World Wine Trade Group

ABSTRACT

Several scientific studies have linked wine's chemical nature as a polyphenolic, high acid and alcohol containing product with anti-microbial properties; as a result, wine has been widely recognized as a low microbiological food safety risk consumer product. Building complex regulatory schemes which must be administered with scarce government resources is wasteful and illogical for a product with a low consumer risk profile as identified by the general principles of risk management endorsed by the WHO and other international advisory bodies.

RISK MANAGEMENT

In 2006, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) developed a generic framework for risk management (*Figure 1*) [1] in order to improve food safety regulators' understanding and use of risk management within their respective national food safety regulations. The FAO's primary goal is to protect public health by controlling risks as effectively as possible through the selection and implementation of appropriate measures.

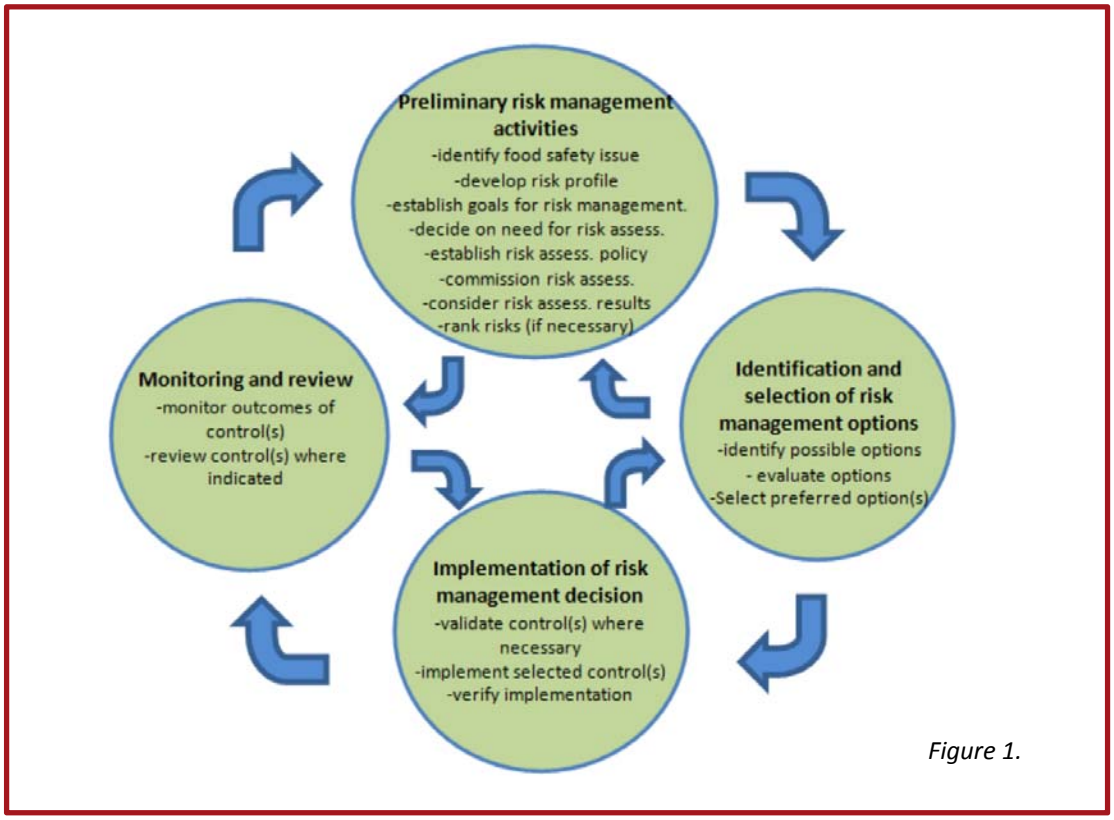

Figure 1.

[1] *Risk Management and Food Safety Report of a Joint FAO/WHO Consultation* (1997). Food and Agriculture Organization of the United Nations in Collaboration with the World Health Organization, http://www.fao.org/3/a-w4982e.pdf (26 August 2015)

In the FAO/WHO framework 'risk ranking' is included in the preliminary risk management activities. The objective of risk ranking is the evaluation of the perceived level of risk each issue presents to consumers, so that risk management resources can be optimally applied to reduce overall food related public health concerns[2]. This is commonly referred to as a 'risk-based' approach to public health protection. In simple terms it means shifting government resources to more heavily regulate products which pose the highest level of risk to consumer safety (i.e. meat, fish and dairy) and streamline approaches to other products which present a lower level of risk.

Wine is a perfect example of a consumer product which presents a low level of risk.

