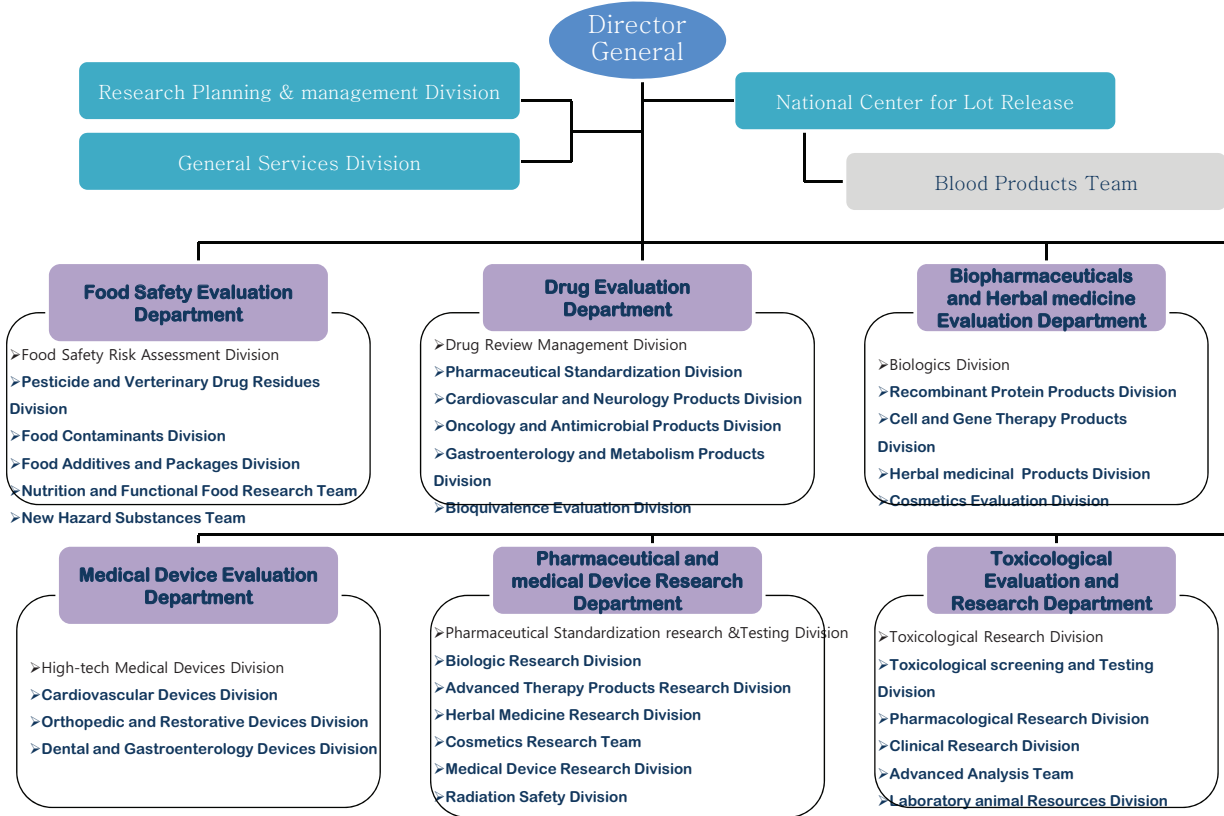
Main Task



Organization of MFDS



National Institute of Food and Drug Safety Evaluation



Organization of MFDS

Food Safety Policy Bureau

- Establishing overall food safety management plans
- Enforcing law against manufacturers to ensure safety and wholesomeness of food
- Cooperation of international food safety
- Standard setting for food, food additive, health functional food, microbiological criteria, etc.

Food Nutrition and Dietary Safety Bureau

- Developing the health functional food policy and food nutrition and dietary safety policy
- Establishing the safety management of children's dietary life
- Preventing food-borne disease outbreaks
- Coordinating and controlling GMO issues

Organization of MFDS

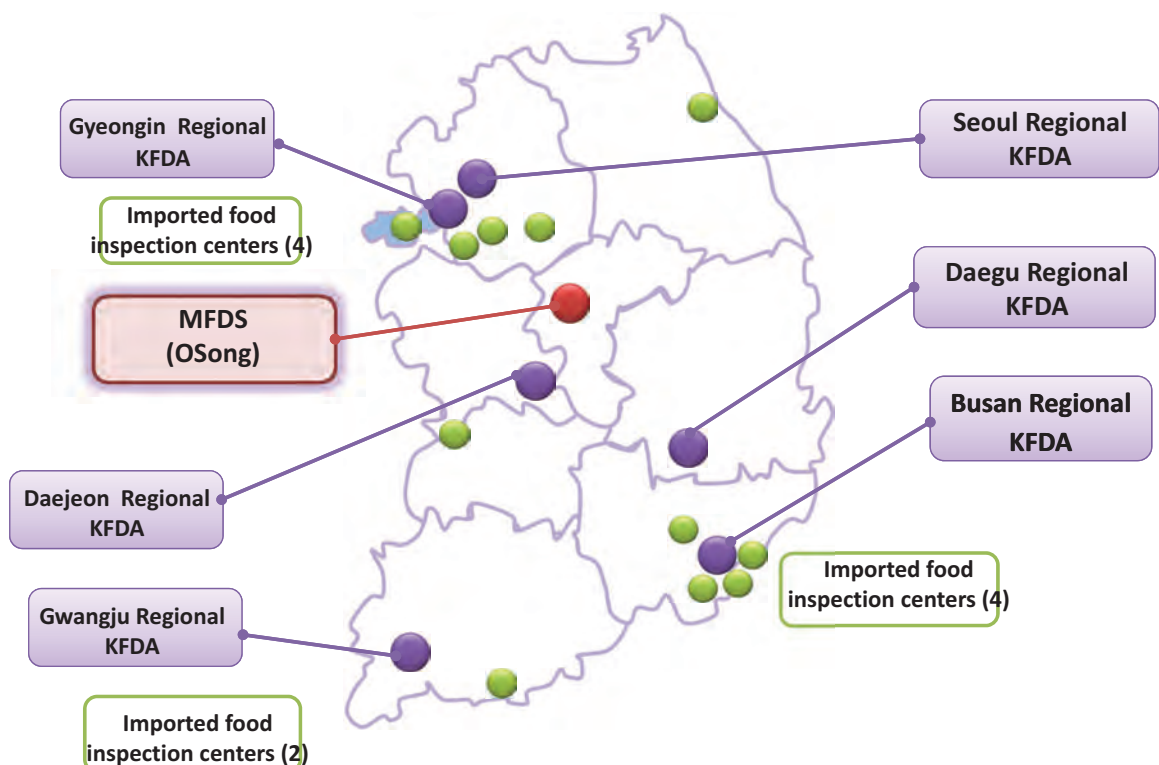
Customer Risk Prevention Bureau

- Setting a strategy plan of risk management
- Designing and controlling the crisis management and response system in emergency situation
- Establishing overall communication plan

Agro-livestock and Fishery Products Safety Bureau

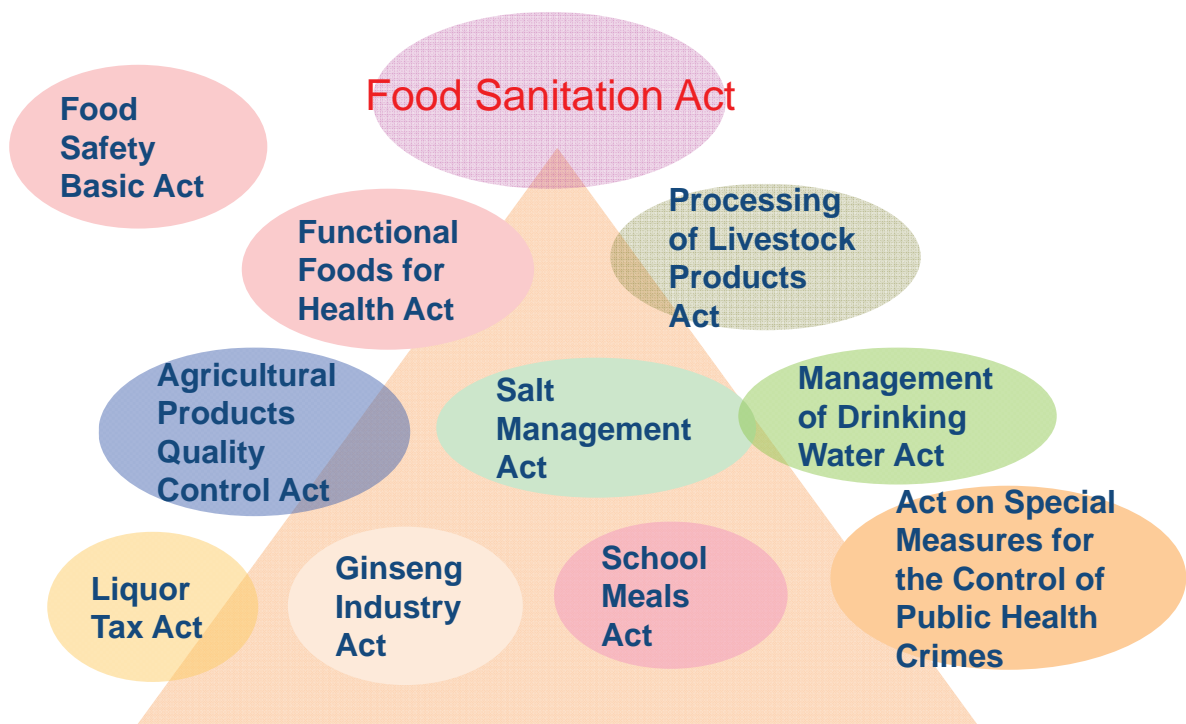
- Oversight, supervising food import, and conducting inspection on imported food
- Developing agro-livestock and fishery products safety management policy

