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Application of failure mode and effect analysis (FMEA) and cause and effect analysis in conjunction with ISO22000 to an almond processing plant

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Abstract. Failure Mode and Effect Analysis (FMEA) model has been applied for the risk assessment of almond manufacturing. A tentative approach of FMEA application to the almond 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 (almond 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 diagrams. Moreover, comparison of ISO22000 analysis with HACCP is carried out over almond processing and packaging. The main emphasis was put on the quantification of risk assessment by determining the Risk Priority Number (RPN) per identified processing hazard. Pasteurisation, fumigation with propylene oxide, packaging, storage and distribution and hulling/shelling were the processes identified as the ones with the highest RPN (240, 225, 180, 144, 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 an almond processing plant is considered imperative.

Keywords. FMEA – ISO22000 – HACCP – Ishikawa diagrams – Preliminary Hazard Analysis – Almond 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 22000 dans une unité de transformation d'amandes

Résumé. *Le modèle d'analyse des défaillances, de leurs effets et de leur criticité (AMDEC) a été appliqué pour l'évaluation du risque dans l'élaboration des amandes. Une ébauche d'application de l'AMDEC pour l'industrie des amandes 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 l'amande), 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 les diagrammes de cause et d'effet. De plus, la comparaison de l'analyse ISO22000 et de l'HACCP se fait sur la transformation et le conditionnement des amandes. L'accent a été mis sur la quantification de l'évaluation des risques par la détermination du Numero de Priorité de Risque (CPR) pour les risques identifiés pendant le traitement. La pasteurisation, la fumigation avec de l'oxyde de propylène, l'emballage, le stockage et la distribution et le décorticage/cassage ont été les processus identifiés comme ayant le plus grand CPR (240, 225, 180, 144, 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 de l'AMDEC. Par conséquent, l'incorporation de l'analyse AMDEC et d'ISO22000 dans le système d'une usine de transformation de l'amande est considérée comme un impératif.*

Mots-clés. *FMEA – ISO 22000 – HACCP – Diagrammes d'Ishikawa – Analyse préliminaire de risques – Transformation des amandes.*

I – Introduction

Almonds had been cultivated for thousands of years before they had an official name. Science finally caught up in 1753, the year that Carolus Linnaeus, the Swedish botanist, classified the cultivated almond and named it *Amygdalus communis* L. But the name would not last. As botanists continued to refine their classifications, they separated almond species from other Prunus (peaches, apricots, etc.) into a subgenus Amygdalus.

Almonds are edible tree nuts, grown principally in California. The nuts are harvested from orchards and transported to almond processing facilities, where the almonds are hulled and shelled.

The function of an almond huller/sheller is to remove the hull and shell of the almond from the nut, or meat. Orchard debris, soil, and pebbles represent 10 to 25 percent of the field weight of material brought to the almond processing facility. Clean almond meats are obtained as about 20 percent of the field weight.

Once the almonds have been harvested, they are transported to the receiving stations. Deliveries begin in early August and are received in either bulk or in very large wooden boxes. As the almonds are received, they are weighed and information is collected regarding the source grower and the variety of the almond. Quality testing is also performed to establish the quality level of the received product.

Almonds are then stored in bulk by variety. The almonds are eventually loaded on trucks and transported for further processing and sales.

The almonds are delivered to the processing facility and are dumped into a receiving pit. The almonds are transported by screw conveyors and bucket elevators to a series of vibrating screens. The screens selectively remove orchard debris, including leaves, soil, and pebbles. A destoner removes stones, dirt clods, and other larger debris. A detwigger removes twigs and small sticks. The air streams from the various screens, destoners, and detwiggers are ducted to cyclones or fabric filters for particulate matter removal. The recovered soil and fine debris, such as leaves and grass, are disposed of by spreading on surrounding farmland. The recovered twigs may be chipped and used as fuel for co-generation plants.

The precleaned almonds are transferred from the precleaner area by another series of conveyors and elevators to storage bins to await further processing. Almonds are conveyed on belt and bucket conveyors to a series of hulling cylinders or shear rolls, which crack the almond hulls. Hulling cylinders are typically used in almond huller facilities.

