ORIGINAL ARTICLE

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

Maddalena Ragona[1], Mario Mazzocchi[1], Agostina Zanoli[1], Anton J. Alldrick[2], Michele Solfrizzo[3] & Hans P. van Egmond[4]

1 Department of Statistics, University of Bologna, Bologna, Italy
2 Campden BRI, Gloucestershire, UK
3 Institute of Sciences of Food Production, National Research Council, Bari, Italy
4 RIKILT – Institute of Food Safety, Wageningen, The Netherlands

Correspondence
Maddalena Ragona, Department of Statistics, University of Bologna, Via delle Belle Arti, 41 – 40126 Bologna, Italy
Email: maddalena.ragona@unibo.it

Abstract

Introduction The aim of socio-economic research in the MoniQA Network of Excellence is to develop a toolbox to support impact assessment of proposed food safety regulatory changes. *Objectives* The scope of this contribution is to present an initial version of such a toolbox with its application to a case study, which concerns a proposal on setting maximum levels of T-2 and HT-2 toxins in cereals and cereal products. A regulatory proposal of 'strict' maximum limits is compared with two alternative options: the 'do nothing' option and the 'soft' regulatory option. *Methods* The proposed toolbox involves a preliminary qualitative assessment of the likely impacts of each of the policy options considered, with a coding/scoring procedure, in order to identify the greatest impacts. A feasibility filter subsequently considers the availability of data necessary for impact quantification. The subsequent quantitative assessment is performed with different methodologies for the most important impacts. Finally, a multi-criteria analysis approach – which allows for a combination of qualitative and quantitative measurements – is used to arrive at a ranking of policy options. *Results* The outcome of this assessment exercise is that the 'do nothing' option is clearly the most preferable option, and, between the two regulatory options (options 2 and 3), the setting out of 'strict' maximum limits is preferable to 'soft' maximum limits. *Conclusion* This case study shows the potentialities of the toolbox as support to policy makers, which will be improved and tested with additional case studies in the remaining years of the MoniQA Network of Excellence.

Introduction

Within the European Union (EU), all major draft laws must be subject to a regulatory impact assessment (RIA). This is a 'process that prepares evidence for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impacts' [European Commission (EC), 2009a, p. 4]. In other words, the change envisaged by the regulatory proposal is compared with other alternative options (including the *status quo* option) regarding their economic, social and environmental consequences. The process includes a set of logical steps: identifying the problem, defining the objectives, developing the main policy options, analysing the impacts of the options, comparing

the options, outlining policy monitoring and evaluation. The rationale underpinning RIA is that 'sound analysis supported by the best data available' contributes to 'better-informed decision making', i.e. to a rational decision (EC, 2009a, p. 6). A decision can be defined rational if, among the set of policy options, the option that most probably will reach most effectively the objectives for the problem identified is chosen, after consideration of the likely impacts of each impact (Kørnøv & Thissen, 2000). The process of choosing an option among a set of alternatives can be considered as a complex problem solving situation, as it has the following characteristics as defined by Sternberg and Frensch (1991): intransparency (only some variables are directly observable), polytely (presence of multiple goals), complexity (large number of variables), high connectivity of variables (changes in one variable may affect the status of many other variables), dynamic developments (the problem can change decrementally and worsen), time-delayed effects (effects often do not occur immediately). Psychologists teach that problem solvers – assessors and policy makers, in our case – face several limitations in their activity (Sternberg & Frensch, 1991; Dörner & Wearing, 1995). Such limitations can be divided in two types: cognitive and resource limitations (humans have limited mental capacity and cannot cope with large volumes of information, furthermore they cannot know all of the alternatives and consequences related to a problem), as well as behavioural variations and biases (human decisions are affected by past experiences, availability of information and examples, norms and values; Kørnøv & Thissen, 2000).

In particular, RIAs in the policy area of food safety are challenging for the difficulty of estimating key impacts such as consequences for public health, the costs of compliance for businesses and the costs of enforcing the regulation for public authorities. In many cases it is almost impossible to quantify the expected benefits for consumers in terms of lives saved, morbidity reduction, medical costs' savings, etc. Without monetization of all individual impacts, it is not possible to achieve a straightforward evaluation of the balance of pros and contra of intervention, i.e. an aggregation across impacts.

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*In CBA, benefits and costs of alternative options are quantified in monetary terms and compared. For a practical and updated guide on the technicalities of CBA see European Commission Directorate General Regional Policy (2008).

