codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

CX/PR 09/41/4-Add.2 March 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Forty first Session

Beijing, China, 20 - 25 April 2009

DRAFT PRINCIPLES AND GUIDANCE ON THE SELECTION OF REPRESENTATIVE COMMODITIES FOR THE EXTRAPOLATION OF MRLS TO COMMODITY GROUPS

The Selection of Representative Commodities, Principles and Guidance

Objective

Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted, but would have similar residue levels. Representative commodities are chosen based on their commercial importance, similar morphology and residue characteristics. Ideally representative commodities are the most economically important crops in production or consumption in a group and have a greater dietary burden and have residue characteristics similar to other members of the commodities group or subgroup. Residue extrapolation is a common consideration utilised by regulators internationally for ensuring that data requirements are only at a level that is scientifically justified in conducting risk assessment and to ensure the regulatory process does not become unnecessarily burdensome especially for minor crops. The objective of this document is to (1) propose criteria for the selection of representative commodities; (2) propose example representative commodities and (3) provide a detailed justification for the selection of the representative commodities (Addendum I). Additional background information is provided in Addendum II to this document.

Representative Commodities

To meet these objectives, Table 1 in this document is provided to (1) separate the selection of representative commodities from the Codex Classification itself; (2) propose representative commodities in parallel with the respective Codex commodity grouping classification revisions; (3) provide flexibility on the selection of representative crops and (4) provide guidance not only to JMPR, but also to product manufacturers and other data generators.

Representative commodities within each Codex Classification commodity group and subgroup will be selected and proposed, based on consideration of all available information and using the following principles:

- A representative commodity should be major in terms of production and consumption.
- A representative commodity should be likely to contain the highest residues.
- A representative commodity should be similar in morphology, growth habit, similar pest problems and edible portion to the related commodities within a group or subgroup.

Addendum I to this document provides detailed background information (bulb vegetables) regarding production, consumption, residues and tolerances, characteristics and justification for selection of the representative commodities according to the indicated principles. This background information assumes that group MRLs will be based on similar GAPs.

To facilitate the global use of the crop groups, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

As proposals for the revision of the Codex Classification are made and revised commodity groupings are developed and provided to the CCPR for their review, proposals on representative commodities will also be provided in parallel with the respective commodity grouping revisions and will advance through the CCPR step process for adoption by the CAC.

As comments are addressed on the revisions of the classification and the proposed representative commodities and these are approved by the CCPR and accepted by the CAC, two separate documents will be created and maintained: (1) the revised Codex Classification (without mention of representative commodities) and (2) a guidance document on the selection of representative commodities

The JMPR should be advised to use the representative crops adopted by the CAC However, JMPR may use other representative commodities (including those which may be specifically requested by member nations) on a case-by-case basis. The JMPR will be requested to provide to the CCPR justification for the use of any alternative representative commodities

Codex Group / Subgroup	Examples of Representative Commodities ^{1,2}	Extrapolation to the following commodities:			
Group 009 Bulb Vegetables	(1) Bulb onion and (2) Spring Onion	Chives; Chives, Chinese; Daylilly; Elegans hosta; Fritillaria (bulb); Fritillaria (green); Garlic; Garlic chives; Garlic, Great-headed; Garlic, Serpent; Kurrat; Lady's leek; Leek; Lily; Onion, Beltsville bunching; Onion, Bulb; Onion, Chinese; Onion, fresh; Onion macrostem; Onion, Pearl; Onion, potato; Onion, Welsh; Shallot; Silverskin onion; Spring onion; Tree onion; Wild leek			
Subgroup 009A, Bulb Onions	Bulb onion	Daylilly; Fritillaria (bulb); Garlic; Garlic, Great-headed; Garlic, Serpent; Lily; Onion, Bulb; Onion, Chinese; Shallot; Silverskin onion			
Subgroup 009B, Green Onions	Spring onion	Chives; Chives, Chinese; Elegans hosta; Fritillaria (green); Garlic chives; Kurrat; Lady's leek; Leek; Onion, Beltsville bunching; Onion, fresh; Onion macrostem; Onion, Pearl; Onion, potato; Onion, Welsh; Spring onion; Tree onion; Wild leek			

Table 1.	Examples o	f the Selection	of Representative	Commodities for	the Extrapolation	of MRLs to Commodity (Froups
----------	------------	-----------------	-------------------	------------------------	-------------------	------------------------	--------

¹ Alternative representative commodities may be selected based on documented regional/country differences in dietary consumption and/or areas of production.

² See Addendum II to this document for detailed background information (bulb vegetables) regarding production, consumption, residues and tolerances, characteristics and justification for selection of the representative commodities according to the indicated principles.

ADDENDUM I to: Draft Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups

The Selection of Representative Commodities, Principles and Guidance

Background

The purpose of this addendum to the document "Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups" is to provide background information on the rationale for the selection of representative commodities in Table 1 of the guidance document according to the proposed principles:

- A representative commodity should be major in terms of production and consumption.
- A representative commodity should be likely to contain the highest residues.
- A representative commodity should be similar in morphology, growth habit, similar pest problems and edible portion to the related commodities within a group or subgroup.

