Review of Tree Nut Risk Assessments

CI/Napasol/September 16th 2019

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Background

All Raw agricultural products are exposed to the environment and to microbiological contaminants. Of concern are the microbes that cause disease such as Salmonella, E. Coli, Listeria and others. If the products are to be consumed raw, they need to be subjected to a preventive control step to eliminate those pathogens. Many Tree Nuts are typically consumed raw but even when processed the pathogens are not always eliminated.

Efforts to reduce exposure to pathogens through GAP/GMP measures are not sufficient to eliminate the risk. Although they are inhomogenously and sparsely distributed, these pathogens are infectious at low doses, they persist in the environment and have long survival times on low moisture foods.

In the context of the implementation of the Food Safety Modernization Act (FSMA) the FDA has conducted research to address the risks specifically associated with Tree Nuts. The published results demonstrate the risk level and the associated Preventive control performance needed to control the risk.

Recalls and outbreaks

Outbreaks are events where people are sickened by the consumption of pathogen tainted food. Many illnesses are unreported, mainly because the patient is not sick enough to warrant medical attention. In the US, information from laboratory confirmed cases for medically followed patients is collected by FoodNet (12) while PulseNet (11) compares the DNA fingerprints of the infectious bacteria. This elaborate structure allows connecting cases of illness nationwide to quickly identify outbreaks, including many that would otherwise go undetected

Recalls are instances where a sampled product shows the presence of a pathogen triggering the intervention of all involved in the supply chain to remove the tainted product from the market.

Border rejections occur when a shipment inspected by authorities reveal the presence of a pathogen. The rejection is notified and the contaminated load quarantined and subsequently either destroyed or shipped back to the sender or to an authorized third party.

A compilation of recalls and outbreaks in the US between 2001 and 2019 (9) is shown in the table below.

	U.S. Recalls of Nuts: 2001 to 2019	
	Recalls	Outbreaks
Almonds (1)	2001, 2004, 2012 (2014,2017, 2018, 2019)	2001, 2004 **(2012, 2014, 2015)**
Pistachios	2016, 2018	2016
Walnuts	2010, 2012, 2014, 2015	No illness reported
Pecan (2)	2015	No illness reported
Cashew	2015, 2016	No illness reported
Hazelnuts-shelled	None	No illness reported
Hazelnuts in-shell	2017	2017
Pine nuts	2015, 2017	No illness reported
Macadamia	2015, 2016	No illness reported

(1) Almonds are subject to a mandatory pasteurization program since 2007. The 2012, 2014 and 2015 outbreaks are for nut butters and nut mixes.
(2) Pecans: in the case of delayed drying there is a tenfold increase in risk

Note: some of the recalls relate to pathogens other than Salmonella: E.coli for macadamias, walnuts and hazelnuts, and Listeria monocytogenes for nut butters and walnuts.

Outside the US, data regarding nut recalls is not readily available. The EU market is the largest consumer of tree nuts, ahead of the US. The lack of recalls in the EU is not due to any superior quality of the nuts consumed in European countries. This may be due to the fact that the national authorities

in charge of surveillance and reporting do not benefit from the elaborate network put in place in the US, but also there is a stronger focus on chemical contaminants in the EU.

What are the consequences

Product recalls, litigation costs, and insurance costs are prohibitive and can damage those businesses that are caught up in the commercialization of contaminated product. Authorities will increase inspection and surveillance and require proof of action to eliminate the risk.

Sampling plans: Testing foods cannot guarantee food safety

Sampling plans are based on statistical models and are indicative of a probability "that a positive load will be accepted" Also "no feasible sampling plan can ensure complete absence of a pathogen" (1). Sampling methodology, sample size, and laboratory methods significantly impact the outcome of a sampling plan. For example, prevalence in the field with larger sample size are as high as >20% (Hazelnuts, Macadamia).

Identifying the origin of recalls and outbreaks

Originally analytical methods were only capable of detecting relatively large number of Salmonella. Increased sensitivity and larger sample size allowed to detect defective lots with lower contamination levels and inhomogeneous distribution of the bacteria. This is particularly important with a bacteria that is found in very low numbers.

