



H2O Express™

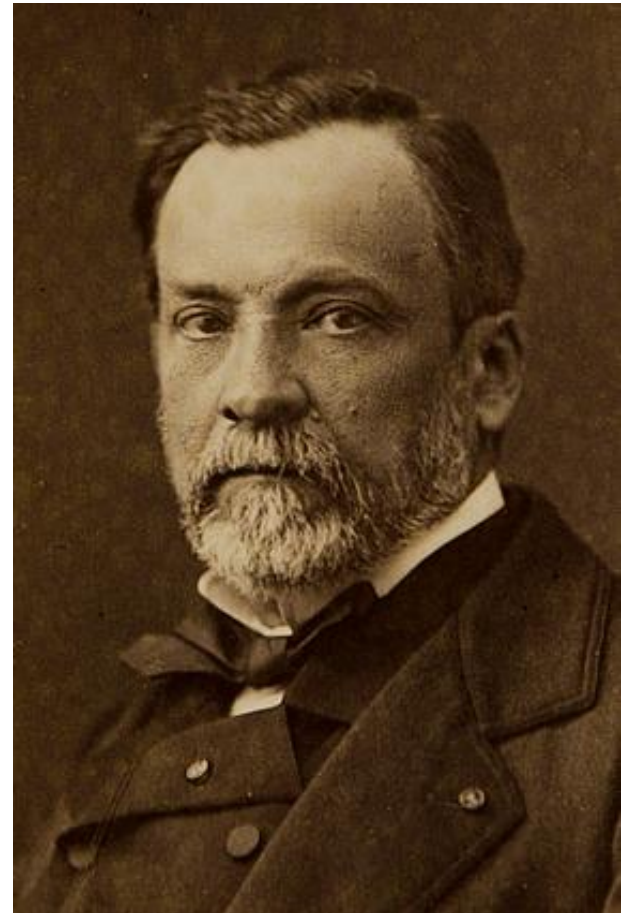
A pasteurization case study

Pasteurization

- The reduction of bacterial contamination by thermal, chemical, irradiation, or other modality
 - 5-log reduction standard
 - Exceptions for 4-log reduction

Background

- Louis Pasteur
 - Milk “Pasteurization”
- Low acid canned food
 - Vegetables
- Sterile medical devices
 - 12 log reduction
 - Band Aids
 - Pacemakers
 - Sutures





