ISSN 1392-2785 ENGINEERING ECONOMICS. 2006. No 1 (46)
COMMERCE OF ENGINEERING DECISIONS

The Study of the Assumptions of Development Quality and Product's Safety Integrated System

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The main purpose of this work is to analyze the food quality regulation system and food safety assurance. This article also highlights the conditions, which must be met for an integrated quality and food safety management system to be implemented at the AB "Vilniaus Pergalė" confectionery plant. This article also examines various international systems of regulating trade and quality. It gives an analysis of the processes in place designed to normalise international standards, technical regulations and rules in the light of current global economic conditions.

With the increasing complexity of the composition and technologies associated with the production of certain food products, the cost of maintaining State inspection services has become an unacceptable financial burden. Governments have started to look for the ways to reduce the financial costs associated with food control without reducing its effectiveness. This changed the definition of inspection in the food industry by returning the responsibility for food quality control and safety to the producer and distributor. Implementing of food safety assurance system – Hazard Analysis Critical Control Points (HACCP) was started.

When comparing the current HACCP system with ISO 22000, certain new requirements can be seen, such as the creation of interactive communication systems within and outside the company, the creation of a system for the prevention of unforeseen situations, implementation of certain necessary programs, etc. The analysis showed that both standards are compatible and ISO 22000 requirements can be easily integrated with other food safety assurance subsystems. An effective communication management system must be created between the producer, suppliers, subcontractors and consumers (first concerning information about the product), government institutions overseeing the food products market or other organizations, which will affect or be affected by the results of the food safety management system.

The integrated safety and quality system is being developed and implemented at AB "Vilniaus Pergalė". This system will include an interactive communications system, procedures to prevent unforeseen events, product labeling procedures, other subsystems and other required programs, which will assure product safety and improve the overall quality at the company.

Keywords: *quality management, safety management, HACCP, ISO 9001, ISO 22000.*

Introduction

Universal international management systems (ISO 9001, ISO 14001, etc.) cannot always be effectively adapted to the management of specific businesses (Ruževičius, 2003, 2004; Ruževičius, 2005 [12 – 16]). Specialized management systems, such as QS 9000 and ISO/TS 16949 (automobile industry), TL 9000 (telecommunications); Tick IT (information technologies), CCM (computer programs), OHSAS 18000 (employee health and safety), etc. have been created to fulfill specific needs. The new ISO 22000 food-safety management systems are also included in this group of specialized management systems. ISO 22000, which includes food safety management requirements, can be applied to any part of a food safety management organizational structure. The *aim* of this work is to analyze the food quality regulation system and food safety assurance. This article also highlights the conditions, which must be met for an integrated quality and food safety management system to be implemented at the AB "Vilniaus Pergalė" confectionery plant. *Research subject* – quality and safety management systems. *Scientific problem* – integration of new products safety management system (ISO 22000 – final draft) with HACCP and quality management system (ISO 9001). This problem is not studied in scientific literature. *Methodology* – this article is prepared using scientific, methodological and normative literature together with the analysis and summary of business practice at AB "Vilniaus Pergalė".

Research results

Food safety and international agreements

With the increasing complexity of food technologies, ingredients and assortment, globalization of sales, the need arose to create the system, which on an international level would guarantee food safety and quality independent of which world region the ingredients and food are imported (Wenger, 2003; Ruževičius, 2005 [15]). The first step of this process began in 1962 when the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization of the United Nations (WHO) created the food standards organization,

called the Codex Alimentarius Commission. This is an international organization joining more than 160 nations. It prepares international standards (Codex Stan) for food products, general labeling, food additive requirements, regulations for good food hygiene practices, special limitations for impurities in food and regulations for good agricultural and veterinary practices.

