How to Measure Food Safety? A Review of Relevant Literature

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Abstract

Approaches for prospective estimation of economic consequences until the last stage of the agri-food chain can rarely be found. Hence, we see the necessity of working out a conceptual assessment model for cost-benefit evaluation of food safety measures along the supply chain. Based on the findings of a thorough literature study a preliminary conceptual framework was developed. The purpose of the framework is to combine most relevant aspects of agri-food production, quality management, risk-analysis and regulatory impact assessment that have to be considered during in the course of an economic assessment of food safety.

Keywords: *Literature review, conceptual framework, food-safety, quality management, public-private, dairy production, bioterrorism, preventive measures, regulatory impact assessment, economic assessment*.

1 Introduction

A number of food-related crises and scandals in recent years raised the awareness of agri-food companies and supply chains to improve product safety. A food scandal over melamine poisoned milk in China in 2008 made it clear that, due to global trade, hazards can be easily spread to other food chains within the same country, and even to other countries (Chan et al. 2008; Ingelfinger 2008; Okazaki et al. 2009). The foodborne outbreak of enterohemorrhagic Escherichia coli (EHEC) in Germany in 2011, causing 53 dead and 3842 diseased people (Appel et al. 2011), demonstrated the seriousness of the consequences not only for the health of consumers, but also for the economy of the affected industries and countries. According to media reports, German farmers association and German hospitals association expect tens of millions of Euros deficit for their members due to the EHEC crisis. The occurrence of dioxin contaminations in feed and food in 2010 in Germany might be regarded as a textbook example for food scandals and the influence of risk perception and risk communication. Although no acute health risk was measurable, public concern and debate were overwhelming, leading to huge short term economic effects (Belaya and Hansen 2011). So the questions arise 'How much safety do we really need and what will it cost?' and 'What methodological approaches for economic assessment of food safety improvement exist and how can they be combined?' Answers to these questions would allow professionals and policy makers in the field of food safety to make optimal decisions for our society. When investigating other similar events it is noticeable that economic assessments of these scandals and crises are mostly ex-post analyses at a single stage of the food chain. Approaches for a prospective estimation of economic consequences until the last stage of the chain can rarely be found. Hence, we see the necessity of working out a conceptual assessment model for cost-benefit evaluation of food safety measures along the supply chain. Therefore, our study has the following research aims: (1) to review the relevant literature about existing methodological approaches for economic assessment of the effectiveness of food safety measures and innovations; (2) to develop a list of possible preventive food safety measures in dairy and beef production chains taking into account their assumed effectiveness; (3) to work out a conceptual framework for economic assessment of the effectiveness of preventive measures for food safety improvement. Our research is done within the scenario of a malicious attack against food safety in the German dairy and beef sector. The next step in our research would be to conduct an empirical investigation of the German dairy and beef chains. This paper describes the current state of literature review as well as a first approach to a conceptual framework.

2 Methodology of research

Goal of this literature study was to capture the current state of knowledge about preventive food safety measures in the dairy chain and the cattle chain, as well as collecting scientific approaches for regulatory impact assessment in the field of veterinary public health. Research was performed mainly by desk research using current scientific databases (SciVerse/ScieneDirect™, ISI Web of Knowledge™, Google Scholar™). More than 500 scientific papers have been examined. The following journals turned out to be the most relevant sources for this topic: *Food Control*, *International Journal of Food Microbiology*, *Preventive Veterinary Medicine*, *Trends in Food Science & Technology*, *Journal of Dairy Science*, *Food and Chemical Toxicology*, and *Livestock Production Science*. Research was done in close collaboration of one university and two German federal research institutes bringing together interdisciplinary knowledge from the field of economics, nutrition and food science, agricultural science, veterinary science and quality management research.

3 Food safety as a system innovation: context of the research

Looking at food safety development as a continuous process of engagement may prove to be a very promising perspective for realizing innovation. According to Bruns (2011) innovations can be classified according to their type (process, product, and organization), their scope (company level vs. global market level) and their degree (incremental vs. radical). The operational approach for industry to deal with food safety challenges is given by the three licenses indicated by Casimir and Dutilh (2003): the license to produce, the license to sell and the license to operate. Complying with the three licenses is crucial for agri-food industry to survive. Attention has primarily been given to the license to sell by delivering safe quality products at a competitive price on global markets. In the next paragraphs we discuss the characteristics of the utilities of food safety innovations and come up with several ideas on how improvement strategies should be approached.

3.1 Food safety stimulated by veterinary public health innovation

Most hazards from food of animal origin are of microbiological, chemical or physical nature (Knura et al. 2006) and are the consequences of different forms of contamination, i.e. primary contamination, secondary contamination, translocation, cross contamination (Kleer 2007). Contamination might occur at every stage of the food production chain (from stable to table) and governmental and legislative bodies (e.g. European Commission, EFSA), international organizations (esp. FAO, WHO, OIE and CAC) and organizations of private agri-food producers and retailers (like BRC, IFS, GlobalGAP) have adopted the idea of food safety assurance along the farm-to-fork continuum: "Food safety and quality are best assured by an integrated, multidisciplinary approach, considering the whole of the food chain" (OIE 2011a). In spite of the fact that food in developed countries can basically be considered safe and their people live in quite healthy societies, there are several reasons why food safety is still a growing issue (Fehlhaber 2007; Blaha 1999; Stringer 2005). Some of these issues (e.g. animal welfare, antibiotic resistance, drug residues) can solely be solved at the primary production stage, i.e. at farm level, attaching importance to instruments and measures of pre-harvest food safety (Blaha 1999). But for some hazards (e.g. *Listeria monocytogenes*, *Campylobacter jejuni*) there is scientific evidence that they cannot be controlled at farm level alone (Adam et al. 2010).

