

FAILURE MODE AND EFFECT ANALYSIS (FMEA) FOR FERMENTED DAIRY  
PRODUCTS

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FAILURE MODE AND EFFECT ANALYSIS (FMEA) FOR FERMENTED DAIRY  
PRODUCTS

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## ABSTRACT

### **FAILURE MODE AND EFFECT ANALYSIS (FMEA) FOR FERMENTED DAIRY PRODUCTS**

Fermented dairy products are the major part of the diet in Turkey. Controlling the risks effectively by selecting and implementing appropriate measures during the production is very important since this measures increase the quality of food products, protect the public health and consumer's trust. In onsite visits, it has seen that prevailing food safety programs might not be sufficient to control the potential hazards during processing. Failure Mode and Effect Analysis (FMEA) is a widely used tool for quality assurance in many manufacturing industries, addressing customer and governmental requirements, quality control and safety. In this study, FMEA methodology has been applied for the risk assessment of yogurt, ayran, kefir, dil cheese, plaited cheese, kashar cheese, cultured white cheese, and traditional white cheese productions. The process flow diagrams for production of the selected dairy foods are constructed based on the most common processes observed during onsite visits to 30 different dairy producing companies in different regions of Turkey. Possible failure modes in the process are identified and the potential hazards for each failure mode are analyzed. The Risk Priority Numbers (RPN) were calculated from multiple of three variables; frequency of occurrence (O) for each failure, seriousness of the failure (S), and possibility of detecting the failure (D); to identify the risk level of each potential failure. Possible corrective actions are suggested for each potential failure mode with risk priority numbers higher than 100. At these points, the RPNs are recalculated to understand the influence of corrective actions on the improvement of the process. The highest total RPN values are calculated for raw material receiving filling/packaging, dry matter adjustment, resting in brine, dry blanching and blanching in water steps in dairy food processes. Improper hygiene, staff practices and cleaning operations are found to be the basic reasons for failure modes. Implementation of FMEA methodology in dairy food manufacturing reduced the RPNs by 81-82% and therefore improved the safety and quality of final products for all processes.

## ÖZET

### FERMENTE SÜT ÜRÜNLERİNDE HATA MODU VE ETKİ ANALİZLERİ (FMEA)

Türkiye'deki sofralarda fermente süt ürünleri önemli bir yere sahiptir. Gıda ürünlerinin kalitesini arttırmak, tüketici sağlığını ve tüketici güvenini korumak için gıda güvenliği risklerini, uygun ölçümleri seçip uygulayarak, etkin bir biçimde kontrol altına almak oldukça önemlidir. Denetimler sırasında mevcut gıda güvenliği sistemlerinin risk değerlendirmede ve kontrolünde yeterli gelemeyebildiği tespit edilmiştir. Hata modu ve etki analizleri (FMEA), dünya çapındaki çeşitli sektörlerin üretim aşamalarında müşteri ve yasal isteklerin düzenlemesi, kalitenin ve güvenliğin sağlanması amacıyla yaygın olarak kullanılmaktadır. Bu çalışmada, yoğurt, ayran, kefir, dil peyniri, örgü peyniri, kaşar peyniri, klasik beyaz peynir ve kültürlü beyaz peynir ürünlerinin üretim aşamaları için FMEA metodolojisi uygulanmış ve risk değerlendirmeleri yapılmıştır. Bu ürünlerin üretim iş akış şemaları, Türkiye genelindeki 30 farklı süt işletmesinin denetimleri sırasında yapılan gözlemlerle, geneli yansıtabilecek şekilde düzenlenmiştir. Üretim aşamalarındaki muhtemel hata modları belirlenmiş ve her hata modu için potansiyel tehlikeler tanımlanmıştır. Her bir potansiyel hata için, hatanın oluşma olasılığı (O), hatanın ciddiyeti (S) ve tespit edilebilirliği (D) olmak üzere üç değişken belirlenmiş ve buna bağlı olarak risk önceliği sayısı (RPN) hesaplanarak risk seviyeleri tanımlanmıştır. RPN değeri 100'den büyük bulunan her bir potansiyel hata için muhtemel düzeltici faaliyetler önerilmiştir. Düzeltici faaliyetlerden sonraki RPN değerleri yeniden hesaplanarak, düzeltici faaliyetin etkileri takip edilmiştir. En yüksek RPN değerleri hammadde alımı, dolum/paketleme aşamaları, kuru madde ayarlama aşaması, salamura dinlendirme aşaması ve kuru ve sulu haşlama aşamalarında hesaplanmıştır. Temelde en yaygın potansiyel hataların hijyen uygunsuzlukları, personel kaynaklı hatalar ve temizlik uygunsuzlukları olduğu gözlemlenmiştir. Fermente süt ürünleri üretimine FMEA metodolojisinin uygulanması sonucunda RPN değerlerinde %81-82 oranında düşüş yaşanmış, sonuç olarak da son ürün kalitesinde ve güvenliğinde iyileşme yaşanmıştır.

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## 1. INTRODUCTION

Food-borne disease can be defined as any disease caused by agents, which enter body through food. According to World Health Organization (WHO), food-borne diseases are widespread and becoming more and more serious for both developed and undeveloped countries all over the world. Although it is nearly impossible to obtain worldwide exact consequences of food-borne diseases, WHO reported that 1.8 million people died from diarrheal diseases in 2005 and most of these cases were caused by infected foods [1]. According to The Centers for Disease Control and Prevention (CDC), every year approximately 6 to 81 million people get food-borne disease in the USA and 9000 cases results in death [2, 3].

Dairy products are responsible for approximately 8.3 % of the biological origin food-borne disease outbreaks in the world [4]. The annual worldwide milk production is approximately 695 million tons. In 2010, 6 745 011 tons of cow's milk are collected in Turkey [5, 6]. TUIK's Dairy Products' Production Statistics indicate that 6 745 011 tons of cow's milk are collected in 2010 in Turkey. 1.090.604 tons of drinking milk, 908,269 tons of yogurt, 453,057 tons of cheese and 397,935 tons of ayran have been produced from the collected milk [6]. These numbers reveal the importance of dairy products in terms of food safety.

Problems in risk assessment and evaluation were observed in most of the companies during on-site food safety audits carried out in all regions of Turkey. It has seen that, traditional Hazard Analysis and Critical Control Points (HACCP) based food safety systems are not always an effective way to eliminate all risks in production. This thesis aims to apply a new safety methodology, Failure Mode and Effect Analysis (FMEA), to dairy processes.

## 2. THEORETICAL BACKGROUND

### 2.1. MILK

Milk is an important nutrient for daily diet. It has 85.5-89.5% water, 2.5-6% fat, 3.6-5.5% lactose (milk sugar), 2.9-5.0 milk proteins and 0.6-0.9% minerals. The composition of milk may show variations depending on the breed of animals, seasonal conditions, and feeding quality of animals, [7].

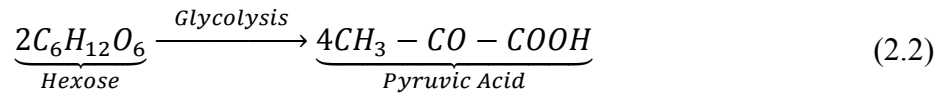
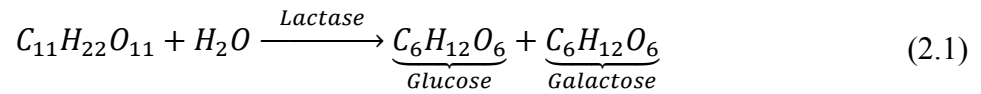
For the purpose of this thesis, cow's milk and cow's milk products are analyzed. In other words, 'milk' refers to cow's milk in this study. Although the composition shows variations milk has 85.5-89.5% water, 2.5-6% fat, 3.6-5.5% lactose (milk sugar), 2.9-5.0 milk proteins and 0.6-0.9% minerals depending on the breed of animals, seasonal conditions, and feeding quality of animals, [7].

### 2.2. FERMENTATION

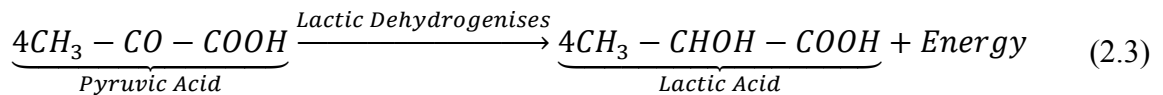
Fermentation is degradation of carbohydrates in foods to different components such as alcohol, carbon dioxide, lactic acid, and acetic acid by microbiological agents [7, 8]. Fermentation has been used since ancient times to increase the shelf-life of food products, to enhance the flavor, texture and the aroma of the food products.

Properties of the end product depend on the type of microorganisms that are used in the fermentation process. In milk fermentation, lactose (milk sugar) is degraded to pyruvic acid by glycolysis, with the help of microorganisms. These acting microorganisms and products are lactic acid bacteria, which synthesize lactic acid, propionic acid bacteria, which synthesize propionic acid, yeast, which produce alcohol, *Clostridium* spp., which synthesize butyric acid and *Coli aerogenes* spp., which synthesize acetic acid, alcohol, acetoin and butanediol [7-11]. Chemical equations of pyruvic acid and lactic acid fermentations are shown in equations 2.1-3 [7-11].

Pyruvic acid fermentation;



Lactic acid fermentation;



Lactic acid leads to gel formation in yogurt, ayran and kefir productions. In cheese processing lactic acid decreases the pH of the medium to help achieving optimum enzyme activity. Other fermentation metabolites are being used for aromatic properties and they also give the characteristic properties of products. In the industry, fermentation of milk can be either spontaneous or achieved by using special cultures. Spontaneous fermentation is a long and a risky process. The quality and safety of products cannot be assured at all times. Therefore, most companies are working with specially prepared cultures. A single strain, multiple strain or mix-strain starter cultures are prepared either industrialized ways or at laboratory. By this selection, not only the production but also some benefits such as inhibition of pathogenic microorganisms, flavor and aroma generation and obtaining stabilized quality can be gained [7-10].

## 2.3. FERMENTED DAIRY PRODUCTS

### 2.3.1. Ayran, Kefir and Yogurt

According to TUIK yogurt is the most popular fermented dairy product in Turkey [6]. Yogurt can simply be described as a coagulated milk product that results from fermentation of lactose in milk by *Lactobacillus bulgaricus* and *Streptococcus thermophilus* [12, 13]. The standards of gel formed yogurt's (set yogurt) are given in

Turkish Food Codex. According to the codex yogurt should have minimum of 3% milk protein, and 0.6% to 1.5% titratable acidity (lactic acid in weight). The fat content should be more than 3.8% for the full-fat yogurt 1.5-2% for the semi-skimmed yogurt and less than 0.5% for the fat-free yogurt [13].

Ayran is a traditional drink which is highly consumed in Turkey [6]. Traditionally, yogurt is mixed with salt and water to make ayran. Although the traditional way is simpler, in industry ayran is made from milk. Solid content of milk is lowered with water addition, than it is fermented with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Both methods are given in the Turkish Food Codex and the products are named as “Ayran” [13]. According to the codex ayran should have minimum of 2% milk protein, 0.5% to 1.0% titratable acidity (lactic acid in weight). Total fat content should be more than 1.8%, for full-fat ayran 0.8 to 1.2% for semi-skimmed ayran and less than 0.5% for fat-free ayran [13, 14].

Kefir is a fermented dairy product. Fermentation occurs either with the help of natural microorganisms on kefir grains or bacterial cultures such as *Lactobacillus kefiri*, *Leuconostoc* spp., *Lactococcus* spp., *Acetobacter* spp., lactose fermenting yeast (*Kluyveromyces marxianus*) and yeast which does not ferment lactose (*Saccharomyces unisporus*, *Saccharomyces cerevisiae* and *Saccharomyces exiguus*) [13, 15, 16]. However, mixed cultures are used rather than kefir grains to achieve controlled fermentation in most industrialized kefir productions,

Ayran, kefir and yogurt are rich in nutrients. The vitamin and mineral compositions are similar to milk. Vitamins B12 and C are consumed by microorganisms and folic acid is produced during fermentation. Some minerals such as calcium are more bioavailable from these products compared to milk. In addition, kefir, ayran and yogurt have less lactose and more lactic acid, galactose, peptides, free amino acids, and free fatty acid compared to milk. In addition, immunologic enhancers and lactic acid bacteria found in these products that may help in controlling intestinal infections, some types of cancer, serum cholesterol levels, and improve digestion of lactose [12, 16-18].

Production processes of these products are very similar. For example, the only difference between kefir and ayran production is the culture used for fermentation. Production steps are given in at appendix part (Figure A.2, Figure A.4 and Figure A.5).

### **2.3.2. Cheese**

Milk is coagulated with organic acids or enzymes such as rennet, to make cheese. After coagulation whey is removed, salt is added and curd is shaped. Cheese can be consumed fresh or ripe. [8].

Coagulation of casein, milk protein, is essential for cheese making. Approximately 80% of milk protein is casein. Casein micelles are in calcium-caseinate-phosphate form. Isoelectric point of casein is between pH 4.6-4.7. Therefore, for coagulating casein organic acids such as lactic acid or enzymes are used. Rennin is the most widely used proteolytic enzyme in cheese industry. It is produced in rennet form abomasums of infant cow and consists of approximately 70-95% rennin and 5-30% of pepsin. Rennet is also produced by genetically engineered microbiological cultures. Optimal working conditions are pH between 6.2-6.4 and temperature between 20-40 °C. The main reason for using rennin is coagulating the milk, but 5-8% of it remains in cheese and shows low proteolytic activity during ripening which gives a characteristic flavor to cheese.[7, 8, 10]

Depending on processes, cultures used, shaping and ripening conditions, cheese can be classified in different groups. The most commonly consumed cheeses in Turkey are kashar and feta cheese groups. Kashar can be described simply as cooked cheese. Curds are cooked with salty water or pressured cooking [19-22]. The best known ones are kashar, dil cheese and plaited cheeses. Differences among these products are associated with what is done after blanching. While kashar cheese is molded after blanching, dil and plaited cheese are rested in brine. All kashar group cheeses have elastic structure initiated by blanching. During blanching, casein micelles combine together and give elastic and fibrous structure to the cheese. Dil is a semi-hard cheese with a characteristic fibrous texture. It is named after its shape, which resembles a tongue. Plaited cheese is made by shaping the cheese strings like pony tail shape of hair. After, cheese is rested on brine. Plaited cheese is semi-



hard and has a compact texture due to scalding and shaping, a salty taste and a whitish or yellowish color changes according to beta-carotene content of milk [7, 8, 19-23]. Production steps of these cheeses are given in appendix part (Figure A.3, Figure A.6 and Figure A.7).

White cheese is one of the most popular cheese in Turkey. There are several types of white cheese but the mostly consumed ones are cultured white cheese and traditional white cheese. White cheeses are generally cubical ( $7 \times 7 \times 7 \text{ cm}^3$ ) or rectangular ( $7 \times 7 \times 10 \text{ cm}^3$ ) in shape with no rind and weighing 350–500 g/block. Depending on the moisture content, it may have semi hard or semi soft structure. Main difference between these white cheeses is fermentation process. While in cultured white cheese, acidity of milk is adjusted by the microbial culture, traditional white cheese is produced by spontaneous fermentation. As mentioned before, in spontaneous fermentation food safety cannot always be assured, therefore traditional white cheeses are ripened in cold rooms for 3-6 months. During ripening, lactic acid bacteria resume fermentation. Acidity and secondary metabolites produced by these bacteria kills the pathogenic microorganisms [7, 8, 10, 19, 24, 25].

#### **2.4. FOOD SAFETY**

Food-borne disease is caused by agents, which enters in to the body with any kind of food. Food-borne diseases are almost as old as mankind's history and number of the cases are continuously increasing [26]. Some of the cases are related to food supply system such as mass production and distribution which may increase opportunity for contamination, and also wider food-borne disease outbreaks may occur. Massive agriculture and animal husbandry production increase the opportunity for contamination of raw foods. The pesticide and veterinary drug contaminated foods can easily internationally be traded and imported. Massive food distribution may increase the opportunity for contamination; survival and growth during transportation and longer food chains can get more difficult to control staff applications. Some of the food-borne diseases are related to health and demographic situation of the consumers such as population growth, which can increase the number of sensitive consumers like infants, elderly and immunologically sensitive people. Some of the food-borne diseases are related to lifestyles such as increased food

consumption outside home, increased rate of travel and exposure to unsafe food, poverty, increased demand on ready to eat foods. There are also some food-borne diseases related to the environmental conditions such as pollution [27]. As a result, consumers are faced with more hazardous foods as time passes.

Hazard is also an important term in food safety. Hazard means “probability to cause harm” and hazards are classified as physical, chemical and biological. Physical hazard term refers to any physical material that can cause a physical harm by taking food such as stones, metals, glass, plastic particles and wood particles. By taking these materials, illnesses such as broken tooth, damaged tongue and mouth, damage to stomach and esophagus [5, 26-43] may occur.

“Chemical hazard” refers to any chemical agent that can cause either an acute disease or disease that may come from its accumulation such as cancer. These chemical agents can either come from food itself, or from external contamination prior to ingestion. Some of the common chemical agents that can cause food-borne diseases are pesticides, veterinary drugs, heavy metal residues, lubricants, and toxins coming from mushrooms, algae and molds [5, 26-43].

Biological hazards are caused by pathogenic organisms such as parasites, viruses and bacteria found in foods [5, 26-43]. Generally, most of the food-borne illnesses are related to microbiological agents such as *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O:157, *Listeria monocytogenes*, *Salmonella* spp., *Shigella* spp., *Vibrio cholera*, *Campylobacter jejuni*, Norovirus, Hepatitis A virus. By consuming foods contaminated with these pathogens, several diseases from diarrhea to death can occur. In addition to this, parasites such as *Cryptosporidium*, *Cyclospora*, *Giardia*, and *Toxoplasma*, flatworms, flukes, tape worms are a massive problem, especially, in under developed countries [44, 45].

These potential hazards bring the term food safety, which means a food that does not contain any of these hazards.

## **2.5. FOOD SAFETY MANAGEMENT SYSTEMS**

### **2.5.1. HACCP**

HACCP was developed in the 1960s by the Pillsbury Company, the U.S. military and NASA have collaborated to develop a system for producing safe food for the space program. Indeed, NASA wanted them to develop a program of total elimination of defects to ensure food security for its astronauts. In 1971, at a conference on food protection, the Pillsbury Company presented the principles of HACCP. Currently, HACCP is recognized as the most reliable guarantee of food safety by many international bodies [5].

In both Europe and Turkey, HACCP principles are defined at legislations and are mandatory for companies to apply. According to Codex Alimentarius Commission [46], these principles in;

- Conduct a hazard analysis.
- Determine the Critical Control Points (CCPs).
- Establish critical limit(s).
- Establish a system to monitor control of the CCP.
- Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- Establish procedures for verification to confirm that the HACCP system is working effectively.
- Establish documentation concerning all procedures and records appropriate to these principles and their application.

### **2.5.2. ISO 22000**

ISO 22000 was developed by ISO Technical Committee 34 Working Group 8 according to the guide ISO-72 and published in 2005. With ISO 22000 the scope of system was enlarged. It is a food safety management system which requires the participation of every part of the company from management to workers. It is not only related to production, but

it includes suppliers, sales and transportation [5, 35]. In addition to these, ISO 22000 brings the risk management concept to HACCP.

### **2.5.3. Failure Mode And Effect Analysis (FMEA)**

Failure mode and effect analysis (FMEA) is a powerful tool for risk management, which aims to eliminate potential failures before they occur. All of the items, which are being a part of system, are taken into consideration and invested by factors of severity (S), probability of occurrence (O) and probability of detection (D) [28, 29, 33, 35-37, 47, 48].

Potential failures of all steps are listed. Severity (S), probability of occurrence (O) and probability of detection (D) values of each potential failure are determined. At this step, values are determined based both on best expert opinion and historical information for similar items of all the possible ways that each component or subsystem might fail to fulfill its intended function. After O, S, D values are determined, Risk Priority Number (RPN) is calculated for each potential failure separately. RPN value is calculated as multiplying O, S, D values, which are scaled 1 to 10. Corrective actions must be applied to any potential failure which has a greater RPN value than selected threshold value.

After applying corrective actions, new O, S, D values are determined again and new RPN value is calculated. If the new RPN value drops under the threshold value, FMEA will be accepted as successful. If not, corrective actions are revised and suitable corrective actions are applied until RPN value drops under the threshold value [28, 29, 33, 35-37, 47, 48]. With this methodology, accumulations of potential failures are not possible and this makes FMEA more rigid system than the prevailing food safety management systems.

### **3. METHODS**

#### **3.1. FMEA METHODOLOGY**

Thirty different Turkish dairy companies are visited during 75 Food Safety Providing System (FSPS) Inspections between the years 2006 and 2011. FSPS inspections are carried out with a questionnaire based on Turkish Food Regulation, HACCP, ISO 22000 FSMS, BRC and IFS. In the questionnaire, there are 5 main topics, about food safety providing system, pest control, management methods and personnel applications, engineering/planning and maintenance and hygiene and sanitation applications. Inspections are established in two phases as field control and documentation control sections. During the field controls, all production stages, from raw material intake to shipment, are inspected by the view of food safety. Processes, production equipment, material structure and lay out of buildings, storage conditions and areas, staff practices are observed. The problems which already arise and potential problems which be anticipated to occur in the future are determined. In the documentation section, all documents of companies that are related to food safety are examined including hazard analysis, quality plans, HACCP plans, prerequisite plans, operational prerequisite plans, flow diagrams, etc. All data obtained from companies are recorded and given back to companies as inspection report.

Detailed flow charts of dairy products containing ayran, kefir, yogurt, dil cheese, plaited cheese, kashar cheese, cultured white cheese and traditional white cheese are prepared with real time data obtained from this FSPS Inspections. Probable hazards/failures and their sources are identified in each production step. Since every company has its own method for production, generalized work charts and the most common and the possible hazards/failures are chosen. The hazards/failures are shown at Table B.1-9. Each failure is classified as physical, chemical and biological. During risk evaluation, risk priority number (RPN) of every hazard has been calculated. RPN is calculated from 3 variables: occurrence of the hazard/failure (O), severance of the hazard/failure consumed by a customer (S) and detectability of hazard/failure (D). O, S, and D variables have been given numerical value for making them scalar variables. O, S and D values are given numeric values 1 to 10,

where 10 is the highest probability of detecting the failure, highest severity effect of failure and highest probability to occur [28, 29, 33, 35-37, 47-50]. O, S and D values are determined due to epidemiological studies about the similar ingredients and the best expert opinions. According to these scales, RPN values are calculated as shown in equation 3.1.1 [29, 47, 48, 50].

$$RPN = O \times S \times D \quad (3.1)$$

Ninety percentage statistical confidence is considered for calculating the threshold limit value. Therefore, when the highest possibility of RPN value is 1000 ( $RPN = 10 \times 10 \times 10 = 1000$ ), the threshold limit becomes ( $1000 \times 0,1$ ) 100. Any RPN value which is higher than threshold limit ( $RPN=100$ ) is considered as potential failure and corrective actions are assigned on them [28, 29, 33, 35-37, 47-50].

Final RPN numbers which are calculated by the assumption of applied corrective actions are suitable and successful. Therefore, for new conditions, O, S, D values are re-determined and RPN is calculated after corrective actions. For evaluating the success of FMEA, Total RPN numbers for each product are calculated by summing up every hazard's/failure's RPN values. The same calculations are made for the RPN values after corrective actions and the difference between these two values gives the success of the results. All the values can be found in the appendix part (Table B.1 - Table B.9).

For classifying the steps, by the means of failures, every product's Pareto diagrams are drawn and given in the appendix part (Figure C.1 – Figure C.20). By the help of Pareto diagrams every product's extremely significant risk containing steps are displayed. Extremely significant risk is determined by steps which are in a range of cumulative percentage of 80 % [28, 36].

## 4. RESULTS and DISCUSSION

### 4.1 MILK PRETREATMENT

Milk pretreatment process is the common process for all dairy processes since it is the main ingredient for all dairy products (see Figure A.1). The potential failures in milk pretreatment process should be eliminated before milk enters into the other processes since the risks from the milk pretreatment process accumulate in other dairy process.

The total risk priority number was found to be the highest for the biological failures (RPN=2928), which was followed by the chemical failures (RPN=1896) and the physical failures (RPN=270) during the milk pretreatment process (see Table B.1).

Raw milk quality is an important parameter which also affects the safety of product. In Turkey, raw milk quality is below the European standards. Declaration of Raw Milk and Heat Processed Drinking Milk (2000/6) is issued in Turkish Food Codex Regulation (TFCR) [51]. This declaration should be considered when controlling raw milk.

Pathogenic microorganisms and parasites are the major risks associated with milk around worldwide. Possibility of presence of pathogenic microorganisms on raw milk is high in Turkey considering poor sanitary conditions in stables (animal welfare), milking equipments, raw milk collection and transportation steps. Therefore, raw milk becomes one of the main contamination sources for pathogens of dairy products. Some of the pathogenic microorganisms, which are known to be found in raw milk, are *Listeria monocytogenes*, *E. Coli* O:157, *Salmonella* spp., *Campylobacter* spp., *Staphylococcus aureus*, *Yersinia* spp., *Shigella* spp., *Mycobacterium tuberculosis*, etc. [52-61].

*Listeria monocytogenes* is one of the pathogenic microorganisms potentially found in milk. It is a Gram-positive, facultative anaerobe, catalase-positive, oxidase-negative, non-spore forming, rod shaped, and a psychotropic bacterium. It is durable in low pH and high salt concentration media. It is a ubiquitous bacterium hence, it can be found in almost

everywhere. Listeriosis is a rare disease with a high mortality rate (30%) [44, 45, 62-65]. *Salmonella* spp. is one of the well known food-borne pathogen. It's gram-negative, facultative anaerobe, catalase-positive, oxidase-negative, non-spore forming, rod shaped bacteria. *Salmonella* has almost 2000 strains and most of them are pathogenic. Very low doses (for example 50 cfu *S.napoli*) are enough to make diseases. The disease rate of *Salmonella* is high but mortality rate is very low (under 1%). Milk, meat, poultry and eggs are the main sources of *Salmonella* [2, 44, 45]. *Escherichia coli* is also well-known and studied microorganism. It's short, Gram-negative, catalase-positive, oxidase-negative, non-spore forming, rod shaped, fermentative bacteria. It's a classical indicator bacterium that indicates fecal contamination, but also some strains can cause food-poisoning as well. The pathogenic *E.coli* is classified into four main groups; Enterotoxigenic *E.coli* (ETEC), Enteroinvasive *E.Coli* (EIEC), Enteropathogenic *E.coli* (EPEC) and Enterohaemorrhagic *E.coli* (EHEC). EHEC is also known as Verotoxin-producing *E.coli* (VTEC), includes *E.coli* O157:H7, which is the one most frequently food poisoning serotype. The infective dose for *E.coli* O157:H7 is very low (10-20 cfu/g). Although the overall mortality rate for *E. coli* O157:H7 is low than 1%, mortality rate increases 3-5% for people developing hemolytic uremic syndrome, which can cause permanent kidney failure [4, 44, 45, 59, 66]. *Staphylococcus aureus* is gram-positive, catalase-positive, oxidase-negative, facultative anaerobe, spherical; typically forming irregular clusters of cells (such as bunch of grapes) bacteria. Only 30% of *S.aureus* strains are able to produce toxins and for producing enough toxins to cause illness,  $10^6$  cfu/g bacteria are needed. In addition, mortality rate is so low. The main source of *S.aureus* is human body, especially nose. 30-40% of healthy individuals carries *S.aureus* and has a potential to contaminate foods by sneezing, coughing, hand etc. Foods such as milk, cream, butter, ham, cheese, etc. are suitable growth media for *S.aureus* and can cause staphylococcal food poisoning [4, 44, 45, 57, 67, 68]. *Shigella* spp. are gram-positive, facultative anaerobe, catalase-positive, oxidase-negative, non-spore forming, rod shaped bacteria. *Shigella* spp. causes bacillary dysentery in humans. Its effective dose is very low (10-100 cfu). Mortality rate is high especially among children worldwide. Shigellosis is a major problem for developing countries [44, 69]. *Vibrio* spp. is gram-negative, facultative anaerobe, catalase and oxidase positive bacteria. The mostly known species are *V. cholera* and *V. parahaemolyticus*. They are slightly halophilic which grow best at 2-4% salt concentration but tolerable up to 8%. Its



effective dose is high for healthy individuals ( $10^{10}$  cfu) but it decreases for individuals with low stomach acidity ( $10^3$ - $10^4$  cfu) [44, 45]. *Campylobacter* spp, are gram-negative, non-spore forming, rod shaped, oxidase positive bacteria. Almost 90 % of food poisoning caused by *Campylobacter* spp. are the results of *C.jejuni* and *C.coli* species. *Campylobacter* spp. is microaerophiles which means they need reduced oxygen for growing. Their optimal growth temperature is 42-45 °C and their infective dose is low (500 cfu) [44, 45]. Parasitic protozoa such as *Cryptosporidium*, *Cyclospora*, *Giardia*, and *Toxoplasma* do not only infect humans via food, but also can pass through from person to person as a result of poor hygiene. Several food-borne outbreaks, which are caused by protozoa, are also reported [44, 70, 71]. They usually contaminate food during the primary production stages.

