2017 Joint International Symposium of NIFDS, ANSES, DTU & BfR

Introduction of the data management & risk assessment program in NIFDS

point
creative
idea
future
SUCCESS

December 1st 2017

Myungsil Hwang, Ph.D
National Institute of Food and Drug Safety Evaluation

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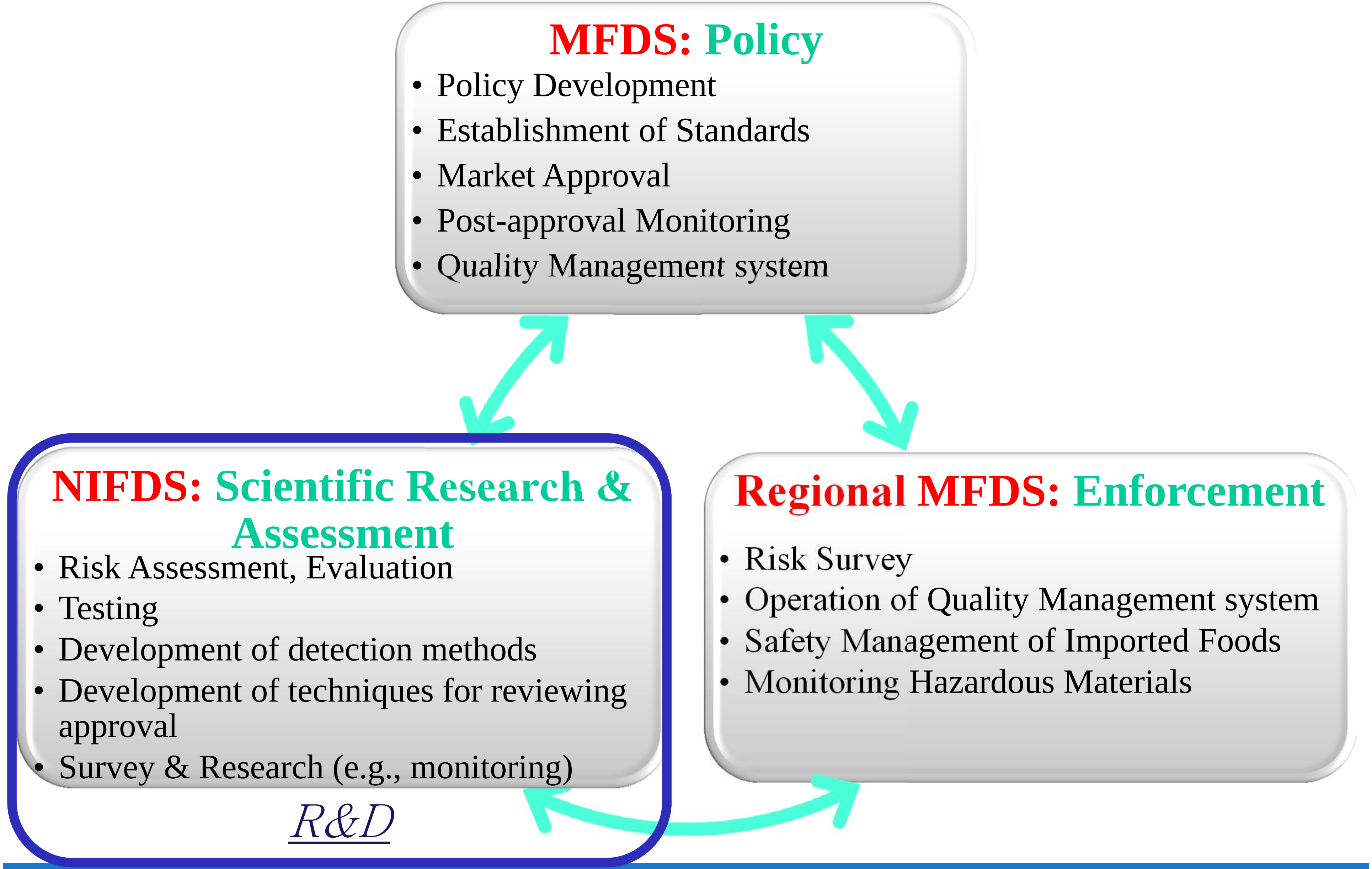
1 • Overview of the Risk Assessment of NIFDS

2 • Introduction of Integrated Information Management System: MIMS/MAP

3 • Conclusion and Future Plan

I. What NIFDS Does



MFDS: Policy

- Policy Development
- Establishment of Standards
- Market Approval
- Post-approval Monitoring
- Quality Management system

NIFDS: Scientific Research & Assessment

- Risk Assessment, Evaluation
- Testing
- Development of detection methods
- Development of techniques for reviewing approval
- Survey & Research (e.g., monitoring)

R&D

Regional MFDS: Enforcement

- Risk Survey
- Operation of Quality Management system
- Safety Management of Imported Foods
- Monitoring Hazardous Materials

I. What NIFDS Does

Safety Evaluation
Risk Assessment
Research & Development

Regulated Products

- Safety Evaluation for Food, Drug, Cosmetics and Medical devices

Hazardous substances

- Provide independent scientific advice & support for risk managers and policy makers on food and drug safety

Scientific Evidence

- Prepare for future risk assessment challenges

I. Target for Risk Assessment of NIFDS

Food

- Food Additives, Pesticides, Food contact Materials
- Contaminants

Cosmetics

- Additives, ingredients, etc.
- Contaminants

Consumer Products

- Substances in detergents, wet tissues, or other household chemical products
- Personal hygienic products
- Other Manufactured products

Ministry of Environment

Ministry of Trade, Industry and Energy

Human

Herbal Medicine

- Active ingredients, Additives
- Residual Materials, Contaminants

Medical Devices

- Active ingredients, Additives
- Residual Materials, Contaminants

Sanitary products

- Substances in detergents, wet tissues, or other household chemical products
- Other Manufactured products

I. Four steps of Risk Assessment for food chemicals

Risk Assessment

1.Hazard Identification

Characterization of innate adverse toxic effects of agents

- Physiochemical properties
- ADME
- Statistically controlled clinical studies
- Epidemiological studies
- Human, animal studies

2.Hazard Characterization

Characterization of the relation between doses and incidences of adverse effects in exposed population

Toxic effect

Health based Guidance Values (ADI, PTWI…)

1.Acute toxicity
2.Genotoxicity
3.Carcinogenicity
4.Reproductive and Developmental toxicity
5.Neurotoxicity, Immunotoxicity, etc.

3.Exposure Assessment

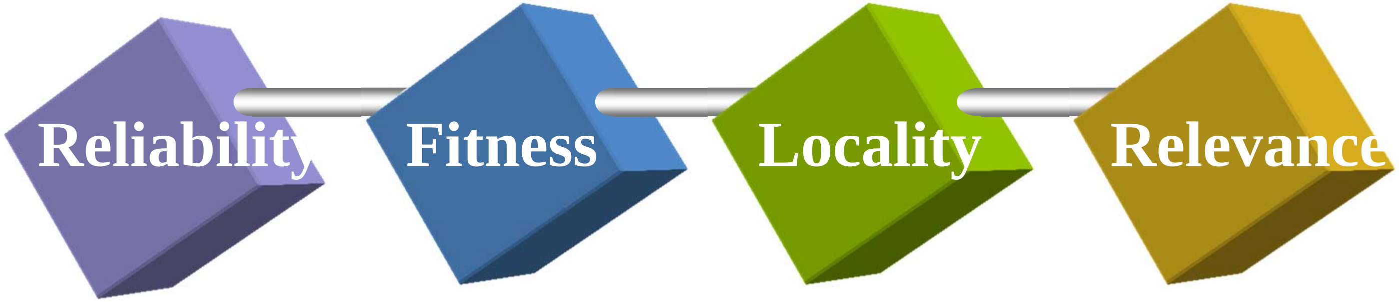
Measurement or estimation of the intensity, frequency, and duration of human exposures to agents

4.Risk Characterization

Estimation of the incidence of health effects under the various conditions of human exposures

RISK
ASSESSMENT

II. Integrated Information Management System



Reliability

Fitness

Locality

Relevance

I. Information collection system of MFDS

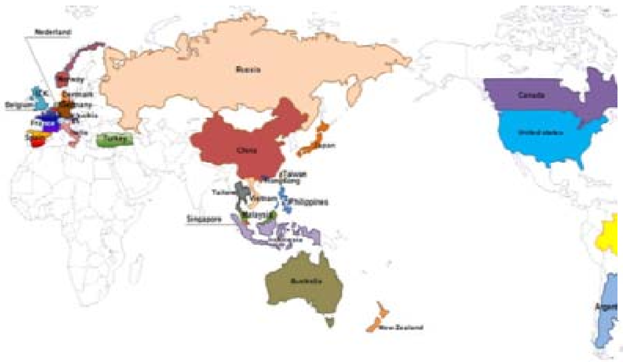
정보공유방
해외정보리포터

해외정보리포터
보고서관리
수시보고서
Ministry of Food and Drug Safety

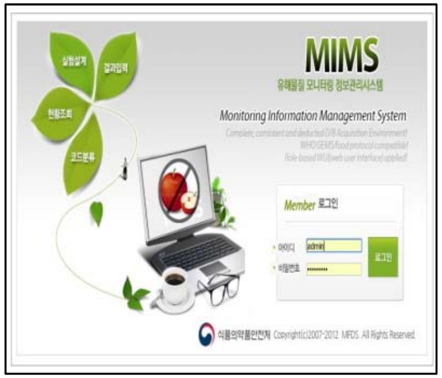
II. Information generation system of NIFDS

온-나라 정책연구
최근 완료된 연구과제
행정안전부

식품행정통합시스템
"식품행정통합시스템"에 오신 것을 환영합니다.