Series of shear rolls are generally used in huller/shellers. The hulling cylinders have no integral provision for aspiration of shell pieces. Shear rolls, on the other hand, do have integral aspiration to remove shell fragments from loose hulls and almond meats. The cracked almonds are then discharged to a series of vibrating screens or a gravity table, which separates hulls and unhulled almonds from the in-shell almonds, almond meats, and fine trash. Almonds are then sorted, graded, diced, sliced, slivered, crosscut, split, cubed, chopped, flaked, smoked, roasted, blanched, flavored, pounded into paste, tested and again re-tested. These end products are jarred, foil wrapped, canned, bagged, boxed, tri-wal-binned, palletized and bar-coded. The products are then stored according to strict guidelines for storage and shelf life. Once orders are received, almond products are shipped all over the world to be used in both retail establishments and as ingredients in other well known products such as cereals and baked goods.

Prerequisite Programs (PPs) are the supportive framework for the HACCP (Hazard Analysis and Critical Control Point) plan. They are specific control plans or procedures developed to deliver a food safe product from harvest to shipment. Prerequisite Programs give creditability to and provide important internal control to the HACCP plan. Having PPs simplify the HACCP plan. If any portion of the prerequisite program for aflatoxin control is absent or is not followed, then additional CCPs (Critical Control Points) may have to be identified, monitored and maintained under the HACCP plan (The Almond Board of California, 2007).

Mycotoxins are secondary metabolites secreted by moulds belonging mainly to the genera *Aspergillus, Penicillium* and *Fusarium*. They can be produced on a wide range of foods and under varied conditions. The presence of mycotoxins in food for human or animal consumption is potentially dangerous because of the diversity of their toxic effects and their high thermal stability. The main classes of mycotoxins considered as important in the food industry are: Aflatoxins, Ochratoxin, Patulin, Fumonisin, Deoxynivalenol and Zearalenone (Pittet, 1998). All mycotoxins are dangerous for human and animal health and cause various diseases, of which some are deadly.

1. Grower/handler responsibility

Growers and handlers are required to take all reasonable measures and precautions to comply with Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) respectively. The intention of the industry's food safety program is to provide a healthful, safe food that will meet the intended needs of our customers and represent a good value. Our harvesting, delivery, storage, processing and quality systems are designed to provide a food safe and sanitary product for our customers.

2. Almond fumigation

Each handler or grower is responsible for fumigation of the almond crop to eliminate insect infestations. Insect damage is highly correlated with aflatoxin, so it is imperative to eliminate insects from harvested crops to prevent the spread of aflatoxin. Licensed fumigators carry out fumigations.

3. Voluntary Aflatoxin sampling program (VASP)

This is a voluntary program for the industry to control aflatoxin in shipments destined for export markets, particularly the European Union (EU) where aflatoxin tolerances are stringent. It sets the protocol for sampling and analysis with an equivalent sensitivity to the protocol currently being used in the EU. The VASP requires a sample size of 15 kilograms analyzed as 3 x 5 kilogram sub-samples. The required sample size for the EU is 3 x 10 kilograms. Because the samples sizes are smaller than the EU protocol, we gain equivalency by decreasing the accept/reject level to 2 ppb total rather than the 4 ppb total used in the EU. All three tests must individually meet this requirement (The Almond Board of California, 2007).

4. Electronic sorting technology and quality

The almond industry has invested in high technology equipment to identify damaged almonds, and to remove almond "rejects" as well as any foreign material. Foreign material (F/M) is considered to be anything that is not an almond nutmeat. Removal of these "rejects" is crucial to the control of aflatoxin. Reject kernels are highly correlated with aflatoxin contamination. The industry recognizes this fact and focuses on electronic and manual sorting to remove reject kernels. Finished product testing confirms that removing rejects reduces aflatoxin contamination (The Almond Board of California, 2007).

5. 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 as can be seen in Table 1 and corrective actions are 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 almond processing

Defective Products							Estimated corrective actions result				
Production step-CCP	**Hazards**	**Causes**	**S**	**O**	**D**	**RPN**	**Corrective actions**	**S**	**O**	**D**	**RPN**
Pasteurization	Pathogens, parasites, aflatoxins	Wrong pasteurization temperature	8	6	5	240	Correct temperature	8	3	3	72
Fumigation	Chemical residues	Wrong temperature and wrong concentration	9	5	5	225	Correct temperature and concentration	9	2	2	36
Packaging	Wrong percentage of chemicals in packaging material	Improper packaging	9	5	4	180	Check sealing and packaging	9	2	2	36
Storage & Distribution	Contamination from wrong temperature or time remaining at room temperature	Improper control of storage conditions and distribution	8	3	6	144	Check storage rooms and distribution vehicles	8	2	2	32

In Table 2 an ISO22000 Analysis Worksheet is designed for determination of the Prerequisite Programs.