While the risk is too high and simple controls are not enough to prevent this failure, a series of control measures and corrective actions should be applied. The RPN values clearly indicated the potential biological failure risks at different stages of the milk pretreatment process. The highest RPN value (RPN=720) was calculated at the receiving raw milk production step. The high number of pathogens in milk, due to improper handling and storage, was observed as the major cause for the potential failure. This potential failure was the highest RPN value among the potential failures stated in this thesis. Controlling pathogens in raw milk receiving is not an easy task for companies. It requires at least 24 hours for microbiological analysis and raw milk should be processed as soon as possible. In addition, pathogen analysis brings a risk for company. The hygienic conditions of laboratory should be kept at nearly sterilized level. Any contamination risk for pathogens cannot be allowed. Therefore, preventative control measures should be applied for this potential failure. Controls must start from stables. Hygienic conditions of stables and milking equipments should be improved. This can be done by trainings of farmers. Trained and controlled farmers can be put on approved supplier list. Immediate cooling of milk after collection from farmers below 7 °C by cooling collection tanks or by building milk collection centers with cooling equipments is also required. Moreover, cold chain should be maintained during transportation to plant. This way the growth and accumulation of pathogenic microorganisms can be diminished. In addition, there might be some data that indicate presence of pathogens in milk such as total microorganism level is high. Due to

the same reasons of pathogen analysis, microbiological analysis of total microorganism is not an efficient way. However, the acidity of milk is also increased with the accumulation of microorganisms. Therefore, doing the pH and/or acidity measurement in every raw milk receiving can also be a way for control. But high pH is not a guarantee for pathogen free milk. After these corrective actions, periodical pathogen analysis can be done for verification of success.

Another extremely significant biological potential failure is microbiological contamination due to inadequate cleaning of equipment which is observed at different stages of almost all dairy processes (RPN=240 for CIP cleaning and RPN=288 for manual cleaning) (see Table B.1, Table B.3 - 9). Cleaning and sanitation is done for eliminating the potential failures of microbiological, physical and chemical contamination. There are several materials that can be used in cleaning and sanitation in food companies. Materials used at cleaning changes are due to the nature and amount of soil, formation conditions of soil, material structure of cleaning area, cleaning method, hardness of cleaning water, characteristics of cleaning agents and required level of sanitation [7]. Dairy products contain fats, proteins and carbohydrates. For this reason, various materials are used at cleaning in dairy products such as alkaline type, acidic type, surfactant cleaners (such as anionic compounds, cationic compounds, amphoteric compounds, non-ionic compounds etc.), polyphosphates and chelating agents, antifoaming agents etc. [7]. These materials are both effective on soil removing and disinfection. From raw milk receiving to filling/packaging stages, every single material, especially food contact materials, should be cleaned and sanitized carefully. Equipments used in production can be contaminated from raw materials, workers, air, other equipments, etc. Although the contamination vehicles are various, with a single step of cleaning and sanitation, the failure risk can be eliminated. There are several methods for cleaning and sanitation process.

CIP (Clean In Place) systems are generally used for closed systems such as pipelines, pasteurization equipments, storage and process tanks. In CIP cleaning, hot alkaline solution-cold water rinsing- hot acidic solution- cold water rinsing process steps are used [72]. Used chemicals are also effective on microorganisms and provide disinfection. The concentration and exposure time to these chemicals are determined by experiments. Every

food producing company has its own kind of soil and needs different solutions for cleaning. Once the concentration and exposure time of cleaning are determined, companies usually use them without a change. However, if the soil changes due to some conditions such as burning of milk, and some residues placed on materials, the effectiveness of cleaning can become less. In addition, if the concentration of used chemicals changed or exposure times of these chemicals are being shortened, desired hygienic quality cannot be reached. Effectiveness of cleaning is important to almost all steps of dairy production. Importance of cleaning increases in the production steps with required intensive handling. While the RPN value of this failure is greater than 100 (for CIP cleaning RPN=240, and for manual cleaning RPN=288) as a corrective action, proper cleaning procedure should be applied, and periodic microbiological analysis should be carried out (swab controls) for verification.

In milk pretreatment procedure, received and processed milk should be stored on a double walled steel tanks for preserving the temperature of the milk. After the heat treatment, either in thermisation or pasteurization, vegetative cell count of milk is decreased. So, microbial growth due to improper storage temperature (RPN=252) becomes a major potential failure at this step. Due to storage tanks conditions or measuring failures, stored milk's temperature can rise above 8 °C and microbiological activity will increase [26, 32, 38, 40, 41, 43, 73]. This microbiological activity also includes pathogenic microorganisms, which gives this potential failure a significant importance. For eliminating this potential failure, assigned corrective actions are the cooler equipped or heat isolated tanks should be employed, the inner temperature of the tank should be measured regularly, and thermometers / probes, which are used for temperature measurements, should be calibrated regularly.

Under some conditions, received milk cannot be processed immediately and should be stored. If duration time is more than 24 h, cold storage cannot be enough to protect the milk. Therefore some additional process steps can be applied for protection. Thermisation is one of microbiological preservation methods for raw milk storage. It's basically low heat-low time pasteurization for raw milk [7]. After raw filtration, raw milk is heated to 63 – 65 °C for 15 seconds and cooled to 4°C for storage. This way fair amount of spoilage and

pathogenic microorganisms will be affected and their growth rate will be decreased. Inadequate processing time and/or temperature is a major risk for this step (RPN=240). Any problems caused by machinery faults, measuring probes and/or worker problems can lead a failure in this step, same as in pasteurization [26, 32, 38, 40, 41, 43, 73-75]. Therefore, assigned corrective actions for this step should be applied, such as; thermisation/cooling process control should be computerized; thermometers / probes, which are used for temperature measurements, should be calibrated regularly; maintenance of equipments (maintenance procedure) should be ensured; and staff should be trained about food safety and the controlling system.

Mastitis is also one of the major problems of milk, which can be simply described as inflammation of breast tissue. Infection of pathogenic microorganisms such as *S.aureus*, *Campylobacter* spp., *Listeria monocytogenes*, *E. coli*, *Mycoplasma* spp. through nipples mainly causes this disease [7, 26, 76-78]. Therefore, Isolation of *Staphylococcus* spp. and *Streptococcus* spp. in milk which might be the indication of animals with mastitis disease potential failure exists in receiving raw milk production step. Its RPN is 200. Mastitis affects the chemical structure of milk and decreases the quality. In addition, the total microorganism level increases and causative agents for disease can also contaminate the milk. Prevention of this disease starts with hygienic quality of stable environment. Both the stable and milking equipments must be kept clean. Working with approved suppliers is one of the corrective actions that can be done. Electrical conductivity analysis of milk in every receiving is another critical control for determining mastitis. Electrical conductivity increase indicates the disease. Somatic cell count is another option for controlling the disease. When the somatic cell count of milk is greater than  $10^6$  is also an indication of the illness. Lastly, periodical veterinary controls on field for any outbreaks can give an opinion of disease conditions and distribution.

Raw filtration is usually performed at open air during the transfer stage of raw milk into the production facility. Generally, milk is manually poured from barrels to vats, or transferred from tanks using various pipes or hoses. Performing the raw filtration, the filtering equipment (textile or metal sieves/filters) is normally placed either directly on the vat or at the end of transferring pipeline. Then, milk is taken to cooling step. However, due

to filtration conditions, there is a major potential failure of microbiological contamination (*E.coli* O157:H7, *Shigella* spp., *Salmonella* spp.) from pests, such as flies (RPN=189). During transfer of milk, flying pests that might carry pathogenic microorganisms can contaminate the milk [79]. Thus, assigned corrective actions for this step would be protecting milk from pests during transferring step at reception area of the facilities and applying effective pest control management.

The total risk priority number was found to be the second highest for the chemical failures. The highest chemical potential failure for milk pretreatment procedure is veterinary drug residues in milk samples due to improper veterinary practices (RPN=392) in receiving raw milk production step. Antibiotics, which are used in animal illnesses, can pass to milk. Assigned corrective actions for this failure are working with approved supplier and antibiotic analysis is done in every receiving with antibiotic kits. Antibiotics analysis with kits is giving an opportunity of rapid and cost effective analysis.

Another observed chemical potential failure in receiving raw milk step is high level of aflatoxin content in milk due to improper agricultural practices and using contaminated feed in farms (RPN=360) [80]. Aflatoxin is a hepatocarcinogenic and mutagenic mycotoxin produced by *Aspergillus flavous*, *Aspergillus paraciticus* and the rare *Aspergillus nomius*. While the *A.flavous* produces only the B type aflatoxin, other species produces both B and G type. When aflatoxin contaminated feed is consumed by lactating animals, it metabolizes and forms Aflatoxin M<sub>1</sub> and M<sub>2</sub>, which are hydroxylated metabolites of Aflatoxins B<sub>1</sub> and B<sub>2</sub>. These metabolites can pass to milk. Although carcinogenic and mutagenic potential of Aflatoxin M<sub>1</sub> is lower than Aflatoxin B<sub>1</sub>, acute toxicity is nearly similar. Therefore both Aflatoxin B<sub>1</sub> and M<sub>1</sub> are classified as 1A (carcinogenic) and 2B (probable carcinogenic) human carcinogens [80-89]. According to Declaration of Maximum Limits of Contaminants on Food Materials [90], maximum limit of Aflatoxin M<sub>1</sub> in raw milk is given as 0,05 µg/kg. Some studies show that, aflatoxin M<sub>1</sub> is an observed problem for Turkey [81-85]. Therefore, assigned corrective actions for this potential failure are; working with approved supplier, and doing a total aflatoxin analysis in every receiving with aflatoxin kits.

Adulteration of raw milk is also another problem for Turkey. Most of adulteration techniques are applied for the fluctuations on quality parameters such as fat content and water content of milk. However alkaline materials are also added for surpassing acidity in microbiologically low quality milks [10]. High acidity in milk will cause protein coagulation on heat treatment. On the other hand, if the acidity gets too high, protein coagulation will occur spontaneously. For solving this problem, collectors and/or farmers might use some surpassing agents on milk. Some agents, such as baking soda ( $\text{NaHCO}_3$ ), are relatively less harmful, but in some cases materials such as bleacher ( $\text{NaClO}$ ) or hydrogen peroxide ( $\text{H}_2\text{O}_2$ ) can also be used (RPN=280). These materials are used either for rising pH or as microbiological preservation. These agents pass to products and can cause health issues for consumers. Corrective actions assigned for this potential failure are working with approved supplier and alkaline analysis in every receiving of milk.

Pesticide residues are also one of observed chemical potential hazards for raw milk (RPN=192). Due to usage of pesticide residues containing animal feed and/or from pest control applications on stables, some pesticides can contaminate milk. At the Turkish Food Codex Regulation's Declaration of Maximum Limit of Allowed Pesticides on Food Products (2009/62) [91], there is list and limits of some pesticides, which can be found on milk. For avoiding this potential failure, milk suppliers should be reliable and periodic pesticide analysis should be carried out.

As mentioned before, there are several cleaning and disinfection materials used at cleaning process for getting a safer food. However, these chemical agents can also be harmful to human health. The effects of these chemicals can be listed as acute and chronic toxicity, irritation, corrosivity, sensitization, repeated dose toxicity, mutagenicity, carcinogenicity, reproduction toxicity and neurotoxicity [92, 93]. For that reason, cleaning and sanitation procedures must end with proper rinsing for removing the cleaning/disinfection agents. There are studies on food products that shows these chemical agent residues can be found [92]. There are several steps on FMEA tables that are related to contamination due to inadequate rinsing (Table B.1, Table B.3-9). In CIP cleaning systems, the probability of occurrence of this hazard is relatively lower than manual cleaning. RPN value for CIP cleaning is measured 168 and 175 for manual cleaning. But as a result, in all steps,

potential failure of detergent and/or disinfectant residue caused by inadequate rinsing after cleaning, has a greater RPN value than 100. For avoiding this potential failure, proper cleaning procedure should be applied and periodic pH and/or electrical conductivity tests should be carried out regularly.

Thirdly, some physical potential failures are observed at milk pretreatment with total RPN of 270. None of the physical potential failures RPN values are greater than 100 (Table B.1). Therefore, no corrective actions are needed for these potential failures.

When looking at overall success for milk pretreatment procedure, it can be seen that 84.7% of RPN decrease after corrective actions.

## **4.2 WATER**

Potential failures that can come from water are specified in FMEA analysis (see Table B.2). Water is an ingredient for all products studied in this thesis except Yogurt. But, the importance of water is not limited to being an ingredient. In the cases where water is not directly in contact with products, it could still affect products through the cleaning process and personal hygiene (hand washing). Therefore, the same conditions are considered for all products. In almost all of the dairy companies in Turkey, they only have one source of water, mostly artesian or well water. From personal cleaning to being used as an ingredient, the same water is used. For this reason, there are some potential failures of water such as physical contamination from water used at factory (RPN=64), presence of heavy metal residues in water (arsenic, antimony, boron, cadmium, chrome, copper, lead, mercury etc.) (RPN=288), presence of pesticide residues in water (RPN=168), nitrite, nitrate contamination to products from water (RPN=168), contamination of chemical substances to products from water (bromate, cyanide, acrylamide, benzene etc.) (RPN=224), pathogenic microorganisms presence in water (RPN=432) and parasite presence in water (RPN=224).

According to Turkish Food Codex Regulation, all food producing companies must use drinkable water in production area. Therefore, companies must at least provide conditions

of the Regulation of Human Use Intended Waters [94]. There are limitations in this regulation for all the stated potential failures above. Before starting production at the company, water analysis should be done for determining the quality of water. If there is a problem, a suitable filtration system should be placed such as reverse osmosis if needed, microbiological treatment must be applied to water by using chemical agents such as chlorine, ozone or UV based systems as corrective actions. After applying these corrective actions, periodic analysis should be carried out for verification and approved maintenance procedure of filtration and/or refining equipments must also be followed for achieving sustainable quality of water.

### **4.3 YOGURT, KEFIR AND AYRAN PRETREATMENT**

Yogurt, ayran and kefir are similar products with common production steps. Therefore, similar production steps are combined and invested as yogurt, kefir and ayran pretreatment. For this procedure, total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 2844, 1862 and 404; respectively. For biological potential failures the total RPN is, once again, higher than the others.

The highest RPN value observed in biological potential failures in yogurt, kefir and ayran pretreatment procedure is microbial growth caused by inadequate processing time and/or temperature at pasteurization production step (see Table B.3). The mechanism of pasteurization is similar to the thermisation step mentioned previously in section 4.1.

Pasteurization is another common step for the production of dairy products. It is a preventative step specially designed for killing the vegetative pathogenic cells by applying a certain heat in a certain time [7]. Pasteurization temperature and time change according to the desired product. However, the pasteurization norms for the same product might also vary according to producers. Hence, the most common norms have been examined in the FMEA tables: 15 min at 85-90 °C for Kefir, Ayran and Yogurt production, 1-5 min at 65-70 °C for kashar group cheese production, 5-10 min at 80-90 °C for cultured white cheese production and 30 min at 65-70 °C for traditional white cheese.



Although pasteurization can be done at open vessels by boiling in some small companies, most of industrialized producers use plate heat exchangers with a counter current flow in which milk is heated with steam flowing through plates and cooled with cold milk. Although, potential failure and corrective actions for this step are almost similar to thermisation but the RPN value is different from thermisation since RPN value of microbial growth caused by inadequate processing time and/or temperature in pasteurization is measured as 300 (see Table B.1).

Second highest biological potential failure for yogurt, ayran and kefir pretreatment process is measured as microbiological contamination caused by contaminated materials that are used during processing, i.e., salt and milk powder at dry matter adjustment step (see Table A.3.). RPN value for this potential failure is measured as 280. Contamination from raw materials is an important issue for food production. For lowering or rising the dry matter content salted water and milk powder can be used for ayran, kefir and yogurt production. Therefore supplier of these materials should be reliable and periodic microbiological analysis should be carried out for verification.

Another biological potential failure observed in yogurt, ayran and kefir pretreatment procedure is microbiological contamination caused by inadequate cleaning (CIP cleaning) with RPN is 240 (see Table B.3). This potential failure has exactly same reasons and corrective actions mentioned before in section 4.1.

Lastly, microbiological contamination from the cream containers potential failure has been observed in yogurt, ayran and kefir pretreatment procedure. RPN of this potential failure is calculated as 168. Although it's not very common, in some cases, cream cans might be the source of microbiological contamination for milk fat adjustment step. Fat, separated at fat separation step, is stored at cream cans. Due to unsanitary production conditions or transportation, cans might be contaminated with pathogenic microorganisms [26, 32, 41, 43, 74]. Therefore, controlling the cleanliness of containers and performing periodic microbiological analysis (swab controls) for verification are assigned corrective actions for this potential failure.

Chemical potential failures of yogurt, ayran and kefir pretreatment procedure can be seen on Table 3. Basically there are 2 different chemical potential failures at this step. Detergent and/or disinfectant residue due to inadequate rinsing after cleaning potential failure can be seen in almost all production steps mentioned at yogurt, ayran and kefir pretreatment procedure with RPN value 168. This potential failure has exactly same reasons and corrective actions mentioned before in section 4.1.

Second chemical potential failure for this procedure is chemical contamination due to mislabeling of containers which can also be seen in other products (Table B.4, Table B.7 and Table B.9) of which RPN is 150. Lots of chemical materials such as salt, detergents, microbiological preservative agents, glue granules are used on packaging.  $\text{CaCl}_2$  and any other chemical materials, which are used on production of dairy products or construction/maintenance of plant, might have similar physical appearance. Although, mostly these chemicals are commercially sold in big packages (such as 10 to 50 kg packages), they are generally used in small amounts. For controlling the used amounts, frequently these chemicals are transferred to production area in cups containing small amounts. Wrong or false labeling of these chemicals might cause severe effects on consumers depending on chemical material. Therefore, labeling the chemicals is an important preventative action. Assigned corrective actions for this potential failure would be training of the staff on handling and labeling of chemicals, daily control of labeling, storage of foods and chemicals separately and filling out inventory forms properly.

Physical potential failures are also important for yogurt, ayran and kefir pretreatment procedure. Total physical RPN for this procedure is calculated as 404. Physical hazards are the most difficult ones to classify. They can either cause harm (such as glass or metal pieces) or act like a carrier for other chemical or biological agents (hair, insect particles etc.). For accepting a physical substance as physical hazard, it must have;

- Evidence of physical injury from ingestion,
- Recognition as a hazard by medical authorities,
- Subsequent processing or intended use of product does not eliminate or neutralize the hazard. (Olsen et al. 2001).

Physical impurities added into milk from impure salt has the highest RPN value among the physical potential failures of yogurt, ayran and kefir pretreatment procedure (RPN=120) (see Table B.3). Contamination from raw materials is an important issue for food production. As mentioned before, for lowering or rising the dry matter content salted water and milk powder can be used on production. The occurrence of physical contamination from milk powder is so low that in this thesis it is not considered as a potential failure. On the other hand, salt is one of the major contamination vessels for physical contamination. In Turkey, salt is generally obtained from mines, lakes and/or sea. Depending on production conditions for industrial salt, dirt can be remained in salt. Dirt containing salt is usually detected while preparing the brine. When salt is dissolved in water, foamy brown formation, which contains dirt and some other physical contaminants, begins to float on water. If dry matter adjusting is done by adding salt and water separately, this dirt cannot be usually detected on direct use. For that reason, assigned corrective actions for this potential failure would be working with approved supplier and physical material control in salt can be achieved by dissolving in water with every receiving. RPN value of other physical potential failures of yogurt, ayran and kefir pretreatment procedure is smaller than 100. Therefore, there is no need to assign corrective actions for them.

Overall success for yogurt, ayran and kefir pretreatment procedure is calculated as 82.5% drop of total RPN value.

#### **4.4 KASHAR GROUP CHEESE PRETREATMENT**

Such as yogurt, ayran and kefir products, some cheese has also similar production steps. Flow diagram of kashar group cheese pretreatment has been given in Figure A.4. As it can be seen from figure, there are two different types of processes in kashar group cheese. One is blanching in water and the other one is dry blanching. Blanching is a unique step for kashar group cheeses. For obtaining an elastic structure, curds are heated to 80-90 °C for app. 5 minutes and mixed. Most companies are started to use dry blanching but blanching in water is traditional way of making kashar group cheese. Therefore, in this thesis, both methods are examined. Dry blanching is done in stainless steel pressured blanching tanks by heating the curd with steam. In this method, for avoiding burning of curd, melting salts

should be added to tank for fluidization of curd. In blanching in water step, curds are blanched in hot brine solution in open tank.

Total RPN value for kashar group cheese pretreatment procedure with blanching in water is measured as 10695. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 6853, 2862 and 980; respectively. Results are also similar for dry blanching, which are; total RPN is 11203, total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 6913, 3310 and 980; respectively. For both production procedures, highest RPN values calculated in biological potential failures.

Highest RPN observed in biological hazards of kashar group cheese pretreatment procedure is microbiological contamination due to inappropriate practices of staff of which RPN is generally calculated as 392. In curding of kashar group cheese, personnel controls the curd through a little hatch placed on top of process tank. Therefore, in steps such as curding, personnel effect to process is too little and RPN value for microbiological contamination due to inappropriate practices of staff is calculated as 280.

In some studies, it has been seen that there are some microbiological contaminants that can be found on worker hands such as *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O:157, *Listeria monocytogenes*, *Salmonella* spp., *Shigella* spp., *Vibrio cholera*, *Campylobacter jejuni*, Norovirus, Hepatitis A virus etc. [3, 5, 95, 96]. Contamination from workers can be categorized as cross contamination transporter (from raw material to processed material, poorly cleaned or uncleaned area to products etc.), contamination from ill workers (porter of bacteria, viruses, parasites etc.) and not or insufficiently cleaned hands when necessary (after handling of contaminated material, after bathroom etc.). In addition, there is a risk of contamination caused from usage of inappropriate disinfectant. If personnel use a poor quality disinfectant, which has a low disinfectant effect, all probable corrective actions will be wasted. Corrective actions for this potential failure are personnel trainings on personnel hygiene and hand washing, working with approved disinfectant dealer, daily control for personnel hygiene and periodically microbiological control from personnel hands (swab control).

Second highest RPN value for biological potential failures seen at pathogens from contaminated materials (such as  $\text{CaCl}_2$ , enzyme and culture) with RPN is 315. The RPN value for this potential failure is higher than the other similar potential failure mentioned at the yogurt, ayran and kefir pretreatment procedure. Differences arise from the nature of materials. In dry matter adjustment step in yogurt, ayran and kefir pretreatment procedure, materials used are limited with salt or milk powder. In terms of biological hazards salt is a safer ingredient than the others. Milk powder is also dry ingredient with a low water activity. On the other hand, materials used for cheese productions are more susceptible to pathogen contaminations.

Other biological potential failures of kashar group cheese pretreatment procedure are microbiological contamination caused by inadequate cleaning, microbial growth caused by inadequate processing time and/or temperature (at blanching and pasteurization steps) and microbial growth caused by inadequate processing time and/or temperature (in cold storage of milk). These potential failures are of the same reasons and corrective actions are similar potential failures mentioned before as well.

When looking at the chemical potential failures of kashar group cheese pretreatment procedure, detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning and chemical contaminants due to the use of empty food containers to store chemicals and mislabeling potential failures exist in both production lines. They occur because of the same reasons and have corrective actions for similar potential failures mentioned formerly.

Another common chemical potential failure for both dry blanching and blanching in water production lines is addition of machine oil in foods from the pedals with RPN value of 168. On top of the tank, there is an engine rotating mill of the pedal. Usually, mill is connected to tank through an aseptic seal, which secures tank from any kind of contamination passes from mill bed. There might be use of lubricating oil for some kind of engines. Any mechanical fault can cause contamination by carrying lubricating oil to products. Mineral based lubricating oils are classified as low toxic compounds and limited to be found in foods by EU food laws [97-99]. Therefore, assigned corrective actions for

this potential failure are applying an effective maintenance program and using food-grade oils.

Difference of total RPN values between dry blanching and blanching in water production lines is stems from next two chemical potential failures from dry blanching step. Dry blanching allows use of microbiological preservatives during production. Sorbic acid or nisin/natamycin can be added to curd before blanching. In preparation or addition there might be some failures, such as wrong measuring caused by equipment or worker fault and makes use of excessive amount of preservatives (RPN=288). Basically nearly same conditions are valid as in packaging step and again assigned corrective actions are the same, which are calibration of scales used for measuring the weight is required, staff should be trained on proper practices and periodic preservative analysis should be carried on for verification.

Again in dry blanching, some amount of waste cheese can be reworked. This waste cheese can come from other processes such as shape cutting and/or in any step of process, cheeses with deformed shape or structure. In addition, in some cases, cheese returned from markets can also be used. Usually cheeses are returned from markets resulting for ending shelf life. Most of microbiological load is not considered as a potential failure because of nature of process causes pasteurization (high temperature – high time). But toxigenic microorganisms can cause problems. Usually, returned cheeses have a mould formation on the surface of cheese. If contaminated moulds are forming mycotoxins, product will also be contaminated (RPN=160). If company insists of using old cheeses, periodic analyses of old cheeses should be carried out.

For physical potential failures of kashar group cheese pretreatment there is three different physical potential failure over a value of RPN=100. Contamination from the staff due to improper practices during the process potential failure with RPN is 120 is one of them. There are also several steps in FMEA tables of all products (see Table B.4 - B.9) containing the potential failure caused by physical contamination from staff. The physical contaminants such as hair, nails, buttons, glove particles, pen itself or particles of it, coins, etc. are the failures that can contaminate from workers, during the process [38, 40, 41].

The corrective actions for these failures are determined as personnel trainings on personnel hygiene, using the personal protective gears (bone, gloves, arm covers, etc.) and daily control for personnel hygiene and protective gears.

Teflon coating particles from the blanching equipment (RPN=120) is also a widespread physical potential failure for kashar group cheese in Turkey. Fluidized curd forms a sticky structure. For avoiding curd sticking to equipments, stainless steel parts of equipments are coated with teflon. By time, teflon coating will be deformed and teflon particles separated from equipment will be contaminating to cheese (RPN=120). For avoiding this potential failure, approved maintenance procedure should be followed.

Physical contaminant from salt is another physical potential failure exists on all products, which is also mentioned before.

As a result, overall success of kashar group cheese pretreatment procedure is calculated as 81.7 % drop of total RPN for wet blanching production line and 82.1 % drop for dry blanching production line.

#### **4.5 KEFIR AND AYRAN PRODUCTION**

Kefir and ayran are similar products with similar production steps. Only differences between them are the culture intent and incubation temperature. Culture inoculation is a critical process step for fermented dairy production. Basically, purpose cultures are used for acid production, proteolysis, flavor and aroma formation and inhibition of pathogenic microorganisms growth [8]. There are several microorganisms which can be used in dairy industry as a culture. For Kefir production culture consists of bacteria's such as *Lactobacillus kefir*, *Leuconostoc* spp., *Lactococcus* spp. and *Acetobacter* spp. and yeast ferments lactose (*Kluyveromyces marxianus*) and yeasts do not ferments lactose (*Saccharomyces unisporus*, *Saccharomyces cerevisiae* and *Saccharomyces exiguus*). For Ayran and yogurt production, culture is made of *S.thermophilus*, *L.bulgaricus* [8, 13, 100].

Total RPN levels for these two products are the same, which is 5229. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 3357, 1464 and 408; respectively.

Highest RPN for biological potential failure for ayran and kefir production is calculated as 392 for microbiological contamination due to inappropriate practices in culture inoculation. This potential failure is basically the same with mentioned ones before. This potential failure also exists in filling step of ayran and kefir. At filling, RPN level of this potential failure is a little bit smaller than other ones (RPN=336). This is an effect of the nature of filling steps. Filling is done with automated machines. Therefore, occurrence of failure is low.

Microbial growth due to temperature abuse during storage/transportation potential failure exists in all products (Table B.5 – Table B.9), in storage and shipment production steps [26, 32, 40, 41, 43, 74, 75]. While the RPN for storage step is calculated as 280, RPN for transportation is calculated as 336. Main reason for this difference comes from the detectability. In the shipment of products, temperature failures are harder to detect. Temperature failures on these stages usually occur from breakdowns of cooling equipments. Therefore assigned corrective actions for shipment stage are the application of standard control program and control of temperature during transportation.