During the last decade food safety research and governance came to realize that a new strategy of collaboration between public health sector and animal health sector is needed as well as a partnership from public and private actors in the agri-food chain. Public authorities, private industries and organizations and universities in the fields of animal health and public health should collaborate regarding regulations and guidelines, scientific methods and research programs, surveillance systems and data exchange (Hueston 2003; Stärk et al. 2006; FAO 2008; Kahn et al. 2009; Tanner et al. 2009; Salman 2009; Wichmann-Schauer et al. 2009; Conraths et al. 2011). This common approach to combat food borne hazards is summed up under the terms "Veterinary Public Health" or "One Health concept". A well known example for veterinary public health is the appreciation of the slaughterhouse as key point of zoonoses surveillance (Codex Alimentarius Commission 2005) with meat inspection having dual responsibility for animal heath (upstream in the food chain) and public health (downstream in the food chain) (OIE 2011a). Since 2002 the World Organisation for Animal Health (OIE) has a mandate to work in collaboration with the Codex Alimentarius Commission (CAC) and other international organizations (OIE 2011c).

Another important development is the growing share of private voluntary standards in food safety regulation and verification of compliance within the last 15 years (Henson for CAC 2009), which was propelled by the introduction of the European General Food Law. Garcia Martinez et al. (2007) use the term "co-regulation" to describe this private-public approach. In some industries the influence of private standards has reached levels that raise questions about legitimacy (Fuchs et al. 2011). Based on that changed pattern of responsibility new forms of collaboration (so-called public-private partnerships) evolve which can act as joint efforts to cope with a steadily increasing food safety level (Figure 1).

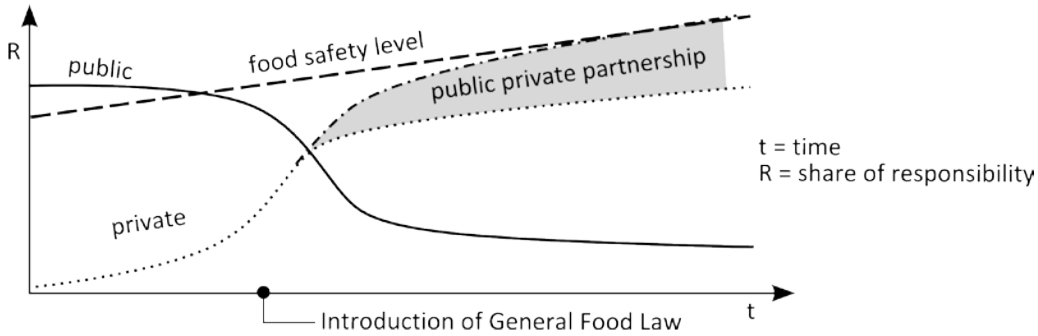

Figure 1. Dynamics in responsibility and opportunity for public private partnerships

3.2 Food safety stimulated by quality management innovation

Private systems of food quality control were established by many food companies due to the need to additionally increase the safety of food in order to meet consumers' demands. According to van der Wiele et al. (1997), quality control systems have evolved from simple inspection activities (e.g. sorting, grading, corrective actions, identification of sources of non-conformance) to the highest level of Total Quality Management (TQM) involving such activities as policy deployment, involvement of suppliers and customers, process management, performance measurement, employee involvement, etc. Food safety is inseparably linked to food quality and food safety is recognized as the main criterion and the main driving force of food quality efforts (Knura et al. 2006; Luning et al. 2006a). Other intrinsic and extrinsic attributes of food quality (Knura et al. 2006) are shelf life requirements, organoleptic characteristics, functional properties, nutrient content, convenience and reliability, environmental aspects, sustainability issues, geographical issues such as controlled appellations, and religious issues such as halal and kosher (Luning et al. 2002; Burlingame et al. 2007). In that respect, there is the justifiable call that food quality should no longer be associated with the product alone but should be extended to the production process itself (Noordhuizen et al. 2005) and that food safety programs have to be integrated into Quality Management Systems (QMS) (Knura et al. 2006). QMS and, as part of it, quality assurance systems and food safety management systems (FSMS) were set up to contribute to food safety along the food chain (Caswell et al. 1998; Petersen 2003; Luning et al. 2006b). The shift from third-party inspection towards control-of-control and certification requires that QMS prove their effectiveness (Manning et al. 2004) and some approaches have been developed (van der Spiegel et al. 2003; Luning et al. 2006b; Luning et al. 2008; Jacxsens et al. 2009; Jacxsens et al. 2011; Luning et al. 2011a; Luning et al. 2011b; Sampers et al. 2012). Nowadays, quality management in agri-food chains becomes more and more embedded into Supply Chain Management (SCM) (e.g. van der Vorst et al. 2007). Brinkmann et al. (2011) stresses the need for supply chain coordination and proposed a model for coordination of quality management systems in food supply chains. This example describes an organizational system innovation including food safety and mobilizing consumer demands (Figure 2).