In Table 3 a decision table is used for critical control point determination during processing of almonds and critical control points, critical limits, process control, corrective actions and verification in almond processing are presented in Table 4.

Finally a flow diagram of almond 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.

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

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 of almonds	YES	YES	NO	YES	YES
Fumigation	YES	YES	NO	NO	NO
Pasteurization	YES	YES	NO	NO	NO
Storage	YES	YES	NO	YES	YES
Hulling/shelling	YES	YES	NO	YES	YES
Handler receiving	YES	YES	NO	YES	YES
Fumigation	YES	YES	NO	YES	YES
Sizing	YES	YES	NO	YES	YES
Mechanical/optical sorting	YES	YES	NO	YES	YES
Manual sorting	YES	YES	NO	YES	YES
QC inspection	YES	YES	NO	YES	YES
Packaging	YES	YES	NO	NO	NO
Aflatoxin analysis	YES	YES	NO	YES	YES
Storage and distribution	YES	YES	NO	NO	NO

Table 3. Decision table for critical control point determination during processing of almonds

Processing stage	Q1 Do preventative control measures exist? (Yes/No) Description of dangers	Q2 Is the step specifically designed to eliminate or reduce the likely occurrence of hazard to an acceptable level? (Yes/No)	Q3 Could contamination with identified hazards(s) or could this increase to unacceptable levels? (Yes/No)	Q4 Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable levels? (Yes/No)	Is this step a critical control point? (Yes/No)
Receiving of almonds	Y Chemical (aflatoxins), Physical (glass, metal)	N	**Y**	Y	PrPs
Fumigation	Y	Y			CCP1
Pasteurization	Y	Y			CCP2
Storage	Y/Aflatoxins	N	**Y**	Y	PrPs
Hulling/ Shelling	Y	N	**Y**	Y	PrPs
Handler receiving	Y	N	**Y**	Y	PrPs

Table 3 (cont.). Decision table for critical control point determination during processing of almonds

Processing stage	Q1 Do preventative control measures exist? (Yes/No) Description of dangers	Q2 Is the step specifically designed to eliminate or reduce the likely occurrence of hazard to an acceptable level? (Yes/No)	Q3 Could contamination with identified hazards(s) or could this increase to unacceptable levels? (Yes/No)	Q4 Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to acceptable levels? (Yes/No)	Is this step a critical control point? (Yes/No)
Fumigation	Y	Y			CCP1
Sizing	Y	N	**Y**	Y	PrPs
Mechanical/ optical sorting	Y/Aflatoxins	N	**Y**	Y	PrPs
Manual sorting	Y/Aflatoxins	N	**Y**	Y	PrPs
QC inspection	Y Total aflatoxin conc. ≤ 2 ppb	N	**Y**	Y	PrPs
Packaging	Y	Y			CCP3
Aflatoxin analysis	Y	N	**Y**	Y	PrPs
Storage and distribution	Y	Y			CCP4

Table 4. Critical control points, critical limits, process control, corrective actions and verification in almond processing

CCP/PrPs	Critical limits	Process control				Corrective action	Verification
		Way	Frequency	Control sheet	Responsible		
Fumigation	Concentration of residual propylene oxide: 0.2- 0.8 ppm (Limit for taking measures: > 1ppm Treatment chamber T not to exceed 52ºC for 4 hours- need to be prewarmed at 30ºC.		Daily - Twice	Residual propylene oxide control sheet Temperature control	Production supervisor	Correct concentration and temperature Control of dosage pump of PPO	-Daily verification -Lab analysis of raw materials recording papers of temeperature
Pasteurization	HTST for less than 1 minute	Temperature control and recording in the specially designed system.	On-line meters	Temperature control sheets	Production supervisor	Correct temperature	-Daily verification -Lab analysis -Microbiological analysis

Table 4 (cont.). Critical control points, critical limits, process control, corrective actions and verification in almond processing

