Prioritization in a PRM Programme

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1. Principles of risk ranking

Risk ={severity, probability}

Severity:

- Toxicity of human health: Acute or chronic, reproduction, development, inheritance and cumulative toxicity, etc.

- Effects on environment: Light degradation, biodegradation and bioaccumulation or bioaccumulation factors, etc.

- Aquatic toxicity: Acute and chronic toxicity for fish and aquatic invertebrates, and aquatic plants, etc.

- Physical and chemical properties of hazards: Active radicals, distribution coefficient of ester water, distribution coefficient of blood, melting point, boiling point and vapor pressure, etc

Principles of risk ranking

Probability:

- **The exposure types of population:** Children, the elderly, the average person, sensitive population;

- **Consumers coverage:** For instance, the consumer group of rice coverage is more than that of honey;

- **Detectable rate and content level over the years;**

- **Consumption habit:** processing factors;

- **Approaches and effects**: Exposed frequency, continued exposure duration, etc.

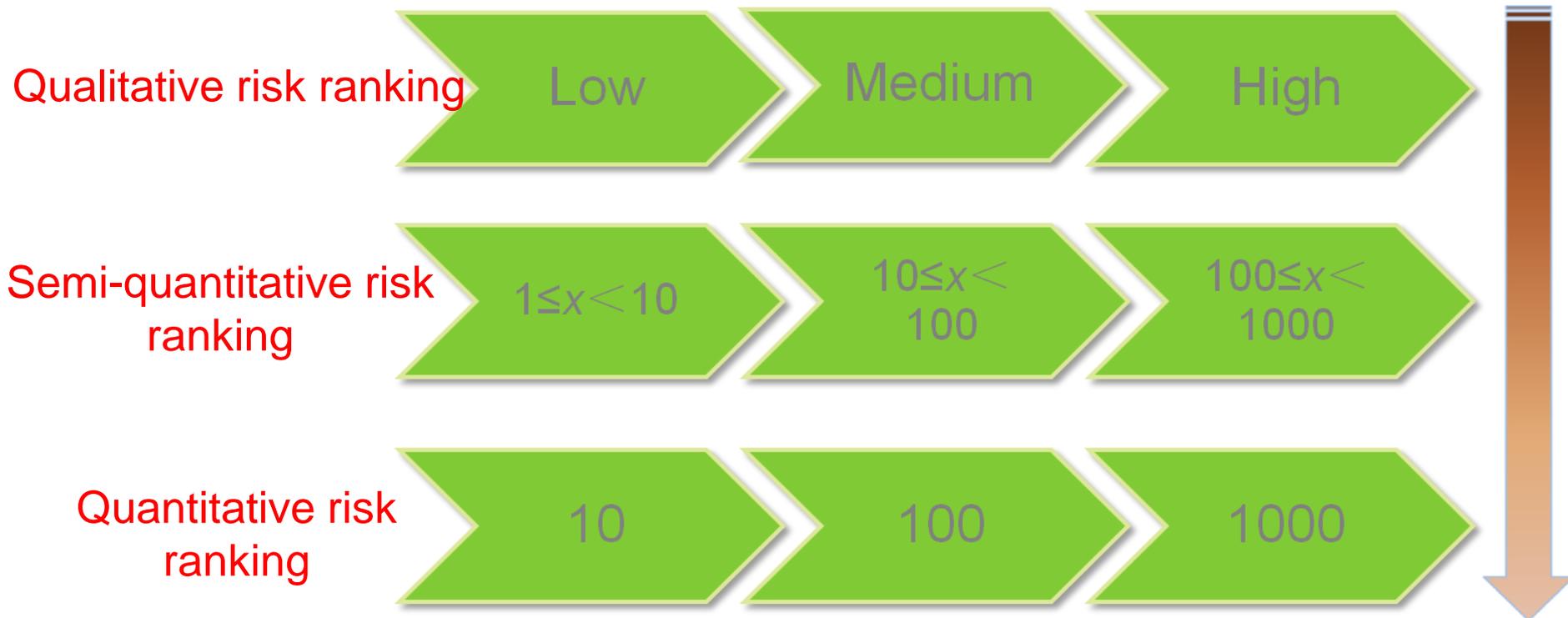- **Food-borne pathogens:** Transmission, pathopoiesis and lethal capacity (QALYs, **DALYs**, HALYs).

