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# Improvement of Food Safety and Quality by Statistical Process Control (SPC) in Food Processing Systems: A Case Study of Traditional Sucuk (Sausage) Processing

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## 1. Introduction

Increasing customer demand for safe food has led food industry to build up food safety and quality systems. The food safety and quality are affected by insufficiency on administration, supplier, production technologies, working environment, human resources and control activities.

Hazard analysis and critical control points (HACCP) is a system that identifies, evaluates and controls hazards which are significant for food safety. It is a structured, systematic approach for the control of food safety throughout the commodity system, from the farm to the plate. It requires a good understanding of the relationship between cause and effect in order to be more pro-active and it is a key element in Total Quality Management (TQM). The HACCP system has 7 elements called the HACCP principles and pre-requisite programs that must be in place for the system to operate effectively. HACCP is focused in two main steps, namely; (1) Hazard analysis and critical control points (CCPs) determination and (2) HACCP plan for the food processing. First step includes hazards identification, hazard assessment, preventive measure establishment, CCPs determination and their critical limits. The following step is to carry out HACCP plan preparation; monitoring system, corrective actions, verification system and related record system on each CCP.

Statistical tools are an effective way for improving process quality and safety. A large number of managers have achieved the benefits from statistical process control (SPC) implementation. SPC includes flow charts, pareto analysis, histograms, cause-and-effect or Ishikawa diagrams, scatter diagrams, and control charts. Control charts enable the monitoring of key variables during production and they give warning when the process is out-of-control. The best-known charts are the  $\bar{X}$  and  $s$  charts that show the temporal variability of the average and standard deviation of the sample subgroups. SPC tools are, particularly control charts, for trend analysis, monitoring and evaluating the critical control points (CCPs) statistically, obtaining advance warning on the status of a critical control point and not just a "Pass/Fail" classification and measuring process outputs and identifying if they vary within statistically defined upper and lower control limits. Use of

these tools is discussed by considering traditional sucuk (sausage) process. Sucuk, is a term used for a fermented dry meat product, is a very popular meat product in Turkey and countries located in Balkans, Middle East and Caucasus. Similar type products are also known in most Middle East countries and in European countries. This meat product has been chosen because of its liability to deteriorate easily.

Assuring HACCP effectiveness for food safety relies on application of many prerequisite programs. In addition, some processes (Documentation and record process, internal audit process, etc) applied with ISO 9000-Quality Management System (QMS) standard are used with the HACCP system. ISO 22000-Food Safety Management System (FSMS) standard is being introduced as organizing all of these requirements; moreover it is desired to be used as a single standard in the world. These management systems require statistical tools to have an effective implementation.

## **2. Food safety and quality systems**

Food safety is a scientific discipline handling, preparation, and storage of food in ways that prevent food borne illness. HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards from raw material to the end product. ISO 22000 concentrates exclusively on food safety and will instruct food producers how they can build up the food safety system itself. Food quality is the quality characteristics of food that is acceptable to consumers. The ISO 9000:2000 includes all management, production, distribution, and product design and service activities.

### **2.1 TQM and ISO 9000-Quality management system standard**

Total Quality Management (TQM) is a comprehensive and structured approach to organizational management that seeks to improve the quality of products and services through ongoing refinements in response to continuous feedback. TQM covers to meet customer requirements, to improve teams, to reduce product and service costs and to provide continuous improvement. TQM techniques have demonstrated an ability to significantly increase productivity and improve profitability. Total Quality Management (TQM) is a comprehensive philosophy of living and working in organizations that emphasizes the relentless pursuit of continuous improvement (Chase & Aquilano, 1995). The principles of TQM and other management systems are summarized in Table 1.

The basic principles for the Total Quality Management (TQM) philosophy of doing business are to satisfy the customer, satisfy the supplier, and continuously improve the business processes. Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations. Nearly every organized activity can be looked upon as a process. This process is supported by an organization consisting of people and their relations, resources and tools. Continuous improvement is an integral part of a total quality management system. Common tool to achieve to continuous improvement could be the plan-do-check-act (PDCA) cycle, often called the Deming Wheel, which conveys the sequential and continual of the continuous improvement process.

ISO 9000:2000 is in fact families of standards developed to assist organizations implement and operate effective quality management systems (QMS). ISO 9000:2000 consisted of quality systems that focused on documenting all quality assurance and improvement

processes in a company (ISO, 1999). Although the ISO 9000:2000 was originally developed for the manufacturing sector, it had been applied to many service organizations and was gaining some acceptance in the food industry.

TQM	ISO 9000:2000-QMS	HACCP	ISO 22000-FSMS
<ul style="list-style-type: none"> <li>• Focus on customer</li> <li>• Leadership</li> <li>• Let everybody be committed</li> <li>• Approaching of process</li> <li>• Focus on system management</li> <li>• Continuous development</li> <li>• Reality approaching</li> <li>• Cooperation with suppliers</li> </ul>	<ul style="list-style-type: none"> <li>• Customer focus</li> <li>• Leadership</li> <li>• Involvement of people</li> <li>• Process approach</li> <li>• System approach to management</li> <li>• Continual improvement</li> <li>• Factual approach to decision making</li> <li>• Mutually beneficial supplier relationships</li> </ul>	<ul style="list-style-type: none"> <li>• Hazard analysis</li> <li>• Critical control points (CCPs)</li> <li>• Critical limits</li> <li>• Monitoring procedures</li> <li>• Corrective actions</li> <li>• Verification procedures</li> <li>• Documentation procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Customer focus</li> <li>• Leadership and team work</li> <li>• Involvement of people</li> <li>• Process approach and food safety</li> <li>• System approach to management</li> <li>• Continual improvement</li> <li>• Factual approach to decision making</li> <li>• Mutually beneficial supplier relationships</li> <li>• Legislation, regulations</li> <li>• Science and experience</li> <li>• Interactive communication</li> </ul>

Table 1. The Principles of TQM, ISO 9000:2000-QMS, ISO 22000-FSMS and HACCP

The ISO 9000:2000 standard describes a basic set of 8 elements by which quality management system can be developed and implemented. Table 2. represents the structure of ISO 9000:2000-QMS Standard.

### 2.2 HACCP and ISO 22000-Food safety management system standard

For the food industry, the HACCP program is currently recognized as the best approach to control food safety. Although concerns such as quality and economic adulteration are not included in the HACCP system, the implementation of an HACCP system means greater control over production process, which results in improvements in both the quality and safety of food. The HACCP system has 7 elements called the HACCP principles (Table 1.) and pre-requisite programs (Table 2.) that must be in place for the system to operate effectively (FAO, 1998; Codex, 2003).

The food processing industry has long used HACCP programs to make their products safer. Application of HACCP systems in many different manufacturing processes has led to more efficient prevention of adverse health effects associated with the consumption or use of the

products. In addition, HACCP focused on the elimination of food-related health hazards. Companies involved in HACCP attempted to identify all critical points at which health hazards could be introduced into food and control those points to eliminate the associate risk (Mortimore & Wallace, 1998).

	<b>Strategic</b>	<b>Operational</b>	<b>Support</b>
<b>ISO 9000:2000-QMS</b>	QP.1 Market Research and Customer Relation QP.2 Internal Communications QP.3 Document and record Control QP.4 Planning QP.5 Resources Management	QP.6 Product Design QP.7 Food Manufacturing	QP.8 Purchasing QP.9 Internal Audit QP.10 Data Analysis QP.11 Maintenance of measurement's and process equipments QP.12 Calibration of measurement's equipment
<b>ISO 22000:2005-FSMS</b>	PR.1 Construction and lay-out of buildings and associated utilities PR.2 Lay-out of premises, including workspace and employee facilities PR.3 The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance	PR.4 Supplies of air, water, energy and other utilities PR.5 Supporting services, including waste and sewage disposal PR.6 Cleaning and sanitizing PR.7 Pest control PR.8 Personnel hygiene PR.9 Measures for the prevention of cross contamination	PR.10 Management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), and supplies

QP: Quality Process, PR: Pre-requisite

Table 2. Some quality processes and prerequisite programs

HACCP is a system that identifies, evaluates and controls hazards which are significant for food safety (FAO, 1998). It is a structured, systematic approach for the control of food safety throughout the commodity system, from the farm to the plate.

ISO 22000-2005 FSMS aims to harmonize the requirements for food safety management in food and food related business (ISO, 2005). ISO 22000-2005 FSMS assists the food manufacturers in the use of HACCP principles. Main elements in ISO 22000:2005 FSMS are compatible with ISO 9000:2000 QMS. Both models consist of 5 major elements. For the proposed-integrated models, the principle aim is to provide simplicity and applicability. A common documentation system is provided by the integration (Figure 1.).