CCP/PrPs	Critical limits	Process control				Corrective action	Verification
		Way	Frequency	Control sheet	Responsible		
Packaging	Check sealing and conc. of gases if added Right labeling of final products (expiry date, product description, Lot Number)	Control of labeling (expiry date, product description, Lot Number)	At every product change	Packaging control sheet	Production supervisor	- Control – repackaging of lots with wrong labeling (Production supervisor)	-Monthly verification -Macroscopic control
QC of finished product	Total aflatoxin conc. ≤ 2 ppb	Sample 15 kg product including at least 50-300 g incremental samples. Mix all incremental samples and split into 3x5 kg individual samples. Analyse each one separately for aflatoxins.	Every product lot	Lab test documentation	Lab chemist	If limit is exceeded shipment is rejected. Reprocessing may be carried out	QC includes at least 15 samples from authorities. Periodic audits Customer test results
Storage and distribution	RH of 55% is recommended		Every product lot	Records	Warehouse supervisor	Adjust temperature and % RH and test product moisture	Periodic management review

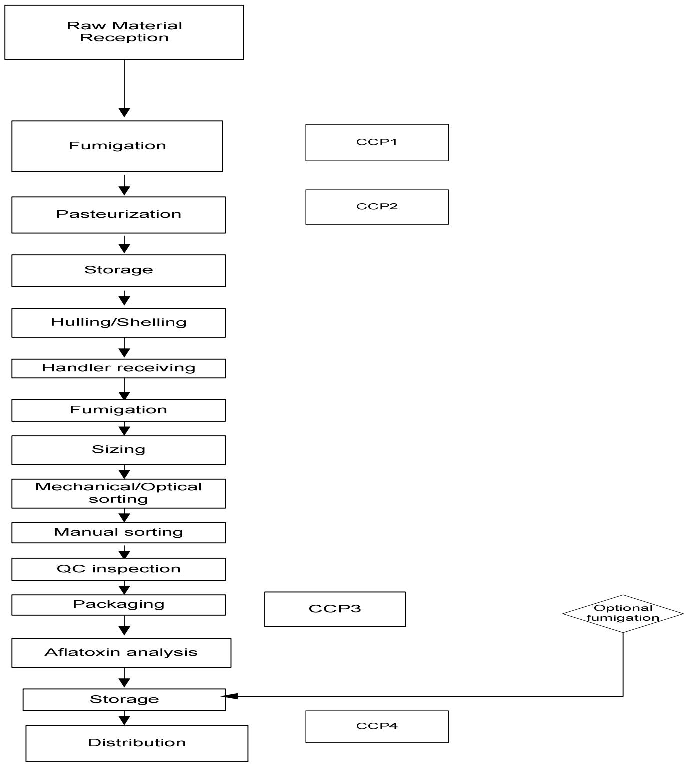

Fig. 1. Flow diagram of almond manufacturing.

In Fig. 2 the Ishikawa is applied to detect the causes that might be due to the physical, chemical and microbiological dangers occurring at the storage and distribution stages. Regarding man the main problem is bad distribution due to the inadequate training of workers. Regarding machines the problem might be due to the wrong placement of packaging, or the bad adjustment of the temperature of the transportation vehicle due to inadequate personnel training.