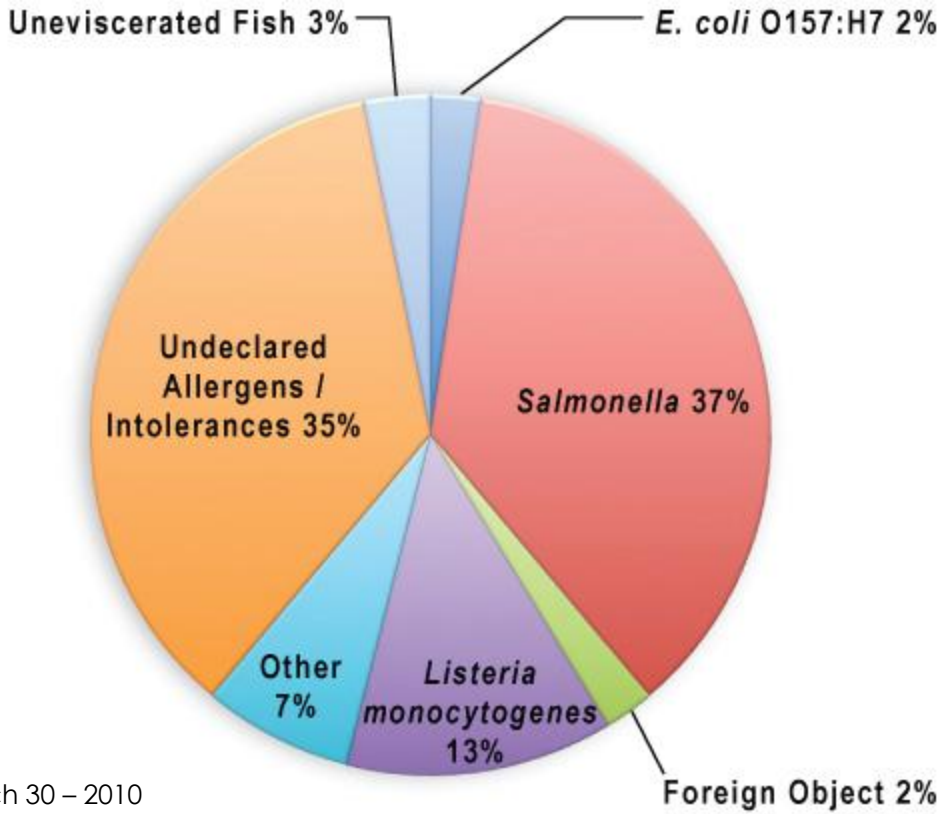
Pasteurization



Food and Drug Administration

- Increased focus on tree nuts
- Reportable food registry sending shockwaves
- Additional inspection and enforcement power from Food Safety Act
- Has the ability to inspect suspect facilities with a microscope
- Your company name on the evening news

Reportable Food Registry



September 8, 2009 – March 30 – 2010
<http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm>

In the News

- Peanut Corporation of America
- Daniele Foods – Pepper coated meats
- Conagra – Peanuts
- Kraft Foods & Setton Pistachios
- McCormick and Co. – HVP
- Albertson's / Safeway – Eggs
- Ready Pac Foods – Spinach
- Paramount Farms – Almonds