Today, with whole genome sequencing, the isolate's DNA sequence can be compared to an online library of collection of isolates with identified origins and /or links to outbreaks. This allows identification and tracing of the Salmonella to specific products and geographic locations. Warning letters issued by authorities are based on such evidence, stating for example: "based on traceback and epidemiological evidence and inspectional evidence, isolates from an outbreak of Salmonellosis in 11 patients were identified with a pistachio processor".

Regulations and Requirements

In the US the FSMA Produce Safety Rules specify that preventative controls are required where a salmonella risk is identified. Salmonella has been identified as a risk on all tree nuts

Preventive control means the reduction of the presence of microorganisms with a pasteurization step. The purpose of the risk assessment is to determine whether a pasteurization step is needed and what level of microbiological reduction is necessary to reduce the risk of salmonellosis to an acceptable level.

For Almonds, pistachios, walnuts and Pecans, the control of the pathogen is defined scientifically with a required log reduction performance of the pasteurization process. For other nuts, where a risk assessment has not been done yet, the pasteurization performance must be sufficient to insure the microbiological safety of the product. This level of safety is somewhere between the 4 and 5 log reduction defined by the risk assessment on those nuts for which a risk assessment was completed.

Outside the US, the presence of Salmonella on foods is also unacceptable but there are no specific guidelines other than the responsibility of putting safe wholesome products on the market. In the EU there is more of a focus on other contaminants such as mycotoxins, pesticide residues, and chemicals.

Food that is produce and that is a raw agricultural commodity is covered by the Produce Safety Rule. This includes a produce that is grown domestically and a produce that will be imported

Risk assessments

The quantitative risk assessment is a tool to estimate the risk of adverse health effects from exposure to a hazard in the food supply and the associated burden of illness for a specific population. It can be used to evaluate potential risk reduction strategies, to determine the adequacy and predicted efficacy of preventive controls, and to guide risk management policies.

Frequency of occurrence and Salmonella concentration levels for each step throughout the production process from harvest to consumption are measured through an intensive and extensive sampling program.

Steps in the production process
ORCHARD
HARVEST
HULLING
DRYING
PASTEURIZATION
STORAGE
RETAIL
CONSUMER

Risk estimates per serving results from combining the FAO/WHO (4) dose-response function with the results of the exposure assessment module (concentration levels of Salmonella per contaminated serving) and the prevalence of contaminated servings.

Prevalence

- In the field

For example, for almonds the frequency of Salmonella contamination (i.e., detection in at least a 100-g sample) on almonds was approximately 1%. For pecans 0.47% to 1.4%, for walnuts (in shell) 0.14% (5) (6) (7)

- At retail (2015-2016 FDA sampling program (12)

Product	Number of samples	Positive samples	% positive
Cashew	733	4	0.55%
Walnut	658	8	1.22%
Hazelnut kernel	577	2	0.35%
Hazelnut in shell	80	0	0
Pine nuts	630	3	0.48%
Pecans	623	0	0
Macadamia	355	15	4.2%

