Key Considerations for Product Design and Manufacture of Salad Dressings

This document is intended to be used only as a guide and is not all inclusive. Users of this document assume all liability that may result as a consequence of implementation of the provisions contained herein. The manufacturing firm should conduct thorough research and testing of product formulations to ensure the finished product is safe for consumption over the product’s shelf life.

I. Must be able to realistically evaluate degree of risk (consumer exposure to issues of public health significance).

A. Complete a qualitative two-phase assessment that will provide the information necessary to support data-based decisions (based on quantitative results when applicable) helping to avoid risk or manage incidents when they occur.

1. Assess product matrix (intrinsic factors).
3. Involves completion of all activities that will help to achieve and maintain microbial integrity and consumer safety through preventative (proactive versus reactive) measures (can use previously developed predictive model information, if available and applicable).
4. Examines the entire microenvironment and helps develop appropriate/required manufacturing fundamentals.

B. Evaluates microbial susceptibility.

1. Not simply by a determination of residual (viable) microbial populations (based on data generated from completion of a “picture in time” inoculated challenge study), but also by the following:
2. Evaluations of what is included in the formula,
3. The impact of the environment, and
4. How it all interacts and impacts the finished goods matrix (environment of the product).

C. The goal is to:

1. Be able to accurately predict product risk using good science to generate data.
2. Make data-based decisions to marry this identified risk with plant capabilities (to include sanitation control practices).

   a. Match the susceptibility of the product with manufacturing practices that will maintain minimal risk.
II. Must develop an understanding of the product matrix.

A. The rate of product degradation (as relates to safety or spoilage) is influenced by:

1. The initial number of bacteria (load) – reduction/death is exponential (i.e., more microbes equal more time to reduce or kill populations).
2. The type of bacteria and any specific protective features.
3. Processing conditions.
4. Storage conditions.

B. To control the above factors, concentrate on the critical growth factors (requirements) that need to be considered (and/or survival depending on the microorganism of concern…remember zero tolerance microorganisms).

1. Water – as percent available (free/unbound) moisture.
2. Food (required nutrient source) – differs in amounts necessary per organism of concern.
   a. Carbon.
   b. Minerals.
   c. Vitamins.
3. Favorable environmental conditions.
   a. Temperature - extremes in temperatures impact microbial populations to some degree. (NOTE: May not kill, but rather only reduce susceptible microbial populations and/or extend lag phase). See Section III.A. below for details.
   b. Acidity or alkalinity – acid additions of appropriate type and in sufficient quantity are effective in controlling microbial populations, however significantly altering pH and titratable acidity (TA) could compromise efficacy and/or consumer preference attributes.
   c. Oxygen content – different microbial populations have different requirements.
      i. Obligate aerobe or anaerobe.
      ii. Facultative aerobe or anaerobe.
   d. Absence of inhibitors/preservatives.
   e. Absence of competition for food.
4. Time.

   NOTE: Deviations from optimum levels will retard growth rates and may positively impact control factors, but microorganisms do not require ideal conditions.

C. Intrinsic control factors.

1. Choice of acid.
a. Principal level and type – not all acids provide equivalent efficacy to control/kill microbial populations of concern.

b. Use of multiple acids versus single acid system.

c. End product TA/pH and potential to drift over shelf life.

d. Verified minimum effective level of acid in aqueous phase.

2. Ingredient content.

a. Nutrients available.

b. Particulate matter (size and percentage) – the larger the size and the higher the concentration, the longer it will take for acids or other treatments (e.g., ultraviolet, brine, heat treatment) to equilibrate across the material matrix and reduce/kill inherent microbial populations.

c. Potential use of culture (at high log cycle levels may provide competition for food).

d. Assess impact of naturally occurring growth niches (e.g., lactobacillus is acetophilic).

e. Identify specific issues related to all raw materials to identify variability and susceptibility.

f. Complete risk classification (high, medium, low) to include grading each product by the potential for inherent loads to proliferate in the environment of the raw material itself or other changes that may occur during inventory at manufacturer and distribution.

g. Identify issues related to use of all natural, fresher or organic ingredients and establish unique control/management requirements, as necessary.

h. Develop ingredient degradation knowledge – may impact finished goods pH over shelf life, use acceptability and/or finished goods integrity.

i. Identify issues related to hydration of materials (in product) on ability to introduce load into product matrix.

j. Identify applicable risk categories for each material.

i. Regulatory.

ii. Safety.

iii. Cost/price.

iv. Microstability/quality.

v. Logistics.

k. Complete risk characterization impact for material.

i. Probability of a negative incident.

ii. Magnitude of impact.

iii. Make data-based decisions (ensure data is accurate).

l. Set up standardized qualification program for suppliers.

i. Sourcing of supplier’s ingredients.

   a) Processing – variability and cleanability.
b) Potential for introduction of post-processing contamination.
c) Difference between supplier benchtop and scale-up production (or other supplier manufacturing site).

ii. Complete testing of unique lots.
iii. Complete on-site visit(s) to supplier based on risk.
iv. Establish ongoing selective testing necessary to ensure the quality/safety of the product (species and load).
v. Determine necessity for ongoing (or some other auditing frequency, e.g., every 10th lot) pre-lot/pre-ship testing evaluations.
vi. Develop Certificate of Analysis (COA) program as appropriate – make sure that for all tests the vendor and manufacturer agree and understand specifics of test methods.

