Ministry of Food and Drug Safety

Foreign Testing Laboratories e-NewsLetter 2016.10 _Vol.6

Message from Director of Consumer Risk Prevention Bureau



Jangyul Robert Kim Director General of Consumer Risk Prevention Bureau

good luck.

I am Jangyul Robert Kim, and very pleased to introduce myself as the new Director of Consumer Risk Prevention Bureau. I have spent most of my career in communication before taking this position which, I believe, allows me to bring years of experience and expertise to help facilitate communication between MFDS and the public. Better communication and public engagement would lead to greater understanding of policy decision-making, thus build public trust and confidence in MFDS.

For food and drug safety, international cooperation is of great importance as well. As the new Director, I will strive to reinforce mutual communication and coordination between MFDS and MFDS-designated Foreign Testing Laboratories (FTLs) by taking various measures. The FTL e-Newsletter is one of the efforts made by Laboratory Audit and Policy Division of MFDS to establish better relationship with FTLs.

After several months of unprecedented hot weather, fall is officially in the air in Korea as trees sway in crisp and chill breeze with leaves starting to change their colors. I wish you beautiful weather and

Website Renewal MFDS Website has been renewed.

www.mfds.go.kr/eng/index

Information on testing and inspection laboratories is available on the website at "MFDS NEWS" > "Management of Testing and Inspection Agencies"

The content includes 1) Inspection procedures of testing and inspection agencies, 2) Foreign testing laboratories, and 3) Evaluation of testing competency

◆ Information on food regulations, including ^FSpecial Act on Imported Food Safety Control can be found at "FOOD" > "Regulations"

The Inspection Procedure on Imported food products, etc. Importer Import Declaration (UNI-PASS) Submission of Application Random Document On-site Laboratory Review Audit Test Sampling Test On-site Audit (Sampling) Laboratory Test (by MFDS or food testing agencies) Issuance of Certificate of Completion of Compliance/ before a lab test Noncompliance Compliance Non-Compliance Certificate Issuance Notice of Customs non-compliance Clearance Return & Market Disposal Distribution Post * Applicable Regulations: Article 20, 21 and 22 of Fthe Special Act on Imported Food Safety Management_J, Article 27 Management ~34 of the Enforcement rule of the same Act

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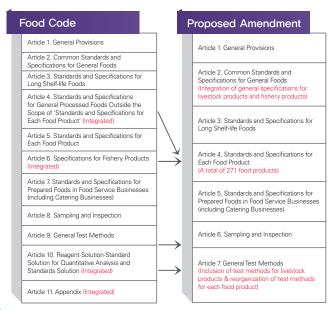
Development of Integrated Standards & Specifications for Foods and Livestock Products

- ▶ Announcement of Partial Amendments to Tthe Livestock Products Sanitary Control Act」 and Tthe Food Sanitation Act」 (April 21, 2016)
- Integration of general standards & specifications for processed livestock products into The Food Sanitation Act
- * Processed livestock products include dairy products, processed meat products and processed egg products.
- Application of the same monitoring standards both to processed foods & processed livestock products.



Consolidation and Reorganization of Standards & Specifications for Foods and Livestock products

- Rearrangement of food types based on ingredient content
- Improvement of standards and specifications for food products that have attracted high levels of consumer complaints



