Food management Using Risk Assessment

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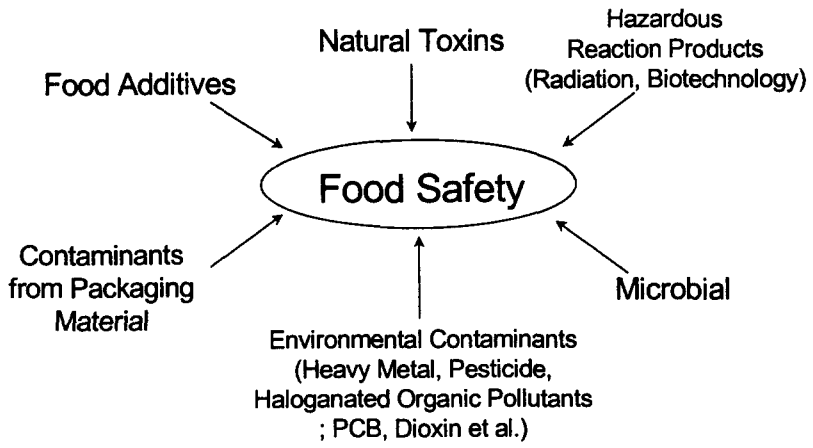
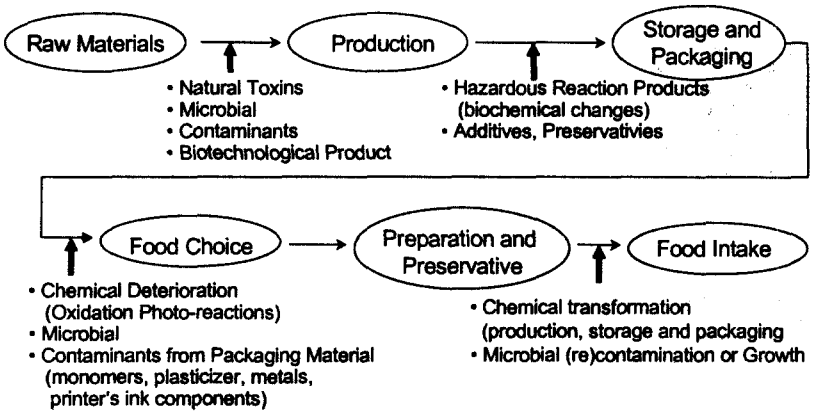
Hazardous Factors Related with Food Safety



Hazardous Factors in Pathway from Raw Material to Consumer



Types of Food Safety and Quality Activities Carried Out by Principal Federal Agencies

Activity		USDA				
	FDA	AMS	FGIS	FSIS	EPA	NMFS
Inspections	x	x	x	x	x	x
Quality grading	•	x	x	•	•	x
Collect/analyze samples	x	x	x	x	x	x
Research	x	a	a	a	x	x
Develop standards for :						
Foods/crops	x	x	x	•	•	x
Facilities	x	x	•	x	•	•
Equipment	•	x	x	x	•	•
Processing procedures	x	x	•	x	•	•
Labels	x	x	•	•	x	•
Packaging	•	x	•		x	x
Approve before use :						
Facilities	•	x	•	x	•	•
Equipment	•	x	x	x	•	•
Processing procedures	•	x	•	x	•	•
Product recipes/formulas	•	x	•	x	•	x
Labels	•	x	•	x	x	•
Packaging	•	x	•	•	•	•
Food colors/additives	x	•	•	•	•	•
Animal drugs/food additives	x	•	•	•	•	•
Pesticide products	•	•	•	•	x	•
Set residue tolerances for :						
Pesticides	•	•	•	•	x	•
Other contaminants	x	•	•	•	•	•

a Agricultural Research Service carries out research for AMS, FGIS, and FSIS.

Principal Food Safety and Quality Legislation and Federal Agencies Responsible for Implementation