Despite the wide body of quantitative methods for monetization of policy impacts (reviewed by Ragona & Mazzocchi, 2008), complete and reliable cost–benefit analyses (CBA)* are an exception rather than the rule in RIAs of food safety regulations. There are many reasons for this, and the most apparent ones are (a) poor data availability, especially for some key impacts (public health, administrative burdens, etc.); (b) difficulty in isolating confounding factors (e.g. market forces, weather, etc.); (c) probabilistic outcome of some actions, as food hazards may still occur with lower risks; (d) uncertainty in compliance levels; (e) different timing in the occurrence and discounting of costs and benefits (e.g. short-term costs for firms versus long-term health outcomes). Recent RIAs from the EC have chosen to privilege a qualitative assessment of costs of benefits across policy options, even after major efforts in collecting data and stakeholder feedbacks as in the 2008 food labelling RIA.†

To cope with the high degree of subjectivity in qualitative assessments of impacts, we propose the adoption of a toolbox based on the multi-criteria analysis (MCA) approach for the impact assessment of food safety regulations. The development of such toolbox is the aim of the socio-economic research in the MoniQA Network of Excellence (NoE) (Mazzocchi *et al.*, 2009). The use of MCA, strictly based on a transparent scoring system, allows a comparison of policy options under uncertainty of impacts, where both qualitative and quantitative indicators can enter the analysis.

In order to achieve rigour and transparency in impact assessment, in the evaluation toolbox:

● standards, coding and procedures for qualitative assessment of impact and in-depth quantitative analysis are provided (i.e. a 'scoring' system),
● policy options are compared using methods that take into account uncertainty in knowledge and information and
● sensitivity of the results is assessed.

In order to test the toolbox, we have chosen – together with the MoniQA food scientists – a specimen case study based on a hypothetical regulatory proposal setting maximum limits (MLs) of T-2 and HT-2 toxins in raw cereals and cereal products.

The reason behind this choice comes from the fact that the EC Regulation 1881/2006 on food contaminants envisaged the opportunity to setting MLs for T-2 and HT-2 toxins in cereals and cereal products by 1 July 2008, but such

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†http://ec.europa.eu/governance/impact/ia_carried_out/cia_2008_en.htm#sanco

MLs are still under discussion. In particular, cereal industry representatives claim that epidemiological data, information on human exposure and analytical methods available at the moment are still not sufficient to set appropriate maximum levels for T-2 and HT-2 (see the presentations held at *Fusarium* toxin forums[‡]). To this purpose, the European Food Safety Authority (EFSA) has been asked by the EC to provide a scientific opinion on the health risks related to the presence of T-2 and HT-2 toxins in food and feed.[§]

The objective of this paper is to illustrate the characteristics of the evaluation toolbox by means of an application to a case study on MLs of T-2 and HT-2 toxins in cereals. The paper is structured as follows. Firstly, the hazard associated with the presence of T-2 and HT-2 toxins in foodstuffs is described. Secondly, the European market for cereals and cereal products is described with statistical data. Thirdly, some background information on EU regulations regarding MLs, official controls, sampling and analytical methods for mycotoxins is given. The three alternative policy options for the RIA exercise are then presented. The MCA approach followed to assess the impacts of the three options is described. Finally, the impacts are assessed for each option and results are discussed, followed by some final considerations.

Problem identification

T-2 is a trichothecene mycotoxin produced by different species of fungi pertaining to the genus *Fusarium*, and HT-2 is a T-2 metabolite. Both mycotoxins can be found in cereals (especially oats) and cereal-based products [Scienti-

fic Committee on Food (SCF), 2001]. T-2 and HT-2 toxins are not normally found in grain at harvest, but arise as a consequence of water damage to the grain such as may occur when it remains for extended periods in the field at or after harvest, especially in cold weather, or in grain that becomes wet during storage.[¶] In general they are chemically stable compounds, both during storage/milling and the processing/cooking of food; they do not degrade at high temperatures (Eriksen & Alexander, 1998, in SCF, 2001).

Animal experiments suggest that T-2 toxin has high acute toxicity, but can be well tolerated under conditions of chronic low exposure. Among acute effects, dermatitis, vomiting, diarrhoea, haemorrhages, disturbances in the circulatory system (hypotension and arrhythmia) have been reported in various *in vivo* animal experiments [Joint Expert Committee on Food Additives (JECFA), 2001; SCF, 2001]. Moreover, *in vivo* and cell culture studies showed that T-2 toxin could inhibit synthesis of DNA and RNA, and proteins (see SCF, 2001). Very little definitive information is available on the toxic effects in humans of T-2 and HT-2 toxins [International Agency for Research on Cancer (IARC), 1993; SCF, 2001]. Regarding carcinogenicity, IARC (1993) concluded that these mycotoxins were not classifiable as to their carcinogenicity to humans. In 2001, a combined temporary tolerable dietary intake (t-TDI) of $0.06\,\mu g\,kg^{-1}$ body weight (bw)/day for T-2 and HT-2 toxins was established by the EU's SCF, which was in line with the provisional maximum tolerable daily intake (PMTDI) derived by JECFA (JECFA, 2001; SCF, 2001). The most recent study on human exposure to mycotoxins – including T-2 and HT-2 – in the EU is quite dated and was undertaken within the SCOOP (Scientific Co-operation on Questions relating to Food) programme, funded by the EC (Gareis *et al.*, 2003). However, updated occurrence data should become available in the near future in response to the already cited EFSA call. Moreover, it is important to note that occurrence data, if collected every year, would vary, because they strongly depend on climatic conditions, so they should be taken with caution. Occurrence data reported by the SCOOP document revealed that the most frequently contaminated cereal samples collected in some European countries were maize (28%), wheat (21%) and oats (21%) for T-2 toxin (with 20% of positive samples) and oats (41%), maize (24%) and rye (17%) for HT-2 toxin (with 14% of positive samples). With the combination of occurrence and consumption data, dietary intake was calculated, and it resulted that the t-TDI of