► Revision of Food Type Classification

	Before Amendment		After Amendment		
Food Group	Food Species	Food Type	Food Group	Food Species	Food Type
Foods for	Formulated foods	Formulated foods for	Foods for	Formulated foods for	Formulated foods for
Special	for infants	infants	Special	infants	infants
Dietary Use	Follow-up formulae	Follow-up formulae	Dietary Use	Follow-up formulae	Follow-up formulae
	Cereal based foods	Cereal based foods for		Cereal based foods for	Cereal based foods for
	for infants and	infants and young children		infants and young	infants and young children
	voung children			children	
	Other foods for	Other foods for infants and	i	Other foods for	Other foods for infants and
	infants and young	voung children		infants and young	voung children
	children	young ciniaren		children	young ciniaren
	Foods for special	Balanced nutritious foods	i	Foods for special	Medical foods
	medical purposes	for patients		medical purposes	
		Foods for patients with	i		
		diabetes			
		Foods for patients with	i		
		renal disorders			
		Hydrolyzed foods for	i		
		patients with bowl disease			
		Thickeners for patients with	i		
		dysphasia			
		Medical foods for providing	i		Medical foods for providing
		calories and nutrients			calories and nutrients
		Foods for patients with	i		Foods for patients with
		inborn error of metabolism			inborn error of metabolism
		Specially formulated foods	i		Specially formulated foods
		for infants and young			for infants and young
		children with milk allergy			children with milk allergy
		Specially formulated foods	i		Specially formulated foods
		for infants and young			for infants and young
		children			children
	Dietary formulae for	Dietary formulae for weight	i	Dietary formulae for	Dietary formulae for weight
	weight control	control		weight control	control
	Foods for	Foods for	i	Foods for	Foods for
	pregnant/lactating	pregnant/lactating women		pregnant/lactating	pregnant/lactating women
	women			women	, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,
Processed	Milk formulas	Fortified milk powders	1	Milk formulas	Formula milk for infants
Milk					and young children
Products		Infant formula milk	1		Follow-up formula milk
		Follow-up milk powders		•	
		Follow-up formula milk	1		
		Other milk powders	1		
		Other formula milk	i		
	Ice cream	Ice cream	Frozen	Ice cream	Ice cream
		Ice milk	desserts		Ice milk
		Sherbet			Sherbet
		Low-fat ice cream			Low-fat ice cream
		Non-fat ice cream			Non-fat ice cream
					Frozen desserts
	Ice cream powders	Ice cream powders		Ice cream mix	Ice cream mix
		Ice milk powders			Ice milk mix
		Sherbet powders			Sherbet mix
		Non-fat ice cream powders	1		Low-fat ice cream mix
	Ice cream mix	Ice cream mix	1		Non-fat ice cream mix
		Ice milk mix	1	Edible ice	Edible ice
		Sherbet mix			
	1		1		
		Low-fat ice cream mix	i		
Confectionary		Non-fat ice cream mix Non-fat ice cream mix Frozen desserts			

Proposed Revision of Standards & Specifications for Food additives



- 1. The standard of "Cross-linked Sodium Carboxymethyl Cellulose" will be established as a coating agent.
- 2. Test methods of a total of 17 items (Silicon resin, L-Monosodium Glutamate, Dammar Gum, Calcium oxide, Steviol glycosides, Rice bran wax, Oxystearin, Quillaia extract, Magnesium carbonate, Calcium carbonate, Tert-Butylhydroquinone, Polysorbate 80, Polyisobutylene, Aluminium Potassium Sulfate, Enzymatically Modified Stevia Glucosyl Stevia, Alkali agents for noodles, Sodium saccharin formulation) will be revised.
- 3. Maximum Residue Limits (MRLs) for Sodium saccharin will be expanded. (Fruit wine: not more than 0.08g/kg, Dried seasoned fish: not more than 0.1g/kg)
- 4. The scope of usage for Calcium Stearyl Lactylate will be expanded to starch-processed foods.
- 5. Talaromyces emersonii will be added to a list of microorganisms that produce B-Glucanase.

Multi Class Pesticide Multi-Residue Methods

The method is applied to cereals, roots and tuber crops, pulses, nuts and seeds, fruits, vegetables and mushrooms.

1. Preparation of test solution

A. Extraction

(1) Method of acetonitrile extraction

i) Prepare a test sample, accurately weighed, (For cereals and pulses, mix about 1kg of the sample and take 50g by grinding it to find powder and passing it through the 420um standard sieve. As for vegetables, fruits, roots and tuber crops, and nuts and seeds, grind about 1kg of the sample in a cutter mixer and take 50g of it. As for tea, take 10g.) and place it into an Omni mixer homogenizer (For cereals and pulses, mix the sample with 30mL of water and let it stand for 2hours. As for tea, mix the sample with 40mL of water and let it stand for 2 hours.).

ii) Add 100mL of acetonitrile and homogenize for 2 to 3 minutes, Filter the solution under vacuum using a Buchner funnel. Transfer it into a 500mL separating funnel containing 10~15g of sodium chloride, shake it vigorously, and allow it

iii) Remove water by passing anhydrous sodium sulphate through the acetonitrile layer and add additional acetonitrile to make 100mL, Take 20mL of the acetonitrile layer and evaporate it in a water-bath at below 40°C

iv) In case of pesticide analysis by gas chromatography (GC), dissolve the residues in 4mL of hexane containing 20% acetone. As for pesticide analysis by liquid chromatography (LC), dissolve the residues in 4mL of dichloromethane containing 1% methanol.