m. Identify processing treatments available to reduce/kill inherent loads as necessary based on finished goods susceptibility.

i. Brine/acid soak – solution, dwell time, additives necessary to protect ingredient integrity.
ii. Irradiation.
iii. Cook step – type, temperature required and dwell time.

n. Identify any order of addition issues.

o. Do not forget issues related to distribution, handling and storage of raw materials received in bulk (e.g., totes or tankers) and raw materials received frozen.


a. Issues of concern:

i. Mixable – able to equilibrate over entire product matrix.
ii. Effective in formula at allowable use dilution.
iii. Need to identify absolute minimum concentration necessary and methods to ensure addition and equilibration.
iv. Need to identify temperature and pH at which agent works best.
v. No regulatory concerns – preferably generally recognized as safe (GRAS).
vi. No significant difference (NSD) to flavor.
vii. No impact to organoleptics over shelf life.
viii. Acceptable cost.
ix. Broad spectrum.
x. Able to easily validate use percentage by in-house T = 0 testing.
xi. Does not require special storage and/or handling.
xii. Does not degrade in inventory, during processing, or in formula (if applicable).

b. May work synergistically with acid to improve control (e.g., sorbic acid plus acetic acid).
c. Naturally occurring in some spices (e.g., spearmint, cloves, pepper, curry).
d. Manufactured as a metabolic by-product (called bateriocins) by some microorganisms.
e. Added as a chemical in food systems.
f. May need to be labeled, but could be negatively perceived by consumers looking for all natural goods.
g. Use dilution regulated by the Food and Drug Administration (FDA).

4. Percent free moisture (not water activity).
   a. Bound water is not available for use by microbial populations.
   b. Unbound water is necessary for proliferation and/or survival.
   c. As percent free moisture increases, risk increases.

5. Acid to moisture ratio.
   a. Identifies total acid in the moisture phase.
   b. As percent acid increases, the environment becomes less conducive to survival and/or proliferation.

6. Oxidation-reduction potential.

D. Product assessments to be completed prior to standard operating procedures (SOP). Preliminary testing is appropriate for candidate prototypes, but after production candidate is chosen, the following measures are critical to managing risk).

1. Finished product inoculated challenge testing to help define analytical targets and ranges.
   a. Not based on calculations, but rather on verified and appropriate testing (scientifically generated data).
   b. Manufactured whenever possible under scale-up production conditions.

2. Completion of storage and ship testing under normal and abuse conditions (e.g., temperature).

III. Must develop understanding of the impact of the processing/fill/storage/distribution environment and product mix.

A. Impact of Temperature.
1. Freezing and refrigeration prevent many microbial populations from growing, but will not necessarily destroy them to the degree required to ensure product safety. Therefore, freezing/refrigeration are not effective as control measures for zero tolerance strains.

2. Once food is placed into a more favorable temperature environment, growth may or will occur even though some total population numbers may be decreased.

3. Need to understand optimal temperature for each specific product.
   a. Identify time to reach optimal temperature.
   b. Identify the potential negatives associated with failures in temperature controls.
   c. Implement all necessary controls.

B. Control of oxygen content.
   1. Headspace oxygen.
   2. Use of modified atmosphere pressure (MAP) packaging.
   3. Deaeration during processing.

C. Mixing capability (type and times) - ability of mixing equipment to equilibrate ingredients across product matrix.

D. Impact of shear on finished goods, percent available moisture and emulsion stability.

E. Considerations prior to scale-up.
   1. Grade the plant by the presence or absence of those requirements identified as necessary to manage risk.
   2. Identify all the potential insults of processing and the plant capability to detect/control/eliminate.
   3. Implement all activities necessary to eliminate/control insults in order to provide/maintain a suitable processing environment. Program must always be based on the requirements for the most susceptible product in the mix.

F. Recommended processing assessments.
   1. General plant practices.
      a. Knowledge of Good Manufacturing Practices (GMPs) and applicable product risk.
      b. Impact of traffic patterns and air currents.
      c. Manpower availability and level of expertise.
      d. Present plant capabilities.
   2. Equipment (processing and lab) to ensure consistent accuracy.
      a. Impact of sanitary design – engineering understanding.
      b. Calibrations (e.g., pumps, meters and scales).
c. Documented autonomous maintenance (AM) and/or preventive maintenance (PM) activities.
d. Appropriateness of testing – sensitivity and precision.

3. Impact of production mix on downtime – includes all equipment and sanitation controls requirements.
   a. Complete testing to identify changeover requirements.
      i. Must be built into production schedules to allow sufficient time.
      ii. Requires pre-identified and documented support activities.
   b. If a kill step is included, identify the potential for post process and/or cross contamination.

4. Knowledge of plant bioburden (species and level) generated from:
   a. Product mix in a given processing location.
   b. The physical location of the manufacturing site (e.g., near an open field).
   c. Configuration of processing areas in proximate locations to one another.
   d. Carried from one location to another by air or traffic patterns.