Nederland
Russia
Norway
Denmark
Germany
Belgium
France
Turkey
China
Japan
Canada
United states
Taiwan
Hongkong
Thailand
Vietnam
Philippines
Singapore
Malaysia
Indonesia
Australia
New Zealand

III. Information management system of NIFDS

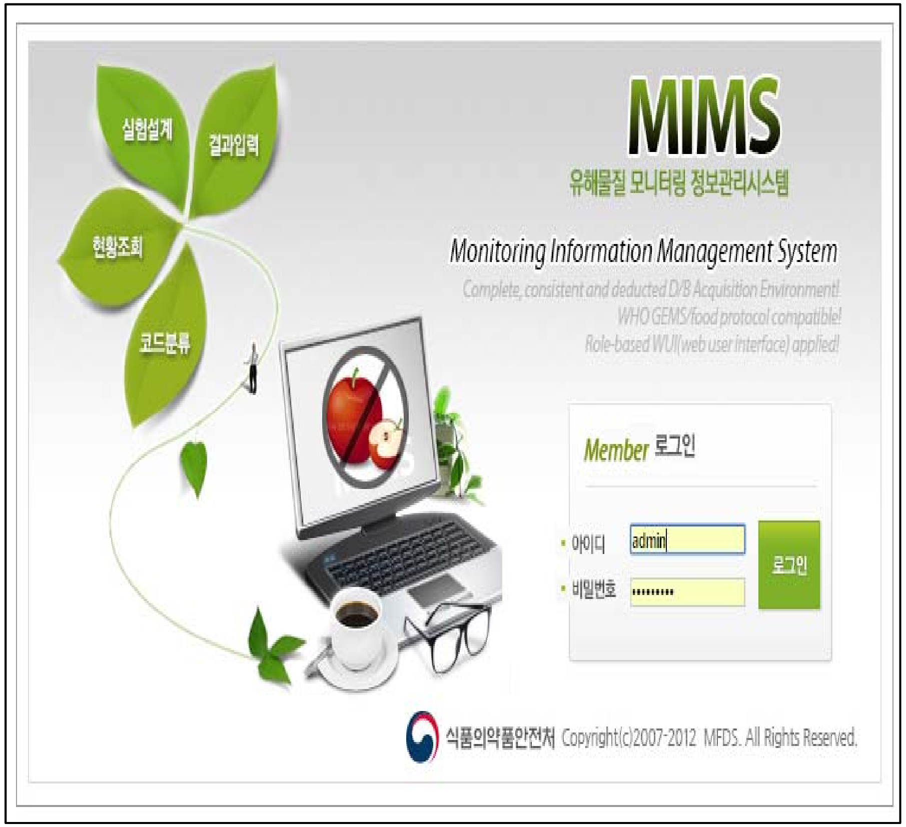

MIMS
유해물질 모니터링 정보관리시스템
Monitoring Information Management System
실험설계
결과입력
현황조회
코드관리
Member 로그인
아이디
비밀번호
로그인
식품의약품안전처 Copyright(c)2007-2012 MFDS All Rights Reserved

III. Introduction of MIMS/MAP

MIMS and MAP are interconnected each other

Monitoring Information Management System

Monitoring database and Assessment Program


실험설계
결과입력
현황조회
코드분류
MIMS
유해물질 모니터링 정보관리시스템
Monitoring Information Management System
Member 로그인
로그인

Complete, consistent and deducted D/B Acquisition Environment!
WHO GEMS/food protocol compatible!
Role-based WUI(web user interface) applied!

아이디 admin
비밀번호 ••••••••

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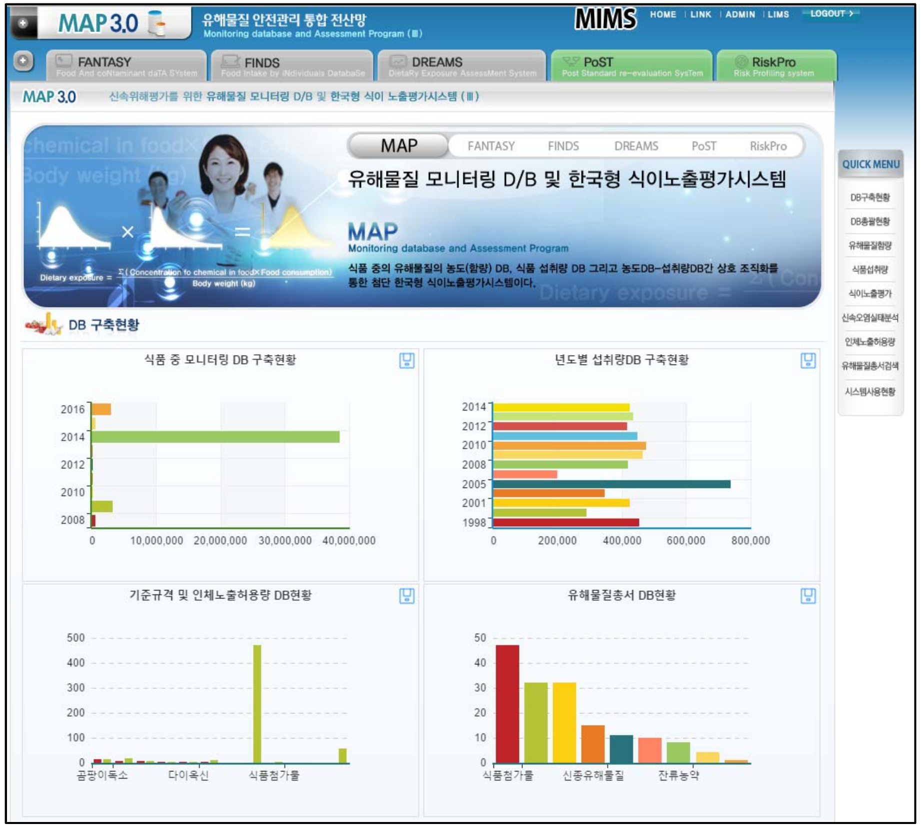

MAP 3.0
유해물질 안전관리 통합 전산망
Monitoring database and Assessment Program (Ⅲ)
MIMS
HOME
LINK
ADMIN
LIMS
LOGOUT
FANTASY
Food And coNtaminant daTA SYstem
FINDS
Food Intake by iNdividuals DatabaSe
DREAMS
DietaRy Exposure AssessMent System
PoST
Post Standard re-evaluation SysTem
RiskPro
Risk Profiling system
MAP 3.0
신속위해평가를 위한 유해물질 모니터링 D/B 및 한국형 식이 노출평가시스템 (Ⅲ)
MAP
FANTASY
FINDS
DREAMS
PoST
RiskPro
Dietary exposure = Σ(Concentration fo chemical in foodX Food consumption) / Body weight (kg)
QUICK MENU
DB구축현황
DB총괄현황
유해물질함량
식품섭취량
식이노출평가
신속오염실태분석
인체노출허용량
유해물질총서검색
시스템사용현황
DB 구축현황
식품 중 모니터링 DB 구축현황
2016
2014
2012
2010
2008
0
10,000,000
20,000,000
30,000,000
40,000,000
년도별 섭취량DB 구축현황
2014
2012
2010
2008
2005
2001
1998
0
200,000
400,000
600,000
800,000
기준규격 및 인체노출허용량 DB현황
500
400
300
200
100
0
곰팡이독소
다이옥신
식품첨가물
유해물질총서 DB현황
50
40
30
20
10
0
식품첨가물
신종유해물질
잔류농약

유해물질 모니터링 D/B 및 한국형 식이노출평가시스템

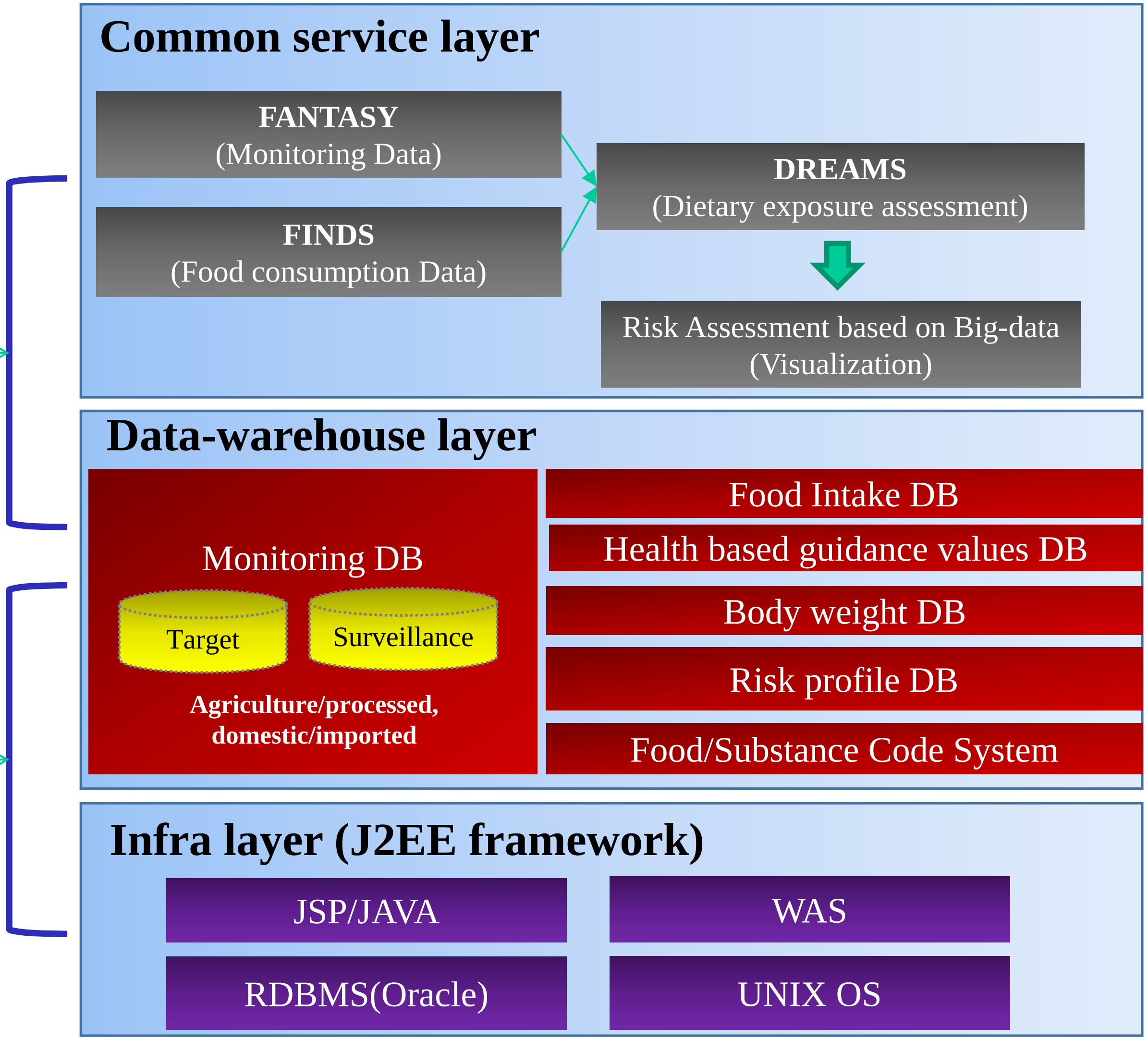
MAP
Monitoring database and Assessment Program

식품 중의 유해물질의 농도(함량) DB, 식품 섭취량 DB 그리고 농도DB-섭취량DB간 상호 조직화를 통한 첨단 한국형 식이노출평가시스템이다.