Regional KFDA Offices

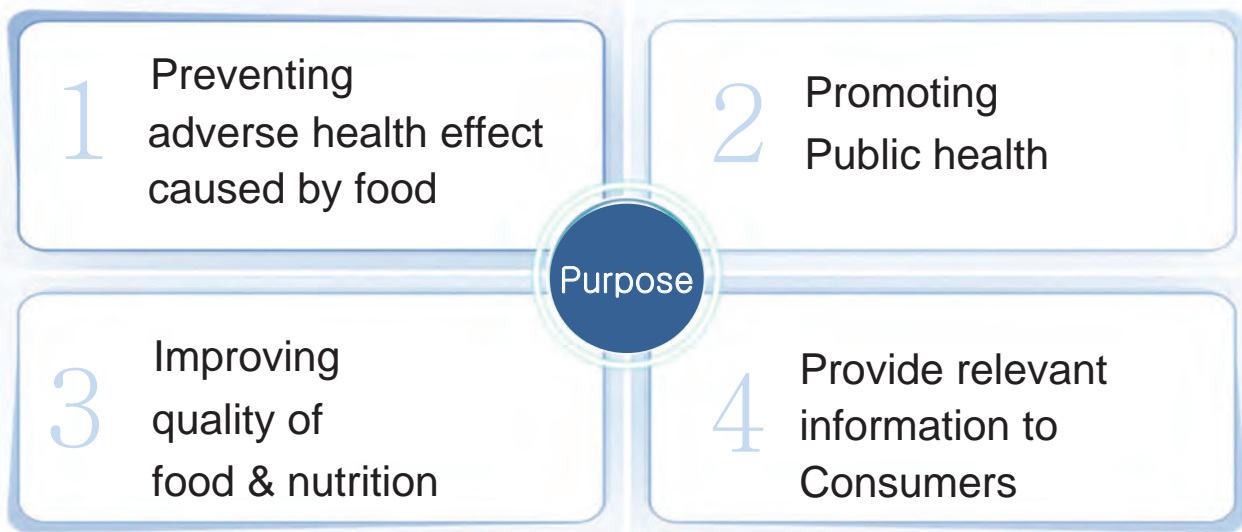


Related Acts and Regulations

Food Laws



Food Sanitation Acts



Food Sanitation Acts

Contents

- Food Sanitation Act & Its Enforcement Rule
- Food Code & Food Additive Code
- Food Labeling Standards
- Foods Import Procedures and Requirements
- Facility and Compliance Requirements for Businesses
- Authorization of official laboratories
- Risk Assessment, Penalties, Administrative Actions, Public Notifications, etc.

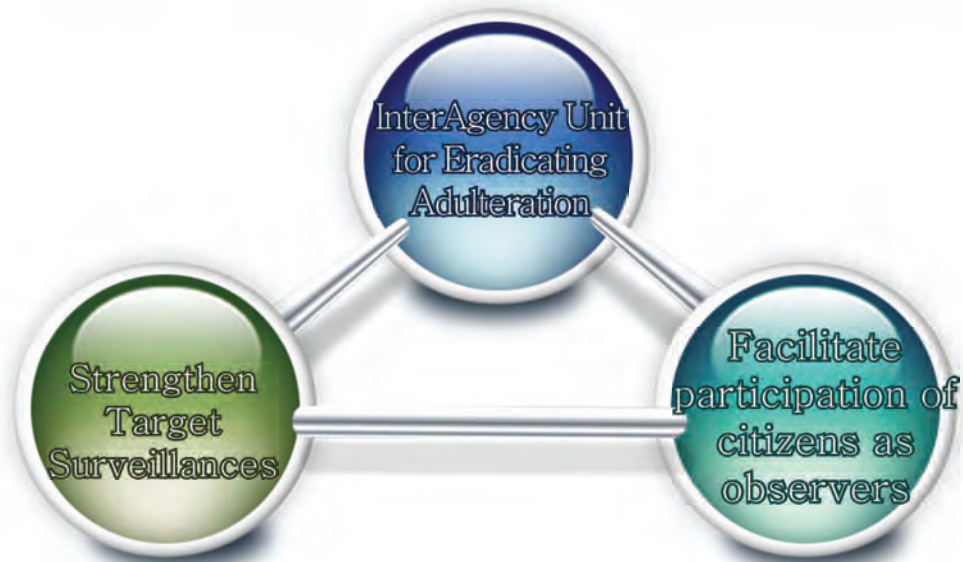
Food Safety Control Policy

Initiatives



1. Special Team for Eradicating Adulterated Foods

InterAgency Cooperation, Share Info & Facilitate Participation



InterAgency Unit

- Special Team for Eradicating Adulterated Foods (April ~)
 - Prime Minister's Office, MFDS, MAFRA, Nat'l Police Agency, Prosecutors
- 5-year Master Plan(**April**)
- Food Safety Campaign with NGOs

Target Surveillances

- Surveillances focus on intentional or repetitive case with data analysis
- Cooperate with MFDS, MAFRA and local governments

Facilitation of Participation

- Consumer, Parents or Industry are encouraged to participate
- Risk communication by Interactive Online measures (**blogs, SNS**)

2. Preventive Actions

Prevent Food Safety Risk Factor & Develop Infrastructure



Strict Food Safety Standard

- Coordinate Food Safety Standard applied variously(Dec)
 - * e.g. Microbiological Standard for Canned Foods
- Develop Standard & Analysis Methods for Novel Hazards
 - * e.g. Novel hazards, Variant *E.coli*
- Enlarge MRLs Settings for Pesticides / Veterinary Drugs(2017)
 - 432 Pesticides / 156 Vet Drugs → 550 Pesticides / 200 Vet Drugs

Student Safety Zone

- Caffeinated Beverages are banned on sale near or in School
- Reserve 'Student Safety Zone'(Ministry of Education) & 'Recommended Food Vendor for teenagers' (MFDS)

* to revise 'Special Act on Children's Dietary Safety (Dec)

Catered Foods

- Foodborne Diseases Alert System link to gov't procurement system to prevent spread of contaminated foods(**Oct**)
- Surveillance for food safety at Catering & suppliers(**Mar, Sep**)
- More Establishment of 「School Catering Support Center」 (22 → 100)

HACCP Accreditation

- Enlarge scope of compulsory HACCP Accreditation
 - Slaughter House → Milk Collector, Dairy Processor
 - 7 Commodities eg. Surimi, Kimchi
 - Preferred Foods by children, Frequently Consumed commodities

Autoblock System & Recall

- More food retailers can apply Autoblock system from Hazardous goods
 - Major distributors → Food Retailers
- Enlarge scope of compulsory Sales Record keeping for recall
 - Beef → Foods for Infants & Toddlers, Dietary Supplements

Sanitation rating on restaurants

- MFDS has introduced the rating system as pilot project in 2013 and has assigned one of three grades to restaurants depending on their sanitation conditions

Grades	Evaluation Score	Contents of Judgment
AAA	Over 90	Sanitation condition is very excellent
AA	80 ~ 89	Sanitation condition is overall excellent
A	70 ~ 79	Sanitation condition is overall acceptable

- Results will be open to public through MFDS website and incentives will be given to high rated restaurants
- New regulations will be proposed in regards to this system under Korean Food Sanitation Act in 2013

Traceability System

- To identify causes and undertake post measures(recall, discard) in the event of problems with food sanitation and safety
- Future plan
 - Obligation of traceability system by stage
 - Manufactures of Infant foods and health functional foods
 - Establishment of liaison system for traceability from production to sales
 - Liaison of food traceability system has been distributed with each ministries such as MFDS, MAFRA and MOF.