(2) Method of acetone extraction

i) Same as the above i) of "Method of acetonitrile extraction"

ii) Add 100mL of acetone and homogenize for 2 to 3 minutes. Filter the solution under vacuum using a Buchner funnel. Transfer the filtered solution into a 1L separating funnel and add 50mL of a saturated solution of sodium chloride and 100mL of water, Add 50mL of dichloromethane to the mixtures, shake it vigorously, and allow for separation. After transferring the dichloromethane layer to another separating funnel, add 50mL of dichloromethane to the aqueous layer again. Shake it vigorously before allowing it to separate and collect the bottom layer.

iii) Remove water by passing anhydrous sodium sulphate through the dichloromethane layer and add additional dichloromethane to make 100mL. Take 20mL of the dichloromethane layer and evaporate it in a water - bath at below 40°C.

iv) In case of pesticide analysis by gas chromatography (GC), dissolve the residues in 4mL of hexane containing 20% acetone. As for pesticide analysis by liquid chromatography (LC), dissolve the residues in 4mL of dichloromethane containing 1% methanol.

* For extraction, either (1) or (2) can be used.

Note 1) Separation can be completed faster at a low temperature.

Note 2) As for fat-based test samples such as cereals, pulses, and nuts and seeds, After running a test i), ii) and iii) of (2), add 30 mL of hexane saturated with acetonitrile (or methanol) to the dried extract to be dissolved. Transfer it to a 250 mL separating funnel before extracting twice using 30 mL of acetonitrile (or methanol) saturated with hexane each time to remove fat, Collect the extracted acetonitrile (or methanol) layer and evaporate it at 40°C . For pesticides analyzed by GC, dissolve the residues completely in 4 mL of hexane containing 20% acetone. For pesticides analyzed by LC, dissolve it in 4 mL of dichloromethane containing 1% methanol.

B. Purification

(1) Pesticides analyzed by GC

Elute 5mL of hexane into a cartridge filled with florisil(1g), carbon(500mg) and aminopropyl(1g) at a flow rate of 2~3 drops per second. Pour 5mL of hexane containing 20% acetone into the cartridge and re-elute. Then pour 4mL of hexane containing 20% acetone into the top of the cartridge and elute at a speed of 1~2 drops per second. While the cartridge is still wet with the solvent, pour 5mL of hexane containing 20% acetone and collect the eluate. Pass it through a carbon cartridge activated with 5mL of hexane and 5mL of hexane containing 20% acetone, and elute at a rate of 1~2 drops per second. Pour 15mL of hexane containing 20% acetone into the carbon cartridge and collect the eluate. After evaporating the eluate under a gentle stream of nitrogen or air in a water bathe at below 40°C, make a test solution by dissolving it in hexane containing 20% acetone and passing it through a membrane filter (PTFE 0.45µm). (A carbon cartridge is used only for removing impurities such as pigments)

Note 3) Make sure that all cartridges should not be dried during the purification. Note 4) When carrying out pretreatment, add 2% diethylene glycol containing 0,2mL of acetone before vacuum concentration.

(2) Pesticides analyzed by LC

Elute 5mL dichloromethane into an aminopropyl-charged cartridge at a speed of 2~3 drops per second. Then pour 4mL of dichloromethane containing 1% methanol into the top of the cartridge and re-elute at a flow rate of 1~2 drops per second. While the cartridge is still wet with the solvent, elute with 7mL of dichloromethane containing 1% methanol and collect the eluate. After evaporating the eluate under a gentle stream of nitrogen or air in a water bathe at below 40°C, make a test solution by dissolving it in acetonitrile and passing it through a membrane filter (PTFE 0.45µm). (A carbon cartridge is used only for removing impurities such as pigments.)

2. Control of test conduct

A. Measurement conditions for GC

(1) GC-ECD, GC-NPD

(a) Column: DB-5(30m × 0.25mm, 0.25µm), DB-17(30m × 0.25mm, 0.25µm) or its equivalent

(b) Carrier gas and flow rate: N2. 1.0mL/min

(c) Oven temperature: Inject the test solution into the column at 80°C and leave it for 2 minutes. Raise the temperature by 7°C per minute until it reaches 250°C. Increase the temperature by 5°C each minute until it reaches 280°C and let it stand for more than 20 minutes.

(d) Injection mode: split mode (20:1)

(e) Detector temperature: 280°C

(2) GC-FPD

(a) Column: DB-5(30m×0.25mm, 0.25um), DB-17(30m×0.25mm, 0.25um) or its equivalent

(b) Carrier gas and flow rate: N2, 1.0 mL/min

(c) Oven temperature: Inject the test solution into the column at 80°C and leave it for 2 minutes. Raise the temperature by 7°C per minute until it reaches 250°C. Increase the temperature by 5°C each minute until it reaches 280°C and let it stand for more than 20 minutes.

(d) Injection mode: splitless mode

(e) Detector temperature: 280°C

(3) GC-MS/MS(including GC-MS)
(a) Column: DB-5ms(30m × 0.25mm, 0.25µm) or its equivalent

(b) Carrier gas and flow rate: He, 0.8mL/min

(c) Oven temperature: Inject the test solution into the column at 70°C and leave it for 3 minutes. Raise the temperature by 20°C per minute until it reaches 180°C. Increase the temperature by 5°C each minute until it reaches 300°C and let it stand for more than 7 minutes.