III. Structure of the MIMS/MAP

http://cheminet.homeip.net:8888/mfds_map201
MAP 3.0
유해물질 안전관리 통합 전
Monitoring database and Assessm
FANTASY
FINDS
MAP 3.0
e.g. Pb Cd

http://cheminet.homeip.net
MIMS
유해물질 모니터링 정보관리시스템
[운영자 - 시스템 관리
자료 관리부서
자료 관리부서
입력현황 모니터링
프로젝트(초기화)
터링 자료입력
별 현황



Common service layer

FANTASY
(Monitoring Data)

FINDS
(Food consumption Data)

DREAMS
(Dietary exposure assessment)

Risk Assessment based on Big-data
(Visualization)

Data-warehouse layer

Monitoring DB

Target

Surveillance

Agriculture/processed, domestic/imported

Food Intake DB

Health based guidance values DB

Body weight DB

Risk profile DB

Food/Substance Code System

Infra layer (J2EE framework)

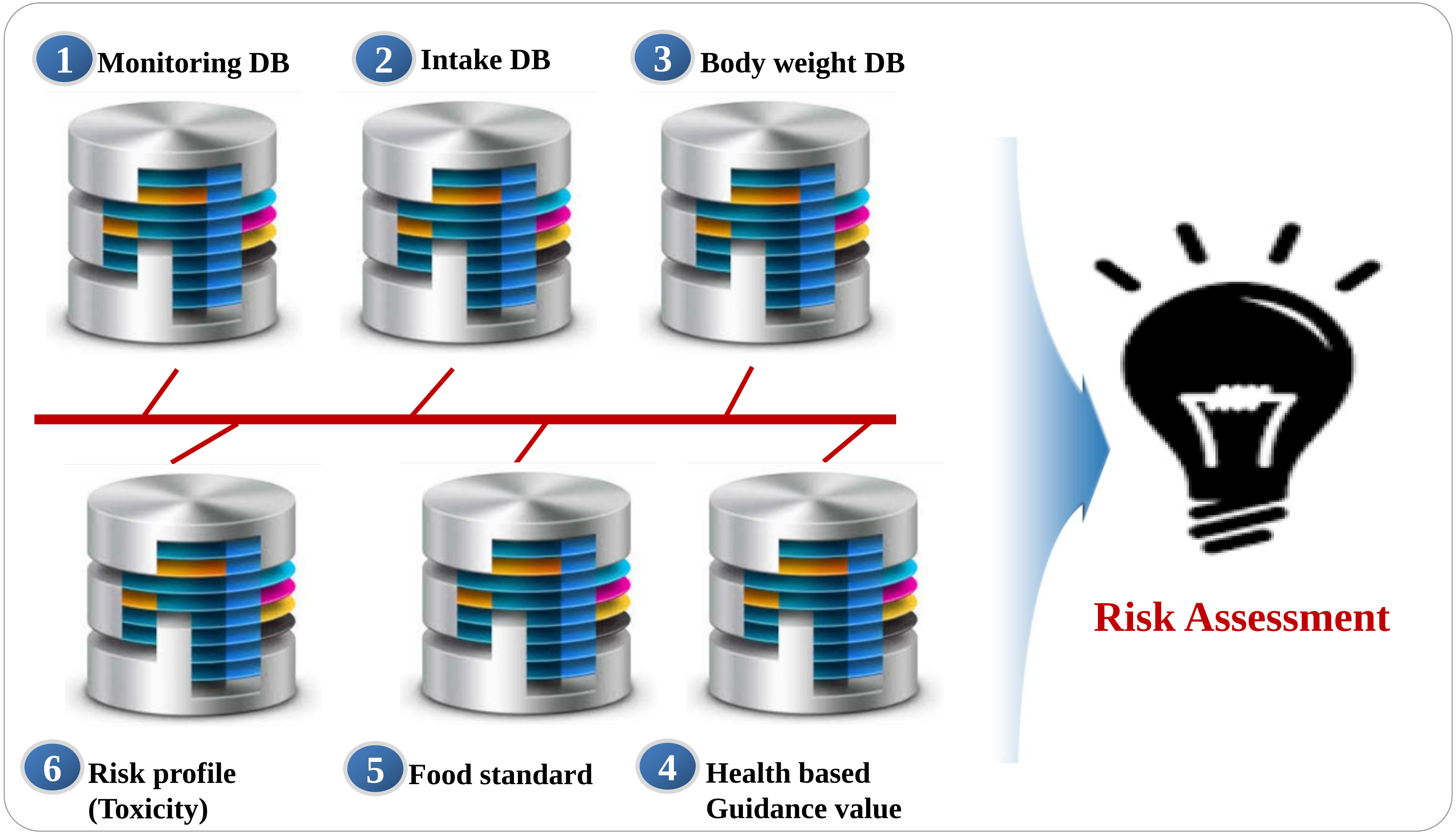
JSP/JAVA

WAS

RDBMS(Oracle)

UNIX OS

III. Structure of the MIMS/MAP
- DATA Warehouse -



1 Monitoring DB

2 Intake DB

3 Body weight DB

6 Risk profile (Toxicity)

5 Food standard

4 Health based Guidance value

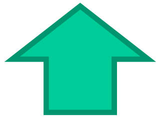
Risk Assessment

III. Monitoring DB of the MIMS

1 The hazardous substances contaminant levels in Foods

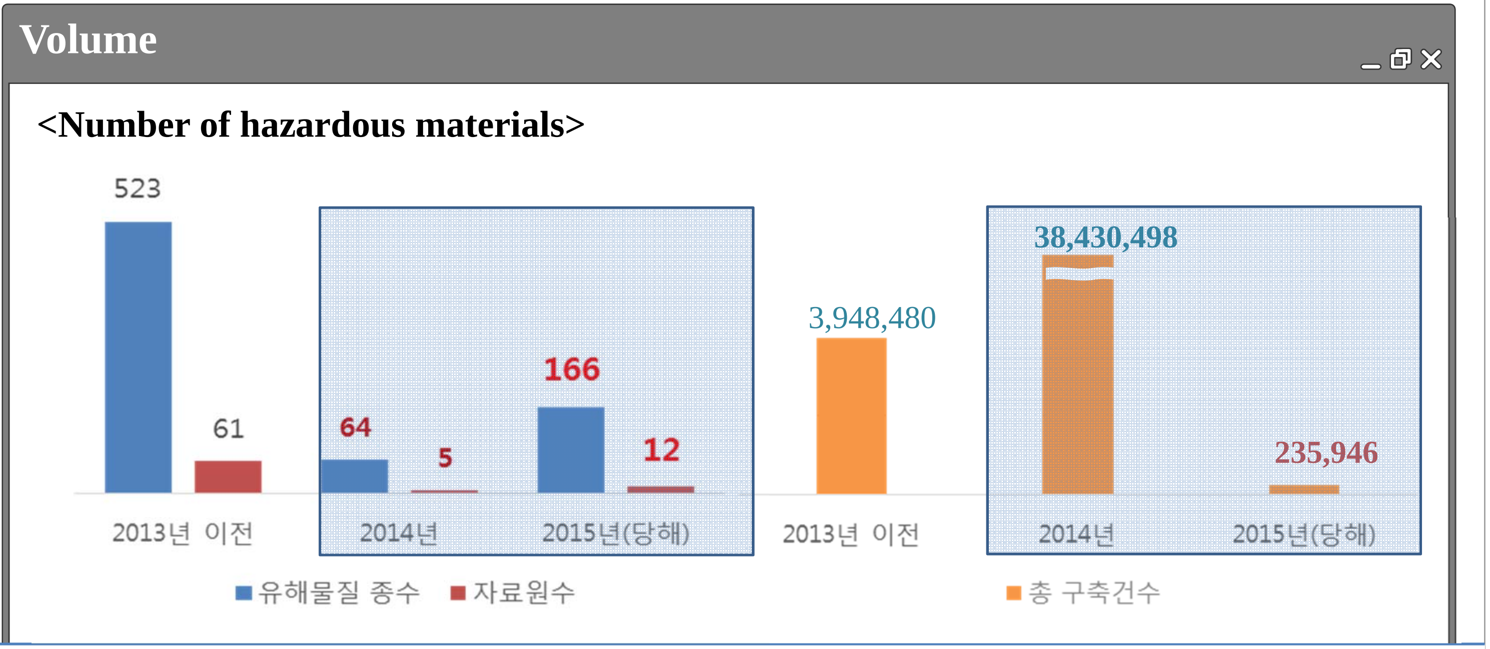
- pesticides, food additives, contaminants such as heavy metals, mycotoxins, etc.

1 Monitoring DB



Survey

Monitoring



Volume

<Number of hazardous materials>

	2013 and before	2014	2015	Total accumulated items
Total number of risky materials	523	64	166	753
No. of data sources	61	5	12	78
Total entries	3,948,480	38,430,498	235,946	42,614,924