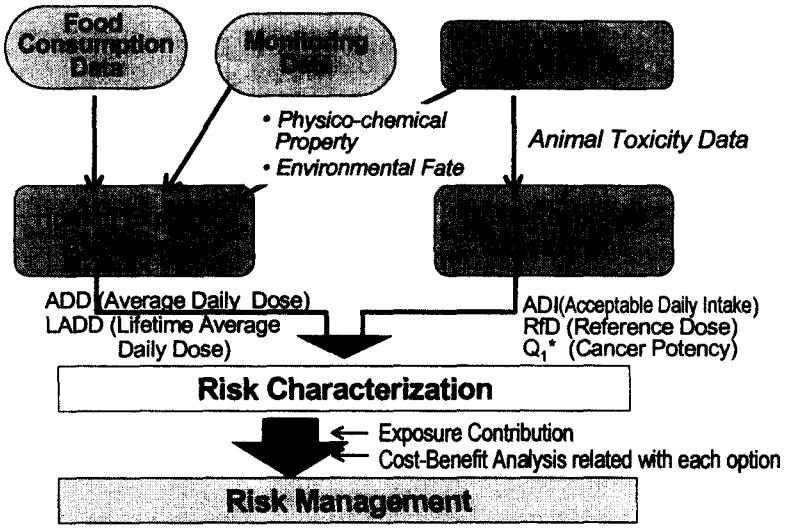
Legislation[a]	FDA	USDA AMS	USDA FGIS	USDA FSIS	EPA	NMFS
Agricultural Marketing Act of 1946 (AMA)	•	X	X	•	•	X
Agricultural Marketing Agreement Act of 1937	•	X	•	•	•	•
Egg Products Inspection Act (EPIA)	X	X	•	•	•	•
Federal Anti-Tampering Act	X	X	•	X	•	•
Federal Food, Drug, and Cosmetic Act (FFDCA)	X	•	•	•	X	•
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	•	•	•	•	X	•
Federal Meat Inspection Act (FMIA)	•	•	•	X	•	•
Federal Import Milk Act	X	•	•	•	•	•
Infant Formula Act of 1980	X	•	•	•	•	•
Lacey Act	•	•	•	•	•	X
Magnuson Fishery Conservation and Management Act	•	•	•	•	•	X
National Ocean Pollution Research and Development and Monitoring Planning Act	•	•	•	•	•	X
Pesticide Monitoring Improvements Act	X	•	•	•	•	•
Poultry Products Inspection Act (PPIA)	•	•	•	X	•	•
Public Health Service Act (PHSA)	X	•	•	•	•	•
Safe Drinking Water Act	X	•	•	•	X	•
Toxic Substances Control Act	•	•	•	•	X	•
U.S. Grain Standards Act (USGSA)	•	•	X	•	•	•

[a] This lists 18 of the principal laws administered by these six agencies, which also administer 10 other less significant food safety and quality laws.

Federal Agencies Responsible for Regulating, Monitoring, or Performing Quality Grading Services for Various Food Industries

Food Industry	FDA	USDA AMS	USDA FGIS	USDA FSIS	EPA	MFS
Dairy	X	X	•	•	X	•
Eggs/egg products	X	X	•	•	X	•
Fruits/vegetables	X	X	•	•	X	•
Grain/rice/pulses	X	•	X	•	X	•
Interstate conveyances	X	•	•	•	•	•
Meat and poultry	•	X	•	X	X	•
Restaurants	X	•	•	•	•	•
Seafood	X	•	•	•	X	X