Pistachios and Almonds were excluded from this sampling

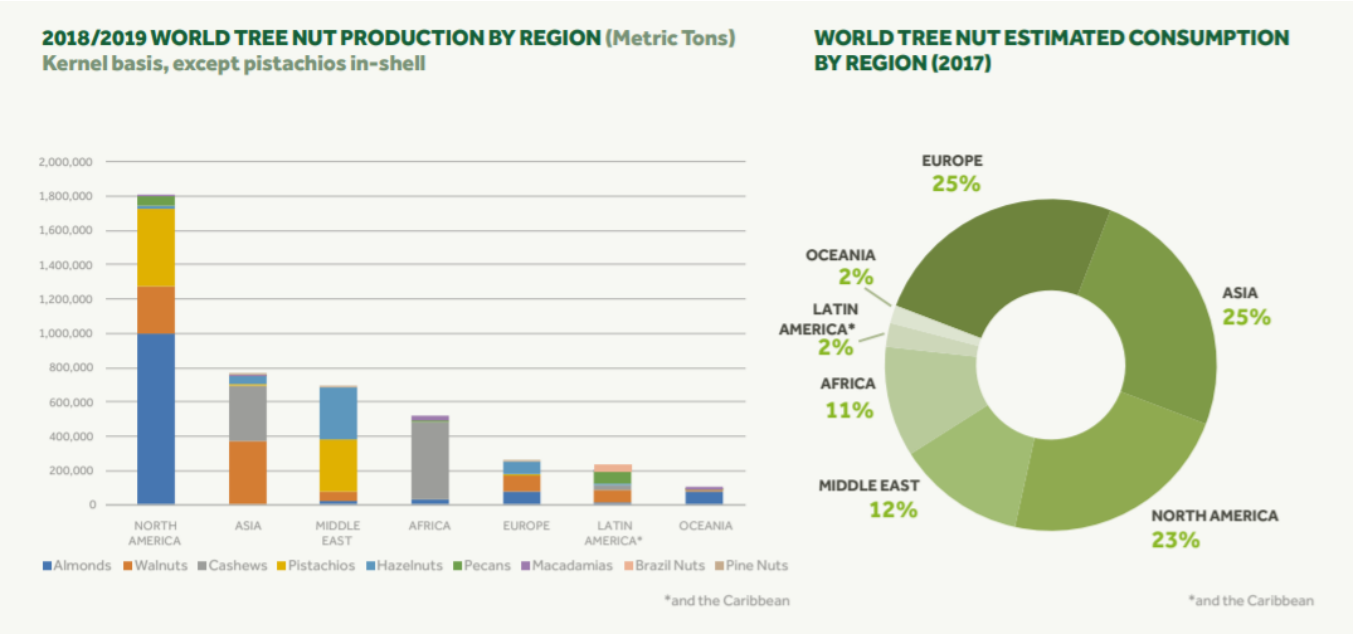
In this retail sampling program, the percentage of positive samples ranged from 0 for hazelnuts in shell and pecans to 4.2% for macadamia. Retail pack labels do not identify whether the nuts were subject to a microbial reduction step which was likely to be the case for some of the samples. This is positive for the consumer but also challenges the data in this study which underestimates the prevalence of contamination at retail and appears to minimizes the need for a preventive control.

Survival

In storage survival is higher at lower water activity (aw) and at lower temperature. Survival is different on different nuts: Pine nuts>Pecans>Hazelnuts and is not related to fat content. Salmonella populations are relatively stable with 1.5-log CFU/g decline over a year. (13)

Consumption data

Consumption of tree nuts has grown worldwide 26% in the last 5 years promoted by their widely publicized health benefits. The US is by far the largest producer of tree nuts in the world with 1'800'000 tonnes, almonds being the largest crop followed by walnuts. The largest tree nut consumption markets are Europe and Asia, both at 25%, followed by the US at 23%.