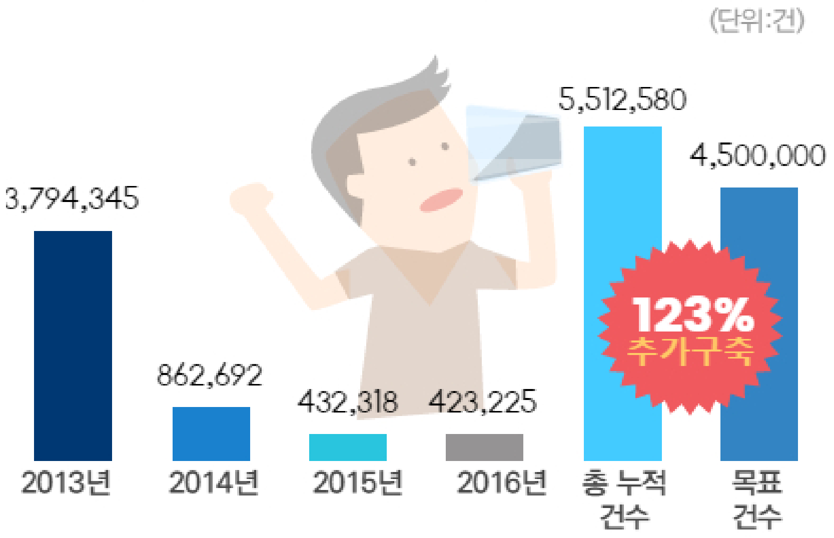
III. Food Consumption DB of the MIMS

2 Food intake level from National Health & Nutrition Survey of Korea since 1998

Food Intake DB

Volume

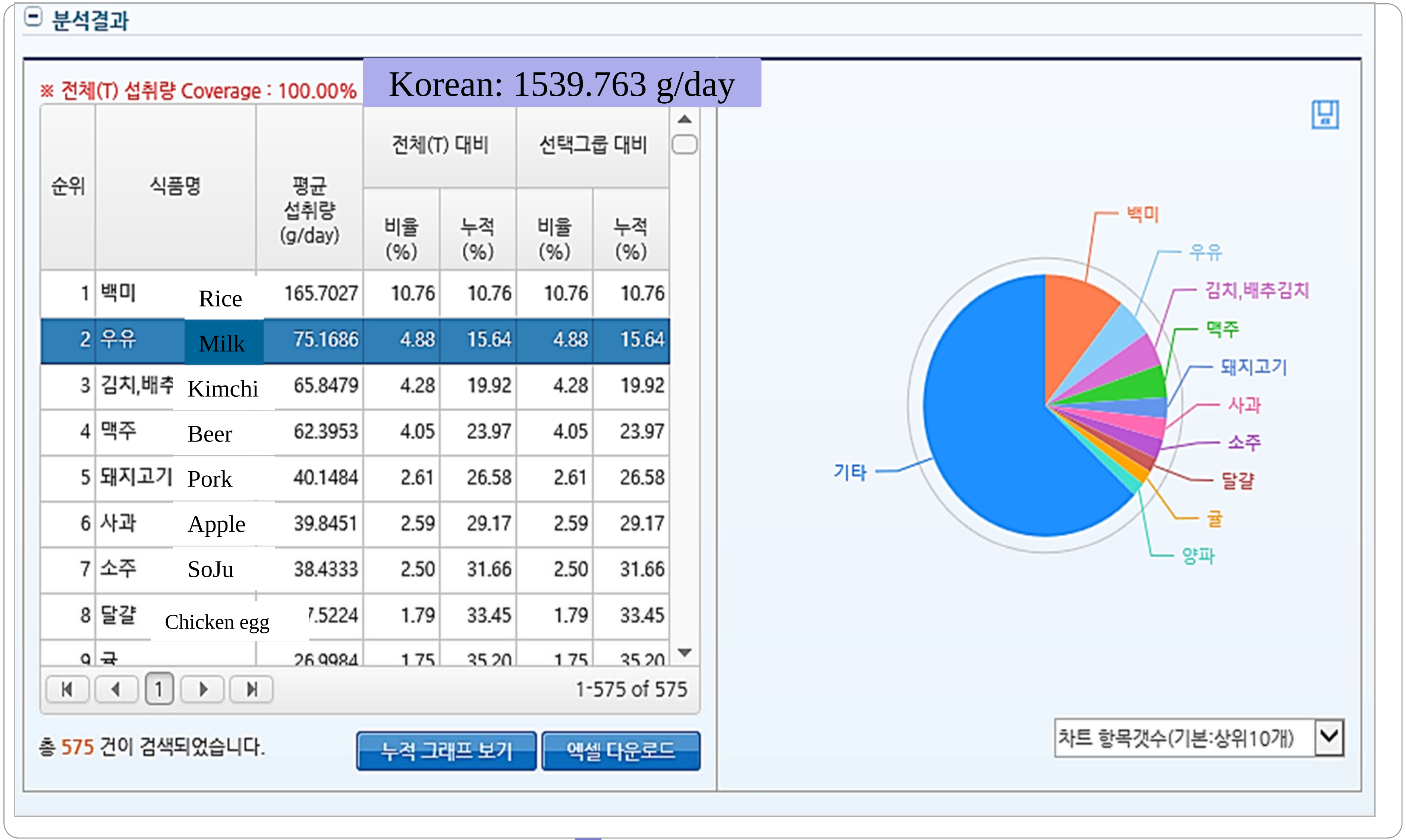
Food Consumption DB



Year	Generations and batches
2013	**1998 ~ 2010** (1st Gen./1st Batch)
2014	**2011 ~ 2012** (5th Gen./2nd Batch)
2015	**2013** (6th Gen./1st Batch)
2016	**2014** (6th Gen./2nd Batch)

5.5 million food intake data

III. Analysis of Food Consumption DB



Korean: 1539.763 g/day

분석결과

※ 전체(T) 섭취량 Coverage : 100.00%

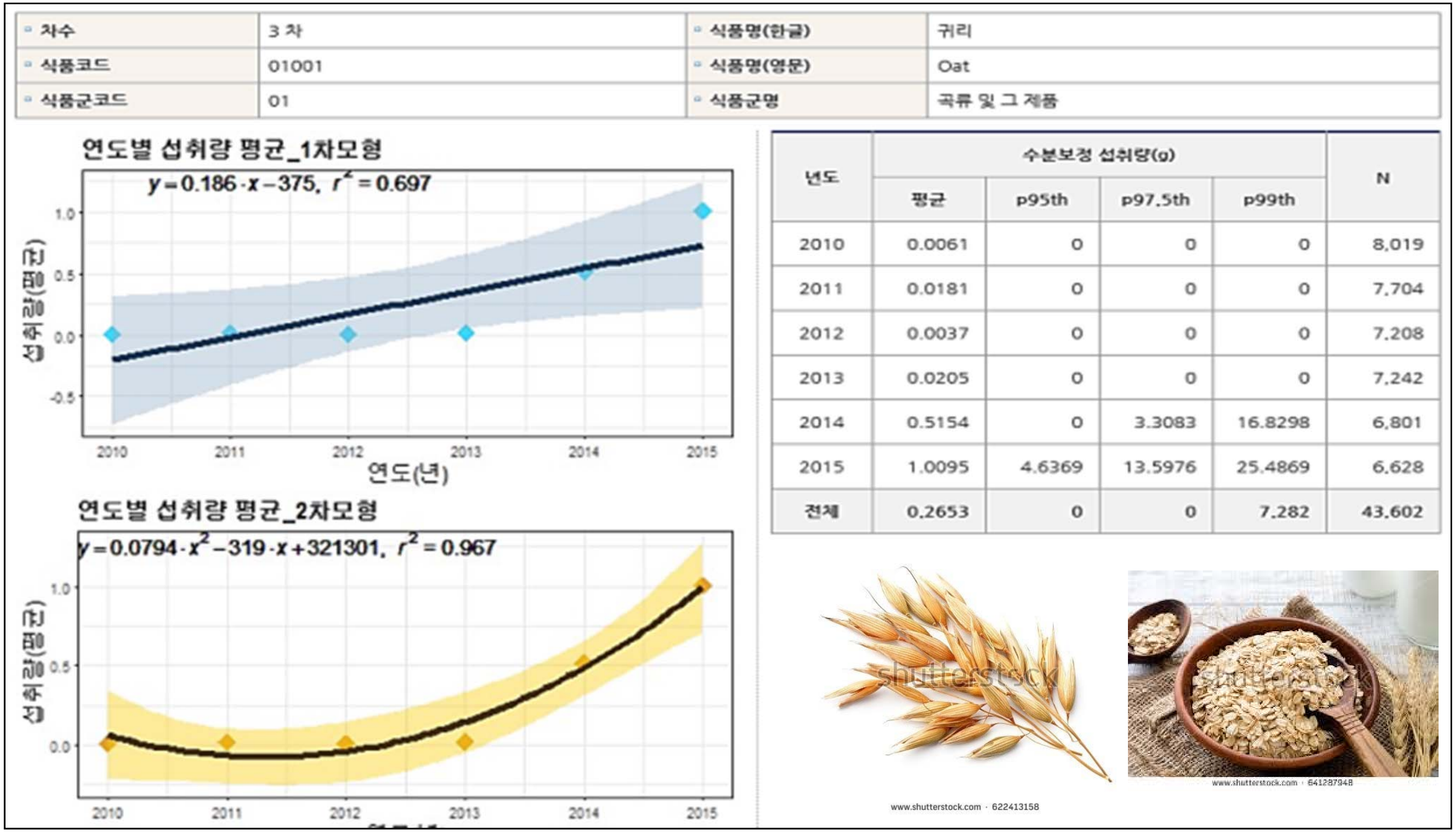
순위	식품명	평균 섭취량 (g/day)	전체(T) 대비		선택그룹 대비	
			비율 (%)	누적 (%)	비율 (%)	누적 (%)
1	백미 Rice	165.7027	10.76	10.76	10.76	10.76
2	우유 Milk	75.1686	4.88	15.64	4.88	15.64
3	김치,배추 Kimchi	65.8479	4.28	19.92	4.28	19.92
4	맥주 Beer	62.3953	4.05	23.97	4.05	23.97
5	돼지고기 Pork	40.1484	2.61	26.58	2.61	26.58
6	사과 Apple	39.8451	2.59	29.17	2.59	29.17
7	소주 SoJu	38.4333	2.50	31.66	2.50	31.66
8	달걀 Chicken egg	7.5224	1.79	33.45	1.79	33.45
9	귤	26.9984	1.75	35.20	1.75	35.20

1-575 of 575

총 575 건이 검색되었습니다.

누적 그래프 보기
엑셀 다운로드
백미
우유
김치,배추김치
맥주
돼지고기
사과
소주
달걀
귤
양파
기타
차트 항목갯수(기본:상위10개)

III. Analysis of Food Consumption DB



▫ 차수	3 차	▫ 식품명(한글)	귀리
▫ 식품코드	01001	▫ 식품명(영문)	Oat
▫ 식품군코드	01	▫ 식품군명	곡류 및 그 제품

연도별 섭취량 평균_1차모형

$y = 0.186 \cdot x - 375,\ r^2 = 0.697$

1.0
0.5
0.0
-0.5
섭취량(평균)
2010
2011
2012
2013
2014
2015
연도(년)

연도별 섭취량 평균_2차모형

$y = 0.0794 \cdot x^2 - 319 \cdot x + 321301,\ r^2 = 0.967$

1.0
0.5
0.0
섭취량(평균)
2010
2011
2012
2013
2014
2015

년도	수분보정 섭취량(g)				N
	평균	p95th	p97.5th	p99th	
2010	0.0061	0	0	0	8,019
2011	0.0181	0	0	0	7,704
2012	0.0037	0	0	0	7,208
2013	0.0205	0	0	0	7,242
2014	0.5154	0	3.3083	16.8298	6,801
2015	1.0095	4.6369	13.5976	25.4869	6,628
전체	0.2653	0	0	7.282	43,602

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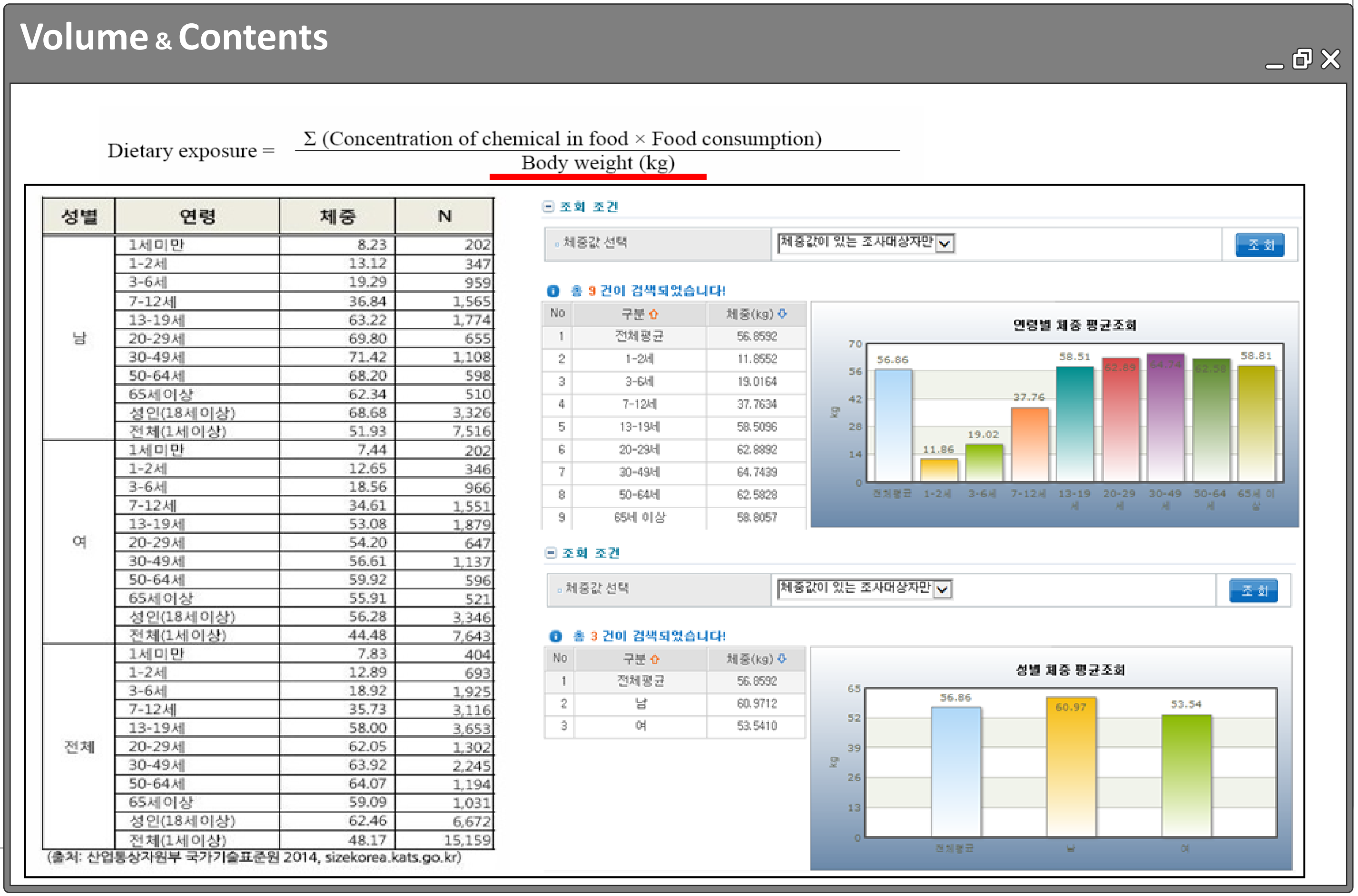
III. Body Weight DB of the MIMS