3. Strict Penalty for Food-related Crimes

Stricter Punishment & illegal profit confiscated



4. Assure Safety of Imported Foods

Safety Management starts from producing countries



Onsite Inspection for Overseas Suppliers

- to enact「 Special Act on Safety Management for Imported Foods
- to sign more MOU with major trade partner countries
 - Import would be banned when it is proved that the commodity was manufactured under poor hygienic condition
- More Attaché in major trading partner countries
 - Only 2 Attaché from MFDS reside in US and China
 - * US FDA operates 13 offices in 10 countries

PREDICT System

- to develop Predictive Inspection System for Imported Foods(PREDICT)
 - to classify imported goods to physical inspection at the border with a database of supplier, importer, compliance records and risk info

Positive List systems

- To protect human health against pesticides, which compounds are not registered in Korea
- Pesticide for which no MRLs have been set (compounds unregistered)
 - It is not permitted to distribute food in which pesticide MRL exceeds 0.01 ppm

Corrupt Enterprisers Expelled

- To differentiate inspection level with non-compliance history
- Easy custom clearance given to importer with good history

5. Enhance Food Label

Consumer guaranteed right-to-know with enhanced food label on the products



Enlarge Labeling of Country of Origin (MAFRA)

- Agri produce & Seafood: (2012) 868 commodities → (2013) 872
- Served or catered Foods : (2012) 12 commodities→ (2013) 16

Enlarge Scope of Nutritional Facts

- to provide correct info for healthy dietary life
 - to promote labeling of nutritional info on foods served in food courts or shopping mall

Label 'Containers/Packages for Foods'

- to prevent consumer Misuse with labeling of 'Containers / Packages only for Foods'
 - 「Food Labeling Standard」 will be revised (Nov)

Readable Food Labeling

- larger size of font, simple name of food additives, introduction of QR code on the product and other alternatives(2014)

Before



After

- Name of pdt : POTATO CHIPS
- category : SNACK(FRIED)
- Manufacturer : △△△△
(Address ○○ ○○ ○○ ○○)
- Use by Date : ○○○○.○○.○○
- Contents : 250g
- Ingredients : Potato 89%(Korea), Sunflower Oil
- Store at room temperature

6. Communicate with Consumer

Transparency in Food Safety Policy with Info Sharing and Efficient Communication



Specialized Unit for Communication

- to hold regular 「Consumer Forum」 to minimize social conflict and to promote sympathy on food safety policy
- 「Communication Unit」 in MFDS, One Voice from Gov't position

More Consumer Participation

- Consumer can participate in surveillance / audit process
 - More than 20 consumers → 5 Consumers can apply for attending
 - Only MFDS → Consumers can apply to Local gov't too

Web-based Consumer Proposal Center

- to integrate Proposal center with consumer complaint report and to review the proposal received
- MFDS listen various opinion on food safety policy

Vision

Safe Food & Drugs, Healthy Nation, Wellbeing of Society

1

Ensuring Safety of the people
to improve quality of life

2

Consumer-Driven safety
management from Farm to
Table

Purpose

3

Realization of Safer and
healthier lives of the people

4

Beyond safety, providing
assurance to the people

Core Strategies

to eradicate
adulterated
foods

safety
management
from Farm
to Table

consumer
participation
&
'Safety First'
atmosphere

Virtuous cycle btw safety & proliferation

Correlation with public health policies

Q & A





Establishment of MRLs in the United States and International Harmonization Efforts and Opportunities

Lois Rossi
Director, Registration Division
Office of Pesticide Programs
United States Environmental Protection Agency
Korean MRL Symposium
November 6-7, 2013

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Overview of Presentation

- **Office of Pesticide Programs (OPP)
Mission and Organization**
- **Authority to Establish MRLs**
- **MRL Setting in the US: Domestic,
Import Only and Harmonization**
- **Minor and Specialty Crops: Programs**
- **Tools for Solutions**
- **Obstacles, Opportunities, and Examples
of Cooperation**
- **Useful Websites**

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EPA's Office of Pesticide Programs

Principal Business

- **Based on high quality scientific evaluations and open transparent processes:**
 - **Protect human health and the environment.**
 - **Ensure access to safe and effective pesticides and pest management technologies.**

International efforts linked to meeting these goals.



Office of Pesticide Programs (OPP)

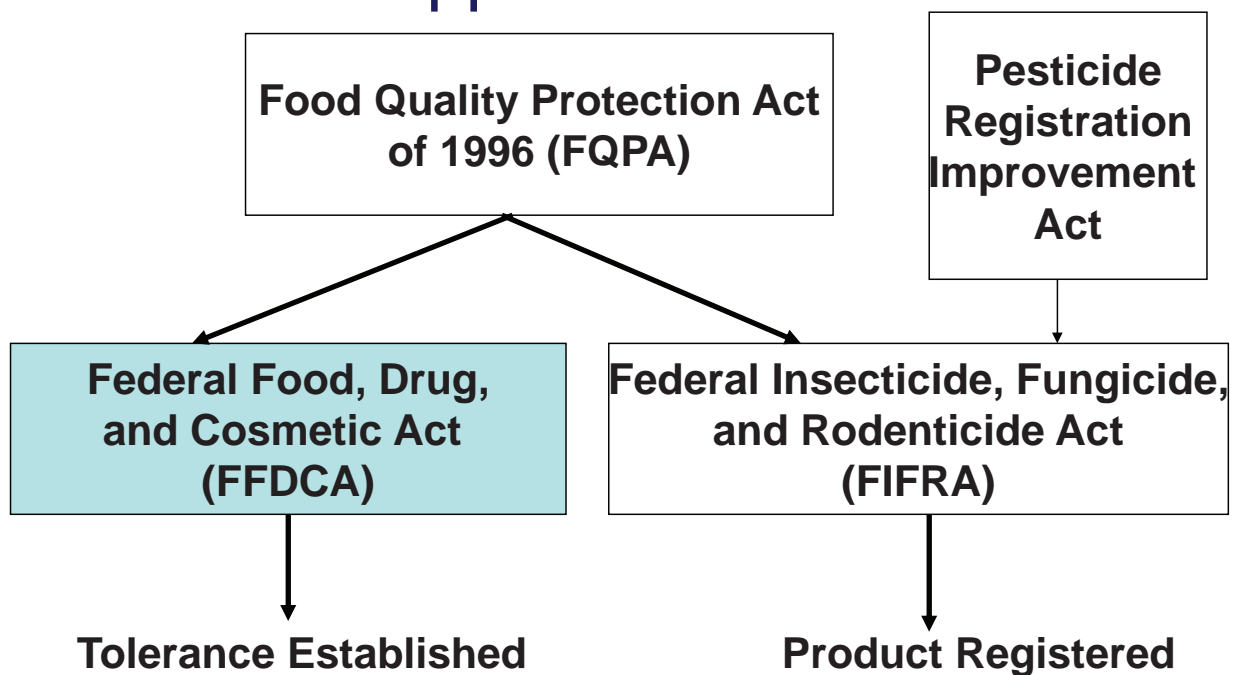
- **There are 9 divisions in the Office of Pesticide Programs:**
 - **Antimicrobial**
 - **Biological and Economic Analysis**
 - **Biopesticides and Pollution Prevention**
 - **Environmental Fate and Effects**
 - **Field and External Affairs**
 - **Health Effects**
 - **Information Technology and Resource Management**
 - **Registration Review**
 - **Registration**



Authority to Establish MRLs (Tolerances) Applicable Statutes



Applicable Statutes





Federal Food Drug and Cosmetic Act (FFDCA)

- **Under section 408 of FFDCA, EPA is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of a pesticide application.**
- **If residues of a pesticide exceed the established tolerance (MRL), or no tolerance (MRL) has been established, the crop is considered adulterated and may be seized by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), or a state enforcement agency.**

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MRL (Tolerance)

- **A tolerance is the maximum residue level (MRL) of a pesticide (usually measured in parts per million, or ppm) that legally can be present in food or feed.**
- **EPA establishes pesticide tolerances (MRLs) only after determining that aggregate exposure to the pesticide is safe.**
- **The requirements of section 408 of the FFDCA apply equally to domestically produced and imported food and feed found to contain pesticide residues.**

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Federal Food Drug and Cosmetic Act (FFDCA)

- **“Safe” means “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”**
- **This includes exposure through drinking water and in residential settings, but does not include occupational exposure.**

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MRL (Tolerance)

- **Data as well as a petition (application) to establish a MRL (tolerance) must be submitted to the U.S. EPA in order for the Agency to establish a MRL (tolerance).**
- **Residue data required:**
 - **Plant Metabolism**
 - **Livestock Metabolism**
 - **Crop Field Trials – residue field trial data should be in accordance with OPPTS Guideline 860.1500**
 - **Processing Studies**
- **The residue field experiments consist of examination of the raw agricultural commodity (RACs) for residues of the pesticide chemical after treatment corresponding to the use directions proposed on the label.**

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Risk Assessment

- **Risk = Hazard X Exposure**
- **Residue field trial data supplied by pesticide companies (or IR-4 often for minor uses) is one component in this equation providing inputs for exposure to food**
- **Exposure = Consumption X Residues**
- **Exposure includes food, water and residential exposures**

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Establishing a MRL (Tolerance) in the US

- **If the required safety finding can be made the decision is published in the Federal Register and the MRL (tolerance) is established.**
- **When making its MRL (tolerance) decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible.**
- **Section 408(b)(4) of FFDCA requires the EPA to consider the international MRLs established by the Codex Alimentarius Commission (Codex), when making its MRL (tolerance) decisions.**
- **EPA may establish a MRL (tolerance) that is different from a Codex MRL; however, EPA is required to explain the reasons for departing from the Codex level.**

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“Import MRLs (Tolerances)”

- Tolerance in absence of a US registration – “import tolerance” is not a legal definition.
- There are no specific requirements in the Federal Food Drug and Cosmetic Act (FFDCA) for import tolerances.
- 40 CFR 180 usually will include a footnote that specifies “There are no U.S. registrations...”