The second step in this process occurred with international agreements at the World Trade Organization:

1. Agreement on Agriculture (AoA) applied the main trade rules to agriculture. The three main principles of this agreement are used to lower trade barriers, reduce national farm subsidies and to decrease export subsidies.
2. TBT – Agreement on Technical Barriers to Trade is an agreement whose purpose is to guarantee that standards and technical regulations, including package labeling and certification requirements, do not create unnecessary barriers to international trade. TBT agreements regulate barriers for the trade of food products and other products. TBT criteria include various areas from automotive safety to energy saving equipment. This agreement also includes packaging and labeling for food products (Export…, 1999; Technical…, 2003; EU…, 2004; Getting…, 2004).
3. SPS – Agreement on Sanitary and Phytosanitary Measures is an agreement that just covers food products and animal feeds, which can pose a health hazard to humans or harm plants. The SPS Agreement includes criteria, whose purpose is to safe guard the health and life of humans and animals from harmful food products; diseases which can pose a hazard to the health and life of humans borne by animals or plants; animals and plants from harmful pests and diseases (Sanitary…, 1998).

Sanitary regulations are those that protect the health of humans and plants. Phytosanitary measures are those that safeguard the health of plants from pests and disease-bearing organisms. The SPS Agreement guarantees clarity, assures that criteria applied to the assurance of the health of humans, animals and plants are accessible to all interested parties and their trading partners. This agreement requires each State, without delay, to publish all sanitary and phytosanitary regulations and on request of another State, to issue clarifications concerning the consumption of certain food products and criteria associated with the health of plants and animals.

Most of the food labeling regulations, caloric values and food quantity criteria, quality and packaging conditions are not sanitary or phytosanitary criteria, therefore they are discussed in the TBT Agreement. On the other hand, regulations related to the microbiological contamination, pesticides or the allowed amounts of veterinary medicines or food additives are discussed in the SPS Agreement. The SPS Agreement does not regulate pharmaceutical products although these products are related to the health of humans. Further, the WTO does not include tobacco as a food product; therefore the TBT Agreement and not the SPS Agreement regulates the labels and warnings placed on a package of cigarettes (Ruževičius, 2005 [15]). The legal and technical quality control system regulations for production and international trade are summarized in **figure.**

The WTO recommends member States to use international standards (ISO, IEC, Codex Stan, etc.) as often as possible in the conduct of international business or trade.

The third step of this process is the implementation of the food safety assurance system. With the increasing complexity of the composition and technologies associated with the production of certain food products, the cost of maintaining State inspection services has become an unacceptable financial burden. Governments have started to look for ways to reduce the financial costs associated with food control without reducing its effectiveness. This changed the definition of inspection in the food industry by returning the responsibility for food quality control and safety to the producer and distributor.

At present in western countries, food safety inspections are defined as those inspections, which are regulated by national and local government agencies working together with the food industry so that activities associated with food manufacturing, storage, transportation and distribution work ed as one system (Anon, 1989; Shapton, 1991; Brown, 2000; Bryan, 2002, Januškevičienė, 2003). This assures that food is suitable for human consumption and meets all safety and quality requirements. Ingredients stated by the products labels must correctly and honestly reflect the composition of the product as required by the law.

The transformation of the definition of food quality control has required food product manufacturers and distributors to take additional responsibility for their manufactured products by implementing strict procedures assuring product safety and quality. In other words, a new food safety and quality assurance system is being developed to prevent food products not suitable for consumption from reaching the market. The survey of companies confirmed that new quality system models stimulate companies to study and implement total quality management (Anand, 1997; Watson, 1995; Anand, 1997; Wenger, 1999; Walsh, 2002; Ruževičius, 2004).

Once this system is implemented, government agencies activities will concentrate on auditing such systems, rather than the quality assurance of the individual products. Currently, to assure food safety, the most widely used system of risk analysis and control is the HACCP system. EU directive 93/43/EEC defines how this system is implemented in the EU, while in the Republic of Lithuania the HN 15:2001. In 1997, AB "Kraft Foods" was the first company in the Republic of Lithuania to implement this food safety and quality assurance system. Seeking to export their products directly to the EU, major milk processors such as AB "Rokiškio sūris", UAB "Pasvalio sūrinė", AB "Panevėžio pienas", AB "Žemaitijos pienas", UAB "Vilkyškių pieninė", AB "Pieno žvaigdės", and other milk processors implemented this system. Production of a safe, quality product helped these companies to markedly expand their export markets. In 2003 UAB "Vilkyškių pieninė" exported approximately 70% of its production to the EU, which is approximately 45% of the cheese export quota to the EU (Slatkevičiene et al., 2005).