Wine Is A Low Food Safety Risk Consumer Product

Many studies, some of which are discussed below, indicate clearly that wine does not support the growth of pathogenic micro-organisms and can have anti-microbial properties due to its fundamental chemical nature as a polyphenolic, high acid, alcohol containing beverage. As a result of these studies, many governments have recognized wine as a low risk consumer product, and have employed a corresponding regulatory framework from a food safety standpoint.

Scientific Studies

Polyphenols & High Acid

A study performed by the Department of Human and Environmental Sciences at the Ochanomizu University in Japan found that "food-borne bacteria were killed in both red and white wine within thirty minutes" [3].

Papadopoulou et al. studied the antimicrobial properties of phenolic compounds in wine and concluded: "The antimicrobial activity and the phenolic composition of the tested white and red wine extracts indicate that some phenolic acids have the potential to inhibit growth of certain pathogens such as *S. aureus*, *E. coli* and *C. albicans* strains" [4] Yet another study carried out in the Republic of Korea demonstrated that red wine had "significant anti-norovirus effects on foodborne viruses"[5].

All three studies concluded the influencing components of wine's antimicrobial properties were its polyphenolic compounds, and high acidity (low pH).

In 2011, the U.S. Food and Drug Administration (U.S. FDA) published a table on *Limiting Conditions for Pathogen Growth*[6] (*Table 1*) detailing the pH ranges required for the growth of several pathogens. Of the fifteen pathogens listed, most require a pH of 4-9.5. Wine pH ranges from 3.1 to 3.9[7], meaning that due to the high acid (low pH) alone; most human pathogenic microorganisms cannot survive in it. The one exception seems to be *salmonella*

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[2] *Scientific Opinion on the development of a risk ranking framework on biological hazards* (2012). European Food Safety Authority, http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2724.pdf (26 August 2015)

[3] Yoshiko Sugita-Konishi, Yukiko Hara-Kudo, Tamami Iwamoto & Kazuo Kondo (2001), *Wine Has Activity against Entero-pathogenic Bacteria in Vitro but not in Vivo*. Bioscience, Biotechnology, and Biochemistry, 65: 954-957

[4] C. Papadopoulou, K. Soulti and I. G. Roussis (2005), *Antimicrobial Activity of Wine Phenolic Extracts*. Food Technol. Biotechnol. 43 (1) 41–46

[5] Mi Oha, Ji-Hye Leeb, Seon Young Baea, Jong Hyeon Seok, Sella Kim, Yeon Bin Chung, Kang Rok Han, Kyung Hyun Kim, Mi Sook Chung (2015), *Protective effects of red wine and resveratrol for foodborne virus surrogates*. Food Control, 47: 502-509

[6] *Fish and Fishery Products Hazards and Control Guidance,* (2011). U.S. Food and Drug Administration, 4: 420

[7] Waterhouse, A. L. (2002), Wine Phenolics. Annals of the New York Academy of Sciences, 957: 21–36.

with the ability to withstand a pH as low as 3.7. However, wine also has other anti-microbial properties that make the proliferation of *salmonella* impossible - such as its relatively high content of ethanol (alcohol).

Alcohol

Alcohol has been recognized as an anti-microbial since the 1800's[8] but historically it has been used for this purpose at high concentrations. However, in a study published in *Applied and Environmental Microbiology*, scientists have researched the effectiveness of alcohol at lower concentrations and have reported data supporting its efficacy as an antimicrobial at levels as low as 2.5% recognizing "[alcohol] may also be used for food preservation" [9, 10].

A second study focused on several different strains of food borne pathogens and found that *Salmonella typhimurium* was most sensitive to wine[11]. Scientists expressly stated that, "When different combinations of ethanol, organic acids, and acidity were tested against the pathogens, it was found that a composition of 0.15% malic acid, 0.6% tartaric acid, 15% ethanol, and pH 3.0 has a strong bactericidal effect". These conditions closely model those found in wine. They further stated that, "The compounds in the mixture seemed to act synergistically against the pathogens."

A third study focused on *Staphylococcus aureus* bacteria, often linked to food poisoning, and alcohol in concentrations of 6-15%[12]. It concluded that in the presence of alcohol, *Staphylococcus aureus'* DNA replication activity was downgraded as energy was channelled to the protection and restructuring of essential proteins. As a result, bacterial replication was inhibited.

Referencing studies like the ones discussed above, the FAO[13] has acknowledged that most organisms cannot survive in either alcoholic or acidic environments. However, the use of additional anti-microbial substances in winemaking is permitted and commonly practiced in most winemaking countries around the world, adding to wine another layer of protection from the growth of pathogens and providing a further assurance of safety to wine consumers.