Example: Import MRL (Tolerance)

§ 180.619 Epoxiconazole; tolerances for residues.

(a) *General*. Tolerances are established for the residues of the fungicide epoxiconazole [(*rel* -1-[[(2R,3S)-3-(2-chlorophenyl)-2-(4-fluorophenyl)oxiranyl]methyl]-1 *H* -1,2,4-triazole)] in or on the following commodities:

Commodity	Parts per Million
Banana*	0.5
Coffee*	0.05
*No U.S. Registration as of August 4, 2006	



Imported Commodities

- **The Federal Food Drug and Cosmetic Act (FFDCA) requires that tolerances (MRLs) for a residue of a pesticide be established in order for a pesticide residue to be present on any food commodity.**
- **Commodities coming into the United States from other countries may be checked at the port of entry for residues of a pesticide.**

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Imported Commodities

- **If pesticide residues are found on a commodity by the United States Food and Drug Administration (FDA) or the United States Department of Agriculture (USDA) and there are no MRLs (tolerances) established by the US EPA for the pesticide/commodity, the commodity is subject to seizure.**

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“Import MRL (Tolerance)”

- **Data as well as a petition to establish an import MRL (tolerance) must be submitted to the US EPA in order for the Agency to establish an import MRL (tolerance).**
- **Residue data should be in accordance with the *NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada.***
- **The chemical company will need to agree to the use of additional data, such as toxicological studies, for purposes of risk assessment.**

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Residue Data Required for Import Tolerance Petitions

- **Plant Metabolism**
- **Livestock Metabolism (if exporting countries export livestock to US)**
- **Crop Field Trials**
- **Processing Studies (if exporting countries export processed commodities to the US, or if fresh crop will be processed in US)**



Import Tolerances for Conventional Chemicals

- **Petition for an import tolerance along with supporting data are submitted to OPP/EPA.**
- **Data are sent for review and human health risk assessments are conducted.**
- **If the required safety finding can be made the decision is published in the Federal Register and the MRL (tolerance) is established.**

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Pesticide Registration Improvement Act (PRIA)

- **PRIA was passed on March 23, 2004 and has been reauthorized twice (PRIA 2 and 3)**
- **Fee-for-Service Act**
- **Created time frames for completion of registration actions**

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Fee Categories under PRIA 3

- **Establish import tolerance; new active ingredient or first food use**
 - **Cost: \$303,878 Timeframe for review: 21months**
- **Establish import tolerance; additional food use**
 - **Cost: \$60,777 Timeframe for review: 15 months**
- **Establish import tolerance; additional food uses; 6 or more crops submitted in one petition**
 - **Cost: \$364,653 Timeframe for review: 15 months**
- **Amend established tolerance; domestic or import applicant-initiated**
 - **Cost: \$43,181 Timeframe for review: 11 months**

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Importance of MRL (Tolerance) Alignment

- **Like the U.S., many countries have their own regulatory schemes and establish MRLs for pesticide residues on food.**
- **Some countries do not have their own regulatory schemes but rely on Codex MRLs.**
- **U.S. growers are required to comply with these requirements when shipping their commodities overseas.**

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Importance of MRL (Tolerance) Alignment

- **In U.S. one of the primary functions of a tolerance is an enforcement tool to ensure compliance with the registered label.**
- **However, tolerances also facilitate trade of agricultural commodities into the U.S.**
- **Lack of tolerances (MRLs) or tolerances (MRLs) at different levels between countries act as trade irritants or limit the pesticide tools growers can use.**

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Minor Uses

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Minor Uses

A site (animal, agricultural crop, or for the public health) where the total acreage for the crop is less than 300,000 acres, or

- **There are insufficient efficacious alternative registered pesticides available for the use;**
- **The alternatives to the pesticide use pose greater risks to the environment or human health;**
- **The minor use pesticide plays or will play a significant part in managing pest resistance; or**
- **The minor use pesticide plays or will play a significant part in an integrated pest management program.**

***FIFRA – section 2(II)**



EPA/OPP Minor Use Program

- **Within the Registration Division, there is a Minor Use Team that coordinates the actions on MRL submissions for minor uses.**
- **Works closely with IR-4 program and stakeholders (registrants and commodity groups).**

Minor Uses and Grower Resources | Pesticides | US EPA - Windows Internet Explorer provided...

http://www.epa.gov/pesticides/minoruse/

File Edit View Favorites Tools Help

Convert Select

Favorites Free Hotmail Web Slice Gallery

Minor Uses and Grower Resourc...

U.S. ENVIRONMENTAL PROTECTION AGENCY

Pesticides: Regulating Pesticides

Recent Additions | Contact Us Search: All EPA This Area Go

You are here: EPA Home » Pesticides » Regulating Pesticides » Minor Uses and Grower Resources

Minor Uses and Grower Resources

Current as of April 2013

This web page provides growers, registrants and other interested parties with information on the programs EPA is implementing to ensure safe pesticide tools are available, particularly for those involved in the minor uses of pesticides. A major part of this effort involves the partnerships with other organizations and stakeholders.

On this page:

- Minor Use Crops and Pesticides
- Codex MRL Nominations
- NAFTA
- MRL Database
- Crop Group Revisions
- Exclusive Use Periods
- Definition of a Minor Use
- Related Information

Minor Use Crops and Pesticides

Minor use crops have fewer than 300,000 acres in production in the United States. The small acreage may provide insufficient economic incentive for pesticide companies (i.e., registrants) to keep their products registered for use on these crops, or to register new minor use pesticides. Many fruits and vegetables qualify as minor crops. Minor uses also include pesticides applied for control of disease vectors such as mosquitoes, ticks, cockroaches, rodents. Disease-causing organisms can be considered minor uses as well.

Codex MRL Nominations

The Codex Committee on Pesticide Residues (CCPR) is responsible for establishing maximum residue limits (MRLs) for pesticide residues in specific food items or in groups of food for Codex.

- More information about Codex
- Nominate a Codex MRL

NAFTA

Activities regarding NAFTA and regional cooperation include:

- Preventing and Resolving Trade Irritants - [The U.S. - Canada Grower Priority Database](#) is a tool for growers, registrants, and regulatory agencies to address trade barriers and trade irritants between NAFTA countries.

Resources

- Reduced Risk Pesticide Program
- Workplan for Registration
- Guidance on RRIA fee waivers and Exemptions
- Nominate a Codex MRL
- Pesticides Registered via Joint Review (PDF) (See 2011-12)
- Index to Tolerance Information
- Crop Group Tables
- US Tolerances (40 CFR Part 180)
- Canadian MRLs (Exit Disclaimer)
- Codex MRLs (Exit Disclaimer)
- IR-4 (Exit Disclaimer)

Contact

- Barbara Madden
Minor Use Officer
(703) 305-6463
madden.barbara@epa.gov

Done Local Intranet 95%



IR-4 Program

Since 1963 IR-4 has been a US government funded research program to facilitate registration of sustainable pest management technology for specialty crops and minor uses.



IR-4 Program

- To facilitate registration of sustainable pest management technology for specialty crops and minor uses.
- Throughout the fifty years, IR-4 has adapted and modified its mission to provide the best service possible to US Specialty crop growers.

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IR-4 Program



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IR-4 Program Funding

Direct Contributions

Over \$18 million

● USDA-NIFA	\$11,000,000
USDA-ARS	\$ 3,800,000
USDA-ARS/DoD	\$ 250,000
USDA-FAS	\$ 500,000
USDA-APHIS	\$ 172,000
State Ag. Exp. Stations	\$ 481,182
Grants from Industry	\$ 1,100,000

- Indirect Contributions - At least \$18 million

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IR-4 Program: Current Objectives

- **Food Program w/ Reduced Risk Products**
 - Residue trials, some efficacy & crop safety
 - Crop Grouping
 - International Harmonization, MRL's and Registrations
- **Biopesticide and Organic Support Program**
 - Regulatory support and efficacy
- **Ornamental Horticulture Program**
 - Efficacy and crop safety
- **Public Health Pesticides**

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IR-4 Program

- **Companies that develop and sell plant protection products focus their resources in major markets where there is favorable return on investment.**
- **Potential sales in small markets does not justify the investment in the development of the required data for registration.**
- **The result is a major void for specialty crop growers to protect their crops (fruits, vegetables, herbs, ornamentals and other high value horticultural crops)**

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IR-4 Minor Use Petitions

- **Interregional Project Number 4 (IR-4) conducts field trial data to support registration of minor uses.**
<http://ir4.rutgers.edu/>
- **IR-4 petitions are given an exemption from PRIA fees.**
<http://www.epa.gov/pesticides/regulating/fees/>
- **Same registration process as other section 3 registrations – same PRIA deadlines.**
- **OPP's Minor Use Team Coordinates the review of IR-4 petitions.**



Minor Use Harmonization Efforts

- **Joint review projects with the Health Canada Pest Management Regulatory Agency (PMRA).**
- **Work share projects with California Department of Pesticide Regulation (CDPR).**
- **When possible OPP will harmonize US tolerances to establish same level as existing Codex MRLs.**
- **EPA and IR-4 are working together to revise the existing crop groups in 40 CFR 180.41.**



Tools for Solutions

- **Crop Grouping**
- **Global Zoning**
- **Global Joint Reviews**
- **JMPR/Codex Process Initiatives**
- **Capacity Building**
- **Global Minor Use Foundation**



Crop Grouping – What is it?