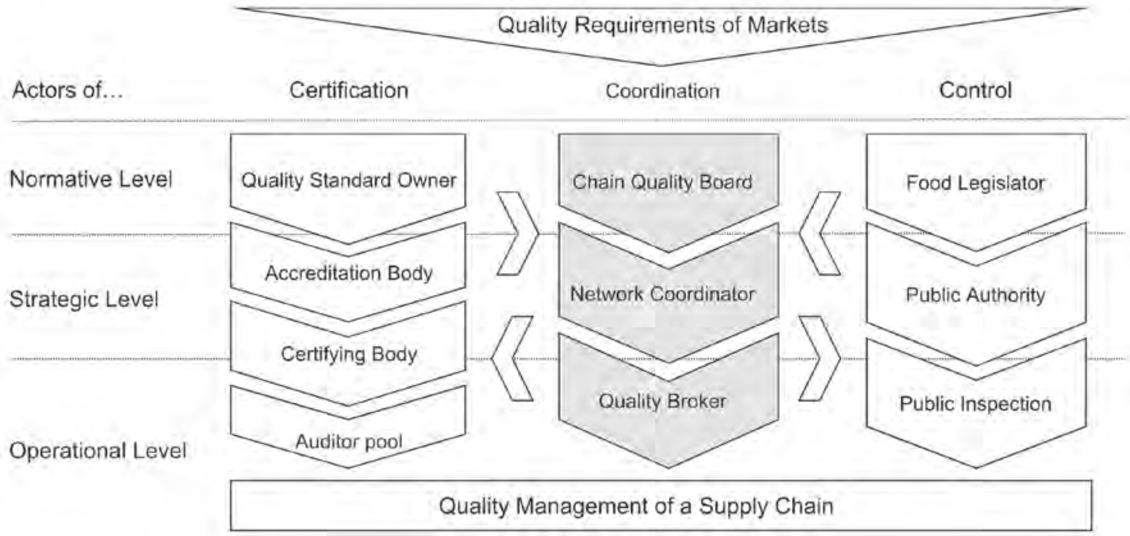

Figure 2. Chain coordination model to encourage quality management strategies (Source: Brinkmann et al. 2011, with minor modifications)

3.3 Instruments of food safety management

A number of different concepts for quality control exist, the most established in the context of food quality and food safety being good manufacturing practice (GMP), ISO–Systems and Hazard Analysis Critical Control Points (HACCP) (Noordhuizen et al. 2005; Knura et al. 2006). Also methods like Failure Mode and Effects Analysis (FMEA) were successfully applied to food safety and animal health (Welz 1994; Schumacher 2003; Schmitz 2006; Gödderz et al. 2006). All these concepts are intended to control food safety and have in common that they are build upon basic hygiene practice and that they encompass preventive measures and intervention measures. This is especially true for HACCP which is sometimes erroneously presented as a standalone preventive tool per se. Instead, compliance with basic hygiene requirements (Untermann 1999), existence of an established hygiene concept (Heeschen 2007), availability of effective controlling and reliable monitoring (Untermann 1998) are preconditions before HACCP can be implemented in an establishment. Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and sanitation standard operational procedures, which some authors also count among these prerequisites (Sperber 2005, Sampers et al. 2012), can be regarded as evolutionary precursors of HACCP and further towards approaches using food safety risk analysis (OIE 2011a).

HACCP has been successfully transferred from its origin in the processing stage to primary production (Horchner et al. 2006; Noordhuizen et al. 2008; Beekhuis-Gibbon et al. 2011a; Beekhuis-Gibbon et al. 2011b; Vilar et al. 2012) and feed production (Johan 2003; Binter et al. 2011). Noordhuizen et al. (2005) even claimed that “food safety, public health, animal health and animal welfare should be integrated into one HACCP-based program”. However, some authors criticize the efforts for “HACCP at farm level”, because hazard are not clearly defined (Sofos 2008), because most hazards are usually controlled at a later stage in the food chain (Horchner et al. 2006; Heggum 2001), because the farmer lacks resources and expertise to design and operate a HACCP program (Heggum 2001) and because of a lack of GAP/GHP preconditions (Raspor 2008).

3.4 Preventive approaches for food safety improvement

Crises and scandals in the agri-food chain are attributed to four different causes: animal diseases, operational misbehavior, natural disasters and malicious attacks. These causes can be further categorized according to what kind of processes are the main areas for prevention: natural and biological processes, technical and managerial processes, decision and communication processes (Petersen 2011). In order to prevent foodborne disease outbreaks or at least to reduce the harmfulness of possible consequences of such an outbreak, ex-ante regulation or prevention is indispensable.

