Design and Implementation of Risk Management based Inspection

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Risk Analysis

Risk Management (Policy base)

Risk Assessment (Science base)

Risk Communication
(Interactive exchange of information and opinions concerning risks)

Research

Strategy decision of safety management based on the result of risk assessment

Exchange step of mutual opinion and information

(WHO)
ZERO RISK
A zero risk cannot be proved therefore the aim is to achieve effective RISK REDUCTION
Things to consider...

• What kind of test...
• How to sample...
• How to analyze...
• How many samples..
2011 Lab test result

Importation declaration (2011)
19,298 cases

Physicochemical & Microbiological

Lab test
2,941 cases
15.2%

Random test
1,745 cases

First time lab test
1,196 cases

Violations
49 cases
1.7%
### Violation cases

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>cases</th>
<th>Coliforms</th>
<th>cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture</td>
<td>2</td>
<td>$E. \text{Coli}$</td>
<td>26</td>
</tr>
<tr>
<td>Milk solid</td>
<td>2</td>
<td>$Listeria \text{monocytogenes}$</td>
<td>3</td>
</tr>
<tr>
<td>Extraneous material</td>
<td>1</td>
<td>$Enteronbacter \text{sakazakii}$</td>
<td>1</td>
</tr>
<tr>
<td>Sugar content</td>
<td>1</td>
<td>$Staphylococcus \text{aureus}$</td>
<td>6</td>
</tr>
<tr>
<td><strong>total</strong></td>
<td><strong>48</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• **First time Lab Test**
  – About 7-8% of imported products
  – Imported products for the first time
  – Problem occurred products

• **Random test**
  – About 9%
  – Same products had been examined
  – Products for tourism business
  – Raw materials for manufacturing products
  – Apply different test cycle by violation rates
<table>
<thead>
<tr>
<th>Test cycle</th>
<th>Test ratio</th>
<th>Declaration</th>
<th>Test cycle</th>
<th>Test ratio</th>
<th>8%+Violation%</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>6.3</td>
<td>1-49</td>
<td>11</td>
<td>9.1</td>
<td>8-8.499</td>
</tr>
<tr>
<td>17</td>
<td>5.9</td>
<td>50-99</td>
<td>10</td>
<td>10.0</td>
<td>8.5-9.499</td>
</tr>
<tr>
<td>18</td>
<td>5.6</td>
<td>100-199</td>
<td>9</td>
<td>11.1</td>
<td>9.5-10.499</td>
</tr>
<tr>
<td>19</td>
<td>5.3</td>
<td>200-299</td>
<td>8</td>
<td>12.5</td>
<td>10.5-11.999</td>
</tr>
<tr>
<td>20</td>
<td>5</td>
<td>&gt;=300</td>
<td>7</td>
<td>14.3</td>
<td>12-13.499</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td>16.7</td>
<td>13.5-15.499</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>20.0</td>
<td>15.5-17.999</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>25.0</td>
<td>&gt;=17.999</td>
</tr>
</tbody>
</table>
Lab. test plan 2012

• 2011 Plan
  – 2,930 / 20,263 expected import (14.5%)
  – Testing : initial + random

• Random Testing periods : about 9 %
  – Passed items : 16 to 20 cycle
  – Violated items : 4 to 11 cycle, based on recent 5 yrs failed test ratio

• Enforcement testing
  – 5 consecutive test
  – Decrease one test cycle
Lab. test plan 2012

• **Radioactivity test**
  – Dairy products and meat extract products from 31 (including Japan) countries
  – Any products from Japan should be tested
  – ‘12 plan : 100 cases

• **GMO test**
  – Imported or domestic meat products
  – Used Soy protein or corn powder
  – ‘11 plan : 100 cases