Additional Factors In The Low Food Safety Risk Of Wine

Sulphur dioxide (SO_2) and sulphites are also known as the food additives INS 220-228. Although naturally produced in small amounts by wine yeast during alcoholic fermentation, most of the sulphites found in wine are added by the winemaker, for two main purposes. Firstly, they are anti-microbial agents, and as such are used to help curtail

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[8] Yosef Ali, Michael J. Dolan, Eleanor J. Fendler, and Elaine L. Larson (2001), *Alcohols. Disinfection, Sterilization, and Preservation*, 229-249.

[9] Indranil Chatterjee, Greg A. Somerville, Christine Heilmann, Hans-Georg Sahl, Hans H. Maurer, and Mathias Herrmann (2006). *Very Low Ethanol Concentrations Affect the Viability and Growth Recovery in Post-Stationary-Phase Staphylococcus aureus Populations*, Applied And Environmental Microbiology, 72: 2627–2636

[10] John S. Novak, Gerald M. Sapers, Vijay K. Juneja (2003). *Microbial Safety of Minimally Processed Foods*, 129

[11] T. Moretro and M.A. Daeschel (2006), *Wine is Bactericidal to Foodborne Pathogens*. Journal of Food Science, 69: M251-M257. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2621.2004.tb09938.x/pdf (2 September 2015)

[12] Jasmine M. Pando, Joanne M. Dupre, Jesus A. Cuaron, John Rivera, Shelly L. Lusetti, Vijayaraj Nagarajan, Song Yang, Atul K. Singh, Mohamed O. Elasri, Ivy W. Yu, Brian J. Wilkinson, and John E. Gustafson (2001). *The Ethanol Induced Bacteriostatic Response of Staphylococcus aureus,* Science against microbial pathogens: communicating current research and technological advances. http://www.formatex.info/microbiology3/abstracts/pdf/28.pdf (30 August 2015)

[13] Mike Battcock, Dr. Sue Azam-Ali (1998). *Fermented Fruits and Vestables. A Global Perspective,* (1998). Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/x0560e/x0560e00.htm#con (27 August 2015)

the growth of undesirable yeasts and bacteria. Secondly, they act as antioxidants, safeguarding the wine's fruit integrity and protecting it against browning[14].

In a 2007 study published in the Journal of Food Science, sulphites in wine were recognized as one of the contributors to the inactivation of food borne pathogens in the product[15].

Potassium sorbate (INS 202) is another substance used in some wines to prevent spoilage by non-pathogenic yeasts and moulds. It is commonly used in sweeter wines. While it will not stop a fermentation which is already in progress, it will stop fermentation from restarting in wine containing residual sugar.

Resulting Regulatory Framework

In light of the overwhelming evidence supporting the categorization of wine as a low risk product, several countries have formally recognized this in their food safety regulations, and scientific bodies, food safety evaluation organizations and reputable food production standards have also acknowledged it (see Table 2. *Reference Guidance Concerning Low Risk Foods*).

In Annex 3, Chapter 1 of the latest edition of its Food Code (2013), and in Table B 1-201.10(B) the US Food and Drug Administration recognizes foods with a pH below 4.2 (that have not been heat treated or have been heat treated but not packaged) as being "non-TCS Foods" (Time Temperature Control for Safety Foods), in terms of the control of both vegetative organisms and spores.[16] Such foods do not require further Product Assessment (PA) to investigate the possibility of the growth or toxin formation of pathogenic microorganisms in the food. These are therefore foods that do not need treatment at a certain temperature for a certain time to control the growth of vegetative pathogenic micro-organisms and their spores, where applicable. Since wine has a pH of 3.1-3.9, is packaged, is stable across a large temperature range and over long time periods, is commonly preserved with sulphur dioxide and sometimes with potassium sorbate, and scientific studies have confirmed that it does not support pathogen growth, it would be regarded as a non-TCS Food under the Food Code. While "non-TCS foods" are not automatically "low risk foods", this approach still confirms that wine will not support the growth of vegetative pathogenic micro-organisms and spores of pathogenic micro-organisms.

The European Food Safety Authority (EFSA) published a scientific opinion[17] in which it presented a decision tree proposing a categorization of risk based on food composition and its impact on pathogens (*Figure 2*). Following the decision points in this tree, it seems EFSA would concur that wine should be considered a low risk product.

