LAND O'LAKES, INC.

Microbiological Validation and Verification of Hygienic Design

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Agenda

1	LOL Overview
2	Food Microbiology Basics
3	Microbiological Validation and Verification of Hygienic Design
4	Impact of Current Food Trends on Hygienic Design

LAND O'LAKES HAS A 96-YEAR HISTORY

- Farmer-owned cooperative
- Unique farm-to-fork view
- Powerful, respected brands
- Industry-leading operations

WE OPERATE FOUR DIVERSIFIED AGRIBUSINESSES, DRIVEN BY INSIGHTS & INNOVATION

WinField® United

Crop Inputs & Insights

Agricultural products, data, technology tools and services

Purina

Animal Nutrition

Solutions that enhance performance and well-being

LAND O LAKES®

Dairy Foods

Milk-based products and ingredients

Land O'Lakes SUSTAIN™

Environmental sustainability solutions

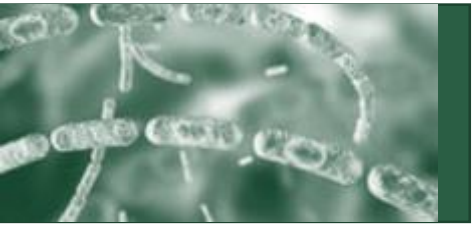
Hygienic Design

…a working definition:

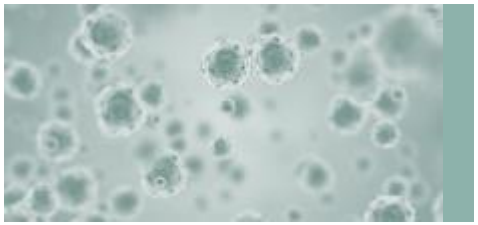
Hygienic design refers to the thoughtful design, construction, and installation of equipment so that it can be effectively and efficiently cleaned and sanitized.