Data Linkage for Food Risk Assessment of Environmental Contaminant



Continuing Survey of Food Intakes by Individuals

WHAT WE EAT IN AMERICA : 1994-1996

DAY ONE INTAKE QUESTIONNAIRE

PLACE CASE LABEL HERE

SAMPLE PERSON# : _____

INTERVIEWER NAME : _____

INTERVIEWER ID ; ___ ___ ___

DAY OF INTERVIEW : _____

FIRST NAME OF
SAMPLE PERSON : _____

DATE OF BIRTH : ___- ___-_____
OR
AGE : _____ YRS.....1
MOS.....2

SEX : M.....1 F.....2

_____ : _____ AM.....1
TIME STARTED PM.....2

_____ : _____ AM.....1
TIME STARTED PM.....2

INTERVIEW CONDUCTED :
IN PERSON.....1
BY TELEPHONE.....2

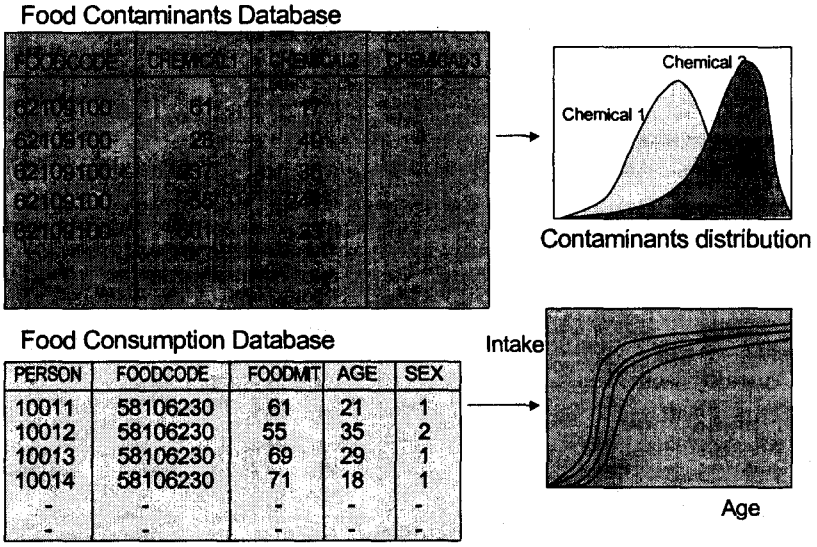
FOR HOME OFFICE USE ONLY

DATE RECEIVED : _____
VERIFIER ID: _____
MC: ___YES ___NO
BATCH # : _____

Individual Intake Form

Q1 Quick List of Food Items	Q2 Time	Q3 Occ. (Hand-Card 12)	Food/Dring And Additions	Q4 Description of Food/Drink and Ingredient Amount
A.	9:00a P		1 Pizza	1 Slice
B.	9:00a p		2 Coke	1 Cup
C.	a p		3 Tomato	1/2 Piece
D.	a p		4	
E.	a p		5	
F.				

Basic Information Needed in Food Risk Assessment

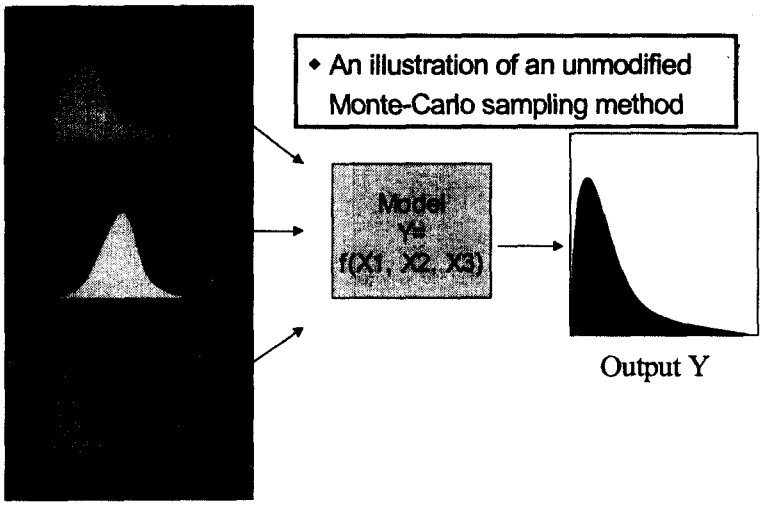


Human Exposure Assessment of Chemical Using Food Ingestion Data

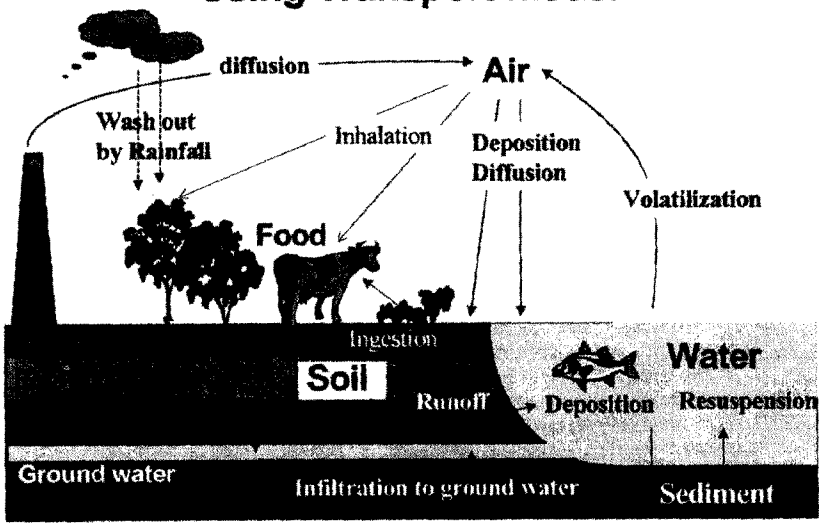
$$ADD,LADD = \frac{C \times CF \times BIO \times Prep}{AT \times Days} \times \sum_{i=1}^{n} \left[\frac{IR_i \times EFi \times ED_i}{BW_i}\right]$$