3 Body weight data from National Health & Nutrition Survey of Korea since 1998

3 Body weight DB



Volume & Contents

$$\text{Dietary exposure} = \frac{\Sigma\,(\text{Concentration of chemical in food} \times \text{Food consumption})}{\text{Body weight (kg)}}$$

성별	연령	체중	N
남	1세미만	8.23	202
	1-2세	13.12	347
	3-6세	19.29	959
	7-12세	36.84	1,565
	13-19세	63.22	1,774
	20-29세	69.80	655
	30-49세	71.42	1,108
	50-64세	68.20	598
	65세이상	62.34	510
	성인(18세이상)	68.68	3,326
	전체(1세이상)	51.93	7,516
여	1세미만	7.44	202
	1-2세	12.65	346
	3-6세	18.56	966
	7-12세	34.61	1,551
	13-19세	53.08	1,879
	20-29세	54.20	647
	30-49세	56.61	1,137
	50-64세	59.92	596
	65세이상	55.91	521
	성인(18세이상)	56.28	3,346
	전체(1세이상)	44.48	7,643
전체	1세미만	7.83	404
	1-2세	12.89	693
	3-6세	18.92	1,925
	7-12세	35.73	3,116
	13-19세	58.00	3,653
	20-29세	62.05	1,302
	30-49세	63.92	2,245
	50-64세	64.07	1,194
	65세이상	59.09	1,031
	성인(18세이상)	62.46	6,672
	전체(1세이상)	48.17	15,159

(출처: 산업통상자원부 국가기술표준원 2014, sizekorea.kats.go.kr)

⊟ 조회 조건

체중값 선택: 체중값이 있는 조사대상자만

총 9 건이 검색되었습니다!

No	구분	체중(kg)
1	전체평균	56.8592
2	1-2세	11.8552
3	3-6세	19.0164
4	7-12세	37.7634
5	13-19세	58.5096
6	20-29세	62.8892
7	30-49세	64.7439
8	50-64세	62.5828
9	65세 이상	58.8057

⊟ 조회 조건

체중값 선택: 체중값이 있는 조사대상자만

총 3 건이 검색되었습니다!

No	구분	체중(kg)
1	전체평균	56.8592
2	남	60.9712
3	여	53.5410

_ ▫ ✕
조 회
연령별 체중 평균조회
kg
70
56
42
28
14
0
56.86
11.86
19.02
37.76
58.51
62.89
64.74
62.58
58.81
전체평균
1-2세
3-6세
7-12세
13-19세
20-29세
30-49세
50-64세
65세 이상
성별 체중 평균조회
65
52
39
26
13
0
56.86
60.97
53.54
전체평균
남
여

III. Risk Profile DB of Hazadous Substances in Food

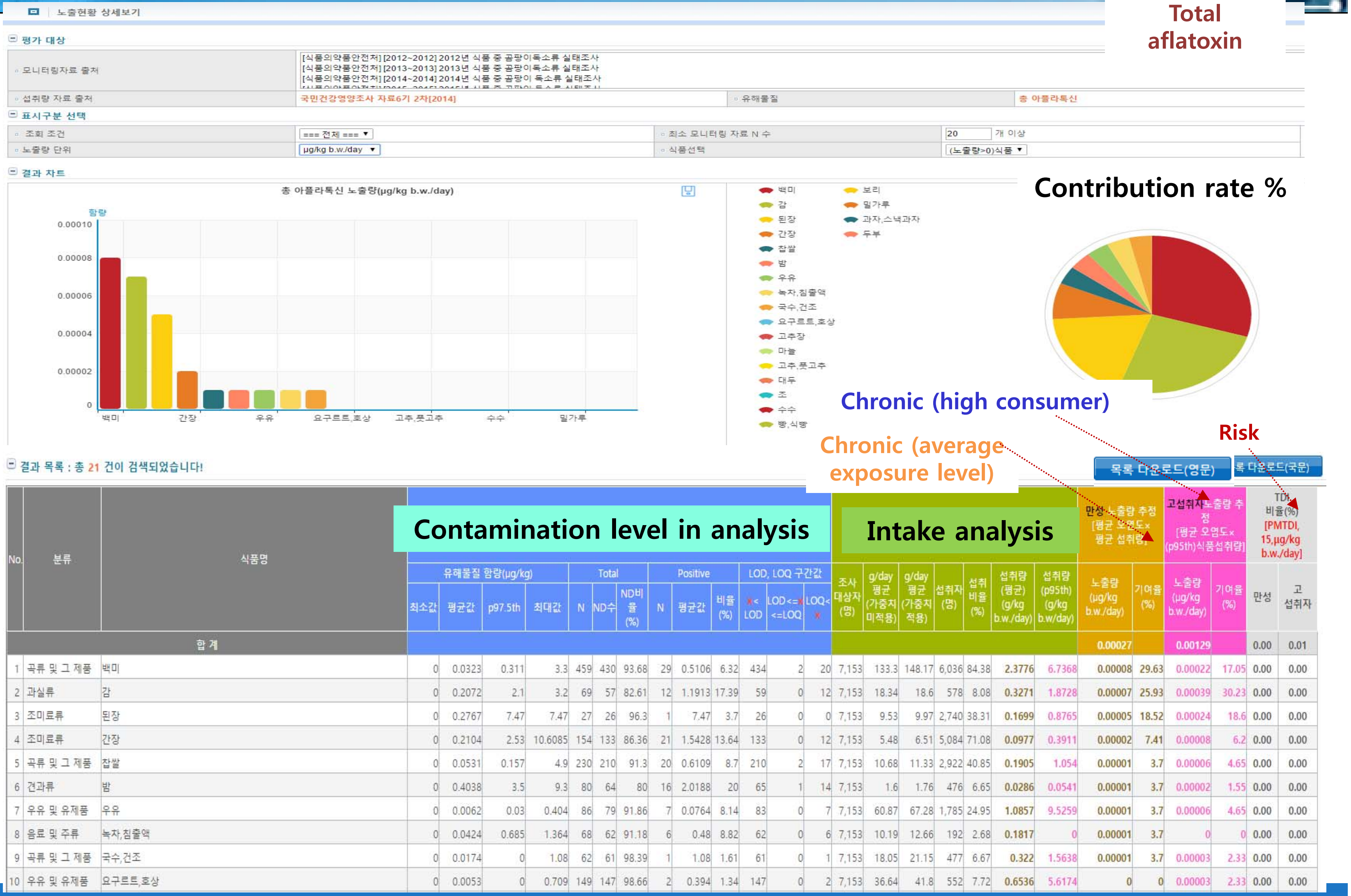
3 Risk profile (Toxicity Information)

contents	Total file number
Food additives	160
Pesticides	450
Contaminants	140

4 Residual standard

Item		No. of entries
Natural toxin (including mycotoxin)	Total aflatoxin (Sum of B1,B2,G1, and G2)	167
	Fumonisin (Sum of B1 and B2)	9
	Ochratoxin A	135
	Others	557
Heavy metal	Lead	5,538
	Arsenic (including total arsenic)	716
	Cadmium	4,843
	Mercury	6,613
Total		

IV. Example of MAPs analysis : Mycotoxin in food



Total aflatoxin

노출현황 상세보기

평가 대상

모니터링자료 출처	[식품의약품안전처] [2012~2012] 2012년 식품 중 곰팡이독소류 실태조사 [식품의약품안전처] [2013~2013] 2013년 식품 중 곰팡이독소류 실태조사 [식품의약품안전처] [2014~2014] 2014년 식품 중 곰팡이 독소류 실태조사		
섭취량 자료 출처	국민건강영양조사 자료6기 2차[2014]	유해물질	총 아플라톡신

표시구분 선택

조회 조건	=== 전체 === ▼	최소 모니터링 자료 N 수	20 개 이상
노출량 단위	µg/kg b.w./day ▼	식품선택	(노출량>0)식품 ▼

결과 차트

총 아플라톡신 노출량(µg/kg b.w./day)

Contribution rate %

Chronic (high consumer)

Chronic (average exposure level)

Risk

결과 목록 : 총 21 건이 검색되었습니다!

목록 다운로드(영문) 목록 다운로드(국문)