Food Microbiology Basics

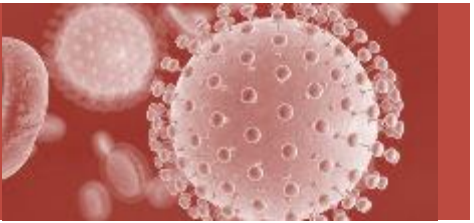
TYPES OF MICROORGANISMS



BACTERIA
SPORE FORMING

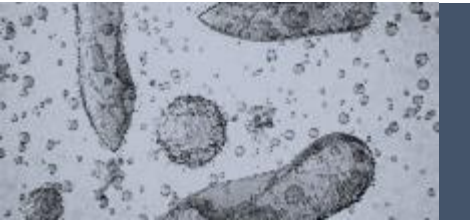


BACTERIA
NON SPORE FORMING

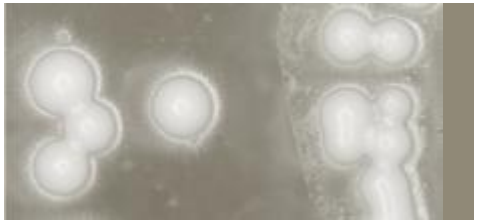


VIRUSES

PARASITES

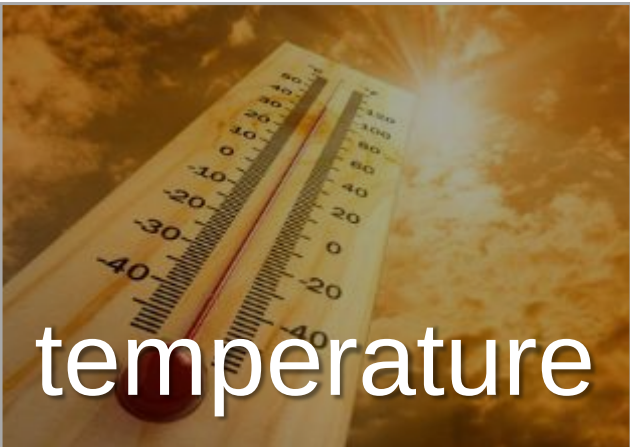


PROTOZOA



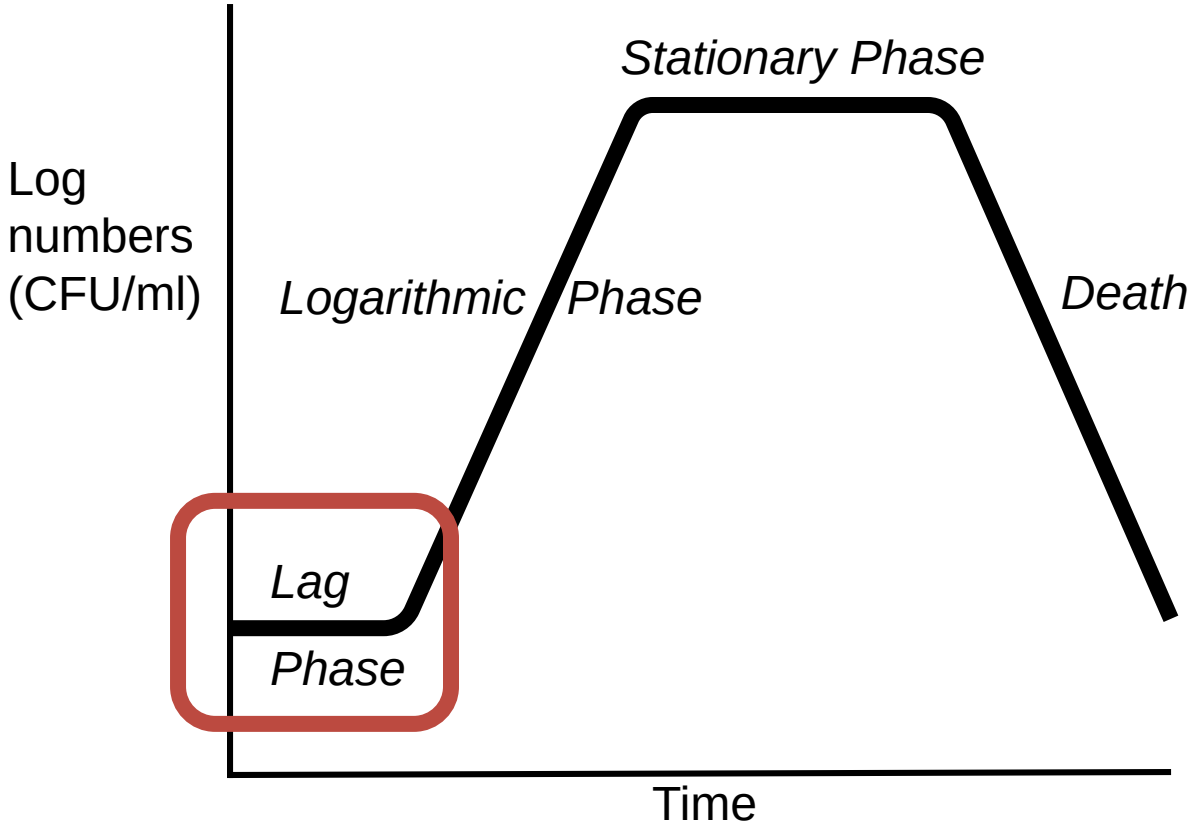
YEAST/MOLD

BACTERIA MUST HAVE SUITABLE CONDITIONS TO GROW

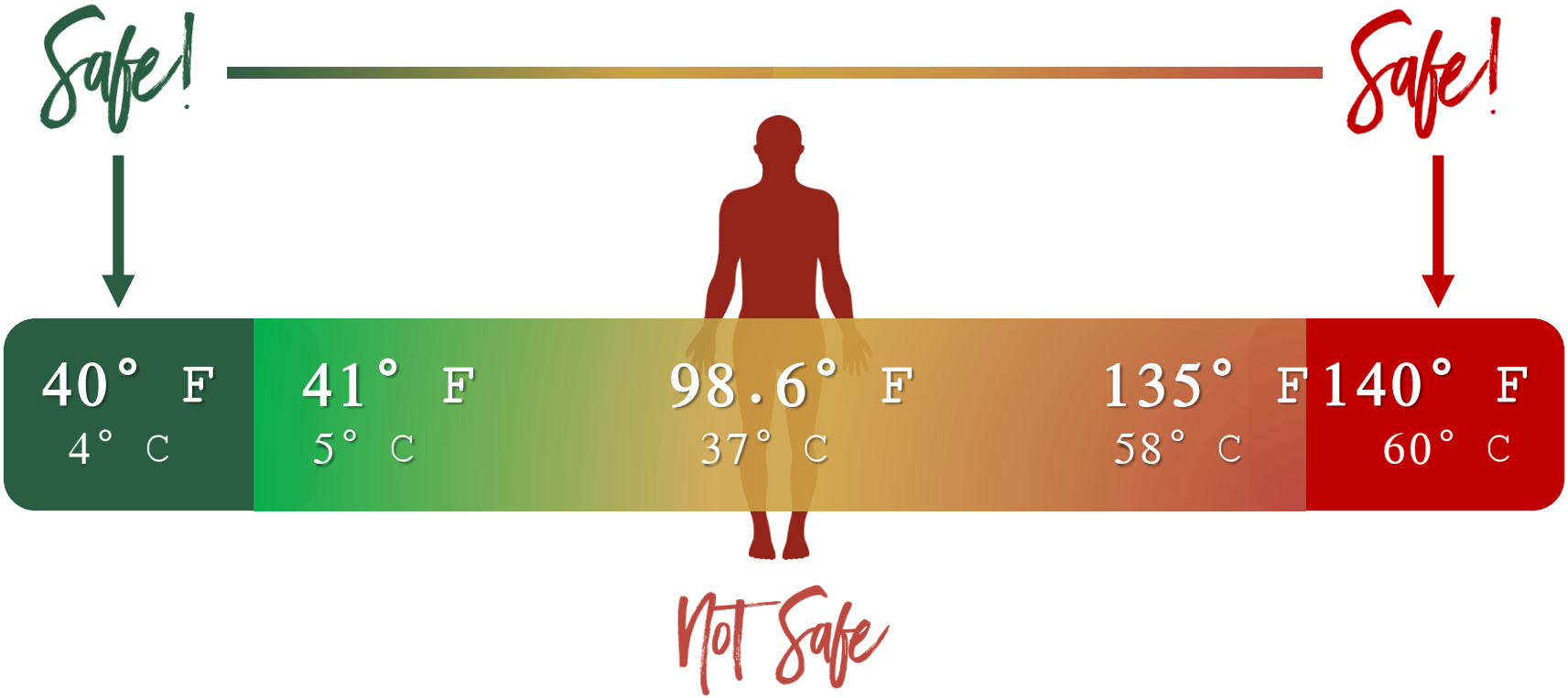


Controlling Bacterial Growth

NEED TO KEEP IN LAG PHASE

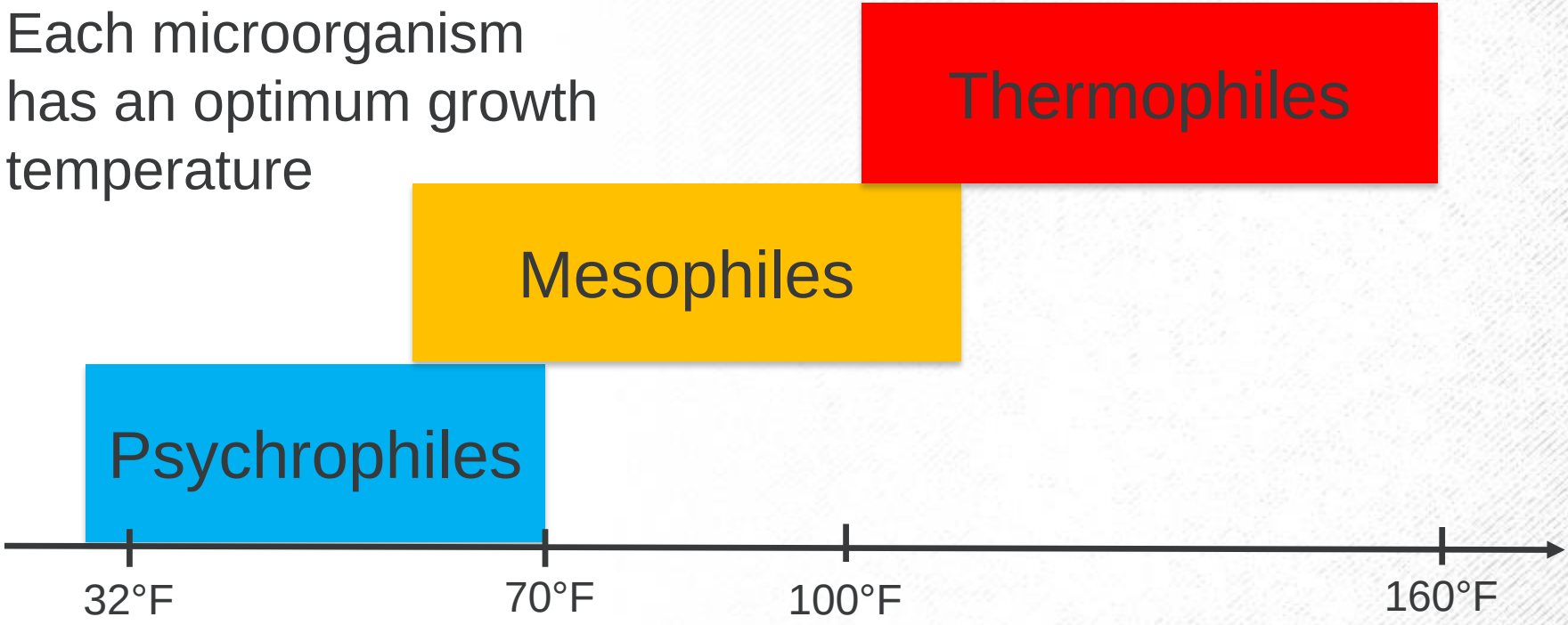


TEMPERATURE CONTROL FOR FOOD SAFETY



Approximate Temperature Ranges for Indicator Microorganisms in Food

Each microorganism has an optimum growth temperature



Microbiological testing commonly employed for verifying hygienic design

Indicator microorganisms are populations of bacteria, yeast, or molds that may be useful in identifying when conditions favorable for undesired outcomes (e.g. food spoilage and/or food safety concern) may be present.

Indicator Microorganisms

Psychrophiles

Microorganisms capable of growth at colder temps (including proper refrigeration temps)

Examples:

- *Listeria* spp.
- Psychrophilic Plate Count
- *Pseudomonas* spp.
- Psychrophilic Yeast
- *Alicyclobacillus* spp.

Locations:

- Cold sections of liquid processing
- Product contact surfaces on equipment in cold rooms