5. Determine ability to consistently complete appropriate and effective sanitation controls.
   a. Why?
      i. Soil load usually includes microorganisms.
      ii. Soil provides nourishment for microorganisms present.
   b. Some key components:
      i. Proper chemical and vendor selection.
      ii. Well-trained, dedicated and appreciated sanitarians.
      iii. Continuous cleaning and housekeeping.
      iv. Adequate environmental monitoring.
   c. Factors affecting the performance of chemicals and sanitizers:
      i. Inability to effectively clean due to equipment design or lack of time.
      ii. Inactivation of sanitizer due to dirty conditions.
      iii. Temperature of solutions.
      iv. Inadequate contact time.
      v. Ineffective concentration.
      vi. Instability of chemicals (especially sanitizers).
IV. Principal food control options to help manage risk – internal quality systems, policies, procedures and SOPs need to be developed to guarantee the safety of finished goods.

A. Education and training for all levels of personnel involved in product development and manufacturing - operators and staff trained to:
   1. Understand the risk of non-compliance and the impact.
   2. Appropriate response to incidents/excursions.
   3. Institutionalize business by authority not permission. Drive empowerment to floor level and expect personnel to develop expertise in their area of responsibility and to take ownership.

B. Develop an understanding of food hazards and control options (Hazard Analysis Critical Control Point (HACCP) type approach) by developing a flow diagram of the process and categorizing risk at each stage of:
   1. Development.
   2. Purchasing.
   3. Receiving and warehousing.
   4. Staging.
   5. Production (compounding).
   6. Packaging.
   7. Warehousing and distribution.
   8. Point of sale.
   9. Point of use.

C. Develop an understanding of personnel hygiene, sanitation and food hygiene.

D. Whenever possible, include formula/processing factors that will negatively impact microbial growth and survival.

E. Implement appropriate programs so decisions can be made based on fact.

F. Complete verification and routine microbial testing to assure adherence to requirements and specifications.
   1. Sample and analyze ingredient components, in-process, finished goods and the environment. Repeat inoculated challenge test at SOPs.
   2. Compare results to a standard, a guideline, a defect action level, etc., and advise accordingly.

NOTE: Microbial testing alone can be misleading and negative results do not ensure quality or safety, especially when contamination levels are low.

G. Inspect/audit processing facilities and food handling practices frequently.
   1. Monitor adherence to recommended or required food handling practices.
   2. Follow a recommended or required guideline (e.g., GMPs).
   3. Cite violations or make records for improving performance.

H. Use statistical process control (SPC) analysis to measure amount of process variability.
I. Use the hurdle concept – reliance on two or more control parameters that act additively or synergistically to control risk.

1. pH/TA.
2. Storage temperature.
3. Atmospheric packaging.
4. Preservatives.
5. Control of raw materials.
7. Sanitation.

SUMMARY

Control decreases as complexity increases due to the variability introduced from raw materials, processing and testing.

A complex combination of four factors must be managed on a continuous basis:

A. The microorganism(s) of concern.
B. The specific product matrix.
C. The product mix (all formulas manufactured on the same or proximate equipment). The manufacturing environment in which the first three factors exist and interact.

For details regarding commercial mayonnaise and salad dressing product formulations, refer to the attached ADS document, “Processing Considerations for Salad Dressings.”
PROCESSING CONSIDERATIONS FOR SALAD DRESSINGS

This document is intended to be used only as a guide and is not all inclusive. The paper has been developed based on a review of the scientific literature and highlights some of the critical control factors to ensure food safety for salad dressings. Food safety refers to the conditions and practices that preserve the quality of food to prevent contamination and foodborne illness (21).

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Introduction
Commercial mayonnaise and salad dressings have a remarkable safety record and research studies have confirmed the safety of these products. There are no reported incidences where foodborne pathogens will grow in commercially prepared mayonnaise or salad dressing. In addition, commercial mayonnaise, dressings and sauces have never been directly identified as the cause of any foodborne illness. In reported studies of these products, foodborne pathogens die off at various rates depending on the organism, acid type, acid concentration, storage temperature, organism adaptability and pH (18).

The Scientific Research
Some of the scientific research studies affirming the safety of commercial mayonnaise and salad dressings are documented below.

Beuchat et al. (4) demonstrated the rapid death rate of Salmonella, Escherichia coli O157:H7 and Listeria monocytogenes in commercially manufactured shelf-stable, dairy-based, pourable full-fat ranch (pH 2.87 -3.72), reduced fat ranch (pH 2.82 - 3.19), full-fat blue cheese (pH 3.08 - 3.87) and reduced-fat blue cheese (pH 2.83 – 3.49) salad dressings stored at 25 °Celsius (C).

Hathcox et al. (11) undertook a study to determine the survivability of low-density populations (10^6 and 10^2 CFU/g) of enterohemorrhagic E. coli O157:H7 inoculated into real mayonnaise (pH 3.86-3.97; titratable acidity of 0.43-0.44%) and reduced-calorie mayonnaise (pH 4.08; titratable acidity of 0.46) and stored at 20 and 30°C. Inactivation patterns at 5°C and inactivation of high-inoculum populations (10^5) were also determined. E. coli O157:H7 did not grow in either mayonnaise formulation, regardless of the inoculum level or storage temperature. Increases in storage temperature from 5 to 20°C and from 20 to 30°C resulted in dramatic increases in the rate of inactivation.