ADD	average daily dose for **non-cancer effects**(mg/kg per day)
LADD	**lifetime average daily dose** for cancer effects(mg/kg per day)
C	chemical concentration in food (mg/kg)
CF	conversion factor (kg/10^3g)
BIO	**relative oral bioavailability factor**, which adjusts for difference in chemical bioavailability, if applicable (unitless)
Prep	reduction in **concentration due to food preparation** (unitless)
IR_i	**ingestion rate** for food in age period i (g/day)
EF_i	**exposure frequency** in age period i (days/year)
ED_i	**duration of exposure** in age period i (years)
BW_i	**average body weight in age period i (kg)**
AT	**averaging time** (70years for carcinogens, duration of exposure for noncarcinogens)
Days	conversion factor (365days/year)

Crystal Ball : *Monte Carlo Simulation An efficient technique for analyzing these types of problems*



Prediction of Food Contamination Using Transport model



Dose-Response Assessment

Developmental Toxicity Risk Assessment (1991) - Guidance

Major Manifestations

- Death of the developing organism (prenatally or postnatally)
- Structural abnormalities (including birth defects or teratogenicity)
- Altered growth
- Functional deficiencies (e.g., neurological, pulmonary, cardiovascular, renal)

Several Default Assumption must be made in Developmental Toxicity Risk Assessment

1) Adverse effects seen in animal studies are assumed to indicate a potential risk for humans.
2) All manifestations of developmental toxicity are of concern.
3) The types of effects seen in animal studies are not assumed to be the same as those in the human.
4) The most appropriate (e.g., based on pharmacokinetics) or sensitive animal species is used to estimate risk to human.
5) In general, a threshold is assumed for the dose-response curve.

Reproductive Toxicity Risk Assessment (1996)

- Guidance

- Visual examination and histopathology.
- Sperm evaluation
  (sperm number-count, morphology, motility)
- Sexual behavior
  (mounts, intromissions, ejaculations)
- Hormone levles
  (Luteinizing hormone, follicle stimulating hormone, testosterone, estrogen, prolactin)
- Developmental effects
  (Testis descent, preputial separation, sperm production, ano-genital distance, structure of external genitalia)

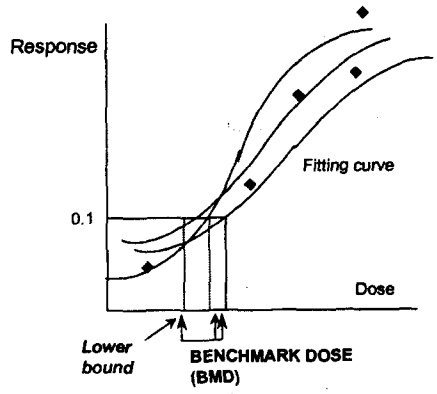
Reproductive Toxicity Risk Assessment (1996)

- Guidance

Major Manifestations

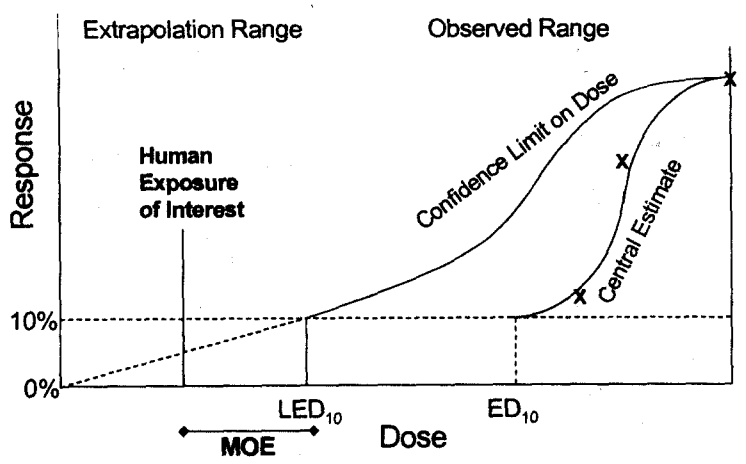
- Visual examination and histopathology
- Estrous (menstrual) cycle normality(Vaginal smear cytology)
- Sexual behavior
  (Lordosis, time to mating, vaginal plugs, or sperm)
- Hormone levels
  (LH, FSH, estrogen, progesterone, prolactin)
- Lactation (Offspring growth, milk quantity and quality)
- Development
  (Normality of external genitalia, vaginal opening, vaginal smear cytology, onset of estrous behavior[menstruation])
- Senescence
  (Vaginal smear cytology, ovarian histology[menopause])