BECAUSE

Equipment had poor sanitary design

The plant was contaminated over a period of nearly two months; Over $20 mm in plant costs to remedy the issue.

57 sick including 23 dead in Maple Leaf Listeria outbreak

The company had cleaned its machines on a daily, weekly and monthly basis as recommended by the manufacturer.

August 2008

Indicator Microorganisms

Mesophiles

Microorganisms capable of growth at moderate temps (including room temp and body temp)

Examples:

- Total/Standard Plate Count
- Yeast & Mold
- Coliforms/Enterobacteriaceae
- Lactic Acid Bacteria (Heterofermentative)

Locations:

- Exposed product contact surface on equipment
- In-process and finished product samples

Indicator Microorganisms

Thermophiles

Microorganisms capable of growth at hotter temps (including temperatures too hot to touch)

Examples:

- Thermophilic Spores
- Thermoduric Count
- Heat Resistant Mold

Locations:

- Hot sections of liquid processing
- In-process and finished product samples

Thermophilic spores in milk powders

- Thermophilic spores are present in raw milk
- Thermophilic spores will survive pasteurization
- Thermophilic sporeformers will grow in hot sections of the liquid process (e.g. separators, evaporators, etc)

Maintaining hygienic design is critical for meeting thermophilic spore specifications in milk powders

Microbiological Validation and Verification of Hygienic Design

Microbiological testing to validate and verify hygienic design

Validation

Collection of data to confirm that the design, installation, and operation of processing equipment is capable of meeting a desired microbiological outcome

Verification

Review of data to confirm that the design, installation, and operation of processing equipment is performing as expected with regards to microbiological outcomes

When to conduct microbiological validation and verification

Validation

May be conducted:

1. When commissioning new equipment
2. When changes occur to the product and/or process

Verification

Typically is conducted:

1. On a routine time frame (e.g. weekly)

NOTE: Results from in-process and/or finished product testing may be used

Microbiological validation and the Food Safety Modernization Act (FSMA)

FDA has stated in the PCHF:

> "Validation is not required for all controls. For example, the rule specifies that validation is not required for certain types of preventive controls (i.e., food allergen controls, sanitation controls, supply-chain controls, and the recall plan)"

Sanitation programs are not just for food safety hazards. Making sure your sanitation program is capable to achieve your desired level of microbiological control is advised.