Figure. International regulations of quality:

1. **Standards** (ISO, IEC, Codex Stan, IDF, EN, ETS, LST, DIN, BS, NF, UNI, GOST / ГОСТ, GOST–R / ГОСТ–Р, etc.); **technical specifications** (international, regional, national, branches of production, organizations).
2. **International legal regulations** (international conventions, agreements, codex, EU directives, technical requirements, regulations associated with good practices, World Trade Organization – WTO decisions).
3. **National legal regulations** (laws, resolutions, decrees, technical requirements, hygiene norms (*lith.* – HN), documents associated with environmental norms (*lith*. – LAND), medical norms (*lith*. – MN), technical building requirements (*lith*. – STR), etc.).
4. **Product conformity assessment and quality certification** (required, voluntary, environmental, origin of product, supplier conformity declaration).
5. **Company activity (production) certification** (***Voluntary*** – quality management systems ISO 9001; environmental management systems ISO14000; Occupational Health and Safety Management Systems OHSAS 18000 – LST 1952: 2004 ; Organizational Social Responsibility systems CSR, ISO 26000, SA 8000; Capability Maturity Models CMM, etc. ***Required*** – food product safety assurance systems – Hazard Analysis Critical Control Points HACCP – ISO 22000 (*lith*. RVASVT); Good Hygiene Practices GHP; Good Manufacturing Practices GMP; Good Distribution Practices GDP, etc.).
6. **Additional quality assurance regulations written in commercial contracts.**
7. **Requirements of society.**

The EU directive 93/43/EEC defines the mandatory requirements for the implementation of the HACCP system. This directive is not fully implemented in all food-managing companies of the Republic of Lithuania. Due to the lack of financing or lack of knowledge as to how the system works, these enterprises implement the lower level rules – the system of good production and hygiene practices.

Preconditions of the implementation of the integrated food safety and quality system at AB "Vilniaus Pergalė"

At this time AB "Vilniaus Pergale" is implementing an integrated quality management (ISO 9001) and food safety management (ISO 22000) system. This decision was made because it was thought that the most effective management systems are those that are integrated into the company's general management activities and are implemented into a structured management framework (Ruževičius, 2004; 2005; ISO…, 2005). Analysis showed that both standards are compatible and ISO 22000 requirements can be easily integrated with other food safety assurance subsystems (**table**).

Table

ISO 22000 management system integration with other subsystems

Good manufacturing rules (GMR)	General food production subsystem (principles, procedures, means), which must be adhered to at a company, seeking to develop suitable conditions for the production of quality products.
Good manufacturing practices (GMP)	Good manufacturing rules and their practical application.
Good hygiene rules (GHR)	General sanitary rules and means whose applications a necessary pre-condition for the integration of other quality management systems at a company.

ISO 22000, GMR, GMP and HACCP integration is very important because the effective application of GMR and GMP creates conditions to concentrate the HACCP plan on the important aspects of food safety. GMP codex and the hygiene requirements stated therein assure the hygiene quality of the product. These requirements must be included in written documents and strictly adhered to. At the stages in the process where critical control points are not found, application of GPR and GHR assures that control at these points is also applied. Hazard analysis, which is applied in the HACCP program, can also be used to improve the procedures used in processes and the production of certain products.

When comparing the current HACCP system with ISO 22000, certain new requirements can be seen such as the creation of interactive communication systems within and outside the company, the creation of a system for the prevention of unforeseen situations, implementation of certain necessary programs, etc. An effective communication management system must be created between the producer, suppliers, subcontractors and consumers (first concerning information about the product), government institutions overseeing the food products market or other organizations, which will affect or be affected by the results of the food safety management system. Since the amount of incoming and outgoing information is large, this information must first be classified, the form of retaining this information and its content, etc. must be determined. The standard requires interactive communications to be planned and supervised in such a way that important food safety factors are identified and adequately managed at each stage of production. All concerned parties must be informed in a timely manner about all technological and management