• **Microbiological test for imported and domestic meats**
  – 7,580 total
  – 4,280 imported, 3,300 domestic
<table>
<thead>
<tr>
<th>Year</th>
<th>Import</th>
<th>First time Lab test</th>
<th>Total</th>
<th>Random test</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>cases</td>
<td>ratio(%)</td>
<td>cases</td>
<td>ratio(%)</td>
</tr>
<tr>
<td>2011</td>
<td>19,298</td>
<td>1,196</td>
<td>6.2</td>
<td>1,745</td>
<td>9.6</td>
</tr>
<tr>
<td>2012 plan</td>
<td>20,263</td>
<td>1,216</td>
<td>6.5</td>
<td>1,714</td>
<td>9.0</td>
</tr>
</tbody>
</table>
Lab test list for violated items

• **Organoleptic**
  – Extraneous materials
  – Appearance
  – Scorched particles

• **General ingredients**
  – Fat, moisture, non-fat milk solid, milk solid, protein, lactose
  – Casein phosphopeptide, milk fat, milk composite, ash
• Quality control
  – Acid Value
  – VBN
  – Specific gravity
  – Phosphatase
  – Butyric acid
  – Amino acid nitrogen
  – Unsaponifiable matter
  – Saponification value

  Iodine value
  Refractive index
  Acidity
  Vacuum index
  Scorched particle
• Food additives
  – Tar colors
  – Antioxidants
  – Preservatives
  – Sugars
  – Vitamins
  – Minerals
  – Artificial sweetener
  – Fatty acids
• **Microbiological test (15)**
  - Bacteria count, bacterial growth count
  - coliform count, E. coli count
  - lactobacillus count, fungi count
  - E. coli O157:H7, salmonella spp.
  - Listeria mono., Staphylo. aureus
  - Clos. Perfringens, Clo. Botulinum
  - Ent. Sakazakii, B. cererus
  - Vibrioparahaemolyticus
• **Residue test**
  – Antibiotics
  – Synthetic antibiotics
  – Pesticides
  – Aflatoxin

• **Heavy metals**
  – Pb, Sn

• **Radioactivity**
  – I-131, Cs-134, Cs-137
The Korean National Residue Program for Veterinary Drugs and Contaminant in Foods of Animal Origin

Toxicology & Residue Chemistry Division
Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA) / MIFAFF
Residues

- Substance used for specific purpose
  - Veterinary drugs
  - Their metabolites

Contaminants

- Substances not intentionally added
  - Pesticides
  - Heavy metals (Pb, Cd, As..)
  - Dioxins, PBDEs
  - Mycotoxin (Aflatoxin M₁), etc.
Risk of Chemical Residues

- Veterinary Drugs
- Environmental contaminants

- General toxicity,
- Antibiotic resistance,
- Hypersensitivity,
- Endocrine disruption,
- Acute or Chronic poisoning,
- Carcinogenesis, etc.
• **1989.3.** Established chemical residue testing program for pork to be exported to Japan
  - 1988, found sulfamethazine in export pork
    > 0.1 ppm (Zero tolerance in Japan)

• Established MRLs & analytical methods (1989.5)

• Implemented National Residue Survey (1989-1995)

• **1996** Established the Korean NRP
Aims to ensure the safety of livestock products by providing guidance for the effective implementation of test and controlling of harmful chemical residues in livestock products.

Focuses on the protection of public health by supplying safe meat for human
- Assesses the risk by chemical residue exposure in human
- Deter slaughtering & processing of adulterated animals
- Identify violative products to prevent it from supplying to human
- Verify HACCP system on slaughtering and processing
Domestic vs. Import Sampling

- Components of samplings system are similar
  - Monitoring plans, Surveillance /Enforcement testing, Exploratory projects
- But purposes are different
  - Domestic: prevent the residue occurrence on farm
  - Import: verify the residue control program of exporting countries
1. Monitoring Plan

