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# **Food Safety Management in a Global Environment: The Role of Risk Assessment Models**

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## Food Safety Management in a Global Environment: The Role of Risk Assessment Models

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### Abstract

Quantitative risk assessment models are playing a minor role in the development of the new EU legal framework for food safety. There is a tendency of the EU institutions to apply the precautionary principle versus the predisposition of the USA institutions to rely on risk analysis. This paper provides a comparison of the role played by quantitative risk assessment models in the development of new policies on food safety in the EU and in the USA, focusing on a study case: the supply chain of shell eggs. We suggest that EU regulatory bodies should reconsider the role that quantitative risk assessment models have to play in order to design more effective food safety management systems.

**Keywords:** *Food safety policy, food safety assurance, risk analysis, risk assessment, precautionary principle*

### Introduction

On the 28th of January 2002, the European Parliament and the Council adopted Regulation (EC) 178 / 2002. In this regulation, the General Principles of Food Law are laid down. In its Article 6(1), the Regulation establishes that “*food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.*” Risk analysis is a process consisting of three interconnected components: risk assessment, risk management and risk communication. Risk assessment can be defined as the scientific evaluation of known or potential adverse health effects which result from human exposure to food borne hazards (Luning et al., 2002). The major objective of risk assessment is to provide an estimate of the probability of a hazard occurring in a given population. On the other hand, the integration of economic models in risk assessment models can provide support to optimize the cost-effectiveness of risk management decisions (Velthuis and Hogeveen, 2004). Cost-effectiveness

is not mentioned in Article 6 of the General Food Law. In its place, Article 6(3) establishes that risk management has to take into account “*the precautionary principle where the conditions laid down in Article 7(1) are relevant,...*”.

Commission Communication on the Precautionary Principle (COM (2000) 1 final, 2 February 2000) establishes a number of considerations and limitations for its application. In its point 5.1.2, this document states that “*An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle... However it is not possible in all cases to complete a comprehensive assessment of risk, but all effort should be made to evaluate the available scientific information.*” From the reading of this document, it could be inferred that the worries on the ability of the precautionary principle to undermine the risk analysis approach proposed by the General Food Law are unfounded. But taking into account all the intervention measures based on this principle that have been adopted in recent years without carrying out previously a comprehensive assessment of risk, it can be suggested that these worries (Morris, 2002; Sperber, 2005) have an actual basis.

It is important to be aware that the whole body of EU food safety law can be seen as sanitary measures in the sense of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Only if requirements of EU food law are in conformity with Codex Alimentarius standards, the SPS Agreement does not require any scientific proof of their necessity. However, if Codex standards do not apply or the measures are stricter than the applicable international standards, in the case of being contested under SPS Agreement as barriers to international trade, EU authorities should prove that the measures are science-based, that is, based on an assessment of risk (van der Meulen and van der Velde, 2006).

In the USA, quantitative risk assessment models are playing an important role in the development of food safety policies. As it is going to be shown below, the Egg Safety Action Plan is a good illustration of the role played by risk assessment models in the development of food safety regulations. It can be concluded that there is a predisposition of the USA regulatory agencies to rely on risk analysis or what is sometimes described as the familiarity principle (Busch, 2002). However, it could be considered that USA is applying the precautionary principle in some cases, such as the USA position on EU unpasteurized cheese (Busch, 2002). Anyway, the tendency of USA institutions to carry out risk assessments before taking risk management decisions have clear advantages in order to fulfill the SPS Agreement provisions.

### **The New Legal Framework for Food safety Management in the European Union**

A first major change in the EU food safety legal framework was the Council Directive 93 / 43 / EC on Food Hygiene. This directive required all companies in the food sector, except those in the primary sector, the implementation of a Hazard Analysis and Critical Control Points (HACCP) system. Before this directive was published, a number of EU member states had begun to develop HACCP or HACCP-like legislation independently of the EU (e.g. the Dutch Quality and Hygiene Assurance Plan) which eventually could become technical barriers to the trade of foodstuffs within the EU (Ropkins and Beck, 2000). At the same time, the EU was implementing the 300 legislative measures proposed in the White Paper “Completing the