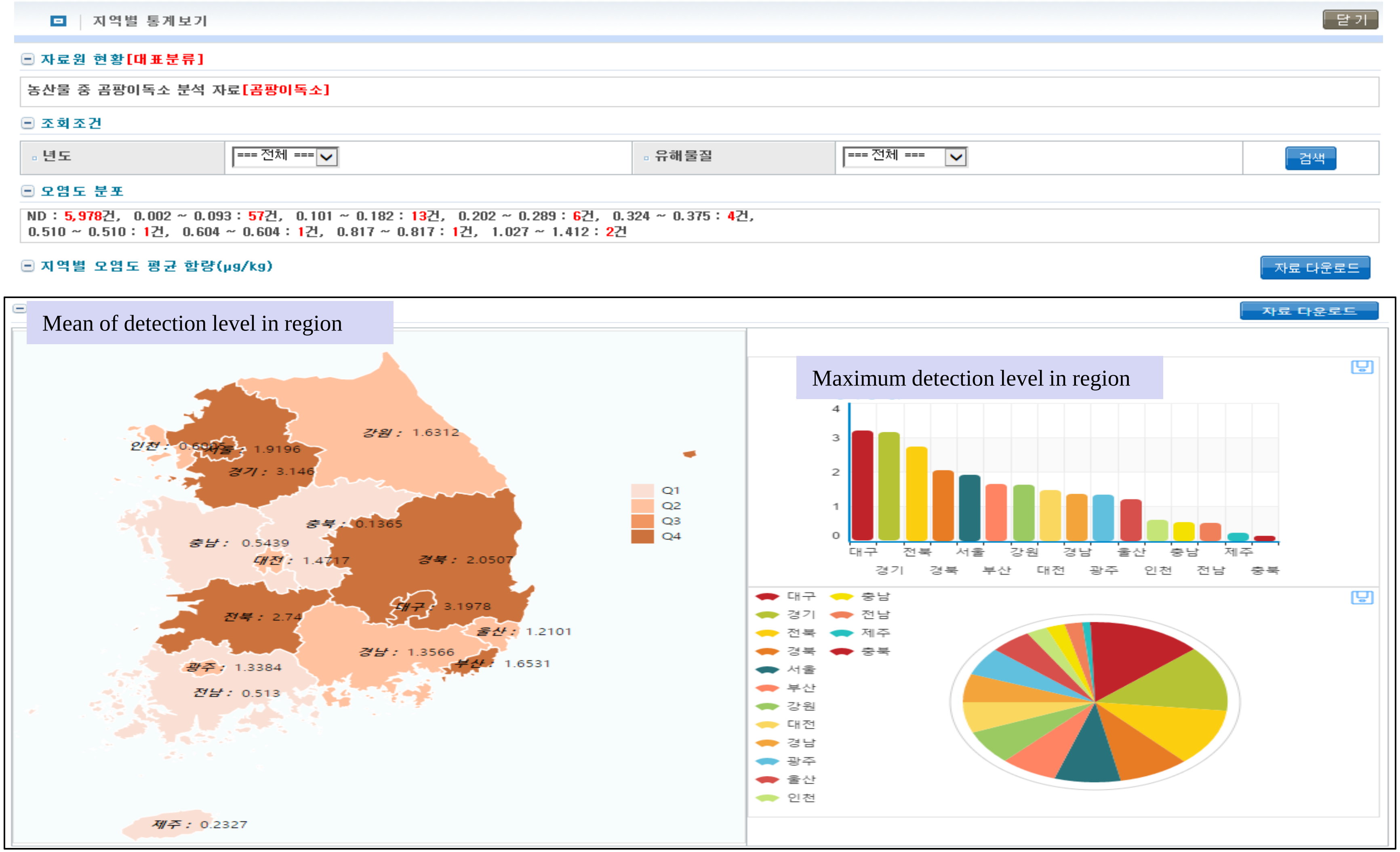
Contamination level in analysis

Intake analysis

No.	분류	식품명	유해물질 함량(µg/kg)				Total			Positive			LOD, LOQ 구간값			조사대상자(명)	g/day 평균(가중치 미적용)	g/day 평균(가중치 적용)	섭취자(명)	섭취 비율(%)	섭취량(평균)(g/kg b.w./day)	섭취량(p95th)(g/kg b.w/day)	만성 노출량 추정 [평균 오염도× 평균 섭취량]		고섭취자 노출량 추정 [평균 오염도× (p95th)식품섭취량]		TDI 비율(%) [PMTDI, 15,µg/kg b.w./day]	
			최소값	평균값	p97.5th	최대값	N	ND수	ND비율(%)	N	평균값	비율(%)	x< LOD	LOD<=x<=LOQ	LOQ<x								노출량(µg/kg b.w./day)	기여율(%)	노출량(µg/kg b.w./day)	기여율(%)	만성	고섭취자
합 계																							0.00027		0.00129		0.00	0.01
1	곡류 및 그 제품	백미	0	0.0323	0.311	3.3	459	430	93.68	29	0.5106	6.32	434	2	20	7,153	133.3	148.17	6,036	84.38	2.3776	6.7368	0.00008	29.63	0.00022	17.05	0.00	0.00
2	과실류	감	0	0.2072	2.1	3.2	69	57	82.61	12	1.1913	17.39	59	0	12	7,153	18.34	18.6	578	8.08	0.3271	1.8728	0.00007	25.93	0.00039	30.23	0.00	0.00
3	조미료류	된장	0	0.2767	7.47	7.47	27	26	96.3	1	7.47	3.7	26	0	0	7,153	9.53	9.97	2,740	38.31	0.1699	0.8765	0.00005	18.52	0.00024	18.6	0.00	0.00
4	조미료류	간장	0	0.2104	2.53	10.6085	154	133	86.36	21	1.5428	13.64	133	0	12	7,153	5.48	6.51	5,084	71.08	0.0977	0.3911	0.00002	7.41	0.00008	6.2	0.00	0.00
5	곡류 및 그 제품	찹쌀	0	0.0531	0.157	4.9	230	210	91.3	20	0.6109	8.7	210	2	17	7,153	10.68	11.33	2,922	40.85	0.1905	1.054	0.00001	3.7	0.00006	4.65	0.00	0.00
6	견과류	밤	0	0.4038	3.5	9.3	80	64	80	16	2.0188	20	65	1	14	7,153	1.6	1.76	476	6.65	0.0286	0.0541	0.00001	3.7	0.00002	1.55	0.00	0.00
7	우유 및 유제품	우유	0	0.0062	0.03	0.404	86	79	91.86	7	0.0764	8.14	83	0	7	7,153	60.87	67.28	1,785	24.95	1.0857	9.5259	0.00001	3.7	0.00006	4.65	0.00	0.00
8	음료 및 주류	녹차,침출액	0	0.0424	0.685	1.364	68	62	91.18	6	0.48	8.82	62	0	6	7,153	10.19	12.66	192	2.68	0.1817	0	0.00001	3.7	0	0	0.00	0.00
9	곡류 및 그 제품	국수,건조	0	0.0174	0	1.08	62	61	98.39	1	1.08	1.61	61	0	1	7,153	18.05	21.15	477	6.67	0.322	1.5638	0.00001	3.7	0.00003	2.33	0.00	0.00
10	우유 및 유제품	요구르트,호상	0	0.0053	0	0.709	149	147	98.66	2	0.394	1.34	147	0	2	7,153	36.64	41.8	552	7.72	0.6536	5.6174	0	0	0.00003	2.33	0.00	0.00

IV. Example of MAPs analysis : Mycotoxin in food

❖MIMS/MAP Rapid Contamination Status Analysis Result according to regions



지역별 통계보기

자료원 현황[대표분류]

농산물 중 곰팡이독소 분석 자료[곰팡이독소]

조회조건

년도: === 전체 ===

유해물질: === 전체 ===

오염도 분포

ND : 5,978건, 0.002 ~ 0.093 : 57건, 0.101 ~ 0.182 : 13건, 0.202 ~ 0.289 : 6건, 0.324 ~ 0.375 : 4건,
0.510 ~ 0.510 : 1건, 0.604 ~ 0.604 : 1건, 0.817 ~ 0.817 : 1건, 1.027 ~ 1.412 : 2건

지역별 오염도 평균 함량(μg/kg)

Mean of detection level in region

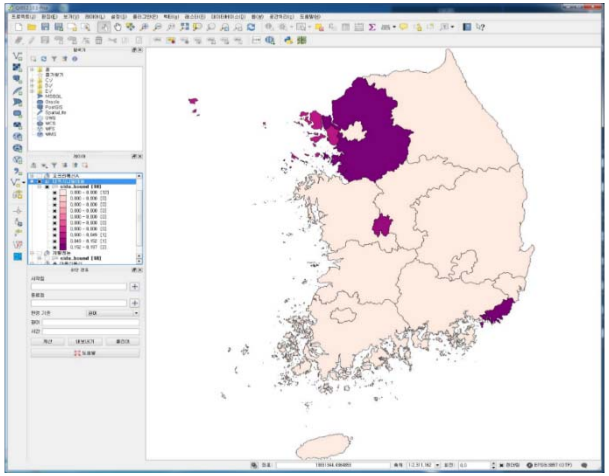
Maximum detection level in region

닫기
검색
자료 다운로드
자료 다운로드
인천 : 0.6005
서울 : 1.9196
경기 : 3.146
강원 : 1.6312
충북 : 0.1365
충남 : 0.5439
대전 : 1.4717
경북 : 2.0507
대구 : 3.1978
전북 : 2.74
울산 : 1.2101
경남 : 1.3566
부산 : 1.6531
광주 : 1.3384
전남 : 0.513
제주 : 0.2327
Q1
Q2
Q3
Q4
4
3
2
1
0
대구
경기
전북
경북
서울
부산
강원
대전
경남
광주
울산
인천
충남
전남
제주
충북
대구
경기
전북
경북
서울
부산
강원
대전
경남
광주
울산
인천
충남
전남
제주
충북

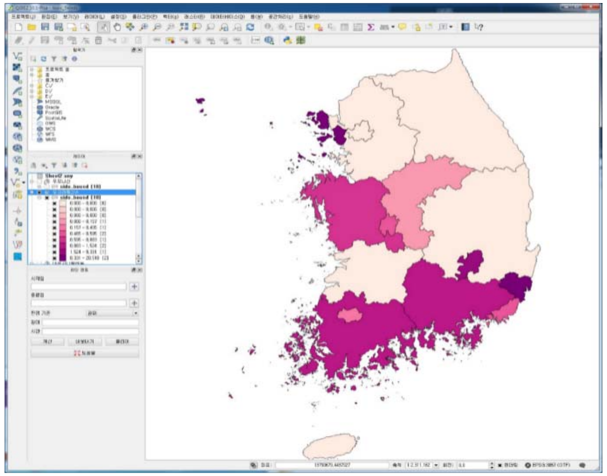
IV. Example of MAPs analysis :
Big-data based on visualization to show the results of Risk assessment

> **Mycotoxin distribution status by areas using OpenSource GIS(QGIS) (As of 2012)**