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[‡]http://www.micotossine.it/pagina.asp?lang=it&rif=2&pag=110#492. *Fusarium* toxin forums (held in Brussels almost every year) are the opportunity for policy makers and interested parties to discuss the recent advances of investigations undertaken including occurrence data and the progress with regard to the application of prevention measures and the development of reliable and sensitive analytical methods.
[§]The opinion should consider any new results of toxicological studies, produce an updated dietary exposure assessment, and determine the daily exposure levels of humans (and other animal species). Last 30 July EFSA published a call inviting Member states, research institutions, academia, industry, trade and any other stakeholders to submit data on levels of T-2 and HT-2 toxins analysed in food and feed (http://www.efsa.europa.eu/en/data/call/datex100729.htm?WT.mc_id=EFSAHL).

[¶]See http://www.inchem.org/documents/jecfa/jecmono/v47je06.htm#1.0

$0.06\,\mu g\,kg^{-1}$ bw for the sum of the two toxins was in most of the cases exceeded. It should be taken into account that 'for T-2 toxin the amount of positive samples was 20% and for HT-2 toxin 14%. It was agreed in this SCOOP task that, in the case of negative samples [occurrence data below the limit of detection (LOD) of the used analytical method], a value of LOD/2 should be taken for the calculation of mean occurrence levels. Therefore, in the case of a limited number of positive samples, mean occurrence levels are strongly influenced by the limit of detection of the used analytical methods and this can contribute to an overestimation of the calculated total dietary intakes' (Schothorst & van Egmond, 2004, pp. 142–143). It was also highlighted that dietary intake calculations are highly influenced by the level of detection of the analytical methods used, and consumption data per population group (children, consumers, etc.) should be collected, to assess more accurately the exposure of European population.

The European cereal sector[||]

Cultivation of cereals is widespread over the whole European territory, as confirmed by the fact that 52% of EU-27 farms produce cereals. The types of cereals of most interest with regards to T-2/HT-2 contamination are wheat, rye, oats, barley and grain maize (Gareis *et al.*, 2003). They represent 93% of the value of production of cereals in the EU-27 in 2008. Soft wheat is the most important cereal, with more than €22 600 m in 2008. Wheat represents 47% of the value of production of all cereals. In the last years barley is rising in importance, as its value has increased from €6500 m in 2006 to more than €11 000 m in 2008. Oats represent only the 4% of the total production value. Seven countries contribute for the 78% of the total European production value of the selected cereals. France is the largest (24%), followed by Germany (15%), Spain (10%), Italy (9%), Poland (8%), United Kingdom (7%) and Romania (5%). The importance of these commodities is confirmed by the import and export values. The cereals discussed above represent 69% of total imported cereals, with relevant percentages for soft wheat (more than €1267 m) and maize (€2021 m). In terms of exports, they are even more relevant, accounting for 97% of the total cereals exported. Also in this case, the most important cereal is wheat (€4171 m), followed by barley (more than €795 m).

Grain mill products and final products derived from cereals are extremely relevant in terms of exports, as in

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[||]Statistics for this section are taken from Eurostat.

2008 they have reached €4986 and €1990 m, respectively, representing 10% and 4% of the total food industry exports. Imports of such products are less relevant, as representing only 2.3% of the total.

Cereal processing firms represent a relevant part of total food firms: in 2006 they were more than 180 000, i.e. the 60% out of the total; the majority of them are micro- and small-size firms (seven employees per firm). However, there are specific categories that are highly concentrated, for example the breakfast cereals' and the baby foods' industries. Interestingly, 'traditional' cereal food categories like bread, biscuits, pastries, cakes and pasta are manufactured by local companies (which might be internationally owned), while 'newer' farinaceous foods (breakfast cereals and baby/infant foods) are mainly produced by multinational companies. Local companies can have more than 10% of the market share at the national (but not EU) level (e.g. plant bakeries in the United Kingdom and Germany), while a few 'international' companies dominate the EU market with more than 10% market share. Finally, it is important to note – in the light of mycotoxin contamination – that production of such 'newer' food is restricted to a few sites. In terms of breakfast cereals, Cereal Partners operates in sites located in the United Kingdom, Spain, France and Germany; while Kellogg's operates from a few sites in the EU (United Kingdom, Germany, Spain and other countries) and also has facilities in Russia.[**] As they supply all of the Member States, it is obvious that a heavy mycotoxin contamination in crops supplied to such sites, which are located in a very few selected areas, would have significant consequences in terms of human exposure, and economic loss should regulatory MLs exist.