Microbiological validation of hygienic design

- What are you validating?
- What is the microbiological target?
- Design an experimental plan
- Execute the experimental plan
- Review the data
- Document the results

Microbiological validation of hygienic design

What are you validating?

- Are you validating a step within a system or the system as a whole?
- What are the controls and critical factors to measure?

What is the microbiological target?

- What are the microbiological routes of failure for the product?
- Are there controls in the process for some microbiological targets?
- What microbial target would be most indicative of control failure?
- What microbiological target(s) would be most resistant to the process?
  - Ex: *Bacillus subtilis* for H2O2 vs *Bacillus stearothermophilus* for steam
- Not microbiological – but don't forget allergens

Microbiological validation of hygienic design

Design an experimental plan

- A cross functional team should be formed to develop the plan
- How many trials will be included?
- Will artificially inoculated samples be used?
- Where will samples be collected?
- What are the success criteria?
- Who will be reviewing and approving the data?

Execute the experimental plan

- Make sure to capture all of the critical measures and information (e.g. processing parameters, concentrations, time, flow rates, temperatures, etc..)

Microbiological validation of hygienic design

Review the data

- Does your data meet all of your success criteria?
- Is your data consistent among trials?
- Where there any observations collected that need to be considered?

Document the results

- Document the validation in a report that is written in way so others (maybe years later) can easily understand what/how the experiments were conducted
- Clearly state the outcome including any limitations in the report
- Do you need an SME and/or Legal review?

Common hygienic design issues leading to microbiological failure

not all inclusive…

1. Leaky or faulty valves
2. Worn gaskets
3. Dead ends in piping
4. Poor quality of Utilities (e.g. compressed air)
5. Clogged or damaged spray balls
6. Unplanned moisture entry into the system
7. Unintended impacts of change

Common reasons for microbiological failure (process complexity)

Simple

Dedicated and linear processes are easiest to maintain over time although they put more constraints on processing options

1. Easier to predict impact of change on the system
2. Easier for non-engineers to understand
3. Less likely to fail

Complex

Desires to create flexibility in processing result in complex interconnections between equipment and processing steps

1. Harder to predict impact of change to the system
2. Harder for non-engineers to understand
3. More likely to fail

Microbiological data to validate less than daily cleaning and sanitation

Extending the operating time beyond 24 hrs requires a review of microbiological data from:

- ✓ Finished product data
- ✓ In-process data
- ✓ Environmental data

Does the current data support extending the time of operation, or are there already issues present?

