Food Safety Information Papers
CORN REFINERS ASSOCIATION, INC.

MICROBIAL ASSESSMENT

QUESTION*: What processes and procedures are in place to minimize the risk that food ingredients from the corn wet milling industry will contain pathogenic microorganisms that might pose a significant health risk in food products?*

Executive Summary

The Corn Refiners Association, Inc. (CRA) member companies manufacture a variety of dry and liquid food ingredients. Good Manufacturing Practices (GMP), the Hazard Analysis and Critical Control Point (HACCP) system of food safety management, and quality management systems in CRA member company plants ensure wholesome and safe food products. With regard to the potential for contamination by microorganisms:

- The corn wet milling and subsequent production processes are enclosed systems. These enclosed systems preclude handling and help prevent microbial contamination.

- The corn wet milling process (high temperature) and intrinsic properties of the resulting liquid and dry products [low pH, low water activity (a_w)] create an inhospitable environment for microorganisms.

- Experimental data demonstrate that liquid and dry corn syrups, sweeteners, starches, and acidulants are not only inhibitory to the growth of bacteria (bacteriostatic), but also have the ability to kill undesirable microorganisms (bactericidal), should any be present, during processing, transportation and storage.

- CRA member companies have established qualitative and quantitative analytical procedures for detecting microorganisms in finished products. However, because the distribution of microorganisms may be heterogeneous in nature, no sampling plan can ensure the absolute absence of pathogenic microorganisms. Therefore, product testing is only a component of a larger food safety program, including GMPs, HACCP, and other quality management systems, to minimize the risk of microorganisms contaminating corn wet-milled products.

In total, the corn wet-milling process, intrinsic nature of the products, and quality management systems implemented at CRA member company plants, indicate that it is very unlikely that corn wet-milled products will contain pathogenic microorganisms that might pose a significant health risk. Importantly, there has not been a documented illness outbreak involving pathogenic microorganisms in corn wet-milled liquid and dry products.

1. Introduction

According to the Centers for Disease Control (CDC), foodborne pathogens cause an estimated 9.4 million illnesses in the U.S. per year.[1] Many foodborne pathogens can be found in the feces of animals, as well as in water, soil, or any material exposed to animal feces. Thus, it is reasonable to assume that crops growing in the field can be exposed to pathogens in this manner. Another possible route of exposure is that as food is processed, undesirable organisms can be introduced by poor manufacturing or sanitation practices (including poor employee hygiene). It is important to note, however, that corn, with its protective husk, is well protected from microbial contamination in the field. In addition, enclosed systems and prerequisite plans in corn wet milling, e.g., Good Manufacturing Practices (GMPs), and supporting Hazard Analysis and Critical Control Point (HACCP) systems, are recognized as very effective means of reducing the risk of microbial contamination during processing. Finally, the inherent nature of the corn wet milling process and resulting ingredients further reduces the risk of microbial contamination, as described further below.

It is not surprising, therefore, that a thorough review of government websites, scientific literature, and government/regulatory reports did not identify a single documented foodborne illness outbreak involving pathogenic microorganisms in corn wet-milled products.[2] Specifically, websites hosted by CDC and the U.S. Food and Drug Administration (FDA) were searched for any information pertaining to liquid or dry corn wet-milled products. Particular attention was focused on CDC's Foodborne Outbreak Online Database (FOOD), as well as FDA's Coordinated Outbreak Response and Evaluation (CORE), and recall, market withdrawal, and safety alert system. Relatively little information was found from any of these sources that related specifically to the corn wet-milled products, and none of the information indicated that any of these products were responsible for foodborne outbreaks or product recalls. Thus, there is an absence of historical evidence associating these products with concerns of pathogenic microorganisms and foodborne illness.

2. Conditions Affecting the Survival or Growth of Microorganisms

In any given environment, a particular microorganism may grow, be killed, or simply survive. Control measures that kill bacteria are known as bacteriocidal, whereas controls that do not kill the bacteria but inhibit growth are known as bacteriostatic. When considering whether a microorganism will survive or grow in any particular environment, three aspects need to be evaluated:

- Environmental or extrinsic factors
- Intrinsic factors
- Characteristics of particular microorganisms of interest

Each of these is discussed below.