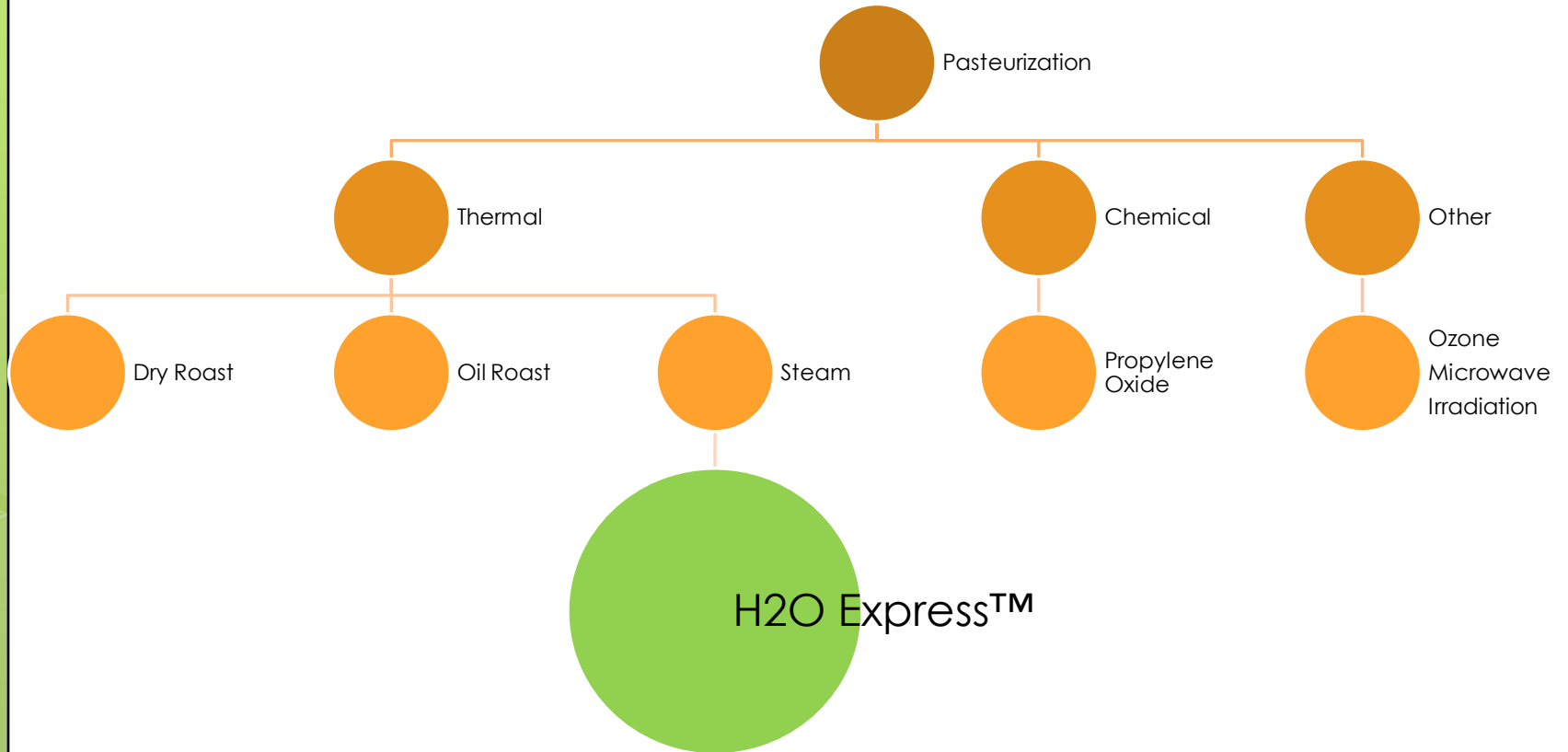
Certificate of Pasteurization

So how do I get one?

Selecting a Technology

- Does it -
 - effectively eliminate pathogens?
 - damage the product or packaging?
 - integrate with material handling and logistics?
 - fit economic realities?
 - meet regulatory requirements for destination market?

Technologies



H2O Express™

- Sub-atmospheric pressure, steam pasteurization
 - Vacuum chamber
 - Batch process
 - 1 – 64 pallets/cycle
 - Typically >162 Deg F.
 - Process time 8 hours