A. Bulb Vegetables

Proposed representative commodities for Group 009 Bulb Vegetables from Table 1 in the Guidance document are as follows:

Codex Group / Subgroup	Proposed Representative Commodities ¹	Extrapolation to the following commodities:
Group 009 Bulb Vegetables	(1) Bulb onion and (2) Spring Onion	Chives; Chives, Chinese; Daylilly; Elegans hosta; Fritillaria (bulb); Fritillaria (green); Garlic; Garlic chives; Garlic, Great-headed; Garlic, Serpent; Kurrat; Lady's leek; Leek; Lily; Onion, Beltsville bunching; Onion, Bulb; Onion, Chinese; Onion, fresh; Onion macrostem; Onion, Pearl; Onion, potato; Onion, Welsh; Shallot; Silverskin onion; Spring onion; Tree onion; Wild leek
Subgroup 009A, Bulb Onions	Bulb onion	Daylilly; Fritillaria (bulb); Garlic; Garlic, Great-headed; Garlic, Serpent; Lily; Onion, Bulb; Onion, Chinese; Shallot; Silverskin onion
Subgroup 009B, Green Onions	Spring onion	Chives; Chives, Chinese; Elegans hosta; Fritillaria (green); Garlic chives; Kurrat; Lady's leek; Leek; Onion, Beltsville bunching; Onion, fresh; Onion, macrostem; Onion, Pearl; Onion, potato; Onion, Welsh; Spring onion; Tree onion; Wild leek

¹ Alternative representative commodities may be selected based on documented regional/country differences in dietary consumption and/or areas of production.

A.1. Introduction – Bulb Vegetables

There are many vegetables in the plant family 'Liliaceae' that are grown commercially and sold and consumed in most regions and countries. There are over 500 *Allium* species alone, but not all are economically important as a food crop. The Codex Classification of Foods and Animal Feeds currently includes 12 commodities in Group 009 Bulb Vegetables. The proposed draft revision includes 10 commodities in Group 009A (Bulb onions) and 17 commodities in Group 009B (Green Onions).

All commodities proposed in the new commodity group are from same botanical family, Liliaceae, which is also called Amaryllidaceae and/or Alliaceae, and 22 of them are from the genus *Allium*. The original Bulb vegetable Group 009 contained only commodities from the genus *Allium* except for the genus *Foeniculum* (Fennel, bulb; Fennel, Italina and Fennel, Roman). Four proposed commodities that are not *Allium* species include the Daylily [*Hemerocallis fulva* (L.) L.]; *Elegans hosta*, [*Hosta sieboldiana* (Hook.) Engl.]; Fritillaria, [*Fritillaria camchatcensis* (L.) Ker. Gawl.]; and Lily [*Lilium* spp.]. These commodities are very similar to some of the *Allium* species in terms of physical characteristics and cultural practices.

Two subgroups are proposed (1) Group 009A, Bulb Onions and (2) Group 009B, Green Onions. Bulb onions are bulb vegetables with mature bulbs. The entire bulb may be consumed after removal of the parchment-like skin. A maximum residue limit for bulb onions would apply to the whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached. Green onions are bulb vegetables with immature bulbs. The immature bulbs and leaves and stems may also be consumed. A maximum residue limit for green onions would apply to the whole vegetable after removal of roots and adhering soil.

A.2. Production – Bulb Vegetables:

Bulb onions and green onions are the most widely grown bulb vegetables in the world with the largest acreage and they represent the majority of the bulb vegetable markets.

Table 2 provides bulb vegetable production in various countries that are members of the International Crop Grouping Consulting Committee (ICGCC) and information on major bulb vegetable production acreages and yield is provided in Table 3 (FAO Statistics). The major world bulb onion producing region is Asia followed by Europe, Africa, and then North America (Table 3). The major green onion producing regions are Asia followed by Central America and then Africa, while the major garlic producing regions are Asia, Europe, South America, Africa, and North America (Table 3).

A.2. Production – Bulb Vegetables (continued):

Production of Other Bulb Vegetables:

Garlic: Asia leads the world in garlic and China produces over 50% of the world supply of garlic.

<u>Shallot</u>: Production regions include Europe with small scale production in the U.S. includes 50 acres in Washington State for dried shallots and about 950 acres in Louisiana and other southern states for green shallots. Ontario, Quebec and British Columbia, Canada with 2200 lbs of seed bulbs yield on average 10,000 to 15,000 lbs of shallots (CHAPUT 2004b).

<u>Fritillaria</u>: Production in U.S.: Fritillarias are distributed in 15 States in the United States. Most widely distributed are *Fritillaria atropurpurea* Nutt (spotted fritillary) in 13 States, and Fritillaria pudica (Pursh) Spreng (yellow fritillary) in 11 States. There is no specific production data for fritillarias but they are grown for their edible bulb and leaves.

<u>Leek</u>: Domesticated in the eastern Mediterranean and now are cultivated throughout the world. Crop yields 500 cases per acre (205 cases/ha) in Ontario, Canada (CHAPUT 2004a). Production in U.S.: Includes California, New Jersey, Michigan, and Virginia, and a total of 594 acres in California in 2004 (SISCO 2004a).