Microbiological contamination caused by improper sealing of cover is a major threat for food safety. RPN value of this potential failure is calculated as 320. Improper sealing causes post process contamination [32, 43], where the companies cannot apply corrective actions. Mostly, problem will be detected by customers in these cases. The contaminated microorganisms can be both spoilage of microorganisms and/or pathogens. The problem can be caused by several reasons such as insufficient heat application (when sealing is done by heat treatment), failures of sealing machinery, inappropriate covers usage, operator faults etc. These problems can be solved by applying the corrective actions such as maintenance program of sealing equipments, periodical control after sealing, trainings of sealing operators.



Pathogen contamination from the contaminated culture and microbiological contamination caused by inadequate cleaning potential failures are examined before. Reasons and corrective actions for these potential failures are same as previously mentioned ones.

RPN values for both microbiological contamination from packaging materials and microbiological contamination from environmental air potential failures are 294. Microbiological contamination from packaging material is not a rare situation [43, 74, 95, 96]. If the hygienic condition of packaging material supplier is poor, there is a great risk of pathogenic microorganism contamination to products. The corrective actions for this failure are working with approved supplier and periodically microbiological analysis for verification.

Some papers mentioned that there can be microbiological presence in air, especially moulds and yeasts [74, 95]. On filling stage, mould and yeast can contaminate to products. Some of moulds such as *Aspergillus* spp, *Penicillium* spp, *Fusarium* spp. etc. can produce mycotoxins [44]. Contamination of these moulds can bring a significant risk on products (RPN=294). Therefore, some corrective actions should be assigned for this potential failure. Positive pressured air ventilation with HEPA-filters should be installed, ventilation system and filters should be maintained and the microbiological quality of air should be controlled regularly.

Microbiological contamination from improperly sealed mixing pedals (RPN=115) exists in mixing production step at ayran and kefir production. After incubation of Ayran and Kefir production, to get a homogenized structure, product mixed on the same tank that incubation has been done. Mixing process is done with stirring pedals, which are attached to the tank. If sealing of these pedals are damaged according to some reasons, microbiological contamination can occur from these openings. Standard maintenance program should be applied for eliminating this potential failure.

Last biologic potential failure seen at ayran and kefir production is microbial growth due to increased time and/or temperature after filling on filling step. RPN for this potential failure is calculated as 108. During the filling step, filled and sealed products are placed into

boxes and these boxes are transferred to cold rooms. Along with the increase in waiting period of products, temperature of products will also increase. In order to prevent this potential failure staff trained on HACCP and the importance of cold chain is required and standard food flow directives should be followed.

As for chemical potential failures, the highest RPN value in ayran and kefir production, calculated at 3 chemical potential failures at filling stage have RPN value 320. These are migration of chemicals from the packaging materials, heavy metal residues from the packaging material and contamination of heavy metal residues from the seal.

Migration can be defined as diffusion of components of packaging material to food. Especially fat containing foods have a greater risk of migration. Fat migrates to plastic material, such as polypropylene and polyethylene. This increases the rate of diffusion of plastic materials components to food [101, 102]. Ministry of Agriculture and Rural Affairs have published that in the Turkish Food Codex Regulation the potentially toxic substance must not be used on food contact packaging materials [103-105]. These potential failures are valid for all product's filling or packaging steps. Corrective actions for migration are determined as working with approved supplier and periodical migration control of packaging material which can be applied for all steps including this potential failure.

Heavy metals such as zinc (Zn), copper (Cu), chromium (Cr), arsenic (As), cadmium (Cd), and lead (Pb) are potential bioaccumulative toxins of the dairy products, and can pass into food through packaging material [106-108]. The accumulation of heavy metals can have middle-term and long-term health risks. Several diseases can be seen caused by heavy metal residues from metal poisoning to cancer [109]. For avoiding heavy metal contamination from packaging materials and caps used in products, supplier should be reliable, only food grade materials should be used, and quality control of packaging materials should be done periodically.

Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning and contamination of machine oil in foods from the pedals chemical potential failures are already mentioned previously.

As physical potential failures for ayran and kefir production, contamination from the staff due to improper practices during process potential failure has also been mentioned before.

Another physical potential failure for ayran and kefir production is packaging material pieces in foods with RPN 120. In every product's filling or packaging stages the risk of contamination from packaging materials exist (Table B.5 – Table B.9). Physically contaminated material changes depend on the nature of packaging material. Considering the nature of packaging material, it can be plastic based and/or metallic based. The plastic particles can cause choking [110]. In addition, there is risk of contamination from metal based packaging materials. Metal pieces have almost the same effect with glass particles, can cause laceration or perforation on gastrointestinal system and additionally, metal pieces can give dental hazards too. [110]. Corrective actions for this failure are designed as working with approved supplier and periodical control of packaging material at receiving. In this way, occurrence probability of the failure is decreased and detectability is increased. RPN after corrective actions are decreased to 36, which means corrective actions are succeeded. Additionally, if the packaging material is plastic based, metal detectors can be used for metallic contaminations.

Total RPN value for ayran and kefir production is calculated as 5229 and after applying corrective actions RPN value decreased 78.9 %. Overall success of ayran and kefir products is calculated as 82%.

#### **4.6 YOGURT PRODUCTION**

Yogurt production procedure's total RPN value is calculated as 6914. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 4898, 1144 and 872; respectively.

Some of biological potential failures observed in yogurt production are all examined before. These potential failures are microbial contamination due to mis-handling, contamination due to improper handling during the process, pathogen contamination from the contaminated culture, contamination from packaging materials and lids, microbial

growth due to temperature abuse during storage/transportation, microbiological contamination caused by inadequate cleaning equipments and in-plant delivery carts, microbial contamination due to mis-handling, microbiological contamination from improperly sealed mixing pedals, contamination from the environment, and microbial growth due to increased time and/or temperature after closing the lids.

Contaminated air coming from the ventilation channels potential failure observed in incubation step has RPN value of 336. During incubation, yogurts caps placed into room without lids are closed. Heating and cooling of incubation room is done with ventilation channels. Due to failures in cleaning and maintenance procedures of ventilation channel, air can contaminate in ventilation channels. This brings a contamination risk from air flow in incubation room. As a corrective action, proper cleaning procedure should be applied, periodical maintenance and a ventilation system control are required and the quality of air should be controlled periodically.

Chemical potential failures of yogurt production is observed as detergent and/or disinfectant residue due to inadequate rinsing after cleaning, heavy metal residues from the packaging material, migration of chemicals from the packaging materials and addition of machine oil in foods from the pedals. All these potential failures are mentioned before, too.

Highest RPN value among physical potential failures in yogurt production was observed as in physical contamination from the lids potential failure at closing the lids step. This potential failure can simply told as physical contamination from packaging material. Lids are placed on cartoon packages in bulk. Therefore, during transportation, storage and process, several contaminations can take place to lids. For avoiding this potential failure staff training on proper handling is required.

Second highest physical potential failure determined as rusty metal particles from the air ventilation channels (RPN=140) at incubation step. In cold rooms, cooling is done by evaporators hanging on wall/ceiling. These evaporators have high speed turning fans and for safety issues, these fans are covered with cage. In most of dairy companies, these cages are not made of stainless steel. They usually made from regular painted steel. In time, these

paints are deformed by several reasons such as cold-moist air of room, vibration of evaporator. This deformation can cause rusting of steel. Rust pieces and deformed paint pieces can contaminate products by blowing air from evaporator. Periodical maintenance and a control of ventilation system is required as a corrective action for this potential failure.

As mentioned before yogurt caps are not closed until the end of sharp cooling step. During incubation, some amount of milk water is vaporizing due to incubation temperature. If lids closed before incubation, there might be some water condensed on lids and this water will accumulate on the surface of yogurt. This kind of condensed water can increase microbial activity of yogurt and cause early mould formation on the surface. For avoiding this failure, most of companies are closing the lids of yogurt caps after incubation and cooling of yogurt. This makes yogurt susceptible to environmental contaminations at incubation and transporting to storage steps (RPN=120). For avoiding physical contaminations from environment, proper cleaning procedure should be applied, environment should be free from waste and pests, and the sanitary conditions of the surroundings should be controlled regularly. But, during transportation of yogurts from incubation room to cold rooms, personnel effect acts a major role of contamination. Therefore, staff training on proper handling is required, personal protective gears (bone, gloves, arm covers, etc.) should be provided and used, personnel hygiene and practices should be strictly controlled for eliminating this potential failure.

Other physical contaminations for yogurt production are explained before.

Total RPN value for yogurt production is calculated as 6914 and after applying corrective actions RPN value decreased 78.2 %. Overall success of ayran and kefir products is calculated as 81.4%.

#### **4.7 PLAITED CHEESE AND DIL CHEESE**

Plaited cheese and dil cheese have similar production steps with an exception. After portioning step (see Figure A.3 and A.6) plaiting step is applied to plaited cheese. Plaiting

is done at plaited cheese to get a unique structure of cheese. It also helps to re-organize the molecular arrangement, makes protein molecules of cheese close and makes more solid structure.

Total RPN value for plaited cheese is calculated as 8688. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 5070, 2594 and 1024; respectively. In addition, Total RPN value for dil cheese is calculated as 8176. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 4678, 2594 and 904; respectively.

Highest RPN values are again calculated for biological potential failures of plaited and dil cheese. All potential failures observed for plaited and dil cheese (See Table B.7) are mentioned before.

In packaging of these products, vacuumed packages are usually used. Feeding of cheeses to packaging machines are done manually. Because of intensive handling, hand sanitizers are widely used at this step. Sanitizers applied to hand by sprayers for increasing the effectiveness of used sanitizers and mostly placed near the line. In field observations, it has been seen that spraying process mostly done over the production line. Therefore, contamination of hand sanitizers of workers during sanitizing hands near the packaging lines exists in packaging step with 294 RPN. In addition, in some companies, sanitizers can be applied by pouring from a dispenser. In this case, if the duration between sanitizing and handling of cheese is short, sanitizers can also contaminate cheeses by hand. In dairy industries, usually alcohol based hand sanitizers are used. The purpose of using alcohol based sanitizers are its wide spectrum effect and easy to vaporize from hand. But, in short duration times, alcohol cannot be removed sufficient enough and will contaminate cheese. In addition, after this contamination, immediate packaging will cause presence of sanitizers in cheeses. Under these circumstances, to avoid this potential failure staff training is required and hand sanitizers should be re-positioned far from the packaging lines.

Excessive used amount of microbiological preservative (spraying type application) chemical potential failure is one of major potential failures for dairy products with 288 RPN. Some microbial preservatives can be used for increasing the shelf life of cheese and eliminating mould formation at the surface. Turkish Food Codex Regulation has limited the use of microbial preservatives and their concentration on foods. In Turkish dairy industry, most common microbial preservatives are nisin/natamycin and sorbic acid based preservatives in cheese. According to Turkish Food Codex Regulation, limit of natamycin is 1 mg/dm<sup>2</sup> and sorbic acid is 1000 mg/kg [111]. There is a possibility of over use of preservatives due to measuring in preparation and/or application of preservatives. Therefore, scales, which are used for weight measurements, should be calibrated regularly, staff training required and periodic preservatives content test should be carried out for the application of verification corrective actions.

Overall RPN decrease for plaited cheese with blanching in water and dry blanching are calculated as 81.6%, and 81.7%, respectively. Additionally, overall RPN decrease for dil cheese with blanching in water and dry blanching are calculated as 81.5%, and 81.7%, respectively.

#### **4.8 KASHAR CHEESE**

Total RPN value for kashar cheese is calculated as 8391. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 5524, 1747 and 1120; respectively.

All biological, chemical and physical potential failures observed in kashar production (Table B.8) are mentioned before except mold growth caused by inadequate removal of moisture biological potential failure exists in resting stage (RPN=168). Resting step is applied to kashar cheeses after transferring cheese to templates. At this point hot cheese is cooled and loses some of its moisture. Cheese gets more solid structure. Some amount of surface moisture is removed and makes the cheese more durable for surface microbiological activity. Under the resting room conditions, moisture can be removed easily from upper parts of cheese. But the bottom of cheese is contacting with the surface

of transferring cars. Without air circulation, moisture removing will not be efficient. If kashar is packed with high moisture content at bottom, getting surface mould formation possibility would be high. To avoid this potential failure, an undercover should be used for kashar cheese blocks for helping to remove moisture and kashar cheeses should be turned periodically.

Same reasons and corrective actions are also valid for other potential failures exist in kashar cheese production.

Overall FMEA success for kashar cheese is calculated as 81% decrease on total RPN value for products blanched in water and 81.2% decrease for dry blanched products.

#### **4.9 WHITE CHEESE**

There are two types of white cheese examined in this thesis, one is cultured white cheese and the other is traditional white cheese. These two types of white cheeses have similar production steps (see Figure A.8). The difference is that there is no addition of culture or calcium chloride to traditional white cheese and traditional white cheese is matured after canning in cold rooms for 4-6 months. FMEA tables are also similar for white cheeses with small diversions (see Table B.9).

Total RPN value for cultured white cheese is calculated as 31489. Total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 18601, 8192 and 4696; respectively. As for traditional white cheese, Total RPN is 28624, total RPN for biological potential failure, for chemical failure and for physical potential failure at this stage are calculated as 16319, 7717 and 4588; respectively.

Most of potential failures observed in white cheese see (see Table B.9) are examined before. Highest RPN value remaining biological potential failure is observed as 300 for pathogen growth due to none ripening potential failure at cold storage (ripening) step of traditional white cheese. Ripening is a long term process which means there will be quite a few of cheese cans to deal. If storage management is not effective on company cheeses can



be served before ripening. To avoid this potential failure FIFO (first in - first out) program must be applied on storage (using by labeling, computerized systems etc.) effectively.

In white cheese production, there are 3 different steps of brine addition. Brine addition to cans, brine addition to packages (only in cultured white cheese) and brine addition to cheese vats (Figure A.8). Brine addition to cheese vats and resting cheese through these steps aim at providing flavor, adjusting structure, helping the crust formation and adjusting the whey content on cheese [8]. At the end of resting step, brine solution is taken from vats and stored for reuse in most of companies. Re-using brings some potential failures such as microbiological contamination due to waiting brine while whey contaminated (RPN=210). During resting step, whey inside the cheese will contaminate brine. Presence of this mixture can make microbiological growth on brine. Therefore, brine should be pasteurized regularly for eliminating microbiological load.

As for chemical potential failures, except from packaging step there are two more steps including migration potential failure (RPN=320). Polyethylene separator sheets and collecting boxes also consist this potential failure. Such as in packaging materials, supplier should be reliable, food grade materials must only be used and quality control of materials should be done periodically for preventing the migration hazard in these steps, too.

Tinplates are usually used as cheese cans in dairy industry [112-114]. These plates are cold-rolled thin steel sheets coated on both faces with a very thin layer of tin [114]. High acidity and salt concentration of cheese and brine can result in dissolving of tin and iron present on cans. In order to avoid heavy metal contamination from cans, lacquer coatings are used. Therefore, lacquer coating is directly affecting the food safety inside the can. For this reason heavy metal residues from the packaging material due to inappropriately covered of lac cans used potential failure exists with 320 RPN value. To avoid coating faults, can suppliers should be reliable and quality control of packaging materials should be done periodically.

During resting on brine step of white cheese there might be some physical contaminations to brine. Re-use of this contaminated brine brings foreign materials from brine (RPN=160) physical potential failure. For avoiding these contaminants to contaminate another party, brine solution should be filtered regularly.

In traditional white cheese, after ripening on cold storage for 4-6 months, if cheese not shipped on cans, small portions of packaging is made. Firstly, cheese cans should be opened for this process. Cans, that are on cold storage, are transported to packaging area and a worker opens their caps with a can opener or adz such as equipment. During opening the cans, top of the cans can be damaged from the impact of adz hits. This damage can torn the top and make it shattered to small pieces, which can contaminate the cheese. To avoid packaging material pieces in foods due to faults on opening (RPN=120) potential failure, staff training is required and standard food flow directives should be followed.

As a result, overall FMEA success for cultured white cheese is calculated as 81.4% decrease on total RPN value and 81% decrease for traditional white cheese.

## **5. CONCLUSION AND RECOMMENDATIONS**

### **5.1 CONCLUSION**

In this thesis, FMEA approach is applied to 8 different fermented dairy products produced in Turkey for revealing the existing risks and their corrective actions. Results also show the main problems in dairy industry of Turkey. The highest total RPN values are calculated in the production steps are mainly because of improper hygiene, staff practices, cleaning operations and unconsciousness of primary producers. Therefore, staff trainings on hygiene and process operations and controlling of primary production are essential in dairy products.

Implementation of FMEA methodology in dairy food manufacturing reduced the RPNs by 81-82% in all products. This shows, FMEA approach is an effective tool for food safety and quality and can be applied in industry.

## 5.2 RECOMMENDATIONS

In this thesis, generalized hazard analysis was conducted by FMEA approach and all corrective actions are applied separately in different plants. For a more precise study, it is recommended that the whole system to be applied a specific plant. Monitoring and evaluating of FMEA system in one plant can give more precise results.

All failure modes in this thesis are observed in field inspections of dairy products. Due to the generalization, some individual failures are not mentioned. Therefore, in application of FMEA on a specific plant, failure modes must be reviewed and rearranged for the plant.

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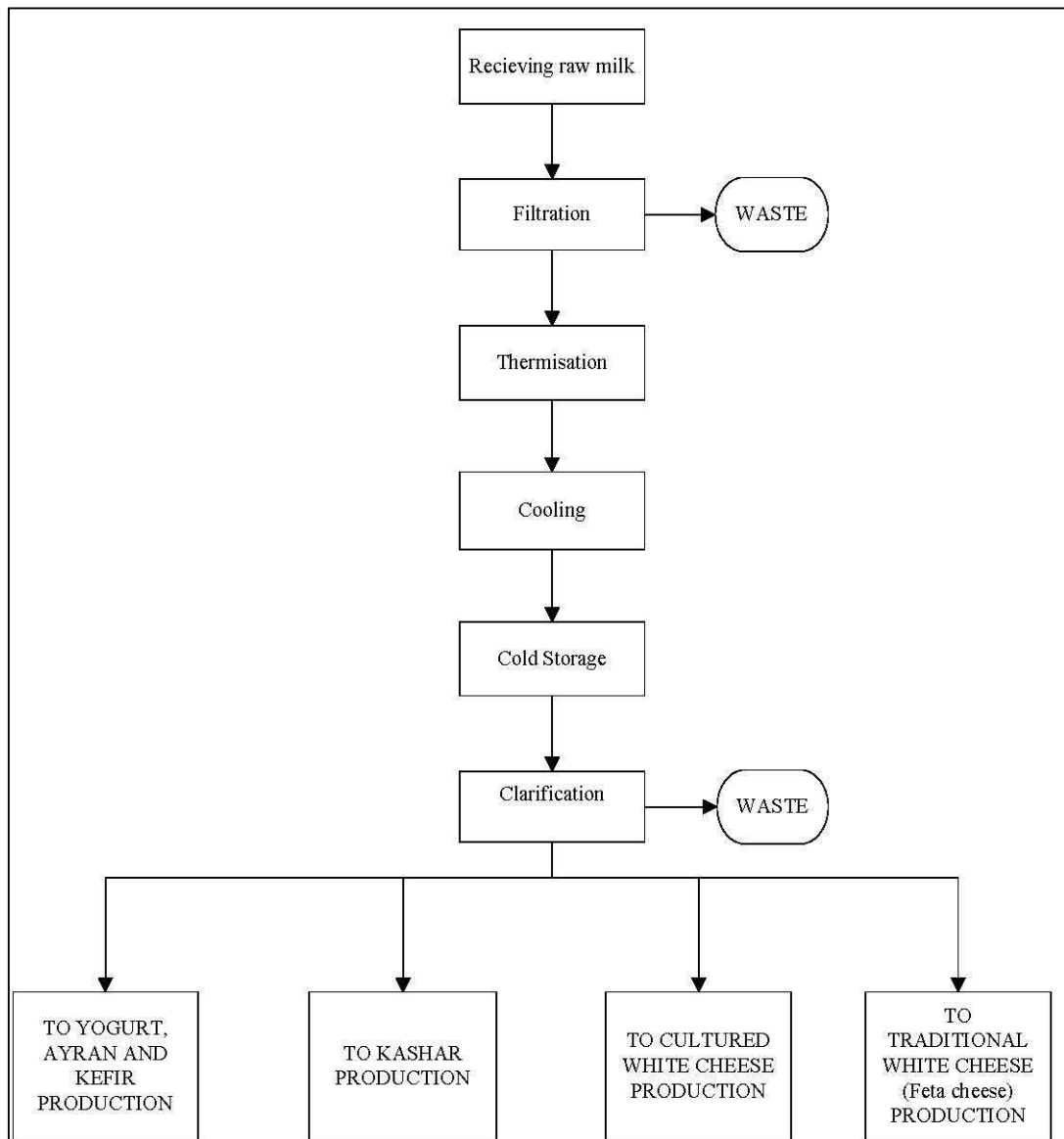
**APPENDIX A: FLOW DIAGRAMS**