HACCP system had been required operational applications such as GMP, GHP, and SSOP before ISO 22000-FSMS Standard had been published. ISO 22000-FSMS Standard has included and organized the definition and detailed contents of these applications. Prerequisite programs, in this study, are classified as strategic, operational, and



supportive programs (Table 2). ISO 22000-FSMS and ISO 9000-QMS have the same framework properties. The standards have built on customer focus, continuous improvement, and process approach. Figure 3 shows the properties and similarities of the standards. ISO 22000-FSMS standard includes HACCP principles with prerequisite programs (ISO, 2005). The prerequisite programs and processes that are required both ISO 9000-QMS and ISO 22000-FSMS are shown in Table 2. For example; the followings are in both standards; documentation and record process (QP 3), which are the fundamental items in both standards are in the article number 4. The planning (QP 4), and internal communication (QP 2) are in the article number 5, resource management process (QP 5) are in the article number 6.

### **2.3 Continuous improvement**

Continuous improvement is a management philosophy that approaches the challenge of product and process improvement. Specifically, continuous improvement seeks continual improvement of machinery, materials, labor utilization, product quality and safety, and production methods through application of suggestions and ideas of team members (Chase & Aquilano, 1995).

ISO 9000:2000 Quality Management System and ISO 22000:2005 Food Safety Management System are based on the process model which includes the continuous improvements from suppliers to the customer chain. In both models the influence of Deming's cycle can be seen (Table 3.). In ISO 9000:2000-QMS and ISO 22000:2005 a far greater emphasis is placed on the use of measurement and analysis of results, feeding into the review and improvement process. The continued auditing and verification of HACCP system demand more attention than the initial development of a HACCP plan. Food companies sometimes focus on the process control portion of HACCP without documenting the product design. Important process in HACCP system verification includes the initial validation of HACCP plan and its periodic revalidation. HACCP is brought to a standard structure with ISO 22000:2005 which has similarities with ISO 9000:2000 QMS. Moreover, integration of standards will provide simplicity in practicing of them.

Figure 1 represents the continuous improvement of process models in product quality with ISO 9000:2000 QMS and product safety with ISO 22000:2005 FSMS. Continuous improvement can be well designed by applying the following steps;

#### **2.3.1 Management responsibility**

In both models top managements make/decide quality and safety policies. After this step, objectives to reach quality and safety policies should be determined. The customer requirements have to be included in this determination. Food quality and food safety management system planning is then followed. Planning will include strategies, resources and cost estimation.

#### **2.3.2 Resource management**

The required resources such as human resources, infrastructures, equipments, and work environment have to be organized. Infrastructure covers the hygienic and sanitary design of equipment and buildings. Required continuing education for employees has to be planned and supplied.

Deming Wheel (PDCA Cycle)	Quality and safety improvement steps	ISO 9000-QMS	ISO 22000-FSMS
<i>Plan (P):</i> The plan phase of the cycle is an improvement area and a specific problem with it to be identified. In this phase, objectives and strategies are developed and necessary sources are determined.	1. Theme Selection	5.3. Quality Policy	5.2. Food Safety Policy
	2. Current situation review and analysis	5.4. Quality planning	5.3. FSMS planning
	3. Preventive action planning	5.4. Quality planning	5.3. FSMS planning
<i>Do (D):</i> The do phase of the cycle deals with implementing the changes according to the plan.	4. Action	7. Product/Service Realization 7.5. Production & Service Provision	7. Realization of safe product 7.9. Operation of FSMS
<i>Check (C):</i> The check phase deals with evaluating data collected during implementation.	5. Analysis	8. Measurement, Analysis, and Improvement	8.2. Monitoring and measuring
<i>Act (A):</i> During the act phase, the improvement is codified as the new standard procedure; necessary revisions are applied and replicated in similar processes throughout the organization.	6. Standardization of the countermeasures	7.5. Production and Service Provision	8.4. Validation of control measure combinations
	7. Identification of remaining problems	8.3. Control of Nonconforming product	8.3. FSMS verification
	8. Evaluation of whole plans and procedures	8.5. Improvement 5.6. Management review	8.5. Improvement 5.6. Management review

Table 3. PDCA cycle with ISO 9000-QMS and ISO 22000-FSMS

### 2.3.3 Product/service realization

Following steps have to be studied in safe product and service realization;

- Planning of safe product and service
- Implementation of pre requisite programs
- Hazard and risk analysis
- Design (Safe product and/or service, HACCP plan, Operational procedures)
- Realization of purchasing after evaluating of supplier
- Realization of safe products and service by customer requirements

### 2.3.4 Measurement, verification, validation and improvement

Data obtained from suppliers, customer satisfaction, product quality and safety, process trends, critical control points, pre-requisite programs and quality-safety system have to be

analyzed. Quality and safety systems are usually analyzed and verified through internal audits (Sperber, 1998). After that, outputs coming from auditing are validated. In both systems, the control of non confirmative products (in terms of quality and safety aspects) is required. Preventive and corrective actions provide us to get improvements. Management starts the review the data obtained through the former stages. Then, re-planning and validation are conducted.

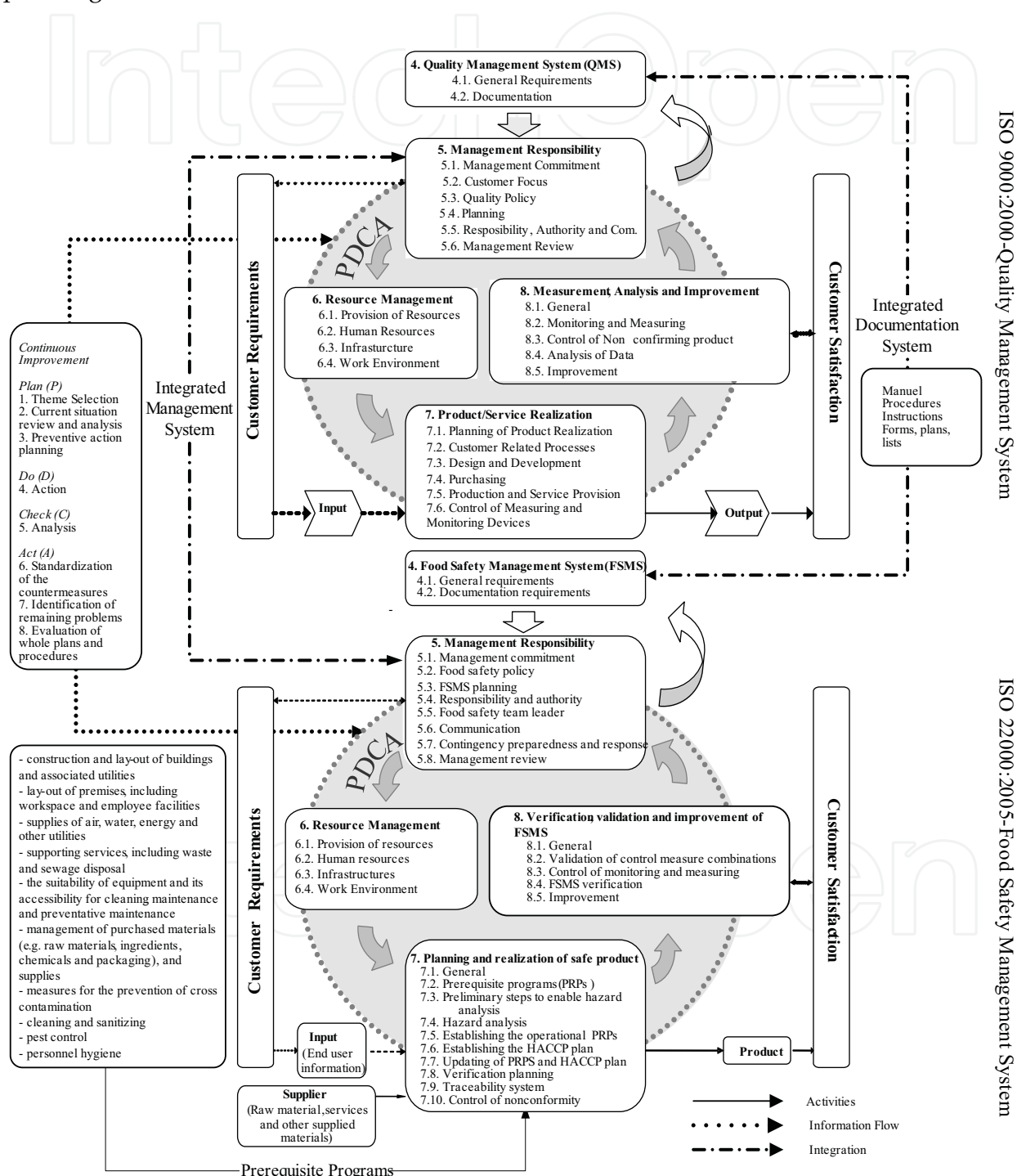


Fig. 1. Continuous Improvement Models in ISO 22000-Food Safety Management System and ISO 9000-Quality Management System (ISO, 1999; ISO, 2005)



## 2.4 Process management

Process is a collection of related, structured activities that produce a specific service or product from inputs given for particular customers. All of these activities are connected to each other with logic relations of processes. They provide the results by using sources of a organization to attain the goals. Process management between functional units of the institution within the hierarchical structure of production is a simple management system that provides work flows. In addition it is an effective management system in which responsibilities of employees are considered, inputs and outputs are clearly stated, performance criteria and the size of success are being measured, and continuous improvements are provided (Juran & Gryna, 1998).