Principles of risk ranking

Uncertain factors:

- Uncertainty of risk assessment: uncertainty of methods, uncertainty of modeling, uncertainty of data, etc.

- Uncertainty of risk management: management operability, management level and ability, etc.

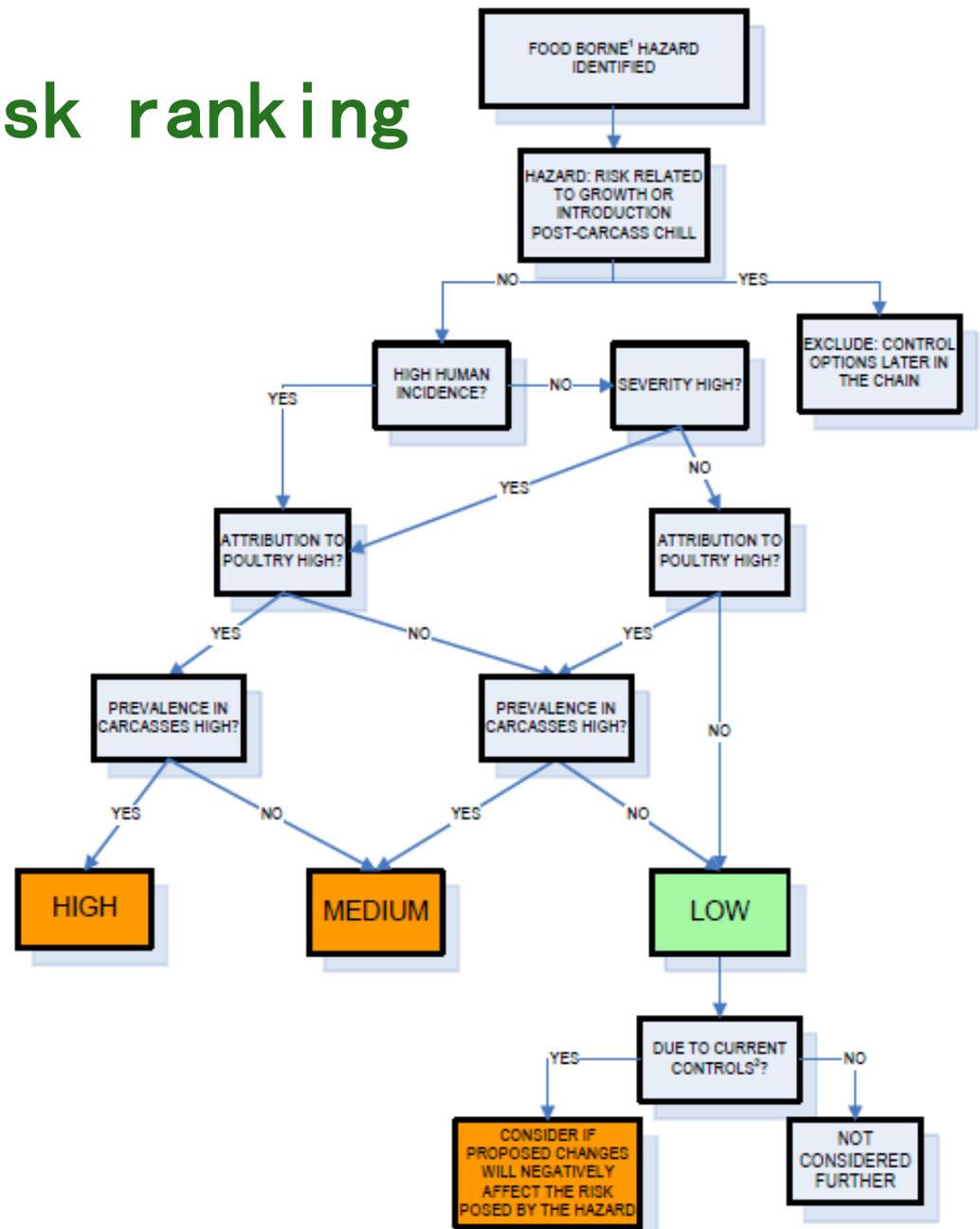- Uncertainty of risk communication: effectively communication about risks, etc.