Weagant et al. (22) demonstrated that E. coli O157:H7 inoculated (initial population of 7.16 to 7.23 log_{10} CFU/g) into commercially prepared mayonnaise (pH 3.65) and stored at 25°C became undetectable after 72-hour storage.
Glass and Doyle (10) demonstrated that properly acidified (pH <4.1) commercial cholesterol-free reduced-calorie mayonnaise and reduced-calorie mayonnaise formulated to contain 0.7% acetic acid in the aqueous phase, will inactivate >10⁷ *Salmonella* and >10⁴ *L. monocytogenes* per gram within 72 hours.

Erickson and Jenkins (9) determined that *Salmonella* spp. strains inoculated into four commercial mayonnaise products: sandwich spread (pH 3.3; 2.2% acetic acid), real mayonnaise (pH 3.9; 1.8% acetic acid), reduced-calorie mayonnaise (pH 3.9; 0.67% acetic acid) and cholesterol-free reduced-calorie mayonnaise (pH 3.9; 0.67% acetic acid) and held at 26.6°C were rapidly inactivated, decreasing ≥8 log₁₀ CFU/g in ≤72 hours, in each of the four products. *L. monocytogenes* strains inoculated into sandwich spread and real mayonnaise were also reduced to ≥8 log₁₀ CFU/g in ≤72 hours. *L. monocytogenes* inoculated into cholesterol-free reduced-calorie mayonnaise was eliminated in ≤120 hours. In addition, *L. monocytogenes* inoculated into reduced-calorie mayonnaise was not detected within 192 hours.

Research by Wethington and Fabian (23) demonstrated that acetic acid (pH 3.8; 0.48% acid) in mayonnaise could kill 10⁸ *Salmonella*/gram within 12 hours at 37°C (24).

**Composition of Mayonnaise and Salad Dressings**

The U. S. Food and Drug Administration (FDA) has established standards of identity for mayonnaise (21 Code of Federal Regulations (CFR) 169.140) and salad dressing (21 CFR 169.150), which specify the ingredients that are permitted and prohibited in the manufacture of these products. However, for pourable salad dressings, except French dressing (21 CFR 169.115), FDA standards have not been developed. Pourable salad dressings are manufactured with a variety of ingredients to provide numerous salad dressing choices to satisfy consumers’ tastes. These ingredients affect the overall composition of the finished product and play a key role in the product’s intrinsic critical control factors. Modified versions of mayonnaise, salad dressings and pourable dressings (e.g., low-fat, reduced-calorie, light) are available in the marketplace, and the composition of these products may also vary by manufacturer.

Intrinsic and extrinsic critical control factors contribute to the safety of commercial mayonnaise and salad dressings. Some of the key formulation factors that should be considered include the pH, percent acid in the water phase, percent salt in the aqueous phase and the amount and type of ingredients. Product formulations vary and the parameters noted in this paper may not be representative of all products.

The composition of mayonnaise has been reported (12):

1. pH range - 3.2 to 4.0 due to acetic acid content;
2. 65 to 80% oil content;
3. 9 to 11% aqueous phase salt content;
4. 7 to 10% sugar content; and
5. water activity (a_w) of ~0.925.

Dr. Richard Smittle (17) reported that mayonnaise has a pH range of 3.6 to 4.0. Acetic acid is the predominant acid and represents 0.29% to 0.5% of the total product. The aqueous phase contains 9.0 to 11.0% salt and 7.0 to 10.0% sugar. Smittle also reported that salad dressings have a pH in the range of 3.2 to 3.9. Generally, the predominant acid is acetic, which represents 0.9 to 1.2% of the total product. The aqueous phase contains 3.0 to 4.0% salt and 20 to 30% sugar (17).
A survey of mayonnaise, salad dressings (including pourable dressings) and sauces produced in the U.S showed the highest reported pH was 4.4 with acetic as the predominant acid and 0.43% titratable acidity as acetic in the water phase (18).

The composition of salad dressings has also been reported (13):

1. pH range of 3.2 – 3.9 with acetic acid typically as the predominant acid (0.9 – 1.2% of total product);
2. 30% vegetable oil content;
3. 3.0 – 4.0% salt in the aqueous phase;
4. 20 – 30% sugar in the aqueous phase; and
5. water activity ($a_w$) of 0.929

**Intrinsic Critical Control Factors**

Intrinsic critical control factors refer to the characteristics or components of foods that control a microorganism’s ability to survive and grow in foods (6). The key intrinsic critical control factors for mayonnaise and salad dressings include pH, aqueous phase acidity, type of organic acid and water activity.

**Acid Level and pH**

Beuchat et al. (4) reported that the most significant factor in salad dressings and mayonnaise that contributes to lethality of pathogens is pH adjusted with acetic acid, followed by the concentration of acetic acid in the aqueous phase.

Smittle (18) reported acidity is the most intrinsic characteristic of mayonnaise, dressings and sauces in determining the growth and survival of pathogenic bacteria. Salt and sugar play minor roles, but they have an interactive effect with acetic acid in vinegar on inhibiting the growth of foodborne pathogens (18).

The interaction of pH with other factors, such as water activity ($a_w$), salt, preservatives and temperature, help to inhibit the growth of pathogens and other microorganisms (12).