- **In the United States established crop groups can be found in the Federal Code of Regulation, Title 40, Section 180.41**
- **The use of crop groups to establish tolerances for multiple commodities based on data from representative commodities provides growers a greater number of necessary pest control tools for U.S. production.**
- **Provides for accurate basis to bridge data for representative crops to related crops within that group.**

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Crop Grouping – What is it?

- **Crop grouping precludes the need to develop residue data for each and every food or feed crop, for every pesticide use on a given food crop.**
- **The EPA still assesses the potential human health risk to exposures to pesticides on all commodities in the crop group.**
- **When the EPA assesses the potential risk for exposure to pesticides on all commodities within a group the agency is ensuring the US food supply is safe when a crop group tolerance is established for a specific chemical.**

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Crop Grouping Activities

- **Multiyear Joint Project involving NAFTA partners (EPA, IR-4, PMRA & AAFC), the International Crop Grouping Consulting Committee (ICGCC) and Codex to evaluate crop (commodity) groups and extrapolation.**
- **NAFTA partners are working to revise existing crop groups (40 CFR 180.41) to add new crops and to create new groups/subgroups.**
- **Additionally the NAFTA partners are working with International stakeholders to modify Codex crop groups to better support global trade and use of extrapolation.**

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U.S. Revision Procedures

The ICGCC Chairperson prepares crop group petitions (Chair Bill Barney – barney@aesop.rutgers.edu).

The ICGCC workgroup reviews and comments on the petitions.

Finalized petitions are submitted to U.S. EPA.

Joint review by both U.S. and Canadian regulatory agencies.

Approval & publication.

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Status of Crop Grouping in the United States

All supporting documentation can be found at [regulations.gov](http://www.regulations.gov) -

Refer to Docket # EPA-HQ-OPP-2006-0766

- **Phase I – Crop Group Project for NAFTA Countries Final Rule Established:**
 - **Crop Group 3-07: Bulb Vegetable Group**
 - **Crop Group 13-07: Berry and Small Fruit Group**
 - **Crop Group 21: Edible Fungi Group**

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Importance of Crop grouping to Minor Uses and Specialty Crops

- **Revision of the Codex Classification of Animal Foods and Feeds (and selection of representative commodities)**
 - **Many difference in MRLs result from differences in crop grouping schemes and different use of representative crops.**
 - **Trying to obtain as much global input into the revision as possible.**
 - **Very important for developing countries – may get MRLs for their crops by simply including them in the classification system.**

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Submission to Crop Group Petitions to NAFTA and Codex

- The U.S. EPA and Canada's PMRA review the crop group petitions submitted by IR-4 and make final recommendations as to what are the appropriate commodities for inclusion in a Crop Group.
- PMRA will adopt these recommendations and the EPA will publish a proposed rule and a final rule to establish crop groups.
- The petition submitted by IR-4 along with the EPA/PMRA recommendations are then submitted to the Chair of the Codex EWG for consideration.

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Status of Crop Grouping in the United States

All supporting documentation can be found at
[regulations.gov](http://www.regulations.gov) -

Refer to Docket # EPA-HQ-OPP-2006-0766

- Phase I – Crop Group Project for NAFTA Countries
Final Rule Established:
 - Crop Group 3-07: Bulb Vegetable Group
 - Crop Group 13-07: Berry and Small Fruit Group
 - Crop Group 21: Edible Fungi Group

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Status of Crop Grouping in the United States

- **Phase II – Crop Group Project for NAFTA Countries**
Final Rule Established:
 - **Crop Group 8-10: Fruiting Vegetable Group**
 - **Crop Group 10-10: Citrus Fruit Group**
 - **Crop Group 11-10: Pome Fruit Group**
 - **Crop Group 20: Oilseed Group**
- **Phase III – Crop Group Project for NAFTA Countries**
Final Rule Established:
 - **Crop Group 12-12: Stone Fruit Group**
 - **Crop Group 14-12: Tree Nut Group**

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Status of Crop Grouping in the US

- **Phase IV – Crop Group Project for NAFTA Countries**
The following pending petitions will be proposed in the Federal Register under Phase IV of the Crop Grouping Project:
 - **Crop Group for Leafy Vegetables**
 - **Crop Group for *Brassica* Head and Stem Vegetables**
 - **Crop Group for Stalk and Stem Vegetables**
 - **Crop Group for Tropical Fruits - Edible peel**
 - **Crop Group for Tropical Fruits - Inedible peel**
- **Anticipate Proposed Rule to Publish March 2014 and Final Rule in Late 2014.**

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Petitions Pending for Future Phases

- **Crop Group for Herbs and Spices**
- **Crop Group for Root and Tuber Vegetables**
- **Crop Group for Leaves of Root and Tuber Vegetables**
- **Crop Group for Legume Vegetables**
- **Crop Group for Foliage of Legume Vegetables**

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Petitions to Be Submitted

- **Crop Group for Cucurbit Vegetables**
- **Crop Group for Cereal Grains**
- **Crop Group for Forage, Fodder & Grasses**
- **Crop Group for Aquatic Vegetables**
- **Crop Group for Teas**

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CCPR: Advance by Commodity Types

- **CCPR first agreed that revise individual commodity groups should not be adopted until all the revisions had been completed.**
- **However, during the 42nd Session of the CCPR it was determined that it would be possible to advance some commodity groups of certain “Commodity Types” as they are completed.**
- **Fruit types is first group to be adopted to date.**

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Codex Progress

- **In 2012 all “fruit type” revisions (citrus fruits, pome fruits, stone fruits, berries and small fruits, and tropical and subtropical fruits- edible and inedible peel) were adopted by the Codex Alimentarius Commission (CAC) and included in the Classification.**
- **The Draft Principles and Guidelines (including Table 1 of representative commodities for fruit type crop groups) were also adopted by the CAC.**

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Codex Progress

- **Groups for bulb vegetables, edible fungi, oilseeds, fruiting vegetables, tree nuts, herbs and spices, Brassica (Cole or Cabbage) Vegetables, Head Cabbages and Flowerhead Cabbages; Leafy Vegetables (Including Brassica Leafy Vegetables); and Stalk and Stem Vegetables are at step 7.**
- **The Committee also began work on additional groups including proposals the Root and Tuber Vegetables Group.**

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Global Zoning and Global Residue Study – Global Tomato Study*

- **The purpose of the Global Residue study is to compare residues of 4 chemicals on tomatoes across a wide variety of geographical and environmental zones.**
- **In order to minimize differences (better focus on location only):**
 - **Identical spray equipment**
 - **Test substances were pre-measured**
 - **A training video on how to conduct the study was posted on YouTube.**
- **Samples included a time zero sample to measure variability other than the environment and samples were taken at 24 and 72 hours after application.**

*funded by US Dept. of Agriculture

GLOBAL RESIDUE STUDY-Tomato



Global Residue Study: Conclusions

- **Calculated MRLs were similar (difference 0.1 ppm or less) across all climatic zones and continents compared to the overall MRL(Complete data set).**
- **Is being analyzed statistically across sample times, climate, etc.**
- **Publication being prepared**



Global Joint Reviews

- **Global Joint Review:** several national authorities evaluate a pesticide active ingredient at the same time- they receive the same submission, develop a joint schedule, and divide the work; at the conclusion each makes its own independent regulatory decision with the goal of harmonization on endpoint selection and MRL establishment.
- **Industry submits the exact same (single) dossier, in OECD format to all regulatory authorities.**

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Global Joint Reviews

- **Now standard way of doing business for new active ingredients.**
- **Expansion of countries involved continues.**
- **Expansion of companies involved.**

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Completed And Current Global Joint Reviews

- **Since 2007 19 joint reviews for new active ingredients have been completed by 3 or more countries.**
- **Currently 10 global joint reviews in progress.**
- **13 proposed global joint reviews for submission in 2013-2017.**
- **Second entry (use expansions); 12 in progress and 21 proposed for 2013-2015.**

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JMPR/Code Process Initiatives

- Streamline of review for priority chemicals
- Continuation of 5/8 Step process in cases where there are no intake concerns
- JMPR use of OECD calculator
- Pilot project on globally reviewed new active ingredient – sulfoxaflor
- Increase capacity of JMPR
- Two active Codex Electronic Working Groups:
 - Minor uses and specialty crops
 - Revision of Codex Classification of Foods and Animal Feeds co-chaired by the Netherlands and the United States.

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Global Capacity Building and Residue Data Generation Project

- US Dept. of Agriculture in cooperation with IR-4, the ASEAN Secretariat, the African Union, and the Inter-America Institute for Cooperation on Agriculture have initiated a global capacity and residue data generation project that will help enable developing countries to contribute to the establishment of international residue standards (i.e., Codex MRLs).
- Funded by Standards and Trade Development Facility with contributions by USDA, US State Dept., US Agency for International Development, the Inter-America Development Bank, and in kind contributions from IR-4, Dow, DuPont, Syngenta, and participating national governments.