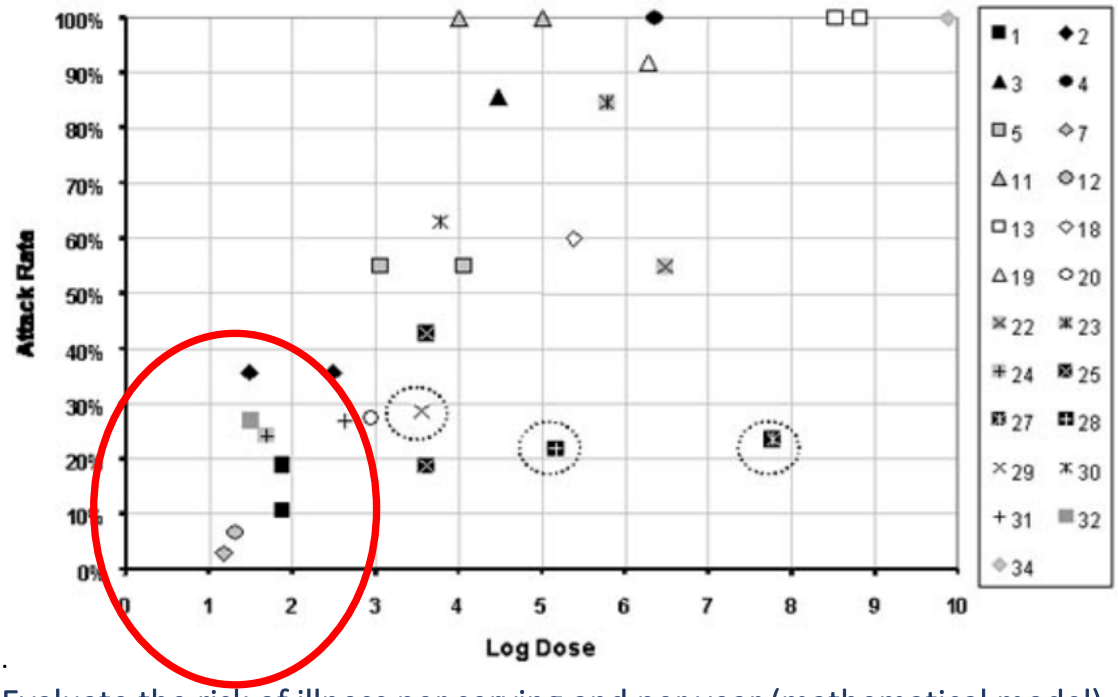
The estimated consumption per capita in kilograms per year is calculated by dividing the total volume consumed in the market by the estimated percentage of population that is considered regular consumer of tree nuts. (3)

US consumption data	Almonds	Pecans	Pistachio (in shell)	Walnuts
Kg per year per consumer	2.14	0.9	0.98	1.02

Dose response model from FAO/WHO

Based on data from historic outbreaks of salmonellosis, the rate of disease can be plotted against the dose of salmonella in the contaminated food. The graph below shows that a relatively low dose between 10 and 100 CFU/g can result in a 40% disease rate. (4)

For almonds, at the handler stage of processing, sampling from the 2001 harvest season has shown that the most probable number of Salmonella microorganisms in positive samples could reach as high as 15cfu/g. (5)



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Evaluate the risk of illness per serving and per year (mathematical model)

Based on the prevalence, survival, contamination level, consumption, and dose response data the risk of salmonellosis cases can be calculated. For example, the data from the almond risk assessment shows that there is a 78% chance of one or more cases of salmonellosis per year, with an overall predicted mean of eight cases per year, and a maximum of $4.4X10^5$ cases per year from consumption of raw almonds (5).

The data also shows that there is a high variability of the predicted number of cases from one year to another

Assess the level of salmonella reduction necessary to result in <1 case par year

Risk assessment for Walnuts, Pistachios, Almonds and Pecan have been published. The estimate number and, in parenthesis, the lower and upper values in which the true value can be found with a 95% probability are shown below. Core uncooked estimated number of cases of Salmonellosis are for unprocessed nuts. The reduction in the estimated number of cases following pasteurization of the nuts at various reduction levels are also indicated.

Number of cases of salmonellosis	Core uncooked	1log reduction	2log reduction	3log reduction	4log reduction	5log reduction
Walnuts	6 (<1-278)	<1 (1-20)	<1 (1-2)	<1	<1	<1
Pistachios	419 (200-1'083)	43 (21-141)	2 (2-17)	<1 (<1-1)	<1	<1
Atypical (1)	(2578-303'418)	(256-49'556)	(26-5'434)	(3-561)	(0-56)	(0-6)
Pecan	529 (213-2'295)	54 (22-235)	4 (2-26)	<1 (<1-3)	<1	<1
Atypical (3)	179'700	18'600	1'800	187	19	2
Almonds	1697 (1'162-3'501)	170 (119-339)	17 (12-36)	2 (1-4)	<1	<1
Atypical (2)	(905-21'355)	(126-3'376)	(15-300)	(1-43)	(<1-4)	<1

(1) Pistachios atypical situation such as delay in drying (6 to 48hr) allows growth of the microorganism necessitating a higher log reduction.
(2) Almonds atypical situation linked to rain event.
(3) Pecan atypical situation in postconditioning (wet process) drying delay of pecan kernels that have been separated from shells through water flotation.