Generally, pathogenic bacteria grow slowly or do not grow at pH levels below 4.6, however, there are some exceptions (12). The table below shows the approximate minimum pH values for the growth pathogens in foods. Optimum and maximum pH values for growth have also been documented. The table highlights those pathogens that are able to grow in the pH range of 4.2 – 4.6, which is the focus of this paper. Because some pathogens will grow or survive between this pH range, it is important to formulate products at pH levels below 4.2 or implement other measures to prohibit the growth or survival of these organisms. When formulating products, a challenge study should be conducted to ensure products will not support the growth or survival of pathogens. Challenge studies are discussed later in this paper.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Minimum pH for growth (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium botulinum</em> toxin</td>
<td>4.6</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em> growth</td>
<td>4.6</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> toxin</td>
<td>4.5</td>
</tr>
<tr>
<td>Enterohemorrhagic <em>E. coli</em></td>
<td>4.4</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>4.39</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>4.2</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>4.2</td>
</tr>
</tbody>
</table>
*pH minimum as low as 3.8 has been reported when acidulants other than acetic acid or equivalent are used (12).

It is essential to use the correct equipment and method to measure the pH and other analytical parameters. One test method for measuring pH is cited in Section IV, “Essential Tests” in the Methods and Procedures Manual published by The Association for Dressings and Sauces (ADS) (2).

**Acetic Acid and Titratable Acidity**

When formulating mayonnaise and salad dressings, it is important to consider the acid type and the minimum level of acid in the aqueous phase. As noted earlier, acetic acid is usually the predominant acid in mayonnaise and salad dressings. Research by Wethington and Fabian (23) demonstrated that acetic acid had the greatest influence on killing *Salmonella* in mayonnaise and salad dressings (24).

The percent acetic acid is often expressed as titratable acidity. For some foods, such as salad dressings, the titratable acidity is a better indicator of microbiological stability than pH (12). Since organic acids are usually undissociated, they do not directly contribute to a food’s pH. Titratable acidity measures the total acid concentration while pH measures the hydrogen ion concentration (12, 13).

The bactericidal activity of vinegar is due to the high acetic acid content, which has been documented. Entani et al. (8) examined the bacteriostatic and bactericidal actions of vinegar on foodborne pathogenic bacteria. The bacterial strains examined included enterohemorrhagic *E. coli* O157:H7, *E. coli* O26:H11, *E. coli* O11:HNM, *E. coli* O11:K58, *S. enteritidis*, *S. typhimurium*, *Vibrio parahaemolyticus*, *Aeromonas hydrophila*, *S. aureus* and *Bacillus cereus*. The growth of all strains examined was inhibited by 0.1% acetic acid. This effect was enhanced when sodium chloride or glucose was added except for *V. parahaemolyticus*. Vinegar also had a bactericidal effect on the pathogenic bacteria including enterohemorrhagic *E. coli* O157:H7 (8).

Medina et al. (15) demonstrated that vinegar (pH 2.9; 5% acetic acid) reduced the counts of inoculated *L. monocytogenes*, *Salmonella* Enteritidis, *S. sonnei*, and *Yersinia* sp. to levels below the detection limit and killed most of the *E. coli* and *S. aureus* cells.

It is important to consider that all acids are not equal in terms of efficacy, and the percentage of one acid may not be as effective as the same percentage of another acid. In addition, the pH value of the acid affects the effectiveness of the antimicrobial action of the acid. Conner et al. (7) determined that the antimicrobial activity of many organic acids was correlated to the concentrations and pH level of the acid. Higher acid concentrations, with correspondingly lower pH levels, were reported to reduce pathogenic microorganisms more effectively than lower concentrations for acetic, lactic, citric and propionic acids (5).

Bornemeier et al. (5) conducted a study to determine the effect of two concentrations (5% and 10%) of citric acid and acetic acid on the survival of *S. aureus* (inoculated with $10^6$ CFU/gram) and *L. monocytogenes* (inoculated with $10^7$ CFU/gram) in a mayonnaise-based surimi salad held at 4°C and 10°C. The pH was also adjusted to approximately 5.0 with 5% citric or acetic acid and adjusted to approximately pH 4.6 with 10% citric or acetic acid. At the same pH level, acetic acid was more effective than citric acid for reducing pathogenic bacteria (5).
Bornemeier et al. (5) also found that the concentration of the acidulant corresponded to its antimicrobial effectiveness. A 10% acetic acid concentration was more effective than a 5% acetic acid concentration in reducing the populations of \textit{L. monocytogenes} at both 4°C and 10°C. The overall effectiveness of added acidulants on the inactivation of \textit{S. aureus} and \textit{L. monocytogenes} were 10% acetic acid > 5% acetic acid > 10% citric acid > 5% citric acid > no acid (5).

Perales et al. (16) demonstrated that \textit{Salmonella} was killed in mayonnaise acidified to pH 4 with acetic acid, but not with citric acid at the same pH (5).

Studies have affirmed that the preservative effect of mayonnaise and salad dressings is attributed to the acetic acid content. However, Beuchat et al. (4) reported that citric, malic, lactic and phosphoric acids may be used in the manufacture of shelf-stable pourable dressings and these acids also contribute to the low pH of these products.

