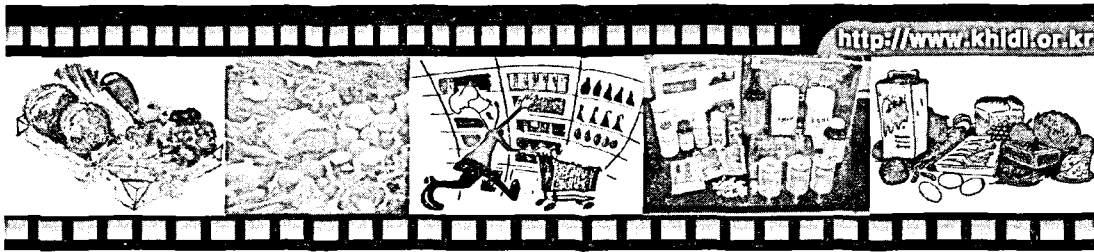


PL-3

Application of Risk Assessment for the Food Safety Management

Chung, Myung Sub, Ph.D.

Korea Health Industry Development Institute

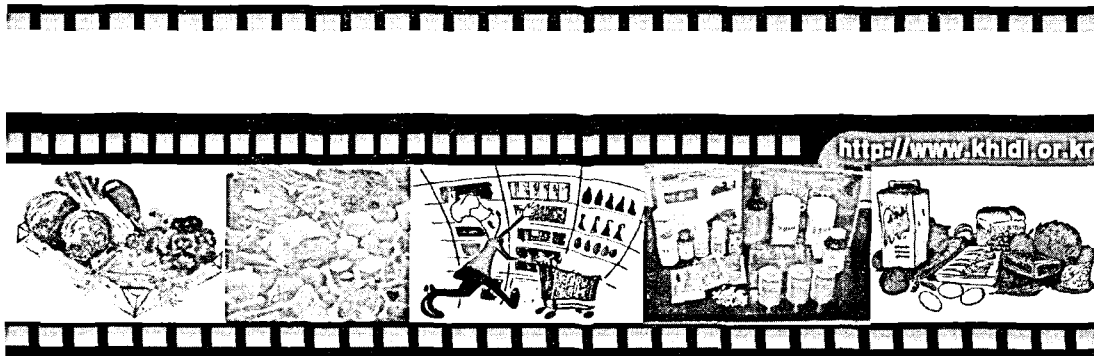


Application of Risk Assessment for the Food Safety Management

2005. 11. 11

Chung, Myung Sub, Ph.D.