For the collection for national residue information

– Statistical random sampling for animals that have passed ante-mortem inspection
– Indicate national prevalence data
– Evaluate and predict the trend of residue
– Identify correctable problems in the farm or industry
2. **Surveillance/Enforcement Testing** (condemnation)
   Investigate and control the occurrence of residue violations in animal populations
   – **Targeted sampling plans**
   – Identify and remove unsafe livestock products
   – **Focus on individual animals or lots that appear unhealthy**
     • Emphasis on populations with high prevalence of residue violations
     • Follow-up producers having non-compliant histories
     • Verify whether an HACCP system effectively controls violation of residues
3. Exploratory Projects

Mostly monitoring for the occurrence of chemical residues without MRLs or safe limits

– Provide supplementary information on compounds to be considered at next NRP monitoring plan

– Use newly developed analytical methods and validate it for the use of future residue monitoring plan
**Sampling & Testing Procedures**

- **Monitoring plan**: samples are collected **randomly** from slaughterhouse for the screening & confirmatory test.

- **Surveillance/Enforcement testing**: samples are collected from animals in slaughterhouse which are originated from the farm with **previous residue-violation** and from animals suspected for the residue violation by an inspector.
  
  - Inspector **hold the carcass** until outcome of lab test and the carcass of exceeding of specific MRL is **condemned**.

- **Exploratory projects**: PVSs send samples randomly selected to QIA according to the annual plan.
MRLs for Veterinary Drugs and Contaminants in Foods of Animal Origin

<table>
<thead>
<tr>
<th>Compounds</th>
<th>CODEX</th>
<th>Korea</th>
<th>USA</th>
<th>EU</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veterinary drugs</td>
<td>64</td>
<td>150</td>
<td>133</td>
<td>150</td>
<td>238</td>
</tr>
<tr>
<td>Pesticides, Dioxins, etc.</td>
<td>105</td>
<td>89</td>
<td>199</td>
<td>326</td>
<td>310</td>
</tr>
<tr>
<td>Total</td>
<td>169</td>
<td>239</td>
<td>332</td>
<td>476</td>
<td>548</td>
</tr>
</tbody>
</table>

- Japan: Positive list system for all residues (0.01 ppm since May 2006), Korea: Positive list system for antibiotics (0.03 ppm since January 2010)
- * Dioxins – Beef 4 pg TEQ/g fat, Pork 2 ppt, Chicken 3 ppt
### List of Negative Substances in Food (zero tolerance)

<table>
<thead>
<tr>
<th></th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nitrofurans (Furazolidone, Furaltaclone, Nitrofurazone, Nitrofurantoine, Nitrovin, etc.) and their metabolites</td>
</tr>
<tr>
<td>2</td>
<td>Chloramphenicol</td>
</tr>
<tr>
<td>3</td>
<td>Malachite green and its metabolite</td>
</tr>
<tr>
<td>4</td>
<td>Diethylstilbestrol (DES)</td>
</tr>
<tr>
<td>5</td>
<td>Dimetridazole</td>
</tr>
<tr>
<td>6</td>
<td>Clenbuterol</td>
</tr>
<tr>
<td>7</td>
<td>Vancomycin</td>
</tr>
<tr>
<td>8</td>
<td>Chlorpromazine</td>
</tr>
<tr>
<td>9</td>
<td>Thiouracil</td>
</tr>
<tr>
<td>10</td>
<td>Colchicine</td>
</tr>
<tr>
<td>11</td>
<td>Pyrimethamine</td>
</tr>
<tr>
<td>12</td>
<td>Medroxyprogesterone acetate (MPA)</td>
</tr>
</tbody>
</table>
Agencies involved in NRP System

MIFAFF
- Make NRP draft
- Report national results
- Enforcement of NRP plan
- Publication of NRP result
- Establish MRLs

QIA
- Report residue test results

KFDA

Provincial Veterinary Services

MIFAFF: Ministry of Food, Agricultural, Forestry & Fisheries
KFDA: Korean Food & Drugs Administration
QIA: Animal, Plant and Fisheries Quarantine and Inspection Agency
(Former National Veterinary Research & Quarantine Service)
Residue Violation Follow-up Actions

