NORTH AMERICAN RENDERERS ASSOCIATION

# THERMAL VALIDATION DATA FOR RENDERING

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**The following white papers were prepared for the North American Renderers Association to assist membership compliance with the Food Safety Modernization Act that requires validation of preventive controls for animal food.**

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# Industry White Paper

# Thermal Parameters for Raw Beef Materials Utilized in Rendering

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The purpose of this industry white paper is to calculate specific cooking time and temperature standards for raw beef materials utilized by the rendering industry. These standards were calculated based on results provided by a study conducted by the Department of Animal and Food Sciences at Texas Tech University (Brashears et al., 2015). The objective of the study was to determine D- and z-values for high-risk raw beef materials using a well-known heat resistant microorganism, *Salmonella* Senftenberg. The D- and z-values generated from this study were used to calculate specific time and temperature combinations sufficient to achieve a 7-$\log_{10}$ or 9-$\log_{10}$ reduction of *Salmonella Senftenberg*. This white paper may be used as supporting evidence that thermal processes may be utilized as a preventive control for *Salmonella* in raw beef materials processed in the rendering Industry. It is also meant to assist facilities during the development of their animal food safety plan by targeting appropriate processing parameters for implementing thermal processing preventive controls.

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## Background

According to the FDA Food Safety Modernization Act (FSMA), the Preventive Controls for Animal Food rule section 21 C.F.R. §507.47 indicates all facilities that use a thermal processing step as a preventive control to control biological hazards must validate its control unless the preventive controls qualified individual prepares written justification that validation is not applicable. One method to validate a thermal treatment is to use scientific evidence to demonstrate that the preventive control is capable of significantly minimizing or preventing a hazard (FDA, 2015).

D- and z-values are commonly used to establish parameters for thermal processes that control biological hazards in a variety of human food products. The advantage of utilizing D- and z-values is that they can be universally applied to many heating processes regardless of the size, output, or design of the cooking apparatus. These values are specific to the raw material matrix and the target organism. They can be used to calculate time and temperature combinations that sufficiently achieve a specific lethality performance standard. The lethality performance standard is also referred to as a $\log_{10}$ reduction which would be specific to the raw material matrix.

## Study Design

Raw Material Matrix: D- and z-values are specific to the raw material matrix because the heat resistance of *Salmonella* is influenced by the environment it is exposed to. The researchers at Texas Tech University targeted a worst case scenario product and formulated a matrix that best protected *Salmonella* cells during the heating process. *Salmonella* cells survive heat treatment best in low moisture/high fat materials so the target was a high fat matrix containing lower than typical moisture levels. In theory, values generated by using this worst case scenario product would be sufficient for all raw beef materials used by the rendering industry (Brashears et al., 2015).

*Salmonella* Strain Selection: D- and z-values are specific to the bacteria strains used in a specific experiment. The researchers targeted a heat resistant organism *Salmonella* Senftenberg. They incorporated it in a cocktail of four other *Salmonella* strains to mimic a worst case scenario contamination event (Brashears et al., 2015).

Determination of D- and z-Values: D-values were determined for 140, 149, 158, and 167°F and z-values calculated using a statistical model (Brashears et al., 2015).

### Lethality Performance Standard

Establishing the maximum load of *Salmonella* in raw material product is an important step in effective mitigation. The target $\log_{10}$ reduction for a given matrix should be statically calculated and universally recognized. This target $\log_{10}$ reduction is commonly referred to as the "Lethality Performance Standard." In many cases, the FDA and/or UDSA have determined "Lethality Performance Standards" for human food matrices. Two examples include ready-to-eat poultry and ready-to-eat beef products. The "Lethality Performance Standard" for *Salmonella* in ready-to-eat poultry products is a 7.0 $\log_{10}$ reduction, whereas ready-to-eat beef products require a 6.5 $\log_{10}$ reduction (FSIS, 1998).

The approach USDA/FSIS took for defining "Lethality Performance Standards" for *Salmonella* in ready-to-eat beef products was to define a "worst case" Salmonella contamination for raw beef material and calculate the probability distribution for the number of surviving *Salmonella* organisms in 100 grams of finished product for various specific lethality reductions (FSIS, 1998).

It is assumed that the FDA will recognize a "Lethality Performance Standard" for *Salmonella* of 7.0 $\log_{10}$ reduction for raw beef materials used in rendering; however, a 9.0 $\log_{10}$ reduction is included in the parameters identified below.

### Parameters

Process controls must include, as appropriate, parameters associated with control of the hazard and the maximum or minimum value to which any biological parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

Using the D- and z-values calculated by Texas Tech University (Brashears et al., 2015) and a thermal lethality model developed by the American Meat Institute (AMI, 2013), the authors of this white paper have calculated specific time and temperature parameters to obtain lethality of *Salmonella* in raw beef products used in rendering operations. These data are intended to establish the proper parameters for thermal processing steps to be used as preventive controls in rendering. These calculations are based on the most current information available to the rendering industry and should only be applied to raw beef products for control of *Salmonella*.

In order to monitor the implementation of process controls, the use and proper placement of parameter monitoring devices should be considered. Monitoring devices should be placed in the coldest area of the preventive control to ensure proper temperature is achieved. Furthermore, verification of monitoring devices is recommended to ensure that the monitoring devices are accurate.

**Table 1. Established time and temperature parameters to achieve a 7.0 or 9.0 $\log_{10}$ reduction of *Salmonella* in raw beef materials presented for rendering.**

| 7.0 $\log_{10}$ Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 167 | 75 | 99.5 | 1.66 |
| 176 | 80 | 74.0 | 1.23 |
| 185 | 85 | 54.9 | 0.92 |
| 194 | 90 | 40.8 | 0.68 |
| 203 | 95 | 30.2 | 0.50 |
| 212 | 100 | 22.4 | 0.37 |
| 221 | 105 | 16.6 | 0.28 |
| 230 | 110 | 12.3 | 0.21 |
| 239 | 115 | 9.2 | 0.15 |
| 248 | 120 | 6.8 | 0.11 |
| 257 | 125 | 5.0 | 0.08 |
| 266 | 130 | 3.7 | 0.06 |

| 9.0 $\log_{10}$ Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 167 | 75 | 128.0 | 2.13 |
| 176 | 80 | 95.0 | 1.58 |
| 185 | 85 | 70.5 | 1.18 |
| 194 | 90 | 52.3 | 0.87 |
| 203 | 95 | 38.8 | 0.65 |
| 212 | 100 | 28.8 | 0.48 |
| 221 | 105 | 21.4 | 0.36 |
| 230 | 110 | 15.9 | 0.26 |
| 239 | 115 | 11.8 | 0.20 |
| 248 | 120 | 8.7 | 0.15 |
| 257 | 125 | 6.5 | 0.11 |
| 266 | 130 | 4.8 | 0.08 |

*Columns one and two are the minimum internal temperatures in Fahrenheit or Celsius that is required to obtain a 7.0 or 9.0 $\log_{10}$ reduction, respectively. Columns three and four are the minimum processing times in seconds or minutes after minimum temperature is reached. Calculations were performed using the following: reference temperature of 75 °C; z-value of 38.61 °C, and; D-value of 2.37 °C* (Brashears et al., 2015).

# Industry White Paper

# Thermal Parameters for Raw Poultry Materials Utilized in Rendering

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The purpose of this industry white paper is to calculate specific cooking time and temperature standards for raw poultry materials utilized by the rendering industry. These standards were calculated based on results provided by a study conducted by the Departments of Animal Science and Poultry Science at Texas A&M University (Taylor et al., 2015). The objective of the study was to determine D- and z-values for high-risk raw poultry materials using a well-known heat resistant microorganism, *Salmonella* Senftenberg. The D- and z-values generated from this study were used to calculate specific time and temperature combinations sufficient to achieve a 7-$\log_{10}$ or 9-$\log_{10}$ reduction of *Salmonella* Senftenberg. This white paper may be used as supporting evidence that thermal processes may be utilized as a preventive control for *Salmonella* in raw poultry materials processed in the rendering Industry. It is also meant to assist facilities during the develop of their animal food safety plan by targeting appropriate processing parameters for implementing thermal processing preventive controls.

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## Background

According to the FDA Food Safety Modernization Act (FSMA), the Preventive Controls for Animal Food rule section 21 C.F.R. §507.47 indicates all facilities that use a thermal processing step as a preventive control to control biological hazards must validate its control unless the preventive controls qualified individual prepares written justification that validation is not applicable. One method to validate a thermal treatment is to use scientific evidence to demonstrate that the preventive control is capable of significantly minimizing or preventing a hazard (FDA, 2015).

D- and z-values are commonly used to establish parameters for thermal processes that control biological hazards in a variety of human food products. The advantage of utilizing D- and z-values is that they can be universally applied to many heating processes regardless of the size, output, or design of the cooking apparatus. These values are specific to the raw material matrix and the target organism. They can be used to calculate time and temperature combinations that sufficiently achieve a specific lethality performance standard. The lethality performance standard is also referred to as a $\log_{10}$ reduction which would be specific to the raw material matrix.

## Study Design

Raw Material Matrix: D- and z-values are specific to the raw material matrix because the heat resistance of *Salmonella* is influenced by the environment it is exposed to. The researchers at Texas A&M University targeted a worst case scenario product and formulated a matrix that best protected *Salmonella* cells during the heating process. *Salmonella* cells survive heat treatment best in low moisture/high fat materials so the target was a high fat matrix containing lower than typical moisture levels. In theory, values generated by using this worst case scenario product would be sufficient for all raw poultry materials used by the rendering industry (Taylor et al., 2015).

*Salmonella* Strain Selection: D- and z-values are specific to the bacteria strains used in a specific experiment. The researchers targeted a heat resistant organism *Salmonella* Senftenberg. They incorporated it in a cocktail of two other *Salmonella* strains to mimic a worst case scenario contamination event (Taylor et al., 2015).

Determination of D- and z-Values: D-values were determined for 150, 155, and 160°F and z-values calculated using a statistical model (Taylor et al., 2015).

## Lethality Performance Standard

Establishing the maximum load of *Salmonella* in raw material product is an important step in effective mitigation. The target $log_{10}$ reduction for a given matrix should be statically calculated and universally recognized. This target $log_{10}$ reduction is commonly referred to as the "Lethality Performance Standard." In many cases, the FDA and/or UDSA have determined "Lethality Performance Standards" for human food matrices. Two examples include ready-to-eat poultry and ready-to-eat beef products. The "Lethality Performance Standard" for *Salmonella* in ready-to-eat poultry products is a 7.0 $log_{10}$ reduction, whereas ready-to-eat beef products require a 6.5 $log_{10}$ reduction (FSIS, 1998).

The approach USDA/FSIS took for defining "Lethality Performance Standards" for *Salmonella* in ready-to-eat beef products was to define a "worst case" Salmonella contamination for raw beef material and calculate the probability distribution for the number of surviving *Salmonella* organisms in 100 grams of finished product for various specific lethality reductions (FSIS, 1998).

It is assumed that the FDA will recognize a "Lethality Performance Standard" for *Salmonella* of 7.0 $log_{10}$ reduction for raw poultry materials used in rendering; however, a 9.0 $log_{10}$ reduction is included in the parameters identified below.

## Parameters

Process controls must include, as appropriate, parameters associated with control of the hazard and the maximum or minimum value to which any biological parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

Using the D- and z-values calculated by Texas A&M University (Taylor et al., 2015) and a thermal lethality model developed by the American Meat Institute (AMI, 2013), the authors of this white paper have calculated specific time and temperature parameters to obtain lethality of *Salmonella* in raw poultry products used in rendering operations. These data are intended to establish the proper parameters for thermal processing steps to be used as preventive controls in rendering. These calculations are based on the most current information available to the rendering industry and should only be applied to raw poultry products for control of *Salmonella*.