Application of Benchmark Dose(BMD)

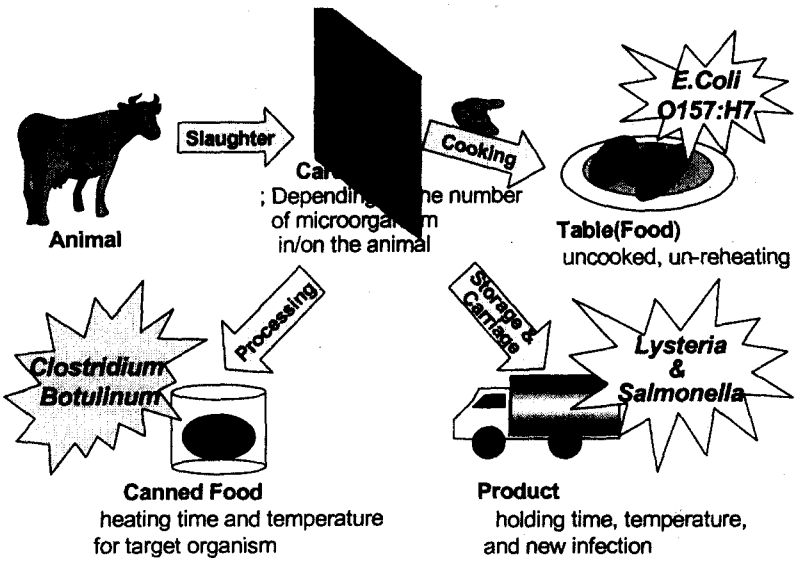


- BMD(Benchmark dose)
  : The lower 95% confidence bound on dose which results in some prespecified level of excess risk
- The benchmark dose is based on a model-derived estimate of a particular incidence level, such as 5% or 10% incidence

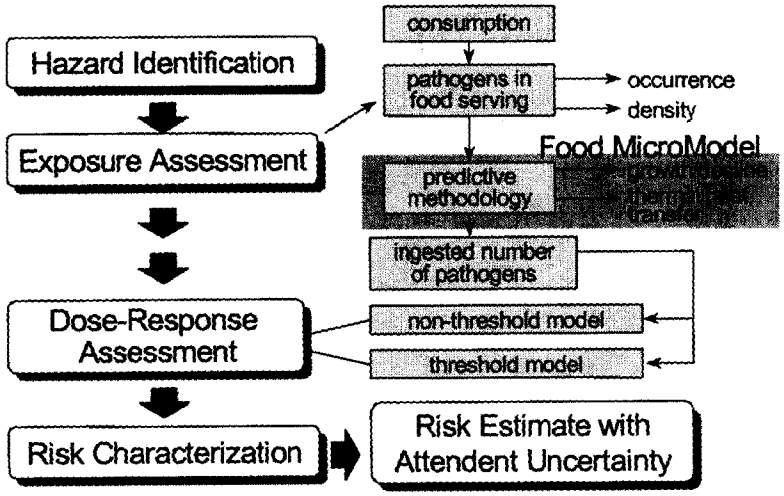
Application of Margin of Exposure using ED_{10}, LED_{10}



Microbial Risk Assessment



Procedure of Microbial Risk Assessment in food



Microbial Risk Assessment

- Hazard identification is accomplished by observing and defining the types of adverse health effects in human associated with exposure to foodborne agents
- Clinical studies, epidemiological evidence(mortality ratios, illness severity, and mortality ratios), surveillance, laboratory animal studies, investigations of characteristics of microorganisms, et.al.

Example). Cases, severity, and mortality associated with *salmonella* and *E.coli* infections in the U.S (Bennett et al., 1987; Gerba et al., 1994; Smith et al. 1993; Meyers 1989)

	Salmonella	E.coli
Annual number of cases	2,000,000	200,000
Annual number of deaths	2,000	400
% Foodborne	96.0	25.0
Mortality ratio(%)	0.1	0.2*
Severity ratio(%)**	4.1	12.7
% Associated with reactive arthriditis	2.3	NA
Mortality ratio in nursing homes	3.8	11.8*