changes. The management system, which is developed, will have to accurately define product labeling procedures, form and content. The implementation of labelling procedures for genetically modified products is very complicated. If the ingredients supplied are genetically modified the supplier must present a certificate indicating the specific nature of the genetic modification. The experience at AB "Vilniaus Pergale" indicates that data about genetically modified products is hard to obtain and the quality of this information is difficult and expensive to check. The quality of this data generally depends on the integrity of the company supplying this information. Allergens are another problem area. There are not enough regulations concerning their management and labeling. Hygiene regulations (HN 119) only define 12 food allergen groups, which must be indicated on the product label. Currently there are no regulations written to define the management and labeling of cross-contamination with allergens and chemical allergens.

Conclusions

Having systematised theoretical and methodological literature and common business practice, the author has prepared a model for quality regulation in international business and trade that takes in seven levels of measures and different methods.

The universal international management systems (ISO 9001, ISO 14001, etc.) cannot always be applied effectively to manage specific areas of business. Specialized management systems are being created which include ISO 22000 defining the requirements for any organization in the food chain. The integrated safety and quality system is being developed and implemented at AB "Vilniaus Pergalė". This system will include an interactive communications system, procedures to prevent unforeseen events, product labeling procedures, other subsystems and other required programs, which will assure product safety and improve the overall quality at the company.

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It is also important to identify, define and manage all potentially hazardous situations (fire, accidents, power loss, forces of nature, etc.) by developing and implementing appropriate management procedures. The management system, which is developed, will have to accurately define product labelling procedures, form and content. The implementation of labelling procedures for genetically modified products is very complicated. If the ingredients supplied are genetically modified the supplier must present a certificate indicating the specific nature of the genetic modification.

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Kokybės vadybos ir produktų saugos integruotos sistemos kūrimo prielaidų tyrimas

Santrauka

Universalios tarptautinės vadybos sistemos (ISO 9001, ISO 14001 ir kt.) ne visada gali būti pritaikomos specifinėms verslo sritims efektyviai valdyti. Todėl yra kuriamos „specializuotos“ vadybos sistemos – QS 9000 ir ISO/TS 16949 (automobilių pramonei), TL 9000 (telekomunikacijoms), Tick IT (informacinėms technologijoms), CMM (programinei įrangai), OHSAS 18000 (darbuotojų sveikatai ir saugai), CSR, SA 8000 bei ISO 26000 organizacijų socialinės atsakomybės vadybai ir kt. Šio tipo sistemoms priskirtina ir nauja ISO 22000 vadybos sistema, apimanti maisto saugos užtikrinimo reikalavimus bet kuriai maisto tiekimo grandinės organizacijai. *Darbo tikslas:* apibendrinti maisto kokybės reglamentavimo sistemą ir jo saugos užtikrinimo raidą bei išryškinti kokybės ir saugos integruotos sistemos diegimo AB „Vilniaus Pergalė“ prielaidas. *Tyrimo objektas* – produktų saugos ir kokybės vadybos sistemos. Darbe sprendžiama naujos produktų saugos užtikrinimo sistemos (pateiktos ISO 22000 standarto projekte), integravimo su dabar įmonėje naudojama Rizikos veiksnių analizės svarbiuose valdymo taškuose (RVASVT) sistema bei kokybės vadybos modeliu (ISO 9001) *mokslinė problema*. Šis klausimas dar nebuvo išsamiau nagrinėtas ne tik Lietuvos, bet ir pasaulio mokslinėje literatūroje. *Metodika:* straipsnis parengtas naudojant mokslinės, metodinės ir normatyvinės literatūros bei AB „Vilniaus Pergalė“ verslo praktikos loginę analizę ir apibendrinimus.