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[1] Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauze, R.V., Widdowson, M-A., Roy, S.L., Jone, J.L., Griffin, P.M. 2011. Foodborne illness acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17(1):7-15. January.

[2] ToxStrategies, Inc. 2013. Corn Refiners Association, Inc. (CRA), Task 1: Data gathering and evaluation of information. Prepared on behalf of the Corn Refiners Association, Inc. March.

Environmental or Extrinsic Factors

The two most important environmental factors influencing microbial survival and growth are temperature and level of oxygen.

Like larger animals, microorganisms have a discrete **temperature** range in which they flourish, and can be classified by the optimum temperatures at which they grow. Most human and animal pathogens belong to the group mesophiles ("middle loving"); their optimum growth range is 20-45°C.[3] Examples of pathogens in this group are *Escherichia coli (E. coli)*, *Salmonella*, *Clostridium botulinum* and *Staphylococcus aureus*. Thermophiles ("hot loving") are microorganisms that grow optimally at high temperatures, 40-70°C, whereas bacteria with cold optimal growth temperatures (0-10°C) that do not grow well at mesophilic temperatures are known as psychophiles. A fourth category is bacteria that grow slowly at temperatures less than 15°C, but prefer growing at warmer temperatures, which are known as psychotrophs.[4] Minimum, optimum and maximum temperature ranges for these groups of microorganisms are summarized in Table 1.

Table 1: Cardinal temperatures for microbial growth[5]

	Temperature (°C)		
Group	**Minimum**	**Optimum**	**Maximum**
Thermophiles	40-45	55-75	60-90
Mesophiles	5-15	30-40	35-47
Psychrophiles (obligate psychrophiles)	-5 to +5	12-15	15-20
Psychrotrophs (facultative psychrophiles)	-5 to +5	25-30	30-35

Microorganisms can also be classified by their **oxygen** requirement for growth. Microorganisms that require oxygen are strict aerobes; without oxygen these organisms may survive, but not grow. Vacuum packaging of foods or hermetically sealing containers, e.g., metal cans, will prevent their growth. Some bacteria and most molds are strict aerobes. Facultative anaerobes comprise the largest group of food-related microorganisms; they are capable of growing whether or not oxygen is present. S*almonella* and *E. coli* are facultative anaerobes. Strict anaerobes cannot grow in the presence of oxygen. These organisms grow in the absence of oxygen, e.g., in well-sealed containers or cans. *Clostridium botulinum*, the microorganism responsible for botulism, is one example of a strict anaerobe.

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[3] US Food and Drug Administration (FDA). 2012. *Bad Bug Book*, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Second Edition.* Washington, DC. http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm2006773.htm.

[4] Ibid.

[5] International Commission on Microbiological Specifications for Foods (ICMSF). 1980. Microbial Ecology of Foods, Volume 1, Factors Affecting Life and Death of Microorganisms. New York: Academic Press.

Intrinsic Factors

The inherent properties of a food product that influence its susceptibility or resistance to microbial growth and survivability are termed "intrinsic factors." The most important of these intrinsic factors are water activity, osmotic pressure, and pH.

Water activity (a_w) is a measure of the state or condition of water in foods (e.g., availability for microbial growth). Water activity values theoretically range from 1.0 (pure water) to 0 (absolutely no water available). The water activity of a food product depends upon the amount and nature of solutes present. Controlling water activity is one of the oldest and most effective methods for preventing the growth of microorganisms in foods. This is usually accomplished by drying foods (getting rid of water) or by adding solutes such as sugars or salts (to bind the water so it is not available for the microorganism).[6,7]

Osmotic pressure is a measure of the force that must be exerted to prevent water from flowing from one side of a membrane to the other. Solutions with a high osmotic pressure have a strong tendency to adsorb water. If a microbe is placed in a solution with a high osmotic pressure, water will flow out of the microbial cell and into the solution, an effect known as plasmolysis. Conversely, if a microbe is placed in a solution with low osmotic pressure, water will flow into the microbial cell. Cytolysis occurs when sufficient water flows into a cell such that the cell bursts. In either case, microbial cells may die as a result of the osmotic pressure of the environment.

pH is the measure of acidity or alkalinity of a food product. All microorganisms have a specific pH range over which they grow and survive. Bacteria tend to prefer a neutral environment, typically pH 5-7. Yeasts and molds prefer an acidic environment, typically pH 2-5. The growth of microorganisms is influenced by both the initial pH and the buffering capacity of the food.