• In case of occurrence of violation, Provincial Veterinary Services (PVSs) notifies warning letters to the producer and other involved parties

• Violators are posted on the QIA website (Internet) with addresses for 6 months and controlled electronically by computer information system

• Competent PVSs do on-site educational visits of farms and investigate the cause of violations
<table>
<thead>
<tr>
<th>No</th>
<th>Name</th>
<th>Farm address</th>
<th>Species</th>
<th>Substances of violation</th>
<th>Enforcement period</th>
<th>Slaughter house</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HJ Kim</td>
<td>1000 Haemang-dong, Gunsan-si, Jeollabuk-do</td>
<td>Pig</td>
<td>Oxytetracycline, Chlortetracycline</td>
<td>2011. 1. 19 ~ 7. 18</td>
<td>JB05</td>
</tr>
<tr>
<td>2</td>
<td>BH Cho</td>
<td>566 Manho-ri, Poseung-Myeon, Pyeongtaek-si, Gyeonggi-do</td>
<td>Chicken</td>
<td>Enrloxacine</td>
<td>2011. 1. 21 ~ 7. 20</td>
<td>GG17</td>
</tr>
</tbody>
</table>
Monitoring & Surveillance & Enforcement - Violation Rates in Korea -

%  

- Monitoring  - Surveillance & Enforcement  - Average
NRP Results of Domestic Samples

- The Causes for Residue Violation, 2003 - 2010

1,417 violative farms

- Inobservance of withdrawal period
- Inadequate feeding at finishing period
- Contamination of non-medicated feed
- Insufficient record of administration
- Feeding of medicated feeds
- Inadequate isolation or identification of medicated animals
- Overdose
- Contamination of the water system by mismanagement
- The others

59.8% (848) - 15.2% (204) - 13.7% (194) - 2.9% (41) - 3.8% (54)

1.3% (18) - 1.8% (26) - 2.1% (30) - 0.1% (2)
Components of Import NRP

• **Monitoring**: statistically based on random sampling and testing

• **Surveillance & Enforcement testing**: follow-up measures are taken when residues violations are suspected in a product from an exporting country

• **Exploratory**: precautionary monitor the residue of chemical without MRLs which suspected as human health concern
Residue Testing (by annual residue control plan)

Random Sampling by AIIS (when an import declaration)

Collection of Samples (at 6 regional offices)

Residue Testing (by annual residue control plan)

Seoul Regional Office (Seoul City)

Fail

Return, Disuse

Youngnam Regional Office (Busan City)

Pass

To the Market

AIIS: Automated Import Information System
Sampling of Import Residue Testing Plan

- **Monitoring**: samples submitted randomly to regional laboratories of QIA
  - about 5,000 cases (15,000 samples) per year

- **Surveillance & Enforcement**: samples submitted directly to regional laboratories of QIA
  - about 150 cases per year

- **Exploratory**: targeted samples submitted randomly to a headquarter laboratory of QIA
  - specific imported products or compounds which may provoke human health concern
NRP Results of Imported Samples

- Residue Violation Rates in Imported Animal Products -

<table>
<thead>
<tr>
<th>Year</th>
<th>Violations</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>2/3,581</td>
<td>0.16%</td>
</tr>
<tr>
<td>2004</td>
<td>3/3,438</td>
<td>0.09%</td>
</tr>
<tr>
<td>2005</td>
<td>10/6,638</td>
<td>0.15%</td>
</tr>
<tr>
<td>2006</td>
<td>6/5,285</td>
<td>0.11%</td>
</tr>
<tr>
<td>2007</td>
<td>5/5,729</td>
<td>0.09%</td>
</tr>
<tr>
<td>2008</td>
<td>2/5,457</td>
<td>0.04%</td>
</tr>
<tr>
<td>2009</td>
<td>3/6,359</td>
<td>0.05%</td>
</tr>
<tr>
<td>2010</td>
<td>1/5,026</td>
<td>0.02%</td>
</tr>
</tbody>
</table>
- Major Residue Violations in Imported Animal Products -