Sudėtingėjant maisto technologijoms, jo sudėčiai ir asortimentui bei stiprėjant maisto prekybos globalizacijai, iškilo būtinumas sukurti sistemą, kuri tarptautiniu mastu garantuotų maisto saugą ir kokybę nepriklausomai nuo to, iš kokio pasaulio regiono įvežamos žaliavos ir maisto produktai. *Pirmasis žingsnis* šioje srityje yra 1962 m. Jungtinių Tautų Tarptautinės maisto ir žemės ūkio organizacijos ir Pasaulio sveikatos organizacijos įkurta Maisto standartų organizacija, vadinama Maisto kodekso komisija. Tai tarptautinė organizacija, jungianti daugiau kaip 160 šalių. Ši organizacija rengia tarptautinius standartus (Codex Stan) maisto produktams, bendruosius standartus maisto ženklinimo ir maisto priedų srityje, geros higienos praktikos nuostatas, specialius apribojimus maisto teršalams, geros žemės ūkio ir veterinarinės praktikos nuostatas. *Antrasis žingsnis* maisto kokybės užtikrinimo srityje buvo Pasaulio prekybos organizacijos susitarimai: Žemės ūkio susitarimas, susitarimas dėl prekybos techninių kliūčių (TBT) ir susitarimas dėl sanitarinių ir fitosanitarinių reikalavimų (SPS)**.** Sanitarinės normos nukreiptos žmonių ir gyvūnų sveikatai užtikrinti, o fitosanitarinės – augalų sveikatai apsaugoti nuo kenkėjų, ligų bei ligas sukeliančių organizmų. SPS sutartis garantuoja aiškumą, užtikrindama, kad taikomi kriterijai, tarnaujantys žmonių, gyvūnų bei augalų sveikatai užtikrinti, yra prieinami visiems besidomintiems bei prekybos partneriams. Sutartis reikalauja, kad valstybės nedelsdamos publikuotų visas sanitarines ir fitosanitarines nuostatas ir, paprašytos kitos valstybės, pateiktų paaiškinimus, susijusius su tam tikrais maisto produktų tinkamumo vartoti ir gyvūnų bei augalų sveikatos kriterijais.

Dauguma maito produktų ženklinimo reikalavimų, energinės ir maistinės vertės kriterijų, kokybės ir įpakavimo sąlygų nėra sanitariniai ar fitosanitariniai kriterijai. Todėl jie aptariami TBT sutartyje. Kita vertus, nuostatos, susijusios su mikrobiologiniu maisto užteršimu, pesticidų ar veterinarinių vaistų likučio leistinu kiekiu ar maisto priedais, aptariamos SPS sutartyje. SPS sutartis nereglamentuoja farmacijos produktų, nors tai susiję su žmogaus sveikata. Kokybės techninio ir teisinio reglamentavimo gamyboje ir tarptautinėje prekyboje sistema apibendrinta paveiksle. PPO rekomenduoja valstybėms narėms kuo plačiau tarptautiniame versle ir prekyboje remtis tarptautiniais standartais (ISO, IEC, Codex Stan ir kt.).

Trečiasis žingsnis – maisto saugos užtikrinimo prevencinių sistemų diegimas. Sudėtingėjant maisto produktų sudėčiai ir technologijoms, valstybės kontrolės tarnybų išlaikymo kaštai tapo per didele finansine našta. Vyriausybės pradėjo ieškoti būdų, kaip sumažinti maisto kontrolės kaštus nemažinant kontrolės rezultatyvumo. Tai pakeitė ir maisto kontrolės definiciją, grąžinant pramonei ir prekybai atsakomybę už produktų kokybės kontrolę bei maisto saugos užtikrinimą. Šiuo metu Vakarų šalyse maisto kontrolė apibrėžiama kaip nacionalinės ar vietinės valdžios reguliuojama veikla bendradarbiaujant su maisto pramone ir prekyba tam, kad maisto gamybos, laikymo, transportavimo ir platinimo procesai veiktų kaip bendra sistema, užtikrinanti maisto tinkamumą žmonių mitybai, jo atitiktį saugos ir kokybės reikalavimams; maisto sudėtis turi būti sąžiningai ir teisingai atspindima etiketėse, kaip tai numato įstatymai. Maisto kontrolės apibrėžties transformacija pareikalavo iš maisto gamintojų ir platintojų imtis papildomos atsakomybės už savo produktus, įvedant griežtas procedūras, užtikrinančias produktų saugą ir kokybę. Kitaip tariant, pradėtos kurti maisto saugos užtikrinimo ir kokybės neatitikčių prevencinės sistemos. Jas įdiegus, valdžios institucijų veikla sutelkiama daugiau į minėtų sistemų auditą, o ne masinę konkrečių produktų kokybės kontrolę.