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Global Capacity Building and Residue Data Generation Project

- Project Objective: 3-4 year project to develop regional capacity in Asia, Latin America, and Africa for conducting high quality, supervised pesticide residue trials for establishment of Codex MRLs, particularly for minor commodities that are economically important for developing countries.
- 3 Project Phases: Training; Field Trials and Analysis; Data Package and Submission to JMPR.
- 37 countries participating in the training component and 17 countries conducting field trials.

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Global Capacity Building and Residue Data Generation Project

- Project focuses on representative commodities for tropical sub-groups and four low risk pesticides: spinetorem; pyriproxyfen; azoxytrobin; and difenoconazole.
- For most commodities 6 residue trials are planned: guava, date, lychee, avocado, papaya, mango, pineapple, dragon fruit, passion fruit.
- For banana, 12 trials are planned.
- Training phase completed and residue field trial and analysis phase in progress.

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Obstacles to Tolerance Alignment

- Different residue definitions
- Different use patterns, formulations used in the residue field experiments to determine pesticide residues.
- Different number of residue field trials.
- Differences in crop groups.
- Differences in procedures to determine tolerance (MRL) levels among

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Cooperation Opportunities

- North America: NAFTA and Regulatory Cooperation Council (RCC)
- The Organization for Economic Cooperation and Development (OECD)
- JMPR and CCPR
- Other: Bilateral partnerships; other regional partnerships; summits; commodity/chemical specific issues.

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Examples of North American Initiatives

- Progress towards a North American work plan for new active ingredients and use expansions.
- IR-4 (US) and PMC (Canada) partnerships.
- Work sharing and joint reviews of new active ingredients, use expansions, and minor uses routine business; increased participation of Mexico.
- Resolving trade irritants and technology gaps retrospectively and avoidance prospectively.

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Examples of North American Initiatives

- **Regulatory Cooperation Council – initiative to identify mechanisms to encourage registrants to submit applications for joint review to Canada and the US that include increased numbers of minor uses.**
- **RCC expected to help facilitate equal access o products and uses in both countries as well as align maximum residue limits where possible.**
- **Pilot application of an aligned joint submission for a use expansion that included a significant number of minor uses including domestic and import MRLs.**

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Issues Still Exist that Need to be Addressed

- **National authorities developing own regulatory schemes.**
- **Further adoption of tools (for example: calculator)**
- **Agreement on needed number of residue trials, particularly for minor crops; and, residue definition.**
- **Determine MRL alignments that are most important.**

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Useful Websites

Minor Uses and Grower Resources :
<http://www.epa.gov/pesticides/minoruse/>

RD Contacts List: http://www.epa.gov/opprd001/contacts_rd.htm

Chemical Fact Sheets : <http://www.epa.gov/opprd001/factsheets>

IR-4 Web Site: <http://ir4.rutgers.edu/>

**e-CFR Part 180 – TOLERANCE AND EXEMPTIONS FOR PESTICIDE
CHEMICAL RESIDUES IN FOOD:**

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=07d1e201e8a2b13b8328911c124fada9&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl

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Cam sah ha me da!

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Update on ASEAN EWG-MRLs and Work Sharing on Residue Study

Nuansri Tayaputch, Ph.D.
Chair, ASEAN EWG-MRLs

2013 International Symposium on Pesticide Residues
Osong, Korea, November 7, 2013

Crop production in ASEAN

- ASEAN 10 member countries :
Brunei, Cambodia, Indonesia, Lao PDR,
Malaysia, Myanmar, Philippines, Singapore,
Thailand and Vietnam.
- Varieties of crops could be produced in the
region, tropical fruits and vegetables are
considered high value due to export
demand.

Pesticide application and problems from pesticide residues

- Heavy application of pesticides to high valued crops to avoid risk from pest attack
- Extensive monitorings in some ASEAN members revealed the residues in some fruits and vegetables exceeded Codex MRLs
- The problems encountered were from unavailability of Codex MRLs on many crops grown in the region

Problems (continued)

- Differences in accepting levels for Codex MRLs in different importing countries
- Agricultural produce that do not comply with import tolerance/MRL will be rejected or treated at LOQ

Harmonization of ASEAN MRLs and work procedures

- The Sectoral Working Group on Crops of the ASEAN Ministries of Agriculture and Forestry had set up the ASEAN EWG/MRLs in 1996
- The objectives aim at obtaining regional cooperation to facilitate intra and extra ASEAN trade of agricultural commodities and to protect consumers' health.

Harmonization (continued)

- Agreement had been made during the first meeting on procedure in establishing ASEAN MRLs, principle of harmonization, priority of crop/pesticide combination, collation of GAP information
- The process of setting up ASEAN harmonized MRLs bases on scientific protocol and follows Codex procedure.

Principles of Harmonization

- Pesticide proposed must be registered in any countries
- ASEAN MRLs could be adopted from Codex MRLs, if available and acceptable
- If Codex MRLs are not acceptable, modification has to be supported with residue data and/or dietary risk assessment
- If Codex MRLs are not available, establishment will follow Codex procedure using local residue trials and dietary risk assessment

Data requirement for ASEAN MRLs

- Residue data from supervised field trials in relation to national GAP
- Dietary exposure estimate, based on food consumption data and food chemical concentration, using different database for chronic exposure and acute exposure assessment

Residue field trials requirements

- A minimum number of 3 trials are required in the region for tropical fruits and vegetables
- Trials must be conducted under worst case scenario or critical GAP, e.g., max. no. of applications, highest rate, etc.
- In the case of increasing or decreasing of application rate the 25% rule is allowed

Dietary risk assessment data

- 1. Chronic exposure assessment by comparing long-term dietary intake (TMDI, NTMDI) with the acceptable daily intake (ADI)
- Acute exposure assessment by comparing short-term dietary intake (IESTI, NESTI) with the acute reference dose (ARfD)

Extrapolation

- ASEAN MRLs established by extrapolation from one crop to similar crop with Codex MRL, e.g., brassica vegetables to set MRL for cabbage, common beans to string bean, leek to garlic stem, etc.
- Extrapolation was made on case by case basis and consensus required for adoption
- Not many ASEAN MRLs were received from extrapolation due to lack of information on crop grouping and representative crops in the region

Current Status of ASEAN MRLs

- Until 2012, 858 ASEAN MRLs have been established, involving 69 pesticides. Among these, 57 MRLs were deleted leaving 801 MRLs in the active list
- Starting from 2008, data generated by ASEAN members such as Thailand, Indonesia, Malaysia and Singapore could be submitted for establishing 38 MRLs (4.7%)
- All MRLs are subjected to be implemented as national MRLs by all member countries.

ASEAN needs

- Capability building in providing residue data from field trials and performing dietary risk assessment are required for creating more ASEAN MRLs
- Development of global crop grouping and representative crops to facilitate extrapolation from major crops to specialty crops to save cost and resources
- Data sharing among ASEAN members for generating local residue data to reduce the cost and enhance regional cooperation
- Database on national food consumption
- Laboratory training on multi-residues analysis

ASEAN Collaboration/Work Sharing under the Project of ASEAN-EWG/ WTO-STDF/ USDA-IR4

Title-ASEAN Pesticide Residue Data Generation

Project : Strengthening regional capacity to meet pesticides export requirements based on international standards.

Malaysia/Singapore	- pyriproxyfen/mango
Indonesia	- azoxystrobin/dragon fruit
Thailand (DOA/Central Lab)	- spinetoram/mango
Philippines	- chlorantraniliprole/pineapple

Conclusion:

The ASEAN initiation and intensification of collaboration in generating residue data on minor crops will bring great benefits to the region. Future of such collaboration should be extended to other regions in Asia to gain more achievement in setting more MRLs for minor crops.

Thank you for your attention

The Extrapolations to Reduce the Need for Pesticide Residue Trials on Minor Crops in Korea

2013. 11. 7

Son, Kyeong-Ae

National Academy of Agricultural Science,
Rural Development Administration

Contents

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II. Purpose

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- **Regulating the use of all pesticides registration**
- **Establishing Pre-Harvest Interval(PHI) of pesticide uses for growing crops**
- **Protecting against unreasonable adverse ecological effects from pesticides use**
- **Encouraging and promoting introduction and use of safer pest management chemicals and practices.**



I . Background

Agrochemicals Control Act (농약관리법)

○ Rural Development Administration Notification (농촌진흥청 고시)

- Guideline for the Registration of Agrochemical Items and Active ingredients 「농약 및 원제의 등록기준」