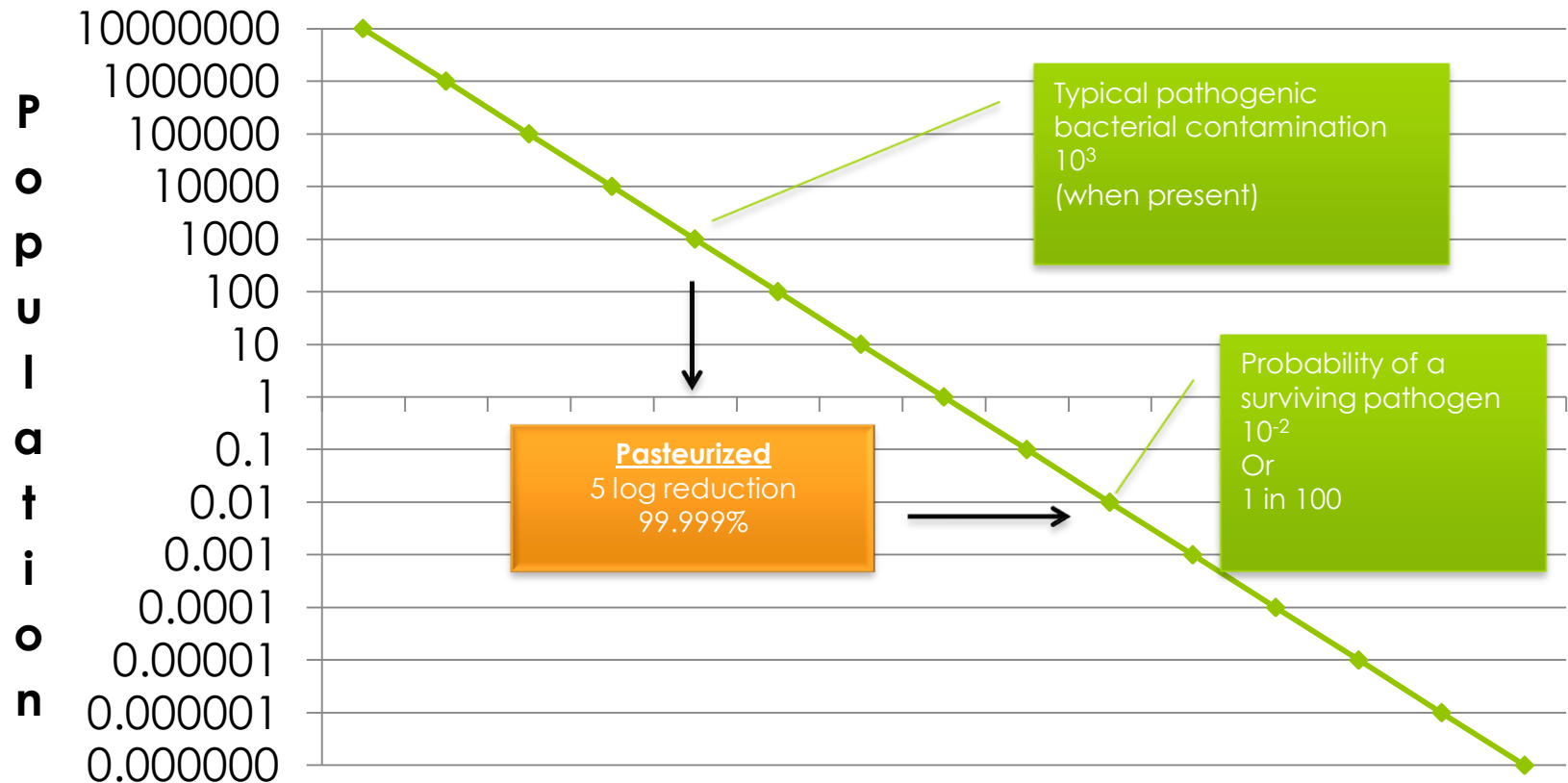
Pasteurization



Pasteurization

- The 5-log reduction of bacterial contamination by thermal, chemical, irradiation, or other modality

A 5-Log Reduction?



Process Validation

- Identify team members and responsibilities
 - Process Authority
- Prepare a written protocol
- Installation qualification
- Operational qualification
- Performance qualification
- Ongoing control
- Revalidation

Installation Qualification

- Documents and verifies the installation of the pasteurization equipment
- Is it installed correctly?
- The IQ may include:
 - Drawings
 - Written descriptions
 - Checklists
- Assists in the identification of critical control parameters
- Particularly important in the conversion of legacy systems, i.e. dry-roasters

Operational Qualification

- Confirms that the equipment performs as designed.
- For an H2O Express™ system this would include:
 - Empty chamber temperature distribution study
 - Vacuum rates
 - Steam quality



Performance Qualification

- Document that the process is effective and reproducible.
- Establish operating tolerance to ensure aq 5-log reduction
 - Test the “worst case”
 - Coldest product
 - Shortest time
 - Lowest gas concentration
 - Lowest temperature
 - Microbiological challenge using surrogate organism

Surrogates

- Non-pathogenic bacteria with a known resistance to the pasteurization technology
- Ideally easy to produce, store, transport and test with low variation in resistance between crops
 - Irradiation – *bacillus radiodurans*
 - Moist heat sterilization – *bacillus stearothermophilus*
 - Ethylene oxide – *bacillus atrophaeus*
 - Propylene oxide – *bacillus stearothermophilus*
 - Moist heat pasteurization – *enterococcus faecium* (*peddiococcus*)

Final report

- Establish validated process limits
 - Maximum PQ temperature → minimum tolerance
 - Maximum PQ exposure time → minimum tolerance
 - Maximum PQ gas concentration → minimum tolerance
- Product characteristics
 - Highest product starting temperature → minimum tolerance
 - Largest load test → Maximum tolerance