Figure A.1. Milk pretreatment flow diagram

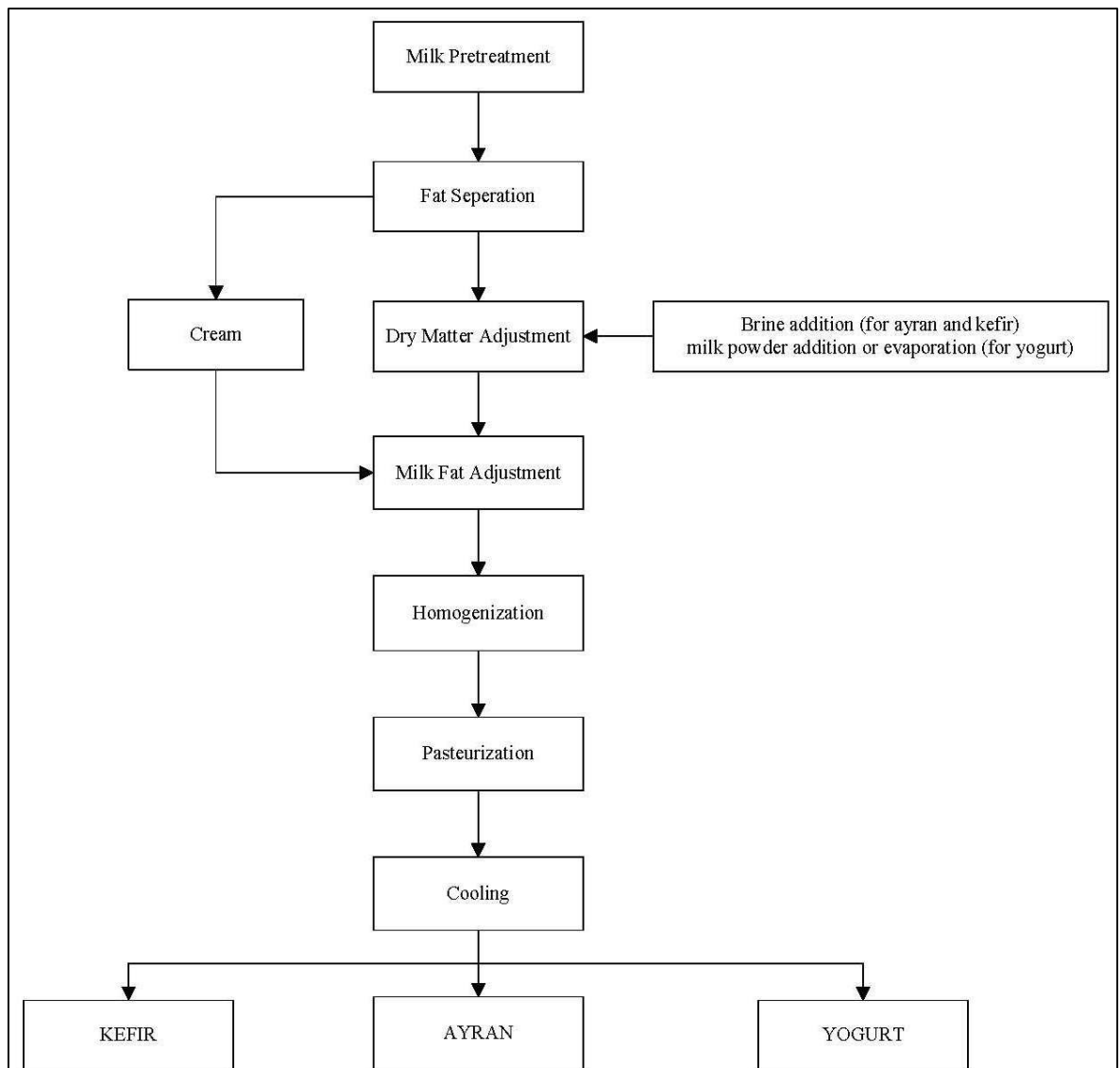


Figure A.2. Yogurt, ayran and kefir pretreatment flow diagram

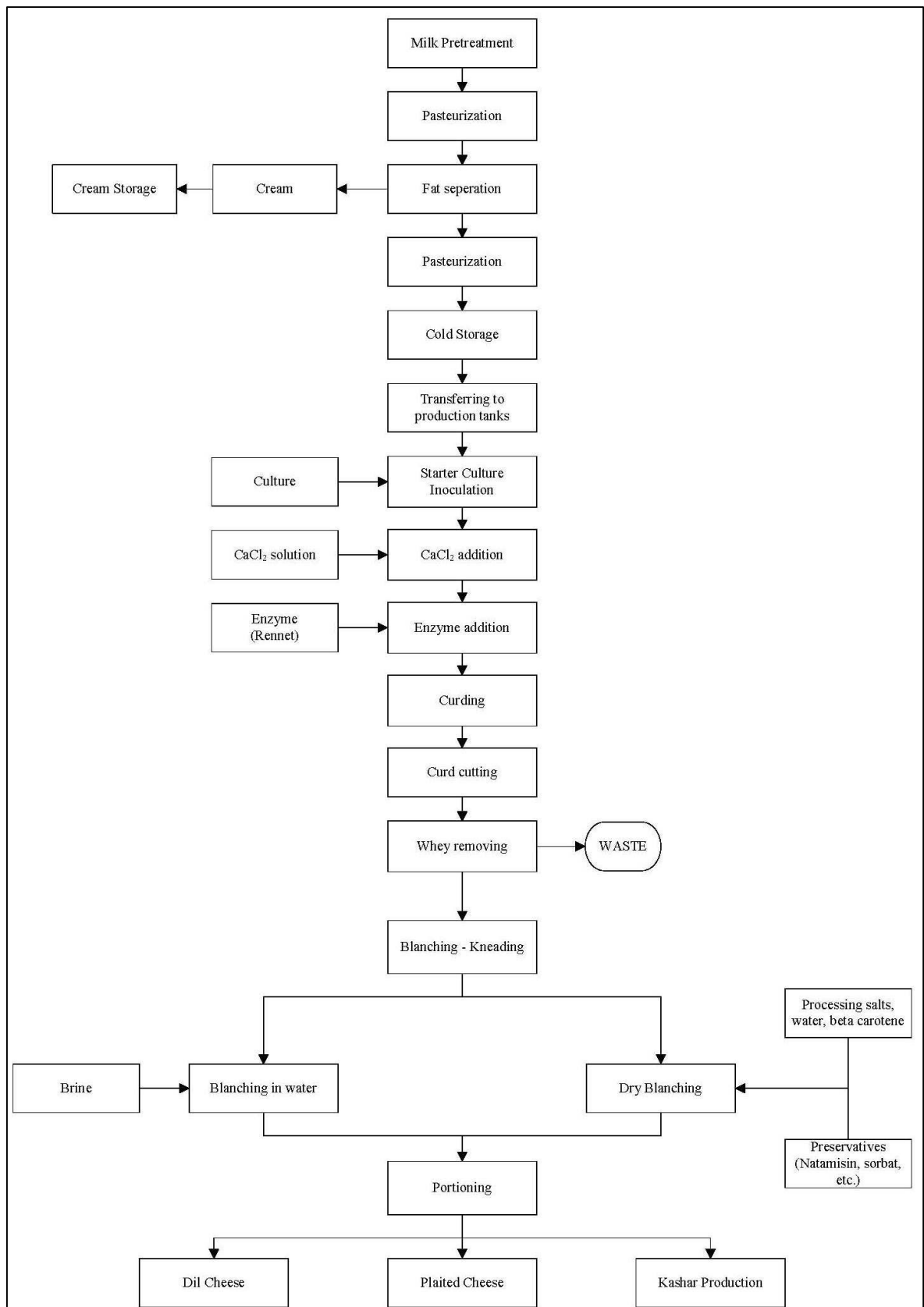


Figure A.3. Kasar group pretreatment flow diagram

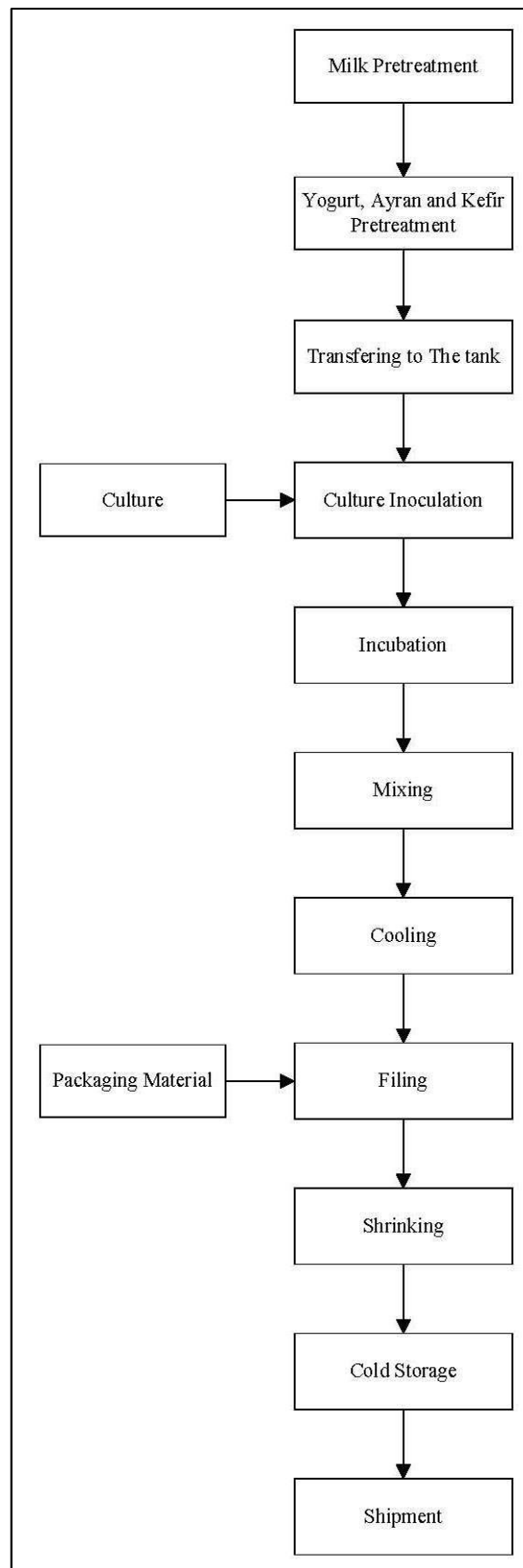


Figure A.4. Ayran and kefir production flow diagram

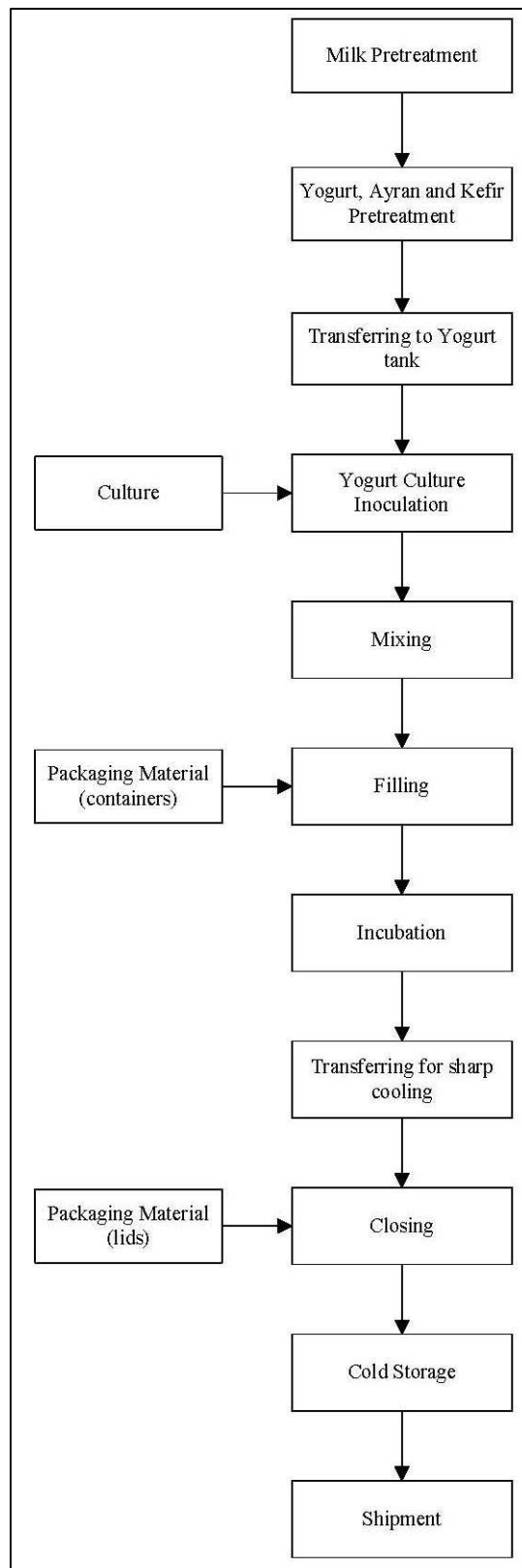


Figure A.5. Yogurt production flow diagram

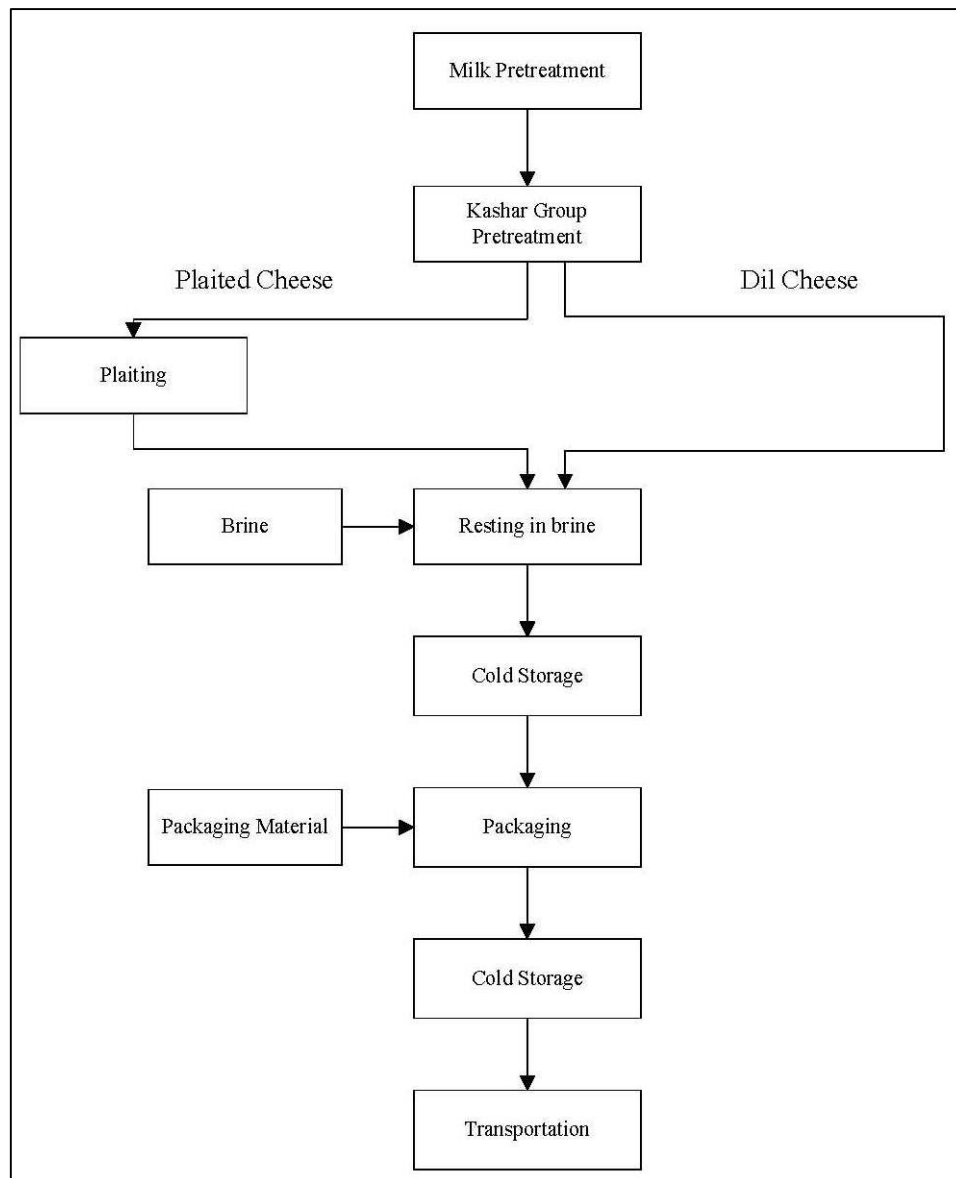


Figure A.6. Dil and plaited cheese flow diagram

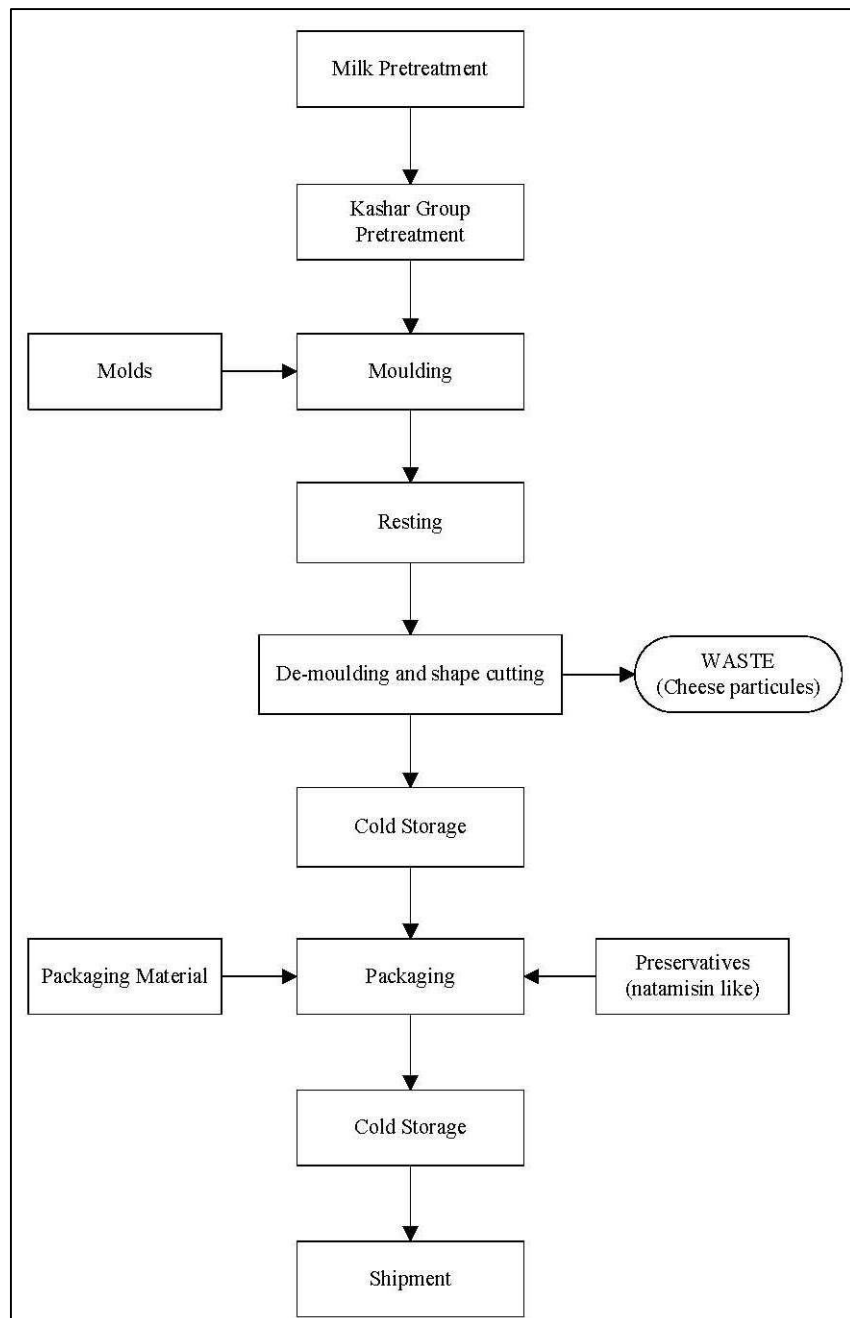


Figure A.7. Kashar cheese flow diagram





## APPENDIX B: FMEA TABLES

Table B.1. Application of FMEA to milk pretreatment

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Receiving raw milk</b>									
<b>Physical Hazards</b>									
Physical contaminants in raw milk due to improper handling and agricultural practices (glass, metal, insect parts, etc.)	5	6	2	60	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Veterinary drug residues in milk samples due to improper veterinary practices	7	8	7	392	Supplier must be reliable. Antibiotics analysis must be carried out for each batch with antibiotic kits	2	8	2	32
High level of aflatoxin in milk due to improper agricultural practices and using contaminated feed in field	5	8	9	360	Supplier must be reliable. Total aflatoxin analysis must be carried out for each batch with aflatoxin kits	2	8	2	32
Detection of chemicals which are not expected to be exist in raw milk due to adulteration of raw milk (alkaline addition)	5	8	7	280	Supplier must be reliable. Alkaline analysis must be carried out for each batch	3	8	3	72
Pesticide residues in milk from contaminated feed (dioxins, organophosphates, etc.)	3	8	8	192	Supplier must be reliable. Periodic pesticide analysis must be carried out.	2	8	5	80
<b>Biological Hazards</b>									
High number of spoilage microorganisms in milk due to improper handling and storage	9	7	5	315	Supplier must be reliable. Immediate cooling below 5 °C is required after receiving. Cold chain must be kept from farm to receiving. The pH and/or acidity controls must be done for each batch	4	7	2	56

Table B.1. Application of FMEA to milk pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
High number of pathogen ( <i>E.coli</i> O157:H7, <i>Salmonella</i> spp., <i>Mycobacterium tuberculosis</i> , <i>Shigella dysenteriae</i> etc.) in milk caused by improper handling and storage	8	10	9	720	Supplier must be reliable. Immediate cooling below 5 °C is required after receiving. Cold chain must be kept from farm to receiving. The pH and/or acidity controls must be done for each batch. Periodic pathogen analysis must be done for verification.	3	10	3	90
Isolation of <i>Staphylococcus</i> spp. and <i>Streptococcus</i> spp in milk which might be the indication of animals with mastitis disease	5	8	5	200	Periodic veterinary controls on fields are required. Somatic cell count must be done regularly	2	8	2	32
Parasites ( <i>Protozoa</i> - <i>Cryptosporidium</i> spp. etc.) in milk from unhealthy animal sources	3	8	8	192	Supplier must be reliable. Parasite analysis must be carried out regularly. Periodic veterinary controls on fields are required.	2	8	5	80
<b>Processing stage: Filtration</b>									
<b>Physical Hazards</b>									
Physical contamination from torn or damaged filtration equipment	4	4	3	48	Not required.	-	-	-	-
Inadequate filtration caused by torn or damaged filtration equipment	6	4	3	72	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out for the rinsing water	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination due to inadequate cleaning of equipment	5	8	4	160	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls)	2	8	2	32
Microbiological contamination due to the use of inappropriate cleaning material (i.e., sponge)	6	7	2	84	Not required.	-	-	-	-
Microbiological contamination ( <i>E.coli</i> O157:H7, <i>Shigella</i> spp., <i>Salmonella</i> spp.) form pests, such as flies	7	9	3	189	The milk receiving facility must be isolated. Effective pest control management is required	2	9	3	54

Table B.1. Application of FMEA to milk pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Therimisation / Cooling</b>									
<i>Physical Hazards</i>									
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	6	8	5	240	The therimisation/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Approved maintenance procedure must be followed. Staff must be trained about food safety and the controlling the system	1	8	1	8
<b>Processing stage: Cold storage</b>									
<i>Physical Hazards</i>									
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Detergents, sanitizers and disinfectants must be stored in a separate area to foods	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination due to improper storage conditions	5	8	6	240	Adequate facilities for hygienic storage must be provided. Proper cleaning procedure must be applied. Periodic controls (swabs) must be carried out for verification.	2	8	4	64

Table B.1. Application of FMEA to milk pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbial growth due to improper storage temperature	6	7	6	252	The cooler equipped or heat isolated tanks must be employed. The inner temperature of the tank must be measured regularly. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly.	2	7	2	28
<b>Processing stage: Clarification</b>									
<b>Physical Hazards</b>									
Impurities due to inadequate clarification resulted in mechanical failures (i.e., press. drop, maintenance etc.)	5	6	3	90	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residues due to inadequate rinsing after cleaning (common in "clean in place" cleaning system)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out for the rinsing water	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning	3	8	4	96	Not required.	-	-	-	-

Table B.2. Application of FMEA to water used in all processes

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Water</b>									
<b>Physical Hazards</b>									
Physical contamination from water used at factory	4	4	4	64	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Presence of heavy metal residues in water (arsenic, antimony, boron, cadmium, chrome, copper, lead, mercury etc.)	4	8	9	288	Periodic analysis must be carried out for verification. A suitable filtration system must be placed like reverse osmosis if needed. Approved maintenance procedure of filtration equipments must be followed.	2	8	3	48
Presence of pesticide residues in water	4	8	6	192	Periodic analysis must be carried out for verification. A suitable filtration system must be placed like reverse osmosis if needed. Approved maintenance procedure of filtration equipments must be followed.	2	8	3	48
Nitrite, Nitrate contamination to products from water	4	7	6	168	Periodic analysis must be carried out for verification. A suitable filtration system must be placed like reverse osmosis if needed. Approved maintenance procedure of filtration equipments must be followed.	2	7	3	42
Contamination of chemical substances to products from water (bromate, cyanide, acrylamide, benzene etc.)	4	8	7	224	Periodic analysis must be carried out for verification. A suitable filtration system must be placed like reverse osmosis if needed. Approved maintenance procedure of filtration equipments must be followed.	2	8	3	48
<b>Biological Hazards</b>									
Pathogenic microorganisms presence at water	6	9	8	432	Periodic microbiological analysis must be carried out for verification. Microbiological treatment must applied to water by using chemical agents like chlorine, ozone or UV based systems. Approved maintenance procedure of refining equipments must be followed.	2	9	2	36

Table B.2. Application of FMEA to water used in all processes (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Parasite presence at water	4	7	8	224	Periodic microbiological analysis must be carried out for verification. Microbiological treatment must be applied to water by using chemical agents like chlorine, ozone or UV based systems. Approved maintenance procedure of refining equipments must be followed.	2	7	2	28

Table B.3. Application of FMEA to yogurt, kefir and ayran pretreatment

Processing stage: Milk Pretreatment*									
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Fat separation</b>									
<i>Physical Hazards</i>					not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
<b>Processing stage: Dry matter adjustment</b>									
<i>Physical Hazards</i>									
Physical contaminants added into milk from the milk powder containers	4	5	3	60	Not required	-	-	-	-
Physical impurities added into milk from impure salt	6	5	4	120	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	1	5	2	10
<i>Chemical Hazards</i>									
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
Detergent and/or disinfectant residues due to inadequate rinsing after cleaning the tanks/evaporator (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14



Table B.3. Application of FMEA to yogurt, kefir and ayran pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbiological contamination caused by contaminated materials that are used during processing, i.e., salt and milk powder	5	8	7	280	Supplier must be reliable. Periodic microbiological analysis must be carried out for verification	2	8	5	80
<i>Potential failure comes from water**</i>				1592					250
<b>Processing stage: Milk fat adjustment</b>									
<b>Physical Hazards</b>									
Metal, glass or plastic particles from the creams containers	4	6	4	96	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residues due to inadequate rinsing after cleaning the pipes (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination from the cream containers	3	8	7	168	Cleanliness of containers must be controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbiological contamination caused by inadequate cleaning of cream pipes (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
<b>Processing stage: Homogenization</b>									
<b>Physical Hazards</b>									
					Not common				

Table B.3. Application of FMEA to yogurt, kefir and ayran pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination due to inadequate cleaning (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
<b>Processing stage: Pasteurization</b>									
<b>Physical Hazards</b>									
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination due to inadequate cleaning (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	5	10	6	300	The pasteurization process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipments (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	2	10	2	40
<b>Processing stage: Cooling</b>									
<b>Physical Hazards</b>									
<b>Chemical Hazards</b>									

Table B.3. Application of FMEA to yogurt, kefir and ayran pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<i>Biological Hazards</i>									
Microbial growth caused by inadequate processing time and/or temperature	6	8	5	240	The thermisation/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipments (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	1	8	1	8

\* FMEA analysis for milk pretreatment is given in Table B.1.  
 \*\* FMEA analysis for water is given in Table B.2.

Table B.4. Application FMEA to kashar cheese group pretreatment

Processing stage: Milk Pretreatment*									
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Pasteurization</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning equipment (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	5	10	6	300	The thermisation/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	2	10	2	40
<b>Processing stage: Cold storage</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue caused by inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbial growth caused by inadequate processing time and/or temperature	6	8	5	240	The thermination/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	1	8	1	8
<b>Processing stage: Transferring to production tanks</b>									
<b>Physical Hazards</b>									
					Not common				
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
<b>Processing stage: Culture inoculation</b>									
<b>Physical Hazards</b>									
Foreign materials from the packages used for culture packaging	4	5	3	60	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
					Not common				

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Pathogens from the contaminated culture	5	9	7	315	Supplier must be reliable. Staff training on proper handling of cultures is required	2	9	4	72
<b>Processing stage: CaCl<sub>2</sub> addition</b>									
<b>Physical Hazards</b>									
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
Contaminants from the staff due to improper practices	3	4	6	72	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contaminants due to the use of empty food containers to store chemicals and mislabeling	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Pathogens from contaminated CaCl <sub>2</sub>	5	9	7	315	Supplier must be reliable. Staff training on proper handling and storage of ingredients is required.	2	9	4	72
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Enzyme addition</b>									
<b>Physical Hazards</b>									
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
Contaminants from the staff due to improper practices	3	4	6	72	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contaminants due to the use of empty food containers to store chemicals and mislabeling	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Pathogens from contaminated enzyme	5	9	7	315	Supplier must be reliable. Staff training on proper handling and storage of ingredients is required.	2	9	4	72
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Curdling</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during the process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Not common									
<b>Biological Hazards</b>									
Contamination due to improper handling during the process	5	8	7	280	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
<b>Processing stage: Curd cutting</b>									
<b>Physical Hazards</b>									
Metal pieces from the worm blades	3	6	4	72	Not required	-	-	-	-
<b>Chemical Hazards</b>									
Contamination of machine oil in foods from the pedals	4	7	6	168	Standard maintenance program must be applied. The food grade oils must be used	2	4	5	40
<b>Biological Hazards</b>									
Microbiological contamination from improperly cleaned or stored blades	6	8	6	288	Proper cleaning procedure must be applied. Staff training on hygiene and sanitation is required	2	8	4	64



Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Whey removal</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>					Not common				
<b>Processing stage: Blanching-kneading</b>									
<i>i- Blanching in water</i>									
<i>Physical Hazards</i>									
Physical contaminants from salt	5	5	4	100	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	2	5	3	30
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Teflon coating particles from the blanching equipment	6	4	5	120	Approved maintenance procedure must be followed.	2	4	5	40
Plastic particles from the damaged equipment used for blanching (plastic measuring caps, plastic drainer etc.)	5	4	3	60	Not required	-	-	-	
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	5	8	6	240	The process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	2	8	4	64
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Potential failure comes from water**</b>									
<b>ii- Dry blanching</b>									
<b>Physical Hazards</b>									
Physical contaminants from salt	5	5	4	100	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	2	5	3	30
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Teflon coating particles from the blanching equipment	6	4	5	120	Approved maintenance procedure must be followed.	2	4	5	40
Plastic particles from the damaged equipment used for blanching (plastic measuring caps, plastic drainer etc.)	5	4	3	60	Not required	-	-	-	-

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
Inadequate or excessive usage of preservatives	6	8	6	288	Calibration of scales used for measuring the weight is required. Staff must be trained on proper practices. Periodic preservative analysis must be carried on for verification	2	8	3	48
Mycotoxin contamination due to the use of mycotoxin containing old cheeses	5	8	4	160	Periodic analyses of old cheeses must be carried out	2	8	2	32
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	5	8	6	300	The pasteurization process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Periodic maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	2	8	4	40
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48

Table B.4. Application FMEA to kashar cheese group pretreatment (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<i>Potential failure comes from water**</i>				1592					250
<b>Processing stage: Portioning</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
* FMEA analysis for milk pretreatment is given in Table B.1. ** FMEA analysis for water is given in Table B.2.									

Table B.5. Application of FMEA to ayran and kefir production

Processing stage: Milk Pretreatment*										
Processing stage: Yogurt, ayran and kefir pretreatment**										
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions	
<b>Processing stage: Transferring to the tank</b>										
<i>Physical Hazards</i>					Not common					
<i>Chemical Hazards</i>										
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14	
<i>Biological Hazards</i>										
Microbiological contamination caused by inadequate cleaning of pipes and tanks (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64	
<b>Processing stage: Culture inoculation</b>										
<i>Physical Hazards</i>										
Foreign materials from the packages used for culture packaging	4	5	3	60	Not required.	-	-	-	-	
<i>Chemical Hazards</i>					Not common					
<i>Biological Hazards</i>										
Microbiological contamination due to inappropriate practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48	
Pathogen contamination from the contaminated culture	5	9	7	315	Supplier must be reliable. Staff training on proper handling of cultures is required	2	9	4	72	

Table B.5. Application of FMEA to ayran and kefir production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Incubation in tanks</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>									
Growth of pathogens due to inappropriate incubation temperature- which effects the acidity of the medium and culture activation	5	9	2	90	Not required.	-	-	-	-
<b>Processing stage: Mixing</b>									
<i>Physical Hazards</i>									
Metal pieces from the worm mixing pedals	3	6	4	72	Not required	-	-	-	-
<i>Chemical Hazards</i>									
Contamination of machine oil in foods from the pedals	4	7	6	168	Standard maintenance program must be applied. The food grade oils must be used	2	4	5	40
<i>Biological Hazards</i>									
Microbiological contamination from improperly sealed mixing pedals	4	7	4	112	Standard maintenance program must be applied.	2	7	3	42
<b>Processing stage: Cooling</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>					Not common				

Table B.5. Application of FMEA to ayran and kefir production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Filling</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
Glass particles from the lamps of the filling machine	2	6	3	36	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Migration of chemicals from the packaging materials	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Heavy metal residues from the packaging material	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Contamination of heavy metal residues from the seal	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of sealing materials must be done periodically.	2	8	5	80
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<b>Biological Hazards</b>									
Microbiological contamination caused by improper sealing of cover	8	8	5	320	Maintenance program on sealing equipments must be applied. Periodic controls must be done after sealing. Sealing operators must be trained.	4	8	2	64
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84

Table B.5. Application of FMEA to ayran and kefir production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Contamination from the environmental	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Microbiological contamination caused by inadequate cleaning of filling equipments (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth due to increased time and/or temperature after filling	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Cold storage</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
<b>Processing stage: Transportation</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>									
Microbial growth due to temperature abuse during transportation	8	7	6	336	The standard control program must be applied. Temperature must be controlled during transportation.	4	7	3	84

\* FMEA analysis for milk pretreatment is given in Table B.1.

\*\* FMEA analysis for yogurt, ayran and kefir pretreatment is given in Table B.3.