2.Categorization of risk ranking methods

Qualitative risk ranking

| Low | Medium | High |

Semi-quantitative risk ranking

$1 \leq x < 10$ | $10 \leq x < 100$ | $100 \leq x < 1000$

Quantitative risk ranking

| 10 | 100 | 1000 |

3. Qualitative risk ranking

European Union
Based on decision tree

4. Semi-quantitative risk ranking

Pesticide residue monitoring and risk ranking of EU

- Background
  - EU Regulation (EC) No. 882/2004.
  - Two monitoring forms: coordinated by EU and member states
- Monitoring scope and parameters
  - Types of samples: 8-9 kinds per year, three year rotation(beans, carrots, cucumbers, oranges and citrus etc).
  - Number of samples: 12-93 samples of each food, a total of 11,610 samples per year.
  - Types of pesticides: 78 kinds. Based on previous monitoring results and RASFF notification options.

Calculation of the acute exposure amount of pesticide residue

- ✓ IESTI (International Estimated Short-Term Intake) is an international assessed value of short-term diet against agricultural products consumed within 24 hours.

- ✓ Data needed: daily food consumption (LP) of most people, single weight (U) of fruits, vegetables and other agricultural products, difference factor (V), etc.

- ✓ The calculation method of IESTI is proposed by JMPR, and calculation is under 3 situations.

- **Situation 1**

✓ Mixed sample residue data can reflect the residue level of the product consumed in a meal. Such as primary agricultural products (granule crops), single weigh of the agricultural products is less than 25g.

$$IESTI = \frac{LP \times HR}{BW}$$

- **Situation 2**

✓ Mixed sample residue data can not reflect the residue level of the product consumed in a meal. The eaten product may contain higher residue than the mixed samples and single weigh of food is higher than 25g. Such situation includes two conditions.

✓ **Situation 2a** The edible parts of a single unprocessed food weigh less than the maximum consumption of an individual meal. Such as: peach, plum and other fruits.

$$IESTI = \frac{U \times HR \times V + (LP - U) \times HR}{BW}$$

- **Situation 2b**
- ✓ The edible parts of a single unprocessed food weigh more than the maximum consumption of the food in an individual meal. Such as: watermelon, celery cabbage, etc.

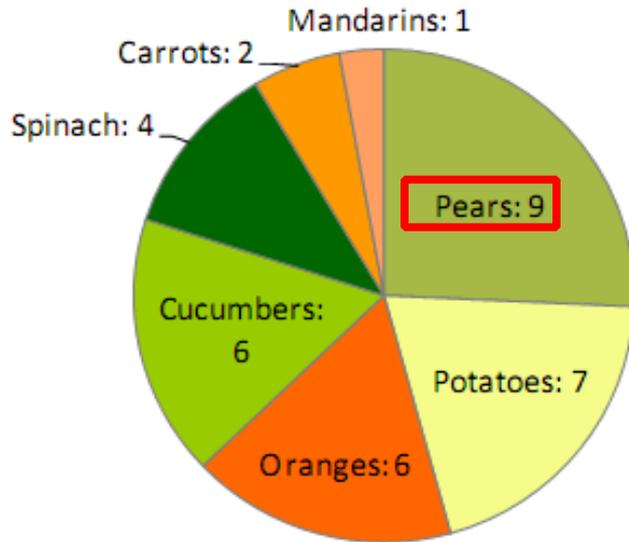$$IESTI = \frac{LP \times HR \times V}{BW}$$