It may be possible to lower the pH using an alternate acidulant combined with acetic acid to reduce the “vinegar bite,” such as organic acids derived from the fermentation of dextrose (cultured dextrose) or a blend of acetic acid and lactic acid.

\textit{Water Activity (a\textsubscript{w})}

The \textsubscript{a}w should also be considered during formulation. The \textsubscript{a}w is a measure of the water available for microorganisms to live and grow. It determines a food’s shelf life in combination with temperature, pH and other factors (14). An \textsubscript{a}w greater than 0.85 will permit pathogens to grow as well as cause bacterial spoilage (14).

Smittle (17) reported the \textsubscript{a}w of mayonnaise is 0.925 and salad dressing is 0.929. These \textsubscript{a}w values are not to be representative of all mayonnaise and salad dressing products as formulations vary. The \textsubscript{a}w values for mayonnaise and salad dressings noted above are intended to provide a point for comparison with the approximate minimum \textsubscript{a}w values for the growth of certain pathogens in the table below.
Approximate minimum $a_w$ values for growth of pathogens (12)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Minimum $a_w$</th>
<th>Organism</th>
<th>Minimum $a_w$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter spp</td>
<td>0.98</td>
<td>V. parahaemolyticus</td>
<td>0.94</td>
</tr>
<tr>
<td>C. botulinum type E (nonproteolytic)</td>
<td>0.97</td>
<td>B. cereus</td>
<td>0.93</td>
</tr>
<tr>
<td>Shigella spp.</td>
<td>0.97</td>
<td>C. botulinum A &amp; B (proteolytic)</td>
<td>0.93</td>
</tr>
<tr>
<td>Y. enterocolitica</td>
<td>0.97</td>
<td>C. perfringens</td>
<td>0.943</td>
</tr>
<tr>
<td>Vibrio vulnificus</td>
<td>0.96</td>
<td>L. monocytogenes</td>
<td>0.92</td>
</tr>
<tr>
<td>Enterohemorrhagic E. coli</td>
<td>0.95</td>
<td>S. aureus (growth)</td>
<td>0.83</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>0.94</td>
<td>S. aureus (toxin)</td>
<td>0.88</td>
</tr>
</tbody>
</table>

The $a_w$ of mayonnaise and salad dressings (~0.925) is not sufficiently low to prevent the growth of S. aureus. However, at pH 4.1 and below, S. aureus does not survive. Mayonnaise and salad dressings also do not support the growth of C. botulinum because of the low pH and $a_w$. The low $a_w$ also prevents the growth of B. cereus (12).

When analyzing multicomponent foods, the $a_w$ may not reflect the actual value in a microenvironment or in the interface among the various ingredients and as such, the $a_w$ should be measured at the interface areas of the food, as well as in any potential microenvironment (12).

**Ingredients**

The quality of ingredients plays a critical role in the safety of foods. Pourable salad dressings may contain a wide variety of ingredients, including cheese, onions, sugar, eggs, garlic, vinegar, lemon juice and vegetables. Some ingredients such as cheeses, vegetables and eggs may support the growth of pathogens if proper controls are not in place. It is imperative that ingredients are carefully screened prior to use. The screening process may involve raw material sampling and testing by the supplier with a certificate of analysis (COA) provided to the manufacturer. The manufacturer may choose to sample ingredients and perform internal testing or submit the samples to a third-party for testing. The frequency of raw material sampling and testing may be determined based on the potential microbiological risks associated with the food. For example, eggs are a potential source of Salmonella contamination and may be analyzed more frequently than another ingredient such as vinegar.

Identifying those ingredients that are susceptible to microbial growth and spoilage is important. Manufacturers and raw material suppliers should develop and implement a Hazard Analysis Critical Control Point (HACCP) plan to identify, evaluate and control the biological, chemical and physical hazards throughout the entire operation (i.e., from raw material receiving to finished product distribution and consumption.) For additional information, refer to Section XIII, “Hazard
A supplier qualification program is also recommended to establish a partnership between the supplier and manufacturer. Under this program, the supplier and manufacturer agree on the criteria for raw material quality and safety, which are documented in the product specification.

Some ingredients may be used to prohibit microbial growth or survival, such as organic acids (acetic, lactic and citric) and preservatives. Ingredients such as salt and preservatives may increase a product’s inherent stability, whereas, ingredients that are added as a solid mass or particulates (e.g., blue cheese crumbles, tomato solids, bacon bits, onions, spices) may decrease inherent stability.

The addition of particulate matter to dressings should be considered during formulation. The particulate size, type and percentage will play a role in the stability of the product and affect the final pH of the salad dressings. The pH of the finished product should be measured after sufficient time has elapsed to allow all ingredients to reach a natural pH balance, i.e., pH equilibrium.

Pretreating certain high-risk ingredients prior to use may serve to reduce or inhibit the growth of microorganisms. The use of irradiated spices and other ingredients in salad dressings should be considered as a factor to help ensure product safety.

Potassium sorbate and sodium benzoate, used singly or in combination, are preservatives commonly used in mayonnaise and salad dressings. Selective use of “natural” preservatives that are declared as cultured dextrose and/or cultured maltodextrin or cultured skim milk may be considered as alternatives to chemical preservatives.