Daylily and Lily: Daylilies are reportedly grown in China, Japan, and Europe and Lilies in Japan (Table 2).

<u>Fresh onion</u>: Grown in China and Japan which grew 751 acres producing 5350 tons in 2000 (NAGASAWA 2004b).

Lady's leek: Widely distributed in the US, Canada and Mexico.

Chinese chive: Both China and Japan have reported production of Chinese chives (Table 2).

Macrostem onion: Grown in China and Korea which has reported 288 ha with 4,290 M/T (OH 2004a).

Tree onion: Tree onion is reported to be grown in Asia and the US (Florida).

<u>Welsh onion</u>: Grown in Europe, China, Japan, and Korea (Table 2). Also grown in California and Hawaii, where in 2002 production was 125 acres (KAWATE 2004a). It is also grown in Europe, China, Japan, and Korea (Table 2).

Table 2. Bulb Vegetable Production Regions/Countries (Based on FAO Statistics and information provided by the members of the International Crop Grouping Consulting Committee)

Commodites	US	Australia	Canada	China	Japan	Korea	Mexico	Africa	Europe	Central America	South America
Chinese chive				\checkmark							
Chive	\checkmark		\checkmark	\checkmark	\checkmark				\checkmark		
Daylily	\checkmark				\checkmark				\checkmark		
Elegans hosta					\checkmark	\checkmark					
Fritillaria	\checkmark		\checkmark								
Garlic	\checkmark	\checkmark									
Canadian garlic	\checkmark		\checkmark						\checkmark		
Great headed garlic	\checkmark										
Leek	\checkmark		\checkmark						\checkmark		
Lady's leek	\checkmark		\checkmark				\checkmark				
Lily					\checkmark						
Beltsville bunching onion	\checkmark		\checkmark		\checkmark	\checkmark					
Bulb onion	\checkmark	\checkmark									
Chinese onion					\checkmark						
Fresh onion				\checkmark	\checkmark						
Green onion	\checkmark	\checkmark									
Macrostem onion						\checkmark					
Potato onion	\checkmark										
Tree onion	\checkmark										
Welsh onion	\checkmark				\checkmark	\checkmark					
Shallot											
Wild leek											
Wild onion											

Note: Shaded commodities are grown world-wide.

Countries	Bulb Onion	Green Onion/Shallot	Garlic
Australia	5,000 Ha 245,000 Tonnes	NA	NA
Canada	6,962 Ha 237,147 Tonnes	NA	NA
China	1,000,900 Ha	27,500 Ha	692,400 Ha
	20,552,000 Tonnes	805,000 Tonnes	12,088,000 Tonnes
India	619,500 Ha 8,178,300 Tonnes	NA	147,000 Ha 645,000 Tonnes
Japan	24,500 Ha	25,000 Ha	2,000 Ha
	1,165,000 Tonnes	560,000 Tonnes	20,000 Tonnes
Korea, Republic of	15,000 Ha	20,000 Ha	27,500 Ha
	855,000 Tonnes	535,000 Tonnes	325,000 Tonnes
Korea, Democractic	7,000 Ha	7,500 Ha	8,500 Ha
People's Republic of	84,000 Tonnes	98,000 Tonnes	95,000 Tonnes
U.S.	64,460 Ha 3,602,090 Tonnes	NA	12,060 Ha 221,810 Tonnes
Africa	312,840 Ha	44,350 Ha	38,873 Ha
	5,033,530 Tonnes	538,525 Tonnes	356,610 Tonnes
Central America	52,665 Ha	12,580 Ha	6,135 Ha
	1,371,916 Tonnes	150,435 Tonnes	50,620 Tonnes
North America	71,427 Ha 3,839,287 Tonnes	NA	12,060 Ha 221,810 Tonnes
South America	157,124 Ha	17,050 Ha	41,435 Ha
	3,795,326 Tonnes	154,500 Tonnes	351,164 Tonnes
Asia	2,425,440 Ha	112,360 Ha	994,489 Ha
	41,556,882 Tonnes	2,319,666 Tonnes	13,881,086 Tonnes
Europe	409,844 Ha	15,415 Ha	106,719 На
	8,252,166 Tonnes	234,300 Tonnes	785,845 Tonnes
World Total	3,451,941 Ha	208,069 Ha	1,204,711 Ha
	64,475,126 Tonnes	3,588,336 Tonnes	15,686,310 Tonnes

A.3. Consumption – Bulb Vegetables:

The bulb vegetable commodities in the proposed crop group are herbaceous annual, biennial or perennial plants cultivated as annuals and grown for their bulb and/or its leaf blades and leaf bases and stalks. Consumption data in the FAOSTAT website only includes the general category of "onion" so these data are not included in this document. However, all of the bulb onions and green onions are used similarly and they are cooked or eaten raw in vegetable dishes, in soups or salads, and used fresh or dehydrated for flavors. Many of these bulb vegetables also have medicinal properties. There are no processed commodities for any members of the Bulb vegetable group. The portion analyzed compared to edible portions consumed are shown in Table 4.