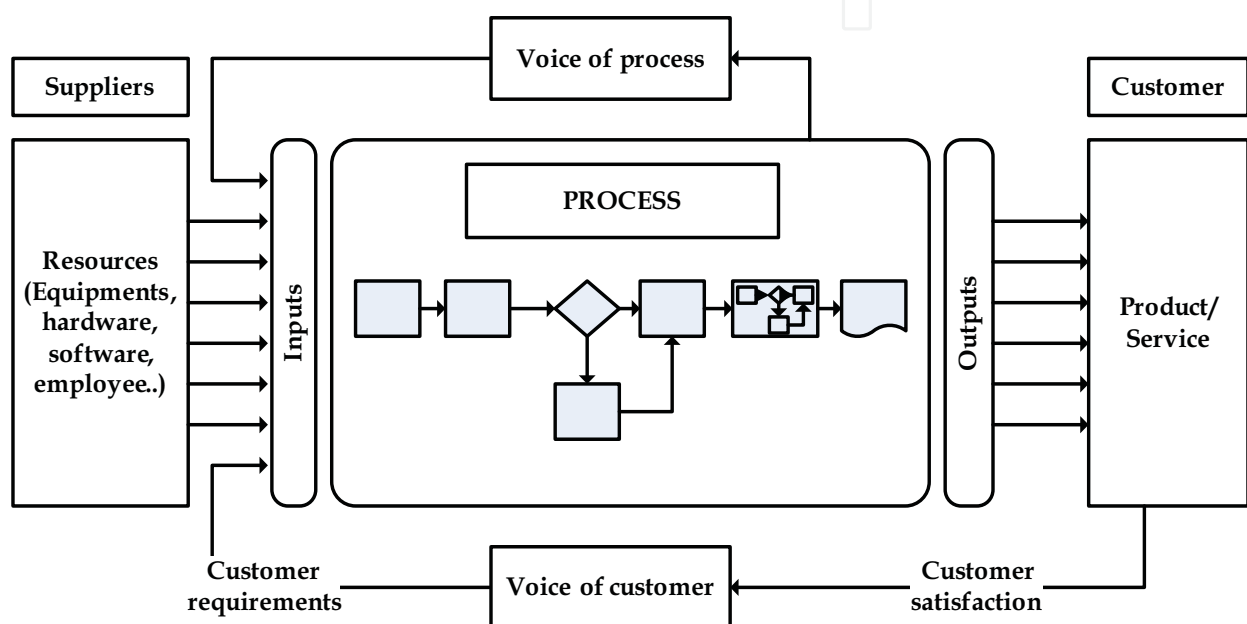


Fig. 2. Process model

ISO 9000:2000-Quality Management System standard requires process management activities, resource management, product / service implementation and identification of processes during monitoring. Within this scope, the processes specified in Table 2 can be prepared.

Documentation required by these processes vary according to the organizational structure, however, the documents should be prepared in accordance with ISO 9000:2000-Quality Management System standard, the necessity, their validities must be approved and implemented.

## 3. Statistical process control

Statistical process control (SPC) is defined as the application of statistical techniques to control a process. SPC is concerned with quality of conformance. There are a number of tools available to the quality engineer that is effective for problem-solving process. The seven quality tools are relatively simple but very powerful tools which every quality engineer. The tools are: flow chart, run chart, process control chart, check sheet, pareto diagram, cause and effect diagram, and scatter diagram (Juran & Gryna, 1998).

### 3.1 Flow charts

Flow charts are defined as the graphical representation of the steps of in a process. Flow charts facilitate an analysis of the steps in a process to determine relationships between the steps.

### 3.2 Check sheets

Check sheets are useful during data collection. They provide a simple means for recording data by categories and enable the analyst to determine the relative frequency of occurrence of the various categories of the data.

### 3.3 Cause and effect diagrams

Cause and effect diagrams (CED) are simple techniques for dissecting a problem or a process. CED identifies all possible relationships among input and output variables, that is, the five categories on the following skeleton (materials, machines, man, methods, and environment).

### 3.4 Histograms and pareto charts

A histogram is a bar chart showing the variation or distribution of the observations from a set of data. The pareto chart is a form of bar chart with each bar representing a cause of a problem and always arranged so that the most influential cause of a problem can be easily recognized, that is, arranging the problems in descending order. This information is helpful in focusing attention on the highest-priority category (Srikaeo & Hourigan, 2002).

### 3.5 Scatter diagrams

Scatter diagramming is a tool to study how different variables relate to each other or how they correlate. A scatter diagram demonstrates the results of a series of experiments which is conducted to document the relationship between the variables. Table 4. represents the mathematical models.

### 3.6 Process control charts

The primary function of a control chart is to determine which type of variation is present and whether adjustments need to be made to the process.

Variables data are those data which can be measured on a continuous scale. Variable data are plotted on a combination of two charts- usually an x-bar ( $\bar{x}$ ) chart and a range (R) chart. The x-bar chart plots sample means. It is a measure of between-sample variation and is used to assess the centering and long term variation of the process. The range chart measure the within sample variation and assesses the short term variation of the process (Juran & Gryna, 1998; Grigg, 1998).

Attribute charting is used for various types of defects, primarily by counting the number of nonconforming units or the nonconformities per units. The most commonly used attribute control chart is p-chart or the percentage of defective unit with variable sample size. The np-chart is used to monitor the percentage defective unit for constant sample size. The c-chart is used to monitor the number of defects on an item for constant sample size. The u-chart is for number of unlimited defects in variable sample size.



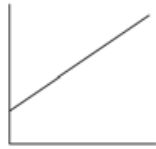
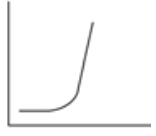
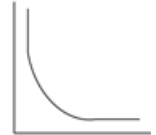

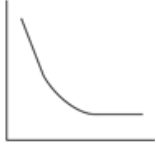

Expression	Mathematical models	Geometric shape	Applications
Sigmoidal (Gompertz)	$y = y_0 + ae^{-e^{-\frac{x-x_0}{b}}}$		Growth curve Inactivation of microorganisms (Banani et al., 2007)Ray
Sigmoidal (Logistic)	$y = y_0 + \frac{a}{1 + (\frac{x}{x_0})^b}$		
Sigmoidal (Sigmoid)	$y = y_0 + \frac{a}{1 + e^{-\frac{x-x_0}{b}}}$		
Sigma (GAB)	$y = \frac{abcx}{(1-ax)(1-ax+abx)}$		Moisture sorption isotherms (Ayranci & Dalgic, 1992)
Polynomial (linear)	$y = y_0 + ax$		Linear relationships (Wu et al., 2007)
Polynomial (Quadratic)	$y = y_0 + ax + bx^2$		(Gao et al., 2007)
Polynomial (inverse first order)	$y = y_0 + \frac{a}{x}$		
Peak (Gaussian)	$y = y_0 + ae^{-0.5(\frac{x-x_0}{b})^2}$		Distribution (Peng & Lu, 2007).
Peak (Lorentzian)	$y = y_0 + \frac{a}{1 + (\frac{x-x_0}{b})^2}$		
Exponential decay	$y = y_0 + ae^{-bx} + ce^{-dx}$		Drying Destruction curve for microorganisms (Bruce et al. 2009)
Exponential growth	$y = y_0 + ae^{bx} + ce^{dx}$		Growth curve (Daniela et al., 2009)

Table 4. Some mathematical models' formulas and their geometric shapes

	UCL & LCL	Mean	n*	A <sub>2</sub>	D <sub>3</sub>	D <sub>4</sub>
X-Chart	$\begin{aligned} \text{UCL}_{\bar{x}} &= \bar{\bar{x}} + A_2 \bar{R} \\ \text{LCL}_{\bar{x}} &= \bar{\bar{x}} - A_2 \bar{R} \end{aligned}$	$\bar{\bar{x}} = \frac{\sum_{i=1}^n \bar{x}_i}{n}$	2	1.88	0	3.27
			3	1.02	0	2.57
			4	0.73	0	2.28
			5	0.58	0	2.11
			6	0.48	0	2.00
			7	0.42	0.08	1.92
R-Chart	$\begin{aligned} \text{UCL}_R &= D_4 \bar{R} \\ \text{LCL}_R &= D_3 \bar{R} \end{aligned}$	$\bar{R} = \frac{\sum_{i=1}^n R_i}{n}$	8	0.37	0.14	1.86
			9	0.34	0.18	1.82
			10	0.31	0.22	1.78

\* Number of observations in each sample, UCL: upper control limit, LCL: lower control limit, A<sub>2</sub>, D<sub>3</sub>, and D<sub>4</sub> are constants

Table 5. The control diagrams for variable data and control chart factors (Juran & Gryna, 1998)

Chart	UCL and LCL	Center line
p	$\text{UCL}\alpha\text{LCL} = \bar{p} \pm 3 \frac{\sqrt{\bar{p}(1-\bar{p})}}{\sqrt{n}}$	$\bar{p} = \frac{\sum np}{\sum n}$
np	$\text{UCL}\alpha\text{LCL} = n\bar{p} \pm 3\sqrt{n\bar{p}(1-\bar{p})}$	$n\bar{p} = \frac{\sum np}{k}$
c	$\text{UCL}\alpha\text{LCL} = \bar{c} \pm 3\sqrt{\bar{c}}$	$\bar{c} = \frac{\sum c}{k}$
u	$\text{UCL}\alpha\text{LCL} = \bar{u} \pm 3 \frac{\sqrt{\bar{u}}}{\sqrt{n}}$	$\bar{u} = \frac{\sum c}{\sum n}$

n: the number of observations in each sample, k: number of samples

Table 6. Control diagrams for attributes

### 3.7 Failure mode and effect analysis

A failure modes and effects analysis (FMEA) is a procedure in product development and operations management for analysis of potential failure modes within a system for classification by the severity and likelihood of the failures. Failure modes are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures.