Mycotoxin regulatory background

MLs for the majority of mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, B1 and B2 fumonisins) in foodstuffs are set out in Regulation EC 1881/2006 (as amended) (Commission of the European Communities, 2006a). T-2 and HT-2 toxins are listed in the table but no indication of maximum levels is given. General rules for the organization of official controls performed to ensure the verification of compliance with the food law are laid down in Regulation EC 882/2004. This gives guidelines to competent authorities for performing official controls in terms of sampling and chemical analysis.

[**]http://www.cerealpartners.co.uk/default.aspx; http://www.kelloggcompany.com/

In terms of mycotoxins specifically, general provisions on the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs are given in Commission Regulation (EC) 401/2006 (Commission of the European Communities, 2006c). A survey on current practices in the use of methods for the determination of main mycotoxins – including T-2 and HT-2 – found in food was carried out recently (Solfrizzo *et al.*, 2009) Out of the 19 (control, commercial and research) laboratories from 12 EU countries participating in the survey, 11 performed analyses for T-2 and HT-2 toxins. Liquid chromatography with tandem mass spectrometry resulted as the most used method (seven labs), followed by enzyme-linked immunosorbent assay rapid test (three labs), gas chromatography with mass spectrometry (one lab) and thin-layer chromatography (one lab).

The EC has made a Recommendation (583/2006) suggesting uniform principles to minimize the occurrence of mycotoxins 'through good agricultural practice (GAP) at the production level, and good manufacturing practices (GMP) during the handling, storage, processing and distribution of cereals' (Commission of the European Communities, 2006b, p. 37). The recommendation takes into account the 'Code of Practice for the prevention and reduction of mycotoxins contamination in cereals' produced by the Codex Alimentarius Commission (2003), which also recommends the HACCP principles as a management system – complementary to GAP and GMP – to be considered 'in the future'. Several interesting studies have been carried out on such important principles (Alldrick, 2003; Aldred *et al.*, 2004; Aldred & Magan, 2004; Magan & Olsen, 2004; Magan, 2006; Magan & Aldred, 2007).

Policy options

The purpose of setting maximum levels for T-2 and HT-2 in cereals and cereal products is to provide consumers with an increased measure of protection against undesirable contaminants, i.e. T-2 and HT-2 in those foods that contribute significantly to the total dietary exposure of consumers to those contaminants. Codex Alimentarius recommends that 'MLs should be set as low as reasonably achievable (ALARA) and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade' (Codex Alimentarius Commission, 1995, p. 7). Given the above principles, policy setting of MLs does not necessarily translate into a significant (or quantifiable) impact on gained health, in cases where the 'normal range of variation' is already associated with negligible health risks. This type of policy may rather be targeted at preventing the possibility of future outbreaks (if some external condition changes) or at guaranteeing integrity in product quality. It is important for the protection of public health that MLs are set also on unprocessed cereals in order to prevent highly contaminated cereals entering the food chain and to encourage and ensure that all measures are taken during the field, harvest and storage stage of the production chain to achieve levels 'as low as reasonably achievable'.

The following three policy options were identified. The first (benchmark) option is the 'do nothing' option as suggested by the European Commission's Impact Assessment Guidelines (EC-IAGs) (EC, 2009a). The second two options are the proper regulatory ones. The second option is a 'softer' regulatory option, in the sense that higher limits are proposed to see if they are more efficient (in terms of cost and benefits) than the limits set out according to the data available insofar. The third option suggests stricter limits.

(1) *Do nothing (option 1)*: Maintenance of the *status quo* would see the continuation of the absence of any limits imposed on the occurrence of the two toxins in foodstuffs.

(2) *'Soft' MLs (option 2)*: We propose to set limits five times higher than the relative 'strict' ones (see option 3). The reason for these apparently very relaxed limits lies on the consideration that the t-TDI of $0.06\,\mu g\,kg^{-1}$ bw is a very conservative measure as it includes a total uncertainty factor of 500 (SCF, 2001). The large uncertainty factor serves to provide assurance that exposure exceeding the TDI for short periods is unlikely to have any deleterious effects upon health, provided the individual's intake averaged over longer periods of time does not appreciably exceed the level set.

Material	Suggested maximum limits ($\mu g\,kg^{-1}$)
Raw cereals (wheat, oats, barley, rye, corn)	500
Processed cereals (wheat flour, oat meal, etc.)	200
Finished products (bread, breakfast cereals)	100
Baby food	50

(3) *'Strict' MLs (option 3)*: Maximum levels are set at a level taking into account the current human exposure in relation

to the TDI of the two toxins. Given the t-TDI 0.06 µg kg^{-1} bw established by JECFA and SCF, and by assuming an average bw of 70 kg, the PMTDI of T-2/HT-2 for an average person is 4.2 µg per day. The average daily consumption of cereals was calculated as 0.348 kg per capita, from the average 'gross human apparent consumption of cereals excluding rice' during the last 3 years (2007–2009).[††] Assuming 0.2 kg per capita as the average daily consumption of cereals, with a ML of 20 µg kg^{-1} for T-2/HT-2 (for 'finished products'), the maximum intake ingested would be 4 µg per day – which is slightly below the maximum tolerable intake of 4.2 µg per day for an average person. Such strict MLs may be reasonable in the light of the ALARA principle.