For the further understanding it is necessary to make a distinction between the terms *prevention* and *control*, as these terms are used and interpreted quite freely in literature. *Control* as the overall term means "prevention, elimination, or reduction of hazards and/or minimization of risks" (Codex Alimentarius Commission 1999). Other authors treat prevention and control as equitable parts of an overall triad "prevention, monitoring and control" (Longworth et al. 2007) and "prevention, intervention and monitoring" (Luning et al. 2008), respectively. In some (minor scientific) contexts *prevention* and *control* are simply used as a contrastive pair of terms to accentuate a paradigm change from traditional end-control checks towards more modern anticipatory concepts (e.g. Burlingame et al. 2007) or the term preventive is simply used for everything that seems to be conducive to food safety regardless how indirect it might be. The term *preventive measures* implies the existence of practically executable measures (e.g. washing hands) performed by a natural person (e.g. dairy farmer) but some measures are quite long term in nature and the effect is not related to action (e.g. installing fences). It must kept in mind that most measures consist of a structural and an organizational part that differ greatly regarding risk reduction, costs, responsibility, verifiability, reliability (e.g. hygiene locks consist of physical equipment plus the compliance to standard operating procedures; access control consists of gates plus the strictness of security personnel). Some measures are purely technological procedures (e.g. pasteurization) while others are sole managerial tasks (e.g. selection of animal for slaughter). Although Luning et al. (2006a) described food quality as a function of the food behavior and human behavior, managerial aspects like mindset, awareness or responsibility that influence prevention only indirectly are basically not covered by the term *preventive measures*.

The attribute *preventive* can be looked upon from different point of views (a temporal view, an epidemiological point of view, the human medicine view, and the competence view). From a *temporal* point of view measures are considered preventive if they happen before the detection of the introduction. This point of view bases on the perception that intervention is not possible until the pathogen is known. That implies that measures which are preventive in nature (e.g. trade restrictions, i.e. reducing a risk factor) belong to the group of intervention measures if they were applied after detection (e.g. in case of a disease outbreak). Main objective of epidemiology is to identify causal relationships between risk factors and outcomes of such as disease or reduced performance (Pfeiffer 2010). From an *epidemiological* point of view measures are considered preventive if they are able to reduce the effect of a known risk factor or to avoid or to eliminate that risk factor. Regarding the temporal aspect of a disease outbreak, even those measures that are applied after detection of disease are named preventive measures. Only those measures that focus on reducing the spread of disease to further epidemiological units are regarded as intervention measures (e.g. culling of animals, Vos et al. 2003). As the concept of Veterinary Public Health involves people, methods and knowledge from human medicine and veterinary medicine this also has consequences for the vocabulary used in that context. *Human medicine* traditionally speaks of primary, secondary, tertiary and quaternary prevention (Hurrelmann et al. 2010). This terminology bases on a different health perception between patient and doctor. Only primary prevention has the goal to prevent infection at all. Secondary prevention focuses on early detection, tertiary prevention covers rehabilitative medicine and quaternary prevention shall avoid unnecessary treatments. A tabular overview shall give an impression of the spectrum of possible measures that we found in dairy and cattle literature and that were referred to as *preventive measures* (Appendix 1). A lot of these measures at farm level belong to On-Farm-Biosecurity and basic animal hygiene. Internal On-Farm-Biosecurity measures are directed against spread within an establishment while external measures shall prevent introduction to and transmission between establishments (Wells 2000; USDA 2001; Food and Agriculture Organization et al. 2010). FAO assigns these measures to three categories “Segregation”, “Cleaning” and “Disinfection” (Food and Agriculture Organization et al. 2010).

Preventive measures have in common that they require a lot more prior information compared to intervention methods. Petersen and co-authors stressed this fact and stated that a shift towards prevention must be supported by establishing chain wide information- and communication systems that integrate private and public systems (Petersen et. al. 2002). Schulze Althoff (2006) elaborated a guideline to introduce cross company information systems and characterized potential users according to “ambition levels”. Conraths et al. (2011) add to this that modern information technology offering world wide data exchange at real time should enable the application of preventive measures as an immediate response to emerging threats.

3.5 Costs of preventive approaches

Ex-ante regulation of food safety involves public and private systems of food quality control (Henson and Caswell 1999). Public systems are based on the requirements of the state and represent the budgetary level of preventive measures of food safety improvement (Figure 3).

	Primary production stage, farm level	Processing stage, retail and food service level	Consumer level
Natural and biological processes	Hygienic feed production and storage, cleaning and disinfection of stables, On-Farm-Biosecurity, vaccination of animals	Good Hygienic Practice, personal hygiene, cleaning and disinfection, sanitation programs	Kitchen hygiene practices (hand washing, cleaning of working surfaces, change of knives, sufficient heating and re-heating)
Technical and managerial processes	On-Farm-Biosecurity, , proper housing conditions, manure management	Pasteurization, Cold Chain Management, HACCP, Food Safety Management System,	Cool and dry storage, refrigeration, transport and cool chain
Decision and communication processes	Visitor control, waiting periods	Training of personnel, traceability exercises, supplier evaluation	Awareness and knowledge about food borne health risks

Budgetary level

Periodic inspections of food-producing farms, food processing facilities and food service establishments on the subject of safety, wholesomeness, and proper labelling, special state programs in improve food safety, etc.