Table B.6. Application of FMEA to yogurt production

Processing stage: Milk Pretreatment*										
Processing stage: Yogurt, ayran and kefir pretreatment**										
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions	
<b>Processing stage: Transferring to the yogurt tank</b>										
<i>Physical Hazards</i>					Not common					
<i>Chemical Hazards</i>										
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14	
<i>Biological Hazards</i>										
Microbiological contamination caused by inadequate cleaning of pipes and tanks (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64	
<b>Processing stage: Culture inoculation</b>										
<i>Physical Hazards</i>										
Foreign materials from the packages used for culture packaging	4	5	3	60	Not required.	-	-	-	-	
<i>Chemical Hazards</i>					Not common					
<i>Biological Hazards</i>										
Microbiological contamination due to inappropriate practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48	
Pathogen contamination from the contaminated culture	5	9	7	315	Supplier must be reliable. Staff training on proper handling of cultures is required	2	9	4	72	

Table B.6. Application of FMEA to yogurt production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Mixing</b>									
<b>Physical Hazards</b>									
Metal pieces from the worm mixing pedals	3	6	4	72	Not required	-	-	-	-
<b>Chemical Hazards</b>									
Addition of machine oil in foods from the pedals	4	7	6	168	Standard maintenance program must be applied. The food grade oils must be used	2	4	5	40
<b>Biological Hazards</b>									
Microbiological contamination from improperly sealed mixing pedals	4	7	4	112	Standard maintenance program must be applied.	2	7	3	42
<b>Processing stage: Filling</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
<b>Chemical Hazards</b>									
Migration of chemicals from the packaging materials	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Heavy metal residues from the packaging material	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Detergent and/or disinfectant residue due to inadequate rinsing after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14

Table B.6. Application of FMEA to yogurt production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Microbiological contamination from in-plant delivery carts	4	8	6	192	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbiological contamination caused by inadequate cleaning of filling equipments (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
<b>Processing stage: Incubation</b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
Rusty metal particles from the air ventilation channels	7	5	4	140	Periodical maintenance and a control of ventilation system is required	2	5	3	30
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Contaminated air coming from the ventilation channels	7	8	6	336	Proper cleaning procedure must be applied. Periodical maintenance and a ventilation system control are required. The quality of air must be controlled periodically.	3	8	3	72

Table B.6. Application of FMEA to yogurt production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Growth of pathogens due to inappropriate incubation temperature- that effects the acidity of the medium and culture activation	5	9	2	90	Not required.	-	-	-	-
<b>Processing stage: Transportation and Sharp cooling</b>									
<b>Physical Hazards</b>									
Foreign substances may enter into foods during transportation to cooling rooms	5	4	6	120	Staff training on proper handling is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Contamination from the environment	5	5	3	75	Not required	-	-	-	-
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbial contamination due to mis-handling	4	8	7	224	Staff training on personnel hygiene and hand washing is required. Personnel hygiene control must be done regularly.	2	8	3	48
Contamination from the environment	4	7	6	168	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
<b>Processing stage: Closing the lids</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Physical contamination from the lids	6	5	6	180	Staff training on proper handling is required	2	5	5	50
<b>Chemical Hazards</b>					Not common				

Table B.6. Application of FMEA to yogurt production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbial contamination due to mis-handling	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Personnel hygiene control must be done regularly.	2	8	3	48
Contamination from the lids	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84
Microbial growth due to increased time and/or temperature after closing the lids	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Cold storage</b>									
<b>Physical Hazards</b>									
					Not common				
<b>Chemical Hazards</b>									
					Not common				
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
<b>Processing stage: Transportation</b>									
<b>Physical Hazards</b>									
					Not common				
<b>Chemical Hazards</b>									
					Not common				
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during transportation	8	7	6	336	The standard control program must be applied. Temperature must be controlled during transportation.	4	7	3	84
* FMEA analysis for milk pretreatment is given in Table B.1.									
** FMEA analysis for yogurt, ayran and kefir pretreatment is given in Table B.3.									

Table B.7. Application of FMEA to plaited cheese and dil cheese production

Processing stage: Milk Pretreatment*									
Processing stage: Kashar group pretreatment**									
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Plaiting<sup>a</sup></b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during the process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Resting in brine</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Physical contaminants from salt	5	5	4	100	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	2	5	3	30
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of resting vats (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42

Table B.7. Application of FMEA to plaited cheese and dil cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Contamination from the environmental	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Biological contamination from salt	6	5	4	120	Supplier must be reliable. Staff training on proper handling and storage of ingredients is required.	1	5	2	10
<b>Potential failure comes from water**</b>									
<b>Processing stage: Cold Storage</b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
Foreign materials from the transferring equipments (boxes, cars, etc.)	6	5	4	120	Proper cleaning procedure must be applied. The sanitary conditions of the equipments must be controlled regularly.	2	5	3	30
Rusty metal particles from the air ventilation channels (evaporator's fan cage)	7	5	4	140	Periodical maintenance and a control of ventilation system is required	2	5	3	30

Table B.7. Application of FMEA to plaited cheese and dil cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of transferring and storage equipments after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of storage equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Contaminated air coming from the ventilation channels	7	8	6	336	Proper cleaning procedure must be applied. Periodical maintenance and a ventilation system control are required. The quality of air must be controlled periodically.	3	8	3	72
Microbial growth due to temperature abuse during storage	7	8	6	336	The standard control program must be applied. The storage room temperature must be controlled properly.	3	8	3	72
<b>Processing stage: Packaging</b>									
<b>Physical Hazards</b>									
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
Contamination from the staff due to improper practices during packaging	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Migration of chemicals from the packaging materials	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Heavy metal residues from the packaging material	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80



Table B.7. Application of FMEA to plaited cheese and dil cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Contamination of hand sanitizers of workers during sanitizing hands near the packaging lines	6	7	7	294	Staff training is required. Hand sanitizers must be re-position far from the packaging lines	2	7	5	70
Usage of excessive amount of microbiological preservative (spraying type application)	6	8	6	288	Scales, which are used for weight measurements, must be calibrated regularly. Staff training is required. Periodic preservatives content tests must be carried out for verification.	2	8	3	48
<b>Biological Hazards</b>									
Microbiological contamination caused by improper sealing of packages	8	8	5	320	Maintenance of equipment (maintenance procedure) must be ensured. Periodic packaging controls must be carried out regularly. Staff training is required.	4	8	2	64
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Microbiological contamination caused by inadequate cleaning of packaging equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth due to increased time and/or temperature after packaging	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Cold storage</b>									
<b>Physical Hazards</b>					Not common				
<b>Chemical Hazards</b>					Not common				

Table B.7. Application of FMEA to plaited cheese and dil cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
<b>Processing stage: Transportation</b>									
<b>Physical Hazards</b>					Not common				
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during transportation	8	7	6	336	The standard control program must be applied. Temperature must be controlled during transportation.	4	7	3	84

\* FMEA analysis milk pretreatment is given in Table B.1.  
 \*\* FMEA analysis for kashar cheese group pretreatment is given in Table B.4.  
 \*\*\* FMEA analysis for water is given in Table B.2.  
 †. only for plaited cheese

Table B.8. Application of FMEA to kashar cheese production

Processing stage: Milk Pretreatment*										
Processing stage: Kashar group pretreatment**										
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions	
<b>Processing stage: Moulding</b>										
<i>Physical Hazards</i>										
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40	
<i>Chemical Hazards</i>										
Detergent and/or disinfectant residue due to inadequate rinsing of moulds after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42	
<i>Biological Hazards</i>										
Microbiological contamination caused by inadequate cleaning of moulds (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64	
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48	
<b>Processing stage: Resting</b>										
<i>Physical Hazards</i>										
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30	
Rusty metal particles from the air ventilation channels(evaporator's fan cage)	7	5	4	140	Periodical maintenance and a control of ventilation system is required	2	5	3	30	

Table B.8. Application of FMEA to kashar cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>					not common				
<b>Biological Hazards</b>									
Contaminated air coming from the ventilation channels	7	8	6	336	Proper cleaning procedure must be applied. Periodical maintenance and a ventilation system control are required. The quality of air must be controlled periodically.	3	8	3	72
Microbial growth due to temperature abuse during storage	7	8	6	336	The standard control program must be applied. The storage room temperature must be controlled properly.	3	8	3	72
Mold growth caused by inadequate removal of moisture	7	8	3	168	An undercover must be used for kashar cheese blocks for helping to remove moisture. Kashar cheeses must be turned periodically	2	8	3	48
<b>Processing stage: De-moulding and shape cutting</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of knives after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination due to improper practices	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Microbiological contamination caused by inadequate cleaning of moulds (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64

Table B.8. Application of FMEA to kashar cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbial growth due to making process in temperature abuse environment	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Cold Storage</b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
Foreign materials from the transferring equipments (boxes, cars, etc.)	6	5	4	120	Proper cleaning procedure must be applied. The sanitary conditions of the equipments must be controlled regularly.	2	5	3	30
Rusty metal particles from the air ventilation channels (evaporator's fan cage)	7	5	4	140	Periodical maintenance and a control of ventilation system is required	2	5	3	30
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of transferring and storage equipments after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of storage equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Contaminated air coming from the ventilation channels	7	8	6	336	Proper cleaning procedure must be applied. Periodical maintenance and a ventilation system control are required. The quality of air must be controlled periodically.	3	8	3	72
Microbial growth due to temperature abuse during storage	7	8	6	336	The standard control program must be applied. The storage room temperature must be controlled properly.	3	8	3	72

Table B.8. Application of FMEA to kashar cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Packaging</b>									
<b>Physical Hazards</b>									
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Migration of chemicals from the packaging materials	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Heavy metal residues from the packaging material	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Contamination of hand sanitizers of workers during sanitizing hands near the packaging lines	6	7	7	294	Staff training is required. Hand sanitizers must be re-position far from the packaging lines	2	7	5	70
Usage of excessive amount of microbiological preservative (spraying type application)	6	8	6	288	Scales, which are used for weight measurements, must be calibrated regularly. Staff training is required. Periodic preservatives content tests must be carried out for verification.	2	8	3	48
<b>Biological Hazards</b>									
Microbiological contamination caused by improper sealing of packages	8	8	5	320	Maintenance of equipment (maintenance procedure) must be ensured. Periodic packaging controls must be carried out regularly. Staff training is required.	4	8	2	64
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84

Table B.8. Application of FMEA to kashar cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Microbiological contamination caused by inadequate cleaning of packaging equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth due to increased time and/or temperature after packaging	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Cold storage</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
<b>Processing stage: Transportation</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>					Not common				
<i>Biological Hazards</i>									
Microbial growth due to temperature abuse during transportation	8	7	6	336	The standard control program must be applied. Temperature must be controlled during transportation.	4	7	3	84

\* FMEA analysis milk pretreatment is given in Table B.1

\*\* FMEA analysis for kashar cheese group pretreatment is given in Table B.4

Table B.9. Application of FMEA to white cheese production

Processing stage: Milk Pretreatment*									
Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Pasteurization &amp; Fat separation</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning equipment (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Microbial growth caused by inadequate processing time and/or temperature	6	8	5	240	The thermisation/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	8	1	1	8
<b>Processing stage: Cold storage</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residues after cleaning of tank (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning of storage tank (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64



Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbial growth caused by inadequate processing time and/or temperature	6	8	5	240	The thermisation/cooling process control must be computerized. Thermometers / probes, which are used for temperature measurements, must be calibrated regularly. Maintenance of equipment (maintenance procedure) must be ensured. Staff must be trained about food safety and the controlling the system	1	8	1	8
<b>Processing stage: Preparation of cheese vats</b>									
<b>Physical Hazards</b>									
Contamination of cloth fibers due to usage of worn cloth	4	4	3	48	Not needed.	-	-	-	
Foreign materials from cheese vats	6	5	4	120	Proper cleaning procedure must be applied. The sanitary conditions of the equipments must be controlled regularly.	2	5	3	30
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Foreign materials from polyethylene separator sheet	4	4	3	48	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residues after cleaning of equipments (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Migration of chemicals from the polyethylene separator sheet	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of polyethylene separator sheet must be done periodically.	2	8	5	80
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of cheese cloth (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination caused by inadequate cleaning of cheese vat (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Microbiological contamination caused by inadequate cleaning of polyethylene separator sheet (manual cleaning) (if disposable sheet not used)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
<b>Processing stage: Transferring milk to cheese vats</b>									
<i>Physical Hazards</i>					Not common				
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of tanks after cleaning (CIP cleaning)	4	7	6	168	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	1	14
<i>Biological Hazards</i>									
Microbiological contamination caused by inadequate cleaning equipment (CIP cleaning)	5	8	6	240	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
<b>Processing stage: Culture inoculation<sup>a</sup></b>									
<i>Physical Hazards</i>									
Foreign materials from the packages used for culture packaging	4	5	3	60	Not required.	-	-	-	-
<i>Chemical Hazards</i>					Not common				

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Pathogens from the contaminated culture	5	9	7	315	Supplier must be reliable. Staff training on proper handling of cultures is required	2	9	4	72
<b>Processing stage: CaCl<sub>2</sub> addition<sup>a</sup></b>									
<b>Physical Hazards</b>									
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
Contaminants from the staff due to improper practices	3	4	6	72	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contaminants due to the use of empty food containers to store chemicals and mislabeling	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Pathogens from contaminated CaCl <sub>2</sub>	5	9	7	315	Supplier must be reliable. Staff training on proper handling and storage of ingredients is required.	2	9	4	72
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Enzyme addition</b>									
<b>Physical Hazards</b>									
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
Contaminants from the staff due to improper practices	3	4	6	72	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Chemical contaminants due to the use of empty food containers to store chemicals and mislabeling	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Pathogens from contaminated enzyme	5	9	7	315	Supplier must be reliable. Staff training on proper handling and storage of ingredients is required.	2	9	4	72
Microbiological contamination caused by inadequate cleaning of measuring caps (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Mixing</b>									
<b>Physical Hazards</b>									
Physical pieces from the worn mixing equipments (metal pieces, polyethylene pieces etc.)	3	6	5	90	Not needed.	-	-	-	
Foreign materials contamination from improperly cleaned or stored mixing equipments	6	5	4	120	Proper cleaning procedure must be applied. The sanitary conditions of the equipments must be controlled regularly.	2	5	3	30
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of mixing equipments after cleaning (manual cleaning) or storing inappropriate places	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination caused by improperly cleaned or stored mixing equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Resting in vats</b>									
<i>Physical Hazards</i>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
<i>Chemical Hazards</i>									
<i>Biological Hazards</i>									
Microbiological contamination caused by improperly cleaned or stored pH measuring equipments (manual cleaning)	8	8	6	384	Proper cleaning procedure must be applied. Staff training on cleaning and handling equipments is required. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	4	64
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
<b>Processing stage: Cutting the curd</b>									
<i>Physical Hazards</i>									
Foreign materials contamination from improperly cleaned or stored cutting equipments	6	5	4	120	Proper cleaning procedure must be applied. The sanitary conditions of the equipments must be controlled regularly.	2	5	3	30
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<i>Chemical Hazards</i>									
Detergent and/or disinfectant residue due to inadequate rinsing of measuring caps after cleaning (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning or storing of cutting equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Removing PE separator sheet</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Covering the curd with cheese cloth</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Foreign materials contamination from improperly cleaned or stored needles	4	4	3	48	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of needles (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
Microbiological contamination caused by inadequate cleaning or storing of needles (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
<b>Processing stage: Pressing</b>									
<b>Physical Hazards</b>									
Foreign materials contamination from improperly cleaned or stored mixing equipments	6	4	4	96	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of pressing plates (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning or storing of pressing plates (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64



Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological contamination caused by waited water comes from cans filled with water used as weight at pressing	4	8	3	96	Not needed.	-	-	-	
<b>Processing stage: End of pressing (Removing the needles)</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Cutting in shapes</b>									
<b>Physical Hazards</b>									
Foreign materials contamination from improperly cleaned or stored cutting equipments (knives and/or rulers)	5	5	3	75	Not needed.	-	-	-	
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of cutting equipments (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning or storing of cutting equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Removing of cheese cloth</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Not common									
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Brine addition (to cheese vats)</b>									
<b>Physical Hazards</b>									
Physical contaminants from salt	6	6	4	144	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	1	6	2	12

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Potential failure comes from water**</b>				1592					250
<b>Processing stage: First ripening at brine</b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbiological growth due to insufficient ripening (pH is not enough)	4	9	2	72	Not needed.	-	-	-	
<b>Processing stage: Turning the cheese at brine</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Dry salt addition</b>									
<b>Physical Hazards</b>									
Physical contaminants from salt	6	6	4	144	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	1	6	2	12
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>									
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>					Not common				

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Collecting cheese to boxes</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Foreign materials from the boxes due to improper cleaning	5	5	3	75	Not needed.	-	-	-	
Contamination of plastic particles due to usage of worn boxes	5	4	3	60	Not needed.	-	-	-	
<b>Chemical Hazards</b>									
Detergent and/or disinfectant residue due to inadequate rinsing of cutting equipments (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Migration of chemicals from the boxes	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of boxes must be done periodically.	2	8	5	80
<b>Biological Hazards</b>									
Microbiological contamination caused by inadequate cleaning of storing of boxes (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbiological contamination due to inappropriate practices of staff	7	8	7	392	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Personal hygiene must be strictly controlled. Periodic microbiological analysis must be carried out (swab controls) for verification	2	8	3	48
<b>Processing stage: Rework of brine</b>									
<b>Physical Hazards</b>									
Foreign materials from brine	8	5	4	160	Brine solution must be filtered regularly	2	5	4	40

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbiological contamination due to waiting brine while whey contaminated.	5	7	6	210	Brine must be pasteurized regularly for eliminating microbiological load.	2	7	2	28
<b>Processing stage: Filling to cans</b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
<b>Chemical Hazards</b>									
Heavy metal residues from the packaging material due to inappropriately covered of lac cans used	5	8	8	320	Supplier must be reliable. Quality control of packaging materials must be done periodically.	2	8	5	80
<b>Biological Hazards</b>									
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
<b>Processing stage: Brine addition (to cans)</b>									
<b>Physical Hazards</b>									
Physical contaminants from salt	6	6	4	144	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	1	6	2	12

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Microbiological contamination caused by contaminated brine	5	7	6	210	Supplier must be reliable. Brine must be pasteurized regularly. Quality control of brine must be done periodically for verification	2	7	2	28
<b>Potential failure comes from water**</b>				1592					250
<b>Processing stage: Pre-ripening on cans<sup>b</sup></b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
<b>Chemical Hazards</b>					Not common				

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Biological Hazards</b>									
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Microbiological growth due to insufficient ripening (pH is not enough)	4	9	2	72	Not needed.	-	-	-	
<b>Processing stage: Closing the cans</b>									
<b>Physical Hazards</b>									
<b>Chemical Hazards</b>									
Heavy metal residues from covers and/or cans due to improper sealing (deformation on cap/can lac cover)	3	8	3	72	Not needed.	-	-	-	
<b>Biological Hazards</b>									
Microbiological contamination caused by improper sealing of packages	8	8	5	320	Maintenance of equipment (maintenance procedure) must be ensured. Periodic packaging controls must be carried out regularly. Staff training is required.	4	8	2	64
<b>Processing stage: Cold storage (ripening)<sup>b</sup></b>									
<b>Physical Hazards</b>									
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
Pathogen growth due to non ripening (using the cans before ripening - 3-6 months)	5	10	6	300	FIFO (first in - first out) program must applied on storage (using by labeling, computerized systems etc.)	2	10	3	60



Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Opening the cans<sup>b,1</sup></b>									
<b>Physical Hazards</b>									
Foreign materials from the environment	6	5	4	120	Proper cleaning procedure must be applied. Environment must be free from waste and pests. The sanitary conditions of the surroundings must be controlled regularly.	2	5	3	30
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Packaging material pieces in foods due to faults on opening	6	4	5	120	Staff training is required. Opening equipments maintenance that equipments must not deform caps	3	4	3	36
<b>Chemical Hazards</b>									
<b>Biological Hazards</b>									
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Microbiological contamination caused by inadequate cleaning of opening equipments (manuel cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64
Microbial growth due to increased time and/or temperature after packaging	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
<b>Processing stage: Packaging<sup>1</sup></b>									
<b>Physical Hazards</b>									
Packaging material pieces in foods	6	4	5	120	Supplier must be reliable. Quality control of packaging materials must be done periodically.	3	4	3	36
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Chemical Hazards</b>									
Migration of chemicals from the packaging materials	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Heavy metal residues from the packaging material	5	8	8	320	Supplier must be reliable. Food grade materials must only be used. Quality control of packaging materials must be done periodically.	2	8	5	80
Detergent and/or disinfectant residue due to inadequate rinsing of cutting equipments (manual cleaning)	5	7	5	175	Proper cleaning procedure must be applied. Periodic pH and/or electrical conductivity tests must be carried out regularly	2	7	3	42
Contamination of hand sanitizers of workers during sanitizing hands near the packaging lines	6	7	7	294	Staff training is required. Hand sanitizers must be re-position far from the packaging lines	2	7	5	70
Usage of excessive amount of microbiological preservative (spraying type application)	6	8	6	288	Scales, which are used for weight measurements, must be calibrated regularly. Staff training is required. Periodic preservatives content tests must be carried out for verification.	2	8	3	48
<b>Biological Hazards</b>									
Contamination from the packaging materials	6	7	7	294	Supplier must be reliable. Periodic microbiological analysis must be carried out (swab controls) for verification.	3	7	4	84
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Contamination from the environment	6	7	7	294	Positive pressured air ventilation with hepa-filters must be installed. Ventilation system and filters must be maintained. The microbiological quality of air must be controlled regularly.	2	7	3	42
Microbiological contamination caused by inadequate cleaning of packaging equipments (manual cleaning)	6	8	6	288	Proper cleaning procedure must be applied. Periodic microbiological analysis must be carried out (swab controls) for verification.	2	8	4	64

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
Microbial growth due to increased time and/or temperature after packaging	6	6	3	108	Staff training is required. Standard food flow directives must be obeyed.	2	6	2	24
Microbiological contamination caused by improper sealing of vacuum packages <sup>b</sup>	8	8	5	320	Maintenance of equipment (maintenance procedure) must be ensured. Periodic packaging controls must be carried out regularly. Staff training is required.	4	8	2	64
<b>Processing stage: Brine addition<sup>a,1</sup></b>									
<b>Physical Hazards</b>									
Physical contaminants from salt	6	6	4	144	Supplier must be reliable. Samples from each batch must be dissolved in water to ensure the purity.	1	6	2	12
Contamination from the staff due to improper practices during process	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
Foreign particles, such as sponge parts and fibers from the cleaning materials used for measuring cups.	3	3	4	36	Not required.	-	-	-	-
<b>Chemical Hazards</b>									
Chemical contamination due to mislabeling of containers	3	10	5	150	Staff must be trained on handling and labeling of chemicals. Labeling controls must be done daily. Foods and chemicals must be stored separately. Inventory forms must be filled properly.	2	10	2	40
<b>Biological Hazards</b>									
Contamination due to improper handling during the process	6	8	7	336	Staff training on personnel hygiene and hand washing is required. Disinfectants must be supplied from the approved sources. Regular hand hygiene control must be done.	2	8	3	48
Microbiological contamination caused by contaminated brine	5	7	6	210	Supplier must be reliable. Brine must be pasteurized regularly. Quality control of brine must be done periodically for verification	2	7	2	28
<b>Potential failure comes from water**</b>				1592					250

Table B.9. Application of FMEA to white cheese production (continue)

Failures and Cause	O	S	D	RPN	Corrective actions	O	S	D	RPN after corrective actions
<b>Processing stage: Closing the packages<sup>a,1</sup></b>									
<b>Physical Hazards</b>									
Contamination from the staff due to improper practices during filling	5	4	6	120	Staff training is required. Personal protective gears (bone, gloves, arm covers, etc.) must be provided and used. Personnel hygiene and practices must be strictly controlled.	2	4	5	40
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbiological contamination caused by improper sealing of packages	8	8	5	320	Maintenance of equipment (maintenance procedure) must be ensured. Periodic packaging controls must be carried out regularly. Staff training is required.	4	8	2	64
<b>Processing stage: Cold storage</b>									
<b>Physical Hazards</b>									
					Not common				
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during storage	8	7	5	280	The standard control program must be applied. The storage room temperature must be controlled properly.	4	7	3	84
<b>Processing stage: Transportation</b>									
<b>Physical Hazards</b>									
					Not common				
<b>Chemical Hazards</b>					Not common				
<b>Biological Hazards</b>									
Microbial growth due to temperature abuse during transportation	8	7	6	336	The standard control program must be applied. Temperature must be controlled during transportation.	4	7	3	84
<p>* FMEA analysis milk pretreatment is given in Table B.1            *** FMEA analysis for water is given in Table B.2.  <sup>a</sup>: only for cultured white cheese  <sup>b</sup>: only for traditional white cheese  <sup>1</sup>: only for small packaging (up to 3 kg)</p>									

## APPENDIX C: PARETO TABLES AND DIAGRAMS

Table C.1.1. Kefir and Ayran Production

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	17,6	17,64	474	17,1	17,14
	Filtration	721	4,7	22,33	100	3,6	20,75
	Thermisation / Cooling	648	4,2	26,55	86	3,1	23,86
	Cold storage	660	4,3	30,84	106	3,8	27,69
	Clarification	354	2,3	33,14	14	0,5	28,20
	Fat separation	408	2,7	35,80	78	2,8	31,02
	Dry matter adjustment	2610	17,0	52,78	458	16,6	47,58
	Milk fat adjustment	672	4,4	57,15	142	5,1	52,71
	Homogenization	408	2,7	59,81	78	2,8	55,53
	Pasteurization	708	4,6	64,42	118	4,3	59,80
02 - Yogurt, Kefir and Ayran pretreatment	Cooling	240	1,6	65,98	8	0,3	60,09
	Transferring to the tank	408	2,7	68,63	78	2,8	62,91
	Culture inoculation	767	5,0	73,62	120	4,3	67,25
	Incubation in tanks	90	0,6	74,21	0	0,0	67,25
	Mixing	352	2,3	76,50	82	3,0	70,21
	Cooling	0	0,0	76,50	0	0,0	70,21
	Filling	2996	19,5	95,99	656	23,7	93,93
	Cold storage	280	1,8	97,81	84	3,0	96,96
	Transportation	336	2,2	100,00	84	3,0	100,00
		Total RPN	15369		Total RPN	2766	