KHIDI Korea Health Industry Development Institute



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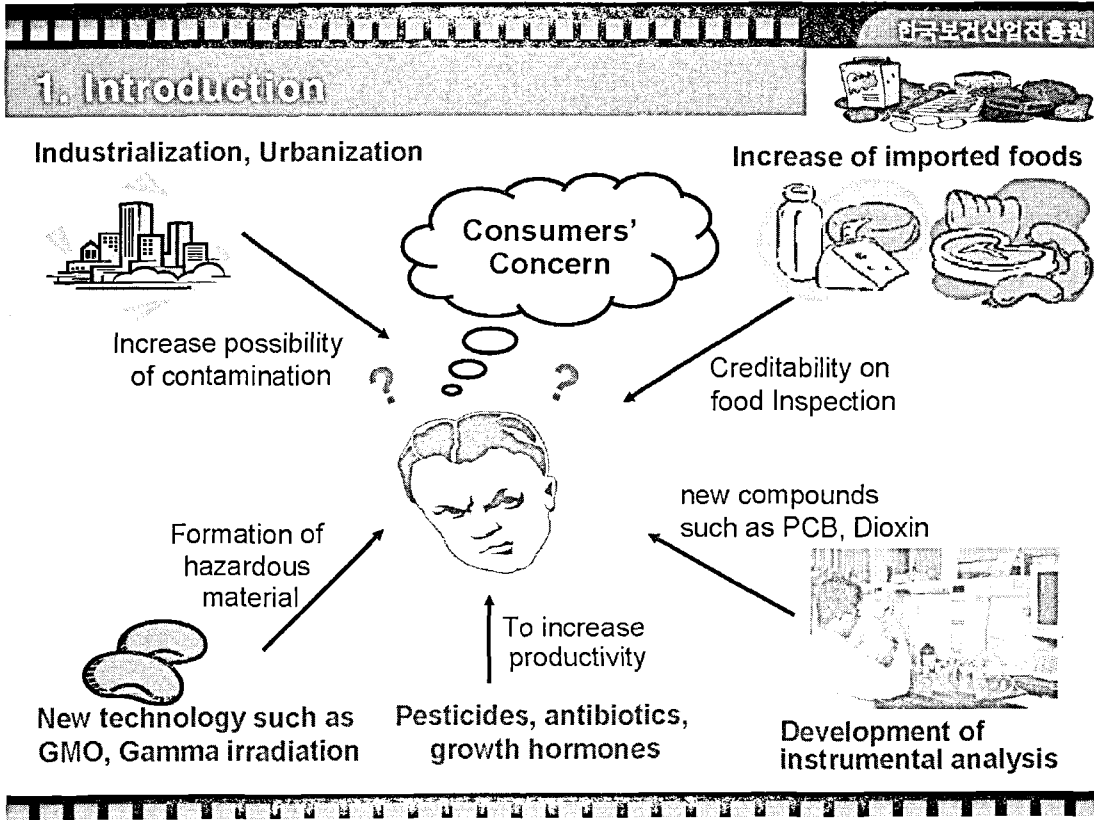
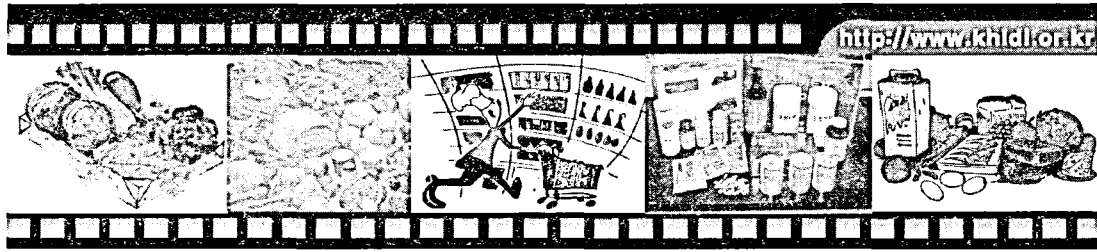


Table 1. Major food scares around the World

- *Salmonella* in beef, Aberdeen, UK 1964
- Toxic cooking oil, Spain 1981
- *Salmonella* in tinned salmon, Birmingham, UK 1986
- Radionuclides contamination, Western Europe, Chernobyl, 1986
- Toxic mustard seed oil, India 1998
- Dioxins in poultry, Belgium 1999
- BSE-CJD, UK 2000
- *E. Coli* O157:H7, Japan 2001
- *E. Coli* O157:H7, Washington & other area 2001
- GMO: despite scientific assurances the general public in certain countries, notably Europe, are unwilling to consume foods containing GM products

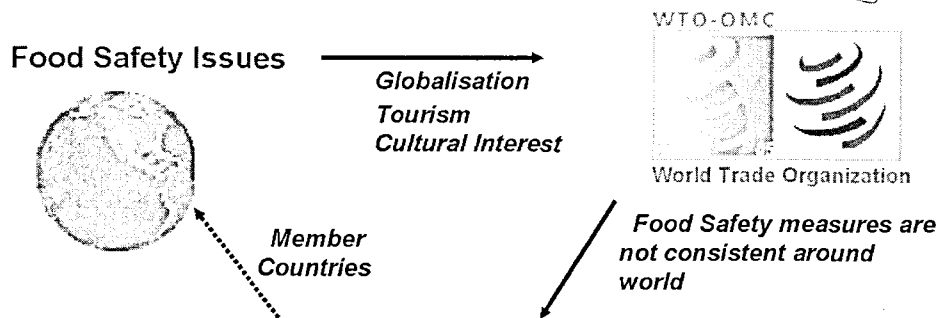
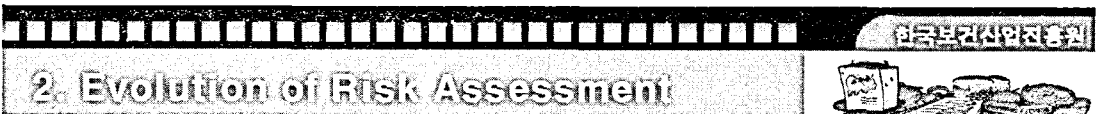
Source: Forsythe (2002)

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- ❖ Agreement on the Sanitary and Phytosanitary (SPS) Measures
 - Scientific Justification (Article 3.3), Harmonization (Article 3), Equivalence (Article 4), Consistency (Article 5), Transparency (Article 7)

"Any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs."