* E.coli O157:H7

** Hospitalized cases/Total cases during outbreaks

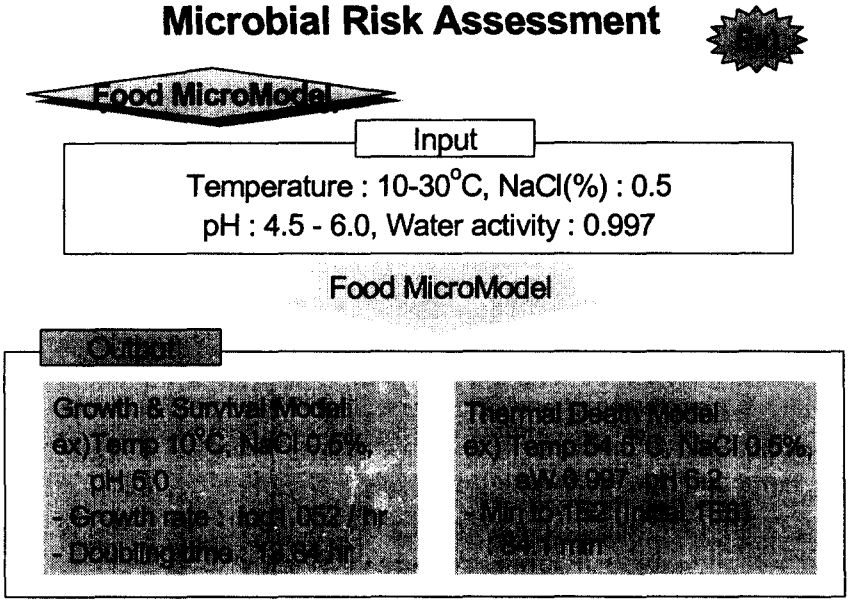
Microbial Risk Assessment

Example) Adverse health effects associated with risks from exposure to salmonella

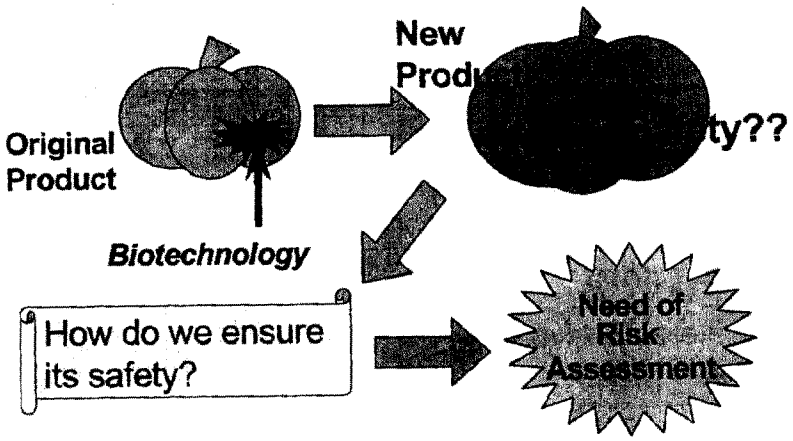
	Exposure: 1 colony forming unit
• Probability of infection Pi = 1-exp(-0.00752 x 1)	7.5×10^{-3}
• Probability of severity (Pi x 0.041)	3.1×10^{-4}
• Probability of motality (Pi x 0.001)	7.5×10^{-6}

Risk of mortality = Pi x mortality ratio

Microbial Risk Assessment

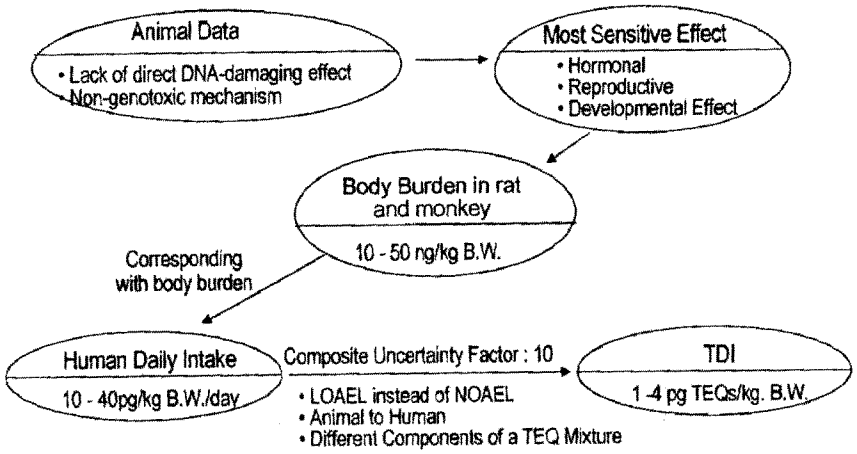


Application of Biotechnology



Management Study Case

WHO Revises the Tolerable Daily Intake (TDI) to the TCDD (Dioxin '98)