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[14] Gawel, Richard. *The Use of Sulfur Dioxide (SO_2) in Wine*. http://www.aromadictionary.com/articles/sulfurdioxide_article.html (2 September 2015)

[15] Waite JG, Daeschel MA (2007), Contribution of wine components to inactivation of food-borne pathogens. Journal of Food Science, 72(7):M286-291

[16] Food Code 2013. Recommendations of the United States Public Health Service. Food and Drug Administration. Page 339. http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

[17] *Scientific Opinion on the development of a risk ranking framework on biological hazards* (2012). European Food Safety Authority, http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2724.pdf (26 August 2015)

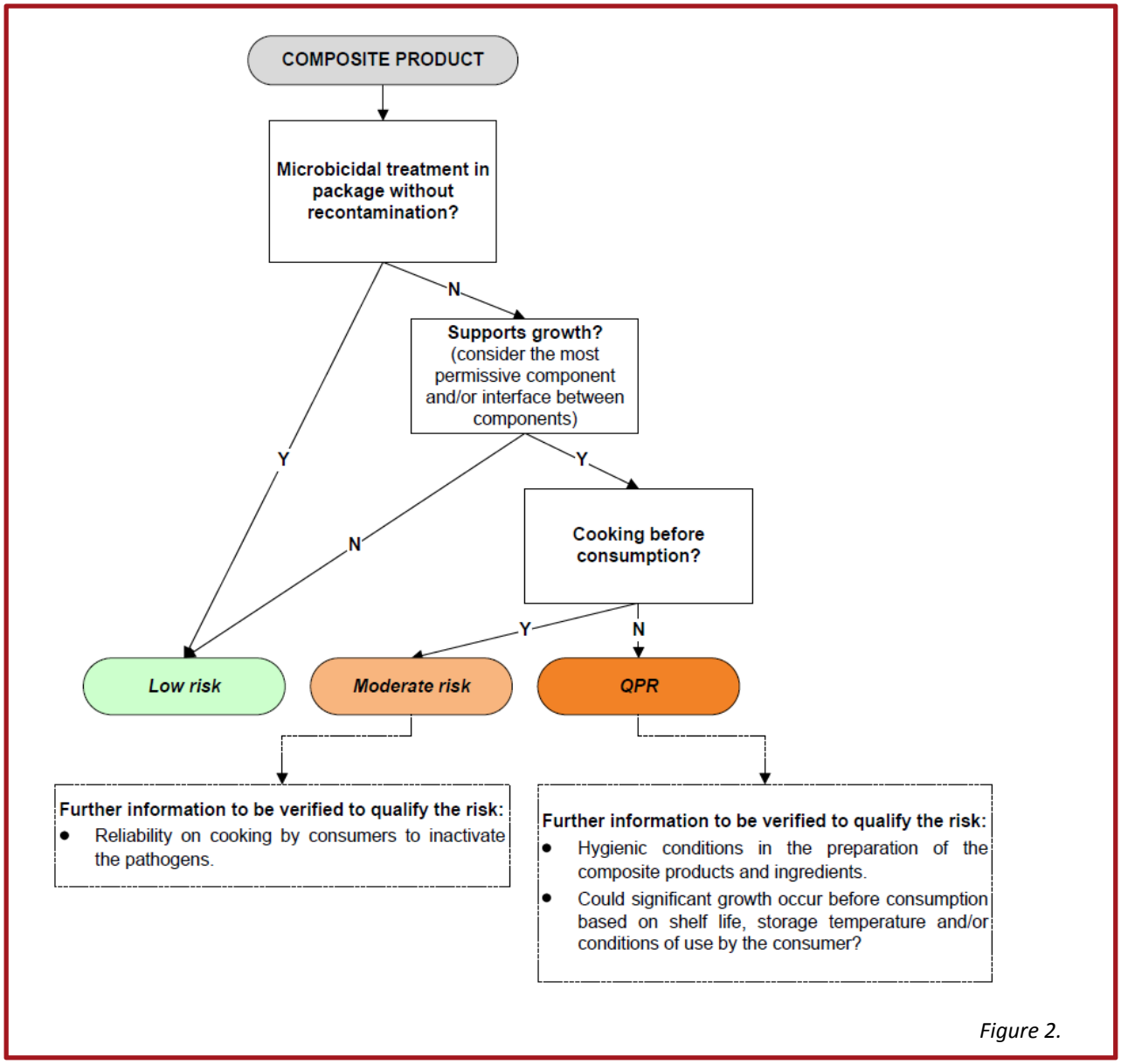

Figure 2.

The Republic of the Philippines Food and Drug Administration has gone one step further. In a 2014 circular regarding procedures for electronic registration, they acknowledged wine's low-risk food categorization with the creation of a simplified registration process[18].