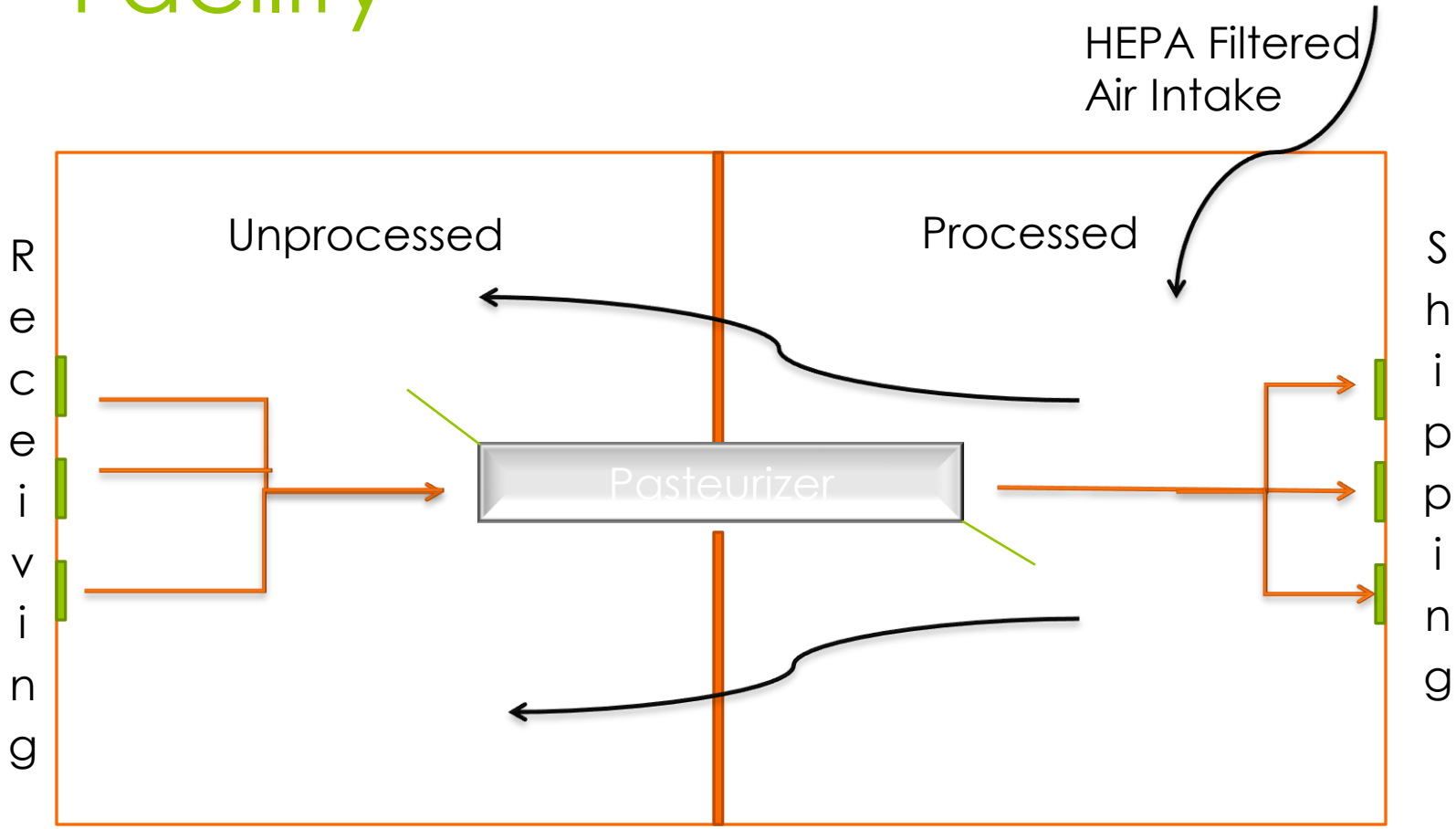
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Ongoing Requirements

- Process control
 - Routine calibration
 - Maintenance
- QC reviews
 - Identify and address root causes of failures
- Periodic revalidation
 - Set frequency, i.e. every 2 years
 - Paperwork review may be acceptable
 - Significant equipment modifications

Facility



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Ensuring Food Safety, Naturally

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Steam
Pasteurization