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Application of failure mode and effect analysis (FMEA) and cause and effect analysis in conjunction with ISO2200 to a pistachio processing plant

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Abstract. Failure Mode and Effect Analysis (FMEA) model has been applied for the risk assessment of pistacchio manufacturing. A tentative approach of FMEA application to the pistacchio industry was attempted in conjunction with ISO22000. Preliminary Hazard Analysis was used to analyse and predict the occurring failure modes in a food chain system (pistacchio processing plant), based on the functions, characteristics and/or interactions of the processes, upon which the system depends. Critical Control points have been identified and implemented in the cause and effect diagram (also known as Ishikawa, tree diagram and fishbone diagram). In this work comparison of ISO22000 analysis with HACCP is carried out over pistacchio processing and packaging. However, the main emphasis was put on the quantification of risk assessment by determining the Risk Priority Number (RPN) per identified processing hazard. Salting and roasting, hand grading of split nuts to remove defects and debris, packaging and storage or shipping, drying of split and non-split nuts to 5-7% moisture as well as dumping of nuts and conveying over an air leg to remove debris were the processes identified as the ones with the highest RPN (280, 240, 147, 144, 130, respectively) and corrective actions were undertaken. Following the application of corrective actions, a second calculation of RPN values was carried out leading to considerably lower values (below the upper acceptable limit of 130). It is noteworthy that the application of Ishikawa (Cause and Effect or Tree diagram) led to converging results thus corroborating the validity of conclusions derived from risk assessment and FMEA. Therefore, the incorporation of FMEA analysis within the ISO22000 system of a pistacchio processing industry is considered imperative.

Keywords. FMEA – ISO22000 – HACCP – Ishikawa diagrams – Preliminary Hazard Analysis – Pistachio manufacturing.

Application de l'analyse des défaillances, de leurs effets et de leur criticité (AMDEC) et de l'analyse de cause à effet en conjonction avec l'ISO dans une unité de transformation de pistaches

Résumé. *Le modèle d'analyse des défaillances, de leurs effets et de leur criticité (AMDEC) a été appliqué pour l'évaluation du risque dans la transformation des pistaches. Une ébauche d'application de l'AMDEC pour l'industrie des pistaches a été tentée, en liaison avec ISO22000. Une analyse préliminaire des risques a été utilisée pour analyser et prévoir les modes de défaillance survenant dans un système de chaîne alimentaire (usine de transformation de pistaches), basée sur les fonctions, caractéristiques et/ou interactions des processus, sur lesquelles repose le système. Les points de contrôle critiques ont été identifiés et mis en œuvre dans le diagramme de cause à effet (également connu sous le nom de diagramme de Ishikawa, diagramme d'arborescence ou schéma en arête de poisson). Dans ce travail, une comparaison de l'analyse HACCP et ISO22000 est réalisée pour la transformation et l'emballage des pistaches. Toutefois, l'accent a été mis sur la quantification de l'évaluation des risques par la détermination du CPR pour les risques identifiés pendant la transformation. Le salage et la torréfaction, le classement manuel des noix scindées pour supprimer les défauts et les débris, l'emballage et le stockage ou le transport, le séchage des noix scindées et non scindées à 5-7% d'humidité ainsi que le déversement de fruits et son transport sur une courant d'air pour enlever les débris ont été identifiées comme les processus ayant le plus grand CPR (280, 240, 147, 144, 130, respectivement) et les actions correctives ont été entreprises. Suite à l'application des mesures correctives, un deuxième calcul des valeurs CPR a été réalisé conduisant à des valeurs beaucoup plus faibles (en dessous de la limite supérieure acceptable de 130). Il*

est à noter que l'application de Ishikawa (Cause et Effet ou arborescence) a conduit à des résultats convergents corroborant ainsi la validité des conclusions tirées de l'évaluation des risques et AMDEC. Par conséquent, l'incorporation de l'analyse AMDEC et ISO22000 dans le système d'une industrie de transformation de pistaches est considérée comme un impératif.

Mots-clés. *Pistache – FMEA – système ISO 22000.*

I – Introduction

Pistachio nuts are seeds from the fruit of *Pistacia vera* L. The nuts are extensively used as food and for yellowish-green coloring in confections. Grown in dry lands in warm or temperate climates, the pistachio tree is believed indigenous to Iran; it is widely cultivated from Central Asia to the Mediterranean region.

The fruits are 0.6 to 0.8 inches long and tend to split at one side without discharging the nut, a kernel enclosed in a thin, tightly adhering skin.

