

Monitoring and **MoniQA** Quality Assurance

Testing a toolbox for impact assessment of food safety regulations: maximum levels for T-2 and HT-2 toxins in the EU

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outline

- regulatory impact assessment (RIA)
- aim of MoniQA socio-economic research: evaluation toolbox
- aim of this presentation: T2/HT2 case-study
- problem identification
- policy options selection
- evaluation procedure + results of the case-study
 - qualitative assessment
 - feasibility filter
 - comparison of options
- final considerations

Regulatory Impact Assessment

- Set of logical steps which helps the European Commission to assess the potential economic, social and environmental consequences (impacts, effects, costs, benefits) of new policy initiatives that the Commission proposes
- The regulatory proposal is compared to other alternative options - including the 'do nothing' option – in terms of differences in costs and benefits
- **Key analytical steps**
 1. Identifying the problem
 2. Defining the objectives
 3. Selecting the policy options
 4. **Analysing the impacts of the options**
 - Qualitative assessment
 - Quantitative assessment
 5. **Comparing the options**
 - Cost-benefit analysis (CBA): monetary
 - Multi-criteria analysis (MCA): qualitative/quantitative
 6. Outlining policy monitoring and evaluation

aim of MoniQA socio-economic research

food safety RIAs:

- (a) poor data availability, especially for some key impacts
- (b) difficulty in isolating confounding factors
- (c) different timing in the occurrence and discounting of costs and benefits



current practice in food safety RIAs: qualitative assessment



high degree of subjectivity



development of an evaluation toolbox
based on the multi-criteria analysis (MCA) approach

an evaluation tool(box)

- Need for transparency / simplicity as opposed to complex reality
- Computer-based procedure
- Steps
 1. Qualitative assessment of each impact for each policy option (coding/scoring procedure)
 2. Feasibility filter (data availability, time, costs)
 3. Quantitative assessment of some impacts
 4. Multi-criteria comparison of options
- Aim of this presentation
 - Present initial version of evaluation toolbox through an application to a case-study on maximum limits for T-2 and HT-2 toxins in cereals and cereal products

problem identification

- T2/HT2 found in cereals (especially oats) and cereal-based products
- Little definitive information available on the toxic effects in humans (SCF, 2001)
- Combined temporary tolerable dietary intake (t-TDI) of 0.06 µg/kg bw/day for T2 /HT2 (SCF, 2001; JECFA, 2001)
- Setting of maximum limits envisaged in Regulation EC 1881/2006 on food contaminants
- Specific reliable data on effects and exposure: still lacking (SCOOP, 2003)
- Official analytical methods for detection: still lacking (Regulation EC 401/2006)
- Negotiations on the opportunity to set maximum limits: still ongoing (see Fusarium Toxins Forums)

policy options

1. 'do nothing' option
2. 'soft' maximum limits

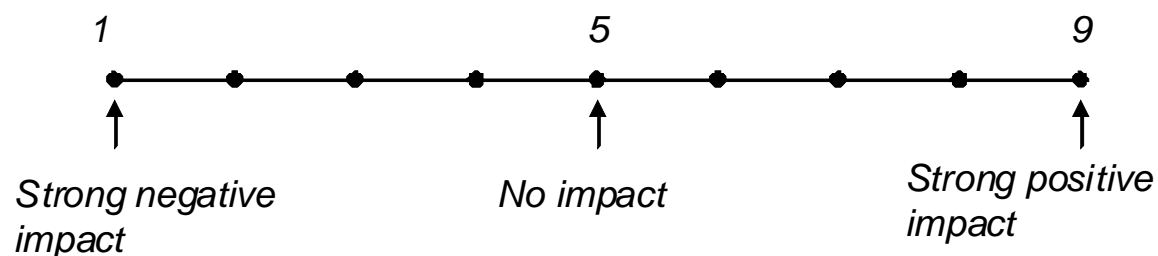
<i>Material</i>	<i>Suggested maximum limits</i>
Raw cereals (wheat, oats, barley, rye, corn)	500 µg/kg
Processed cereals (wheat flour, oat meal, etc.)	200 µg/kg
Finished products (bread, breakfast cereals)	100 µg/kg
Baby food	50 µg/kg

3. 'strict' maximum limits

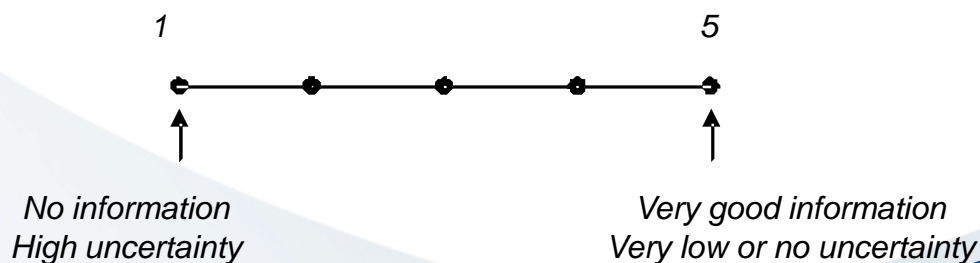
<i>Material</i>	<i>Suggested maximum limits</i>
Raw cereals (wheat, oats, barley, rye, corn)	100 µg/kg
Processed cereals (wheat flour, oat meal, etc.)	40 µg/kg
Finished products (bread, breakfast cereals)	20 µg/kg
Baby food	10 µg/kg

evaluation toolbox – qualitative assessment

- each policy option is assessed for each of the likely impacts
- qualitative indicator **X** on a 1-9 scale