PCDDs/PCDFs Level in Food by Nations (Dioxin '98)

Food	Level	Nation	Year
Milk	0.84pg TEQ/g lipid	USA	1998
Beef	1.36pg TEQ/g lipid		1971
Potato	0.8 pg TEQ/kg wet		1994-1997
Chicken	2.54ng TEQ/g lipid	Russia	1998
Fish	173.0 pg TEQ/g lipid		1998
Butter	0.55 pg TEQ/g fat	Germany	1996
Beef	0.46 ng TEQ/kg fat		1998
Poultry	0.22 ng TEQ/kg fat		1998
Beef	1.75 pg TEQ/g fat	Netherlands	1990-1991
Milk	1.49 pg TEQ/g fat		1990-1991
Salmon	56 ng TEQ/g wet	Sweden	1994
Seafish	0.87 ng TEQ/kg fat	Japan	1996
Market fish	0.33 ng TEQ/kg fat		1996

Contaminants in Swedish Human Milk Decreasing Levels of Organochlorine and Increasing Levels of Organobromine Compounds.

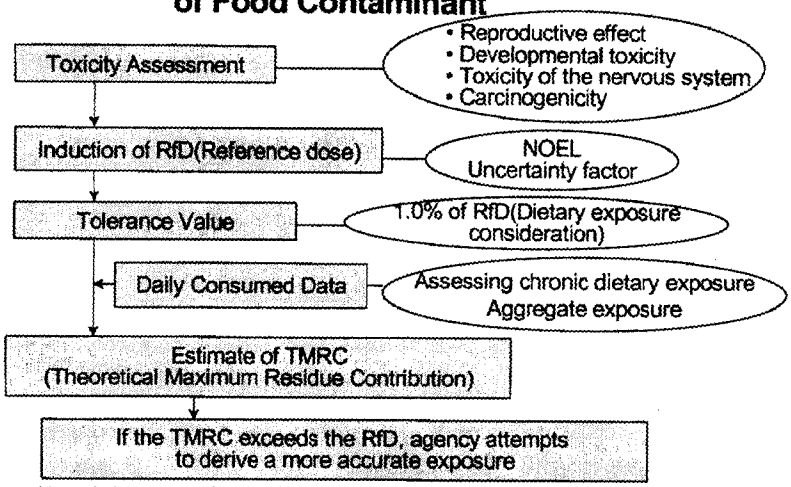
Year	Pollution Contribution (human milk)
1972	DDE > PCB > DDT > HCB 57% 24% 16% 13%
1997	PCB > DDE > DDT > HCB > PBDE 67% 27% 3% 2% 1%

Half Life Estimation of Hazardous Compounds in Human Milk.

Compound	Half-life	Compound	Half-life
DDT	4 years	PCN	8 years
DDE	6 years	TEQ PCDDs/PCDFs/PCB	15 years
PCB	14 years	HCB	6 years

Management Study Case

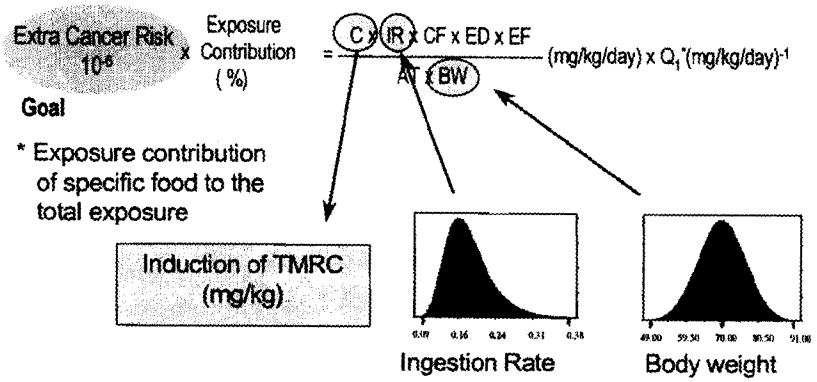
Induction of Theoretical Maximum Residue Concentration (TMRC) for management of Food Contaminant



* intended to account for variation in susceptibility among human population , i.e. high risk group