- **Situation 3**
- ✓ As for unpackaged foods or mixed processed foods, STMR-P represents the highest possible residue concentration. Such as fruit juice, milk etc.
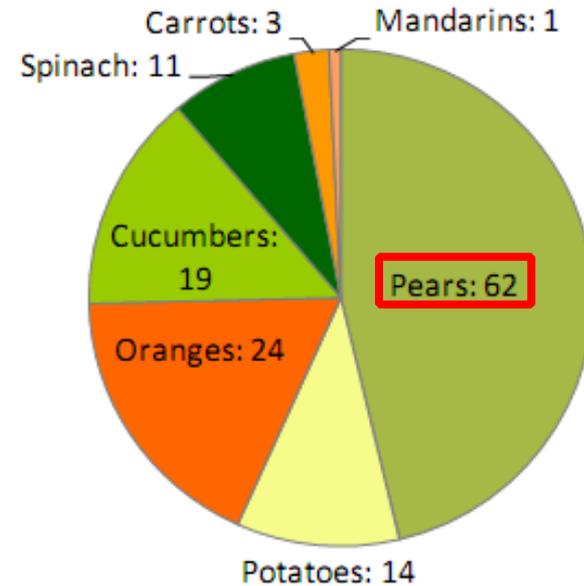
$$IESTI = \frac{LP \times STMR - P}{BW}$$

Pesticide residue monitoring and risk ranking of EU

Types of pesticides in different agricultural products that may cause acute risks

Quantity of agricultural products that may cause acute risks

Pesticide residue monitoring and risk ranking of EU

Food-pesticide combination that indicate risks in acute risk assessment results

Pesticide	Crop	2008 MRL (whole crop) (1) mg/kg	Total number of samples analysed	% samples exceeding the MRL (*)	Highest residue measured (HRM) mg/kg	Highest residue measured corrected with PF (HRMc) mg/kg	Max IESTI (% ARfD)	Most critical diet	Thres-hold residue in edible portion (2) (mg/kg)	Number of samples above the threshold residue	% samples above the threshold residue	Exceedence of ARfD is considered "Exceptional", "seldom" or "not seldom" event? (3)
Azinphos-methyl	Pears	0.5	1441	0.21	1.1		1001.8	DE child	0.110	38	2.64	non seldom
Carbaryl	Oranges	0.05*	1161	0.17	0.51	0.242	320.9	UK infant	0.075	2	0.17	seldom
Carbaryl	Potatoes	0.05*	1671	0.12	0.69		1060.9	UK infant	0.065	2	0.12	seldom
Carbendazim/Benomyl	Pears	0.2	1054	0.28	1.4		637.5	DE child	0.220	3	0.28	seldom
Chlormequat	Pears	0.2	455	0.88	1.1		143.1	DE child	0.770	1	0.22	seldom
Chlorpropham	Potatoes	10	1611	0.06	18.39	6.07	186.7	UK infant	3.251	6	0.37	seldom
Chlorpyrifos	Potatoes	0.05*	1830	0.27	3.71		570.4	UK infant	0.650	1	0.05	exceptional
Diazinon	Oranges	0.01*	1478	0.88	0.6		318.3	UK infant	0.189	2	0.14	seldom
Dimethoate/omethoate	Oranges	0.02*	1355	0.96	0.23		1525.1	UK infant	0.015	16	1.18	non seldom
Dimethoate/omethoate	Pears	0.02*	1421	0.21	0.38		1730.4	DE child	0.022	3	0.21	seldom
Dimethoate/omethoate	Potatoes	0.02*	1758	0.06	1.4		10763.1	UK infant	0.013	1	0.06	exceptional

Risk ~~Total Score = (A+B)×(C+D+E) ×F~~ ue
of ve

Total Score = (A+B)×(C+D+E) ×F

A
Drug properties
(0–6 scores)

Partition
according to
drug toxicology
materials

B
Toxic effect
(0–3 scores)
Partition
according to
ADI value of
drugs

C
Exposure dose 1
(0–3 scores)
Proportion of
foods containing the
drug accounting for
total diet