Failure mode and effect analysis is a tool that examines potential product or process failures, evaluates risk priorities, and helps determine remedial actions to avoid identified problems. The spreadsheet format allows easy review of the analysis (Arvanitoyannis & Varzakas, 2007 and 2008).

#### 4. A case study: Some applications of SPC in traditional sucuk processing

A traditional sucuk processing was partly investigated by SPC. The process data were retrieved from an industry and analyzed by SPC techniques. Data were obtained over a period of 3 months. The process variables considered were and moisture content, pH change during ripening. In addition to these, some and product variables (flavor, texture, saltiness etc.) were determined from a survey conducted in Gaziantep, Turkey. The SPC techniques included Check sheets, Cause and effect diagrams, Histograms and pareto charts, Scatter diagrams, Process control charts, Failure mode and effect analysis

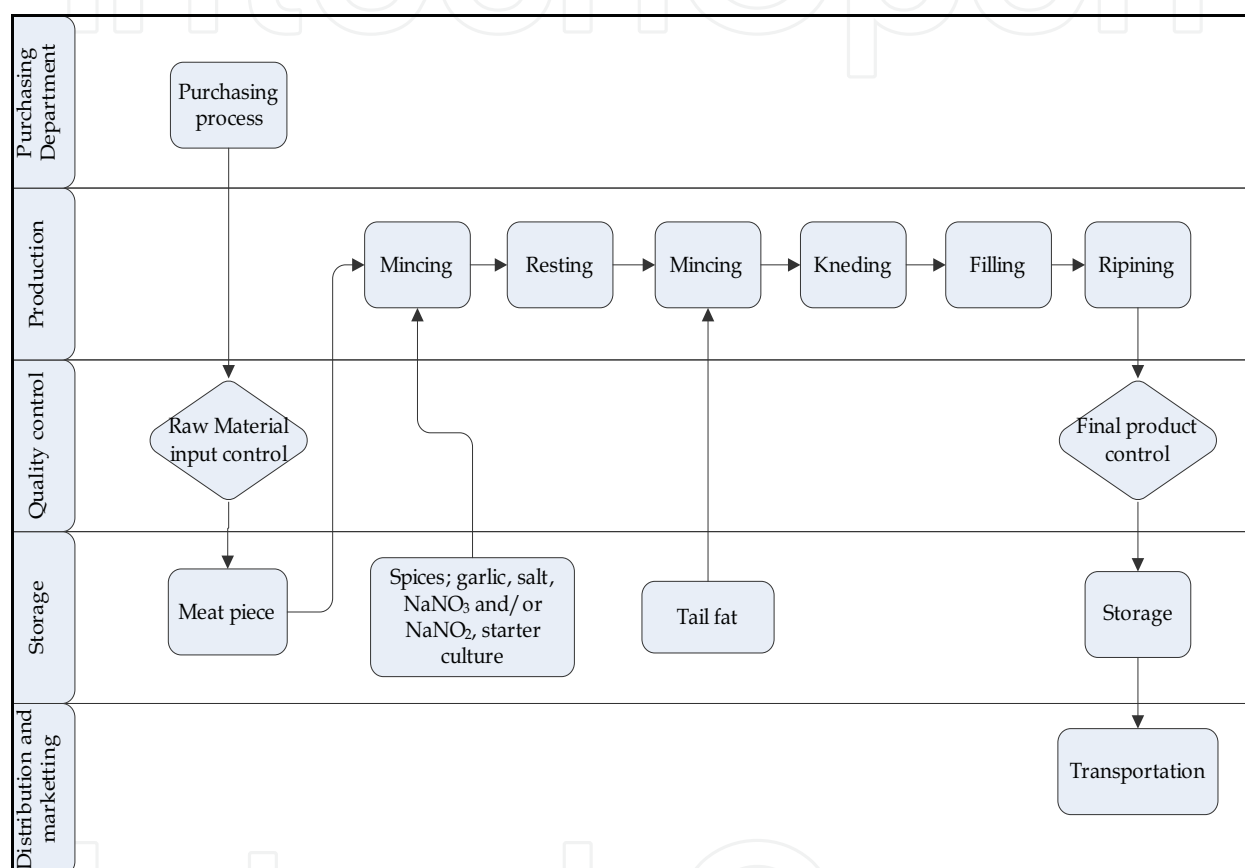


Fig. 3. Sucuk manufacturing process flow chart by various departments

##### 4.1 Traditional sucuk processing and properties

Sucuk dough is prepared from meat (about 18% fat) mixed with tail fat, salt, sugar, clean dry garlic, spices, NaNO<sub>2</sub>, NaNO<sub>3</sub>, vegetable oil (generally olive oil), antioxidants and antimicrobial. Meat, fat and spices are added into sucuk dough according to the following recipe; 900 g sheep red meat (about 18% fat), 200 g tail fat, 5.5 g cumin, 1.1 g cinnamon, 11.42 g allspice, 0.48 g cloves, 5.5 g red pepper, 11 g black pepper, 20.76 g garlic, 4.4 g sugar, 18 g salt and 2.1 g olive oil are used to prepare sausage dough. A flow-chart of sucuk preparation is given in Figure 3. The meat is minced in a meat mincer to about 1.3–2.5 cm. After that spices and starter culture are added and mixed with minced meat. Starter culture mixture (*P. acidilactici*, *L. plantarum* and *S. carnosus*) is used as a 20 g commercial culture mixture per 100 kg meat. After that nitrate/nitrite, potassium pyrophosphate, dipotassium hydrogen



phosphate, ascorbic acid and potassium sorbate which are dissolved in 25 ml of distilled water, are added into the prepared of sucuk dough. The sucuk dough is conditioned at 0-4 °C for 12 hours. The minced refrigerated tail fat is added and mixed into the sucuk dough. After that, the dough is filled into artificial collagen casings, of 38 mm diameter, under aseptic conditions, using a filling machine. Sucuks are fermented and matured from 95% to 60% RH and from 22 to 18 °C during 15 days. Sucuk samples are then stored at 50% RH and 30 °C (Bozkurt & Erkmen, 2007).

#### 4.2 Application of pareto analysis in traditional sucuk processing

A survey study was done to collect customer complaints about the properties of sucuk products. According to Pareto analysis; the percentage of complaints are listed by the descending order and cumulative percentages are obtained by adding each other to previous ones. The priority problems are being identified by this order.