The pistachio is a relative of both the cashew and the mango. The plant is deciduous (drops its leaves each year) and dioecious (separate sexes and both a male and a female tree needed to produce edible nuts). The trees are wind-pollinated rather than bee-pollinated, with the male trees bearing pollen and the female trees bearing nuts. Like many other nut trees, the pistachio is "alternate bearing", producing a heavy crop one year and a lighter crop the next. The genus *Pistacia* contains only 11 species, of which *P. vera* is by far the most important economically.

The pistachio has been considered a delicacy since the beginning of recorded history, and has been cultivated throughout its native range for centuries. Imported pistachios originate in Iran, Turkey, Syria, Greece and Italy. Greece is famous worldwide for the "Aegina pistachios", one of the best varieties in the world. This excellent variety comes from the island of Aegina, and is considered one of the world's premier gourmet products. At one time, all US pistachios were imported, but this is no longer the case. In the United States, pistachios are utilized "in-the-shell" for fresh consumption (75%), or processed for use in candy, baked goods, and ice cream (25%).

The pistachio was introduced into California in 1854, but commercial plantings did not develop until 1970. Currently, almost all US pistachio consumption is serviced by domestic sources. California production is an offshoot of the almond industry. Many of California's almond growers became interested in almond production as a tax- and income-sheltered business. Legislation in the 1960s ended the practice. This prompted some of the growers to diversify into pistachios. The American hostage crisis at the United States Embassy in Iran in the late 1970s interrupted exports from the world's leading pistachio producer to one of its top importing markets. The Iranian Revolution sent pistachio prices to unheard of levels, and the new California nuts became a hot high-value commodity. California's first major commercial crop was harvested in 1976. California production has increased so rapidly it has all but eliminated the need for pistachio importation into the United States.

Approximately 98 percent of U.S. pistachios are produced in California and the majority of the remaining production is in Arizona and New Mexico with some limited production in west Texas. In California, pistachios are grown as far north as Shasta County and as far south as Riverside County. Because of their desert-like climate and soil, the San Joaquin Valley counties of Kern, Madera, Kings, Fresno and Tulare are major producing areas. California is second only to Iran in overall production. Of the world's 476,244 metric tons (MT), the major producers are: Iran, 314,000 MT; United States, 49,900 MT; Turkey, 40,000 MT; Syria, 34,000 MT; and Greece 5,000 MT (FAO, 1999).

II – FMEA Analysis

In FMEA analysis, risk of contamination and its presence at Hazardous Fraction in the final product, is expressed with the Risk Priority Number (RPN) which is defined as follows:

RPN=S×O×D

Where S: Severity of contamination risk, O: Occurrence of contaminated ingredient, D: Detection probability of contaminated ingredient.

Corrective action is carried out when RPN is greater than 130.

The classification of hazardous elements occurs according to the RPN assessment that can be seen in Table 1 together with corrective actions proposed per identified hazard. Following calculation of the new RPN (the RPN' after undertaking corrective actions), a new classification of Hazardous Elements is shown in Table 1.

Table 1. FMEA of hazardous processing methods for pistachio processing

Defective Products								Estimated corrective Actions result			
Production step-CCP†	**Hazards**	**Causes**	**S**	**O**	**D**	**RPN†**	**Corrective actions**	**S**	**O**	**D**	**RPN**
Salting and roasting of split nuts	Pathogens, parasites, Heavy metals, toxins	Wrong roasting temperature	8	5	7	280	Correct temperature	8	2	2	32
Hand grading of split nuts	Pathogens, pesticide and aflatoxin residues	Wrong handling from the personnel	8	6	5	240	GMPs, GHPs, PrPs	8	2	2	32
Packaging, storage & distribution	Contamination from wrong temperature or time remaining at room temperature	Improper control of storage conditions and distribution	7	7	3	147	Check storage rooms and distribution vehicles	7	2	2	28
Drying of filled split and non-split nuts to 5-7% moisture		Unsuitable drying	8	6	3	144	Check and correct moisture	8	2	2	32
Dumping and conveying over air to remove debris	Foreign matter	Contaminated air	8	5	3	120	Foreign matter control and air control	-	-	-	-

CCP: Critical Control Point. RPN: Risk Priority Number.
†When RPN is above 130, corrective actions are required.

In Table 2 an ISO22000 Analysis Worksheet is designed for determination of the prerequisite programs.

A flow diagram of pistacchio processing is presented in Fig. 1.

Ishikawa or Fishbone diagrams analyse all the dangers at all processing stages where CCPs are incorporated. These diagrams consist of five basic axes: man, machine, materials, methods and environment. In these axes the danger is described. An Ishikawa diagram is presented in Fig. 2 for the storage and distribution of pistachios.