Appendix 6: Guidance for the reviewing field trial data

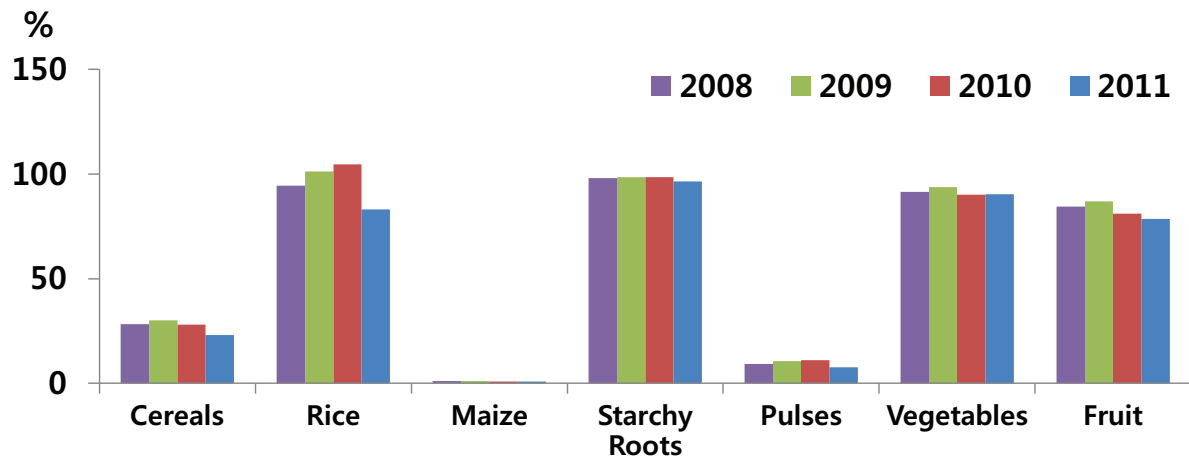
「농약의 잔류성 시험성적서 검토기준」

6-1-1-4-4 After grouping **minor crops with low consumption**, the residue data of the representative crop can be used as data of any crop in the same group/subgroup .

국민의 식품섭취비율이 낮은 소면적 재배작물은 작물군을 분류하여 동일 작물군내의 잔류시험자료를 상호 적용할 수 있다



Self-sufficiency rate of each crop group in Korea



(Source : Korea Rural Economic Institute)



II. Purpose

- Grouping leafy vegetables according to similarity in growth habit, morphology and edible portion
- Comparison of residue levels in crops and dissipation pattern
- Propose example representative crops for each crop group
- Points should be considered in support of some extrapolations



III. Method

- Leafy vegetables field trial
 - ✓ Two times trial for each crop
 - ✓ Two times application with 7 days interval
 - ✓ Four times sampling after last application



- The concentration of diluted solutions

Pesticide	Concentration (mg/kg)	Pesticide	Concentration (mg/kg)
Bifenthrin	10	Dimethomorph	73.4
Chlorfenapyr	20	Pyraclostrobin	41
Fludioxonil	50	Imidacloprid	40
Boscalid	235	Methoxyfenozide	80
Cyazofamid	90		



IV. Results

One time harvesting leafy vegetables



• Growth characteristics and consumption

Crops	Spinach	Edible chrysanthemum	Korean aster
Taxonomy	Chenopodiaceae	Compositae	Compositae
Sowing*/planting	April~October	Year round	Year round
Harvesting	spring 40 days summer 30~35 days fall 50~60 days after sowing	40 days after sowing	Year round Harvest intervals 25~40 days
Consumption (g/person/day)	7.4	0.7	0.02



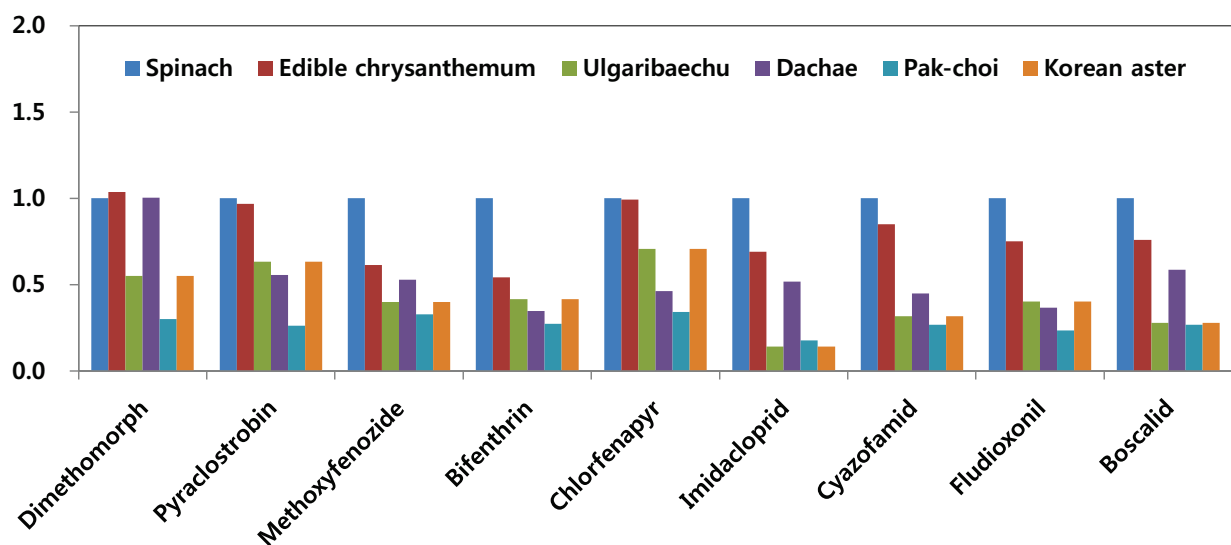


• Growth characteristics and consumption

Crops	Dachae	Ulgaribaechu	Pak-choi
Taxonomy	Cruciferae	Cruciferae	Cruciferae
Sowing	Year round	Year round	Year round
Harvesting after sowing	25~40 days	30~40 days	summer 30~35 days spring, fall 45~50 days
Consumption (g/person/day)	0.02	6.44	0.04



• Comparison of residues in Spinach with those in other crops





• Leafy vegetable group

Group	Representative crop	Extrapolation to the following crop	Characteristics	Codex
1	Ulgaribaechu	Ulgaribaechu, Pak-hoi, Dachae, Chinese cabbage(non-head), Rape	One time harvest, Cruciferae	13B
2	Spinach	Spinach, Edible chrysanthemum, Korean aster(except Gom-chwi)	One time harvest	13A



Continuous harvesting leafy vegetables



• Growth characteristics and consumption

Crop	Perilla leaves	Lettuce	Mustard greens
Taxonomy	Labiatae	Compositae	Cruciferae
Sowing*/planting	Late August	Year round	Year round
Harvesting*	Early October ~ late June	Year round	Year round
Planting space (cm)	10~15× 20~30	15×20	40×20
Consumption (g/person/day)	2.2	3.9	0.3

* The period for raising seedling is about 30 days.

** First harvesting from 50-60 days after sowing



• Growth characteristics and consumption

Crop	Swiss chard	Red leaf chicory	Kale
Taxonomy	Chenopodiaceae	Compositae	Cruciferae
Sowing*/planting	Year round	Year round	Year round
Harvesting**	Year round	Year round	Year round
Planting space (cm)	30×30	20×30	40×40
Consumption (g/person/day)	0.4	0.15	0.15

* The period for raising seedling is about 30 days.

** First harvesting from 50-60 days after sowing

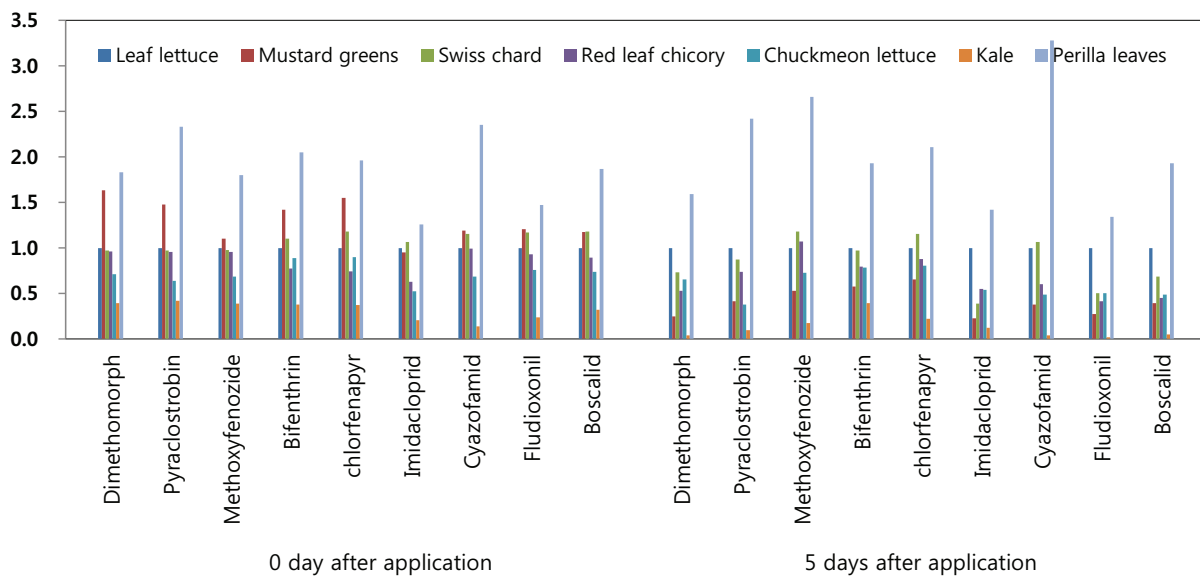




- **Perilla leaves, embossed lettuce & lettuce**
 (Chukmeon lettuce) (Leaf lettuce)