Figure 3. Overview of preventive measures of food safety improvement along the supply chain

The described measures usually require more or less expensive financial investments such as long lasting capital investments (e.g. hygienic design of a slaughterhouse) or short-term investments (e.g. disinfection materials) (Mangen et al. 2005). Regarding the assurance of a desired level of food safety this costs can be regarded as quality cost. Traditionally, quality costs are categorized as the failure-related costs, appraisal costs (or inspection costs) and fault-prevention costs (Campanella 1999). Another perspective is the distinction between conformity-costs and non-conformity costs (Pfeifer 2002). Generally, prevention costs are costs associated with activities preventing poor food quality. Examples of such costs include new product review, quality planning, supplier capability surveys, process capability evaluations, quality improvement team meetings, quality improvement projects, quality education and training. Appraisal costs occur when the product has already been produced in order to guarantee food safety before the product reaches the purchaser. These costs include, for example, inspection and testing, laboratory analyses, audits, calibration of measuring and purchase of test equipment. Therefore, food business operators and policy makers face a trade-off: Shall they decide to invest into prevention measures reducing the risks of an food borne health issue to an level that is acceptable for themselves and for the society or to live with the consequences in case the investments into the preventive activities were not sufficient (Abelson et al. 2006).

4 Theoretical framework for the assessment of preventive approaches

When talking about methodological approaches for assessment of the effectiveness of preventive measures for food safety improvement one should differentiate between risk assessment and regulatory impact assessment. This issue involves the time perspective of condu

cting the economic assessment – ex-ante or ex-post. Therefore, the literature on the economic assessment of food safety associated with foodborne risks can generally be divided into incidence-based and prevalence-based studies. The first type of assessment (ex-post or incidence-based) is done after the outbreak of a food-borne disease has occurred and involves calculating the economic losses caused by the outbreak as well as the intervention measures in order to stop or to decrease the spread of contamination. The second type of assessment is caused by the estimates of present and future costs resulting from potential diseases and measures designed to reducing food-borne risks or to increase food safety (ex-ante or prevalence-based assessment). These assessments are usually used to evaluate the cost-effectiveness of public policies designed to decrease microbial contamination of the food supply (Antle 1999) and are useful for planning and budget decisions. Ex-ante assessment usually is done by conducting cost-benefit analyses based on the preliminary assessment of the situation.

The benefits of food safety regulation measures are designed to reduce the risks of morbidity and mortality associated with consuming potentially contaminated foods. The costs of food safety regulation measures include the costs of preventive measures that are carried by the industry and by publicly financed systems. Another aspect which should be mentioned when conducting the economic assessment of food safety is the classification of costs and benefits into tangible and intangible (e.g. Sockett 1991; Henson and Trail 1993). Tangible costs are usually such types of costs which can be measured in monetary terms. The quantification of intangible costs appears in many cases to be more problematic, since there is no direct market for intangible goods. Tangible benefits are practically avoided tangible costs. The same applies for intangible benefits and costs.

4.1 Risk Assessment

Hazards that are a target of food safety control pose risks on consumer health, animal health, economy and the society in general. This risk depends mainly on the possible extent of damage and the probability of occurrence. Further criteria to classify a risk are its statistical uncertainty, spatial or geographic dispersion, temporal extension, reversibility, delay effect and its potential of public mobilization (Klinke et al. 1999, cited by Mack et al. 2006). An assessment of this risk is necessary to support the decision-making regarding governance and regulation. Risk assessment forms the (scientific) basis for every further steps of risk analysis, i.e. risk management and risk communication (Codex Alimentarius Commission 1999). CAC and EU define risk analysis as the umbrella term that incorporates subordinate tasks of risk assessment, risk management and risk communication. Risk assessment is further divided into hazard identification, exposure assessment, hazard characterization and risk characterization. This scheme has become an integral part of the EU food hygiene legislation and was propelled by World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement, WTO World Trade Organization 1995) which requires that all protective measure have to be risk based (OIE 2011a). It should be mentioned that in the field of business administration (ISO 31000 family of standards) and quality management (Pfeifer 2001) risk management is considered the broader term which consists of hazard identification, risk assessment and risk control.

The output of a risk assessment study is intended to be used as input for risk management, i.e. the selection, recommendation or the development of appropriate control measures (prevention and intervention). For the purpose of risk management the results of the risk assessment step have to be transferred into regulations, legislation and even more concrete into process definitions and operating procedures of concepts like HACCP, GHP, etc. The step from risk assessment to risk management looks obvious and small in theory but is quite large and challenging in practice. Concerning animal health issues it is possible to calculate the financial value of animals and it is permissible to safeguard one part of the animal population at the cost of another part. But this is not permissible in the case of a threat for human health because it is a societal and political task to debate the value of health and life of human beings. According to Stringer (2005) it is extremely difficult for any government body or international agency to quantify the level of risk that a society is willing to tolerate or accept or even to specify who has the ultimate responsibility and legitimacy to make such a decision. As soon as such an "Appropriate Level of Protection (ALOP)" (WTO 1995) is found for a society it can be used to derive acceptable amounts of hazards to be present at the consumer level. These so called Food Safety Objectives (FSO) (Codex Alimentarius Commission 2005) are formulated per product and hazard and can be regarded as a functional link between the overall goal formulated as ALOP and practical instruments like HACCP (Swarte et al. 2005).