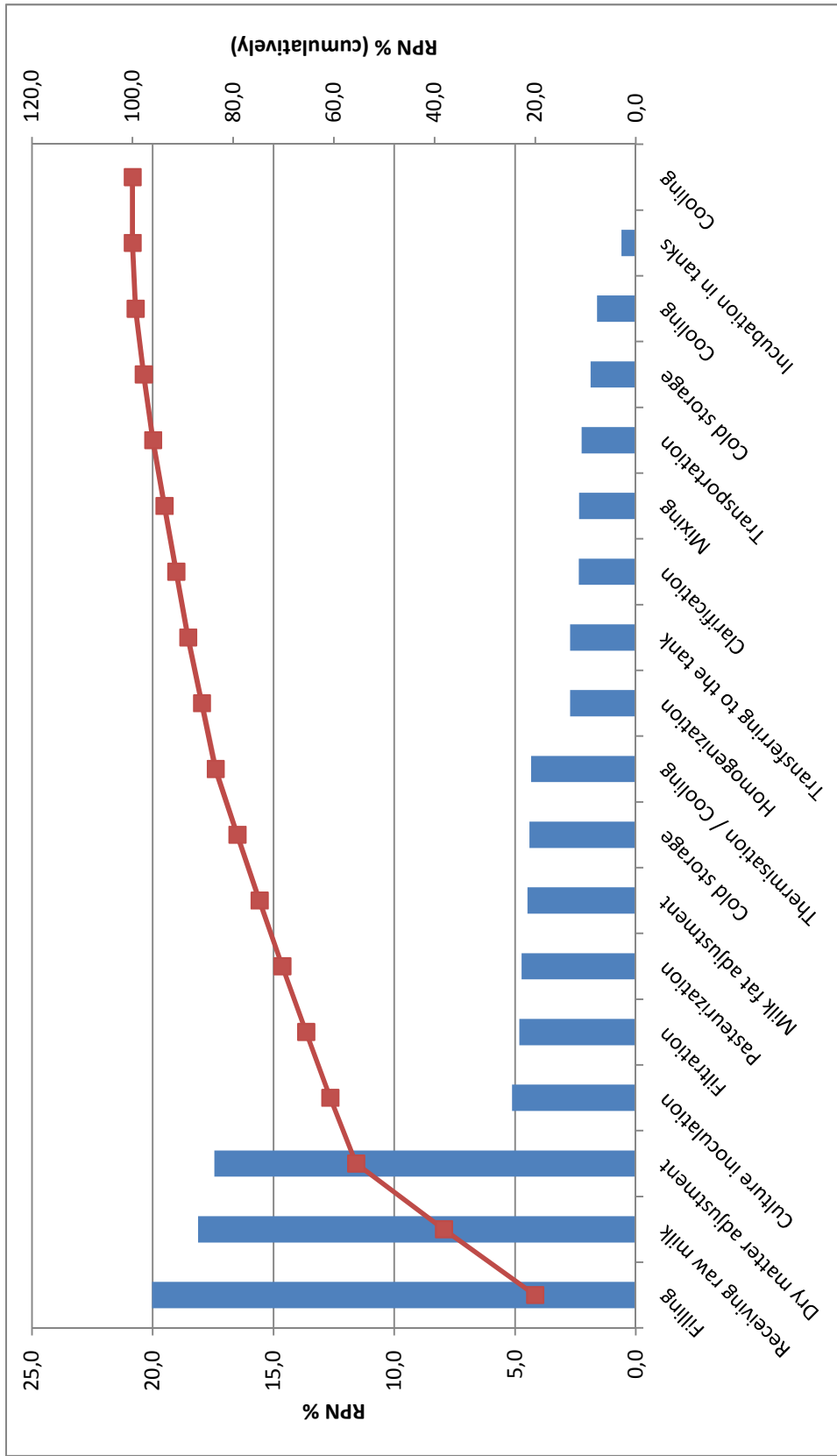


Figure C.1.1. Pareto diagram of Kefir & Ayran production

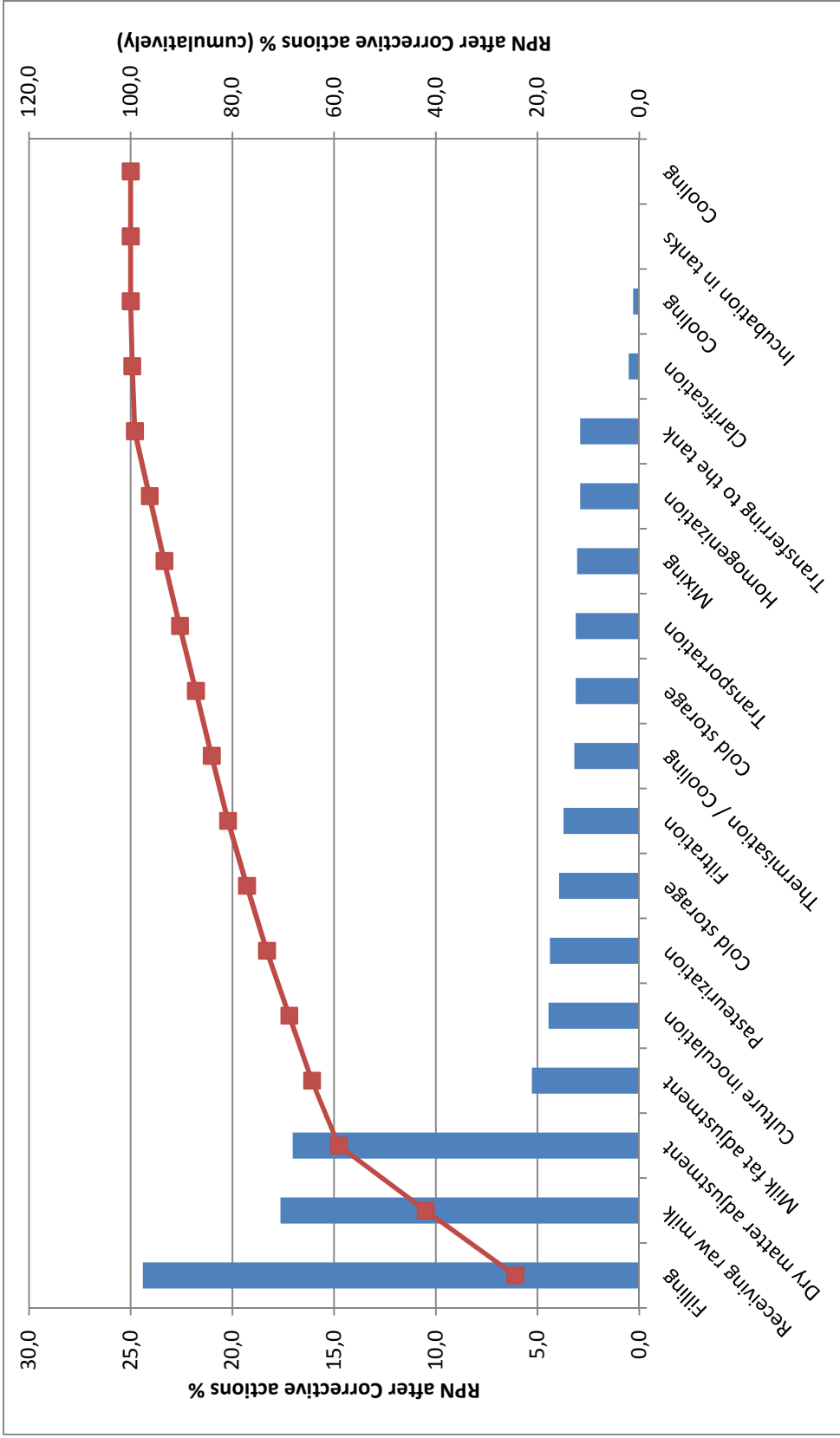


Figure C.2. Pareto diagram of Kefir & Ayran production after Corrective actions





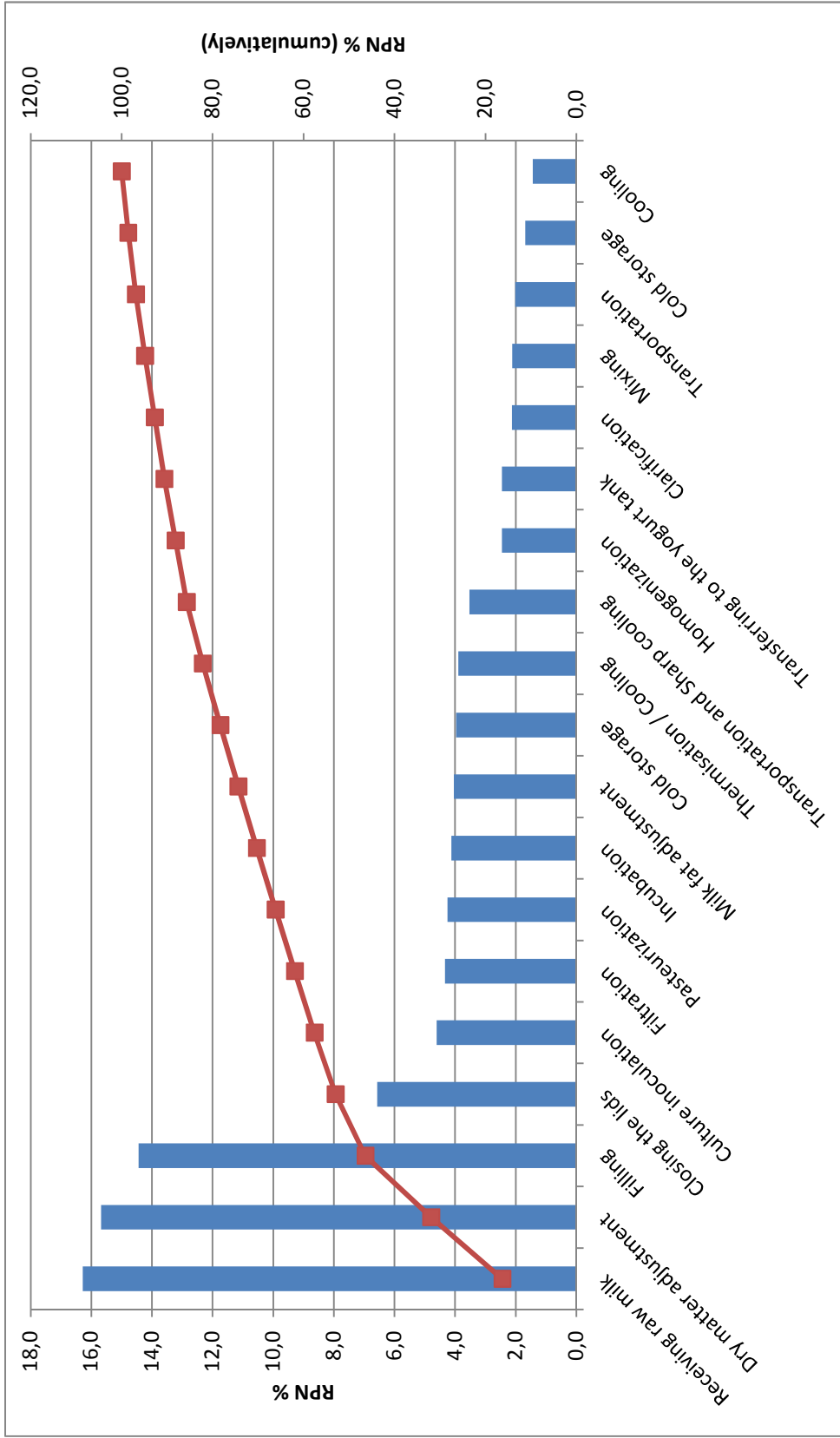


Figure C.3. Pareto diagram of Yogurt production

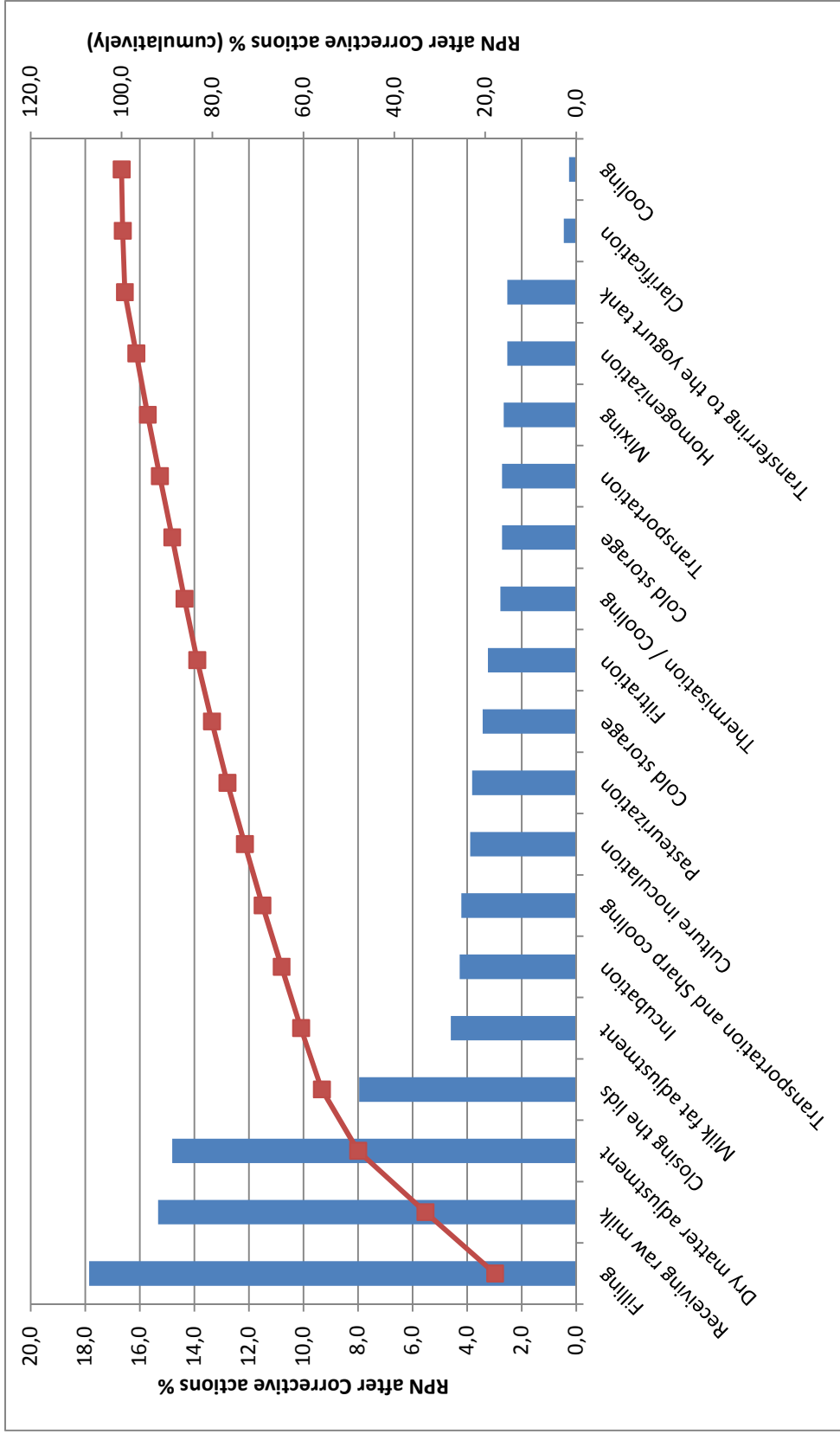


Figure C.4. Pareto diagram of Yogurt production after Corrective actions

Table C.3. Dil Cheese Production (i- Blaching in water)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	11,31	11,31	474	10,72	10,72
	Filtration	721	3,01	14,32	100	2,26	12,98
	Thermisation / Cooling	648	2,70	17,02	86	1,94	14,93
	Cold storage	660	2,75	19,78	106	2,40	17,32
	Clarification	354	1,48	21,26	14	0,32	17,64
	Pasteurization	708	2,95	24,21	118	2,67	20,31
	Fat seperation	408	1,70	25,91	78	1,76	22,07
	Cold storage	408	1,70	27,62	22	0,50	22,57
	Transferring to production tanks	408	1,70	29,32	78	1,76	24,33
	03 - Kashar cheese group pretreatment	Culture inoculation	767	3,20	32,52	120	2,71
CaCl2 addition		1428	5,96	38,48	266	6,02	33,06
Enzyme addition		1428	5,96	44,44	266	6,02	39,08
Curding		400	1,67	46,10	88	1,99	41,07
Curd cutting		528	2,20	48,31	104	2,35	43,42
Whey removal		0	0,00	48,31	0	0,00	43,42
Blaching in water		3237	13,51	61,82	618	13,98	57,39
Portioning		975	4,07	65,88	194	4,39	61,78
Resting in brine		2943	12,28	78,16	502	11,35	73,13
Cold Storage		1515	6,32	84,49	340	7,69	80,82
06 - Dil Cheese	Packaging	3102	12,94	97,43	680	15,38	96,20
	Cold storage	280	1,17	98,60	84	1,90	98,10
	Transportation	336	1,40	100,00	84	1,90	100,00
	Total RPN	23965		Total RPN	4422		

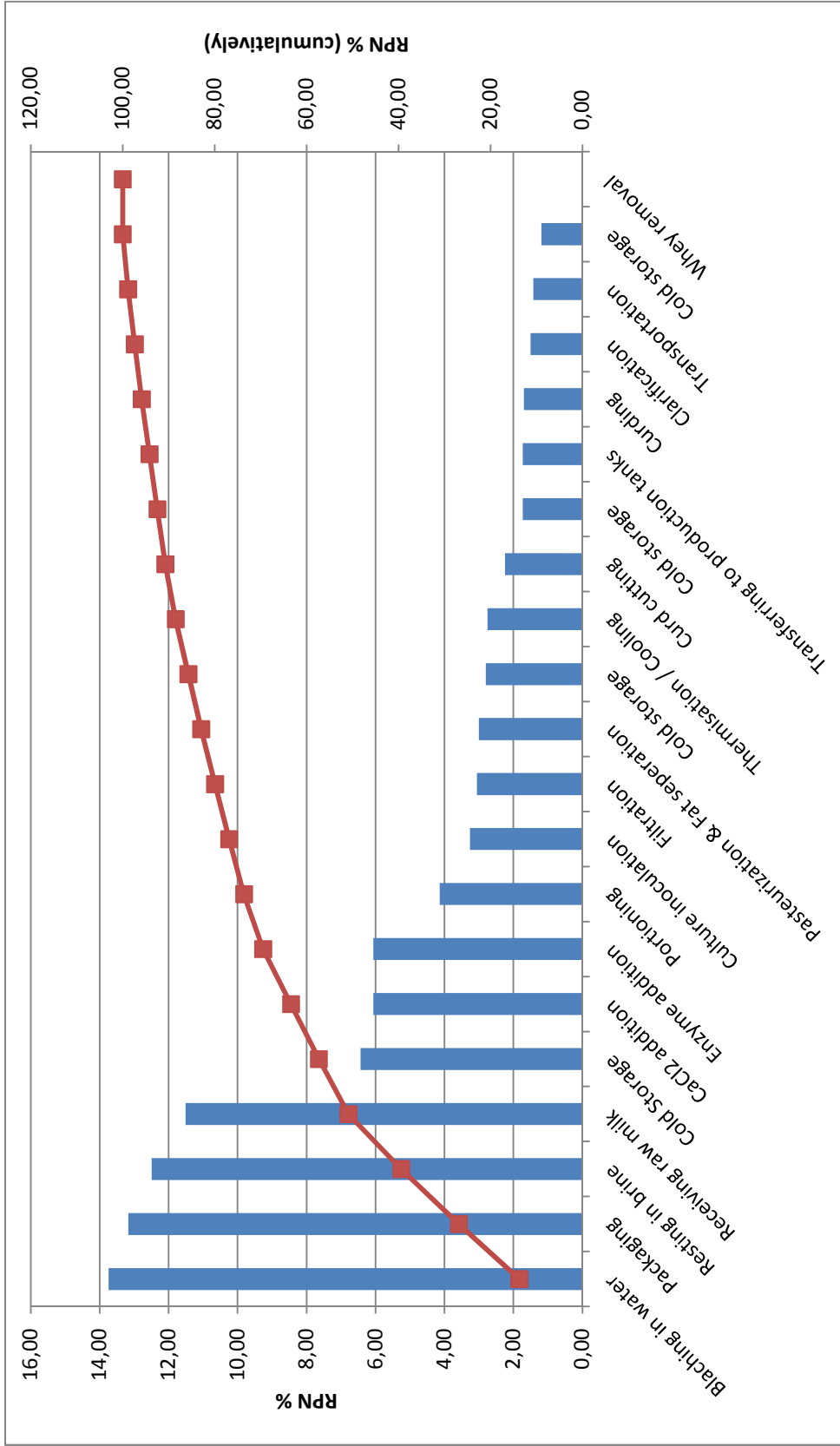


Figure C.5. Pareto diagram of Dill Cheese production (blanching in water)

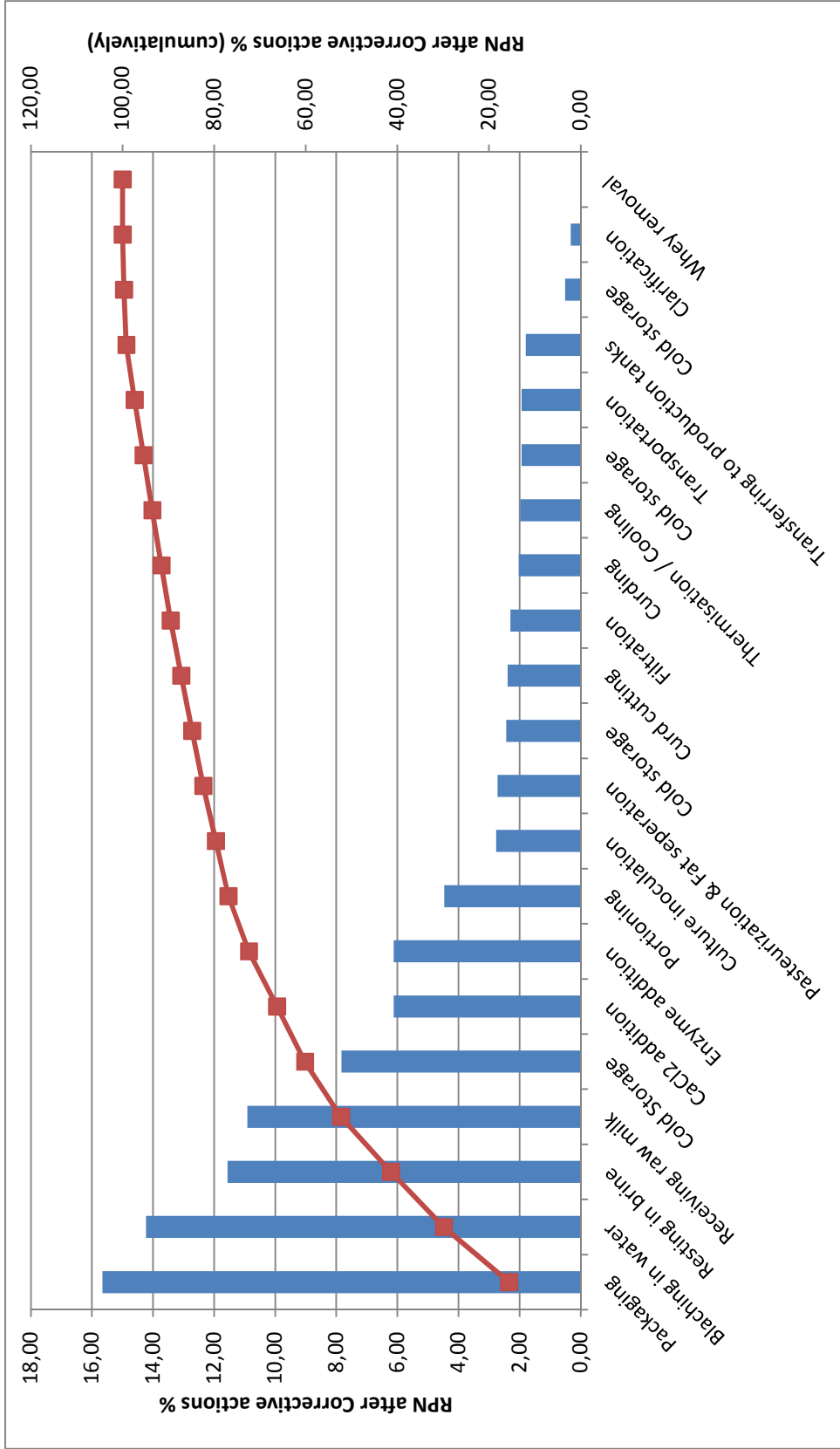


Figure C.6. Pareto diagram of Dil Cheese production (blanching in water) after Corrective actions

Table C.4. Dil Cheese Production (ii- Dry Blanching)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	11,08	11,08	474	10,59	10,59
	Filtration	721	2,95	14,02	100	2,23	12,82
	Thermisation / Cooling	648	2,65	16,67	86	1,92	14,74
	Cold storage	660	2,70	19,37	106	2,37	17,11
	Clarification	354	1,45	20,81	14	0,31	17,42
	Pasteurization	708	2,89	23,71	118	2,64	20,05
	Fat separation	408	1,67	25,37	78	1,74	21,80
	Cold storage	408	1,67	27,04	22	0,49	22,29
	Transferring to production tanks	408	1,67	28,71	78	1,74	24,03
	03 - Kashar cheese group pretreatment	Culture inoculation	767	3,13	31,84	120	2,68
CaCl2 addition		1428	5,84	37,68	266	5,94	32,65
Enzyme addition		1428	5,84	43,51	266	5,94	38,59
Curding		400	1,63	45,15	88	1,97	40,55
Curd cutting		528	2,16	47,31	104	2,32	42,88
Whey removal		0	0,00	47,31	0	0,00	42,88
Dry blanching		3745	15,30	62,61	674	15,05	57,93
Portioning		975	3,98	66,59	194	4,33	62,26
Resting in brine		2943	12,03	78,62	502	11,21	73,47
Cold Storage		1515	6,19	84,81	340	7,59	81,06
06 - Dil Cheese	Packaging	3102	12,68	97,48	680	15,19	96,25
	Cold storage	280	1,14	98,63	84	1,88	98,12
	Transportation	336	1,37	100,00	84	1,88	100,00
	Total RPN	24473		Total RPN	4478		

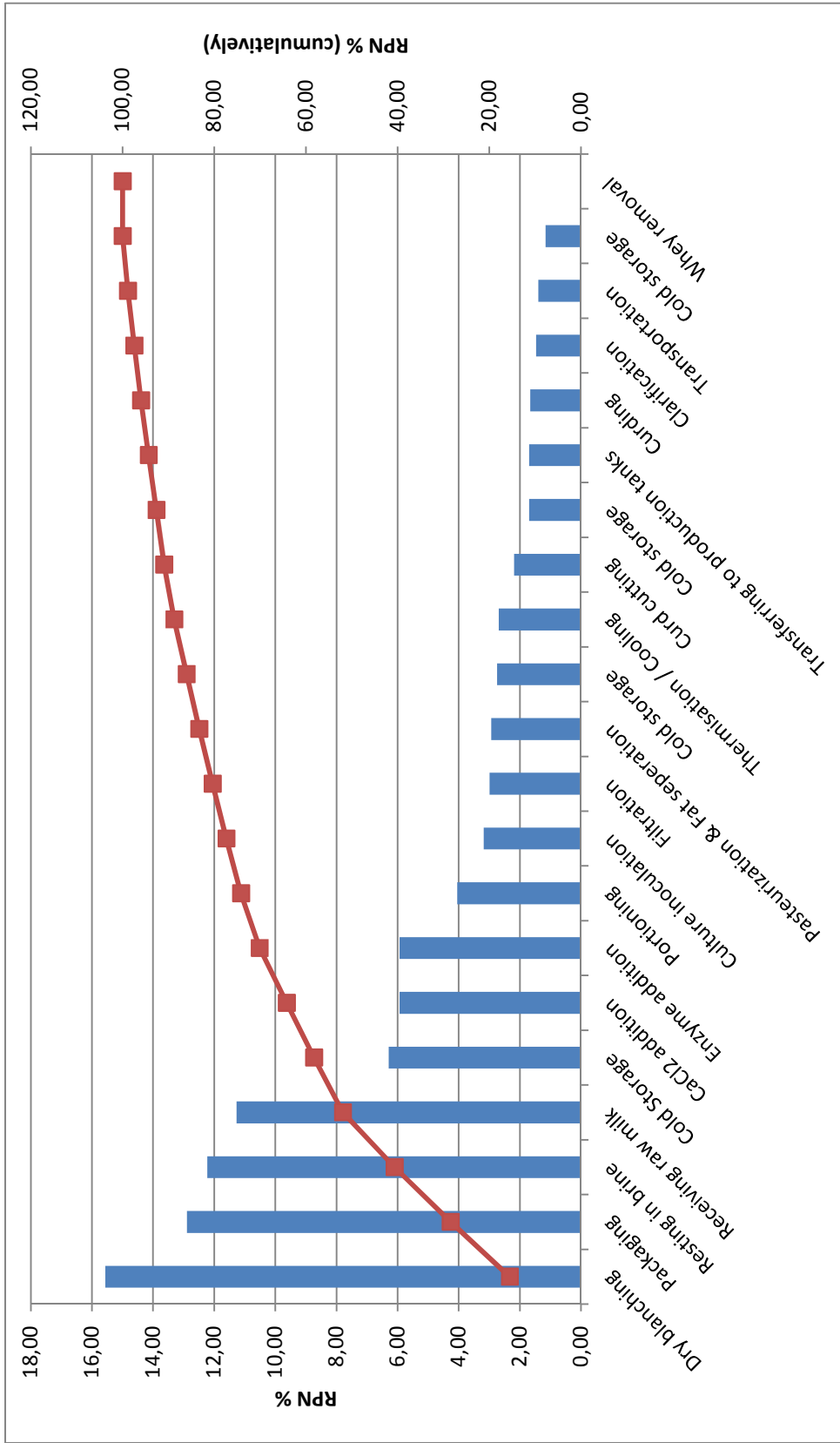


Figure C.7. Pareto diagram of Dil Cheese production (dry blanching)



Figure C.8. Pareto diagram of Dil Cheese production (dry blanching) after Corrective actions



Table C.5. Plaited Cheese Production (i- Blaching in water)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	11,08	11,08	474	10,51	10,51
	Filtration	721	2,95	14,02	100	2,22	12,73
	Thermisation / Cooling	648	2,65	16,67	86	1,91	14,63
	Cold storage	660	2,70	19,37	106	2,35	16,98
	Clarification	354	1,45	20,81	14	0,31	17,29
	Pasteurization	708	2,89	23,70	118	2,62	19,91
	Fat seperation	408	1,67	25,37	78	1,73	21,64
	Cold storage	408	1,67	27,04	22	0,49	22,13
	Transferring to production tanks	408	1,67	28,70	78	1,73	23,86
	Culture inoculation	767	3,13	31,84	120	2,66	26,52
03 - Kashar cheese group pretreatment	CaCl2 addition	1428	5,83	37,67	266	5,90	32,42
	Enzyme addition	1428	5,83	43,51	266	5,90	38,31
	Curding	400	1,63	45,14	88	1,95	40,27
	Curd cutting	528	2,16	47,30	104	2,31	42,57
	Whey removal	0	0,00	47,30	0	0,00	42,57
	Blaching in water	3237	13,22	60,52	618	13,70	56,27
	Portioning	975	3,98	64,51	194	4,30	60,58
	Plaiting	512	2,09	66,60	88	1,95	62,53
	Resting in brine	2943	12,02	78,62	502	11,13	73,66
	Cold Storage	1515	6,19	84,81	340	7,54	81,20
06 - Plaited Cheese	Packaging	3102	12,67	97,48	680	15,08	96,27
	Cold storage	280	1,14	98,63	84	1,86	98,14
	Transportation	336	1,37	100,00	84	1,86	100,00
	Total RPN	24477		Total RPN	4510		

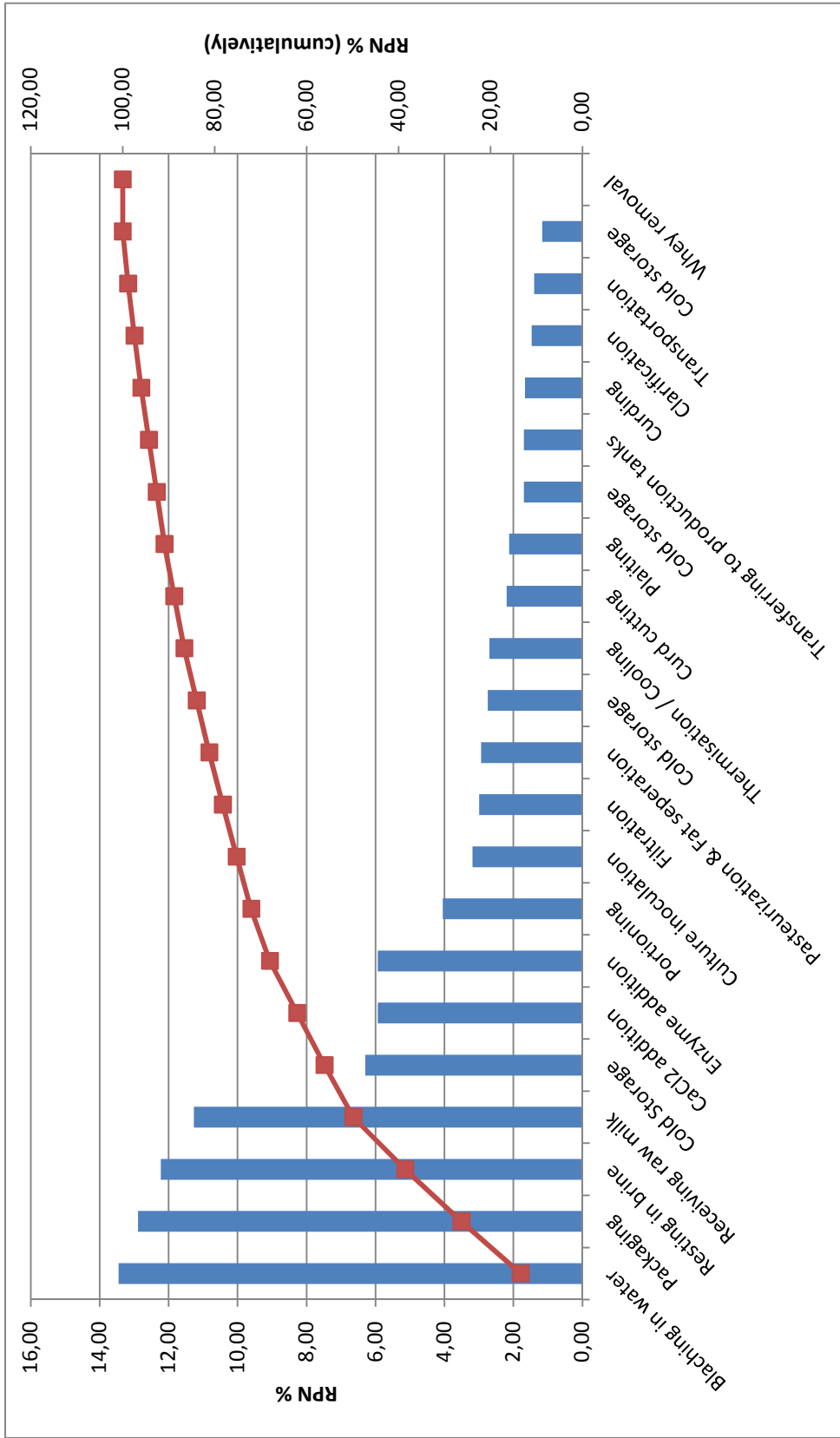


Figure C.9. Pareto diagram of Plaited Cheese production (blanching in water)

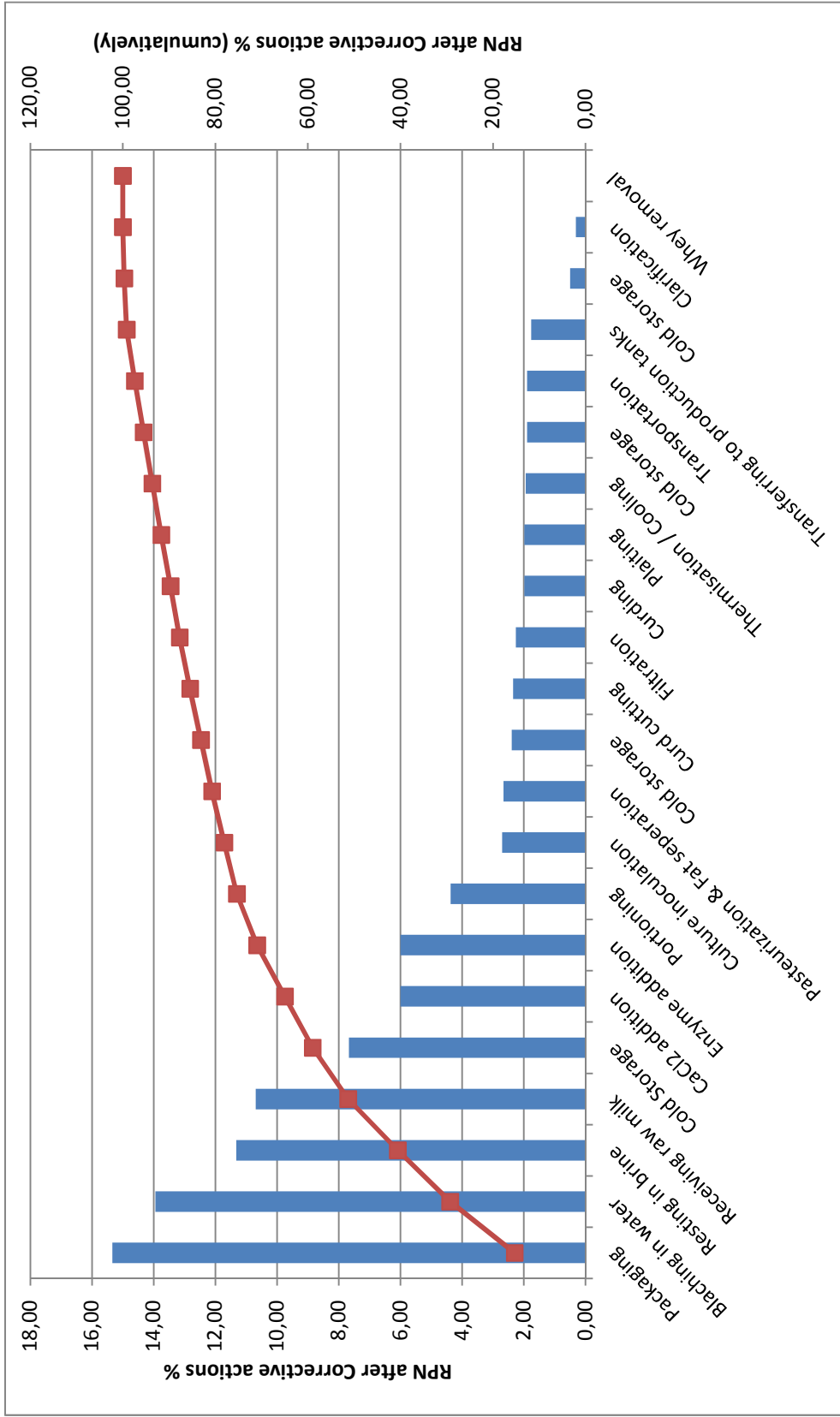


Figure C.10. Pareto diagram of Plaited Cheese production (blanching in water) after Corrective actions

Table C.6. Plaited Cheese Production (ii- Dry Blaching)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	10,85	10,85	474	10,38	10,38
	Filtration	721	2,89	13,74	100	2,19	12,57
	Thermisation / Cooling	648	2,59	16,33	86	1,88	14,45
	Cold storage	660	2,64	18,97	106	2,32	16,78
	Clarification	354	1,42	20,39	14	0,31	17,08
	Pasteurization	708	2,83	23,22	118	2,58	19,67
	Fat separation	408	1,63	24,85	78	1,71	21,38
	Cold storage	408	1,63	26,49	22	0,48	21,86
	Transferring to production tanks	408	1,63	28,12	78	1,71	23,57
	03 - Kashar cheese group pretreatment	Culture inoculation	767	3,07	31,19	120	2,63
CaCl2 addition		1428	5,72	36,91	266	5,83	32,02
Enzyme addition		1428	5,72	42,62	266	5,83	37,84
Curding		400	1,60	44,22	88	1,93	39,77
Curd cutting		528	2,11	46,34	104	2,28	42,05
Whey removal		0	0,00	46,34	0	0,00	42,05
Dry blanching		3745	14,99	61,32	674	14,76	56,81
Portioning		975	3,90	65,23	194	4,25	61,06
Plaiting		512	2,05	67,28	88	1,93	62,99
Resting in brine		2943	11,78	79,06	502	10,99	73,98
06 - Plaited Cheese	Cold Storage	1515	6,06	85,12	340	7,45	81,43
	Packaging	3102	12,42	97,53	680	14,89	96,32
	Cold storage	280	1,12	98,66	84	1,84	98,16
	Transportation	336	1,34	100,00	84	1,84	100,00
	Total RPN	24985		Total RPN	4566		

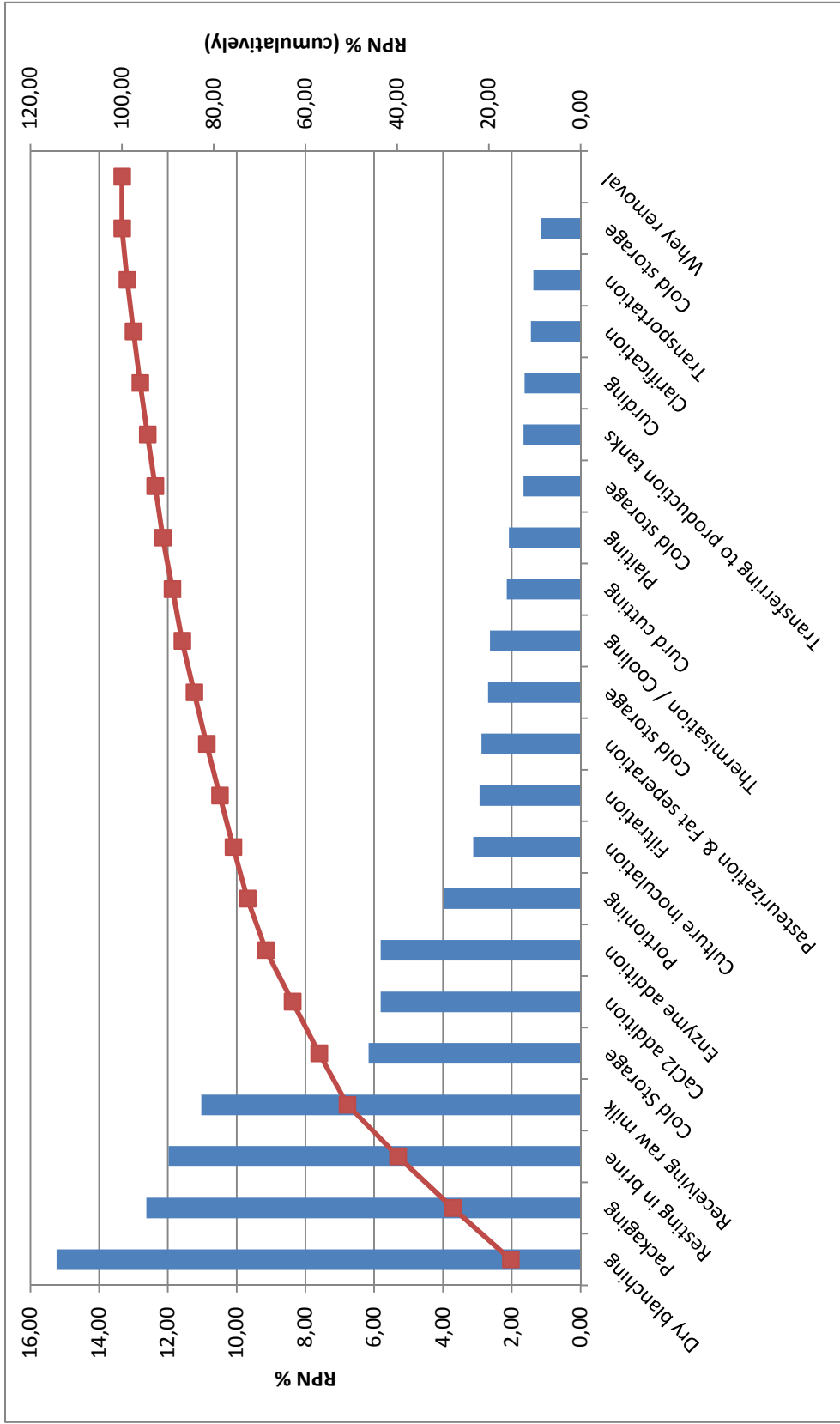


Figure C.11. Pareto diagram of Plaited Cheese production (dry blanching)

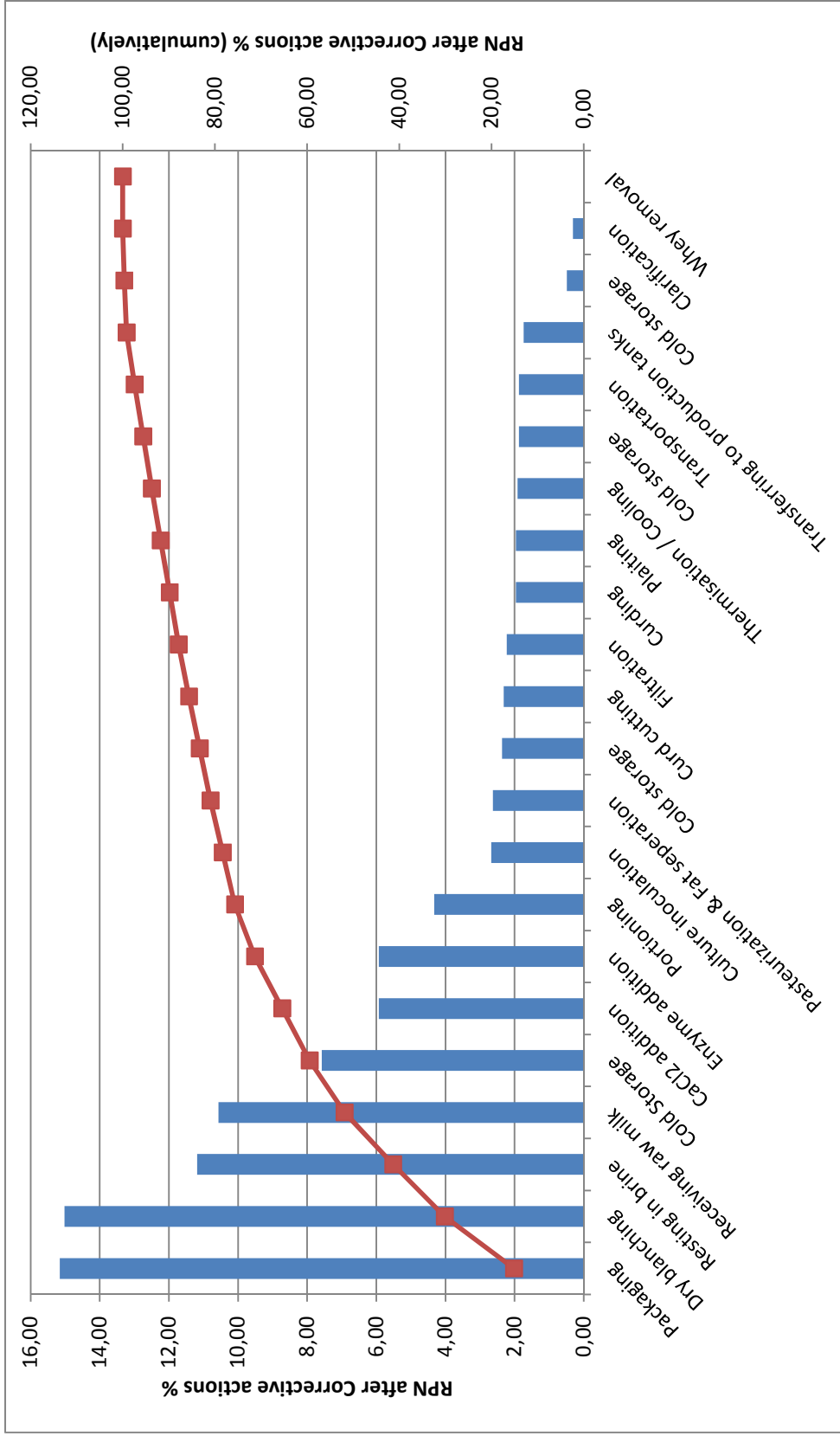


Figure C.12. Pareto diagram of Plaited Cheese production (dry blanching) after Corrective actions

Table C.7. Kashar Cheese Production (i- Blaching in water)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	11,21	11,21	474	10,34	10,34
	Filtration	721	2,98	14,19	100	2,18	12,52
	Thermisation / Cooling	648	2,68	16,87	86	1,88	14,40
	Cold storage	660	2,73	19,60	106	2,31	16,71
	Clarification	354	1,46	21,07	14	0,31	17,02
	Pasteurization	708	2,93	24,00	118	2,57	19,59
	Fat separation	408	1,69	25,68	78	1,70	21,29
	Cold storage	408	1,69	27,37	22	0,48	21,77
	Transferring to production tanks	408	1,69	29,06	78	1,70	23,47
	Culture inoculation	767	3,17	32,23	120	2,62	26,09
03 - Kashar cheese group pretreatment	CaCl2 addition	1428	5,91	38,13	266	5,80	31,89
	Enzyme addition	1428	5,91	44,04	266	5,80	37,70
	Curding	400	1,65	45,69	88	1,92	39,62
	Curd cutting	528	2,18	47,88	104	2,27	41,88
	Whey removal	0	0,00	47,88	0	0,00	41,88
	Blaching in water	3237	13,39	61,27	618	13,48	55,37
	Portioning	975	4,03	65,30	194	4,23	59,60

Table C.7. Kashar Cheese Production (i- Blaching in water) (continue)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)	
07 - Kashar Cheese	Moulding	975	4,03	69,33	194	4,23	63,83	
	Resting	1100	4,55	73,88	252	5,50	69,33	
	De-moulding and shape cutting	1083	4,48	78,36	218	4,76	74,08	
	Cold Storage	1515	6,27	84,62	340	7,42	81,50	
	Packaging	3102	12,83	97,45	680	14,83	96,34	
	Cold Storage	280	1,16	98,61	84	1,83	98,17	
	Transportation	336	1,39	100,00	84	1,83	100,00	
		Total RPN	24180		Total RPN	4584		



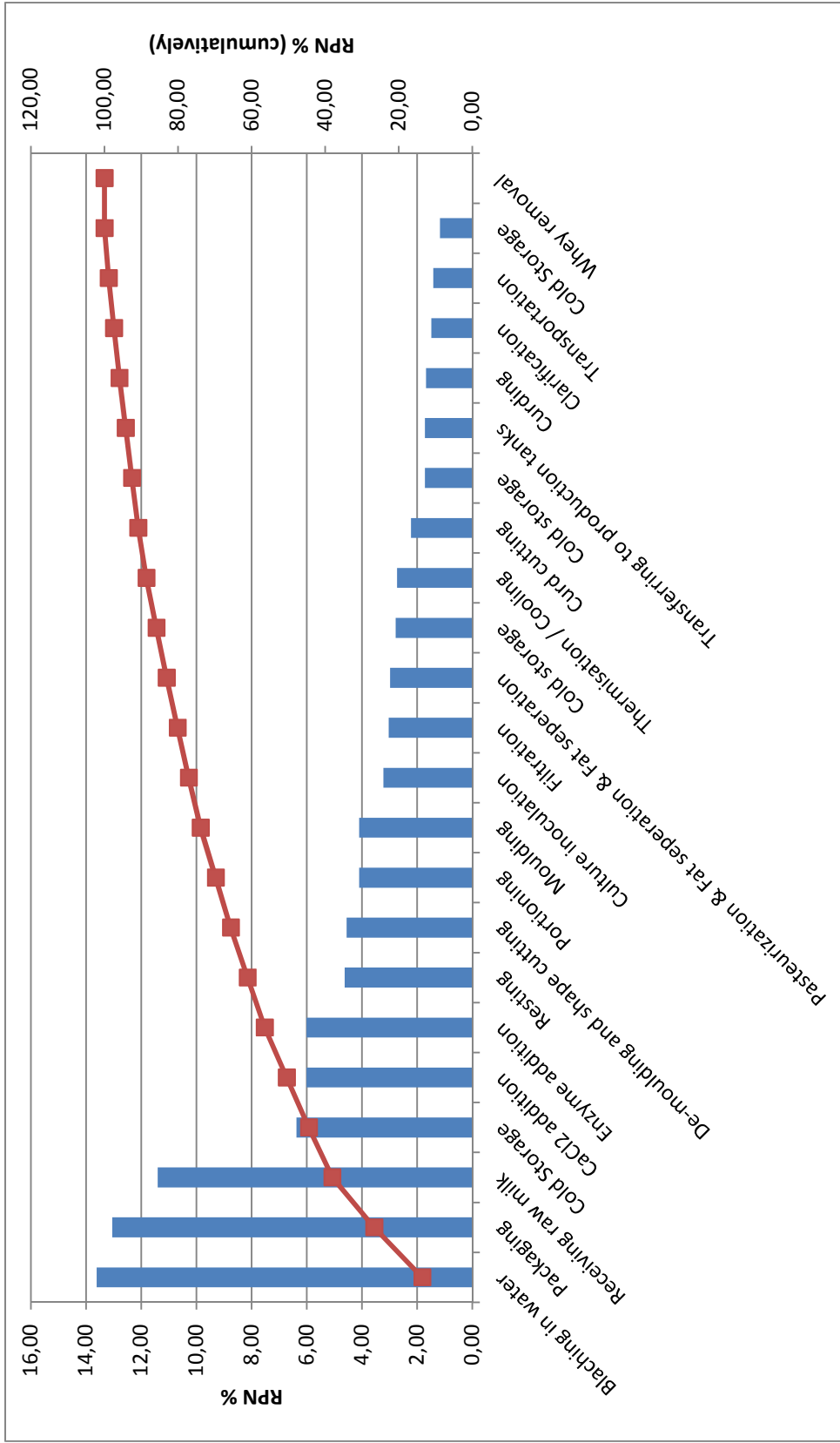


Figure C.13. Pareto diagram of Kashar Cheese production (blanching in water)

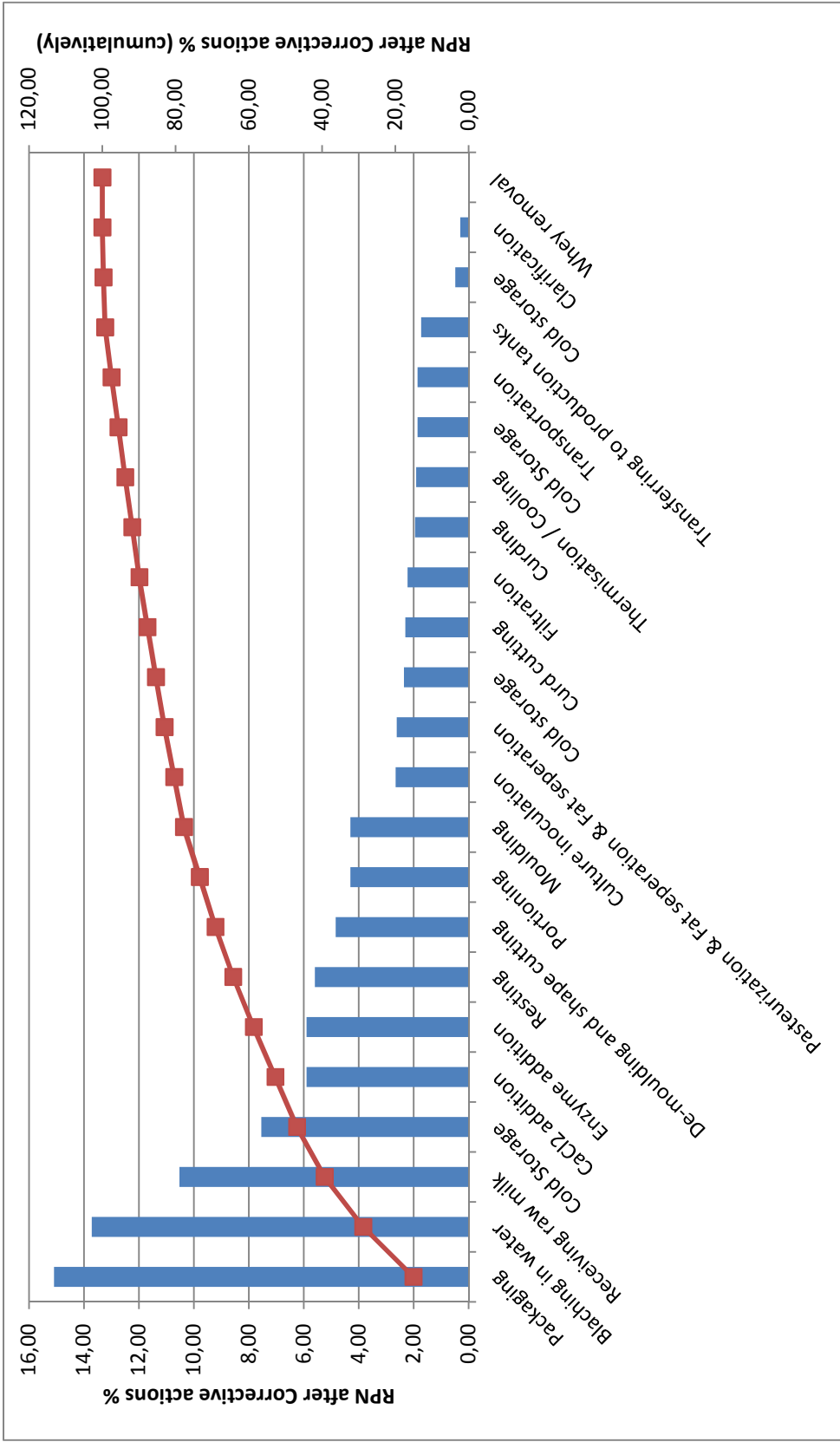


Figure C.14. Pareto diagram of Kashar Cheese production (blanching in water) after Corrective actions

Table C.8. Kashar Cheese Production (ii- Dry Blaching)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	10,98	10,98	474	10,22	10,22
	Filtration	721	2,92	13,90	100	2,16	12,37
	Thermisation / Cooling	648	2,62	16,53	86	1,85	14,22
	Cold storage	660	2,67	19,20	106	2,28	16,51
	Clarification	354	1,43	20,63	14	0,30	16,81
	Pasteurization	708	2,87	23,50	118	2,54	19,35
	Fat separation	408	1,65	25,15	78	1,68	21,03
	Cold storage	408	1,65	26,81	22	0,47	21,51
	Transferring to production tanks	408	1,65	28,46	78	1,68	23,19
	03 - Kashar cheese group pretreatment	Culture inoculation	767	3,11	31,57	120	2,59
CaCl2 addition		1428	5,78	37,35	266	5,73	31,51
Enzyme addition		1428	5,78	43,13	266	5,73	37,24
Curding		400	1,62	44,75	88	1,90	39,14
Curd cutting		528	2,14	46,89	104	2,24	41,38
Whey removal		0	0,00	46,89	0	0,00	41,38
Dry Blaching		3745	15,17	62,06	674	14,53	55,91
Portioning		975	3,95	66,01	194	4,18	60,09

Table C.8. Kashar Cheese Production (ii- Dry Blaching) (continue)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
07 - Kashar Cheese	Moulding	975	3,95	69,96	194	4,18	64,27
	Resting	1100	4,46	74,42	252	5,43	69,70
	De-moulding and shape cutting	1083	4,39	78,80	218	4,70	74,40
	Cold Storage	1515	6,14	84,94	340	7,33	81,72
	Packaging	3102	12,56	97,50	680	14,66	96,38
	Cold Storage	280	1,13	98,64	84	1,81	98,19
	Transportation	336	1,36	100,00	84	1,81	100,00
	Total RPN	24688		Total RPN	4640		