Commodity	Commodity Analyzed	Edible Portion Consumed
Daylily	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Young shoots, flowers, and bulbs.
Fritillaria, bulb	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Bulb
Garlic	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Cloves (small bulbs enclosed in scales).
Garlic, Great- headed	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Cloves (small bulbs enclosed in scales).
Garlic, Serpent	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Flower stalk or scape and bulb.
Lily	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Bulblets and leaves.
Onion, Bulb	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Whole bulb after peeling
Onion, Chinese	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Bulb
Shallot	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Bulb with scales removed for dry
Silverskin onion	Whole bulb commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	Bulb

Table 4.	Bulb	Vegetable	Portion	Analyze	ed for t	he RA	C and	the	Edible	Portion	Consumed	1.

Commodity	Commodity Analyzed	Edible Portion Consumed
Chives	Whole vegetable after removal of roots and adhering soil	Leaves, pseudostems, and immature bulb
Chives, Chinese	Whole vegetable after removal of roots and adhering soil	Mainly leaves and young inflorescences (buds and stalks) flower
Elegans hosta	Whole vegetable after removal of roots and adhering soil	Flower is edible, and young leaves and leaf stalks are eaten when soft.
Fritillaria (green)	Whole vegetable after removal of roots and adhering soil	Leaves and young inflorescences (buds and stalks)
Garlic chives	Whole vegetable after removal of roots and adhering soil	Leaves and young inflorescences (buds and stalks)
Kurrat	Whole vegetable after removal of roots and adhering soil	Whole plant without leaves
Lady's leek	Whole vegetable after removal of roots and adhering soil	Leaves and bulb
Leek	Whole vegetable after removal of roots and adhering soil	Leaves and bulb
Onion, Beltsville bunching	Whole vegetable after removal of roots and adhering soil	Bulblet and leaves
Onion, fresh	Whole vegetable after removal of roots and adhering soil	Leaves and pseudostems.
Onion, macrostem	Whole vegetable after removal of roots and adhering soil	Corn-like shoots and bulbs.
Onion, pearl	Whole vegetable after removal of roots and adhering soil	Bulb
Onion, potato	Whole vegetable after removal of roots and adhering soil	Bulb after outer scales
Onion, Welsh	Whole vegetable after removal of roots and adhering soil	Thick leaves and leaf bases, and seeds.
Spring Onion	Whole vegetable after removal of roots and adhering soil	Whole plant, leaves, pseudostems and immature bulb
Tree Onion	Whole vegetable after removal of roots and adhering soil	Top bulblets or bulbils and leaves
Wild leek	Whole vegetable after removal of roots and adhering soil	Whole plant without roots

Tabl	e 4 (continued).	Bulb	Vegetable Portion	Analyzed for	the RAC and th	e Edible Portion	Consumed.

A.4. Residues and Tolerances – Bulb Vegetables:

Table 5 shows bulb vegetable tolerances from Codex, the EU and the US. Green onion tolerances are generally higher than bulb onion tolerances. During pesticide applications the stalk and stems of green onions are exposed to pesticide applications and hence the stalk and stem of green onion are also analyzed. This supports the establishment of the two proposed subgroups. There are many established tolerances for the proposed representative commodities (bulb onions and spring onion) which supports the establishment of these commodities as representative crops for their respective subgroups.

Table 5. Tolerances established on BulbVegetable Group 009

	Garlic (ppm)			Garlic, Great Headed (ppm)			
	(Group	009A, Bulb	(Group 009A, Bulb Onions)				
Compound	US	Codex	EU	US	Codex	EU	
Acetamiprid	0.02		(0.01)	0.02			
Azinphos-methyl	2	(0.5)	(0.05)	2	(0.5)		
Azoxystrobin	1		(0.05)	1			
Bensulide	0.1			0.1			
Boscalid	3		(0.5)	3			
Bromoxynil	0.1		(0.05)	0.1			
Captan	0.05		(0.02)	0.05			
Carbaryl							
Carboxin	0.2		(0.1)	0.2			
Carfentrazone-ethyl	0.1		(0.01)	0.1			
Chlorothalonil	0.5		0.5	0.5			
Chlorpyrifos	0.5		(0.05)	0.5			
Clethodim	0.2	0.5	0.5	0.2			
Cymoxanil	0.05		0.05	0.05			
Cypermethrin	0.1		0.1	0.1			
Cyprodinil	0.6		(0.3)	0.6			
Cyromazine	0.2		(0.05)	0.2			
DCPA	1		1	1			
Deltamethrin	0.1		0.1	0.1			
Diazinon	0.75		(0.01)	0.75			
Dicloran	5		(0.5)	10			
Dimethenamid	0.01	0.01	0.01	0.01			
Dimethomorph	2		(0.1)	2			
Ethofumesate	0.25		(0.05)	0.25			
Fluazifop	0.5		2	0.5			
Fludioxonil	0.02		0.05	0.02			
Flumioxazin	0.02		0.05	0.02			
Fluopicolide	7		(0.01)	7			
Fluroxypyr	0.03		0.05	0.03			
Fosetyl-Al	0.5		2	0.5			

(FASonline: mrldatabase.com; tolerances as of February 11, 2009)