In combination, these intrinsic factors can prevent or significantly limit a microorganism's ability to survive or grow in a particular food product; however, these factors would not necessarily be relied upon as the sole basis for ensuring product safety.

Characteristics of Particular Microorganisms of Interest

There are four groups of microorganisms that are of concern for food safety: bacteria, molds, viruses, and protozoans. Molds are a concern only because they may produce mycotoxins.[8] In contrast to bacteria and molds, viruses and protozoa cannot grow in foods. Control of viruses and protozoa in foods relies on exclusion and inactivation.

Some Gram-positive bacteria, such as *Bacillus* and *Clostridium* species, are capable of producing spores, a very stable, dormant stage of the bacteria. These are not known to be an issue with corn wet-milled products.

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6 Ibid.

7 Troller, J.A. 1983. Effect of Low Moisture Environments on the Microbial Stability of Food. In: Economic Microbiology Volume 8, Food Microbiology. Rose, A.H., ed. New York: Academic Press.

8 Corn Refiners Association (CRA). 2011. Food Safety Information Paper, Micotoxins. Prepared by WHITE *Technical Research* GROUP. March. http://www.corn.org/wp-content/uploads/2009/12/mycotoxins.pdf.

Table 2 lists the temperature, pH and water activity ranges that can promote the growth of common pathogenic microorganisms, provided the required nutrients are also present.

Table 2: Ranges of conditions favoring pathogen growth[9].

Pathogen	Temperature (°C)	pH	Water Activity
Bacillus cereus	4 – 55	5.0 – 8.8	≥0.93
Clostridium perfringens	12 – 50	5.5 – 9.0	0.93 – 0.97
Escherichia coli	7 – 46	4.4 – 9.0	≥0.95
Listeria monocytogenes	-0.4 – 45	4.4 – 9.4	≥0.92
Salmonella	5.2 – 46[a]	3.8 – 9.5	0.94 – >0.99
Staphylococcus aureus	10 – 48[b] (7 – 48)[c]	4.5 – 9.6[b] (4 – 10)[c]	0.87 – >0.99[b,d] (0.83 – >0.99)[c,e]

[a]Most serotypes fail to grow at < 7°C
[b]Toxin production
[c]Growth
[d]Aerobic (anaerobic 0.90 – >0.99)
[e]Aerobic (anaerobic 0.92 – >0.99)

As a general rule, pathogenic microorganisms grow most favorably at temperatures below 50°C, within a pH range of 4.5 – 9.5 and at water activity values above 0.86. However, *Salmonella* is an exception to this rule because *Salmonella spp.* have been shown to survive in low-moisture foods and environments [e.g., low-moisture (a_w = 0.176), high-fat (31.8%) confectionary[10], peanut butter with an a_w that did not exceed 0.33[11]]. Importantly, these foods have relatively neutral pH values, in contrast to the lower pH values of most of the corn wet-milled products discussed in the next section.

3. Properties of Corn Wet-Milled Products That Prevent or Inhibit Growth and Survival of Microorganisms

Liquid Products

Liquid corn syrups and sweeteners typically have water activity, osmotic pressure, and pH values that do not permit microorganisms to survive or grow. For liquids, water activity and osmotic pressure are interrelated: solutions with low water activity have high osmotic pressures. Any microbe in syrups experiences a water activity that is too low to support growth and an environment that actually pulls water out of the cell, resulting in death. In fact, the use of high concentrations of solutes, such as sucrose, fructose, and corn syrup, is one of the oldest known food preservation methods.[12]

Table 3 details typical water activity and pH of several liquid corn wet milling products. When compared to the optimal water activity and pH needs of common pathogens (Table 2), one can see that corn syrups and sweeteners are an inhospitable environment for growth or survival of pathogenic microorganisms.

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[9] International Commission on Microbiological Specifications for Foods (ICMSF). 1996. Microorganisms in Foods 5. Characteristics of Microbial Pathogens. London; Blackie Academic & Professional.

[10] Kotzekidou, P. 1998. Microbial stability and fate of *Salmonella* Enteriditis in halva, a low-moisture confection. J. Food Protect. 61:181-185.