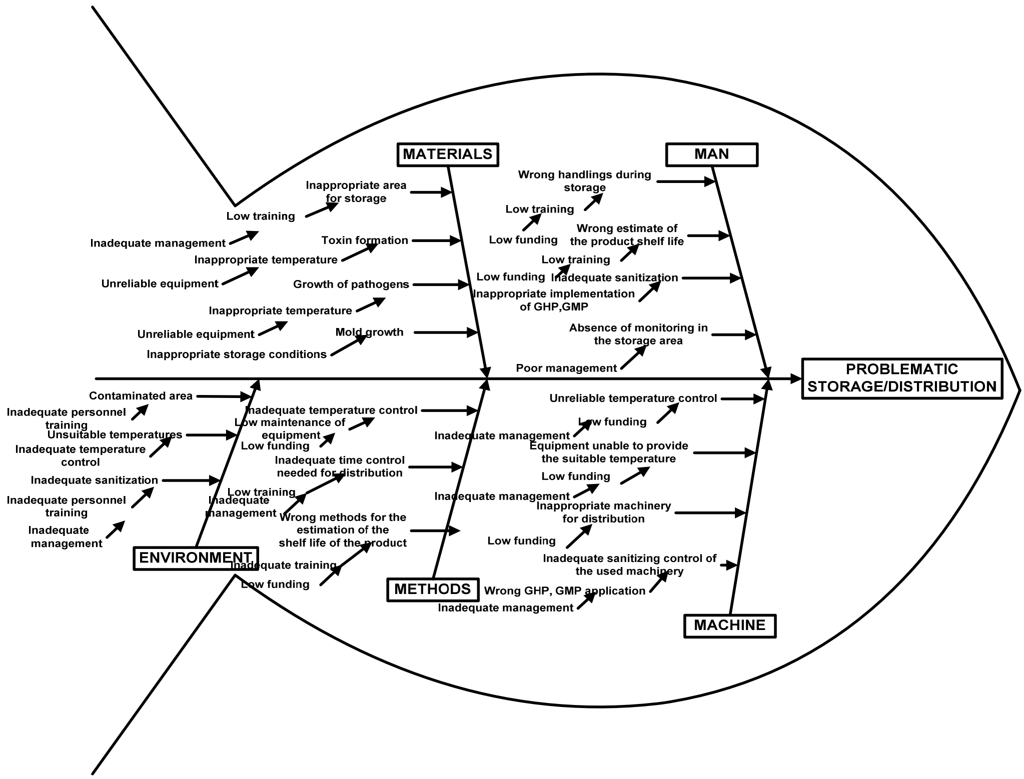

Fig. 2. Application of the Cause-and-Effect diagram (Ishikawa diagram) to almond manufacturing (CCP problematic storage/distribution of almonds.

Almonds should be stored or displayed in a cool, dry place away from all heat sources; also avoid prolonged exposure to direct sunlight, which tends to darken shelled almonds and decrease their stability.

Dry warehouse storage is satisfactory during cool months if the storage temperature does not rise above 7ºC. Otherwise, regular inspection and insect control or removal to cold storage is necessary.

Ideal cold storage temperature is 2-7ºC, since some storage insects can remain active above 7ºC temperatures. Recommended warehouse relative humidity is 55-65%.

Roasted or toasted almonds in vacuum tins or nitrogen-flushed packs sustain quality for prolonged periods of time, but cold storage is advised for long-term storage of several months. Under extended cold storage conditions, tins should be checked periodically for rusting.

Storage in ammonia-cooled rooms should be avoided, since ammonia fumes can ruin almonds quickly. If brine-cooled storage facilities are not available, a guarantee against ammonia damage should be obtained from the warehouse.

Almonds may be permeated by strong odors and should never be stored in the same room with pungent commodities such as onions, apples, fish, paint, cleaning compounds, etc.; nor in rooms (cooled or otherwise) where such products have been recently stored.

Almonds can be freezer stored. It extends the shelf life of almonds significantly. However, proper packaging must be used to seal the almonds to protect from ice formation and moisture, which can result in mold.

Retailers should be cautioned against improper display or storage: Almonds left at room temperature more than one week should be in insect-proof containers; or if left in cartons or paper-lined packages, the almonds should be inspected weekly.

Other factors that influence the rate of deterioration of almond products except oxygen include the age of the product, roasting, size of pieces, the moisture content, exposure to light and exposure to certain metals. Generally, the greater the surface area, the greater the opportunity for the autoxidation process to proceed, depending on the process used in size reduction of whole almonds.

Increases in moisture can result in increases in oxidative and biological processes which in turn lead to a reduction in shelf life.

Light increases oxidative processes by initiating free radical formation, and certain metals can increase oxidative processes by acting as catalysis.

Cutting, blanching, roasting,the addition of moisture or poor quality roasting oil can all decrease shelf life of almonds. Research has shown that under ambient storage conditions, dry roasted almonds have a longer shelf life than oil roasted almonds.

Antioxidant application or chocolate coating can increase shelf life of almonds. Effective synthetic antioxidants for almonds are: BHA, BHT and TBHQ. A commercial product, mixed tocopherols, is an effective natural antioxidant.

II – Conclusions

In this work comparison of ISO22000 analysis with HACCP is carried out over almond processing and packaging. However, the main emphasis was put on the quantification of risk assessment by determining the RPN per identified processing hazard. Pasteurisation, fumigation with propylene oxide, packaging, storage and distribution and hulling/shelling were the processes identified as the ones with the highest RPN (240, 225, 180, 144 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 an almond processing plant is considered imperative.

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