It is a combination of various ingredients used in the production of mayonnaise and salad dressings that help to ensure the safety of these products. According to Beuchat et al. (4), “the presence of acetic acid, and to a lesser extent, lactic and citric acids, in the aqueous phase, coupled with a low pH, salt, natural antimicrobials, and preservatives such as sorbic acid and/or benzoic acid create a harsh environment for foodborne bacterial pathogens such as Salmonella, E. coli O157:H7, L. monocytogenes, and Staphylococcus.”

Commercial mayonnaise and dressing manufacturers also use pasteurized eggs to ensure product safety (18). Unpasteurized eggs may serve as a potential source for Salmonella contamination. The FDA has mandated by regulation (21 CFR Part 101.100) that acidic dressings manufactured with unpasteurized eggs must have a pH less than or equal to 4.1, an acetic acid level in the aqueous phase of greater than or equal to 1.4%, and be held for 72 hours prior to shipping (20, 24). It has been reported that since the early 1970’s, the use of unpasteurized eggs in commercial mayonnaise and salad dressings has been discontinued (10).

**Extrinsic Critical Control Factors**

Extrinsic critical control factors are those external environmental factors that may have impact on the stability of the product. External factors may also impact the safety risk of concern for products that are close to the maximum ranges for critical factors.
Storage/distribution temperature (ambient storage versus refrigerated)

Storage temperatures can affect the rate of growth of spoilage microorganisms in addition to the physical stability and sensory quality of salad dressings (4). For mayonnaise and salad dressings, studies have shown that storage temperatures for the control of pathogens appears to be more effective at ambient temperatures versus refrigerated temperatures.

Research undertaken by Hathcox et al. (11) demonstrated that *E. coli* O157:H7 inoculated into mayonnaise at populations >10^6 CFU/g dies rapidly when held at 22°C to 25°C. The study determined that *E. coli* O157:H7 does not survive in commercial mayonnaise or reduced-calorie mayonnaise and the rate of inactivation is most rapid at temperatures (20°C – 30°C) at which commercially processed mayonnaise is distributed and stored. *E. coli* O157:H7 inoculated at a population of 0.23 to 0.29 log_{10} CFU/g in reduced-calorie mayonnaise and real mayonnaise held at 30°C were reduced to undetectable levels within 1 and 2 days, respectively; viable cells were not detected after 1 day at 20°C. In both products containing an initial inoculum of 2.23 log_{10} CFU/g, viable cells were not detected after 4 days at 30°C or at 7 days at *E. coli* O157:H7 cells (11). At an inoculum level of 6.23 log_{10} CFU/g, viable *E. coli* O157:H7 cells were not detected in reduced-calorie mayonnaise or real mayonnaise after 4 or 7 days of incubation at 30°C. When stored at 20°C, *E. coli* O157:H7 was detected in real mayonnaise stored for 17 days and was undetectable in reduced-calorie mayonnaise at 11 days (11).

Hathcox et al. (11) also demonstrated that in reduced-calorie mayonnaise and real mayonnaise containing 2.23 log_{10} CFU/g, viable cells were not detected after 28 and 58 days of storage at 5°C, respectively. *E. coli* O157:H7 inoculated into both products at a population of 6.23 log_{10} CFU/g was not detected in reduced-calorie mayonnaise held at 5°C for 58 days and was approaching undetectable levels in real mayonnaise after 93 days (11).

Zhao and Doyle (24) reported that *E. coli* O157:H7, when initially present at 6.5 x 10^3 CFU/g can survive in mayonnaise (pH 3.6 to 3.9) at 20°C for 21 days and at 5°C for 55 days; however, populations did not grow at either temperature.

Refrigerated Salad Dressings

Intrinsic and extrinsic critical control factors for refrigerated, pourable salad dressings are not directly addressed in this paper. Similar to formulations for shelf-stable salad dressings, formulations for refrigerated salad dressings vary by manufacturer. Refrigeration serves as a method of preservation for these products. Similar to shelf-stable salad dressings, if formulating refrigerated salad dressings, it is imperative to perform a challenge study to ensure product safety.

The 2005 Food Code states that refrigerated potentially hazardous food (time/temperature control for safety food) shall be held at a temperature of 5°C (or 41°F) or below when received (19). The 2005 Food Code is discussed later in this paper on page 11.

Temperature recording devices should be used in the manufacturing facility and during transport of refrigerated salad dressings to ensure these products are maintained at a temperature of 5°C/41°F. Temperature indicator labels or devices may be employed as a tool to monitor the temperature of ambient, refrigerated and frozen foods. If the product undergoes temperature abuse, the label or device is programmed to provide a signal indicating a temperature change in the product.
Plant Hygiene and Food Handling Practices
Implementation of a Hazard Analysis Critical Control Point (HACCP) program is a tool to assist processors in the identification of food safety hazards. One element of the HACCP program is the development of procedures and limits to control critical hazards. In addition, documented sanitation standard operating procedures (SSOPs) are established to ensure adequate equipment and sanitation. Prerequisite programs (e.g., preventative maintenance program, product recall and traceability program) are also elements of a HACCP program.

As mandated by FDA regulation (21 CFR 110), current good manufacturing practices (CGMPs) must be adhered to during the manufacture of foods (20). These regulations address employee hygiene and sanitation procedures for buildings and grounds, equipment and utensils as well as production and process controls.