2. Evolution of Risk Assessment

한국보건산업진흥원



"Recognizes right of governments to protect health of their people from hazards which may be introduced with imported food by imposing sanitary measures, even if this meant trade restriction".

"Obliges governments to base such sanitary measures on risk assessment to prevent disguised trade protection measures".

"Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, appropriate to the circumstance, of the risk to human, animal or plant health, taking into account risk assessment techniques as described by relevant international organizations".

❖ Agreement on the Technical Barriers to Trade (TBT)



2. Evolution of Risk Assessment

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53rd World Health Assembly, Geneva 2000
Dr. Gro Harlem Brundtland,
The WHO Director General

❖ Three major challenges to protect the health of the consumer

1. Re-establish consumer confidence from farm to table by reassessing and improving existing food safety systems.
2. Ensure that reasonable food safety standards apply throughout the world and assist all countries to reach those standards.
3. Develop global standards for pre-market approval systems of genetically modified food to ensure that these new products not only are safe, but also beneficial for consumers and more efficient than existing products.

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2. Evolution of Risk Assessment




Table 2. FAO/ WHO Codex Alimentarius Commission (CAC)
Chronology of Activities

1991~1993	Joint FAO/WHO Conference (19 th 1991 and 20 th 1993) Incorporation of risk assessment principles
1994	Codex executive committee urged FAO and WHO to convene a consultation on risk analysis
1995	Recommended basic terminology and principles of risk assessment by Joint FAO/WHO Expert Consultation. To convene further consultations on risk management and risk communication
1996	Codex Committee on Food Hygiene(CCFH) published " <i>Principles and guidelines for the application of microbiological risk assessment</i> "

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2. Evolution of Risk Assessment




Table 2. FAO/ WHO Codex Alimentarius Commission (CAC)
Chronology of Activities (*contd*)

1997	Reported risk management framework and elements CAC adopted definitions of risk analysis terms related to food safety and published Codex Alimentarius procedural manual
1998	Joint FAO/WHO Expert Consultation, " <i>Application of risk communication to food standards and safety matters</i> "
1999	Joint FAO/WHO Expert Consultation, " <i>Risk assessment of microbiological hazards in foods</i> " CAC, " <i>Principles and Guidelines for the conduct of microbiological risk assessment</i> "
2000	Joint FAO/WHO Expert Consultation, " <i>WHO/FAO guidelines on hazard characterization for pathogens in food and water</i> " Joint FAO/WHO Expert Consultation, " <i>Interaction between assessors and managers of microbiological hazards in foods</i> "

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2. Evolution of Risk Assessment




Table 2. FAO/ WHO Codex Alimentarius Commission (CAC)
Chronology of Activities (contd)

<p>2000 Joint FAO/WHO Expert Consultation, "Risk assessment of microbiological hazards in foods" Joint FAO/WHO-CCFH document, "Draft principles and guidelines for the conduct of microbiological risk management"</p> <p>JEMRA</p> <ul style="list-style-type: none"> - Hazard identification and hazard characterization of <i>Listeria monocytogenes</i> in ready-to-eat foods (Buchanan & Lindqvist, 2000) - <i>Salmonella</i> in broilers and egg (Fazil et. al, 2000) - Exposure assessment of <i>Salmonella enteritidis</i> in eggs (Ebel et. al, 2000) - Exposure assessment of <i>Salmonella</i> spp.in broilers (Kelly et. al, 2000) - <i>Campylobacter</i> spp.in broilers & <i>Vibrio</i> spp. In sea foods (2001)
--

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2. Evolution of Risk Assessment




Table 3. Eleven principles of microbiological risk assessment

- | |
|--|
| <ol style="list-style-type: none"> 1. RA should be soundly based on science 2. Functional separation between risk assessment and management 3. Conduct hazard identification, exposure assessment, hazard characterization and risk characterization 4. State the purpose of the exercise 5. Should be transparent 6. Constraints (cost, resource, time) should be identified and their possible consequences described 7. Should contain description of uncertainty 8. Data collection system should be precise to minimize uncertainty 9. Consider dynamics of MO's growth, survival, and death in foods 10. Re-assess over time by comparison w/ personal illness data 11. Re-evaluate as new relevant information available |
|--|

Source: CAC (1999)

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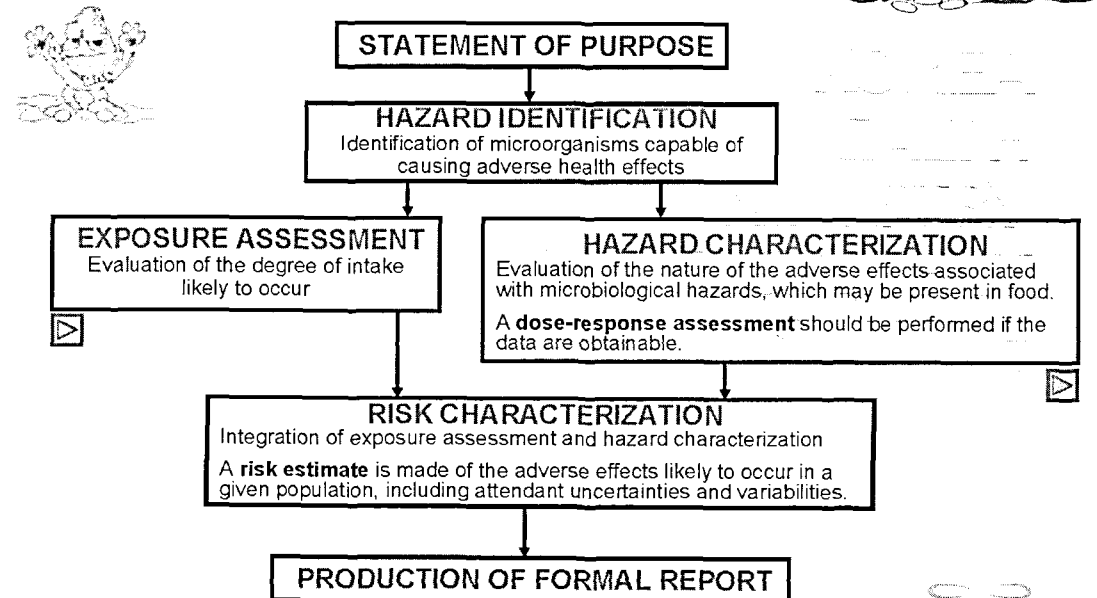


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3. Implementation of Risk Assessment



Source: Notermans *et al.* (1996)



3. Implementation of Risk Assessment

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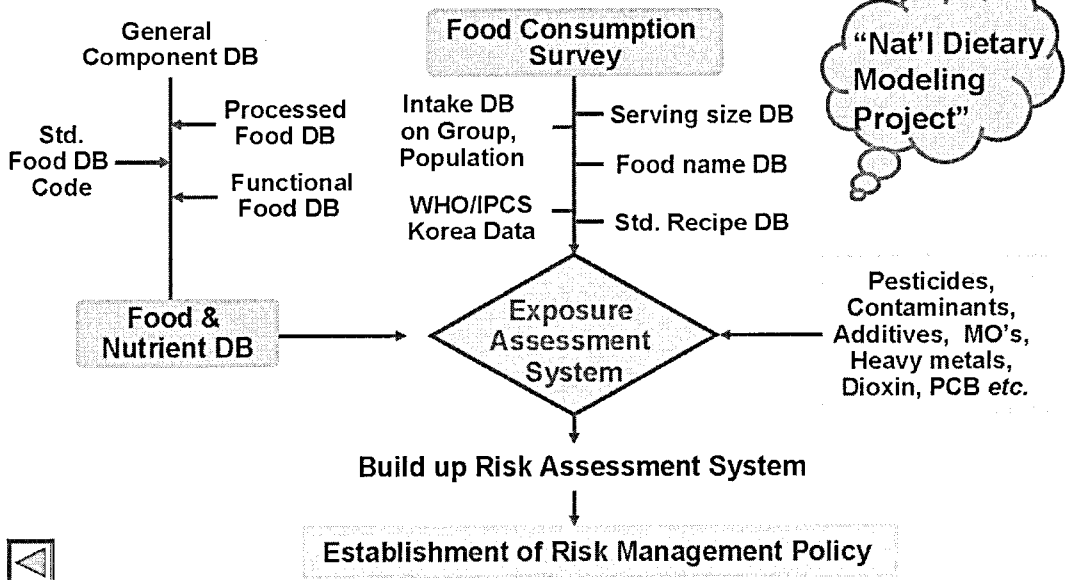
EXPOSURE ASSESSMENT

- Nat'l Health & Nutrition Survey
 - by MOHW-KHIDI w/ Nat'l Health Promotion Fund (1,400 Million Won).
 - every 3 Years & seasonal survey
- Contaminants Monitoring by KFDA in 2005
 - Mercury in Fishery Products & Total Aflatoxin (140 Million Won).
 - Hazardous heavy metals in Agricultural Products (2,000 Million Won).
 - Pb, Cd, Cu, Fe in blood of the adolescents, smokers (50 Million Won).
 - Heavy metals in meats and by-products & Ochratoxin (110 Million Won).
 - Exposure Assessment on hazardous heavy metals (50 Million Won).
- Nat'l Pesticides Monitoring by KFDA in 2005
 - 20 frequently using pesticides (125 Million Won).
- Food Additives Monitoring by KFDA in 2005
 - SO₂, NaNO₂, NaNO₃ & KNO₃ in Foods (150 Million Won).
- Pathogenic Bacteria Monitoring
 - 9 pathogenic bacteria monitoring (290 Million Won)



3. Implementation of Risk Assessment

한국보건산업진흥원



3. Implementation of Risk Assessment



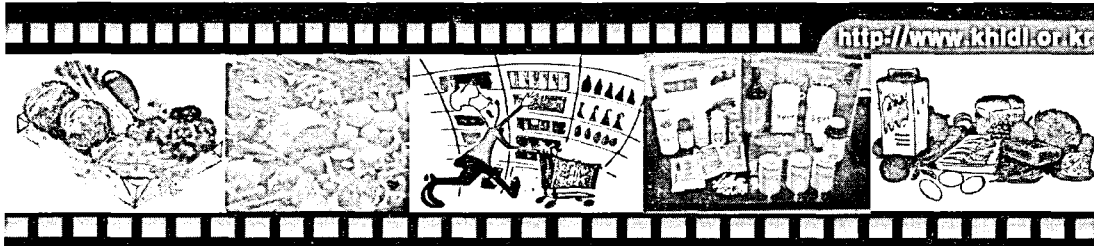
HAZARD CHARACTERIZATION

- Mainly use Reference ADI, PTWI
 - Joint Expert Committee on Food Additives (JECFA)
 - Joint Meeting on Pesticide Residues (JMPR) of WHO/FAO
- Establishment of ADI of Pesticides in KFDA
 - Chemical Residues Team, KFDA
 - 5 Years project (50 Million Won/year)



RISK CHARACTERIZATION

- Using tools on uncertainty analysis
 - Monte Carlo Simulation
 - @Risk, Palisade Corporation
 - Crystal Ball 2000, Decisioneering
 - Analytica Lumina Decision Systems, Inc.



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4. Risk Management

Risk Management Elements

Risk Evaluation



Risk Management
Option Assessment

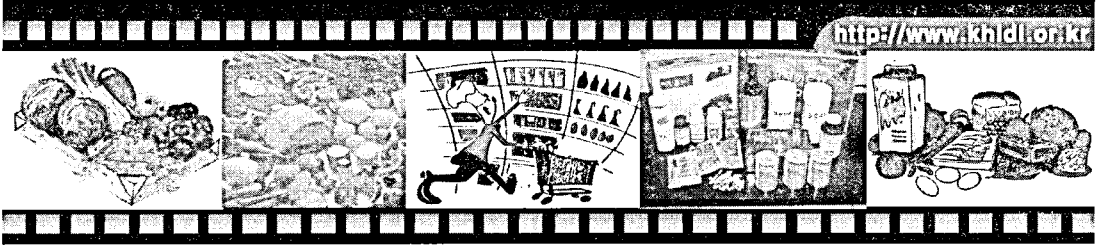


Implementation and
Management of
Decision



Monitoring and
Review

- **사전관리**
 - 다각적 정보수집, 현재 및 예측상황 파악, 정책결정시 고려사항 도출
- **정책검토**
 - 위해평가결과 식품안전관리 대안을 검토하여 소비자 보호할 수 있는 충분한 수준 도출
 - 효율성, 유효성, 기술적 가능성, 실용성 반영한 정책 적용 적정성 판단(비용-효율 분석 등)
- **정책검정**
 - 위해성관리 실행단계 (HACCP 적용)
 - 안전관리 목표 도달까지 정책방향 일관성 유지
- **감사-재검토**
 - 자료수집 분석
 - 안전관리 목표 미달시 규정 개정



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5. Risk Communication

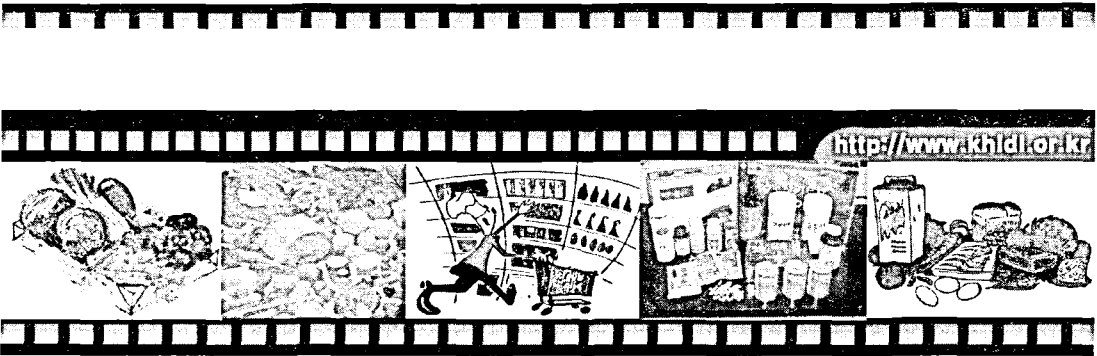
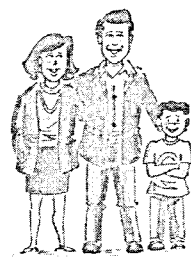


Risk Communication

- An exchange of information and opinions throughout the risk analysis process concerning risk, risk related factors and risk perception, among all interested parties, to explain risk assessment findings and the basis of risk management decision.

Risk Communication Elements

- Nature of Risk
- Nature of Benefit
- Uncertainties in Risk Assessment
- Risk Management Option



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한국식품위생안전성학회

4. National Center for Risk Analysis



Foundation

- National Center for Risk Analysis (NCRA) aims to develop scientific base for safety management on food and drug by conducting research on risk analysis.
- NCRA aims to enhance competence of the technical skills on risk analysis by technology transfer, education and assistance of research grant

Function

- Education and planning and coordination of policy on risk analysis
- International cooperation and harmonization on risk analysis



Source: KFDA (2005)



한국식품위생안전성학회

4. National Center for Risk Analysis



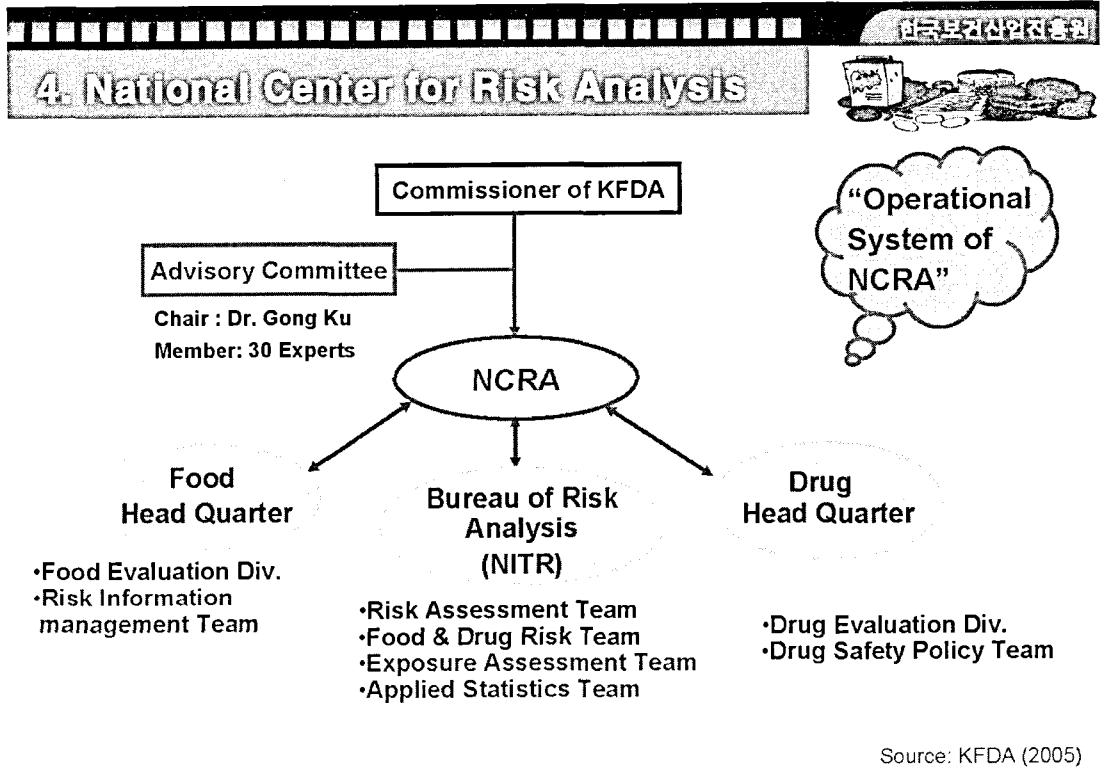
Chronology

- 2005. 5. 18 MOU between WHO/IPCS and MOHW/KFDA
- 2005. 6. 29 Education for employees of KFDA and NITR
(5 days short course)
- 2005. 7. 11 Opening National Center for Risk Analysis (NCRA)
- 2005. 8. 31 MOU between JIFSAN/CFSAN and KFDA
- 2005. 10. 4 Education for employees of Regional KFDA
(2 days short course)
- 2005. 11. 23 Education on Risk Management by JIFSAN in Seoul
(3 days short course)



Source: KFDA (2005)





식품안전관리위원회

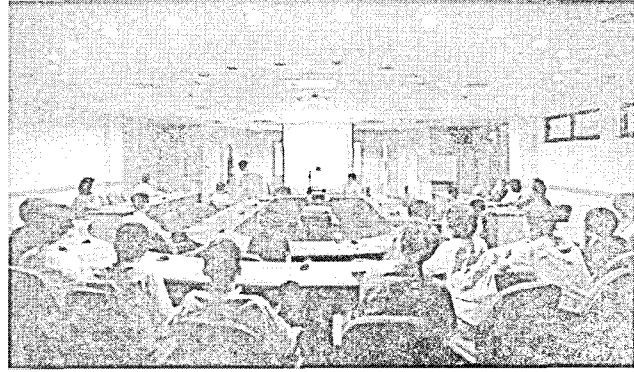
4. National Center for Risk Analysis

Table 4. Projects and budget for key chemicals and microorganisms in 2005 and 2006
(Unit: Million Won)

Targets	Toxicity	Monitoring	Exposure Assessment	Std. & Spec.
Acrylamide				
Trans fatty acid		Nutrition Team	'06 : 30	
Stevioside	'06: 100			
Analogues of Viagra	'06: 50	'05 30		
Dioxins (PCB)		'06 149		
Cd		'05 3,000*		
Iodine				
Cyanides				
<i>B. cereus</i>		'05 150		
<i>S. aureus</i>		'05 150		

*: Hazardous heavy metals in 10 agricultural products

Source: KFDA (2005)



Thank You