	Garlic (ppm) (Group 009A, Bulb Onions)			Garlic, Great Headed (ppm) (Group 009A, Bulb Onions)			
Compound	US	Codex	EU	US	Codex	EU	
Gamma Cyhalothrin	0.1			0.1			
Glyphosate	0.2		(0.1)	0.2			
Inorganic bromide resulting from fumigation	50		(0.05)	20			
Iprodione	0.1		0.2	0.5			
Lambda Cyhalothrin	0.1		(0.02)	0.1			
Malathion	8		(0.02)	8			
Maleic hydrazide	15		15	15			
Mancozeb	0.5		(0.1)	0.5			
Mandipropamid	0.05		(0.01)	0.05			
Maneb	7	(0.5)	(0.1)	7			
Metalaxyl	3		(0.5)	3			
Methyl Parathion	1		(0.02)	1			
Oxamyl	0.2		(0.01)	0.2			
Oxydemeton- methyl	0.05		(0.02)	0.05			
Oxyfluorfen	0.05		0.05	0.05			
Paraquat dichloride	0.1		(0.02)	0.1			
Pendimethalin	0.1		(0.05)	0.1			
Permethrin	0.1		(0.05)	0.1			
Propiconazole	0.2		(0.05)	0.2			
Pyraclostrobin	0.9	(0.05)	(0.2)	0.9			
Pyrimethanil	0.1		(0.05)	0.1			
Pyriproxyfen	0.7		(0.05)	0.7			
S-metolachlor	0.1		(0.05)	0.1			
Sethoxydim	1		(0.5)	1			
Spinetoram	0.1		(0.05)	0.1			
Spinosad	0.1		0.1	0.1			
Spirotetramat	0.3		(0.1)	0.3			
Tebuconazole	0.2		(0.1)	0.2			
Thiophanate-methyl	0.5		(0.1)	0.5			
Trifluralin	0.05		0.5	0.05			
Zeta-Cypermethrin	0.1		0.1	0.1			

(FASonline: mrldatabase.com; tolerances as of February 11, 2009)

	Onion, Bulb (ppm) (Group 009A, Bulb Onions)				
Compound	US	Codex	EU		
Acetamiprid	0.02		(0.01)		
Azinphos-methyl	2	(0.5)	(0.05)		
Azoxystrobin	1		(0.05)		
Bensulide	0.1				
Boscalid	3		3		
Bromoxynil	0.1		(0.05)		
Captan	0.05		(0.02)		
Carbaryl					
Carboxin	0.2		(0.1)		
Carfentrazone-ethyl	0.1		(0.01)		
Chlorothalonil	0.5	0.5	0.5		
Chlorpyrifos	0.5	(0.2)	(0.2)		
Clethodim	0.2	0.5	0.5		
Cymoxanil	0.05		0.5		
Cypermethrin	0.1	0.1	0.1		
Cyprodinil	0.6	(0.3)	(0.3)		
Cyromazine	0.2	(0.1)	(0.05)		
DCPA	1		1		
Deltamethrin	0.1	(0.05)	0.1		
Diazinon	0.75	(0.05)	(0.05)		
Dicloran	10	(0.2)	(0.2)		
Dimethenamid	0.01	0.01	0.01		
Dimethomorph	2		(0.1)		
Ethofumesate	0.25		(0.05)		
Fenamidone	0.2		(0.02)		
Fluazifop	0.5		(0.3)		
Fludioxonil	0.2	0.5	(0.1)		
Flumioxazin	0.02		0.05		
Fluopicolide	7		(0.01)		
Fluroxypyr	0.03		0.05		
Fosetyl-Al	0.5		50		
Gamma Cyhalothrin	0.1				
Glyphosate	0.2		(0.1)		
Inorganic bromide resulting from fumigation	20		(0.05)		

Note: That shaded cells indicate that the tolerance is established for the respective crop group rather than for the individual commodity.

(FASonline: mrldatabase.com; tolerances as of February 11, 2009)

	Onion, Bulb (ppm) (Group 009A, Bulb Onions)					
Compound	US Codex EU					
Iprodione	0.5	(0.2)	(0.2)			
Lambda Cyhalothrin	0.1		(0.02)			
Malathion	8	(1)	(0.02)			
Maleic hydrazide	15	15	15			
Mancozeb	0.5	0.5	1			
Mandipropamid	0.05		(0.01)			
Maneb	7	(0.5)	(1)			
Metalaxyl	3	(2)	(0.5)			
Methyl Parathion	1		(0.02)			
Oxamyl	0.2		(0.01)			
Oxydemeton-methyl	0.05		(0.02)			
Oxyfluorfen	0.05		0.05			
Paraquat dichloride	0.1		(0.02)			
Pendimethalin	0.1		(0.05)			
Permethrin	0.1		(0.05)			
Propiconazole	0.2		(0.05)			
Pyraclostrobin	0.9	(0.2)	(0.2)			
Pyrimethanil	0.1	0.2	0.1			
Pyriproxyfen	0.15		(0.05)			
S-metolachlor	0.1		(0.05)			
Sethoxydim	1		(0.5)			
Spinetoram	0.1		(0.05)			
Spinosad	0.1		0.2			
Spirotetramat	0.3		(0.1)			
Tebuconazole	0.2		(0.05)			
Thiophanate-methyl	0.5		(0.1)			
Trifluralin	0.05		0.5			
Zeta-Cypermethrin	0.1	0.1	0.1			

