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SHORT COMMUNICATION

Assessing the socio-economic dimension of food quality and safety regulations: research challenges and recent advances

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Abstract

Introduction Monitoring and Quality Assurance (MoniQA) is a multidisciplinary network of experts aiming at harmonizing worldwide food quality, safety monitoring and control strategies, dealing with socio-economic impact assessment and working for better regulations (Poms *et al.*, 2009). *Objectives* MoniQA provides support for a systematic assessment of the socio-economic effects of new European food quality and safety regulations. Impact is evaluated in terms of efficiency, effectiveness and consistency of application, and with respect to different stakeholders (consumers, industry, regulatory bodies, etc.). As a result, socio-economic impact assessment will enhance the effectiveness and the efficiency of new food quality and safety regulations. *Methods* Following the European guidelines for regulatory impact assessment, MoniQA has developed a generic Evaluation Framework, dealing with food safety challenges, such as the costs and benefits of strict control measures targeting the agriculture and food industry, the implications of imposing controls independently on export markets, the costs and benefits of extensive training programmes, and the risks associated with lowering standards and relaxing controls. In parallel, MoniQA is developing a decision support system, which compares the effectiveness of policy implementation at the level of the individual enterprise (micro level) with the success of policies within and across countries (macro level). As there are so many stakeholders (e.g. small versus large enterprises, differences in risk profiles and management structures, sectors and geographic location, etc.), this tool is expected to allow an understanding of the different scenarios and facilitate policy-making at various levels (e.g. regional, national, European Union, etc.). An Evaluation Toolbox, based on the complementarities of the Evaluation Framework and the decision support system, will provide information about: data availability, gaps and quantitative and qualitative collection procedures; a systematic classification of impacts; validated results from the case studies; and up-to-date guidelines on evaluation strategies. *Results* The expected output of our overall research work is a toolbox (intended as a set of procedures) that can be used by policy makers better to assess the potential impacts of future food quality and safety regulations. This toolbox will provide methodological instruments for qualitative and quantitative assessment in the important policy area of food quality and safety. *Conclusion* The co-operation being fostered among food scientists and socio-economic scientists within the MoniQA network is

essential for applying the procedures for impact assessment that are being explored in the socio-economic research. This is in line with the MoniQA objective to achieve a sustainable network of food quality and safety experts in the long term.

Setting the scene: the governance of food safety – a web of rules, standards and regulations

The foundation of the current European policy framework governing food quality and safety was laid down in response to food scandals during the 1990s. The BSE scandal, in particular, decreased consumer confidence levels and prompted a systematic reform of regulatory and institutional systems in the European Union (EU) and its Member States. Before and in the midst of these food scandals, risk assessment tasks as well as the representation of both producer and consumer interests were often vested in the same government department in European Member States.

Consequently, institutions were locked in a conflict of interest between protecting producers and consumers. The European Commission (2000) shed light on the institutional inability to cope with both tasks and forced policy makers to redefine the framework essential to ensure the functional and institutional separation of three key components in risk analysis, i.e. risk assessment (scientific advice and information analysis), risk management (regulation and control) and risk communication.

As envisaged in the White Paper, the European Food Safety Agency – mandated to carry out and co-ordinate risk assessment and communication at EU level – was set up, and shortly afterwards several Member States also established food agencies similar to European Food Safety Agency. At the national level, there are still considerable differences, particularly with regard to the effectiveness and efficiency of controls as well as the application of the Hazard Analysis Critical Control Point rules.

As a result of these reforms, Europeans enjoy one of the highest levels of food safety in the world, but this has not come without a cost. Policy makers need to be informed about the likely (*ex ante*) and actual (*ex post*) consequences of policies and regulations and monitor their effects during application. These consequences may be positive (benefits) or negative (costs) or both; they may be monetary (actual costs) or non-monetary (e.g. lost confidence); and they may affect differing actors (consumers, industry, institutions, etc.) at different levels (economic, environmental, social, etc.).

