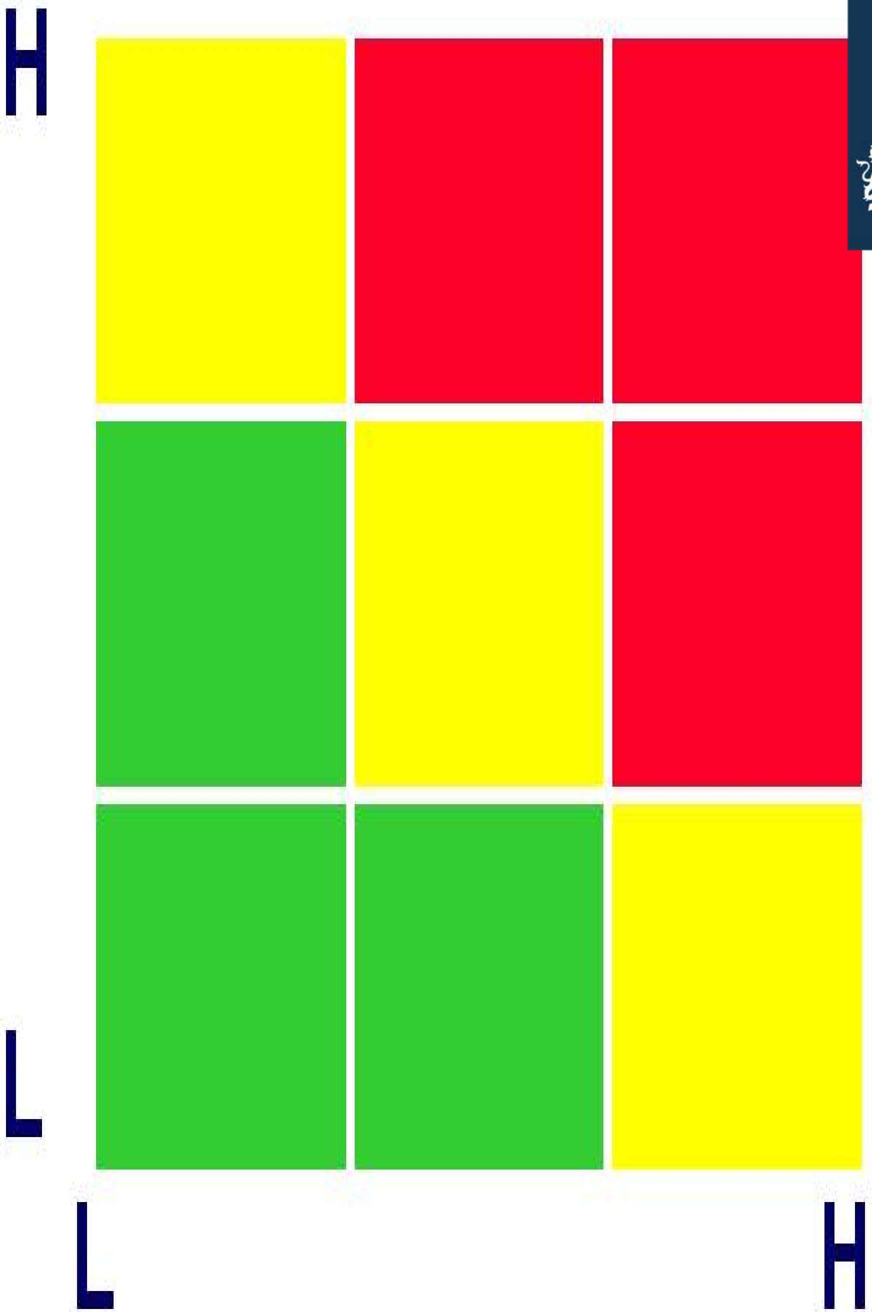

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Ministerie van Volksgezondheid,
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Ranking of chemical risks in food

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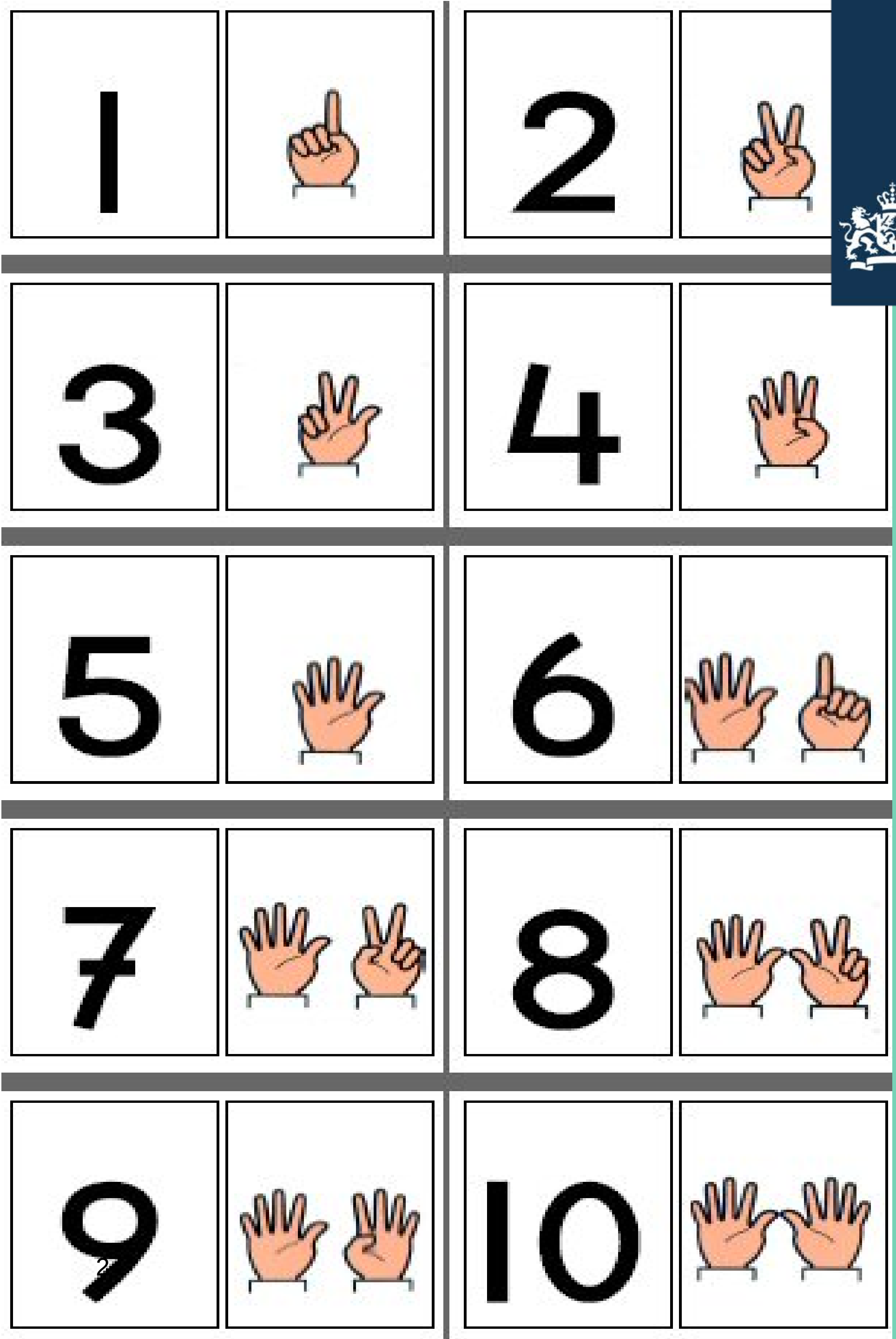

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Content

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2. Qualitative method
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Goal

To develop a method for the ranking of chemical risks in food.

Application

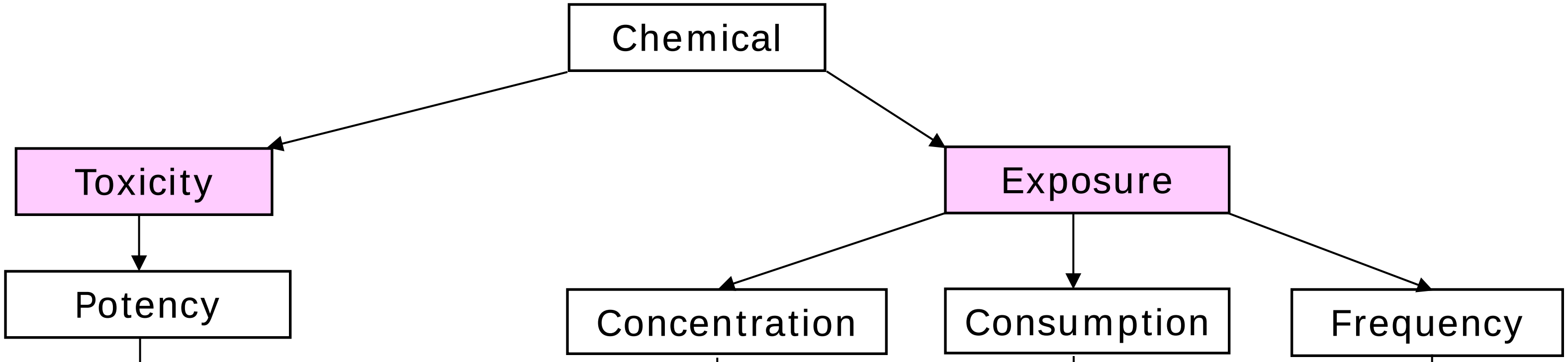
1. To use the outcome of risk ranking for the risk-based control of the food chain.
2. To record the process of risk ranking in a systematic and transparent way.

Approach

Research carried out in 3 phases:

- Inventory and evaluation of existing risk ranking systems using several criteria;
- Development of a qualitative method for ranking of chemical risks in food;
- Development of a semi-quantitative method for ranking of chemical risks in food.

Risk ranking with a qualitative method



Potency

Score	*Classification*
0	Very low
2	Low
4	Average
6	High
8	Very high
10	Gen. Carcinog.

Concentration

Score	*Classification*
1	Very low
2	Low
3	Average
4	High
5	Very high

Consumption

Score	*Classification*
1	Very low
2	Low
3	Average
4	High
5	Very high

Frequency

Score	*Classification*
-2	Low
-1	Average
0	High

End score = Potency + (Concentration + Consumption + Frequency)

Exposure – question 1 (concentration)

What is the average (background) concentration of chemical X in the food product? For convenience sake we assume that all of the particular food product is contaminated with chemical X.

Concentrations (µg/kg or ng/g)	Examples (chemicals with legal maximum levels within the given range)	Score	PFOS
< 1	Clenbuterol	1	
1 – 10	OTA, PAHs, Diclofenac	2	
11 – 100	Patulin, Lead, Cadmium (meat), Amoxicillin	3	3
101 – 1000	Cadmium (fish), Mercury, Sulphonamides	4	
> 1000	Dichlorvos	5	

Exposure – question 2 (consumption)

How much of the contaminated food product is consumed? Estimate the quantity consumed by the average consumer on the day the food product is actually consumed. If multiple food products are contaminated you add up the estimated quantities (e.g. meat + milk).

Quantity (g/day)	Examples (food intake belonging to the given range)	Score	PFOS
< 10	Sweetener	1	
10 – 32	Fat	2	
33 – 100	Fish, Eggs, Sugar	3	3
101 – 333	Fruit, Vegetables, Grain, Meat, Milk products	4	
> 333	Beverage (alcoholic and non-alcoholic)	5	

Exposure – question 3 (frequency)

In case of long term exposure it is important to estimate the frequency of consumption. Therefore, you need to estimate how often the average consumer will consume the contaminated food product(s).

Frequency of consumption of contaminated food product(s)	Score	PFOS
Once a month	- 2	
Once a week / a few times per month	- 1	- 1
Once a day / a few times per week	0	

Toxicity: Potency

Determine or estimate the acceptable or tolerable daily intake (ADI or TDI) of chemical X.

Acceptable/tolerable intake (in µg/kg bw/day)	Examples (chemicals belonging to the given range)	Score	PFOS
none	Genotoxic carcinogens	10	
< 0,1	Dioxins	8	
0,1 – 1	Methyl mercury*, Cadmium*, PFOS, OTA	6	6
1,1 – 10	Trimethoprim, Tetracyclines, Dichlorphos	4	
11 – 100	Sulphonamides, Chlorpyrifos	2	
> 100	Copper	0	

* Derived from the Tolerable Weekly Intake (TWI)

Visualisation of risk ranking

Toxicity												
high	10	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
	8	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*
	6	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*
	4	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*
	2	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
low	0	*0*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
		0	1	2	3	4	5	6	7	8	9	10
		Exposure (= Cc+Cs+F)										
		low										*high*

Strengths and weaknesses

Strengths:

- Simple to use for chemicals with a chronic adverse health effect
- Visualisation of the contributing parameters to the end score

Weaknesses:

- For chemicals with an acute effect another module will have to be developed
- Each group of consumer will have to be scored separately
- The distinctive power might be low because toxicity and exposure of many chemicals (may) fall within the same range(s)

Semi-quantitative ranking

Several (semi-) quantitative methods have been or are being used:

Risk assessment of pesticides: exposure is expressed as % of the Acute Reference Dose (ARfD), referred to as Hazard Quotient

REACH: Risk Characterisation Ratio (RCR): the ratio of measured or modelled exposure level to the health hazard information. The latter can be expressed by the Derived Minimal Effect Level (DMEL) or the Derived No-Effect Level (DNEL)

Environmental risk assessment (EPA): ratio of Estimated Environmental Concentration (EEC) and effect level: the Risk Quotient.

Semi-quantitative method

For chemicals (with a threshold effect level) we use the ratio of the exposure and the health based guidance value, the **Risk Quotient (RQ)**

$$\text{Risk Quotient} = \frac{\text{Exposure}}{\text{Health Based Guidance Value (HBGV)}}$$

Exposure: Concentration x Consumption

- Concentration: actual or legal maximum level (MRL)
- Consumption: acute (P95) or daily (P50 or P95)

Health Based Guidance Value (HBGV): ARfD, ADI, TDI, DNEL, etc.

Questionnaire for risk ranking

Exposure:

- Estimate the concentration of a chemical in food by using actual concentrations or (legal) maximum levels
  - ➢ *Maximum (residue) levels are available at the internet*
- Estimate the consumption of contaminated food product(s) by using national food consumption survey(s)
  - ➢ *For the Netherlands food consumption data are described in a public RIVM report*
  - ➢ *Depending on the situation: P95 (acute/chronic, ARfD pesticides: P97.5)*

HBGV:

- Use established HBGV (ARfD, ADI, TDI, etc.)
  - ➢ *Available at the internet*

Important annotations

Uncertainty:

- Indicate an over- or underestimation of the intake and/or the HBGV

Exposure:

- Indicate if the intake is based on incidental exposure of some food products and/or (background) exposure through the total diet

Population:

- Indicate for which (relevant) population group the RQ is estimated

Chemical	RQ	Uncertainty	Exposure	Group
A	1.2	+ / -	2 products	Adults
B	0.5	* / +	Total dietary intake	Infants

Distinctive power

$$RQ = \frac{Exposure}{HBGV}$$

Keeping denominator or numerator constant

HBGV constant:

- Veterinary drugs with a comparable ADI

Consumption constant:

- Three age groups consuming the same food ingredient (lettuce)

Distinctive power (1)

$$RQ = \frac{Exposure}{HBGV}$$

HBGV constant

Veterinary drugs with ADI's of 5 - 10 µg/kg bw/day (n=33)

- Concentrations: MRL's for edible products
- Consumption according to the Food Basket of the EMA, comparable with P95 or P97.5

Result

- 0.13 < RQ < 1.03 median: 0.73. Variation was large enough to distinct the individual RQs

Distinctive power (2)

$$RQ = \frac{Exposure}{HBGV}$$

Consumption constant

Pesticides with ARfD and MRL on lettuce (n=255)

- 80% of the MRL’s lie between 0.01 and 1 mg/kg

Consumptions for 3 age groups constant (P97.5)

- 2-6 years (140 gram); 7-15 years (129 gram); 16-69 years (127 gram)

Results

- Most RQs were smaller than 0.1
- The variation of the RQs > 0.1 was large enough to distinct the individual RQs

Application of RQ to contaminants

EFSA

- Approximately 50 food contaminants, that have been evaluated by the European Food Safety Authority, were ranked
- Overview was made of published exposure scenarios and health based guidance values

Results

- Exposure: scheme of possible exposure calculations (scenarios) for various consumer groups will be presented
- The RQs of the high exposure groups will be presented

Strengths and weaknesses

Strengths

1. One common measure (RQ) can be used for chemicals with an acute and/or chronic health effect;
2. Whenever the HBGV (of a group of chemicals) or the consumption (of a certain food product) was kept constant, the variation between the RQs was still sufficient to distinct and rank the RQs;
3. Numerator and denominator can be quantified in a probabilistic manner thereby opening other doors.

Weaknesses

1. RQs could but should *not* be used as absolute numbers;
2. The contribution of the parameters is not (yet) visualised.

Conclusions

1. Qualitative method is simple but needs to be adapted for different exposure scenarios.

2. Semi-quantitative method is applicable to different exposure scenarios.

3. Semi-quantitative method can also be used for ranking chemicals in other frameworks outside the food chain.

4. Additional information relating to uncertainty, exposed population group(s) and exposure scenarios is important to mention.

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