- “confidence” (or uncertainty) indicator **U** on a 1-5 scale, for each indicator **X**



indicator X

- Direction (D)
 - D: -1 = negative 0 = neutral 1 = positive
- Magnitude (M)
 - Severity (Se) (specific for each type of impact)
 - Se: 1 = low severity 2 = medium severity 3 = high severity
 - Scale (Sc) (specific for each type of impact)
 - Sc: 1 = small scale 2 = medium scale 3 = large scale
- Likelihood (L)
 - L: 1 = low 2 = medium 3 = high

case study – qualitative assessment

<i>Impacts</i>	<i>Do nothing</i>		<i>Soft MLs</i>		<i>Strict MLs</i>	
	<i>X</i>	<i>U</i>	<i>X</i>	<i>U</i>	<i>X</i>	<i>U</i>
Public health	5	5	5	2	7	2
Firm competition	5	5	5	3	4,7	3
Conduct of businesses/SMEs	5	5	2,6	3	2,7	3
Administrative burdens on businesses	5	5	1	4	1	4
Public authorities	5	5	1	3,5	1	3,5
Innovation and research	5	5	7	3	8	3
Consumers	5	5	5	3	5	3
International trade	5	5	5,5	2,7	5,5	2,7
Macroeconomic environment	5	5	5	3	5	3
Labour markets	5	5	5	3	5	3
Environment	5	5	4	2	3	3
Distributive effects (negative)	5	5	4	4	4	4
Distributive effects (positive)	5	5	6	4	6	4
Social sensitivity	5	5	5	4	5	4

feasibility filter

C1	availability of quantitative data	no
		yes
C2	costs to collect data	1 too expensive compared to resources
		2 affordable
		3 negligible
C3	time constraint	1 not feasible due to time constraint
		2 affordable time constraint
		3 minor time constraint
X	relevance of impact	1 strong negative impact
		2
		3
		4
		5 no impact
		6
		7
		8
		9 strong positive impact
U	uncertainty of impact	1 no info, high uncertainty
		2
		3
		4
		5 excellent info, no uncertainty

case study – feasibility filter

Impacts	Qualitative		Quantitative			Suggestion	Decision
	X	U	Availability	Costs	Time		
Public health	7	3	No	1 - too expensive	1 - not feasible due to time constraint	Qualitative	Qualitative
Firm competition	5,3	4	Yes	2 - affordable	2 - affordable time constraint	Quantitative	Qualitative
Conduct of businesses/SMEs	7,6	4	Yes	2 - affordable	2 - affordable time constraint	Quantitative	Qualitative
Administrative burdens on businesses	9	4	No	2 - affordable	2 - affordable time constraint	Qualitative	Qualitative
Public authorities	9	4	Yes	2 - affordable	2 - affordable time constraint	Quantitative	Qualitative
Innovation and research	8	4	Yes	2 - affordable	2 - affordable time constraint	Quantitative	Qualitative
Consumers	5	4	No	1 - too expensive	1 - not feasible due to time constraint	Qualitative	Qualitative
International trade	5,5	3	Yes	3 - negligible	3 - minor time constraint	Quantitative	Qualitative
Macroeconomic environment	5	4	Yes	2 - affordable	2 - affordable time constraint	Ad hoc decision	Qualitative
Labour markets	5	4	No	2 - affordable	3 - minor time constraint	Qualitative	Qualitative
Environment	7	3	No	2 - affordable	2 - affordable time constraint	Qualitative	Qualitative
Distributive effects (negative)	6	4	No	1 - too expensive	2 - affordable time constraint	Qualitative	Qualitative
Distributive effects (positive)	6	4	No	1 - too expensive	2 - affordable time constraint	Qualitative	Qualitative
Social sensitivity	5	4	No	1 - too expensive	3 - minor time constraint	Qualitative	Qualitative

comparison of options - MCA procedure

- Series of binary comparisons between each pair of policy options, for each impact
- Comparison based on the computation of 'credibility' of individual statements on the superiority of a policy option over the other option, for every impact
- The larger the difference between the X values, the more credible is the statement of the superiority of the policy with a larger positive impact (or a smaller negative impact)
- Weighted aggregation of the individual criteria (impacts). Aggregation based on the pairwise dominance of each criterion
- Weight may be implicit or explicit

case study - MCA procedure

“Best option” index

Do nothing	Soft MLs	Strict MLs
0,2658	0,0089	0,0444

“Worst option” index

Do nothing	Soft MLs	Strict MLs
0,0442	0,1356	0,1390

- Results should be taken with great caution (exemplificatory purpose so far)
- The scoring system tends to privilege impacts with high probability of occurrence and high level of information certainty.
- Food safety regulations have one prominent impact, public health, on the benefit side, whilst several important impacts (conduct of businesses, administrative burdens, public authorities, etc.) are on the cost side
- Costs for businesses are almost negligible for each firm, but occur with high certainty in case of a regulation, and the aggregate costs can be significant, given the high number of businesses involved

concluding remarks

- MCA approach:
 - Takes into account uncertainty in evaluation and data
 - Allows for combination of qualitative and quantitative assessments
 - Transparent support to decision makers
- Evaluation toolbox to be further developed and tested within MoniQA research
 - More 'tools' to be considered
 - Fuzzy and uncertain measurements accounted for
 - Tests on other case studies
 - Sensitivity analysis