4.2 Regulatory impact assessment

Evidence-based policy (EBP), a concept that originated in Great Britain in the 1990s (Shaxson 2005, Pawson 2006), demands that political decision making has to be scientifically informed as far as possible. On behalf of the German Bertelsmann Foundation Jun et al. (2008) elaborated a sound review about EBP and its possible implications for Germany. An important instrument of EBP is the Regulatory Impact Assessments (RIA), which is basically a form of cost-benefit analysis. When conducting an economic evaluation, the costs and the outcomes or consequences of alternative measures or interventions are compared with each other in order to identify the best outcome under the use of the scarce resources. The main aim of such an assessment is to compare the societal benefits and costs among different programs and prevention measures and to set priorities for applying the most efficient programs (Buzby et al. 1996). Costs that are taken into account in RIA are summed up as so-called regulatory costs. The measurement of costs and benefits can be done from different perspectives regarding time and scale (Riedel 2009): A top-down approach has a macroeconomic view on all those affected while a bottom-up approach looks upon the consequences for individuals (microeconomic). An ex-post approach calculates only for regulations that are already in force, while ex-ante approaches try to assess future regulations.

Concerning food safety regulations RIA have to consider the effectiveness of prevention and intervention measures to control the level of pathogens in food and its further consequences on human health. The economic literature which deals with assessment of the effectiveness of food safety interventions generally identifies the following four main types of economic evaluations: Cost-minimization analysis (CMA), cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and cost-utility analysis (CUA) (Schmidt 2011). According to Drummond et al. (1988) one has to consider all four of these types of assessments to be "full" economic evaluation methods.

Cost-benefit analysis (CBA) can be distinguished from other types of economic evaluations due to the use of benefits in from of monetary outcomes (Adhikari et al. 1999). Therefore, the main advantage of CBA is its suitability for determining the desirability of different food safety programmes by comparing direct outcomes expressed in monetary units. In case the objective measurement of the value of the outcomes is not possible, subjective measurements could be applied by using willingness-to-pay approach (WTP). WTP is mainly designed for estimating the benefits of public health programs (Golan and Kuchler 1999). It involves several economic evaluation techniques: *Contingent valuation* (hypothetical scenario involving the choice between different risk levels of food contamination), *conjoint analysis* (ranking of a number of product profiles consisting of several attributes), *experimental auctions* (choice between conventional products and products with improved safety, giving undivided attention to the valuation process), *hedonic pricing* approach (assumes that the final price of a product reflects the desirability of all its characteristics) and *averting expenditure* approach (uses expenditures on actions to avoid exposure to contaminated food – like thorough cooking, proper storage). According to Rodríguez et al. (2008) the term "willingness-to-pay" represents the monetary difference between consumers' surplus before and after adding or improving a given food product attribute. Since this approach represents the full value of food safety improvements based on individual consumer preferences, it is very useful when the price of a specific good is not known and estimates this price that people are willing to pay for the good. In order to conduct WTP analysis the economist has to create hypothetical markets or scenarios using different survey techniques. However, this approach also has some shortcomings. Since it is based on hypothetical estimations and opinions of various people on what they would be prepared to pay for the good (in our case improved food safety), it is considered to be inaccurate. According to Latouche et al. (1998) the possibility of biased responses due to the use of hypothetical survey techniques could be a starting point for information bias. However, since there may be some difficulties in quantifying economic benefits, other types of economic evaluations may be used instead of CBA.

Cost-minimization analysis (CMA) is used to determine the best program on the basis of comparing the costs, since in this case the outcomes or effects of alternative programs are equal. This technique has a special appeal to policy decision-makers due to its simple use. If two alternative programmes have the same outcome, only the costs need to be compared in order to identify the program with the lowest costs involved. The main difference of cost-effectiveness analysis (CEA) to CBA is the fact that it does not involve the use of monetary benefits. In this case the benefits of alternative programs are expressed as effects (e.g. lives saved, numbers of pathogens reduced, etc.). The main idea of CEA is to identify and compare the outcomes of the project with and without the specific preventive activity. However, Boardman (2001) warns that the results of CEA should be interpreted with great caution when used as a measure of efficiency.

The forth type of economic evaluation which needs to be mentioned in this respect is cost-utility analysis (CUA). This technique is very similar to CEA, but it involves more generic outcomes of the alternative programs (e.g. QALY). Since the outcomes are more generic, it helps to compare different programs with multiple objectives by applying a relative merit. In fact, due to the similarities of both types of economic evaluations, CEA is sometimes referred to as generalized CEA (Drummond et al. 2005). In practice, when comparing alternative programs with each other multiple effects of different measures can be indeed expected (e.g. quality and length of life). Therefore, since the outcomes of CUA are more designed to compare programs with multiple outcomes, this technique has more applicability.

There is a number of indicators designed to reflect the generic outcomes of regulatory impact: Years of potential life gained (YLG), Healthy years of life gained (HYLG), Health-

Adjusted Life Years (HALY), Disability adjusted life years gained (DALY), Quality adjusted life years (QALY), Years Lived with Disability (YLD), Years of Life Lost due to premature mortality (YLL), etc. Depending on the goal of the economic assessment, the different described types of economic evaluation can be applied.

5 Scenario of bioterrorism in the German dairy sector

The background of this study builds a research project about implications of potential bioterrorist attacks in German agri-food chains (SiLeBAT - Securing the Feed and Food Supply Chain in the Event of Biological and Agroterrorism Incidents). The scenario investigated starts with the deliberate contamination of bacterial pathogens in the dairy and cattle chain (Filter et al. 2011).