Material	Suggested maximum limits (µg kg^{-1})
Raw cereals (wheat, oats, barley, rye, corn)	100
Processed cereals (wheat flour, oat meal, etc.)	40
Finished products (bread, breakfast cereals)	20
Baby food	10

Evaluation toolbox for impact assessment

The RIA of the proposal of setting MLs of T-2 and HT-2 toxins in cereals and cereal products is carried out by following a procedure developed within the MoniQA NoE.[‡‡]

The procedure is an evaluation toolbox specifically targeted at the impact assessment of food safety regulatory proposals, and is strictly based on the EC-IAGs, which have been updated recently (EC, 2009a, 2009b), and on MCA methodology. This toolbox is still at a preliminary stage of development and needs to be further improved and refined. A visual representation of the toolbox is given in Figure 1.

The toolbox involves a preliminary qualitative assessment of the likely impacts of each of the policy options considered, with a coding/scoring procedure, in order to identify the greatest impacts. A feasibility filter then considers availability of data necessary for impact quantification, in terms of monetary and time constraints for data collection. The subsequent quantitative assessment is performed with

different methodologies for the most important impacts. Finally, a MCA approach – which allows for a combination of qualitative and quantitative measurements – is used to arrive to a ranking of the policy options. The principle at the basis of each assessment step is the concept of proportionate level of analysis, where any unnecessary effort should be avoided (EC, 2009a).

Looking at each of the assessment steps, each policy option is initially assessed for each of the likely impacts to be considered when assessing food safety regulations.[§§] Such procedure requires the alternative policy options to be qualitatively assessed by 'experts' in a structured (and transparent) manner.

Our approach requires qualitative evaluation of an impact using a 1–9 discrete scale. This score can either (a) enter the comparison of policy options, if the use of more detailed quantitative information is not feasible or (b) serve as a basis for the selection of the most relevant impact for more accurate quantification, if the process is feasible in terms of data availability, costs, timing, etc. For the case study, considering the relative importance and the difficulty in estimating the costs and benefits in quantitative terms, we remain with the qualitative assessment (first step of the procedure) to compare the policy options.

For each impact – for each policy option – a qualitative indicator X on 9 levels is established, ranging from 1 (strong negative impact) to 9 (strong positive impact).
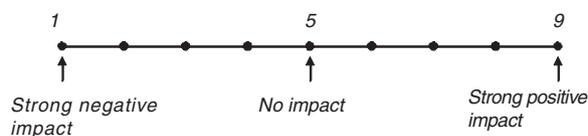
For each indicator, a 5-level 'confidence' (or uncertainty) indicator U is also produced, ranging from very low ($U = 1$) to very high confidence ($U = 5$) in the assessment of each specific impact. This allows incorporating uncertainty into the final analysis of the different policy options.

A set of rules for assigning values to these indicators is essential. We used three parameters, based on the principles of the EC-IAGs (EC, 2009a, p. 37), which were implemented to test the scoring system. The parameters refer to:

- Direction of the impact (D)

D: Negative $= -1$ Neutral $= 0$ Positive $= 1$

[††]From Eurostat, data available for selected countries.

[‡‡]This procedure is described in detail in specific deliverables of the MoniQA NoE, which are available from the authors on request.

[§§]The types of likely impacts were firstly identified by Ragona and Mazzocchi (2008), then the list was updated to include 14 impacts in total (described in deliverables of the MoniQA NoE).
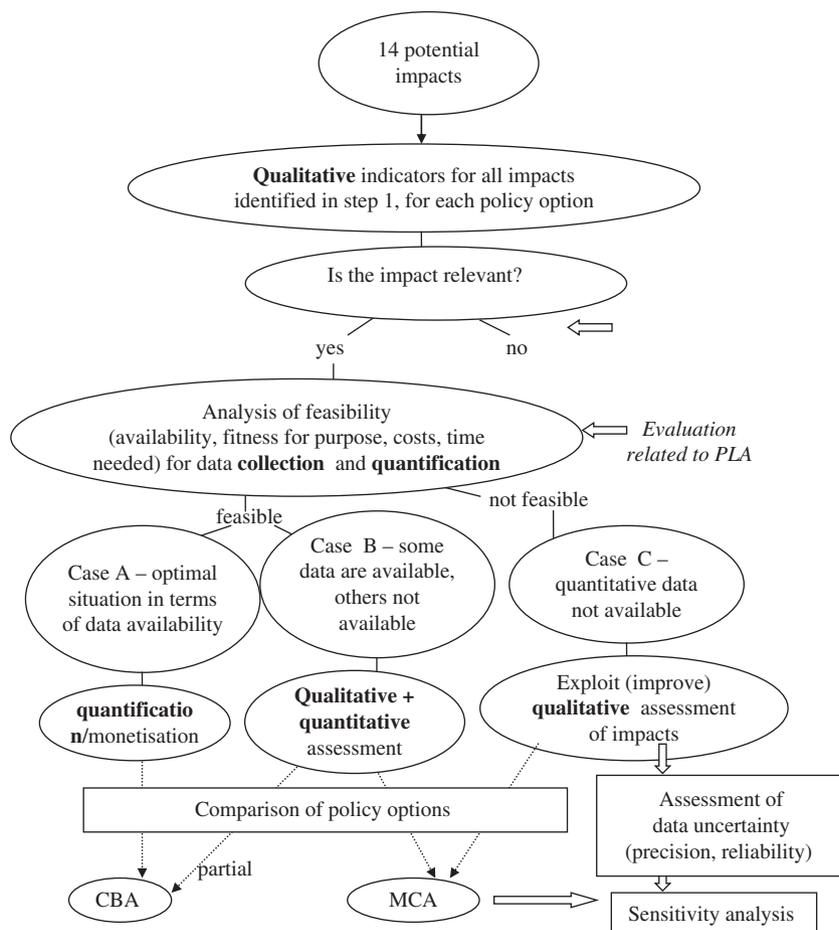
Figure 1 Structure of the evaluation toolbox.