In order to monitor the implementation of process controls, the use and proper placement of parameter monitoring devices should be considered. Monitoring devices should be placed in the coldest area of the preventive control to ensure proper temperature is achieved. Furthermore, verification of monitoring devices is recommended to ensure that the monitoring devices are accurate.

**Table 1. Established time and temperature parameters to achieve a 7.0 or 9.0 $log_{10}$ reduction of *Salmonella* in raw poultry materials presented for rendering.**

| 7.0 log Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 150 | 66 | 106.6 | 1.78 |
| 155 | 68 | 72.2 | 1.20 |
| 160 | 71 | 36.1 | 0.60 |
| 165 | 74 | 21.4 | 0.36 |
| 170 | 77 | 12.7 | 0.21 |
| 175 | 79 | 7.5 | 0.12 |
| 180 | 82 | 4.4 | 0.07 |
| 185 | 85 | 2.6 | 0.04 |
| 190 | 88 | 1.6 | 0.03 |
| 195 | 91 | 0.9 | 0.02 |

| 9.0 log Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 150 | 66 | 137.1 | 2.29 |
| 155 | 68 | 92.9 | 1.55 |
| 160 | 71 | 46.4 | 0.77 |
| 165 | 74 | 27.5 | 0.46 |
| 170 | 77 | 16.3 | 0.27 |
| 175 | 79 | 9.6 | 0.16 |
| 180 | 82 | 5.7 | 0.10 |
| 185 | 85 | 3.4 | 0.06 |
| 190 | 88 | 2.0 | 0.03 |
| 195 | 91 | 1.2 | 0.02 |

*Columns one and two are the minimum internal temperatures in Fahrenheit or Celsius that is required to obtain a 7.0 or 9.0 $log_{10}$ reduction respectively. Columns three and four are the minimum processing times in seconds or minutes after minimum temperature is reached. Calculations were performed using the following: reference temperature of 150 ºF, 155ºF or 160ºF depending on the reference temperature; z-value of 21.948 ºF, and; D-value of 0.254ºF, 0.172ºF or 0.086ºF depending on the reference being calculated* (Taylor et al., 2015).

# Industry White Paper

# Thermal Parameters for Raw Used Cooking Oil (UCO) Utilized in Rendering

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The purpose of this industry white paper is to calculate specific cooking time and temperature standards for raw UCO materials utilized by the rendering industry. These standards were calculated based on results provided by a study conducted by the Department of Animal Sciences at Colorado State University (Woerner et al., 2014). The objective of the study was to determine D- and z-values for raw UCO materials using a well-known heat resistant microorganism, *Salmonella* Senftenberg. The D- and z-values generated from this study were used to calculate specific time and temperature combinations sufficient to achieve a 5-$\log_{10}$ or 7-$\log_{10}$ reduction of *Salmonella* Senftenberg. This white paper may be used as supporting evidence that thermal processes may be utilized as a preventive control for *Salmonella* in raw UCO materials processed in the rendering Industry. It is also meant to assist facilities during the development of their animal food safety plan by targeting appropriate processing parameters for implementing thermal processing preventive controls.

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## Background

According to the FDA Food Safety Modernization Act (FSMA), the Preventive Controls for Animal Food rule section 21 C.F.R. §507.47 indicates all facilities that use a thermal processing step as a preventive control to control biological hazards must validate its control unless the preventive controls qualified individual prepares written justification that validation is not applicable. One method to validate a thermal treatment is to use scientific evidence to demonstrate that the preventive control is capable of significantly minimizing or preventing a hazard (FDA, 2015).