5.1 Prevention of bioterrorism in the food chain

Preventive measures against terrorism in general encompass campaigns against radicalization of potential terrorists, breaking up existing terrorist structures (BMI 2010), security checks, visa restrictions, law enforcement, raising public awareness and improvement of information flow between public authorities (Waldmann 2005). According to (Meltzer 2005) measures that reduce the impact of a potential bioterrorist attack or a catastrophic infectious disease event can be divided into actions that reduce the occurring of attacks (protective interventions) and actions that are planned to reduce the impact of an attack (reaction interventions). Protective measures and intervention measures can be further sub-divided by their time of execution (pre-event and post-event) (Meltzer 2005). The term *food defense* is used to sum up all kind of activities against malicious attack against the food chain (FDA 2011). *Food defense* therefore covers mainly (additional) preventive measures like pre-employment prudence, building employee inclusiveness, screening of visitors, restrict access to those with a clear business function, protecting raw materials and equipment (BSI British Standards Institution 2010). Although HACCP might be used as a first wall against intentional contamination (Rasco et al. 2005; Manning L. 2005; Sekhata et al. 2006) it remains a fact that HACCP systems are circumvented if contamination occurs after the last control point (Khan et al. 2001).

5.2 Characteristics of the German dairy sector

Germany, as the largest producer in the EU, produces 29.6 million tons of raw milk per year (MIV 2011) and dairy industries achieves a turnover of more than 22 billion EUR while employing more than 36 000 people. More than 93 000 farmers are milking 4.1 million cows two to three times per day and sell their raw milk (approx. 0.30 EUR per kg) to the dairies. About 100 cooperative and private dairies with 220 production sites process 96.8% of the raw milk (77 000 000 kg per day). Because the milking process has the biggest impact on the microbiological status of raw milk preventive measures of milking hygiene are fundamental. Dairy farmers set up On-Farm-Biosecurity measures on their farms in order to safeguard animal health (production diseases like mastitis as well highly contagious animal diseases). Most preventive measures base on common sense, sectoral guidelines and GHP. HACCP-based programs to assist farmers in enhancing their biosecurity-level and milk hygiene have been developed, but some concerns remain regarding the compliance and the attitude of dairy farmers towards such recommendations (Heffernan et al. 2008; Gunn et al. 2008; Nöremark et al. 2010; Kristensen 2011). In collaboration with the dairies a private QA system ("QM Milch") has been established that covers aspects of animal supervision, medical documentation, milking technology and milking hygiene, animal identification and registration as well as environmental issues. Dairies use the result of QM Milch audits as an instrument of supplier evaluation within their QMS. Typical problems during risk assessments in the meat or dairy chain are the lack of valid epidemiological models and relevant scientific information on public health hazards derived specifically from animals and their products (OIE 2011b). And because of the difficulty to calculate for side-effects or cumulative effects measures are often assessed separately, leading to significant under- or over-estimates (cf. Vos et al. 2005; Fasina et al. 2012).

6 Development of a conceptual framework

Based on the findings of our literature study a preliminary conceptual framework was developed. The purpose of the framework is to combine most relevant aspects of agri-food production, quality management, risk analysis and regulatory impact assessment that have to be considered during in the course of an economic assessment of food safety (Figure 4).

<table>
<tr><th colspan="7">Economic assessment of the effectiveness of preventive measures for food safety improvement</th></tr>
<tr><td rowspan="2">Uncertainty</td><td colspan="5">Agri-food chain</td><td rowspan="2">Public-Private cooperation</td></tr>
<tr><td>Farm</td><td>Livestock Trade</td><td>Processing</td><td>Retail</td><td>Consumer</td></tr>
<tr><td>Risk assessment</td><td colspan="5">Veterinary medicine, livestock production systems, epidemiological relationships, clinical trials, network analysis, human medicine, terrorism and security research</td><td>1. Animal diseases
2. Operational behavior
3. Natural disasters
4. Malicious attacks</td></tr>
<tr><td>Portfolio of available preventive measures</td><td colspan="5">specificity regarding hazards, effectiveness of risk reduction (introduction, establishment, spread), need for special skills and knowledge, integration in routine work, feasibility, compliance, verification and documentation, legal requirements, social and cultural acceptability, responsibility, sustainability</td><td>A. Nature and biology
B. Technique and management
C. Decision and communication</td></tr>
<tr><td>Regulatory impact assessment</td><td colspan="3">1. Benefits expressed in outcome/output:
a. Cost-effectiveness analysis (CEA)
Cost-utility analysis (CUA)
Cost-minimization analysis (CMA)
b. Disability adjusted life years gained (DALY)
Health-Adjusted Life Years (HALY)
Quality adjusted life years (QALY)
Years Lived with Disability (YLD)
Years of Life Lost (YLL)
Years of Life Gained (YLG)
Healthy Years of Life Gained (HYLG)</td><td colspan="2">2. Benefits expressed in money terms:
a. Assessment of costs (direct costs): Costs of improving the transparency in the supply chain, QM-systems, etc.
b. Assessment of benefits: (In)tangible benefits = avoided (in)tangible costs</td><td>Willingness-To-Pay Approach (WTP), hypothetical value assessment:
• Contingent valuation
• Conjoint analysis
• Experimental auctions
• Hedonic pricing approach
• Averting expenditure approach</td></tr>
<tr><td>Risk perception</td><td colspan="5">Integration into quality management systems</td><td>Supply chain coordination</td></tr>
</table>