(FASonline:	mrldatabase.	com; tolerances	s as of February	11, 2009)
-------------	--------------	-----------------	------------------	-----------

	Oni (Group	Onion, Green (ppm) (Group 009B, Green Onions)		Onion, Potato (ppm) (Group 009B, Green Onions)		
Compound	US	Codex	EU	US	Codex	EU
Acetamiprid	4.5			0.02		
Azoxystrobin	7.5					
Boscalid	3			3		
Bromoxynil						
Captan	0.05			0.05		
Carfentrazone-ethyl	0.1			0.1		
Chlorothalonil	5					
Clethodim	2					
Cymoxanil	1.1			0.05		
Cypermethrin	6		(0.05)			
Cyprodinil	4					
Cyromazine	3			3		
Deltamethrin	1.5					
Diazinon	0.75					
Dimethenamid	0.01					
Dimethomorph	2			2		
Fenamidone	1.5					
Fludioxonil	7			0.02		
Flumioxazin						
Fluopicolide	7			7		
Fosetyl-Al	10					
Glyphosate	0.2			0.2		
Inorganic bromide resulting from fumigation	20					
Malathion	8	(5)	(3)			
Mandipropamid	4					
Metalaxyl	10					
Methomyl	3					
Methoxyfenozide	5					

(FASonline:	mrldatabase.com	; tolerances as	of February	11, 2009)
-------------	-----------------	-----------------	-------------	-----------

	Onion, Green (ppm) (Group 009B, Green Onions)		On (Group	(ppm) n Onions)		
Compound	US	Codex	EU	US Codex		EU
Paraquat dichloride	0.05					
Pendimethalin	0.2					
Propiconazole	9					
Pyraclostrobin	0.9			0.9		
Pyrimethanil	2	3				
Pyriproxyfen	0.7			0.7		
S-metolachlor	2					
Sethoxydim	1			1		
Spinetoram	2			0.1		
Spinosad	2			0.1		
Spirotetramat				0.3		
Tebuconazole	1.3			0.2		
Thiophanate-methyl	3					
Trifluralin	0.05			0.05		
Zeta-Cypermethrin	3					

(FASonline: mrldatabase.com; tolerances as of February 11, 2009)

	Onion, Tree (ppm) (Group 009B, Green Onions)		Onion, Welsh (ppm) (Group 009B, Green Onions)			
Compound	US	Codex	EU	US Codex		EU
Acetamiprid	4.5			4.5		(0.01)
Boscalid	3			3		(0.5)
Captan	0.05			0.05		(0.02)
Carfentrazone-ethyl	0.1			0.1		(0.01)
Cymoxanil	1.1			1.1		(0.05)
Cyromazine	3			3		(0.05)
Dimethenamid				0.01		0.01
Dimethomorph	2			2		(0.3)
Fenamidone				1.5		(0.02)
Fludioxonil	0.02			0.02		0.3
Fluopicolide	7			7		(0.01)
Glyphosate	0.2			0.2		(0.1)
Methoxyfenozide	5			5		(0.02)
Pendimethalin				0.2		(0.05)
Pyraclostrobin	0.9			0.9		(0.02)
Pyriproxyfen	0.7			0.7		(0.05)
Sethoxydim	1			1		(0.5)
Spinetoram	0.1			0.1		(0.05)
Spinosad	0.1			0.1		0.2
Tebuconazole	1.3			1.3		(0.5)
Trifluralin	0.05			0.05		0.5

(FASonline: mrldatabase.com; tolerances as of February 11, 2009)

	Leeks (ppm) (Group 009B, Green Onions)					
Compound	US Codex EU					
Acetamiprid	4.5		(0.01)			
Boscalid	3		5			
Captan	0.05		2			
Carfentrazone-ethyl	0.1		(0.01)			
Cymoxanil	1.1		(0.05)			
Cyromazine	3		(0.05)			
Dimethenamid	0.01		0.01			
Dimethomorph	2		(0.2)			
Fenamidone	1.5		(0.02)			
Fludioxonil	0.02		0.05			
Fluopicolide	7		(0.3)			
Glyphosate	0.2		(0.1)			
Lambda Cyhalothrin	0.15		0.3			
Malathion	8		(0.02)			
Methomyl	3		(0.05)			
Methoxyfenozide	5		(0.02)			
Pendimethalin	0.2		(0.05)			
Pyraclostrobin	0.9	(0.7)	(0.5)			
Pyriproxyfen	0.7		(0.05)			
Sethoxydim	1		(0.5)			
Spinetoram	0.1		(0.05)			
Spinosad	0.1		0.5			
Tebuconazole	1.3		(1)			
Trifluralin	0.05		0.5			

A.5. Characteristics (morphology, edible portions, growth habits, pest problems and livestock feed items) – Bulb Vegetables:

The 27 commodities in the proposed group are herbaceous annual, biennial or perennial cool season plants cultivated as annual crops. Onions are one of the few vegetables that are monocots. The cultivation of onions for over 5,000 years has led to a huge range of cultivars that can vary widely in edible bulb shapes, leaf and flower types. They are grown for their edible bulb and/or its leaf blades and leaf bases, flowers, and stalks. The Alliums are best known for their distinctive smell and taste. Characteristics that identify the onion family include bulb growth (single or in clusters), time of flowering, flower color, absence of bulbils in the inflorescence, and type of food storage structure. Plant breeders have found that many members of the bulb vegetable group can cross and bear fertile hybrids. When a species or hybrids include many cultivars such as the Alliums, they are arranged by taxonomists in groups. For example shallots belong to the "Aggregatum group", which includes the potato onion. Both bulb onion and green onions have similar uses and are cooked or eaten raw in vegetable dishes, in soups or salads, and used fresh or dehydrated for flavors. Most of these bulb vegetables also have medicinal properties.