Cross-contamination of mayonnaise and salad dressings by contact with raw food ingredients (e.g., meats) dirty utensils or equipment must be avoided. Unsanitary food handling practices during manufacture and post processing may result in the contamination of foods with pathogens and spoilage organisms.

Other Considerations
The manufacturer should also consider how the product will be ultimately used and stored by the consumer or customer and possible conditions under which the product could be abused. Performing a shelf-life study and/or challenge study using various parameters may show areas where food safety might be compromised and should be done by each manufacturer for each product as deemed necessary.

Food Code
The Food Code was developed to ensure food safety in food service establishments, retail food stores and other food establishments at the retail level (19). The provisions in the Food Code are enforceable and States are encouraged to adopt these principles.

In 2005, the FDA revised the definition of the “potentially hazardous food” (PHF) to mean “a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.”

The classification of a food as potentially hazardous is determined, in part, by two tables (Tables A and B), which take into account the pH and water activity (aw) of the product. The parameters to determine if a food is potentially hazardous are based on whether the food is heat-treated to eliminate vegetative cells and then packaged (Table A) or whether the food is raw or heat-treated but not packaged (Table B). A product assessment to determine whether the product requires time/temperature control may be needed depending on the pH and aw of the food. A food may be designated as non-potentially hazardous (non-PHF) if the product assessment demonstrates that growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in the food is prevented due to the food’s intrinsic and/or extrinsic factors. At this time, the FDA has not yet defined what a product assessment entails but the Agency has noted that inoculation studies or “some other acceptable evidence” should be conducted to determine whether the food is PHF/TCS or not (19).

If the food is intended to be held at <5°C (41°F) or >57°C (135°F) for safety and/or quality, use of the pH/aw tables is not needed. If a food is intended for storage at ambient temperatures, the tables should be used to determine if the food is non-PHF/non-TCS.
Of interest to manufacturers of salad dressings, Table B shows that products with a pH between 4.2 – 4.6 and \( A_w \) greater than 0.92 are required to undergo a product assessment to demonstrate the product does not require time/temperature control for safety.

### Table A. Interaction of pH and \( A_w \) for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

<table>
<thead>
<tr>
<th>( A_w ) values</th>
<th>pH values</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.6 or less</td>
<td>&gt; 4.6 - 5.6</td>
<td>&gt; 5.6</td>
</tr>
<tr>
<td>( \leq 0.92 )</td>
<td>non-PHF*/non-TCS FOOD**</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
</tr>
<tr>
<td>( &gt; 0.92 - .95 )</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
<td>PA**</td>
</tr>
<tr>
<td>&gt; 0.95</td>
<td>non-PHF/non-TCS FOOD</td>
<td>PA</td>
<td>PA</td>
</tr>
</tbody>
</table>

* PHF means POTENTIALLY HAZARDOUS FOOD  
** TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD  
*** PA means Product Assessment required

### Table B. Interaction of pH and \( A_w \) for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

<table>
<thead>
<tr>
<th>( A_w ) values</th>
<th>pH values</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 4.2</td>
<td>4.2 - 4.6</td>
<td>&gt; 4.6 - 5.0</td>
</tr>
<tr>
<td>( &lt; 0.88 )</td>
<td>non-PHF*/non-TCS FOOD**</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
</tr>
<tr>
<td>0.88 – 0.90</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
</tr>
<tr>
<td>( &gt; 0.90 - 0.92)</td>
<td>non-PHF/non-TCS FOOD</td>
<td>non-PHF/non-TCS FOOD</td>
<td>PA</td>
</tr>
<tr>
<td>&gt; 0.92</td>
<td>non-PHF/non-TCS FOOD</td>
<td>PA</td>
<td>PA</td>
</tr>
</tbody>
</table>

* PHF means POTENTIALLY HAZARDOUS FOOD  
** TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD  
*** PA means Product Assessment required

Tables A and B copied from the FDA’s 2005 Food Code

**Challenge Studies**

When a product is developed or a critical control factor (e.g., pH, acid type and concentration) has been changed, a challenge study should be performed. A microbiological challenge study is defined as a laboratory assessment of the “susceptibility” exhibited by a specific formulation to the presence of relevant microorganisms. A well-designed challenge study should be considered only as a screening tool and can be used in combination with raw material and environmental evaluation to assess whether the barriers included in the final product are sufficient to prevent the “growth” of microorganisms associated with economic spoilage and/or the “growth” or survival of microorganisms associated with issues of public health. The design
of the challenge study is critical and should include analyses to determine the appropriate challenge study microorganisms, level of inoculum, storage temperature, frequency of testing and packaging parameters. Interpretation of the data is based on observed trends of the microorganism’s growth over time. For additional information on challenge studies, refer to ADS’ “Challenge Study Guidelines,” in Section XI, “Industry Guidelines” of the Quality Assurance Guidelines Manual (1).
REFERENCES

   http://www.adsmembers.org

   http://www.adsmembers.org

   http://www.adsmembers.org


   http://www.cfsan.fda.gov/~comm/ift4-toc.html


20. United States Food and Drug Administration. Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food. 21 *Code of Federal Regulations* Part 110