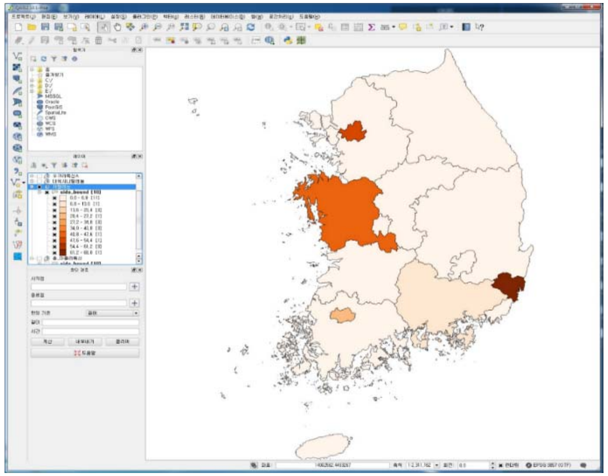
Deoxynivalenol



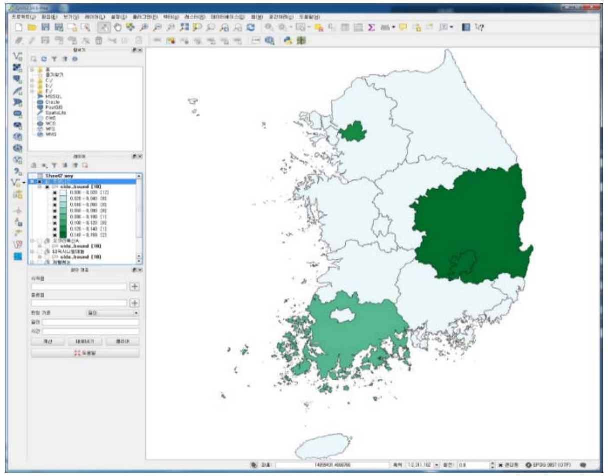
Ochratoxin A



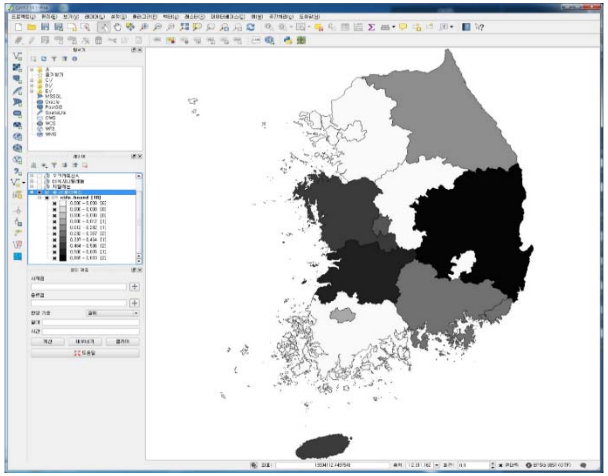
Zearelanone



Fumonisin



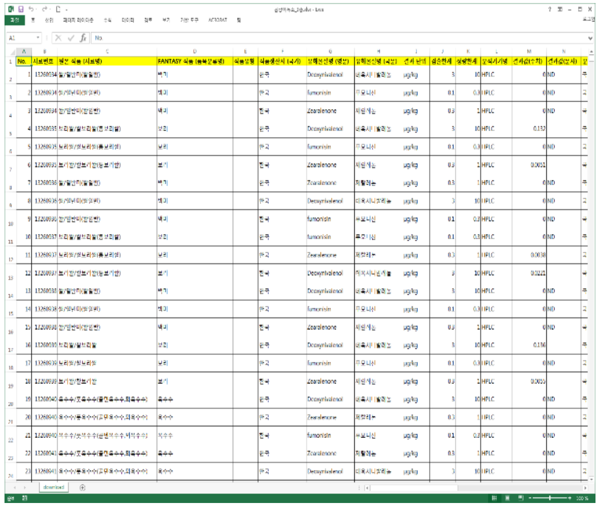
Total aflatoxin



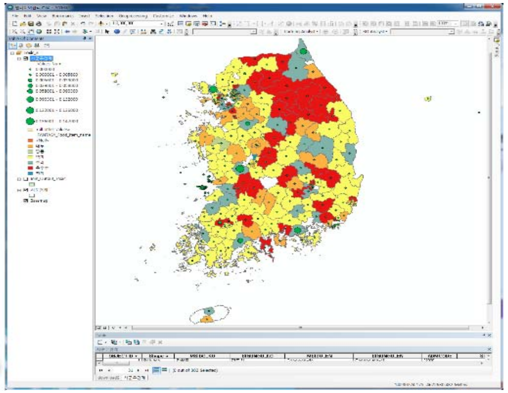
IV. Example of MAPs analysis :
Big-data based on visualization to show the results of Risk assessment

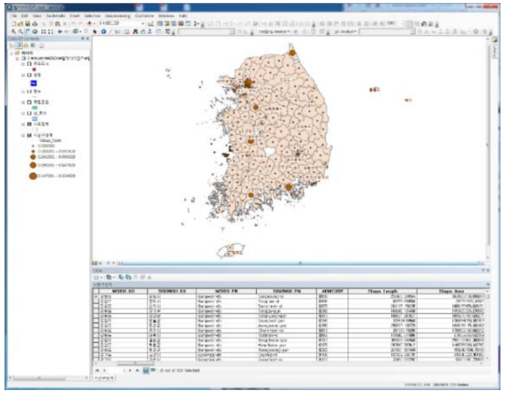
❖ Development of hazardous substance visualization tools using GIS

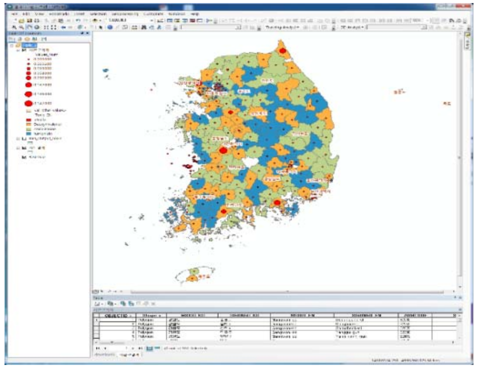
- ✓ Use commercial GIS to develop visualization methods for agricultural products-hazardous substances distribution status.
- ✓ Analyze the distribution of toxin based on the raw data on three mycotoxins (in conjunction with 1 details)
- ✓ Analyze and design an open source GIS to be applied to the risk assessment system


Raw data on three mycotoxins

Data
+
GIS information



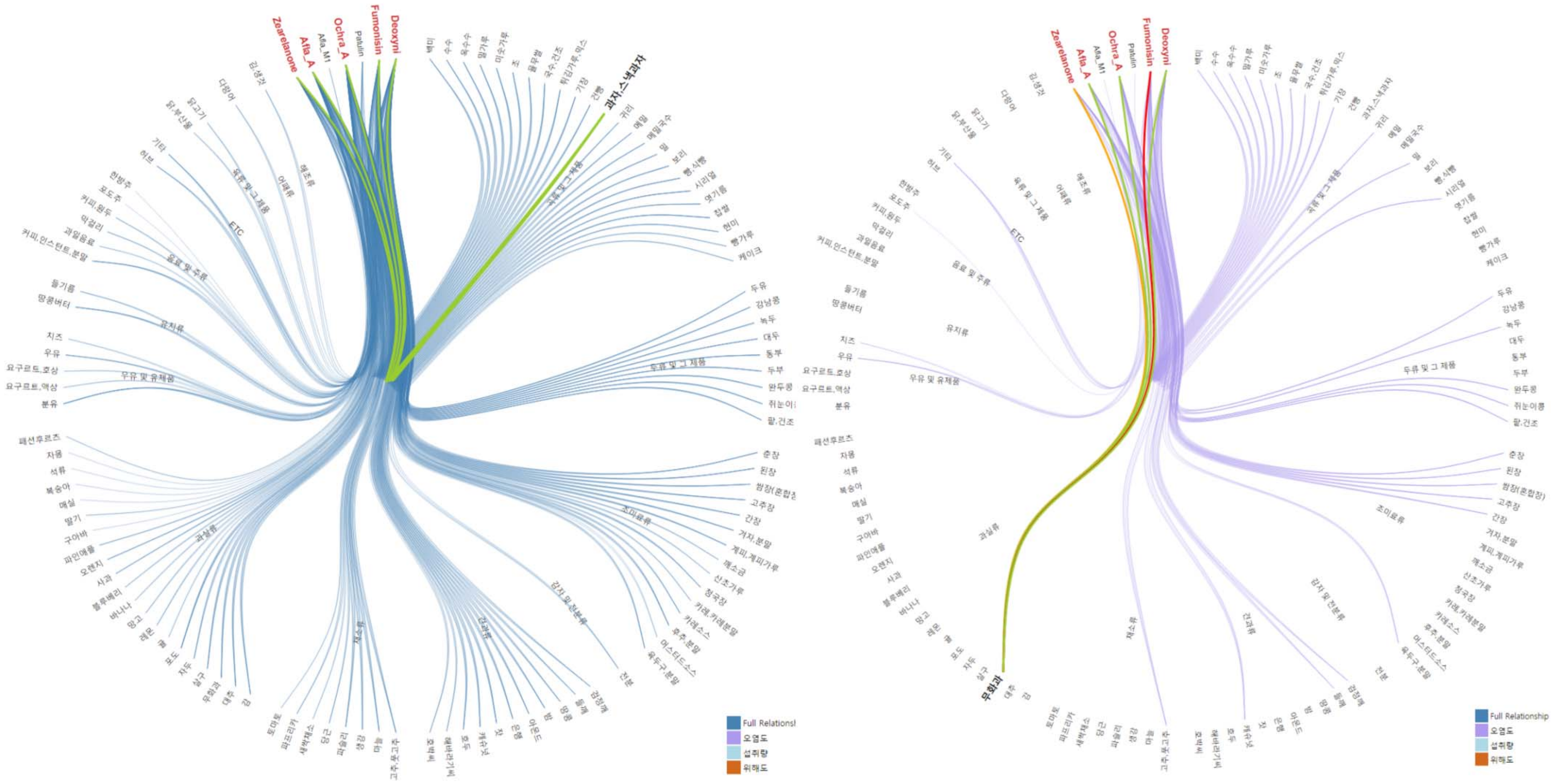




IV. Example of MAPs analysis :

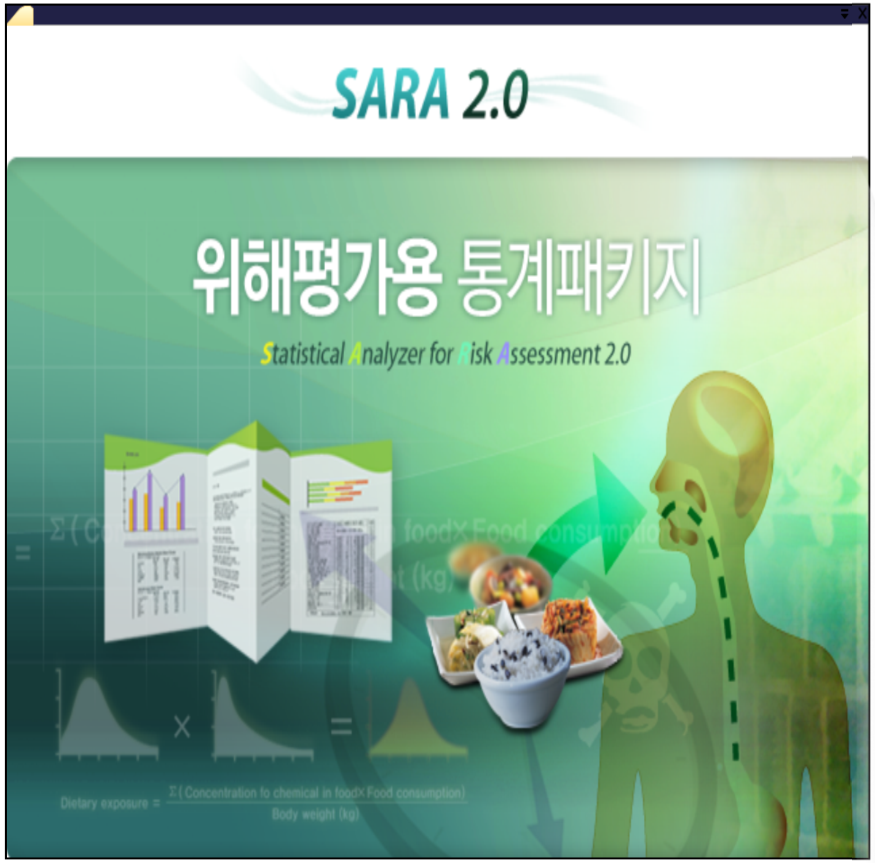
Big-data based on visualization to show the results of Risk assessment

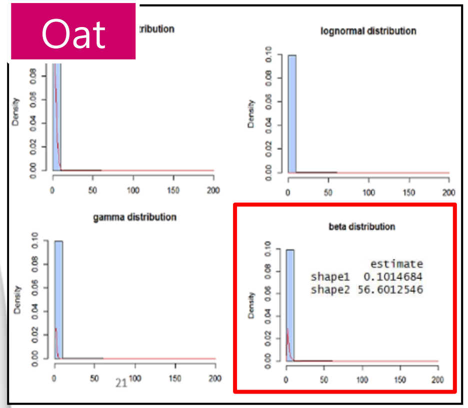
Infographic Tool for Food-hazardous substances risk assessment


Zearelanone
Afla_A
Afla_M1
Ochra_A
Patulin
Fumonisin
Deoxyni
백미
수수
옥수수
밀가루
미숫가루
조
율무쌀
국수,건조
튀김가루,믹스
기장
건빵
과자,스낵과자
귀리
메밀
메밀국수
밀
보리
빵,식빵
시리얼
엿기름
찹쌀
현미
빵가루
케이크
곡류 및 그 제품
두유
강낭콩
녹두
대두
동부
두부
완두콩
취눈이콩
팥,건조
두류 및 그 제품
춘장
된장
쌈장(혼합장)
고추장
간장
겨자,분말
계피,계피가루
깨소금
산초가루
청국장
카레,카레분말
카레소스
후추,분말
머스타드소스
육두구,분말
조미료류
감자 및 전분류
전분
감자
고구마
견과류
채소류
과실류
무화과
ETC
음료 및 주류
유지류
우유 및 유제품
치즈
우유
요구르트,호상
요구르트,액상
분유
들기름
땅콩버터
커피,인스턴트,분말
과일음료
막걸리
커피,원두
포도주
한방주
허브
기타
닭고기
육류 및 그 제품
어패류
해조류
다랑어
김,생것
Full Relationship
오염도
섭취량
위해도

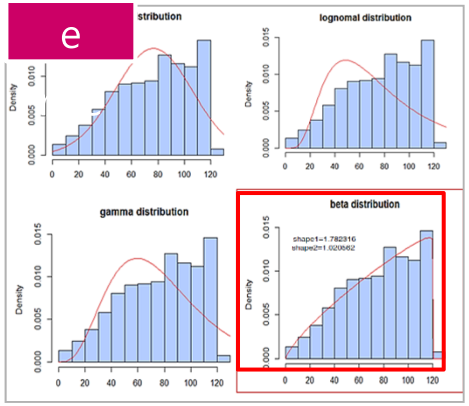
V. Research outcomes of the MIMS/MAP

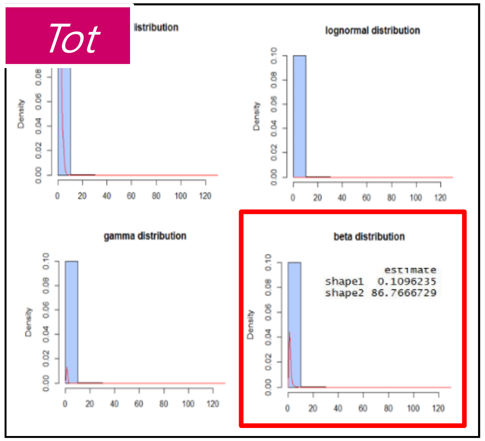
- Use SARA 2.0(Statistical Analyzer for Risk Assessment) to complete the estimation of the appropriate distribution for food products and by the National Health Code (1st, 2nd, 3rd)


SARA 2.0
위해평가용 통계패키지
Statistical Analyzer for Risk Assessment 2.0
Dietary exposure = Σ(Concentration to chemical in foodX Food consumption) / Body weight (kg)



```
   estimate
shape1  0.1014684
shape2 56.6012546
```





```
   estimate
shape1  0.1096235
shape2 86.7666729
```

V. Research outcomes of the MIMS/MAP

❍ Analysis of the report process based the risk assessment cases

- ➢ Open the risk assessment report of 8 mycotoxins in 2016

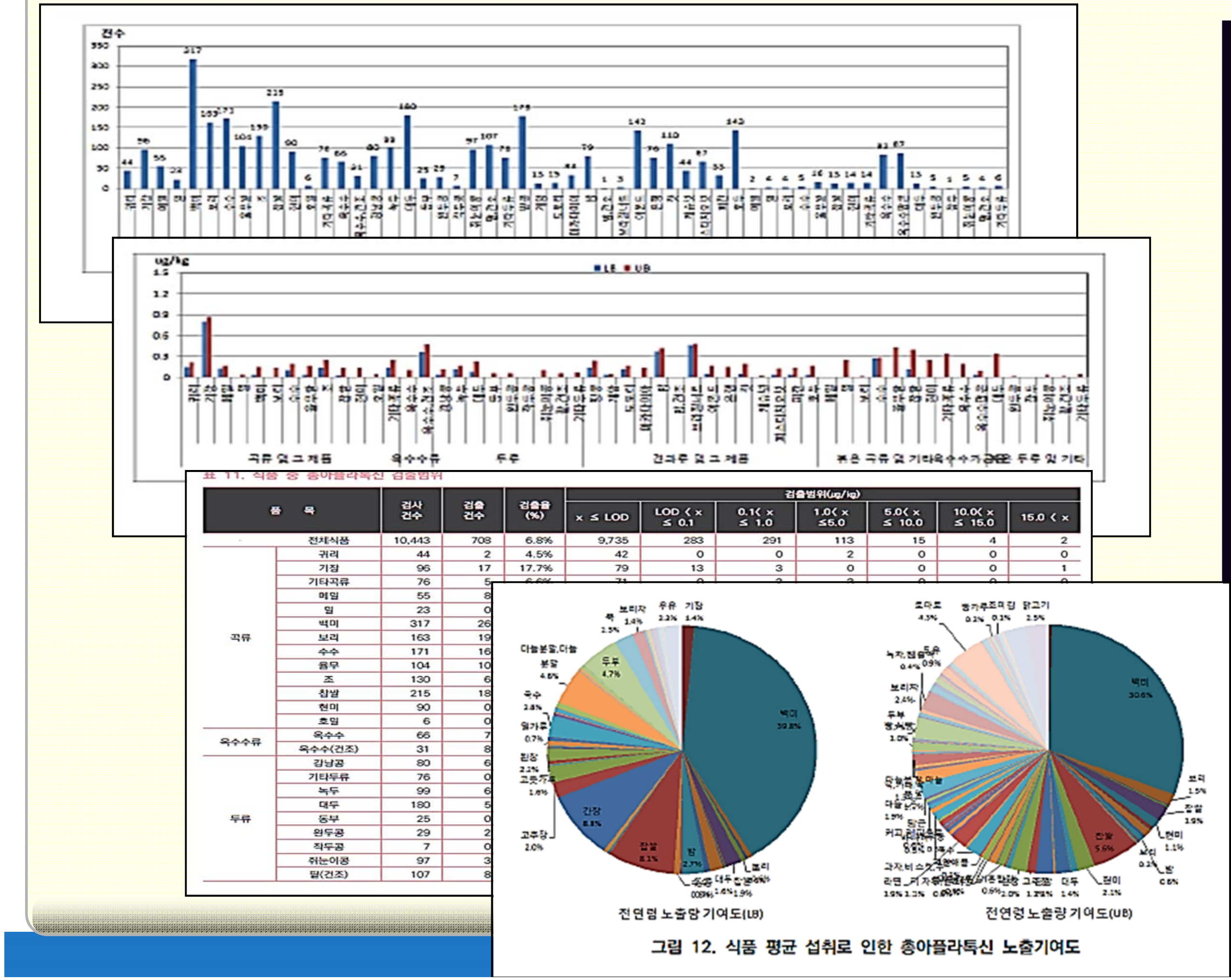


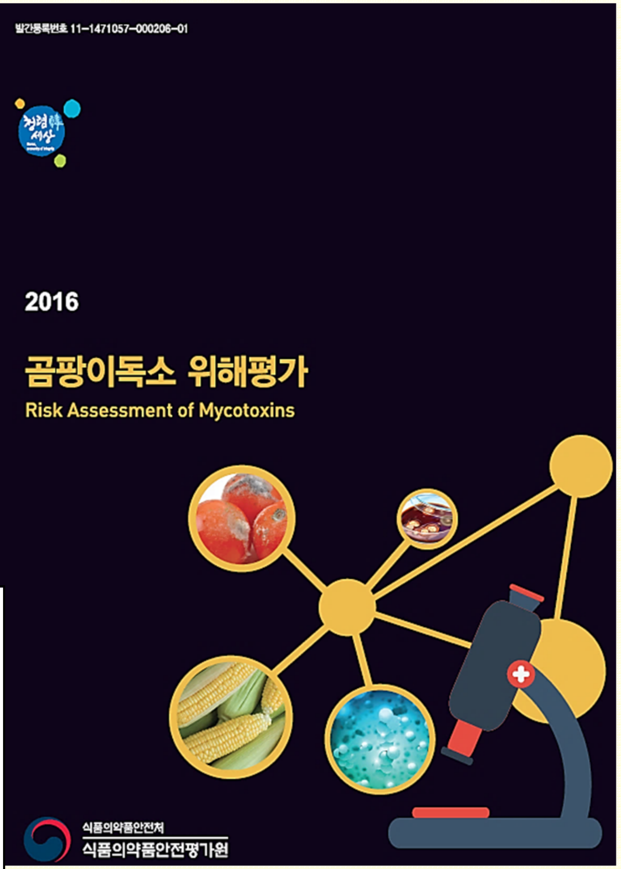
표 11. 식품 중 총아플라톡신 검출범위

품 목		검사 건수	검출 건수	검출율 (%)	검출범위(ug/kg)						
					x ≤ LOD	LOD < x ≤ 0.1	0.1< x ≤ 1.0	1.0< x ≤5.0	5.0< x ≤ 10.0	10.0< x ≤ 15.0	15.0 < x
	전체식품	10,443	708	6.8%	9,735	283	291	113	15	4	2
곡류	귀리	44	2	4.5%	42	0	0	2	0	0	0
	기장	96	17	17.7%	79	13	3	0	0	0	1
	기타곡류	76	5								
	메밀	55	8								
	밀	23	0								
	백미	317	26								
	보리	163	19								
	수수	171	16								
	율무	104	10								
	조	130	6								
	찹쌀	215	18								
	현미	90	0								
	호밀	6	0								
옥수수류	옥수수	66	7								
	옥수수(건조)	31	8								
두류	강낭콩	80	6								
	기타두류	76	0								
	녹두	99	6								
	대두	180	5								
	동부	25	0								
	완두콩	29	2								
	작두콩	7	0								
	쥐눈이콩	97	3								
	팥(건조)	107	8								

전연령 노출량기여도(LB)

전연령 노출량기여도(UB)

그림 12. 식품 평균 섭취로 인한 총아플라톡신 노출기여도



발간등록번호 11-1471057-000206-01

2016

곰팡이독소 위해평가

Risk Assessment of Mycotoxins

식품의약품안전처

식품의약품안전평가원

VI. Conclusion

- Risk Assessment is useful tool for Public health goals for food safety
- Integrated information management is necessary for the accuracy of risk assessment.
- MIMS/MAP is useful information management system for risk assessment
- Need for technical development to improve MIMS/MAP

Thank you!

- hwang1963@korea.kr