Less than daily sanitation

The process is the same with a few exceptions

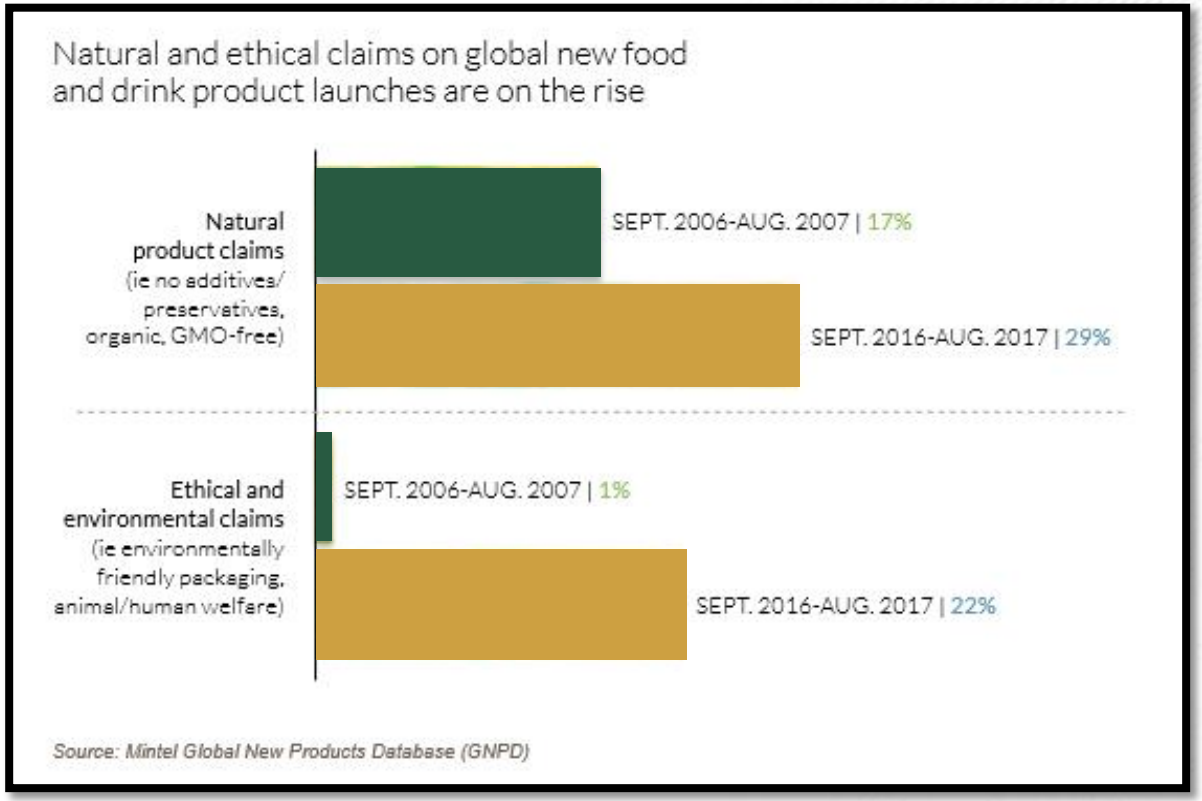
- In Grade A Milk and Milk Products – work with your State first to get regulatory approval
- In non-Grade A products – refer to State regulations

The PMO provides less than daily sanitation for certain equipment under certain conditions

- Up to 72 hrs on storage tanks with temperature recording charts
- Up to 44 hrs for evaporators
- Dryers and powder handling per manufacturers recommendations