Score	Definition
0	Non-toxicity
1	Reversible drug effects
2	Reversible organic damage
3	Cause animal irritability
4	Animal carcinogenic effects
5	Mutagenicity Neurobehavioral effects
6	Carcinogenic substance to humans

Score	ADI µg/kg bw/day
0	>10
1	0.1-10
2	0.001-0.10
3	<0.001

Score	Percent
0	<2.5%
1	2.5%-20%
2	20%-50%
3	50%-100%

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Total Score = (A+B)×(C+D+E)×F

D

Exposure dose 2
(0-3 scores)

Usage frequency
of drugs

E

Exposure dose 3
(0-3 scores)

If there is
high exposure
population

F

Amount of
residue(1-4
scores)
Level of
monitored drug
residue

Score	Percent
0	<2.5%
1	2.5%-20%
2	20%-50%
3	50%-100%

Score	Definition
0	No high exposure population
1	Tiny probability of high exposure population
2	High probability of high exposure population
3	There is high exposure population or unable to estimate

Score	Definition
1	No residue record at monitoring result
2	Residue is less than MRL/MRPL
3	Residue is more than MRL/MRPL
4	Residue is more than ten times of MRL/MRPL

Malachite Green

Category	Rationale	Score
Hazard (A)	Studies suggest it is prudent to regard leucomalachite green as a genotoxic carcinogen	6
Potency (B)	May not be a threshold to effects	3
Diet (C)	Only farmed fish – small proportion of the diet	0
Use (D)	Very low use now <1%	0
High Exposure (E)	High exposure groups likely	2
Detectable residues (F)	Residues 10 x the MRPL	4
Total	(A+B) x (C+D+E) x F	72

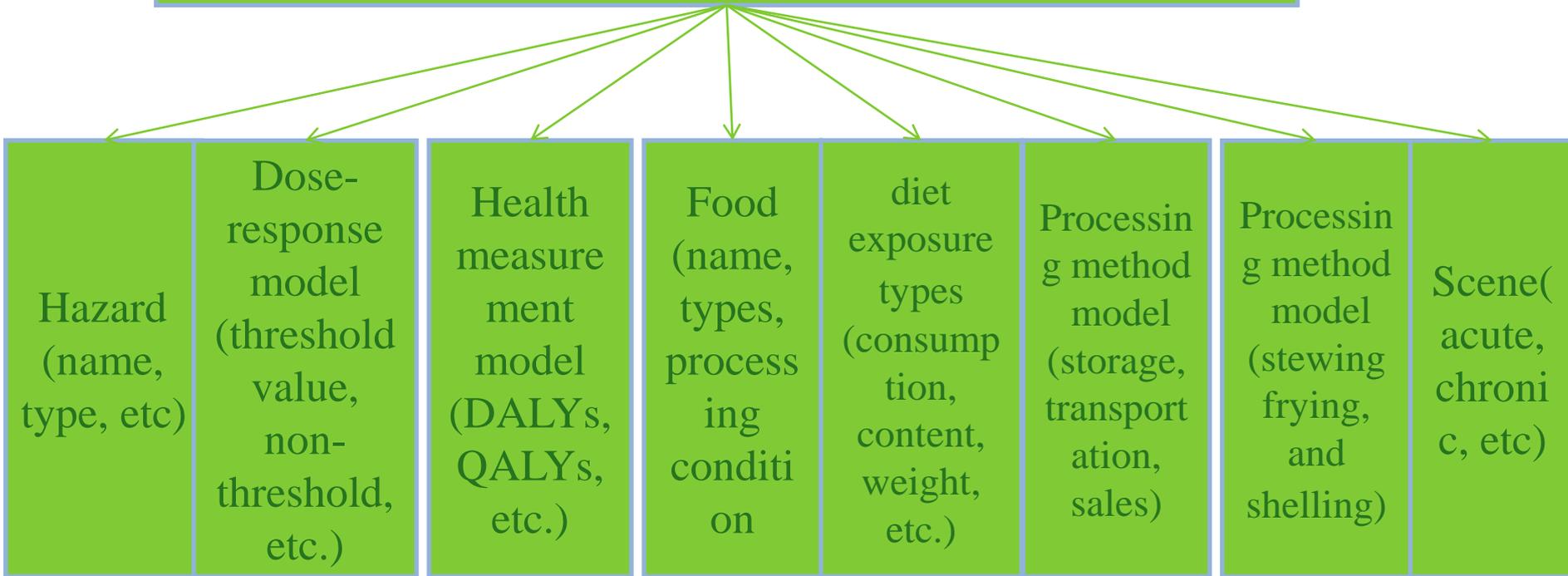# UK residue of veterinary drugs monitoring and risk ranking