Figure 4. Conceptual framework for economic assessment of the effectiveness of preventive measures for food safety improvement

This framework shall focus on the assessment of truly preventive measures. Costs which result from the spread and establishment of a foodborne hazard are not covered with that framework. The same applies to intervention measures, those that are applied after onset of the accident. Scientific uncertainty, differences in risk perception, aspects of supply chain coordination and the cooperation of public and private actors are the cornerstones of our framework, as they have to be kept in mind at all steps of an assessment. Further, the particularities of each stage of the food chain have to be considered. The step risk assessment bases on scientific facts associated with four origins of risks (1-4). The next step has the goal to characterize the portfolio of available preventive measures at each stage which can be addressed to three main areas (A-C). The final step builds the Regulatory Impact Assessment. We divided this in two alternative steps according to whether costs can be expressed in financial terms or not.

7 Concluding remarks

The main objective of our study was to review existing literature on the topic of assessing preventive food safety measures and innovations to develop the basis for a conceptual framework for conducting economic assessment of food safety. We reviewed the current state of research concerning the interplay of food safety, veterinary public health and quality management from an innovation point of view. We clarified the concept of preventive measures in order to understand what kind of measure we are talking about. And we put these preventive approaches in a context of quality management in the agri-food chain. Besides, we looked at different methodological approaches designed to conduct economic evaluations and discussed their main principles, advantages and disadvantages. The main contribution of our study is the establishment of a foundation for future research on conducting the economic assessment of food safety related to foodborne disease outbreaks. The findings of this research should be seen within the context of some limitations which could stimulate further research. We hope that both academics and professionals would be interested in further investigations of this area of research, which would increase the effectiveness of practical and theoretical implications. And we hope that our interdisciplinary approach of research will open several new avenues for further system innovation. We believe that the contributions of our study to the theory will fuel the future scientific work in this area of research.

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Appendix 1: Examples from literature for preventive measures in the dairy and beef chain (bold faced terms are those that we interpret as preventive measures)

Preventive measure	Source and context
- Risk assessment - On-farm evaluation - **Footbaths or disposable boots** - **Clean clothing** - **Control visitor access** - **Perimeter fence or other control** - **Vehicle disinfection** - **Control vehicle access** - **Vector control** - **Equipment and tool disinfection** - **Manure management or methods to prevent feed and water contamination** - Animal or lot identification numbers - Maintain health records - **Quarantine new additions or returning stock** - **Closed herd or all-in–all-out** - **Limit new additions** - Test new additions - Young stock management - **Vaccinate**	(Moore et al. 2008) Compilation from educational materials with biosecurity recommendations for dairy farms, USA
- Risk assessment - **Employee training** - **Control visitor access** - **Perimeter fence or other control** - **Locked gates and doors** - **Control vehicle access** - **Vector control** - **Manure management or methods to prevent feed and water contamination** - Maintain health records - **Limit new additions** - Encourage disease reporting	(Moore et al. 2008) Compilation from educational materials with biosecurity recommendations for cattle farms, USA
- **Washing** - **Drying** - **Foremilking** - **Predipping** - **Segregation/Cluster disinfection** - **Milking machine hygiene** - **Liner quality** - **Teat disinfection** - **Adequate working milking machine** - **Teat preparation** - **Treatment protocol** - **Hygiene** - **Shed layout** - **Stocking**	(Beekhuis-Gibbon et al. 2011b) Dairy farming, HACCP at farm-level, Ireland

- **Instituting a feed ban for animal protein supplements** - **Removal of Specified risk materials (SRM), also called Category I materials, at slaughterhouse**	(Benedictus et al. 2009) BSE-Prevention and control in the Netherlands
- **Hygienic design of equipment and facilities** - **Cooling facilities** - Sanitation programs - **Personal hygiene requirements** - Raw material control - **Product specific preventive measures**	(Sampers et al. 2012) Evaluation of performance of FSMS of dairy in Japan
- **Reduction of fecal contamination of food products** - **Excellent hygienic standards for housing and milking centers and cleanliness of cows** - **Hygienic milking practices and the effective use of predipping and forestripping** - **Market only clean and healthy cull cattle** with minimal BCS standards	(Ruegg 2003) Food Safety Interventions for Dairys, USA
- **Dry and clean bedding,** - **Stable rearing groups,** - **Empty and clean water troughs every 2–3 weeks,** - **Rodent control,** - **Closed herd (or at least closed young stock section),** - **Avoid young stock contact between herds,** - **Leave a down-time period between manure spreading on or close to grazing fields before allowing cattle to graze**	(Ellis-Iversen et al. 2008) : Prevention of VTEC O157, Campylobacter jejuni/coli and Salmonella serovars in young cattle, USA
- **Clean, chlorinated drinking water** - Adequate pen management - **Feed contamination prevention** - **Vaccines**, antibodies, bacteriophage - Antibiotics - **Clean feed bunkers** - **Feed additives** - **Competitive exclusion** - **Clean transportation** - **Hide cleaning** - **Organic acid sprays** - **Sanitizer sprays** - **Steam vacuum cleaning** - **Thermal pasteurization, steam or hot water** - **Carcass spacing in cooler**	(Sperber 2005) Interventions that could be used as food safety control measures in beef animal production and slaughter, USA