Members of the bulb vegetable group 009 are attacked by many leaf and/or bulb pests, which include several insect, plant disease organisms (bacterial, fungal and viral), nematode and weed pest problems. Onions are weak competitors with weeds. The fact that most of these bulb vegetables are in the same genus with similar biological and cultural aspects indicates they should also encounter similar pest problems, hence have similar needs for pest control products with similar use patterns.

There are no significant animal feed items associated with any of the current or proposed members of the Bulb vegetables group 009. Members of the bulb vegetable group are considered undesirable as a livestock feed for dairy cattle because they leave a distinct odor to the milk. Therefore, since there are no animal feed items, there is a no reasonable expectation of residues in meat, milk, poultry or eggs.

A.6. Conclusion – Bulb Vegetables:

Representative crops (Bulb onion and Spring onion) for Group 009 Bulb Vegetables were selected based on the principals in the Guidance document as follows:

(1) <u>A representative commodity should be major in terms of production and consumption:</u>

The proposed representative crops (bulb onion and spring onion) are the most widely grown bulb commodities throughout the world (see Tables 2 and 3).

(2) <u>A representative commodity should be likely to contain the highest residues.</u>

The similarities in green onion tolerances which are generally higher than bulb onions support the establishment of the two subgroups (Bulb onions and green onions).

Residues for the proposed representative commodity (bulb onion) for subgroup 009A are similar to the residues of garlic and the great headed garlic (Table 5). This would be expected given the similar morphology and growth habits of these commodities. Given the higher production of bulb onions compared to garlic it is reasonable to propose bulb onion as the representative commodity for subgroup 009A.

Residues of the proposed representative commodity (spring onion) for subgroup 009B are generally higher than residues of the potato onion, the tree onion and the Welsh onion (Table 5). Given the higher production of spring onion (Table 3), it is reasonable to propose spring onion as the representative commodity for subgroup 009B.

(3) <u>A representative commodity should be similar in morphology, growth habit, similar pest problems and edible portion to the related commodities within a group or subgroup:</u>

The bulb vegetable commodity group and subgroups consists of commodities with similar cultural practices, edible food portions (bulb vs. leaves), residue levels, geographical locations, similar pest problems and lack of animal feed items.

A.7. References – Bulb Vegetables:

CHAPUT 2004a: Chaput, J. 2004a. Personal communications. Bulb Vegetables in Canada. 17 Aug. 04.

- CHAPUT 2004b: Chaput, J. 2004b. Personal communications. Bulb Vegetables in Canada. 10 Sept. 04.
- FAO Statistics: FAO Statistics 2007. http://faostat.fao.org/faostat/form?collection=Production. Crops.
- KAWATE 2004a: Kawate, M. 2004a. Personal communications. Bulb vegetables data from "Hawaii Statistics of Agriculture of 2002". Honolulu, HI. 30 April 04.
- NAGASAWA 2004a: Nagasawa, N. and J. Ikeda 2004a. Personal communications. Bulb vegetables data from "Statistics of Agriculture, Forestry and Fisheries" by Japanese MAFF. Japan, 31 May 04.
- NAGASAWA 2004b: Nagasawa, N. and J. Ikeda 2004b. Personal communications. Bulb vegetables data from "Statistics of Agriculture, Forestry and Fisheries" by Japanese MAFF. Japan, 23 to 25 Aug. 04.
- OH 2004a: OH, B-Y 2004d. Personal communications. Bulb vegetables data. Korea, 11 Oct. 04
- SISCO 2004a. Sisco, R. 2004a. Personal communications. Bulb Vegetables. University of California at Davis, Davis, CA. 11 MAY 04.

ADDENDUM II: Background Information for the Draft Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups

Background

- 1. Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same crop group or subgroup for which trials have not been conducted, but would have similar residue levels. Representative commodities are chosen based on their commercial importance, similar morphology and residue characteristics. Ideally representative crops are the most economically important crops in production or consumption in a crop group and have a greater dietary burden and have residue characteristics similar to other members of the crop group or subgroup. Residue extrapolation is a common consideration utilised by regulators internationally for ensuring that data requirements are only at a level that is scientifically justified in conducting risk assessment and to ensure the regulatory process does not become unnecessarily burdensome. This is critical because it is not always economically attractive for a product manufacturer to conduct trials on the many crops which are grown in relatively small amounts/areas (minor crops), but which may nonetheless be scientifically supported via extrapolation. Residue extrapolation may be used to simply estimate the residue level of a commodity on the basis of data generated for a similar commodity or, as is currently extensively practiced, it may be used in conjunction with established crop groupings to establish residue levels for an entire commodity grouping or subgroup.
- 2. The Residue Chemistry Expert Group (RCEG) of the OECD (Final Report: OECD Residue Chemistry Expert Group Meeting, Paris, Jan. 22-24, 2008) drafted a Representative Crops and Extrapolation document (Annex I) that provided background, described national approaches, classification criteria and provided a table comparing representative crops for the US, EU, Australia and Japan. The OECG RCEG will adopt the new Codex Food and Feed Classification when it is finalized.
- 3. JMPR currently uses representative commodities for estimation of MRLs for commodities of minor crops or crop groups on a case-by case basis according to the paragraph "Estimation of group maximum residue levels" of the *FAO manual on the submission and evaluation of pesticide residues data for the estimation of residue levels in food and feed*, 2002, page 58. The lack of formal criteria or an agreed mechanism to determine the members of a group for which data are needed before a group MRL can be established at the international level limits the ability of the JMPR to apply extrapolations on a regular basis. Extrapolations to group Codex MRLs have historically been limited to a few groups: citrus fruit, pome fruit, stalk and stem vegetables, cereal grains, and stone fruit (*IR-4/USDA International Croup Grouping Symposium Proceedings*, 2002, page 51).

JMPR gave their view on estimating group MRLs in the paragraph "Estimation of group maximum residue levels" of the FAO manual and some of the relevant listed principles are summarised below:

- The Codex Classification is the basis for recommending MRLs for individual and grouped commodities.
- In the absence of sufficient data for one commodity, data from a similar crop for which GAP is similar may support the estimation of MRLs.
- Data on residues in all or most of the major commodities with the potential for high residues within a group may allow estimates of MRLs to be extrapolated to other crops in the group.
- In order for a group limit to be proposed, not only must residue levels in the major commodities in the group not to be different, but the physical nature and other characteristics of the crops that might influence residue levels, as well as cultural practices and GAP for the individual commodities, must also be taken into account.

The premise of this approach is that if data are available for representative crops, and if GAP and cultural practises among the individual members are similar, the residue levels will not vary widely and a maximum residue level can be estimated that will suffice for other members of the group for which no data are available.

JMPR further addressed the issue of representative crops and crop groups in General Consideration 2.8 of the 2006 Report (Updating the Principles and Methods of Risk Assessment).

Codex MRLs are used as trade standards. MRLs for control-of-use are parochial (national, local), whereas MRLs for trade purposes should be global.

From the trade perspective, it is preferable to have an MRL than no MRL if residues are likely in the food/feed commodity. A more liberal policy is needed for extrapolation of MRLs to groups, and JMPR recommends the following scientific minimum conditions for group MRLs: (1) The pesticide is registered or authorized for use on the crop group [or many individual members of the group, JMPR 2008] and (2) Relevant and adequate residue data are available for at least one major commodity of the group. All relevant data for commodities of the group should be considered.

- 4. Residue extrapolation was included in the scope of the work in the extended revision of the Codex Classification of Foods and Animal Feeds, approved by the CAC 2006.
- 5. The CCPR 2007 in Beijing, China agreed that the Electronic Working Group of the Codex Classification of Foods and Animal Feeds, led by The Netherlands and the United States, should prepare a draft document outlining the principles of and guidance on the selection of representative crops for the purpose of extrapolation of MRLs. It was agreed that the guidance on selection of representative crops should be developed as a separate document to be provided to the JMPR rather than as a part of the Codex Classification itself (ALINORM 07/30/24, paragraphs 142 152).
- 7. At the CCPR 2008 in Hangzhou, China, the Delegation of the USA presented Addendum II on the selection of representative crops. This document considered the available information on the use of representative commodities by international regulatory authorities and noted that the principles were generally similar. It was also noted that the selection of suitable representative commodities should be flexible to account for differences in worldwide production. For the purpose of residue extrapolation, the US proposed that the principles presented in Addendum II would be used and that representative commodities would be selected in parallel with the revision of the respective crop grouping classification. The guidance document on the selection of representative commodities will be a separate document from the Codex Classification of Foods and Animal Feeds. The Meeting requested that the JMPR comment upon Addendum II (ALINORM 08/31/24, paragraphs 113 115).
- 8. The 2008 JMPR considered Addendum II (Report 2008, General Item, The Meeting offered the following comments: (1) Groupings should be formed so that members would be (typically) subject to the same GAP and would form a group with similar residue characteristics and (2) Representative commodities should be chosen according to (1) commercial importance and (2) residue characteristics.

Criteria (1) and (2) may conflict, that is, the most important commercial crop may not be the most important from a residue perspective, e.g., chilli peppers and sweet peppers. The JMPR considers all available data; the residue data driving the group MRL will not necessarily be from the suggested "representative" commodities.

A group MRL should normally not be set based only on data from a minor crop. The selection of representative crops and corresponding commodities for particular crops and commodity groups "would be very valuable to proponents planning residue trials."

9. Conclusion of JMPR 2008: The JMPR looks forward to further progress with commodity grouping and representative commodities. Careful attention to grouping will assist the JMPR to propose group MRLs more often.