Šiuo metu AB „Vilniaus Pergalė“ kuriama integruota kokybės vadybos (ISO 9001) ir maisto saugos vadybos (ISO 22000) sistema. Šį sprendimą lėmė tai, kad efektyviausios vadybos sistemos yra tos, kurios integruojamos į bendrąsias įmonės vadybos veiklas ir yra diegiamos struktūrizuotos vadybos sistemos rėmuose. Atlikta analizė parodė, kad abiejų minėtų standartų modeliai yra suderinami, o ISO 22000 reikalavimai nesunkiai gali būti susieti su kitais maisto saugos užtikrinimo posistemiais.. ISO 22000 ir RVASVT tarpusavio suderinimas yra labai svarbus, nes rezultatyvus jų taikymas sudaro sąlygas nukreipti RVASVT planą ir priemones į svarbiausius maisto saugos aspektus. Palyginus dabar naudojamą RVASVT sistemą su ISO 22000, galima išskirti tokius naujus reikalavimus kaip interaktyvios komunikacijos sukūrimas įmonės išorėje ir viduje, nenumatytų atvejų prevencijos sistemos įdiegimas, kai kurios naujos būtinosios veiklos programos ir kt. Turi būti sukurtos ir rezultatyviai valdomos informacijos priemonės su tiekėjais, subrangovais, vartotojais (visų pirma dėl informacijos apie produktą), maisto rinkos priežiūrą vykdančiomis valdžios institucijomis, kitomis organizacijomis, turinčiomis poveikį, arba kurias paveiks maisto saugos vadybos sistemos rezultatyvumas. Kadangi informacijos srautai iš išorės ir į išorę yra dideli, informacija pirmiausia turi būti suklasifikuojama, nustatomos duomenų įrašų apie šį informavimą formos, turinys ir kt. Standartas reikalauja, kad interaktyvi komunikacija būtų planuojama ir prižiūrima taip ir tam, kad visi svarbūs maisto saugos rizikos veiksniai būtų identifikuojami ir adekvačiai valdomi kiekviename maisto tvarkymo etape ir kad aplinkos subjektai būtų laiku informuojami apie visus technologinius bei vadybinius pokyčius. Be to, būtina identifikuoti, apibrėžti ir valdyti visas potencialiai pavojingas situacijas (pvz., gaisras, avarijos, elektros energijos tiekimo pertrūkiai, stichinės nelaimės ir kt.) ir sukurtos bei įdiegti šių situacijų valdymo procedūros. Kuriamoji sistema turėtų tiksliai apibrėžti produkcijos ženklinimo procedūras, formą bei turinį. Labai sudėtingas yra genetiškai modifikuotų (GM) produktų ženklinimo reikalavimų vykdymas. Jeigu tiekiama žaliava yra genetiškai modifikuota, jos teikėjas privalo pateikti genetinės modifikacijos ypatumų sertifikatą. Problemiška yra ir tai, kad nėra pakankamai reglamentuotas alergenų valdymas bei ženklinimas – higienos normoje HN 119 yra nurodytos tik 12 maisto alergenų grupės, kurias privaloma nurodyti gaminių sudėties ženklinime. Iki šiol nereglamentuotas kryžminio užteršimo alergenais bei cheminių alergenų valdymas ir ženklinimas.

AB „Vilniaus Pergalė“ kuriamoje integruotoje kokybės ir saugos vadybos sistemoje naujai kuriamos arba tobulinamos interaktyvios komunikacijos, nenumatytų atvejų prevencijos, produktų ženklinimo ir kitos posistemio bei naujos būtinosios veiklos programos leis garantuoti produkcijos saugą, pagerinti bendrąją veiklos kokybę ir konkurencingumą.

Raktažodžiai: *kokybės vadyba, saugos vadyba, RVASVT, ISO 9001, ISO 22000.*

The article has been reviewed.

Received in January, 2006; accepted in February, 2006.