[11] Burnett, S. L., E. R. Gehm, W. R. Weissinger, and L. R. Beuchat. 2000. Survival of *Salmonella* in peanut butter and peanut butter spread. J. Appl. Microbiol. 89:472-477.

[12] Gomez, R. and A. Herrero. 1983. Chemical Preservation of Foods (Chapter 3). In: Economic Microbiology, Vol. 8, Food Microbiology, Rose, A.H. ed. London: Academic Press.

Table 3: Syrup processing and product properties deterring pathogen growth and survival.[13]

Product	Processing Temperature (°C)[14]	% solids	pH	Water Activity
42% HFCS	>60	71	3.9	0.76
55% HFCS	↓	77	4.4	0.66
25 DE Corn Syrup		78	3.7	0.74
36 DE Corn Syrup		80	5.0	0.70
63 DE Corn Syrup		81	5.2	0.59
65% High Maltose Syrup		81	5.0	0.69

Niroomand and co-workers[15,16] inoculated corn and sucrose ingredients with a broad spectrum of bacterial pathogens and followed viability over time. The researchers attempted to inoculate so as to deliver approximately 10^4 to 10^5 cells of each microorganism per gram of product. **This inoculation level was intended to represent a worst-case scenario of intentional contamination or improper handling.** Pathogens tested included *Salmonella*, *Listeria monocytogenes*, *Staphylococcus*, and *E. coli*. Their data supported the following conclusions:

- The number of microorganisms fell below the detection limit in less than three days when syrups and sweeteners were stored at normal holding temperatures (32-46°C).
- When products were stored at the lower temperature limit reached during transportation (27°C), a reduction in the number of microorganisms was still observed, but occurred at a slower rate.
- The fastest rates of reduction were observed in 42 and 55% HFCS.

As noted above, the experiments of Niroomand *et al.* were conducted to mimic a worst-case scenario (high inoculum). Their results suggest that **incidental contamination** of corn syrups and sweeteners with undesirable microorganisms does not present a public health hazard. The authors attribute this finding to final product pH, water activity and osmotic pressure and even suggest that "because the liquid sweeteners cause the destruction of vegetative pathogens, these ingredients can be considered to be free of microbiological hazards." **Thus, when considering the hazard potential of environmental pathogens in liquid corn syrup and sweeteners, the likelihood of occurrence is extremely low**.

Dry Products

CRA member companies make a variety of dry products for the food industry, including acidulants, corn syrup solids, dextrose and starches. Table 4 provides typical pH and water activity for these products. As shown, corn wet-milled dry products are also characterized by

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[13] Niroomand, F., W.H. Sperber, V.J. Lewandowski and L.J. Hobbs. 1998. Fate of bacterial pathogens and indicator organisms in liquid sweeteners. *J. Food Protection*. 61(3): 295-299.

[14] At a minimum, processing temperatures will reach >60˚C; however, depending on the specific product or step in the process, temperatures above 60˚C will vary considerably.

[15] Niroomand, F., W.H. Sperber, V.J. Lewandowski and L.J. Hobbs. 1998. Fate of bacterial pathogens and indicator organisms in liquid sweeteners. *J. Food Protection*. 61(3): 295-299.

[16] Lewandowski, V.J. 1998. Fate of microorganisms in corn milling products. *Bev Tech 98*, Savannah GA, March 30 – April 1.

extremely low water activity—even lower than corn wet-milled liquid products (see Table 3). This exceedingly low water activity, in combination with processing temperatures above 60°C, low product moisture and acidic final product pH values, indicates that corn wet-milled dry products are an inhospitable environment for pathogenic microorganisms.

Table 4: Dry product processing and properties deterring pathogen growth and survival.[17]

Product	Processing Temperature (°C)[18]	pH	Water Activity
Citric Acid	>60	1.8	0.15
Sodium/Potassium Citrate	↓	8.5-8.8	0.12-0.13
Corn Syrup Solids		4.4-5.5	0.14-0.17
Dextrose		4.3	0.12
Food Starches		4.6-8.7	0.28-0.46