[18] *FDA Circular No. 2014-029 Procedure for the Use of Electronic Registration (E-Registration) System for Raw Materials or Ingredients and Low Risk Pre-Packaged Processed Food Products*, Republic of the Philippines Food and Drug Administration, http://www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/209495-fda-circular-no-2014-029 (3 September 2015)

SUMMARY

Wine is a complex product containing several components with antimicrobial properties. Its high polyphenol content, high acid content (pH 3.1 to 3.9), relatively high alcohol content (7% to 15%), and sulphite content (10 to 350 ppm[19]) work synergistically to prevent the growth of food-borne pathogens and spoilage microorganisms. Research studies such as those cited in this paper have been widely accepted and have resulted in regulatory frameworks around the world recognizing that the "low risk food" category is most appropriate for wine.

[19] Regulation Comparison, Wine Composition- Sulphur dioxide. FIVS-Abridge https://fivs-abridge.com/fa/member/regulationCompareMarkets.htm?grouping=default&beverage=beverage.wine&topic=topic.composition&subtopic=336&allMarkets=true (3 September 2015)

TABLE 1. LIMITING CONDITIONS FOR PATHOGEN GROWTH

PATHOGEN	MIN. A_w (USING SALT)	MIN. pH	MAX. pH	MAX. % WATER PHASE SALT	MIN. TEMP.	MAX. TEMP.	OXYGEN REQUIREMENT
BACILLUS CEREUS	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
CAMPYLOBACTER JEJUNI	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
CLOSTRIDIUM BOTULINUM, TYPE A, AND PROTEOLYTIC TYPES B AND F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
CLOSTRIDIUM BOTULINUM, TYPE E, AND NON-PROTEOLYTIC TYPES B AND F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
CLOSTRIDIUM PERFRINGENS	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
PATHOGENIC STRAINS OF ESCHERICHIA COLI	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
LISTERIA MONOCYTOGENES	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
SALMONELLA SPP.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
SHIGELLA SPP.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS GROWTH	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]
STAPHYLOCOCCUS AUREUS TOXIN FORMATION	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
VIBRIO CHOLERAE	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
VIBRIO PARAHAEMOLYTICUS	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
VIBRIO VULNIFICUS	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
YERSINIA ENTEROCOLITICA	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

1. Has significantly delayed growth (>24 hours) at 131°F (55°C).
2. Requires limited levels of oxygen.
3. Requires the absence of oxygen.
4. Grows either with or without oxygen.

TABLE 2. REFERENCE GUIDANCE CONCERNING LOW RISK AND NON-TCS FOODS (NON-EXHAUSTIVE)

COUNTRY/SCIENTIFIC REFERENCE BODY	LEGISLATION/GUIDANCE
Australia New Zealand Food Authority	*Standard 3.2.2 Food Safety Practices and General Requirements* https://www.foodstandards.gov.au/publications/documents/3_2_2.pdf
Government of South Australia: Food Policy and Programs Branch	*South Australian Food Business Risk Classification* http://www.sahealth.sa.gov.au/wps/wcm/connect/c30973804209353ab856bdf8b1e08c6d/131213+Food+Business+Risk+Classification+Final.pdf?MOD=AJPERES&CACHEID=c30973804209353ab856bdf8b1e08c6d
State Government Victoria: Department of Health	*Making Food Safety Your Business Information for Class 4 Food Businesses* http://www.health.vic.gov.au/foodsafety/downloads/class4.pdf
Wine Australia	*The Realm of the State Health Department* http://www.awri.com.au/wp-content/uploads/2013/09/light-w36-awitc15.pdf
British Retail Consortium	*Understanding High Risk and High Care BRC Global Standard for Food Safety Issue 6* http://brcglobalstandards.com/Portals/0/Books/Understanding_high_risk/highrisk.html#/4/zoomed
Canadian Food inspection Agency	*Guide to Food Safety* http://www.inspection.gc.ca/food/non-federally-registered/safe-food-production/guide/eng/1352824546303/1352824822033
European Food Safety Authority	*Scientific Opinion on the development of a risk ranking framework on biological hazards* http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2724.pdf
Republic of the Philippines Food and Drug Administration	*FDA Circular No. 2014-029 Procedure for the Use of Electronic Registration (E-Registration) System for Raw Materials or Ingredients and Low Risk Pre-Packaged Processed Food Products* http://www.fda.gov.ph/issuances-2/food-laws-and-regulations-pertaining-to-all-regulated-food-products-and-supplements/food-fda-circular/209495-fda-circular-no-2014-029
U.S. Food and Drug Administration.	Food Code 2013. Recommendations of the United States Public Health Service. Food and Drug Administration. Page 339. Table B. http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf