

Implementing the risk profile: The German risk assessors` experience

Dr. Mark Lohmann

**Unit Risk Research, Perception, Early
Detection and Impact Assessment**

Department Risk Communication

Structure of BfR-Opinions

Health assessment of soft drinks with added brominated vegetable oils

BfR opinion No 023/2014, 4 July 2014

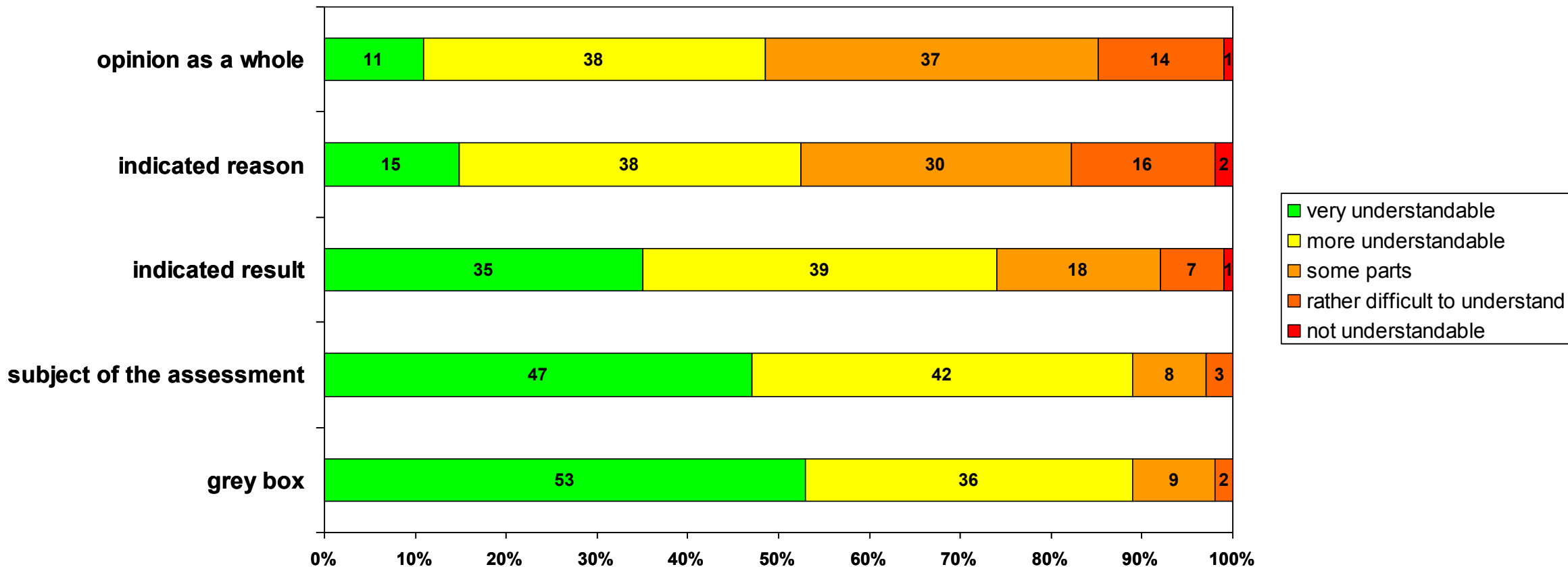
Brominated vegetable oils can be used as stabilisers for aroma oils in fruity flavoured beverages. In the USA these substances are approved for up to 15 mg/L (15 ppm). In the European Union (EU), these vegetable oils are not permitted as additives. For this reason, products containing brominated vegetable oils and / or their components (brominated fatty acids) cannot, irrespective of the content, be traded. At the instance of the German food safety authority which rejected two beverages imported from the USA, the BfR was asked to assess the health effects of soft drinks to which brominated vegetable oils are added.

Animal experiments with brominated vegetable oils have shown that brominated fatty acids may be deposited in various organs. In case of high dosage, the weight of the organs can increase, and the organs themselves may change as a result. At very high doses, the substances had an effect on fertility. No long-term studies required to derive no observed adverse effect levels (NOAEL) have been published as yet.

Based on the current state of knowledge, no acute risks from soft drinks with contents up to 15 mg/L of brominated fatty acids can be derived. The case studies cited in this context about a connection between high consumption of soft drinks containing added brominated vegetable oils and adverse health effects are not plausible from a scientific viewpoint, nor do they prove a general risk. In the opinion of the BfR, it is notably not sufficiently clear whether brominated fatty acids may have any long-term health effects. The same applies to their accumulation potential in humans which may be higher than in the tested animal species. In this context, the high accumulation levels observed in children in particular requires clarification. As a general principle, the use of substances which have high accumulation potential in humans is to be seen as undesirable in food production.

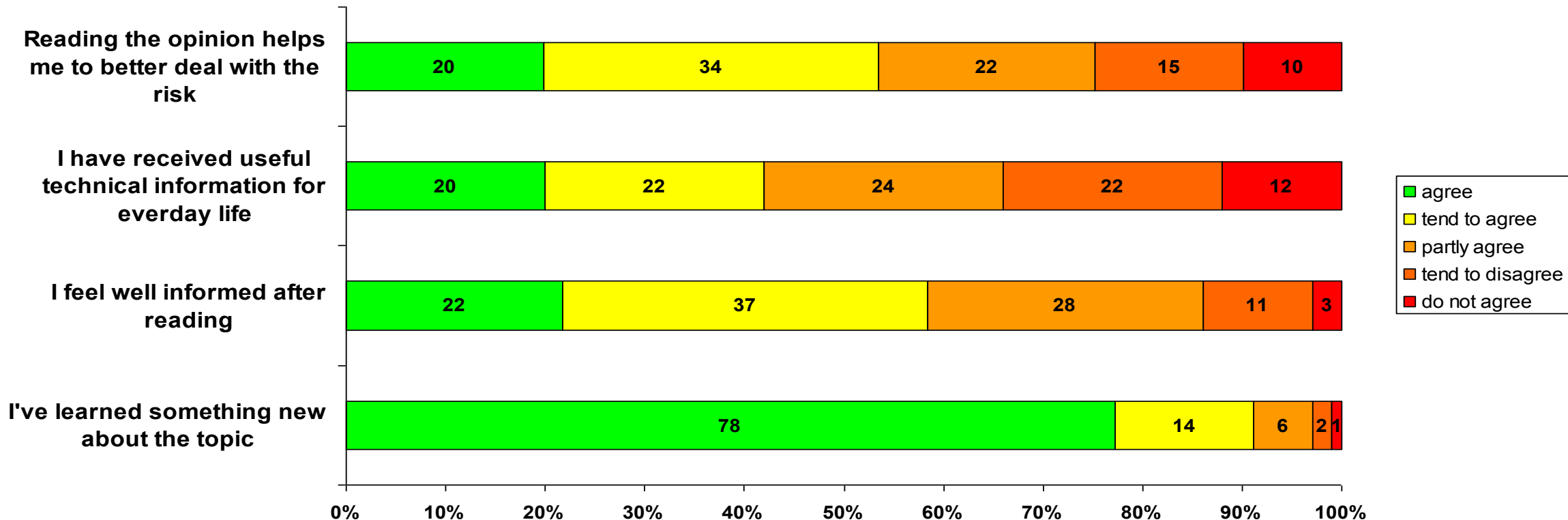
Evaluation of BfR-Opinions I

Consumer survey, n = 200, laboratory conditions, duration of the interview: 60 min, evaluation of four opinions, values in %



Evaluation of BfR-Opinions II

Consumer survey, n = 200, laboratory conditions, duration of the interview: 60 min, evaluation of four opinions, values in %



On the development of the BfR-Risk Profile

1. Literature research on existing risk profiles

2. Inhouse consultation and evaluation processes:

- Standardised **interviews** with seven authors of BfR Opinions from five departments (May-June 2009)
- Experimental **online survey** among BfR scientists to revise the indicator “Probability of health impairment” (30 of 243 scientists contacted in writing took part; February-April 2010)
- **Survey** of twelve employees in the Risk Communication Department for evaluation of the revised Risk Profile (November 2010)
- **Test phase** with the Food Safety Department on the use of the revised Risk Profile and a new variant; the participants were six authors of BfR Opinions (March-June 2011)

3. External evaluation and feedback processes:

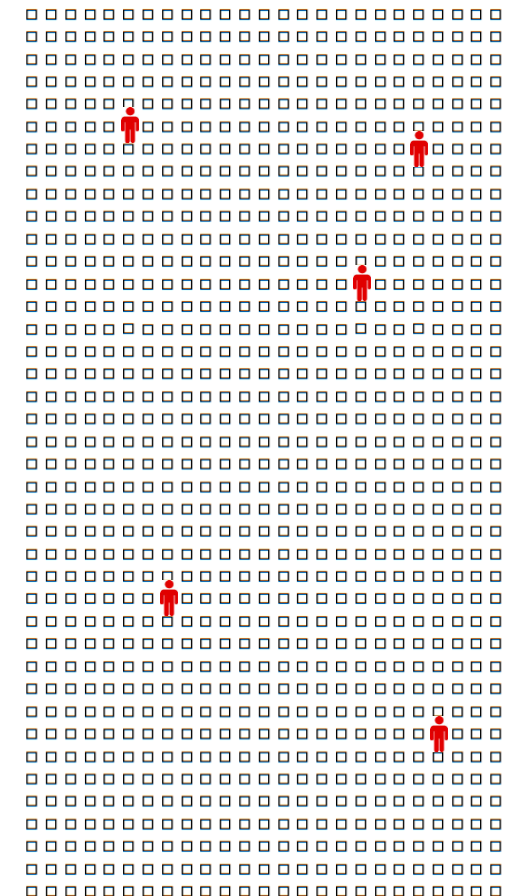
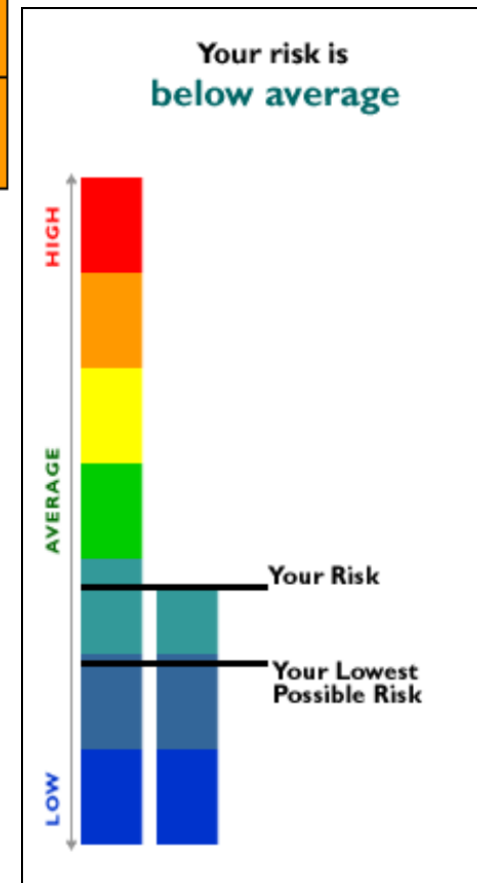
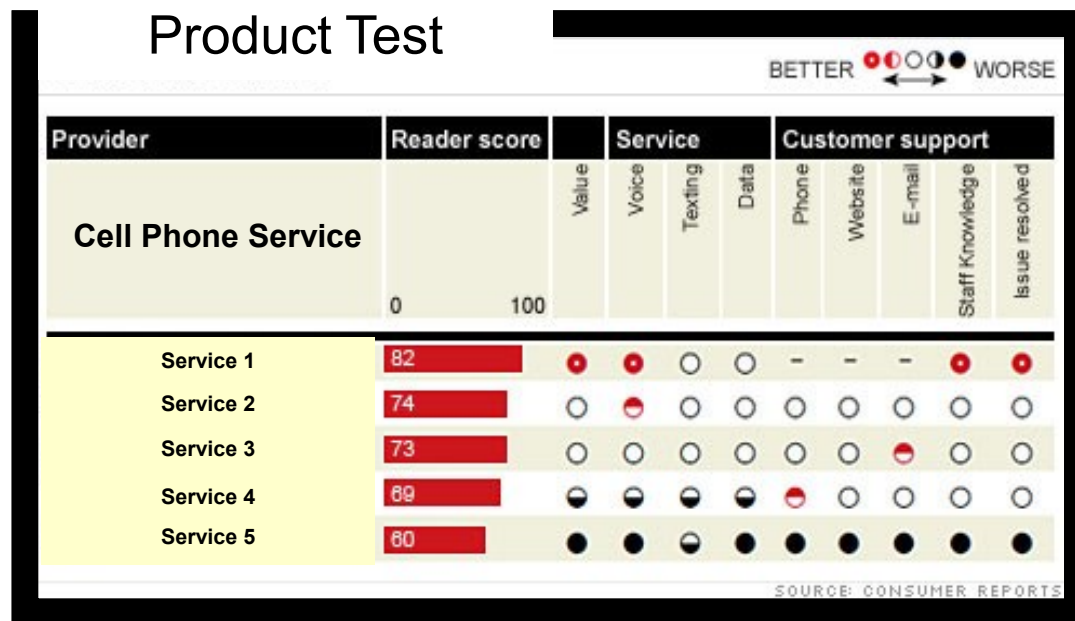
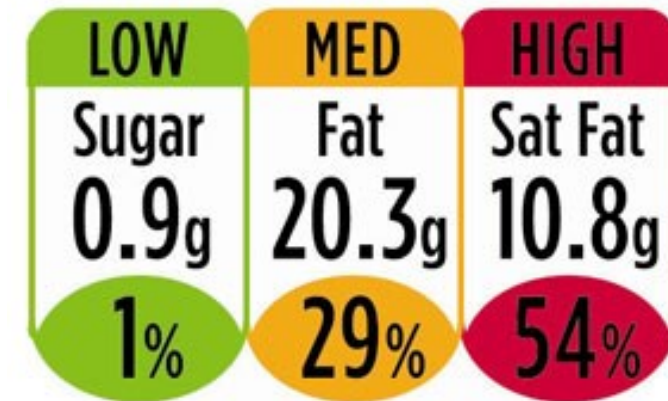
External evaluation (August-October 2011): 47 people from ministries, authorities and the world of science were contacted in writing; 38 of them returned a questionnaire.

4. Focus group interviews (August 2015):

Representatives of consumer protection associations, risk management, scientists, journalists, industry associations, general public

Examples of visualization tools

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Severe
Almost certain	M	H	H	E	E
Likely	M	M	H	H	E
Possible	L	M	M	H	E
Unlikely	L	M	M	M	H
Rare	L	L	M	M	H



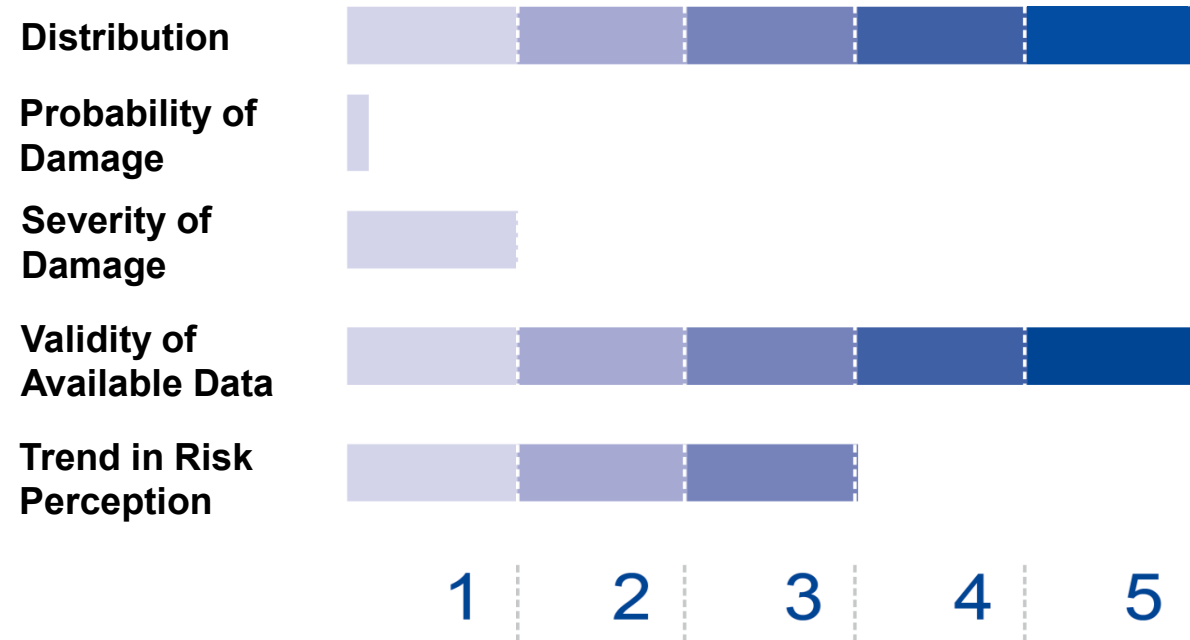
Numerical assessment of verbal probability information

Expression	25%	Median	75%	IQR	Expression	25%	Median	75%	IQR
Always	99.6	99.7	99.8	.3	Not often	10.3	19.7	24.8	14.5
Almost always	89.7	91.7	95.2	5.5	Not very often	5.3	10.1	19.6	14.3
Certain	98.7	99.6	99.8	1.1	Possible	7.5	38.5	50.2	42.7
Almost certain	87.5	90.2	95.0	7.5	Impossible	.2	.3	.5	.3
Very frequent	75.3	82.6	89.7	14.5	High chance	77.5	80.4	89.1	11.7
Frequent	60.0	72.2	75.3	15.2	Better than even chance	53.3	57.6	60.2	6.9
Not infrequent	32.7	49.6	57.3	24.6	Even chance	49.7	50.0	50.2	.5
Infrequent	10.1	17.3	22.6	12.5	Less than an even chance	39.6	40.2	45.0	5.4
Very infrequent	3.6	5.2	10.0	6.4	Poor chance	8.4	10.3	19.7	11.3
Very high probability	89.8	92.5	95.2	5.4	Low chance	5.0	9.8	12.8	7.8
High probability	77.1	82.3	87.2	10.1	Liable to happen	59.8	68.2	77.7	17.9
Moderate probability	40.1	52.4	58.7	18.5	Might happen	19.9	37.6	50.1	30.2
Low probability	7.8	15.0	22.3	14.5	Usually	65.6	75.1	82.2	16.7
Very low probability	1.9	4.9	7.6	5.7	Unusually	9.9	17.4	26.1	16.3
Very likely	80.1	87.5	90.2	10.1	Sometimes	17.5	25.0	35.0	17.5
Likely	62.6	71.1	77.6	15.0	Once in a while	9.9	15.3	22.4	12.5
Unlikely	9.8	17.2	22.7	13.0	Not unreasonable	23.5	37.6	52.6	29.1
Very unlikely	2.7	5.0	9.8	7.1	Occasionally	12.5	20.0	27.7	15.2
Very probable	81.5	89.7	90.4	8.9	Now and then	9.8	15.1	25.0	15.1
Probable	64.7	70.2	77.7	13.0	Seldom	7.4	10.2	17.5	10.1
Improbable	7.6	12.5	22.3	14.7	Very seldom	3.2	4.9	7.7	4.5
Very improbable	1.5	4.8	7.5	5.9	Rarely	3.6	7.2	10.0	6.5
Very often	77.5	82.8	89.9	12.4	Very rarely	1.2	3.0	5.0	3.8
Often	65.0	72.5	75.4	10.4	Almost never	1.2	2.9	4.6	3.4
More often than not	57.1	59.8	60.4	3.3	Never	.1	.3	.4	.3
As often as not	49.8	50.0	50.3	.6					
Less often than not	34.8	40.0	42.7	7.9					

n = 238; Science writers from USA and Canada

Mosteller and Youtz; Statistical Science 1990, Vol. 5, No. 1, 2-34

Prototypes of the BfR-risk profile for internal evaluation 1

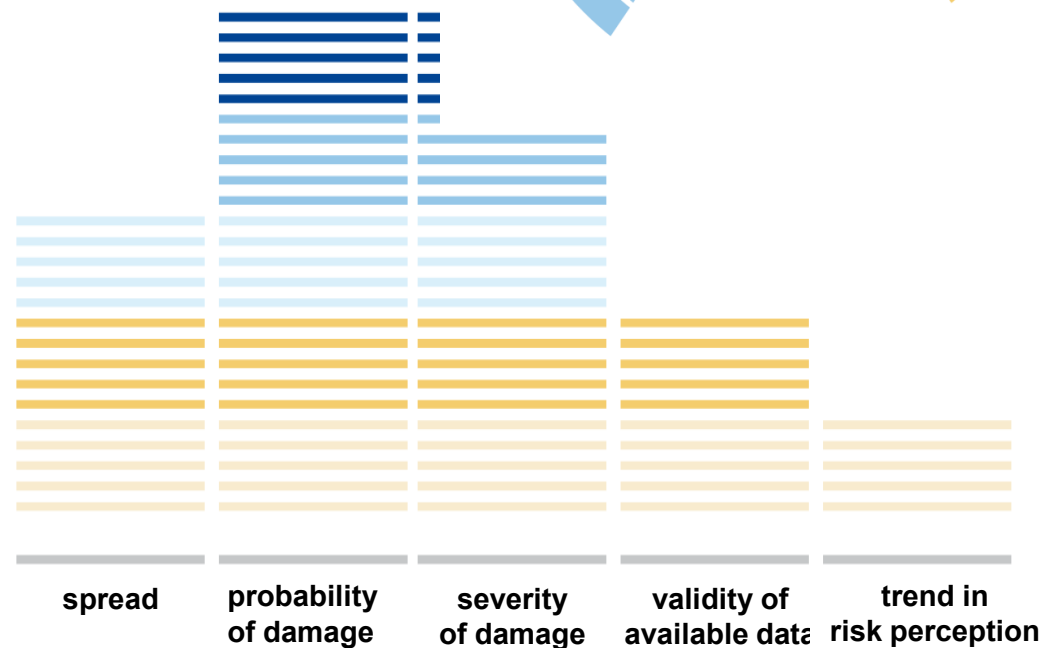


	Distribution	Probability of Damage	Severity of Damage	Validity of Available Data	*Trend in Risk Perception
5	total population	certain	danger of life	high quality	very great concern
4	majority of population	probable	serious impairment irreversible	Generally recognized proof	great concern
3	larger sub-group	possible	serious impairment reversible	plausible suspicion	mode
2	smaller sub-group	improbable	slight impairment irreversible	Fear without concrete evidence	low concern
1	single person	practically impossible	slight impairment reversible	high quality	very low concern
–	not known	not known	not known	not known	not known

*Estimated from surveys

Prototypes of the BfR-risk profile for internal evaluation 2+3

Risk Group: Children

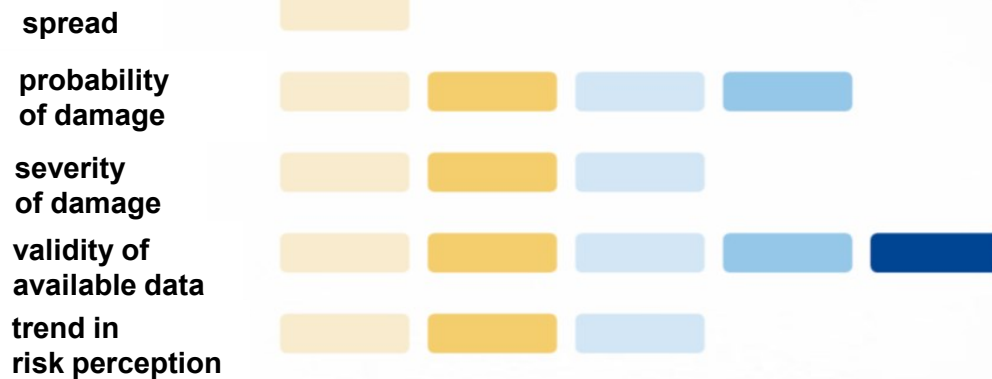


Risk Group: Pregnant

- 1 spread
- 2 probability of damage
- 3 severity of damage
- 4 validity of available data
- 5 Trend in risk perception

Prototypes of the BfR-risk profile for internal evaluation 4

Risk Group: Pregnant



Prototype 5: The Slider Model

BfR Risk Profile: Risk Topic X

Distribution	not known	single person (1)	smaller sub-group (2)	larger sub-group	majority of the population		total population
Probability of Damage	not known	Practically impossible	Improbable	Possible	Probable		certain
Severity of Damage	not known	no health impairment	slight impairment, reversible (2)	slight impairment, irreversible	serious impairment, reversible (1)	serious impairment, irreversible	danger to life
Validity of Available Data	high		medium		low		very low
Controllability by the consumer	control not necessary		controllable through precautionary measures		controllable through avoidance		not controllable



Visibility very difficult when presented in small size
Confusion with digestive system



Reminiscent of changing room symbol
Reflects only infants










Active seniors do not feel addressed or even feel offended

Prototype 6 : The Matrix Model

BfR Risk Profile: Risk Topic						
Severity of health impairment	Danger to life					
	Serious impairment, irreversible					
	Serious impairment, reversible	children				
	Slight impairment, irreversible					
	Slight impairment, reversible				whole population	
	No impairment					
	Not known					
	Not known	Practically impossible	Improbable	Possible	Probable	Certain
Probability of health impairment						

Validity of available data	High	Medium	Low	Very Low
Controllability by the consumer	Control not necessary	Controllable through precautionary measures	Controllable through avoidance	Not controllable

The BfR Risk Profile at a glance – example

BfR Risk Profile								
Cleaning products with nitric acid concentrations of 20-30 %								
Opinion no. 041/2010								
A	Affected group						General population Children	 
B	Probability of health impairment in the event of contact with cleaning products with a nitric acid concentration of 20-30%	Practically impossibleImprobablePossible					Probable (due to skin contact or inhalation of vapours)	Certain (due to oral intake)
C	Severity of health impairment in the event of contact with cleaning products with a nitric acid concentration of 20-30%	No impairmentSlight impairmentModerate impairment					Serious impairment, reversible or irreversible	
D	Validity of available data	High: the most important data is available and there are no contradictions			Medium: some important data is missing or contradictory		Low: much important data is missing or contradictory	
E	Controllability by the consumer [1]	Control not necessaryControllable through precautionary measures			Controllable through avoidance		Not controllable	

Text fields with dark blue background highlighting characterise the properties of the risk assessed in this Opinion (for more detailed information, please refer to the text in BfR Opinion No 041/2010 dated 6 September 2010).

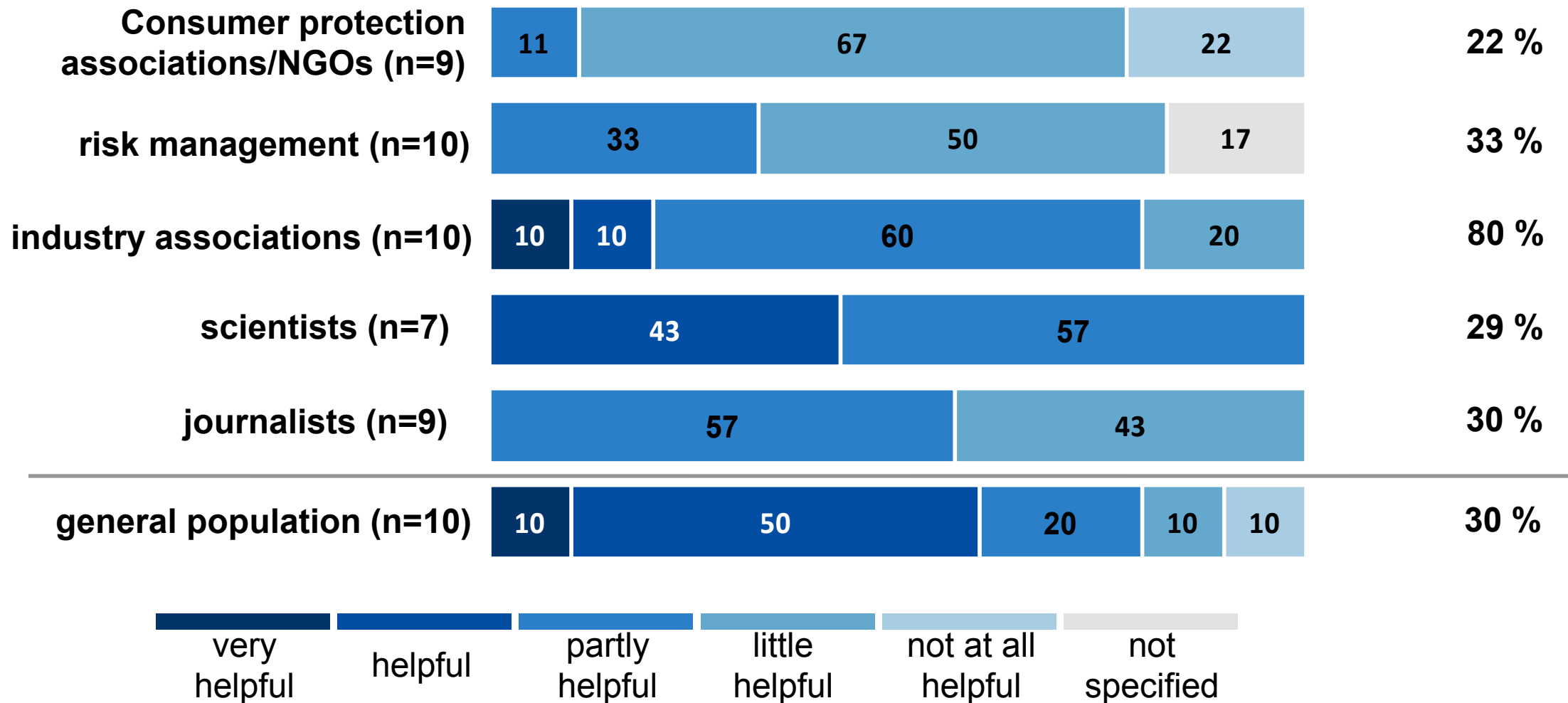
It is the aim of the risk profile to visualize the risk described in the opinion. It is not intended to provide risk comparisons. The risk profile should be read only in conjunction with the opinion.

Row E - Controllability by the consumer

[1] - The indication in the row "Controllability by the consumer" is meant as a descriptive character. BfR assessed household cleaning products containing 20 to 30% nitric acid as not suitable for use in the household and consequently BfR strongly advise against the use of these products. BfR recommends further measures to restrict the marketing of such consumer products containing nitric acid.

Focus group results: **benefits and understanding**

„understandable“



Focus group results:

Suggestions and wishes for improvement

Traffic light system is preferred for indication

Concrete quantities: What dose, duration, quantity is dangerous (exposure)?

Concrete recommendations: Should product be consumed or better not? What are the alternatives?

Demarcation of risky products: Which product groups and / or producers are affected? (from a specific manufacturer or in general all products?)

Concrete description of the adverse health effect: What kind of health impairment is to be expected?

Focus group results: **Summary**

- The majority of the general population considers the BfR risk profile to be **helpful**
- The **majority of experts** does not see a **concrete use** for the BfR risk profile for their own professional activities.
- The BfR risk profile is **suitable to decide** whether to read the statements or not
- All groups are mainly **asking for more specifications**
- The BfR risk profile has a **clearly arranged structure** and gives a first rough impression

Acknowledgement

Gaby-Fleur Böhl

Astrid Epp

Dept. Risk Communication

Federal Institute for Risk Assessment, Berlin



HOPP & PARTNER

COMMUNICATION RESEARCH, BERLIN

Thank you for your attention!

Mark Lohmann

Federal Institute for Risk Assessment

Max-Dohrn-Str. 8-10 • 10589 Berlin

Tel. +49 30 - 184 12 - 3931 • Fax +49 30 - 184 12 - 63931

mark.lohmann@bfr.bund.de • www.bfr.bund.de