Regulatory evaluation performed by the EC in all policy areas – not just food safety – has been reviewed recently in response to the call for better regulation and more evidence-based policies. As was agreed at the Gothenburg (June 2001) and Laeken (December 2001) European Councils, the EC has launched a new approach to impact assessment (European Commission, 2002a), which was listed as a concrete action of the Better Regulation Action Plan (European Commission, 2002b) and aims at simplifying and improving the European regulatory environment. This new approach will integrate, reinforce and replace the sector-based impact assessment carried out earlier. This change was made in order to demonstrate politically the Commission's intention to improve the quality of EU legislation and make its workings more transparent.

We have reviewed both the theoretical foundations and empirical applications of a range of methodologies used for evaluating food safety regulations, such as cost–benefit, cost–effectiveness, risk–risk, health–health and multi-criteria analyses, together with a survey of the statistical and econometric methodologies for specific impact quantification (Ragona & Mazzocchi, 2008a). In particular, we have examined the different approaches to regulatory impact assessment used in selected countries within the EU and investigated the procedures used to assess the impact of regulatory choices as well as the individual quantitative and statistical methodologies employed for benefits and costs calculation. The impression that emerges is that the valuation of food safety regulations is still at an early stage, while there is a well-developed economic analysis, like environmental regulation, for other types of regulation. We have noted that official regulatory impact assessment employs simple cost–benefit analyses that evaluate costs with the cost of compliance methods and estimate benefits using the cost of illness approach. Such methodologies are transparent and easily understood by non-economists, but the results are less robust. There is a trade-off between simple, but less robust methods and complex, but more robust methods (see Giorgi & Lindner, 2009 for a detailed discussion).

Developing an evaluation framework (EF)

Following the (regulatory) impact assessment guidelines published by the European Commission (2005a, 2005b), MoniQA has developed a generic EF for assessing the impact of compliance with food safety regulations in an individual country, thus establishing a basis for systematically assessing the costs and benefits of alignment or harmonization at the

multilateral level. The EF has been designed to fit different products and contaminants, as well as countries with different economic structures and hence different challenges to both trade and economic development. The framework builds on the evaluation literature and state of the art. In order to test this generic EF, *four case studies* will be carried out on the likely and actual cost of new regulations and testing methods:

(a) aflatoxins in hazelnuts (Turkey),
(b) melamine in dairy and other products (China),
(c) T-2 and HT-2 toxins in cereals (Italy),
(d) dioxin testing (Germany and United Kingdom).

These case studies allow for the analysis of different policy options when dealing with food safety challenges including

(a) implications and costs and benefits of strict control measures targeting the agriculture and food industry – under situations of market concentration or diffusion;
(b) implications of imposing controls independently on export markets (rather than on both domestic and export markets);
(c) costs and benefits of extensive training programmes;
(d) success potential of cash transfers to producers;
(e) risks associated with the lowering of standards and relaxing of controls;
(f) effectiveness of a monitoring system in a federal-like system like the EU, where comprehensive controls are carried out only in one rather than all Member States, the *de facto* situation for several contaminant groups at present.

Although not all the policy options will be assessed for each country under investigation, the investigators expect to obtain enough information to be able to compare the different options at a more generic level and, on this basis, draw conclusions and make recommendations for better implementation of food safety within Europe and worldwide. Therefore, the *key output of this activity* will be a validated general EF, which will provide insight into the impact of regulation in the food chain within and across different countries.

Towards a policy decision support system (DSS)

MoniQA is developing a DSS, which compares the effectiveness of policy implementation at the level of the individual enterprise (micro) with the success of policies within and across countries (macro) (for a description of this multilevel model, see Fritz & Schiefer, 2008). As there are so many stakeholders (e.g. small versus large enterprises, differences in risk profiles and management structures, sectors and geographic location, etc.) an assessment procedure is needed that allows an understanding of the different scenarios and facilitates policy making at various levels (e.g. regional, national, EU, etc.).

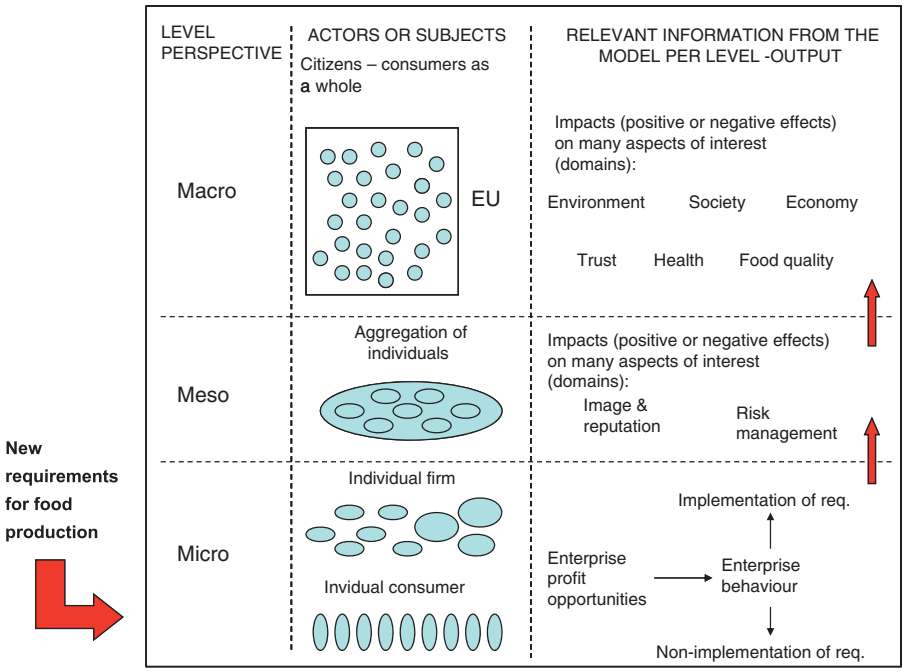

Figure 1 Definition of the model categories.

The logical pathway in the model moves from requirements to the consequences for citizens, in combination with cause–effect relationships, which involve all those affected by the new regulation. Because citizens depend on manufacturers and retailers (enterprises), it is important to include the view of enterprises in the assessment. If enterprises do not implement a new regulation on food safety appropriately, food safety cannot be improved. The model focuses particularly on linking the enterprise behaviour (micro level) with consequences for citizens (macro level). To describe this connection, the horizontal part of the model forecasts behaviour with respect to new requirements in food safety. The subsequent vertical part of the model connects the consequences of enterprise behaviour with the final effect on citizens. Both are included in the outline, which will lead to a unique computational system.

The model is modular, which means it is applicable to a specific region or nation. Figure 1 shows the view of the subject or actor considered: the individual enterprise, the group of enterprises with common features and interests, with society as the final aggregation of all the end-consumers in the EU.

The core advantages of this multi-level approach are as follows:

- The representation of enterprise behaviour, which leads to a higher probability of an improvement being achieved in policy efficiency.
- More effective impact forecasting by means of the ability to connect the causes and effects between macro, meso and micro levels.
- A broader view of the aspects affected by the new regulation (environmental, economic and social factors).

The major challenges in using the decision support model to arrive at an understanding of the final impacts of new regulation on food safety are the following:

1. Understanding and forecasting enterprise behaviour.
2. Connecting enterprise behaviour to real consequences and taking the magnitude of the latter into account.
3. Understanding enterprise group dynamism and its ability to influence corporate decisions.
4. Connecting the consequences to the output table of the model by means of the correct indicators.
5. Understanding linkages and interconnections between the different level domains in order to understand the impacts of the regulation.

In summary, the main output in this activity is:

(1) a DSS that allows the behaviour of individual companies and its impact to be separated, providing a helpful tool for stakeholders at the policy-making level,

(2) the socio-economic assessment of developments in analytical methods from a business-level perspective.

Developing an evaluation toolbox

The EF and DSS will provide support for the systematic assessment of new regulations in food quality and safety. This toolbox, based on the complementarities of the EF and the DSS, will provide a set of procedures, which explicitly take research evidence and empirical validation from MoniQA into account. More specifically, the toolbox is expected to:

(1) gather information on data availability issues and data problems, also suggesting quantitative and qualitative collection procedures,
(2) provide a systematic classification of impacts, linked to existing literature and knowledge,
(3) provide detailed evaluation examples based on the results from the MoniQA case studies,
(4) contain up-to-date guidelines on evaluation strategies in the food safety and quality area.

The toolbox is being created in two steps. Step 1 is concerned with data collection and discussion, based on evidence from the pilot case studies of task 1 and from the DSS prototype of task 2, plus the indications from a MoniQA-EC workshop (that will be held in October 2009) and an extension of the pilot case study on T-2 and HT-2 toxins in cereals to the European level. Once the data collection schemes have become available and outputs from task 1 and task 2 have provided results on the generic EF and the DSS, the toolbox will synthesize these outputs into a structured 'information centre' as described above. In conclusion, the final output of this activity will be an evaluation toolbox, including validated procedures for the systematic assessment of food safety regulations both at the individual and the aggregate levels, which provides support for evaluators and policy makers.

Outlook

The socio-economic impact assessment of food safety regulations is part of the joint research activities of the MoniQA Network of Excellence, including the development of harmonization guidelines for risk assessment and the standardization of detection methods and technologies, the assessment of the implications of advanced processing and monitoring technologies implemented in modern Hazard Analysis Critical Control Point systems, and the

development of a database on food quality and safety issues (analytical methods, Rapid Alert System for Food and Feed, contaminants, commodities, etc.).

MoniQA partners are working together to combine their research activities and share personnel and resources (via joint education and training programmes, personnel exchange and a mobility programme, and the shared use of research infrastructure), in order to form the basis for a global network of food safety and quality experts, which will continue to exist long after the 5-year duration of the project.

The co-operation being fostered among food scientists and socio-economic scientists within the network is essential for developing case studies applying the procedures for impact assessment, which are being explored in the MoniQA research.

Our first year was devoted to a comprehensive review of current practices in evaluation procedures and the regulatory environment concerning food quality and safety, and more specifically

- role of stakeholders in the decision and implementation process,
- rules, standards and regulations in the EU as compared with the United States and Codex legal frameworks,
- quality systems used in the agro-food sector,
- Procedures for the impact assessment of regulations and quantitative methodologies for estimating impacts.

During the second year, the conceptual basis for the socio-economic analysis was established via two expert working groups (WG) communicating with social scientists outside the network (Expert WG) and other MoniQA WGs (Socio-economic WGs). The Expert and Socio-economic WGs have

- designed a theoretical EF at the macro level,
- formulated a preliminary structure for a DSS taking the micro level into consideration,
- outlined a set of case studies for the empirical application of the assessment frameworks.

In the third year, our activities are concentrating on

- creating a prototype of the DSS and the preliminary results of mapping costs/benefits of innovations in analytical methods,
- data collection schemes for the evaluation toolbox,
- preliminary testing of the EF: results of pilot case studies,
- preliminary evaluation toolbox and the results from its application to the T-2 and HT-2 case study.

The expected output of our overall research work is a toolbox (intended as a set of procedures) that can be used by policy makers better to assess the potential impacts of future food quality and safety regulations. This toolbox will provide methodological instruments for qualitative and quantitative assessment in the important policy area of food quality and safety.

The preliminary achievements of our work have been widely disseminated, including on the MoniQA homepage, where executive summaries of the deliverables produced can be found. A dedicated sub-page on socio-economic activities has also been set up at http://www.moniqa.org/socioeconomics (MoniQA 2009a). Additionally, a socio-economics factsheet has been produced and can be downloaded at http://www.moniqa.org/factsheets (MoniQA 2009b). A number of papers have been published in scientific journals or presented at seminars and congresses (e.g. Mazzocchi *et al*., 2008; Ragona & Mazzocchi, 2008a, 2008b, 2008c).

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