Impact of current food trends on hygienic design

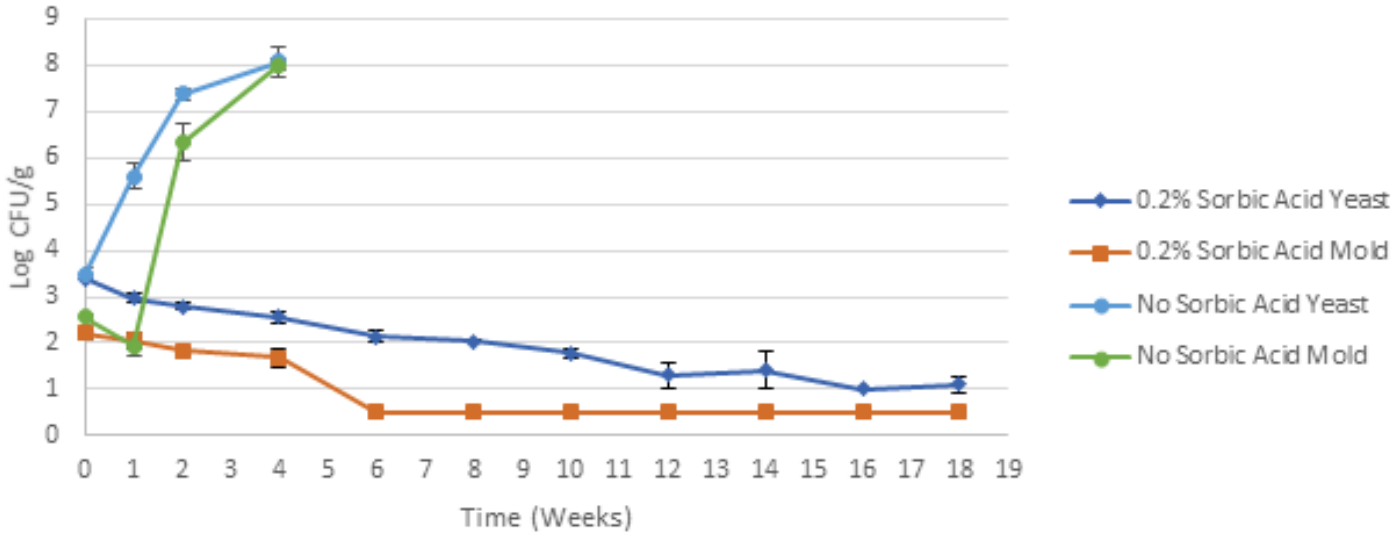
A few current food trends



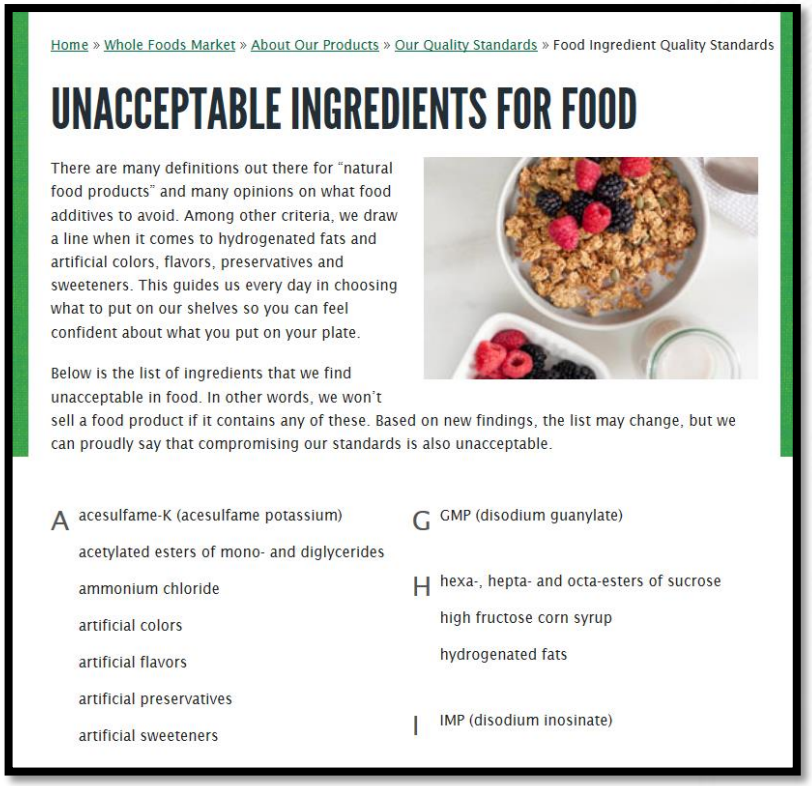
- "Clean" label
- Absence claims
- Animal raising claims
- Precautionary allergen labeling
- Specialty ingredients

Impact of current food trends on the demands of hygienic design

Growth of spiked yeast and mold in a dairy product formulated with and without 0.2% sorbic acid and held at 7°C



Impact of current food trends on the demands of hygienic design



Home » Whole Foods Market » About Our Products » Our Quality Standards » Food Ingredient Quality Standards

UNACCEPTABLE INGREDIENTS FOR FOOD

There are many definitions out there for "natural food products" and many opinions on what food additives to avoid. Among other criteria, we draw a line when it comes to hydrogenated fats and artificial colors, flavors, preservatives and sweeteners. This guides us every day in choosing what to put on our shelves so you can feel confident about what you put on your plate.

Below is the list of ingredients that we find unacceptable in food. In other words, we won't sell a food product if it contains any of these. Based on new findings, the list may change, but we can proudly say that compromising our standards is also unacceptable.

A
- acesulfame-K (acesulfame potassium)
- acetylated esters of mono- and diglycerides
- ammonium chloride
- artificial colors
- artificial flavors
- artificial preservatives
- artificial sweeteners

G
- GMP (disodium guanylate)

H
- hexa-, hepta- and octa-esters of sucrose
- high fructose corn syrup
- hydrogenated fats

I
- IMP (disodium inosinate)

Whole Foods and several other retailers have developed lists of unacceptable ingredients for foods

If you remove formulation barriers for microbiological growth, then the impact of poor hygienic design on product quality, expected shelf life, and production efficiency increases dramatically


Thank you!
LAND O'LAKES, INC.