(d) Injection mode: splitless mode

(e) Interface temperature: 300°C

(f) Solvent delay time: 4 min

(g) Collision gas: Ar

B. Measurement conditions for LC

(1) HPLC-FLD (including Post-derivatization)

(a) Column: C18 (3.9mm × 150mm, 5µm) or its equivalent (b) Detector: Excitation 340nm, Emission 455nm

(c) Mobile phase: water/ methanol - After changing the concentration ratio from methanol: water (3:7) to methanol: water (7:3) for 23minutes, let it flow for more than 5minutes.

(d) Flow rate: 0.8 mL/min

(e) Post reaction pump flow rate: 0.5mL/min (NaOH 0.25mL/min, OPA 0.25mL/min) or other optimum conditions

(2) HPLC-UVD

(a) Column: C18(4.6mm × 250mm, 5µm) or its equivalent

(b) Detector: UV photometric detector (254nm)

(c) Mobile phase: water/acetonitrile

acetonitrile/water (20/80, v/v, 0min) to (80/20, v/v, 40 -50min)

- methanol/water (35/65, v/v, 0min) to (90/10, v/v, 40 -50min)

* For the mobile phase condition, either can be used.

(d) Mobile phase flow rate: 1.0 mL/min

(3) LC-MS/MS (including LC-MS)

(a) Column: C18 (2.0mm × 100mm, 3µm) or its equivalent

(b) Mobile phase: A(Water containing 0.1% formic acid + 10mM ammonium acetate), B(Acetonitrile containing 0.1% formic acid + 2mM ammonium acetate) or its equivalent

- A/B(95/5, v/v, 0 min) to (5/95, v/v, 20-30min)

(c) Flow rate: 0.2mL/min

(d) Column temperature: 40°C

(e) Injection volume: 2uL

(f) Ionization: ESI positive-ion or negative-ion mode

3. Qualitative test

The test results under the above condition shall be identical to the results obtained in a standard solution, regardless of measurement conditions.

Note 5) Using a GC-MS (including MS/MS) and/or LC-MS (including MS/MS) detector, components of each pesticide can be identified by retention time and mass spectrum.

4. Quantitative test

Evaluations are made based on the peak heights and peak areas obtained under the same conditions as in the qualitative test.



The 3rd International Symposium on Food and Drug Safety Emergency Response

Theme: Responses to food and drug safety incidents, and future response

strategies

Date: 09:30~17:10, September 1, 2016

Location: Emerald Hall (3F), Convention Center, Grand Hilton Seoul

Host: The Ministry of Food and Drug Safety

Official Language: Korean - English (Simultaneous Interpretation)

Attendees: domestic and foreign government agencies, industries, academia

Time		Program	Speakers	
9:30~10:00	30"	· Registration	MC	
10:00~10:10	10"	· Opening Ceremony	Minister of Ministry of Food and Drug Safety	
10:10~11:00	40″	· Keynote Lecture I Trend of policy about risk management : Field of Food and Drug	Dohyeong Kim (Professor, The University of Texas at Dallas)	
10:50~11:30	40"	· Keynote Lecture II Change of National Emergency Management System	Jaeeun Lee (Professor, Chungbuk national University)	
11:30~13:00	90"	Lunch		
13:00~13:40		Accident _F Incident and Lesson from Response Case: Field of Food a Lesson and implication of Food safety management crisis response in Japan	nd Drug (Moderator: Jibeom Jung) Keiko Kitagawa (Professor, Seitoku University)	
13:40~14:20	40"	Case and implication of food and drug safety crisis response	Sungho Kim (Director, Ministry of Food and Drug Safety)	
14:20~15:00	40"	· Crisis response case and crisis response plan in corporation of domestic and foreign	Bohyeong Lee (CEO, Macoll in Korean branch)	
15:00~15:30	30"	Coffee Break		
Session II	Crisis n	nanagement strengthening and future response for preparing new crisis type:	Field of Food and Drug (Moderator: Sangdo Ha)	
15:30~16:10	40″	· Implication and response activities of food terror in US	Jennifer van de Ligt (Associate Director, Food Protection and Defense Institute)	
16:10~16:50	40"	Risk communication strategy of government and corporation	Cha Huiwon	





>> Please submit the following documents to MFDS by email.

- A list of test reports issued in the year of 2015
- Copies of performance evaluation documents issued by the pertinent government in 2015 or obtained through participation in international proficiency testing programs in 2015

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