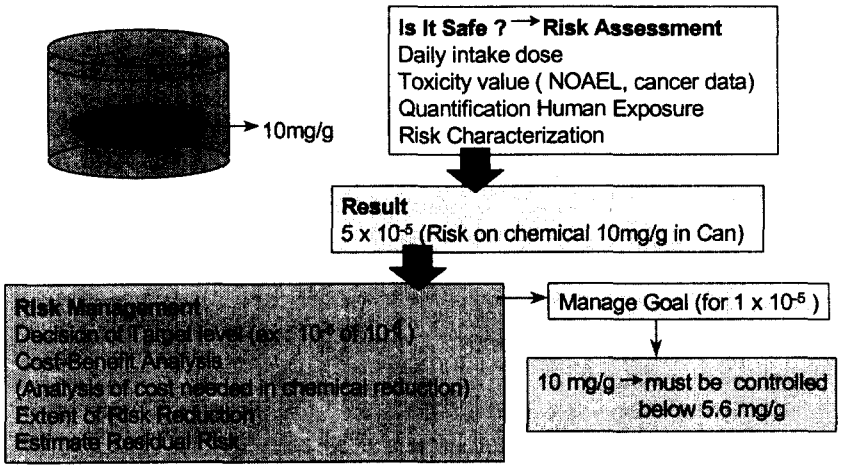
Management Strategy

Finding of TMRC (Theoretical Maximum Residue Concentration) Value for Carcinogen Using Current Consumption Data



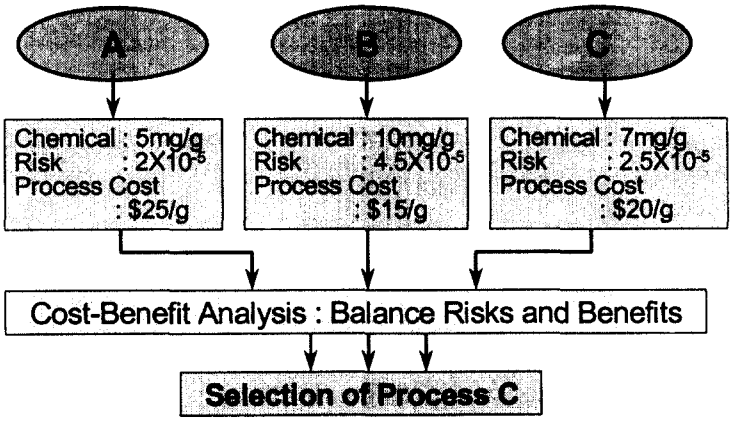
Application of Risk Assessment for Food Management

Ex) Management on chemical A in some food



Cost-Benefit Analysis

Treatment method



RISK MANAGEMENT FRAMEWORK

ELEMENTS OF RISK MANAGEMENT

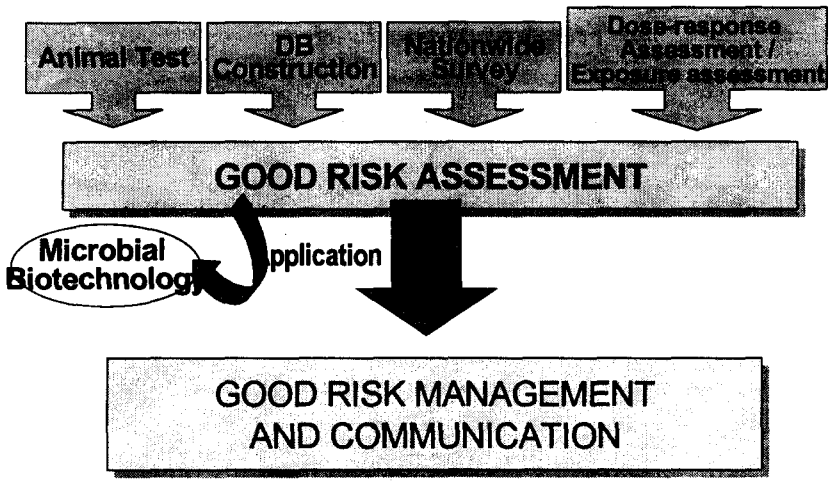
A. Risk evaluation
- Identification of a food safety problem
- Establishment of a risk profile
- Ranking of the hazard for risk assessment and risk management priority
- Establishment of risk assessment policy for conduct of risk assessment
- Commissioning of risk assessment
- Consideration of risk assessment

B. Risk management option assessment
- Identification of available management options
- Selection of referred management option, including consideration of an appropriate safety standard.
- Final management decision

C. Implementation of management decision

D. Monitoring and review
- Assessment of effectiveness of measures taken
- Review risk management and /or assessment as necessary

Management Goal of Food



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