Niroomand, Sperber, Lewandowski and Hobbs extended their work with liquid sweeteners to study the fate over time of microbial pathogens inoculated into dry sweeteners, starches and citrates.[19,20] In this case, the researchers targeted inoculating the samples to approximately 10^5 to 10^6 cells of each microorganism per gram of product, **which again was intended to represent a worst-case scenario of intentional contamination or improper handling**. Not surprisingly, they observed that dry products also exhibit bacteriostatic and bacteriocidal properties against *Staphylococcus*, *Salmonella* and *E. coli*. For citric acid, the number of organisms fell below the detection limit within minutes, which the authors attributed to the low pH. For the remaining dry products, the rate of decline was slower than for citric acid and the liquid products, with some organisms completely dying off by the end of the observation period (12 months) in some products, while other organisms declined substantially, but did not die off completely, in other products. Although the authors concluded that there is need for controls to prevent post-process bacterial contamination of corn wet-milled dry products such as citrates, starches, and dry sweeteners, it is important to note that this study utilized a very high inoculum level (10^5 to10^6 cells per gram) as compared to what might be more typical for these products (1 to 10 cells per gram). **Thus, to assess the hazard potential of environmental pathogens in citrates, starches and dry sweeteners, the likelihood of occurrence is very low.**

4. Pathogen Management by the Corn Wet Milling Industry

GMP, HACCP and Quality Management Systems

CRA member companies have each implemented their own quality management systems to ensure the safety of their products. These voluntary, self-regulatory systems are each comprehensive in scope, encompassing a number of critically important programs including design and process control, GMPs, sanitation, pest control and personal hygiene. These programs are often coupled with the implementation of a HACCP program. Through the use of hazard analysis, significant food safety hazards are identified and critical control points in the

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17 Cargill, Inc. 1999. Fate of Microorganisms in Dry-Wet Corn Milling Products. Unpublished data. September 28.

18 At a minimum, processing temperatures will reach >60˚C; however, depending on the specific product or step in the process, temperatures above 60˚C will vary considerably.

19 Cargill, Inc. 1999. Fate of Microorganisms in Dry-Wet Corn Milling Products. Unpublished data. September 28.

20 Lewandowski, V.J. 1998. Fate of microorganisms in corn milling products. *Bev Tech 98*, Savannah GA, March 30 – April 1.

manufacturing process are established as necessary. These points are then controlled and routinely monitored to minimize or eliminate all identified hazards. Other process control points, although not considered "critical" under HACCP, are also routinely monitored to ensure product safety. These programs, in combination with the inherent properties of the products themselves (low water activity and low pH), minimize the risk of pathogen contamination in corn wet-milled products.

Product Sampling and Testing

CRA member companies have established qualitative and quantitative analytical procedures for detecting microorganisms in their finished products. This sampling and testing is conducted as a verification of the effectiveness of the process controls. Pathogen testing of the liquid products is less frequently conducted because the inherent properties of the products make pathogen survival virtually impossible. The 2007 Edition of *CRA Microbiological Methods of the Member Companies* contains the following microbiological methods:[21]

- Mesophilic Aerobic Bacteria
- Mesophilic Yeasts and Mold
- Osmophilic Yeasts, Mold and Bacteria
- Coliform Group of Bacteria
- *Salmonella* species
- Thermophilic Spore-forming Bacteria
- Coagulase Positive *Staphylococci*
- Anaerobic Bacteria
- *Pseudomonas* species
- *Bacillus cereus* count
- Mesophilic Aerobic Spore-formers
- Rapid Microbiological Methods.

Product specifications, process controls, and quality assurance programs form the basis to control microbial pathogens in corn wet-milled products.

[21] Corn Refiners Association, Inc, *CRA Microbiological Methods of the Member Companies,* 2007 Edition. http://www.corn.org/publications/industry-resources/microbiological-methods/microbiological-methods-toc/.

5. Conclusions

The presence of foodborne pathogens is a matter of significant public health concern. There are no governmental guidelines or specifications for microorganisms specific to corn wet-milled products; therefore, the corn refining industry has taken a leadership role in conducting research, establishing testing protocols, specifications, GMPs, HACCP, and other Quality Management Systems on a voluntary, self-regulatory basis to help control microbial pathogens in corn wet-milled products. These measures, in addition to the intrinsic nature of the products, indicate that it is very unlikely that corn wet-milled products will contain pathogenic microorganisms that might pose a significant health risk. The member companies of the CRA are justifiably proud of the fact that no corn wet-milled product has ever been implicated in an outbreak of illness involving foodborne pathogens. They will continue to work diligently to maintain that record.