- Magnitude of the impact (M), including

○ Severity of the impact (Se)

Se: On a scale 1–3 (specific for each type of impact)
1 = low severity   2 = medium severity   3 = high severity

○ Scale of the impact (Sc)

Sc: On a scale 1–3 (specific for each type of impact)
1 = small scale   2 = medium scale   3 = large scale

- Likelihood of the impact (L) (intended as 'probability that the expected impact will occur')

L: Low = 1   Medium = 2   High = 3

[¶¶]Described in a deliverable of the MoniQA NoE.

The scores are then combined to produce a single transparent and consistent indicator of impact X on a 1–9 scale through some relatively simple computational steps.[¶¶]

The decision whether to proceed with a further and more detailed quantification of the impact is guided by a feasibility filter (Table 1), which takes into account:

- the availability/accuracy of data for quantification,
- the magnitude of monetary and time costs for quantitative data collection,
- the relevance of the impact (according to qualitative evaluation, indicator X),
- the uncertainty level in qualitative evaluation (indicator U).

Depending on the combination of the above evaluations,[||||] the filter provides options for further progression, viz. to proceed to quantitative analysis or a more

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[||||]Described in a deliverable of the MoniQA NoE.

Table 1 Possible values of parameters for the feasibility filter

C1	Availability of quantitative data	
	No	
	Yes	
C2	Costs to collect data	
	1	Too expensive compared with 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

Table 2 Qualitative assessment of impacts for each policy option

	Option 1		Option 2		Option 3	
	X	U	X	U	X	U
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

interviews with members of the MoniQA working group on mycotoxins and phycotoxins. To this purpose, the interdisciplinary and multi-stakeholder environment of the MoniQA NoE was an ideal environment to collect and mediate experts' opinions on the impacts for the current case study. Quantitative data were collected from statistical databases and interviews with experts, and were only used to support experts' assessment within this stage.

Results and discussion

Table 2 shows the qualitative assessment based on the scoring system for each impact (X and U for each policy option). Here we provide a descriptive assessment of each impact that has lead to the values obtained in the table.

As option 1 represents the *status quo*, there would be no incremental costs or benefits from following this option, so the impact is considered as neutral with no uncertainty ($X = 5$, $U = 5$) and the discriminatory qualitative assessment is limited to the regulatory options 2 and 3.

Impact 1 – public health

There is still no certain information on the risks of T-2 and HT-2 toxins to human health (JECFA, 2001; SCF, 2001), although a new risk assessment has recently been undertaken by EFSA. It is difficult to foresee what kind of impact the two regulatory options would have on public health, but it can be guessed that option 3 would slightly improve well-being of at least a portion of the population (e.g. children) without necessarily reduce morbidity or mortality. This is especially consistent with the negligible risk of acute intoxication given the market conditions in Europe, while

accurate ad hoc assessment of costs and constraints for quantitative analysis.

Where quantitative assessment is feasible, impacts can be estimated through one of the quantitative methods explored elsewhere (see Ragona & Mazzocchi, 2008).

Finally, a MCA approach – which allows for a combination of qualitative and quantitative measurements – is used to arrive at a ranking of the policy options. Within the MoniQA research programme, we are developing a spreadsheet-based simplified multi-criteria approach specifically designed for the evaluation of food safety regulations. The development of the electronic instrument is based in three steps: (1) MCA of qualitative indicators; (2) introduction of fuzzy analysis; (3) introduction of quantitative stochastic impact measurements. To this date we have developed the instrument to the first stage (analysis of qualitative indicators), mainly based on classic principles of MCA developed in other areas (see especially the NAIADE approach by Munda, 1995).

The qualitative impact matrix for this demonstrative case study was compiled by the project researchers based on

accepting scientific uncertainty on potential cumulative long-term effects. The information available on toxicity and exposure is still very incomplete, so the uncertainty of the assessment is relatively high.