1999  Endosulfan  in beef (Australia),  PCBs in pork (Belgium)
2000  Sulfaquinoxine in duck (Thailand)
2001  Oxytetracycline in bovine product (Canada)
2002  Chlortetracycline in swine product (USA)
2003  Dioxins in pork (Chile),
    Nitrofuran metabolites (AOZ) in egg products (India)
2004  Chlortetracycline in swine product (USA)
2005  Nitrofuran metabolites (AOZ/AMOZ) in pork (Mexico)
    Enrofloxacin in pork (Spain),  Endosulfan in beef (New Zealand)
2006  Dioxins in beef (USA)
2007  Sulfamethazine in pork (Spain, USA)
2008  Chloramphenicol in egg products (China),  Dioxins in pork (Chile),
    Endosulfan in bovine products (New Zealand)
2009  Clenbuterol in beef bone extract (China),  Chloramphenicol in chicken (Brazil)
2010  Enrofloxacin/Ciprofloxacin in pig neck bone (Spain),  Enrofloxacin/Ciprofloxacin in chicken (Brazil),
    Doxycycline in pork (France)
2011  Sulfamethazine in pig intestine (USA)
• Improve sampling system based on risk assessment
  - Determine monitoring compound and sample size
  - Increase surveillance & enforcement testing samples

• Improve analytical methodology for multi-class multi-residue screening and confirmation

• More focused exploratory project for anti-inflammatory agents (NSAIDs, glucocorticoids, etc.) and other banned veterinary drugs

• Reinforce the management of residue violators
  - on-site education, increase the penalty
• Korea : http://www.qia.go.kr
• Japan : http://www.mhlw.go.jp
• USA : http://www.fsis.usda.gov
• UK : http://www.vmd.gov.uk/vrc
• Australia: http://www.daff.gov.au/agriculture-food/nrs
• New Zealand : http://www.nzfsa.govt.nz
Legal and Regulatory Framework
Governing the Inspection and Quarantine

UNESCAP Expert Group Meeting
4-5 July, 2012 Ulaan Baatar, Mongolia

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Livestock Products Standards Division
Animal, Plant and Fisheries Quarantine & Inspection Agency
Legal basis for animal health

- Livestock epidemics prevention and control Act
  - Enforcement Ordinance of the livestock epidemics prevention and control Act
  - Enforcement Regulation of the livestock epidemics prevention and control Act
- Import Prohibited Areas of Designated Quarantine Product (MIFAFF No.2011-57)
- Scope and Standards for sterilization, pasteurization, processing of item designated quarantine items (QIA No.2011-36)
- Electronic declaration for import of the livestock products
  - QIA No.2011-33
- Quarantine methods and standard for the designated quarantine items
  - QIA No. 2011-35
- Import Health Requirement
  - 83 MIFAFF Notifications
  - 33 countries
• New Zealand
  – Deer embryo, deer semen, cloven-hoofed animals
• Japan
  – Poultry meat, pigs & pork products, cloven-hoofed animals & their products
• China
  – Poultry meat, heat-treated poultry meat products
• Thailand
  – Poultry meat, heat-treated poultry meat products
• Australia
  – Poultry meat, goat & sheep semen, cloven-hoofed animals & products, ratites, Kangaroo meat & products
Legal basis for animal origin food

- Livestock Product Sanitary Management Act
  - Enforcement Ordinance of Livestock product sanitary management act
  - Enforcement Regulation of the Livestock product sanitary management act
- Residues Monitoring Program for meats (MIFAFF No. 2011-39)
- Microbiological Monitoring Program for Meats (MIFAFF No. 2011-53)
- Standard for processing and ingredients specifications for Livestock products (QIA No. 2011-43)
- Labelling standards for the livestock products (QIA No. 2011-45)
- Declaration and inspection guidelines for the imported livestock products (QIA No. 2011-28)
Standard for Processing and Ingredients Specifications of Livestock Products
notification