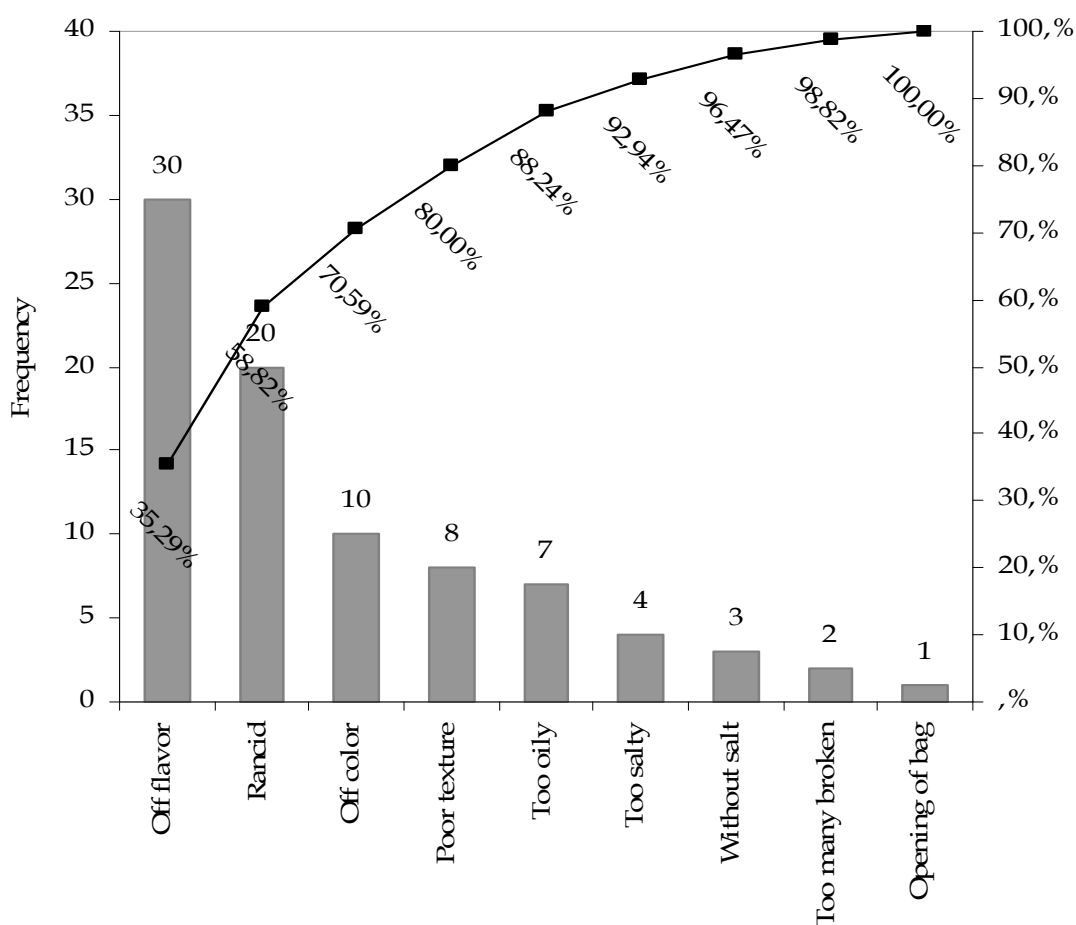


Fig. 4. Pareto analysis of customer complaints for sucuk product

#### 4.3 Application of control charts in traditional sucuk processing

The amount of moisture in the production of sucuk is one of the quality parameters. Moisture content should be around 40%. The X-bar ( $\bar{x}$ ) and R-chart graphics in Table 7 are created from the moisture contents of 5 samples of 10 runs. The control limits drawn in both plots were obtained by using equations given in Table 5.

n	Final moisture content for each run (kg water/100 kg total sucuk)									
	1	2	3	4	5	6	7	8	9	10
1	43,36	43,54	42,38	41,17	40,15	43,25	41,15	40,97	40,75	39,98
2	42,45	44,05	43,56	43,78	42,38	42,97	43,54	41,43	43,35	42,75
3	43,38	42,48	42,15	43,56	43,75	44,06	41,91	44,38	44,09	44,75
4	42,96	43,54	43,75	44,17	44,51	43,65	42,54	43,76	42,75	43,75
5	43,78	44,15	42,96	41,24	43,75	43,54	43,89	42,54	41,76	42,75
$\bar{X}$	43,19	43,55	42,96	42,78	42,91	43,49	42,61	42,62	42,54	42,80
UCL- $\bar{X}$ =44,52										
LCL- $\bar{X}$ =41,37										
$\bar{\bar{X}}$ =42,94										
R	1,33	1,67	1,6	3	4,36	1,09	2,74	3,41	3,34	4,77
UCL- $\bar{R}$ =5,77										
LCL- $\bar{R}$ =0										
$\bar{R}$ =2,73										

Table 7. A control chart showing the amount of moisture in a sucuk production line

#### 4.4 Application of scatter diagrams in traditional sucuk processing

The formation of lactic acid bacteria in fermented meat products prevents the formation of undesirable bacteria. The lactic acid produced during ripening decreases pH to 5.3. If the value of pH is below 5.3 the water holding capacity of meat proteins decreases and the product dries quickly. Table 8 shows changes in pH during the ripening process. The parameters given in Table 8 are obtained with these experimental data modeled with the logistic equation.

In this application, Logistic model was applied to determine the best fit for the experimental data of ripening of sucuk. Modeling was carried out using the least square method and the Microsoft Excel spreadsheet (Microsoft Office 2003, USA) was used to perform this task using the SOLVER tool based on the Generalized Reduced Gradient (GRG) method of iteration. This is a search method to minimize the sum of squares of the differences between the predicted and experimental data (Hii et al., 2009).

Logistic parameters			
$y_0$	$x_0$	a	b
5,43	2,38	0,93	3,44
Time (day)	$pH_{exp}$	$pH_{pre}$	$(pH_{exp}-pH_{pre})^2$
0	6,35	6,36	0,0001321
1	6,33	6,32	0,0001823
3	5,71	5,72	6,714E-05
6	5,50	5,47	0,0012100
9	5,43	5,44	5,581E-05
12	5,39	5,43	0,0017230
15	5,45	5,43	0,0004161
Sum			0,0037865

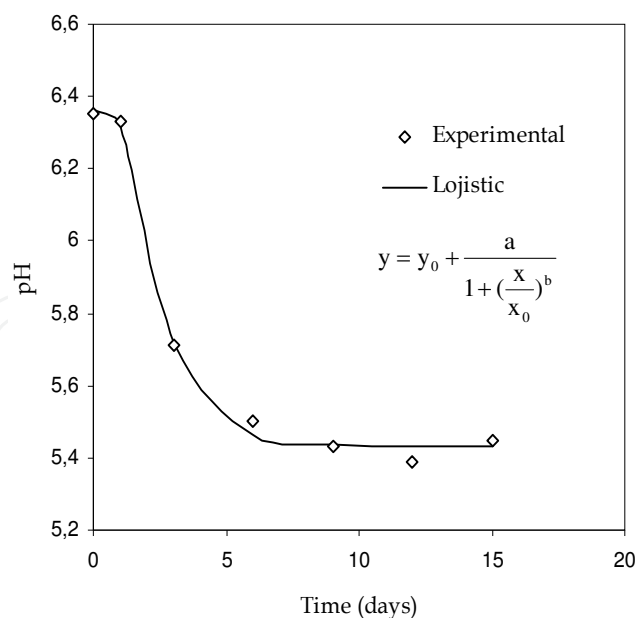


Table 8. Scatter diagram of pH during ripening

#### 4.5 Failure mode and effect analysis of sucuk processing

Hazard analysis begins with identification of food safety hazards associated with the raw material. First, a complete list of hazards that could potentially be of concern is prepared. Cause analysis is based on determine potential hazard sources and classifying the causes (Arvanitoyannis & Traikou, 2005). This classification is done by fish bone diagram (Figure 5) and results are shown in Table 9.

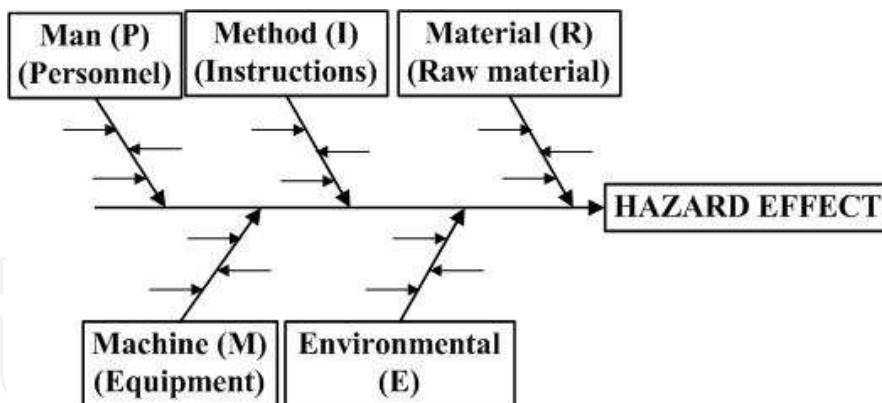


Fig. 5. Cause and effect analysis (Fish bone diagram)

A number of questions given in Figure 6 have to be answered for each hazard to identify significant hazards that could be of concern at each sucuk production step (ILSI, 2004). Hazard analysis starts questioning of the presence of a potential hazard whether it is significant or not in raw materials or in the processing steps. Questions and their results are shown in Table 9.

Sucuk processing basically consists of dough formation (mincing and kneading) and fermentation/ripening steps. One of the main hazards comes from properties of raw materials such as microorganisms, antibiotics, hormones and biogenic amines. Additives and spices may contain foreign matters, insects, mycotoxins etc. In fermentation and

ripening process, residual nitrate and nitrite may have a potential chemical hazard. Metal contamination is a major hazard during mincing since these processes are mechanic. These hazards, as shown in Table 9., have to be tested and controlled in every batch. Results obtained from hazard analysis give a sign for the magnitude of hazard in a next step, moreover, whether it is a CCP or not.

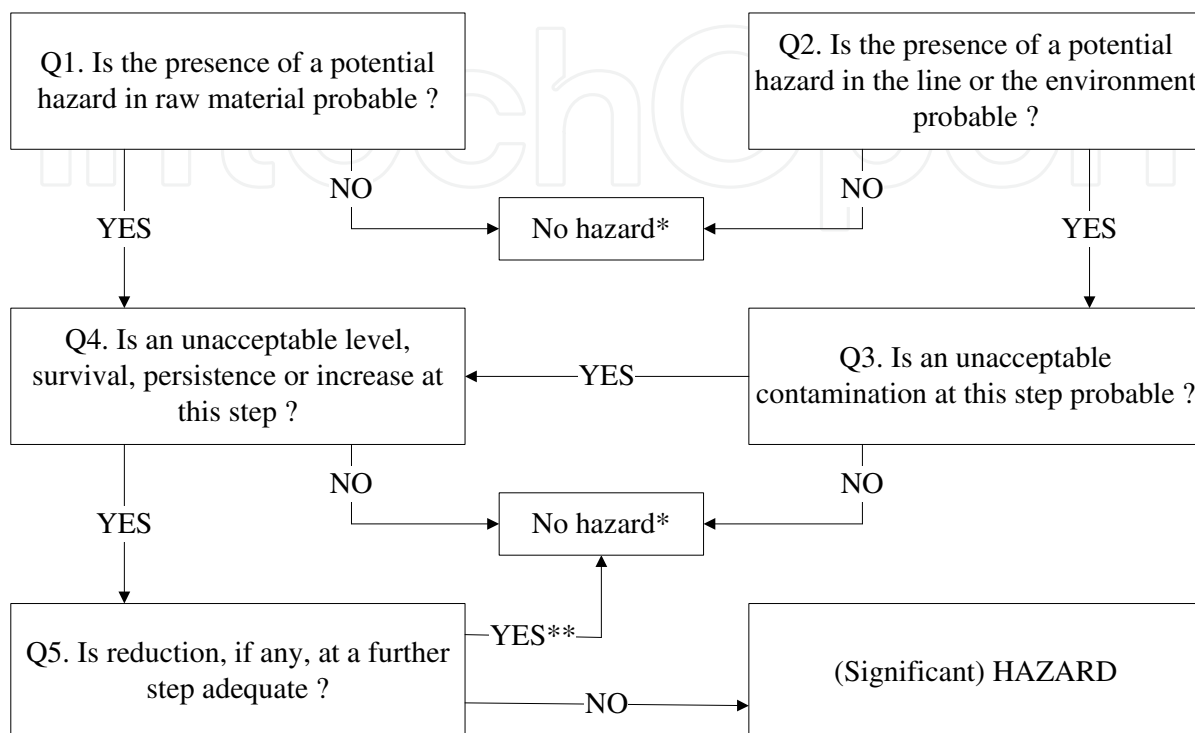


Fig. 6. Hazard analysis (decision tree)

It is generally agreed that risk assessment should be an independent scientific process, distinct from measures taken to control and manage the risk. The overall risk analysis process includes risk assessment, risk management and risk communication, and also involves political, social economic and technical considerations (ILSI, 2001; Serra et al, 1999; Sperber, 2001) reported that hazard analysis was qualitative and risk assessment was quantitative process. Therefore risk assessment after hazard analysis done has to be quantified. It was stated that risk assessment was a compound of probability and severity (Barendsz, 1998). In this study, probability and severity of the hazards are considered as a five class hazard score matrix. This is shown in Table 10. Significant hazards found in hazard analysis (Table 9) are used for determination of risk assessment by five class hazard score matrix which was given in Table 11. Microorganisms in both meat and additives are found to be 4<sup>th</sup> risk class (Table 11) by risk analysis after determining hazard analysis. Interestingly almost all processes are classified as 4<sup>th</sup> risk class.

ISO 22000-Food safety management system standard requires definition of all hazards starting from raw materials to finished products in the plant (clause 7.4.2. of ISO 22000-FSMS). In the mean time, the possible severity of unfavorable health effects and the likelihood of their occurrence have to be evaluated (clause 7.4.3. of ISO 22000-FSMS). After assessment of hazards, control measures have to be considered for preventing, eliminating, or reducing these food safety hazards to be defined acceptable level (clause 7.4.4. of ISO 22000-FSMS) (ISO, 2005).

Table 9. Failure mode and effect analysis of sucuk manufacturing process  
 \*Fish bone diagram (Figure 6), \*\* Hazard analysis (Figure 7), SH: Significant hazard

Process name/step	Process descriptions	Potential Hazards	Cause analysis*
			Causes (Sources and reasons)
Raw Material Reception (meat)	Meat is receptioned and analyzed (Microbiological, antibiotic)	B: microorganisms C: antibiotics, hormones, biogenic amines (BA) P: bone pieces	Farm environment, slaughtering BA are generated in course of microbial and animal metabolism. Slaughtering
Raw Material Reception (Additives, Spices )	Additives and spices are receptioned and analyzed (Microbiological, foreign matter, insects)	B: microorganisms C: pesticide residues, mycotoxins P: metal	Handling, processing Mycotoxins produced by m.o. under undesirable storage and processing conditions. Agricultural harvesting
Meat storage	Storage between 0-4 °C.	B: microorganisms	Temp. increase
Mincing	Spices and additives addition	B: microorganisms C: insufficient nitrate and nitrite addition P: metal contamination	Temp. increase during mincing Process formulation Equipment
Conditioning	12 hr between 0-4 °C.	B: microorganisms	Temp. inc. during conditioning
Mincing and kneading	Addition of tail fat and mincing of meat dough	B: microorganisms P: metal contamination	Temp. increase during mincing Equipment
Filling	Filling into casings	B: microorganisms P: tearing, air pockets	Natural casings Processing
Fermentation /ripining	Decrease in pH	B: microorganisms C: residual of nitrate and nitrite	Processing Processing
Metal detection	Metal detection	P: metal residue	Metal analysis
Product storage	50% RH and 30 °C	B: microorganisms	Storage



			Risk Classes					
Severity	Catastrophic	Death or lasting damage	E	3	4	4	4	4
	Critical	Many concerned people and lasting or continuous damages	D	3	3	4	4	4
	Serious	Many concerned people, no lasting damages	C	2	3	3	4	4
	Low	Single case, no lasting damages or minimal concentration	B	2	2	3	3	4
	Ignorable	Hazard to be discovered prior to consumption or minimal indisposition	A	1	2	2	3	3
Control measures				I	II	III	IV	V
Risk classes	1. No measure necessary.			Unlikely (< per 1 years)	Rare (per year)	Occasional (per semester)	Frequent (per month)	Very frequent (per week)
	2. Periodic measures are measures which often cover a one-time activity.							
	3. General control measures and prerequisite programs							
	4. Specific control measures are specifically developed and used to control the risk.							
				Probability				

Table 10. Five-class hazard scoring matrix

#### 4.5.1 Critical control points in the sucuk processing

Critical control points are location, operation, procedure, or process where control can be carried out to remove the hazards for food safety or to reduce them to an acceptable level. Critical control points of Bulgur processing were determined. A decision tree was used for determining steps which could be designated as critical control points (ILSI, 2004; Bolat, 2002; Lee & Hathaway, 1998; Sandrou & Arvanitoyannis, 2000a, 2000b; Arvanitoyannis & Mauropoulos, 2000) (Figure 7). Critical control points of sucuk processing are listed on Table 11.

After questioning, all processing steps of traditional sucuk manufacturing are found to be in CCP structure. Significant hazards at those processes have to be followed by special monitoring systems.

Critical limits are minimum and/or maximum values to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level to the occurrence of a food safety hazard. These limits show if the identified hazards can be put under control or not. Critical limits may be determined for factors like temperature, time, physical dimensions, etc. Critical limits for each critical control points for sucuk processing were evaluated on Table 12. These were taken from literature, legal provisions, or from comparable standard procedures. Identified CCPs have to be and to be controlled in HACCP plan as defined in clause 7.6.2. of ISO 22000-FSMS.