Impact 2 – firm competition

The entry into force of a regulation on MLs (options 2 and 3) would not affect the structure of the European cereal sector, as it is applicable to all food operating businesses in the import, production, processing, storage, distribution and sale of cereals and in this respect is not disproportionate on any business or group of businesses. In any event, it could create between small and significant effects on competition if a negative event would occur (e.g. non-compliance with the regulation, due to various possible reasons, e.g. negative climate conditions in a particular area), as other businesses not interested by the negative event could take commercial advantage of the situation by selling their product of 'higher' quality. Moreover, different types of business might have different capabilities to respond to the crisis. However, the global competitive position of EU firms could improve by the sale of 'safer' food.

Impact 3 – conduct of businesses

In a normal situation (good climatic conditions), compliance with such regulation (options 2 and 3) would impose no or few costs to all agri-food businesses interested by the regulation. In some cases it could lead to a positive impact due to a competitive advantage. Costs for businesses would mainly include costs for sampling and analyses. Cost for analyses could be higher in option 3 as rapid tests (which are cheaper than standard laboratory methods) are not as reliable as standard laboratory methods in detecting low quantities such as those indicated in option 3. The increase of costs could be passed on to operators along the food chain, although would probably not pass on to final consumers. For example, millers could charge a higher price for flour to bakeries, pasta makers, etc.

If a negative event would occur (e.g. non-compliance with the regulation, due to various possible reasons described previously) the impact of the regulation on businesses could be negative. The stricter the regulation, the higher the likelihood of negative impact (because of higher probability of rejected lots). Nevertheless, the probability of such an event could be relatively low, let us say approximately once in 5 years. In the event of this happening a derogation form the regulation could be given – as seen for other mycotoxins in crops harvested during periods of

extremely negative weather conditions. SMEs could face slightly higher costs than other businesses as they cannot benefit from economies of scale. This impact can be assessed with a high level of certainty.

Impact 4 – administrative burdens on businesses

The regulatory options (2 and 3) would impose very small burdens on businesses, with no differentiation depending on the level of the standards.

Impact 5 – public authorities

Costs for enforcing the regulation by competent authorities at the national and European levels would be small, as they already perform official controls for other mycotoxins. Costs would be slightly higher for option 3 than option 2 for the same reason as costs for businesses (actual rapid tests could not be used as not so reliable in detecting low concentrations of toxins in food).

Impact 6 – innovation and research

A regulation on MLs for T-2 and HT-2 toxins would possibly stimulate improvements of rapid tests and analytical methods, especially in case of 'stricter' standards (option 3). This can be stated with a moderate level of uncertainty.

Impact 7 – impact on consumers

There would be no impact on cereal taste and prices. The market structure would make any additional cost absorbed by the supply sector, by reducing profits but not raising prices.

Impact 8 – international trade and third countries

Impact on international trade, if any, could be positive in terms of exports of cereals from the EU, which could improve as cereals from the EU would be 'safer' than cereals from other countries. As maize is not so much affected by T-2 and HT-2, and wheat and oats are mainly grown in the Northern hemisphere and not exported from developing countries, regulations on T-2 and HT-2 would impose no (or very small) impact on developing countries. Any conclusion would depend on potential regulatory change in trading countries (thus the level of uncertainty would rise).

Impact 9 – macroeconomic environment

There would be no impact on the macroeconomic environment within the EU.

Impact 10 – labour markets

There should not be any impact in terms of job loss and job creation. In addition, in a general downward trend in workforce in the agri-business sector it would be impossible to accrue any (negligible) loss of jobs to such a type of regulation.

Impact 11 – environment

The regulation (only option 3; option 2 would have a negligible impact) would have slightly negative environmental consequences, in terms of additional transport for control procedures. In the case of a rejection of a lot for non-compliance, the lot might be transported somewhere else for an alternative use (e.g. animal feed), destruction, (possibly) for another attempt at a different mill, or even entry into the black/grey market.

Impacts 12 and 13 – positive and negative distributional effects

Regulation on MLs would have specific positive effects on children, elderly and pregnant women, especially the stricter regulation (option 3). SMEs in general would be slightly more affected – in negative terms – by regulation (more by option 3 than 2). Also sites specifically devoted to oats have a higher probability of negative consequences for the regulation, as they are typically located in areas frequently subject to climatic conditions that favour mycotoxin contaminations. Farmers in general might suffer from stricter standards.

Impact 14 – social sensitivity

The issue is not known to the public, and there is no public concern on T-2 and HT-2 toxins (like for mycotoxins in general). Socially sensitive issues could be associated with children and farmers.