Internal Market” (COM(85) 310, 28-29 June 1985) in order to have a real common market with no internal borders. The proposed schedule established that the objective of the internal market had to be achieved by the last day of 1992. In this context, the European Commission decided to develop a systematic approach to HACCP for adoption throughout the EU. First, three ‘vertical’ directives were developed for specific foodstuffs (DIR 91/493/EC for fishery products, DIR 92/5/EC for meat and meat-based products, and DIR 92/46/EC for milk and dairy-products). Finally, it was decided to develop a ‘horizontal’ directive (DIR 93/43/EC) that was intended as a framework for the standardization of EU member state's food hygiene legislation. Because this directive did not contemplate the development of common official guidelines for implementing HACCP systems or common official criteria to evaluate the degree of compliance in individual food companies, adoption of these directives by EU member states has varied widely (Ropkins and Beck, 2000). Under the EU directive, individual food companies were responsible for developing, implementing and maintaining their own HACCP procedures. The lack of specific details (e.g., monitoring criteria, regulatory limits or defined procedures) in the directive supposed that individual food companies could each interpret the compliance with the directive in significantly different ways. Similar harmonization problems were faced by the state member authorities responsible for inspecting and controlling the implementation of effective HACCP systems in individual food companies.

The new EU regulations on food safety have extended the legal requirement of implementing an HACCP system or some food safety management system, like Good Hygienic Practices (GHP) in the case of operators in the primary production sector, to the entire food chain (Table 1). Only in Regulation (EC) 852 / 2004, the development of official national and community guidelines has been explicitly contemplated by the legislator. An overview of Table 1 suggests that the implementation of food safety management systems in all stages of the food chain will allow a thorough application of the farm-to-table strategy adopted by the EU. However, many intervention measures are being implemented without considering not only their estimated costs (Velthuis and Hogeveen, 2004) but also some estimate of their effectiveness based on the output of some risk assessment model. This could limit the EU institutional ability to implement consistently a farm-to-table approach for food safety management. Food safety risk assessments that include the whole food supply, from feed manufacturers to consumers, could allow food safety managers to identify most effective points along the supply chain for intervention strategies (Velthuis and Hogeveen, 2004).

### **Mandatory Implementation of HACCP Systems in the United States of America**

In the USA, the US Food and Drug Administration (FDA) introduced the use of Hazard Analysis Critical Control Point (HACCP)-based inspection systems when setting up their low-acid food canning regulations in the 1970s (Kvenberg et al., 2000). In 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) set up the distinct differences between the roles of industry and government regulatory authorities in the implementation of the HACCP concept for food safety management (Kvenberg et al., 2000). According to this document, the main responsibilities of government regulatory authorities were: (1) mandating regulatory requirements for HACCP implementation; (2) verifying that HACCP plans were working in conformity with the mandated General Principles and

Guidelines; (3) setting up mandated critical limits when necessary; (4) establishing criteria, methods, and sampling plans when necessary; and (5) verifying that the HACCP plans of individual production plants were adequate for assuring food safety. An additional activity of government regulatory authorities was the use of epidemiological and scientific data to identify hazards and carry out risk assessments in order to provide information which could be used to improve HACCP plans (Kvenberg et al., 2000).

Following these recommendations, the FDA and the USDA's Food Safety and Inspection Service (FSIS) have issued regulations that made HACCP mandatory for three different food processing segments: fish and seafood products (FDA regulation issued in 1995), meat and poultry processing plants (FSIS regulation published in 1998), and juice processing and packaging plants (FDA regulation released in 2001). In other food processing segments, another food safety approach adopted by USA competent authorities is making mandatory Prerequisite Programs that include Good Manufacturing Practices (GMPs), raw material control programs, vendor certifications, sanitary standard operating procedures (SSOPs), and recall and traceback procedures (Goodrich et al., 2005).

From a review of the official site information available in the web, it is possible to deduce that some key differences between the mandatory HACCP programs implemented in the USA and the EU regulations on mandatory HACCP implementation are: (1) the USA regulatory authorities develop official guidelines which include mandated Prerequisite Programs as well as mandated critical limits, criteria, methods, and sampling plans if they are considered necessary; (2) the inspection staff of these regulatory agencies receives a common training on auditing procedures to verify that the HACCP plans of individual production plants are adequate for assuring food safety; (3) usually the experience acquired with the HACCP implementation in large companies is used to provide extensive official technical assistance to smaller companies; (4) effectiveness of the mandatory HACCP programs is continuously reviewed and evaluated; and (5) risk assessment models play a major role in providing information that can be used to improve HACCP plans and to identify further research needs.

### **A Case Study: The Supply Chain of Shell Eggs**

Intake of shell eggs or egg products contaminated by *Salmonella* is considered the most important hazard in this food supply chain. The EU legal requirements for the implementation of food safety management systems were summarized in Table 1 (GHP, HACCP, and traceability). Sector associations, industry councils, or product boards are playing an important role in the development of guidelines to facilitate food chain operators the implementation of HACCP systems or the adaptation to GHP requirements. Some specific schemes for egg safety assurance have been developed. In the Netherlands, the IKB integrated chain control system for eggs and the GMP+ system for animal feed jointly provide a food safety assurance scheme covering all steps in the production chain (Luning et al., 2002). The British Egg Industry Council developed the Lion Quality mark, a food safety assurance scheme with Code of Practice that includes compulsory vaccination against *Salmonella* Enteritidis (SE) of all pullets destined for Lion egg-producing flocks (British Egg Information Service, 2004).

**Table 1.** Mandatory implementation of systems for food safety management and control in the European Union

SECTOR	LEGAL REQUIREMENT	LEGISLATION
<b>Animal Feeding</b>	HACCP System (1/01/2006)	Regulation (EC) 183 / 2005
<b>Primary Production</b>	Good Hygienic Practices (1/01/2006)	Regulation (EC) 852 / 2004
<b>Industry</b>	HACCP System (1/02/1996)	Directive 93 / 43 / EC
<b>Distribution</b>	HACCP System (1/02/1996)	Directive 93 / 43 / EC
<b>All Food Chain Operators</b>	Traceability (1/01/2005)	Regulation (EC) 178 / 2002

Consumer risk perception of microbiological risks is a key issue in the case of shell egg production. Verbeke et al. (2006) have analyzed why consumers perception on food safety often differs from scientific facts or expert views. These authors refer to the concept of a so-called perception filter to explain the bias between food safety facts and consumer perception of these facts. This perception biases are difficult to change by using risk communication (Verbeke et al., 2006). In any case, effective management of food safety in food supply chains requires objective information on actual risks. Risk assessment models for *Salmonella* in shell eggs and egg products have been recently developed (WHO / FAO, 2002; USDA / FSIS, 2004). These models can contribute to establish scientific facts, uncertainties, and further research needs. The availability of objective scientific information is especially important in the case of consumers' product liability claims. Currently, classification and packaging equipments stamp a code identifying the egg production facility in each individual egg. This information can be used for backward traceability purposes. Likewise, it can be used for consumers' product liability claims against individual producers of eggs. In this food supply chain, the primary sector could face increasing financial risks due to the costs of food safety insurance premiums, liability claims, and regulatory authorities' sanctions. This is a completely new scenario for the EU shell egg producers.

In the US, the USDA's FSIS is the regulatory agency responsible of ensuring food safety in the production of shell eggs and egg products. In 1996, FSIS, in collaboration with the FDA, initiated a risk assessment for SE in eggs and egg products. Results of the assessment indicated multiple interventions along the farm-to-table chain were necessary to reduce significantly the risk of illnesses from SE. The results of this risk assessment served as a basis for a comprehensive and coordinated Federal and State action plan to address shell egg and egg product safety. In 1999, The President's Council on Food Safety presented "The Egg Safety Action Plan" that identified the systems and practices that must be implemented to reduce and, ultimately, eliminate eggs as a source of human SE illnesses (The President's Council on Food Safety, 1999). The Plan offered industry the flexibility to choose from two equivalent SE reduction strategies, each delivering eggs into distribution and to the consumer at an equivalent

level of safety. The strategy selection by egg producers and packer/processors will determine the point at which the pathogen reduction steps are taken:

- Strategy I: SE testing-egg diversion system on farm
- Strategy II: Lethal treatment, or "kill step" at packer/processor

The requirement of implementing an HACCP system with a "kill" step was only contemplated for the packaging centers that chose Strategy II. For the ones choosing Strategy I, a Prerequisite Program was required.

In 2004, the FSIS completed a new risk assessment for SE in eggs and egg products (FSIS, 2004). The results of this risk assessment were used to develop a new regulation issued by the FDA in 2004 (FDA, 2004). This new regulation aimed at improving the safety of shell eggs produced on the egg production farms following Strategy I under the Egg Safety Action Plan. The regulation included the following SE prevention measures:

- Cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for SE
- Refrigerated storage of eggs at the farm
- Producer testing of the environment for SE in poultry houses. If the environmental test is positive, FDA proposed that egg testing for SE be undertaken, and that, if the test is positive, the eggs be diverted from the table egg market

The expected annual cost of this new regulation was estimated in \$82 million. The actual cost would vary with the number of poultry houses and layers under production and was estimated to range from a low of 19 cents per layer to \$1.00 per layer per year. The benefits were estimated from an expected reduction of 33,450 illnesses due to SE annually. This figure was obtained by using the new risk assessment model. The cost per illness due to SE was estimated in \$2,450 per illness prevented. According to these estimates, the proposed regulation would provide expected total annual benefits of \$580 million resulting in \$498 million in net benefits annually. Despite the level of uncertainty of these estimates, cost-benefit analysis contributes to a better understanding of the potential socioeconomic impact of regulatory initiatives.

Table 2 summarizes the strengths and weaknesses of the food safety approach adopted in the EU for the specific case of the shell egg supply chain. These strengths and weaknesses are qualitatively related to their potential impact on actual risks and perceived risks for the major stakeholders in the food supply chain. A major component of business risk would be the financial risk due to the likelihood of external failure costs due to food safety insurance premiums, liability claims, regulatory authorities' sanctions and loss of customers in case of involvement in a foodborne illness outbreak. With the technologies currently available for *Salmonella* contamination prevention, the risk of *Salmonella* can be minimized but not eliminated. In the case of egg producers and packaging centers, other component of business risk is the decreased net benefit by egg as a consequence of the prevention costs required to fulfill food safety requirements of legal authorities and retailers.



**Table 2.** Qualitative relationships between SWOT analysis components and risks of major stakeholders in the supply chain of shell eggs

SWOT ANALYSIS COMPONENTS	EGG PRODUCERS / PACKAGING CENTERS	RETAILERS	CONSUMERS	
	Decrease business risk?	Decrease business risk?	Decrease food safety actual risk?	Decrease food safety perceived risk?
<b>STRENGTHS</b>				
Farm-to-table approach	-	++	++	+
Food chain operators' primary responsibility for ensuring compliance with food law	--	+	+	0
Traceability and rapid alert systems	---	++	++	+
<b>WEAKNEASSESS</b>				
Effectiveness of HACCP systems implemented by individual businesses can vary widely	--	-	-	0
EU competent authorities can apply quite different criteria to verify the ability of HACCP plans of individual plants to ensure food safety	--	--	-	0
Overuse of the Precautionary Principle without previous risk assessment and cost-effectiveness analyses	--	-	+	+

This qualitative analysis is intended as a framework for discussion between industry experts and researchers. Although it requires empirical validation, it can be used as a qualitative tool to design more effective strategies for food safety management. This first analysis suggests that risk assessment models can contribute to the development of more effective GHP and HACCP practices for decreasing the actual risks that consumers are facing when consuming eggs. For these initiatives, a minor impact in the risk perceived by consumers is expected. But continuous monitoring of the expected decrease in foodborne outbreaks is the best way of demonstrating the ability of a food safety management approach to decrease foodborne risks.

## Conclusions

Both the discussion and the qualitative analysis carried out above suggest that EU regulatory bodies should reconsider the role that quantitative risk assessment models have to play in order to design more effective food safety management systems. International collaboration is needed to carry out comprehensive risk assessments. The Codex Alimentarius is an excellent forum to launch joint international projects on the development of quantitative risk assessment models. A greater involvement of the European Food Safety Authority in developing risk assessment models could also contribute to improve the effectiveness and the efficiency of EU food safety policies. Quantitative risk assessment models could be used by the European Food Safety Authority for defining the levels of uncertainty that would require the application of the Precautionary Principle.

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