Top 10 risk factors in UK residue of veterinary drugs monitoring recent years

Substance	Nature of the hazard (A)	Potency of the Substance (B)	Diet (C)	Usage (D)	High Exposure groups (E)	Evidence of Detectable Residues (F)	Total (A+B) x (C+D+E) x F	Ranking
Nitrofurans	6	3	3	1	1	4	180	1
Phenylbutazone	6	3	1	3	2	3	162	2
Chloramphenicol	6	3	2	0	2	4	144	3
Metronidazole	6	3	1	1	2	4	144	3
Albendazole	6	2	2	2	2	3	144	3
Zeranol	5	3	3	0	1	4	128	6
Fipronil	3	2	1	2	3	4	120	7
Naphthalene	3	3	1	1	2	4	96	8
Malachite Green	6	3	0	0	2	4	72	9
Crystal violet	6	3	0	0	2	4	72	9
Bromopropylate	3	0	1	2	3	4	72	9
Tetracyclines	2	2	3	2	1	3	72	9
Lasalocid	2	2	3	2	1	3	72	9

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5. Quantitative risk ranking

US FDA risk ranking system - iRISK system technical framework:

The diet exposure risk during food consumption

| Hazard (name, type, etc) | Dose-response model (threshold value, non-threshold, etc.) | Health measurement model (DALYs, QALYs, etc.) | Food (name, types, processing condition | diet exposure types (consumption, content, weight, etc.) | Processing method model (storage, transportation, sales) | Processing method model (stewing frying, and shelling) | Scene(acute, chronic, etc) |

Risk = （severity ×probability）

5. Quantitative risk ranking

iRISK ranking system based on MCA simulation technique

- A single ki
- Different h

pathogens and

- Various haz

Detailed Results:

Population Groups	Consumption		Mean Probability of Illness	Number of Illnesses per year	Total Metric Per Year (DALYs)
Adults 60+	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo;1.8E8 eo/yr	Dose Response: Adults 60+ DR Dose unit: cfu (Exponential (r:8.39E-12);100%)	1.25E-8	2.25	5.84
		Hazard Metric: Adults 60+ DALY (2.6 DALYs)			
Intermediate Aged (5-59)	Triangular (Minimum: 10, Mode: 28, Maximum: 168) g/eo;1.7E9 eo/yr	Dose Response: Intermediate Aged (5-59) DR Dose unit: cfu (Exponential (r:5.34E-14);100%)	1.41E-10	0.240	1.20
		Hazard Metric: Intermediate Aged (5-59) DALY (5.0 DALYs)			
Perinatal	Triangular (Minimum: 10, Mode: 28, Maximum: 85) g/eo;1.2E7 eo/yr	Dose Response: Perinatal DR Dose unit: cfu (Exponential (r:4.51E-11);100%)	7.26E-8	0.871	12.2
		Hazard Metric: Perinatal DALY (14 DALYs)			

5. Quantitative risk ranking

- BASED ON EXCEL
- RAMA
- CBMDD V1.0 CBMDC V1.0

6. Summary and discussion

- Risk ranking is the inevitable trend in line with international conventions

- It is the inevitable trend of cost beneficial optimization

- It is the inevitable trend of realizing the quality and safety of agricultural products