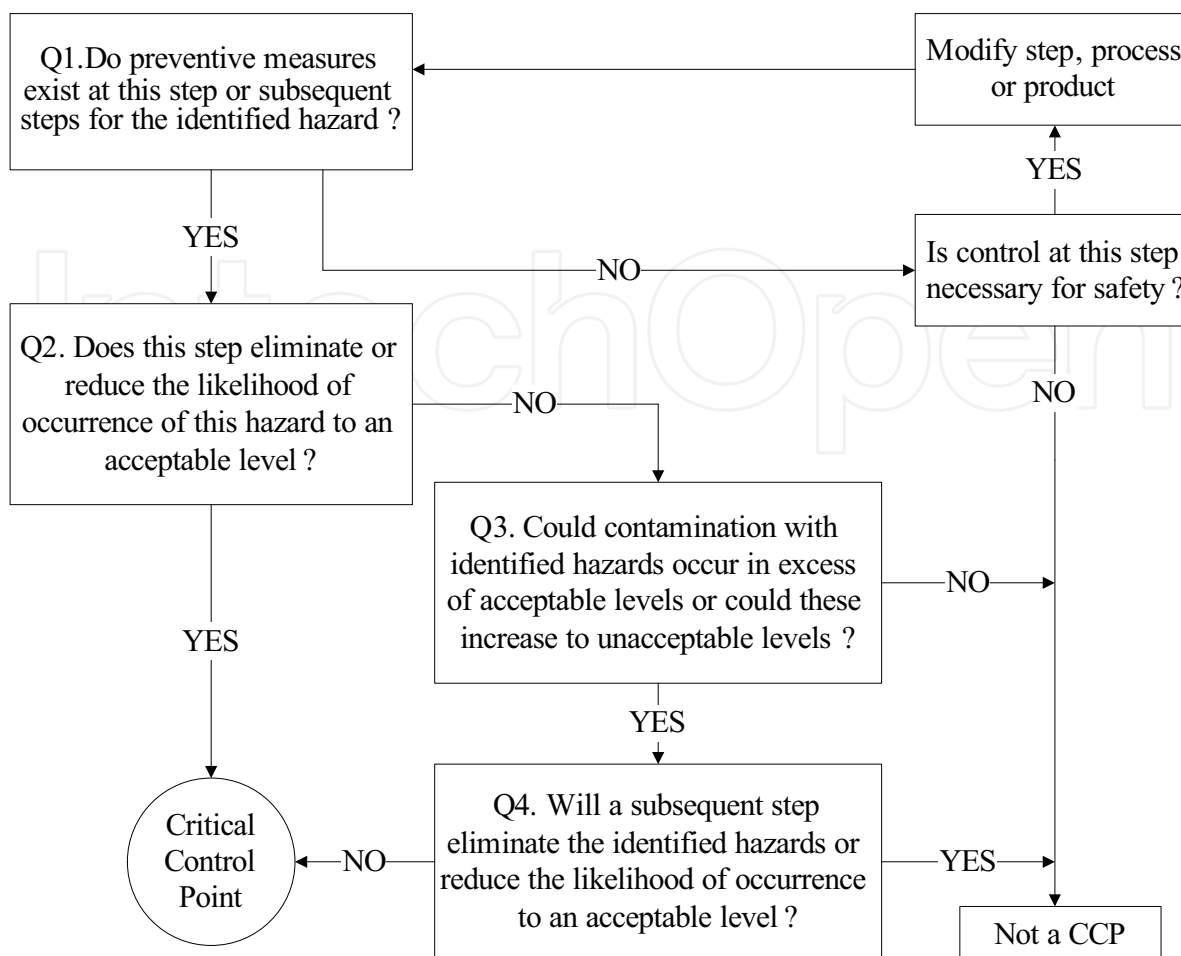


Fig. 7. CCP analysis (Decision tree)

**4.5.2 Implementation of HACCP system-HACCP plan**

Ideally, a HACCP study should be carried out as part of product and process development, so that potential hazards can be “designed out” at the earliest stage. In any case, a HACCP study results in a HACCP plan that should be correctly implemented to ensure that the appropriate control measures are put in place before products are put on the market.

The HACCP plan is a controlled document which consists of significant hazards, critical control points, critical limits for each hazard at each CCP, monitoring procedures for each hazard at each CCP, and corrective actions if critical limits are exceeded. Some hazards are considered to be control points (CPs) because the hazards can be controlled by prerequisite programs (Derosier et al., 2002).

Monitoring is systematic and planned observation to make sure that CCPs are under control. When monitoring results show that criteria are not met, appropriate and immediate precautions should be taken to correct the deviations. For example, corrective actions may be re-heating or re-operating, increasing the operation temperature, extending operation time, decreasing pH, changing equipment of measurement, changing equipment of process and maintaining, extra training for employees, revising HACCP documents, change in process flow, etc. Procedures should be improved for corrective actions (Arvanitoyannis & Traikou, 2005; Efstratiadis & Arvanitoyannis, 2000).

Process name /step	Significant hazards	Risk assessment*			Preventive actions/control measures	CCP analysis (Y/N)**				
		S	P	RC		Q1.	Q2.	Q3.	Q4.	no:
Raw Material Reception (meat)	B: microorganisms	E	IV	4	Certified suppliers with HACCP program, Microbiological analysis	Y	N	Y	N	1b
	C: antibiotics, hormones, biogenic amines (BA)	E	III	4	Chemical analysis	Y	N	Y	N	1c
	P: bone pieces	B	III	3	Physical observations	Y	Y	-	-	1p
Raw Material Reception (Additives, spices)	B: microorganisms	D	IV	4	Certified suppliers with HACCP program, Microbiological analysis	Y	N	Y	N	2b
	C: pesticide residues, mycotoxins	B	III	3	Chemical analysis	Y	N	Y	N	2c
	P: metal	B	II	2	Metal detector	Y	N	Y	Y	2p
Meat storage	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	3
	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	4b
Mincing	C: insufficient nitrate and nitrite addition	E	III	4	Chemical analysis	Y	N	Y	N	4c
Conditioning	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	5
Mincing and kneading	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	6
	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	7b
Filling	P: tearing	C	IV	4	Physical observations	Y	N	Y	N	7c
	B: microorganisms	E	III	4	Temp. control	Y	N	Y	N	8b
Fermentation/ripening	C: residual of nitrate and nitrite	E	III	4	Chemical analysis	Y	N	Y	N	8c
	P: metal residue	E	III	4	Calibration	Y	Y			9
Product storage	B: microorganisms	E	II	4	Temp. control	Y	N	Y	N	10

\*Risk assessment (Table9), \*\*CCP analysis (Figure 8), S: severity, P: probability, RC: risk class

Table 11. Risk assessment and CCPs in the processing of sucuk

Natural casings must be controlled for each batch. Temperatures of storage, mincing, conditioning and fermentation processes have to be monitored. Monitoring results should be continuously recorded.

Verification is the effort to determine whether the HACCP plan is valid and whether the system operates as planned or the HACCP plan is scientifically and technically evaluated. All stages in the process should be documented in order to enable retrospective observation, verification, and validation of the HACCP system. A recording procedure should be

Process name/step	CCP No:	Significant hazards	Critical limits	Monitoring**			Corrective action
				M.	F.	R.	
Raw Material	1b	B: microorganisms	*	MA	EB	LT	Reject
Reception (meat)	1c	C: antibiotics, hormones	No	CA	EB	LT	Reject
	1p	P: Bone pieces	No	CA	EB	LT	Reject
Raw Material Reception (Additives, spices)	2b	B: microorganisms	Usually no, depends on types of spice and additives	MA	EB	LT	Reject
	2c	C: pesticide residues, mycotoxins	No	CA	EB	LT	Reject
	2p	P: metal	No	CA	EB	LT	Reject
Meat storage	3	B: microorganisms	*	MA	EB	LT	Discard
Mincing	4b	B: microorganisms	*	MA	EB	LT	Discard
	4c	C: insufficient nitrate and nitrite addition	150 ppm nitrite, 300 ppm nitrate	CA	EB	LT	Discard
Conditioning	5	B: microorganisms	*	MA	EB	LT	Discard
Mincing and kneading	6	B: microorganisms	*	MA	EB	LT	Discard
Filling	7p	P: tearing, air pockets	No	PE	EB	LT	Discard
	7b	B: microorganisms	*	MA	EB	LT	Discard
Fermentation/ ripening	8b	B: microorganisms	*	MA	EB	LT	Discard
	8c	C: Biogenic amine	Depends on types of amines	CA	EB	LT	Discard
Metal detection	9	P: Metal residue	No	Metal detector	EB	LT	Discard
Product storage	10	B: microorganisms	*	MA	EB	LT	Discard

\* Microorganisms limits: No E.coli,  $5 \times 10^2$  S. aureus, No Salmonella (Anon 2000)

\*\* MA: Microbiological analysis, CA: Chemical analysis, PE: Physical examination, EB: Every batch, LT: Lab. technician M: Method, F: Frequency, R: responsible

Table 12. HACCP plan for the processing of sucuk

prepared documenting the methods applied and the procedures followed. Verification should be implemented through internal audits with involves reviewing the pre-requisites, the hazards and risk assessment, critical control points, and critical limits.

The followings should be included in the HACCP plan according to the clause 7.6.2. of ISO 22000-FSMS; food safety hazards to be controlled at the CCP, control measures, critical limits, monitoring procedures, corrective actions to be taken if critical limits are exceeded, responsibilities, authorities and records of monitoring.

#### 4.5.3 Quality system for the sucuk processing

ISO 9000:2000-QMS consisted of quality systems that focused on documenting all quality assurance and improvement processes in a company (ISO, 1999). Although the ISO 9000:2000-QMS was originally developed for the manufacturing sector, it had been applied to many service organizations and was gaining some acceptance in the food industry.

As seen in Figure 1., ISO 9000-QMS standard is consisted of five main parts. Namely; these are Quality management system, Management responsibility, Resource management, Product realization, Measurement, analysis and improvement. Standard articles are in Deming's cycle (PDCA) are continuously improved. The standard is worked out by essential processes. The processes are classified as strategic, operational and supportive processes are shown in Table 2. As seen in Figure 1, those processes cover all articles of the standard and also some procedures along with these processes are mandatory.