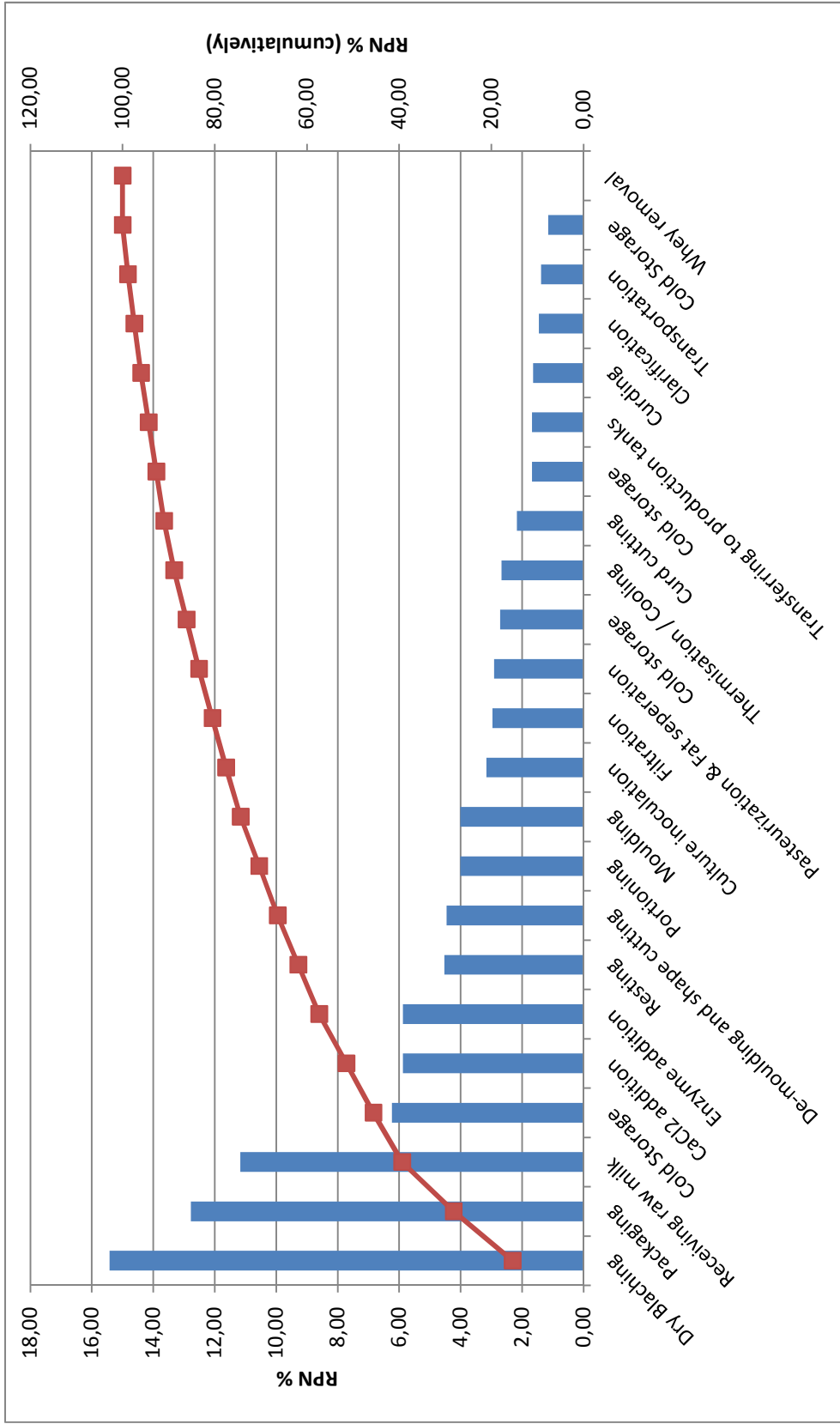


Figure C.15. Pareto diagram of Kashar Cheese production (dry blanching)

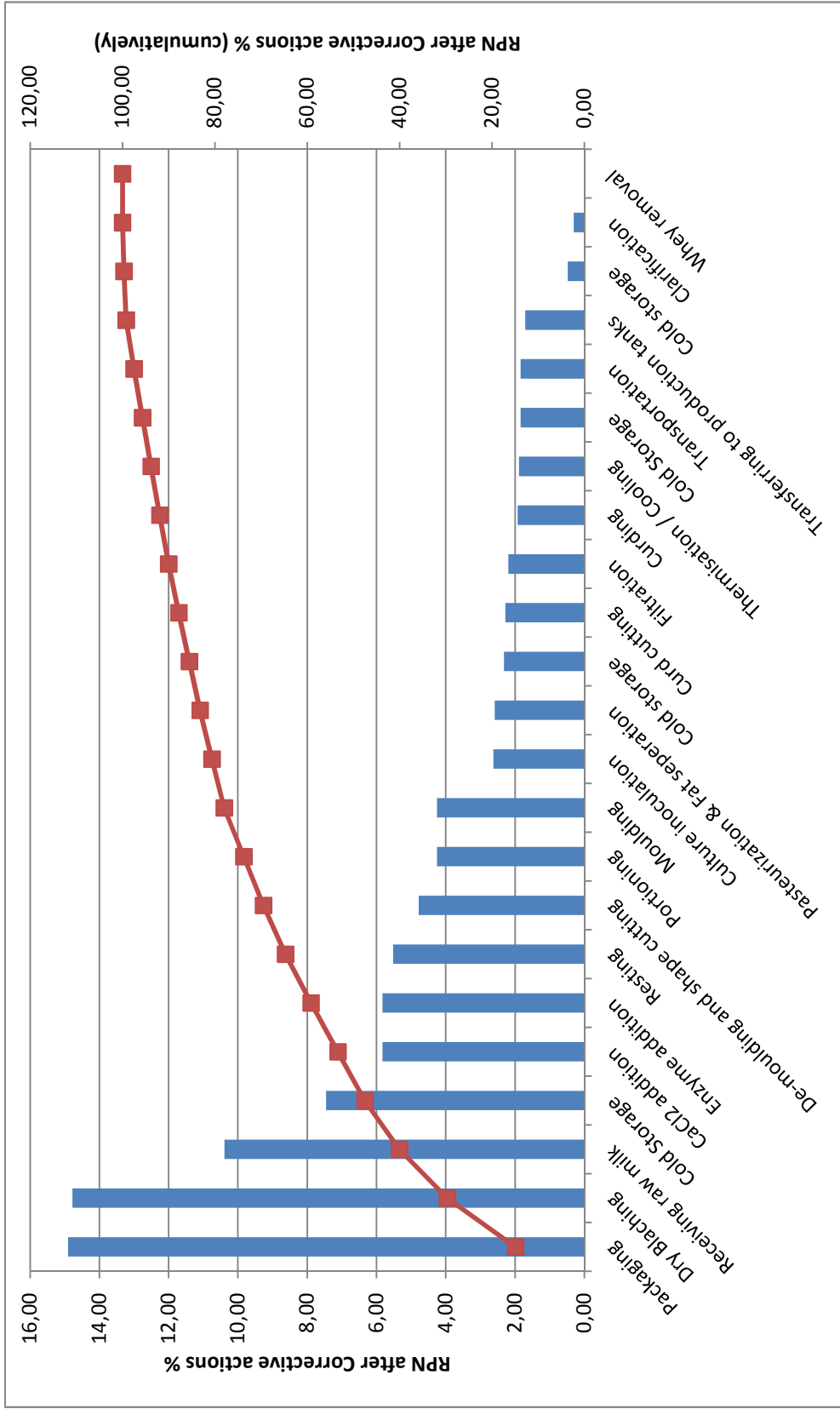


Figure C.16. Pareto diagram of Kashar Cheese production (dry blanching) after Corrective actions

Table C.9. White Cheese Production (Cultured)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	7,41	7,41	474	7,14	7,14
	Filtration	721	1,97	9,38	100	1,51	8,65
	Thermisation / Cooling	648	1,77	11,15	86	1,30	9,95
	Cold storage	660	1,80	12,96	106	1,60	11,54
	Clarification	354	0,97	13,92	14	0,21	11,75
	Pasteurization	648	1,77	15,70	86	1,30	13,05
	Fat separation	408	1,12	16,81	78	1,18	14,23
	Cold storage	648	1,77	18,58	86	1,30	15,52
	Preparation of cheese vats	2031	5,55	24,13	432	6,51	22,03
	Transferring milk to cheese vats	408	1,12	25,25	78	1,18	23,21
08 - White Cheese	Culture inoculation	767	2,10	27,35	120	1,81	25,02
	CaCl2 addition	1428	3,90	31,25	266	4,01	29,02
	Enzyme Addition	1428	3,90	35,15	266	4,01	33,03
	Mixing	1185	3,24	38,39	224	3,38	36,41
	Resting in vats	798	2,18	40,57	136	2,05	38,46
	Cutting the curd	1095	2,99	43,57	224	3,38	41,83
	Removing PE separator sheet	512	1,40	44,97	88	1,33	43,16
	Covering the curd with cheese cloth	1023	2,80	47,76	194	2,92	46,08
	Pressing	655	1,79	49,55	106	1,60	47,68
	End of Pressing (Removing needles)	512	1,40	50,95	88	1,33	49,01
	Cutting in shapes	1050	2,87	53,82	194	2,92	51,93
	Removing of cheese cloth	512	1,40	55,22	88	1,33	53,25
	Brine addition (to cheese vats)	2398	6,55	61,78	390	5,88	59,13

Table C.9. White Cheese Production (Cultured) (continue)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)	
08 - White Cheese (continue)	First ripening at brine	486	1,33	63,11	72	1,08	60,22	
	Turning the cheese at brine	512	1,40	64,51	88	1,33	61,54	
	Dry salt addition	414	1,13	65,64	92	1,39	62,93	
	Collecting cheese to boxes	1430	3,91	69,55	274	4,13	67,06	
	Rework of brine	370	1,01	70,56	68	1,02	68,08	
	Filling to cans	1190	3,25	73,81	288	4,34	72,42	
	Brine addition (to cans)	2588	7,07	80,88	418	6,30	78,72	
	Closing the cans	392	1,07	81,96	64	0,96	79,69	
	Packaging (for cultured)	2957	8,08	90,04	658	9,92	89,60	
	Brine additiona,1	2588	7,07	97,11	418	6,30	95,90	
	Closing the packagesa,1	440	1,20	98,32	104	1,57	97,47	
	Cold Storage	280	0,77	99,08	84	1,27	98,73	
	Transportation	336	0,92	100,00	84	1,27	100,00	
		Total RPN	36583		Total RPN	6636		



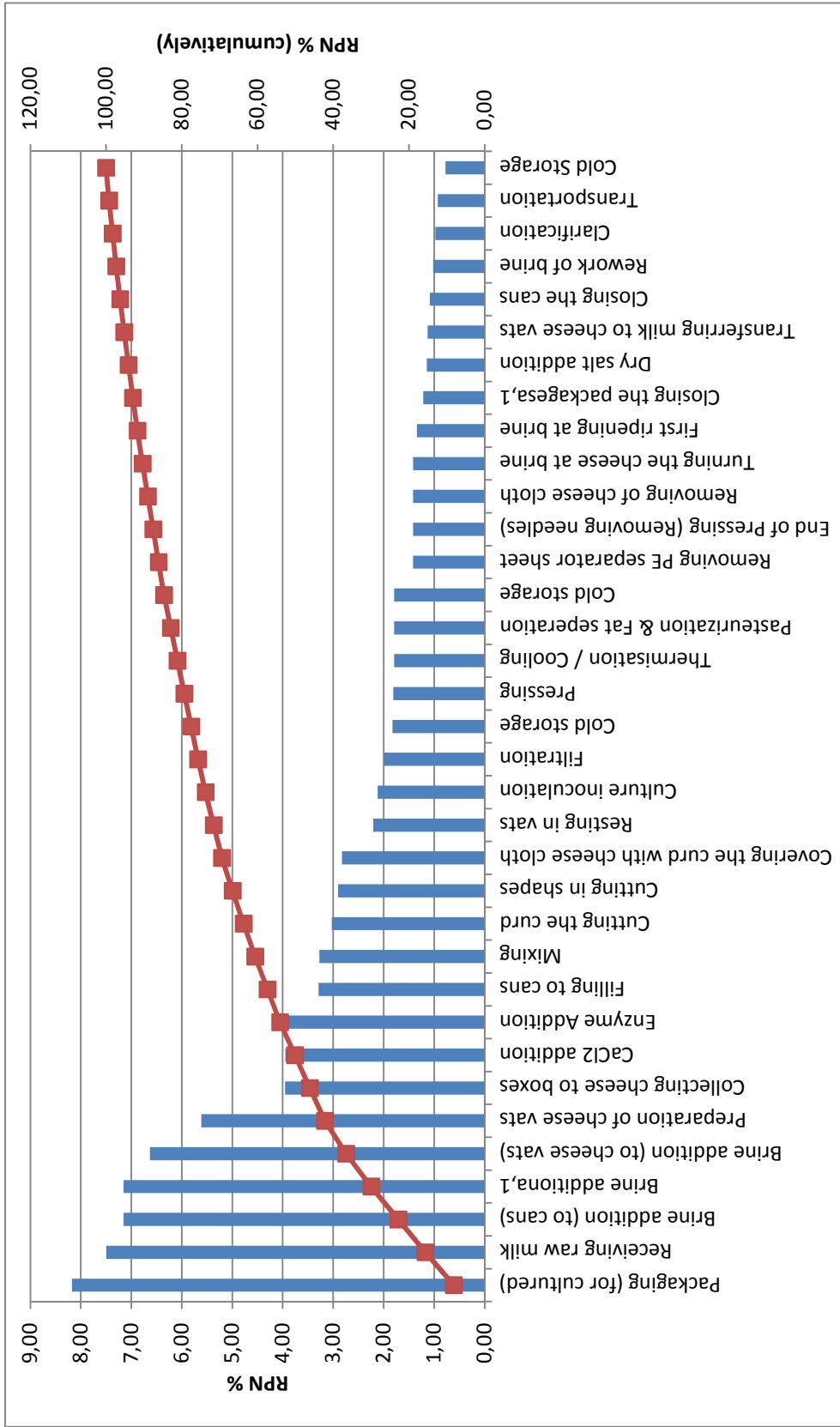


Figure C.17. Pareto diagram of Cultured white cheese

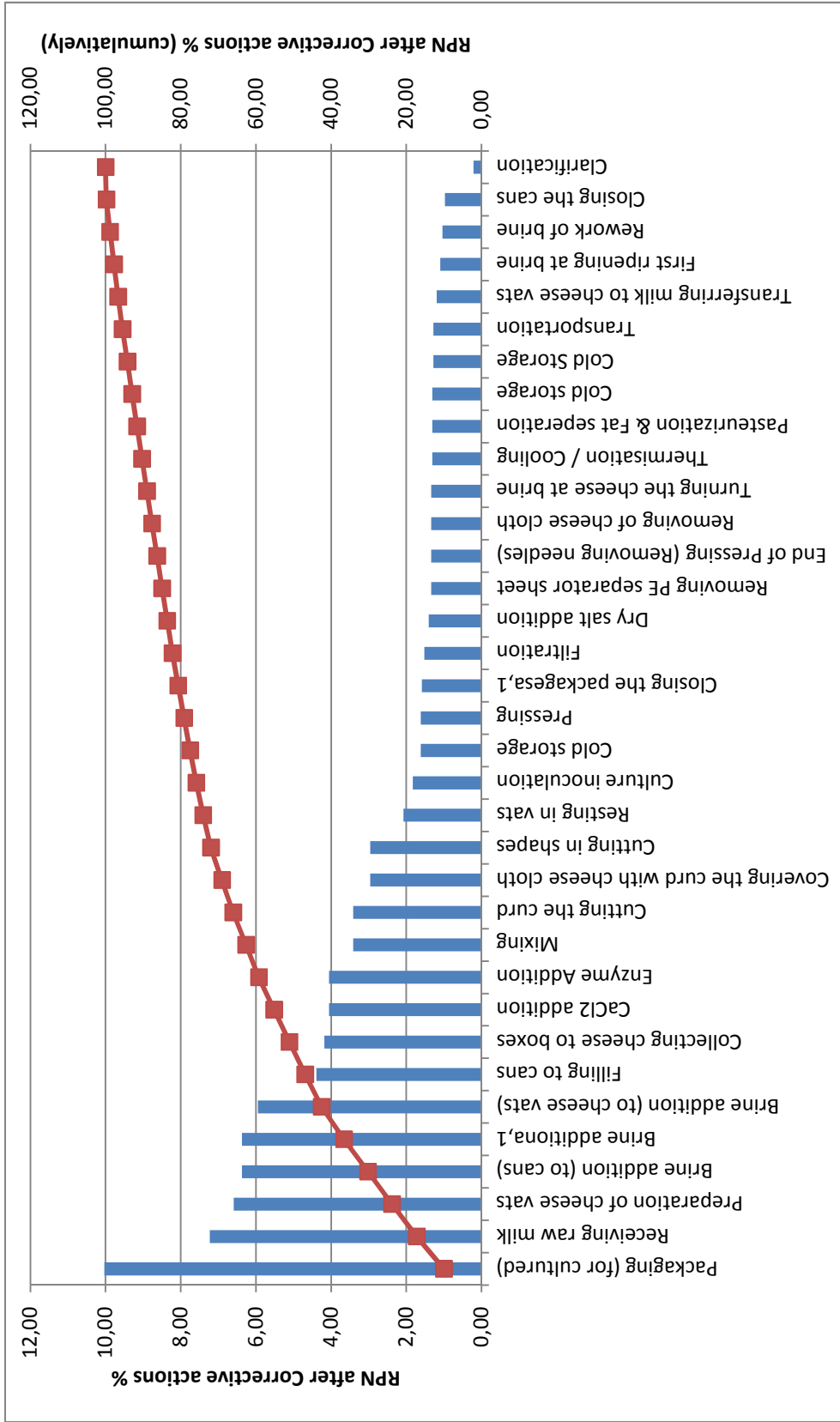


Figure C.18. Pareto diagram of Cultured white cheese after Corrective actions

Table C.10. White Cheese Production (Traditional)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
01 - Milk pretreatment	Receiving raw milk	2711	8,04	8,04	474	7,63	7,63
	Filtration	721	2,14	10,18	100	1,61	9,24
	Thermisation / Cooling	648	1,92	12,10	86	1,38	10,62
	Cold storage	660	1,96	14,06	106	1,71	12,33
	Clarification	354	1,05	15,11	14	0,23	12,55
	Pasteurization	648	1,92	17,03	86	1,38	13,94
	Fat separation	408	1,21	18,24	78	1,26	15,19
	Cold storage	648	1,92	20,16	86	1,38	16,58
	Preparation of cheese vats	2031	6,02	26,18	432	6,95	23,53
	Transferring milk to cheese vats	408	1,21	27,39	78	1,26	24,78
08- White Cheese	Enzyme Addition	1428	4,24	31,63	266	4,28	29,06
	Mixing	1185	3,51	35,14	224	3,60	32,67
	Resting in vats	798	2,37	37,51	136	2,19	34,86
	Cutting the curd	1095	3,25	40,76	224	3,60	38,46
	Removing PE separator sheet	512	1,52	42,28	88	1,42	39,88
	Covering the curd with cheese cloth	1023	3,03	45,31	194	3,12	43,00
	Pressing	655	1,94	47,25	106	1,71	44,71
	End of Pressing (Removing needles)	512	1,52	48,77	88	1,42	46,12
	Cutting in shapes	1050	3,11	51,89	194	3,12	49,24
	Removing of cheese cloth	512	1,52	53,40	88	1,42	50,66
	Brine addition (to cheese vats)	2398	7,11	60,52	390	6,28	56,94

Table C.10. White Cheese Production (Traditional) (continue)

	Stages	Total RPN for Step	RPN %	RPN% (cumulatively)	Total RPN after Corrective actions	RPN after Corrective actions %	RPN after Corrective actions % (cumulatively)
08- White Cheese (continue)	First ripening at brine	486	1,44	61,96	72	1,16	58,09
	Turning the cheese at brine	512	1,52	63,48	88	1,42	59,51
	Dry salt addition	414	1,23	64,70	92	1,48	60,99
	Collecting cheese to boxes	1430	4,24	68,95	274	4,41	65,40
	Rework of brine	370	1,10	70,04	68	1,09	66,50
	Filling to cans	1190	3,53	73,57	288	4,63	71,13
	Brine addition (to cans)	2588	7,68	81,25	418	6,73	77,86
	Pre-ripening on cansb	486	1,44	82,69	72	1,16	79,02
	Closing the cans	392	1,16	83,85	64	1,03	80,05
	Cold storage (ripening)b	580	1,72	85,57	144	2,32	82,36
	Opening the cans b, 1	1092	3,24	88,81	242	3,89	86,26
	Packaging (for traditional)	3157	9,36	98,17	686	11,04	97,30
	Cold Storage	280	0,83	99,00	84	1,35	98,65
	Transportation	336	1,00	100,00	84	1,35	100,00
		Total RPN	33718		Total RPN	6214	

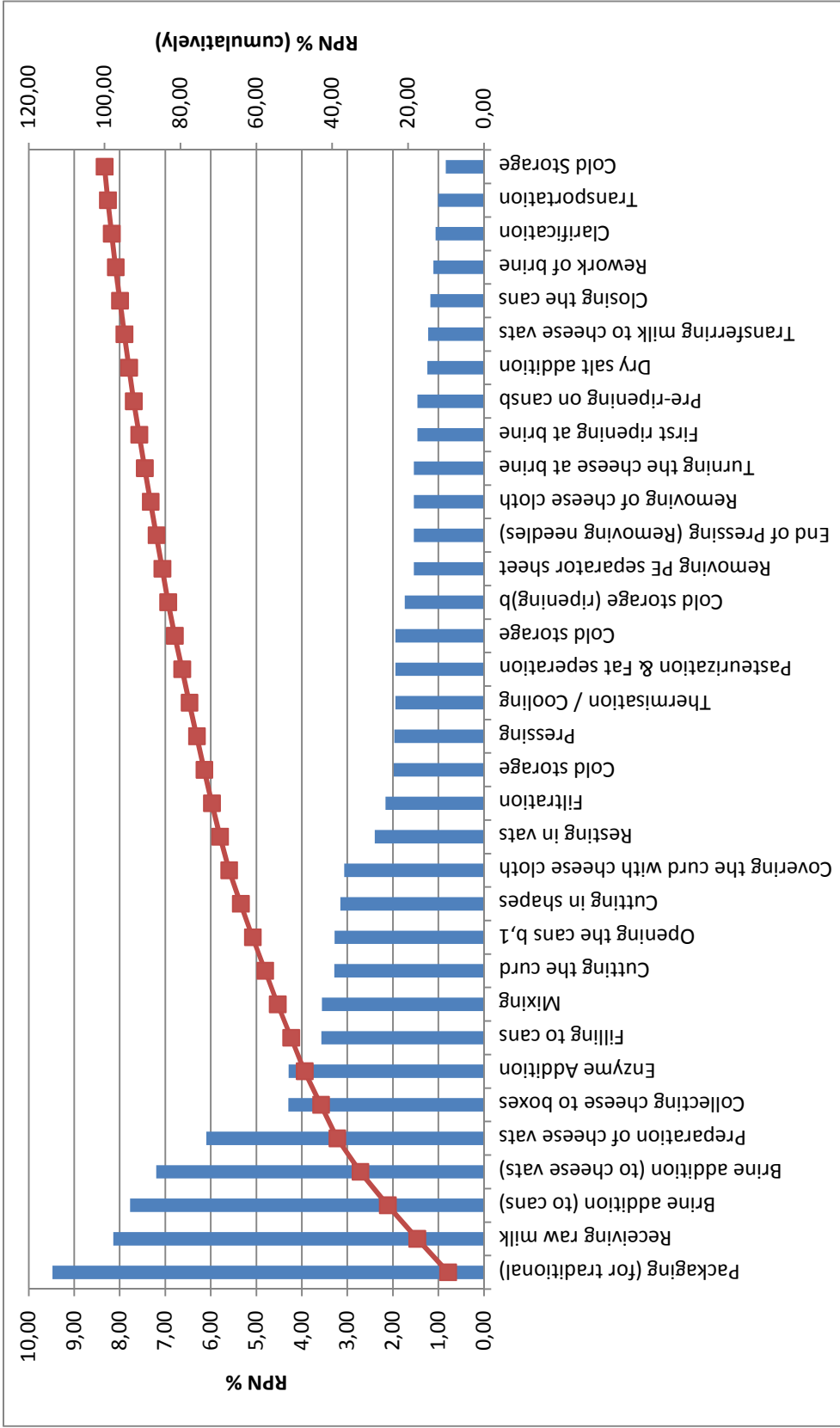


Figure C.19. Pareto diagram of Traditional white cheese

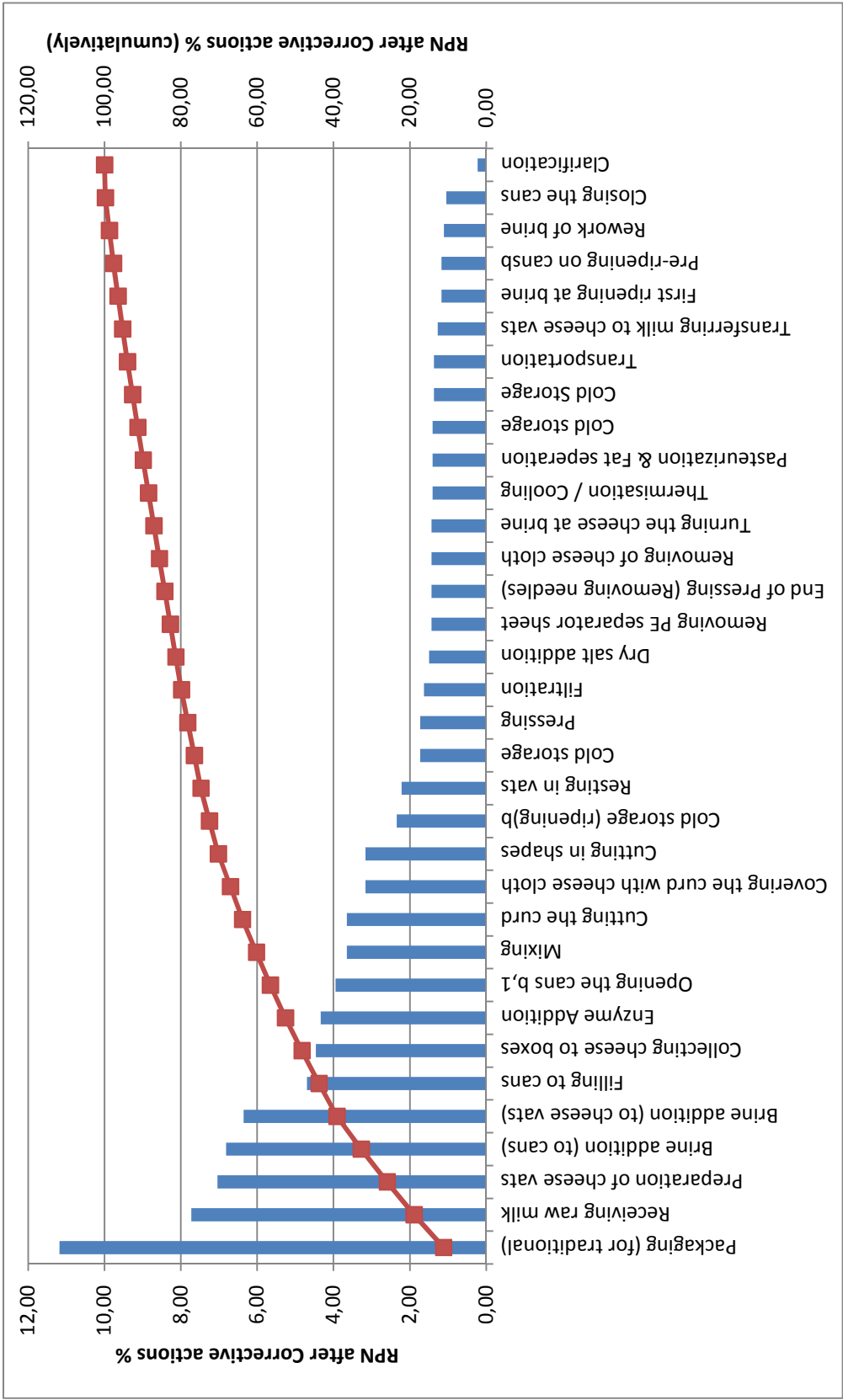


Figure C.20. Pareto diagram of Traditional white cheese after Corrective actions