Based on the above table, MCA derives two aggregate measures for each option. The first one (here labelled as 'best option' index) measures the credibility that the policy option is the best one within a range between 0 and 1. Albeit improperly, it may be interpreted as a sort of probability measure, where 1 means certainty that the statement is correct, and 0 certainty that the statement is wrong. The second index (worst option) measures the credibility that the same option is the worst one. While a technical description of the MCA instrument adopted in the MoniQA toolbox goes beyond the scope of this paper, it may be useful to have an intuitive view of the process to obtain these two measures. First, the MCA procedure performs a series of binary comparisons between each pair of options for each individual impact. The comparison is based on a computation of the credibility of individual statements on the superiority of a policy option compared with the alternative. For each impact, the larger is the difference between the X values, the more credible is the statement of the superiority of the option with a larger positive impact (or a smaller negative impact). For example, if one looks at the public health impact of option 3 ($X = 7$) compared with option 2 ($X = 5$), the credibility that 3 is better than 2 will be much higher than the other way round (where the statement might have a credibility of 0). Once all of the credibilities are estimated, the MCA process continues with a (weighted) aggregation of the individual criteria. Again, the aggregation is not a simple average, but it is rather based on the pairwise dominance of each criterion. A policy, which dominates the others for very few criteria is less likely to be the 'best' one compared with another which is invariably superior for all criteria. The technical implementation is slightly more complex (and requires – e.g. – the definition of thresholds to establish credibility), but the results are quite straightforward, as shown in Table 3.

The 'do nothing' option is by far the option with the highest 'credibility' (0.26 in a range between 0 and 1) to be the best one, and is the most unlikely to be the worst choice.

With a much lower credibility, option 3 (strict regulation) has some slight chance to be the best option (0.04), while – given the criteria and assessments – one would rule out that option 2 can be the best one, as its index is close to 0. Interestingly, option 3 has also a slightly higher (the highest) credibility to be the worst one, as there is no strong constraint on symmetry. This can be justified on the grounds of uncertainty in judgements. Options 2 and 3 are more likely to be the worst ones than option 1, but the low indices also suggest some caution in using these results. This is another advantage of using MCA (especially in its fuzzy version), as the ranking of policy options is accompanied by some measure of 'intensity' in the overall evaluation. Furthermore, if a consistent and transparent impact classification and scoring system is adopted for a given policy type – in our case food safety policies – it could become possible to produce comparisons across different

Table 3 Results of multi-criteria analysis

	Option 1	Option 2	Option 3
'Best option' index	0.2658	0.0089	0.0444
'Worst option' index	0.0442	0.1356	0.1390

interventions and develop 'standards' on the levels for these credibility indices.

The results of this case study can be easily explained by the fact that the scoring system tends to privilege impacts with high probability of occurrence and high level of information certainty. Moreover, food safety regulations typically have one prominent impact, public health (which is very difficult to be assessed with certainty), on the benefit side, while several important impacts (conduct of businesses, administrative burdens, public authorities, etc.) are on the cost side, so there is not an equally distributed balance in the number of impacts on the cost and benefit 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.

While the basic procedure assigns weights automatically, based on the size of the impacts, it is possible to vary these weights to check for the sensitivity of the solution. Thus, we tested a different impact weighting procedure, by manually ranking the options in order of importance. In our case, we checked for the effects of an extreme change in weighting, by giving the highest importance to public health, and the lowest importance to negative impacts (costs), but the results (ranking of options) were robust and did not change, despite – as expected – a smaller distance in terms of credibility among the three options.

Given that this is just a preliminary and demonstrative case study and should not yet be taken as relevant for a meaningful policy evaluation, the results are potentially very interesting from a policy perspective. It seems that, given the high uncertainty in the effects on human health from a regulation on MLs for T-2 and HT-2 toxins, and the certainty of costs borne by businesses, the 'do nothing' option emerges as the best solution, at least until more evidence-based information becomes available (e.g. the output from the risk assessment recently undertaken by EFSA) and can lead to the possible preference for another policy option rather than the 'do nothing' option.

Between the two regulatory options, setting soft limits would not give a 'moderate' and preferable solution as one might imagine, as the costs would be only slightly lower for businesses, without improving the level of safety for consumers.

Thus, this is an emblematic case where the intuitive statement that 'in medio stat virtus' (virtue stands in the middle) does not hold. The 'soft' option, which might be the easiest in political terms given the conflicting interests of

stakeholders, is unlikely to be the best choice, as highlighted by the results of the decision-support toolbox. As already mentioned, this is just the first impact assessment exercise in order to test the evaluation toolbox, and results and relative policy discussion should be taken with great caution.***

Final considerations

The *ex ante* evaluation of food safety regulations and policy options is subject to many difficulties, which make monetization impossible or unreliable. The use of MCA approach is thought to be a useful tool as it takes explicitly into account uncertainties in measurement and impact evaluation and allows for a combination of qualitative and quantitative measurements. The application of the toolbox to a practical case study has revealed its valuable advantages. Among all, it provides an extremely transparent support to decision makers, who, like everyone else, face several cognitive and behavioural limitations when coping with complex problem solving situations such as undertaking RIAs. However, the evaluation toolbox still needs to be further developed and tested with additional case studies in the remaining years of the MoniQA NoE.

Acknowledgements

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***In order for an application of the toolbox to be considered as meaningful for policy decision making, further improvements to the toolbox are needed, several application exercises should be carried out, and more resources should be devoted for its development.

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