- Standards for Processing & Ingredients Specifications of Livestock Products
- Livestock product sanitary management act chapter 4. section 2
- Director of QIA can notify standards and specifications
Structure

- Part 1. General standards and specification of livestock products
- Part 2. Standards and specification of individual items
- Part 3. Analysis methods for livestock products
Overview

• Part 1. General Standards and Specifications
  – Definition
  – Requirements for ingredients
  – Permissible food or food additives
  – Main Ingredient of Livestock products
  – Manufacturing and Processing Standards
  – Ingredient Standards for livestock
  – Applicability of Standards and Specifications
  – Storage and Distribution Standards
Overview

• Part 2. Standards and Specifications for Individual livestock products
  – Chapter 1. Dairy products
    • Milk, Low fat milk etc
  – Chapter 2. Meat products & Packaged meat
    • Common standard
    • Hams, sausages, etc
  – Chapter 3. Egg Products

• Part 3. Test Method for Livestock Products
Livestock products
40 categories
101 sub-categories

Milk products
• Milk etc 20 categories
• 73 sub-categ.

Meat products
• Hams etc 11 categ.
• 19 sub-categ.

Egg products
• Egg products 9 categ.
Labeling Standards for Livestock Products
<table>
<thead>
<tr>
<th>Regulations related to Labelling of Livestock Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Livestock Products Sanitary Management Act</strong></td>
</tr>
<tr>
<td>General standard for Labelling of Livestock Products Standards on Claims, HACCP marking, etc</td>
</tr>
<tr>
<td><strong>Food Sanitation Act</strong></td>
</tr>
<tr>
<td>Things commissioned by Livestock Products Sanitary Management Act(e.g. Labelling of GMO, marking of Food additive, etc)</td>
</tr>
<tr>
<td><strong>Agricultural Products Quality Control Act</strong></td>
</tr>
<tr>
<td>Labelling of origins, Marking of Geographical Indication Labelling of GMO(only agriculture) Marking of Quality Certification</td>
</tr>
<tr>
<td><strong>Food Industry Promotion ACT</strong></td>
</tr>
<tr>
<td>Marking of Organically Processed food</td>
</tr>
<tr>
<td><strong>Environment-friendly Agriculture Promotion Act</strong></td>
</tr>
<tr>
<td>certification of ‘organic agriculture’</td>
</tr>
<tr>
<td><strong>Act on the Traceability of Cattle and Beef</strong></td>
</tr>
<tr>
<td>Traceability</td>
</tr>
<tr>
<td><strong>Foreign Trade Act</strong></td>
</tr>
<tr>
<td>Labeling of Origins</td>
</tr>
<tr>
<td><strong>Industrial Standardization Act</strong></td>
</tr>
<tr>
<td>Marking of KS(Korean Standard)</td>
</tr>
<tr>
<td><strong>others</strong></td>
</tr>
<tr>
<td>Trademark Act Measures Act Act on the Promotion of Saving and Recycling of Resources Act on the Justifying of Labeling and advertising Unfair Competition Prevention and Trade Secret Protection Act, etc</td>
</tr>
</tbody>
</table>
Purpose

Relevant Regulation

- Livestock Products Sanitary Management Act: Article 6
- Livestock Product Labeling Standards

- to give accurate information to consumer
- to ensure fair practices in the food trade
Application

- Processed livestock products
- Imported livestock products
- Packaged meat
- Table eggs
Items of Labeling

1. Name of Product
2. Type of Livestock
3. Name and Address of Business
4. Date of Manufacture
5. Sell-by-date
6. Net Contents
7. The names and quantities of raw materials/components
8. Nutrition
9. Miscellaneous
Labeling for imported livestock products

- **Products selling in exporting country**
  - Original label + Korean label (sticker, label, tag)
  - Adhered firmly
  - Do not cover original major info
  - Korean labeling packaged products: do not use sticker

- **Exporting country & manufacturing co.**
  - Can use Original language
Thank you!