- **Comparison of residues in lettuce with those in other crops**



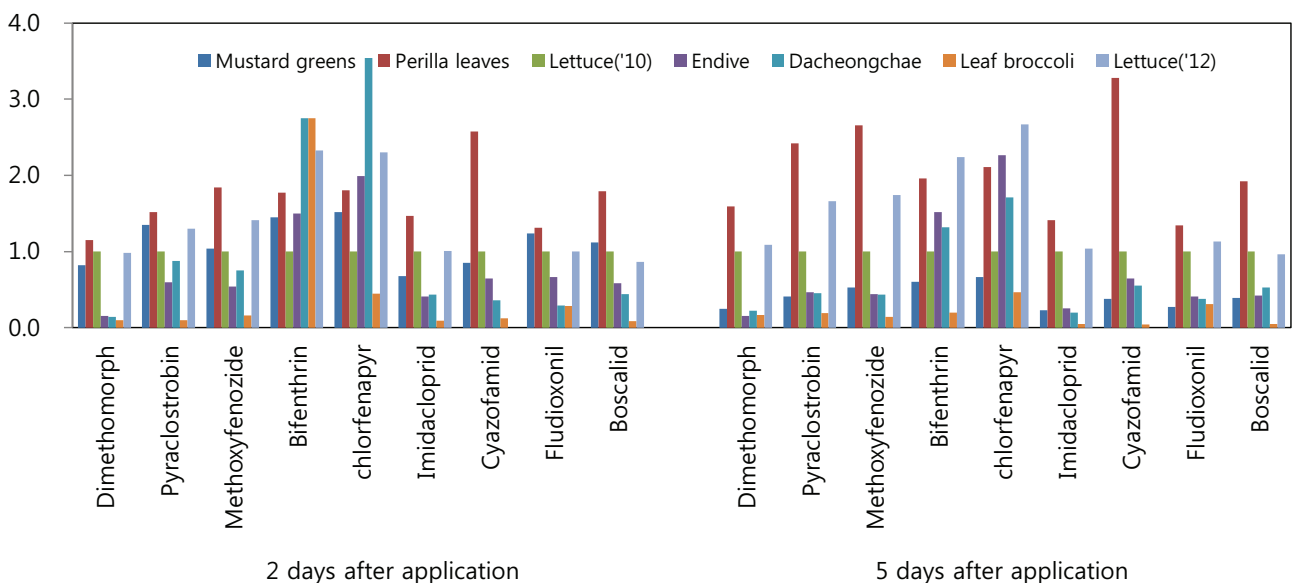


• Growth characteristics and consumption

Crop	Japanese honewort	Leaf broccoli	Dacheongchae
Taxonomy	Umbelliferae	Cruciferae	Cruciferae
Sowing/planting	March ~ April	Year round	Year round
Harvesting	April ~ June	Year round	Leaf 20-30 days, plant 30-50 days after sowing
Harvesting interval	40-45 days	5-10 days	3-10 days
Planting space (cm)	close planting	20x20	Summer 18x20, Fall, Spring 15x15
Consumption (g/person/day)	0.05	0.05	-



• Comparison of residues in lettuce with those in other crops





• Leafy vegetable group

Group	Representative crop	Extrapolation to the following crop	Characteristics	Codex
3	Mustard greens or Perilla leaves	Mustard greens, Leaf broccoli, Kale, Dacheogchae, Korean cabbage	Continuous harvest, Cruciferae	13B
4	Leaf lettuce or Perilla leaves	Leaf lettuce, Swiss chard, Red leaf chicory, Perilla leaves, Endive, Beet leaves	Continuous harvest	13A



Stalk and stem vegetables



Representative crop for field trial ?



Crop	Plant height (cm)	Weight (g)
celery	60~70	700~1000



Crop	Plant height (cm)	Weight (g)
celery	43.4±2.9	253.8±63.2



• Growth characteristics and consumption

Crops	Shallot	Chinese chives
Taxonomy	Liliaceae	Liliaceae
Sowing/planting	Year round	Year round
Harvesting	Year round 45~60 days after sowing	Year round harvest interval 20~25 days
Consumption (g/person/day)	10.95 (Welsh onion)	1.77

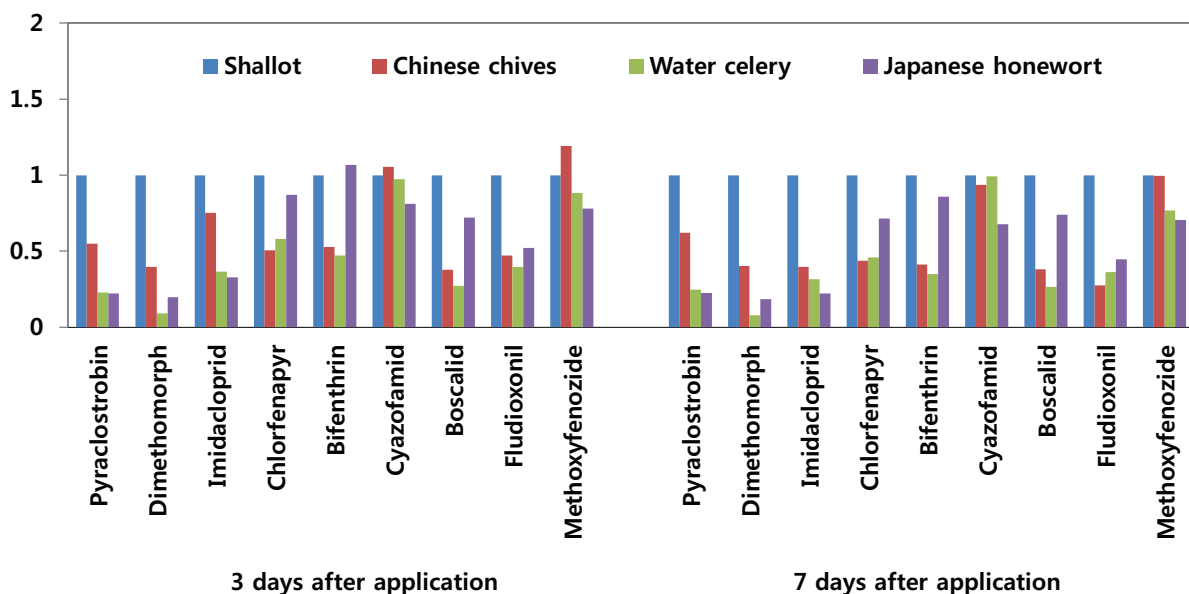


• Growth characteristics and consumption

Crops	Water celery	Japanese honewort
Taxonomy	Umbelliferae	Umbelliferae
Sowing/planting	August~September	March~April
Harvesting	November~April 30~50 days after sowing	April~June harvesting interval 40 days
Consumption (g/person/day)	1.4	0.05



• Comparison of residues in shallot with those in other crops





• Leafy vegetable group

Group	Representative crop	Extrapolation to the following crop	Characteristics	Codex
5	Water celery or shallot	Water celery, Japanese hornwort, Celery	One time harvest, Umbelliferae	17A, 17C
6	Shallot	Shallot, Chinese chives, Leek, Welsh onion, Garlic stem/leaf	One time harvest, Liliaceae	9B



V. Future outlook

Project in progress

The ex officio test on registration of agrochemicals for **Minor use and crops**

- Period : '13 ~ '18
- Budget : \$ 170 million for 6 years



1. Investigation research about incidence in Minor crops of plant diseases, pest and weed and damage
2. Test about Efficacy and crop safety
3. Crop field trials for the generation of data concerning residues
4. Improvement of the system on registration
 - Efficacy evaluation: Efficacy and crop safety extrapolations for minor uses



Summary

- **Data requirements: Extrapolation**

(1) **Efficacy: Does the GAP that can control pest 'X' on crop 'Y', control the same pest on crop 'Z'**

(2) **Crop safety**

(3) **Residues**

① **Critical GAP: outdoors & greenhouse, one time harvesting & continuous harvesting, application rate, spray intervals, pre-harvest interval**

② **Trial parameters: formulation, method etc.**



• Leafy vegetable group

Group	Representative crop	Extrapolation to the following crop	Characteristics	Codex
1	Ulgaribaechu	Ulgaribaechu, Pak-choi, Dachae, Chinese cabbage(non-head), Rape	One time harvest, Cruciferae	13B
2	Spinach	Spinach, Edible chrysanthemum, Korean aster(except Gom-chwi)	One time harvest	13A
3	Mustard greens or Perilla leaves	Mustard greens, Leaf broccoli, Kale, Dacheogchae, Korean cabbage,	Continuous harvest, Cruciferae	13B
4	Leaf lettuce or Perilla leaves	Leaf lettuce, Swiss chard, Red leaf chicory, Perilla leaves, Endive, Beet leaves	Continuous harvest	13A
5	Water celery or Shallot	Water celery, Japanese hornwort, Celery	One time harvest, Umbelliferae	17A, 17C
6	Shallot	Shallot, Chinese chives, Leek, Welsh onion, Garlic stem/leaf	One time harvest, Liliaceae	9B



감 · 사 · 합 · 니 · 다

Thank You