It was determined that cases of salmonellosis per year from consumption of raw almonds can be reduced from 78 % to less than 1 % by using a process achieving a 5-log reduction (2) Currently there is a mandated 4log reduction pasteurization requirement under the California Almond Federal Marketing Order issued by the U.S. Department of Agriculture.

Note that atypical conditions do occur and the proper level of safety should dictate the log reduction performance for the worst conditions. Although 4log reduction may be appropriate and approved for almonds, several of the validated processes achieve >5log without problems.

Adequate preventive controls

The risk assessment indicates the salmonella reduction needed for a process to adequately address the risk. However, the suitability of the process needs to be scientifically demonstrated through a Validation process that establishes the critical parameters to be met with the record keeping to allow verifying and controlling that the process delivers the performance expected.

For example, the Almond Board has defined validated processes parameters for the TERP (technical Expert Review Panel) approved technologies described below.

Processes	Temperature		Time	Process	Reduction	Organoleptic
Blanching	190°F	88°C	2 minutes	Wet needs a drying step	>5log	Peeled
Oil roasting	260°F	127°C	2 minutes	Dry	>5log	Roasted
Roasting	300°F	148°C	9 minutes	Dry	4log	Roasted
PPO	124°F	51°C	4 hours (2-4-day ventilation)	Dry	>5log	Raw
Napasol (vacuum/steam)	190°F	88°C	9 minutes	Dry steam	>5log	Raw
Other (Ambient pressure steam)	212°F	100°C	DNK	Wet steam needs a drying step	4log	Raw

Chemical processes such as PPO (Propylene Oxide) achieve >5log and maintains raw characteristics but as an oxidant it affects shelf life.

Thermal processes transforming the product such as blanching and oil roasting produce >5log reduction. Dry roasters can achieve >4log at high temperatures but over-roasting is difficult to prevent.

Thermal processes such as steam tunnels at ambient pressure achieve >4log reduction but wet the product that subsequently needs drying. The vacuum steam processe achieves >5log reduction by applying dry saturated steam and as a consequence the product does not need subsequent drying.

There is no pasteurization requirement for tree nuts other than almonds, however contamination with salmonella has been found on all tree nuts. There is an obligation for the processors to comply with the produce safety rule which requires preventive control to mitigate the risk of Salmonellosis. (5) (6) (7) (8). A 4log to 5log reduction level is what is expected as a validated preventive step for tree nuts.

Conclusion

The presence and survival of salmonella on tree nuts is demonstrated and the concomitant risk to the consumer clearly estimated. A full risk assessment is available for Almonds, Pistachios, Pecans and Walnuts. Because the presence of salmonella can result in disease, salmonellosis can be life threatening, preventive controls must be implemented to eliminate the risk. In the case of Salmonella, the preventive control is pasteurization.

Risk assessments conducted on tree nuts allows evaluating the microbiological reduction level needed to insure the safety of the nut.

In the case of almonds, a variety of technologies have been validated: PPO, oil roasting, blanching, proprietary steam treatments. The log reduction performance mandated by USDA for almonds is a 4log reduction to decrease the risk to an acceptable level.

In the case of other tree nuts there is no mandated reduction criterion. However, the responsibility of complying with the produce safety rule and putting on the market safe food falls entirely on the

shoulders of the processor. The cost of recalls and the associated negative publicity and increased regulatory surveillance needs to be weighed against the insurance that a pasteurization step provides.

In the case of processed nuts for example there is a desire to use the process not only to transform the raw nuts (blanching, roasting) but also to provide a kill step that would insure the microbiological safety of the product. The pasteurization of raw nuts necessitates applying effective processes (PPO, steam) that do not alter the raw characteristics of the nuts. Any process that purports to be a kill step and preventive control for salmonella needs to go through a validation to insure the reliability and repeatability of the pasteurization process.

The strongest driver for implementation of preventative controls is the food industry and retailers. Specifications that require the absence of salmonella (and other pathogens) need to be met not only with a laboratory certificate and proper sampling methodology but quality control requirements now extend to proof of validation of the performance of microbiological reduction steps.

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