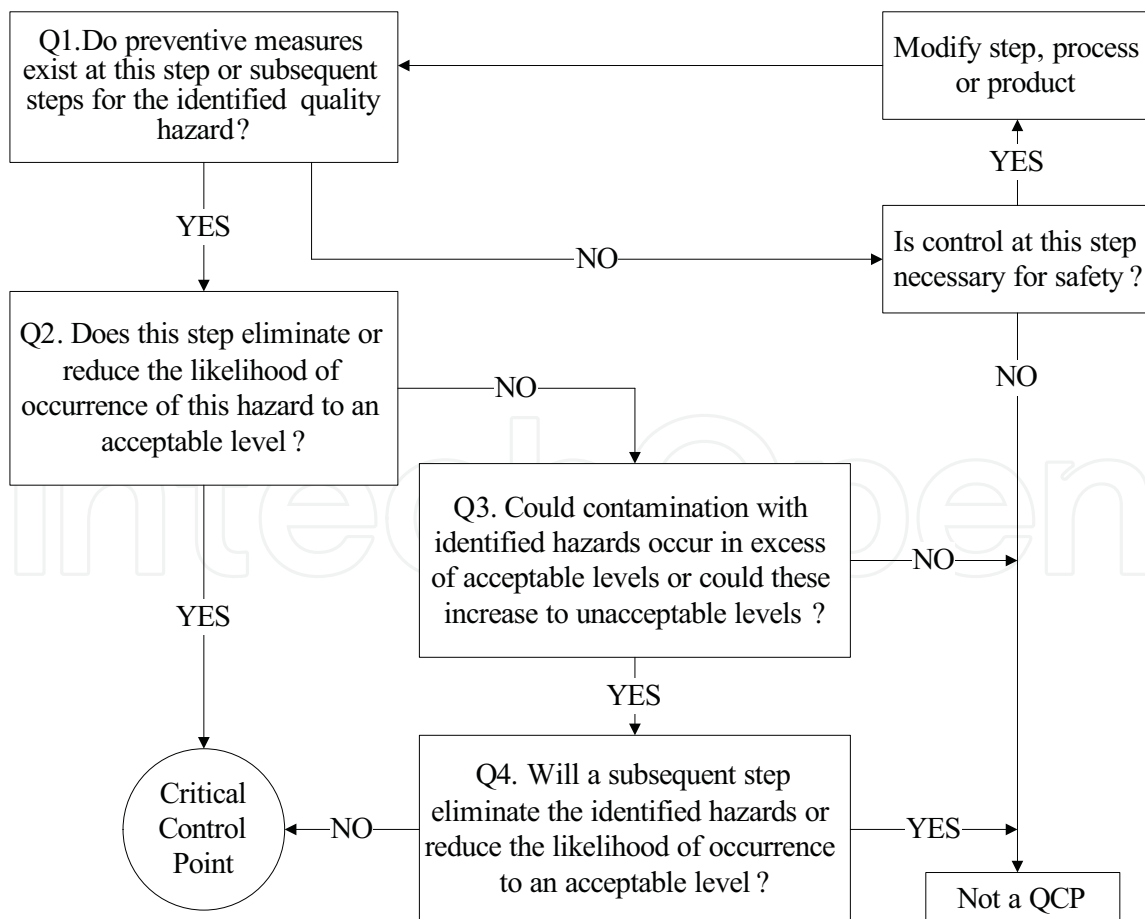


Fig. 8. Quality control points analysis (Decision tree)



Traditional sucuk processing is not a long-chain process. However, biological processes are usually involved in sucuk processing. Quality parameters of sucuk processing in small scale plants are affected by technological and administrative applications. Quality parameters of sucuk processing and quality hazards in the process are given in Table 13.

Quality control point (QCP) means a procedure where a control can be applied and a quality hazard (for example, taste, appearance, nutrition, color and so on) can be prevented, eliminated or reduced to acceptable levels (Figure 8).

Raw materials reception, mincing, conditioning, fermentation and ripening processes are analyzed as quality control points (Table 14). Defects on meat and additives directly affect quality, are however not able to be eliminated through the process. Color is an important quality parameter during many processes. Color of the sucuk is desired to be bright red color. This is usually controlled by temperature and other processing parameters as well as by addition of nitrite/nitrate. Critical limits, monitoring and corrective actions of quality parameters determined through the QCPs are given in Table 13.

Process name/step	Quality Hazard	Preventive actions/control measures	QCP analysis (Y/N)*				
			Q1.	Q2.	Q3.	Q4.	no:
Raw Material Reception (meat)	Rigor meat, dark or light red color, acidity	Effective supplier assurance	Y	N	Y	N	1
Raw Material Reception (Additives, spices )	Not having their specific color and flavor etc.	Effective supplier assurance	Y	N	Y	N	2
Meat storage	Color	Time and temp. control	Y	N	Y	N	3
Mincing	Color	Temp. control	Y	N	Y	N	4
Conditioning	Color, juiciness, drip loss	Temp. control	Y	N	Y	N	5
Mincing and kneading	Heterogeneous ingredients distribution	Cutter operation parameters control	Y	N	Y	N	6
Filling	Heterogeneous fat appearance on natural casings, bursting of casings	Casing control	Y	N	Y	N	7
Fermentation/ ripening	Dark red color, Water lost, Soft or hard texture formation, case hardening, pH	Time, temp. and relative humidity control	Y	N	Y	N	8
Metal detection							
Product storage	Water lost or gain	Temp. and relative humidity control	Y	N	Y	N	9

Table 13. QCPs in the processing of Sucuk

QCP No:	Process name /step	Quality parameter /hazard	Limits	Monitoring			Corrective action
				M.	F.	R.	
1	Raw Material Reception (meat)	Rigor meat, dark or light red color, acidity	Bright red color	VE	EB	LT	Reject
2	Raw Material Reception (Additives, Spices )	Not having their own specific color and flavor etc.	Their own specific color and flavor etc.	VE	EB	LT	Reject
3	Meat storage	Color	Bright red color	VE	EB	LT	Adjustment of nitrate level
4	Mincing	Color	Bright red color	VE	EB	LT	Adjustment of nitrate level
5	Conditioning	Color, juiciness, drip loss	Bright red color	VE	EB	LT	Adjustment of nitrate level
6	Mincing and kneading	Heterogeneous ingredients distribution	Mosaic appearance	VE	EB	LT	Reprocess
7	Filling	Heterogeneous fat appearance on natural casings, Bursting of casings	no	VE	EB	LT	Reprocess
8	Fermentation/ ripening	Dark red color, Water lost, Soft or hard texture formation, Case hardening, pH	40 % water content, pH:5.4	VE & CA	EB	LT	Reprocess
9	Product storage	Water lost or gain	40 % water content	VE & CA	EB	LT	Reclassify

\*\* VE: Visual examination, CA: Chemical analysis, EB: Every batch, LT: Lab. technician M: Method, F: Frequency, R: responsible

Table 14. Quality plan for the processing of Sucuk

## 5. Conclusion

The SPC techniques in food processing operations can play an important role of quality control and safety. The use of SPC techniques enables plant operators to take corrective actions quickly when needed before the variation affects significantly the CCPs of the plant. Traditional sucuk processing was used as a demonstrated process and some simple SPC techniques were used as the tools. Pareto analysis indicates that the priority problems of customer complaints. First five problems, namely off flavor, rancid, off color, poor texture and too oily cover approximately 90 % of total complaints. Control charts show that the process is in statistical control for moisture content in traditional sucuk production line. The control charts did not show out-of-control conditions in this study. Of course, we may expect out-of-limits. The pH change during ripening was modeled to Logistic equation. Scatter diagram of this change indicated a decrease and a leveling in pH after 5 days.

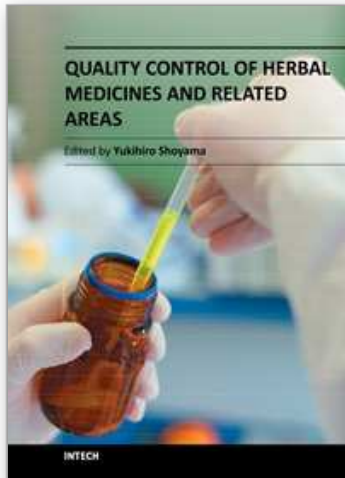
In this work, an effort was made for safety and quality parameter analyses (e.g. Failure mode and effect) of traditional sucuk production by describing and outlining the incoming

hazards in every process stage, starting from raw materials to the final product. Hazard, cause and risk analyses for traditional sucuk production lead to have CCPs in every production steps. All production steps were also determined to be quality control points. A more efficient correction of the process is possible by use of these SPC tools.

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## **Quality Control of Herbal Medicines and Related Areas**

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The authors of this thematic issue provide a comprehensive summary of most recent knowledge and references on quality control in wide fields. Quality control is essential for natural products like natural medicine and related food products. In this issue fifteen chapters have been included, discussing in detail various aspects of quality control. It will certainly prove useful not only for phytochemical researchers, but also many scientists working in numerous fields. Much effort has been invested by the contributors to share current information. Without their efforts and input 'Quality Control of Herbal Medicine and Related Areas' could not exist.

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