Table 2. ISO22000 Analysis Worksheet for determination of the prerequisite programs for pistachio procesing

Processing step	Are the technical infrastructure and the preventative maintenance program adequate?	Is it feasible to evaluate them?	Do they contribute in the control of recognisable food safety hazards?	Does the effectiveness of the remaining control measures depend on them?	Is it a prerequisite program?
Receiving	YES	YES	NO	YES	YES
Dumping and conveying over air to remove debris	YES	YES	NO	NO	NO
Separation of 9 kg unhulled sample for separation and grading	YES	YES	NO	YES	YES
Hull removal from nuts	YES	YES	NO	YES	YES
Drying of filled split and non-split nuts to 5-7% moisture	YES	YES	NO	NO	NO
Storage at ambient temperature	YES	YES	NO	YES	YES
Separation of split nuts from non-split by needle picking drum	YES	YES	NO	YES	YES
Mechanical splitting of non-split nuts	YES	YES	NO	YES	YES
Electronic color sorting of split nuts	YES	YES	NO	YES	YES
Hand grading of split nuts	YES	YES	NO	NO	NO
Salting and roasting of split nuts	YES	YES	NO	NO	NO
Packaging, storage of final product and distribution	YES	YES	NO	NO	NO

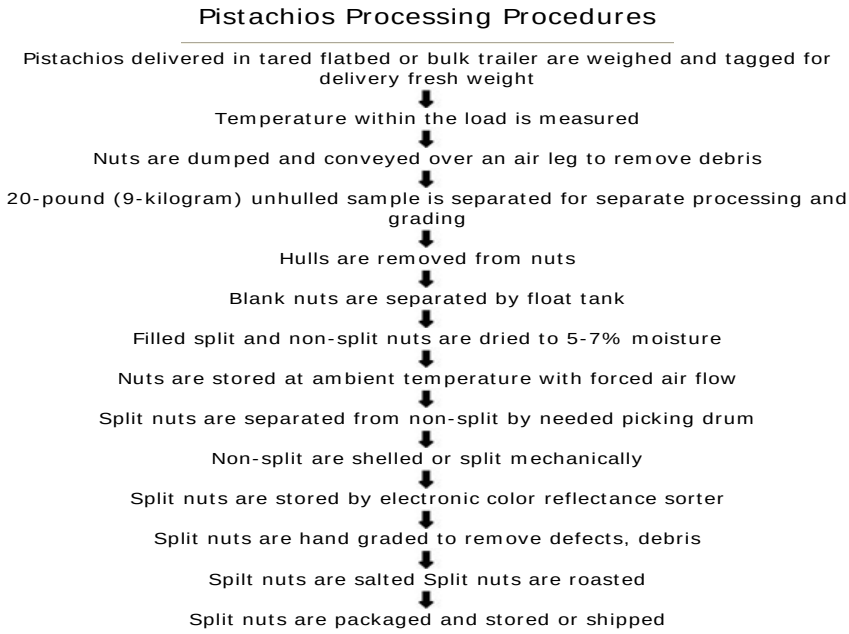

Fig. 1. Flow diagram of pistachio processing.

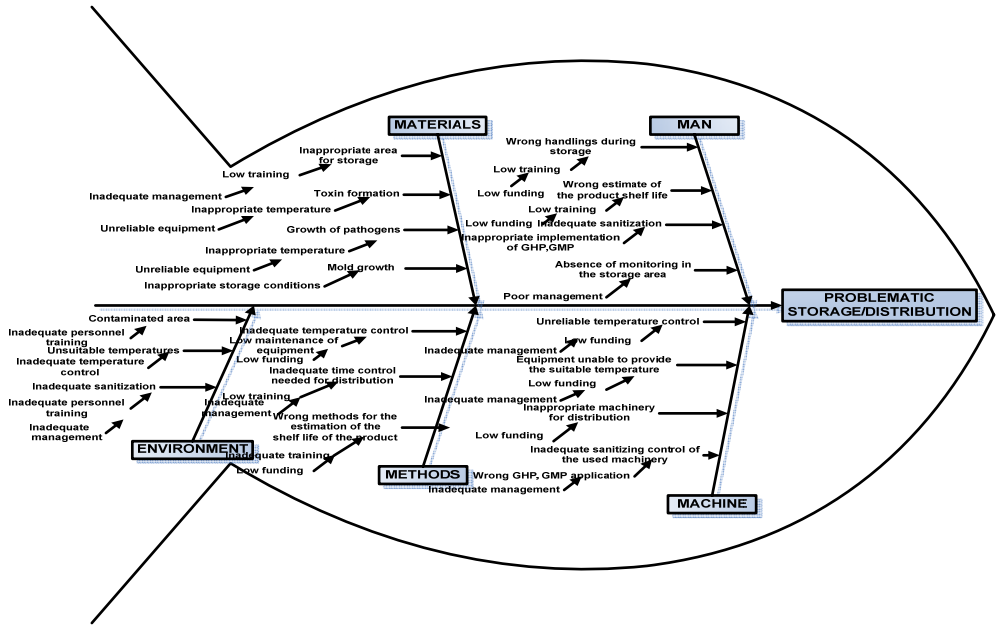

Fig. 2. Application of the Cause-and-Effect diagram (Ishikawa diagram) to pistachio manufacturing (CCP problematic storage/distribution of pistachios.

Packaging is another processing stage where an Ishikawa diagram could be drawn. Regarding man's bad practices the main problem is the bad disinfection of hands and this could be due to the low concentration of disinfectants or the inadequate training due to lack of money.

As far as machines are concerned the main problem is the bad sealing of packaging and this could be due to the faulty calibration of equipment which could be due to the inadequate maintenance, which could be due to inadequate training.

Regarding materials the main problem is the raw materials which are not very well sterilized due to contamination with other dangerous raw materials or the growth of aflatoxins due to humidity.

1. Postharvest processing

When pistachios become ripe, they are shaken down and then gathered manually from the ground, or they are picked by means of a special machine (only in California) and are directly transported to a mobile reservoir. Nuts must be subsequently shelled and dried in order to keep their high quality and perfect appearance. Nuts are dried in hot air at a temperature between 150 and 160℃.

Freshly picked nuts contain some 45% of humidity which is reduced to 5% after approximately ten hours of drying. Pistachios are then sorted according to size, quality, colour and shape by means of sorting machines.

The processing procedure begins with transportation of raw nuts to processing warehouses, where they are weighed and provided with a label showing the exact weight and the owner. Pistachios are unloaded and stored temporarily and cleaned by means of flowing air. A sample for quality classification is then taken. Nuts are peeled and peelings are separated for possible later use. The top layer must be removed from picked fruit which must be dried within 24 hours so that shells do not become dirty and possibly contaminated with dangerous aflatoxins. The peel closing nuts is removed by means of machines having two rubber cylinders moving in the opposite directions and rotating at different speeds. Pistachios are then stored in silos depending on their quality and prepared for dispatch.

The nuts are delivered in flatbed or bulk trailers, and are weighed and tagged for "delivery fresh weight".

Temperature within the load is checked and the nuts are off-loaded into temporary storage and may be conveyed over an air-flow table to remove debris. At this point, a 9-kg sample is taken for separate processing and grading. The nuts are de-hulled and the hulls separated for later use in other products or for disposal. Harvested fruit must be hulled and dried within 24 hours to avoid shell staining and potentially dangerous aflatoxin contamination.

The hull-enclosed nuts are hulled by using machines that have two parallel rubber belts that rotate at different speeds. The nuts are then separated in a float tank. The filled-split and non-split nuts are dried to five -percent to 7% moisture, after which the nuts are stored at ambient temperature, but with forced-air circulation. Split nuts are separated from non-split nuts within a specialized drum separator. The non-splits are then shelled or split mechanically.

Split nuts are then sorted and stored by use of electronic color-reflectance sorting machines. Split nuts may then be hand graded as a final quality-control check to remove misshapen nuts or detritus. Spilt nuts and the shelled nuts may then be refrigerated "fresh" for some specialty markets, but usually are salted and roasted. They are then packaged and stored or shipped. Like most nut crops, pistachios can be stored for many months once dried and salted.

III – Conclusions

In this work comparison of ISO22000 analysis with HACCP is carried out over pistacchio processing and packaging. However, the main emphasis was put on the quantification of risk assessment by determining the RPN per identified processing hazard. Salting and roasting, hand grading of split nuts to remove defects and debris, packaging and storage or shipping, drying of split and non-split nuts to 5-7% moisture as well as dumping of nuts and conveying over an air leg to remove debris were the processes identified as the ones with the highest RPN (280, 240, 147, 144, 130, respectively) and corrective actions were undertaken. Following the application of corrective actions, a second calculation of RPN values was carried out leading to considerably lower values (below the upper acceptable limit of 130). It is noteworthy that the application of Ishikawa (Cause and Effect or Tree diagram) led to converging results thus corroborating the validity of conclusions derived from risk assessment and FMEA. Therefore, the incorporation of FMEA analysis within the ISO22000 system of a pistachio processing plant is considered imperative.