D- and z-values are commonly used to establish parameters for thermal processes that control biological hazards in a variety of human food products. The advantage of utilizing D- and z-values is that they can be universally applied to many heating processes regardless of the size, output, or design of the cooking apparatus. These values are specific to the raw material matrix and the target organism. They can be used to calculate time and temperature combinations that sufficiently achieve a specific lethality performance standard. The lethality performance standard is also referred to as a $\log_{10}$ reduction which would be specific to the raw material matrix.

## Study Design

<u>Raw Material Matrix</u>: D- and z-values are specific to the raw material matrix because the heat resistance of *Salmonella* is influenced by the environment it is exposed to. The researchers at Colorado State University targeted a worst case scenario product and formulated a matrix that best protected *Salmonella* cells during the heating process. *Salmonella* cells survive heat treatment best in low moisture/high fat materials so the target was a high fat matrix containing lower than typical moisture levels. In theory, values generated by using this worst case scenario product would be sufficient for all raw UCO materials used by the rendering industry (Woerner et al., 2014).

<u>*Salmonella* Strain Selection</u>: D- and z-values are specific to the bacteria strains used in a specific experiment. The researchers targeted a heat resistant organism *Salmonella* Senftenberg. They incorporated it in a cocktail of four other *Salmonella* strains to mimic a worst case scenario contamination event (Woerner et al., 2014).

<u>Determination of D- and z-Values</u>: D-values were determined for 62, 71, and 82°C and z-values calculated using a statistical model (Woerner et al., 2014).

### Lethality Performance Standard

Establishing the maximum load of *Salmonella* in raw material product is an important step in effective mitigation. The target $log_{10}$ reduction for a given matrix should be statically calculated and universally recognized. This target $log_{10}$ reduction is commonly referred to as the "Lethality Performance Standard." In many cases, the FDA and/or UDSA have determined "Lethality Performance Standards" for human food matrices. Two examples include ready-to-eat poultry and ready-to-eat beef products. The "Lethality Performance Standard" for *Salmonella* in ready-to-eat poultry products is a 7.0 $log_{10}$ reduction, whereas ready-to-eat beef products require a 6.5 $log_{10}$ reduction (FSIS, 1998).

The approach USDA/FSIS took for defining "Lethality Performance Standards" for *Salmonella* in ready-to-eat beef products was to define a "worst case" Salmonella contamination for raw beef material and calculate the probability distribution for the number of surviving *Salmonella* organisms in 100 grams of finished product for various specific lethality reductions (FSIS, 1998).

It is assumed that the FDA will recognize a "Lethality Performance Standard" for *Salmonella* of 5.0 $log_{10}$ reduction for raw UCO materials used in rendering; however, a 7.0 $log_{10}$ reduction is included in the parameters identified below. Raw UCO is considered to be low risk because it is derived from used, edible fats and oils.

### Parameters

Process controls must include, as appropriate, parameters associated with control of the hazard and the maximum or minimum value to which any biological parameter must be controlled in order to significantly minimize or prevent a hazard requiring a process control.

Using the D- and z-values calculated by Colorado State University (Woerner et al., 2014) and a thermal lethality model developed by the American Meat Institute (AMI, 2013), the authors of this white paper have calculated specific time and temperature parameters to obtain lethality of *Salmonella* in raw UCO products used in rendering operations. These data are intended to establish the proper parameters for thermal processing steps to be used as preventive controls in rendering. These calculations are based on the most current information available to the rendering industry and should only be applied to raw UCO products for the control of *Salmonella*.

In order to monitor the implementation of process controls, the use and proper placement of parameter monitoring devices should be considered. Monitoring devices should be placed in the coldest area of the preventive control to ensure proper temperature is achieved. Furthermore, verification of monitoring devices is recommended to ensure that the monitoring devices are accurate.

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**Table 1. Established time and temperature parameters to achieve a 5.0 or 7.0 $log_{10}$ reduction of *Salmonella* in raw UCO materials presented for rendering.**

| 5.0 log Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 143.6 | 62 | 402.0 | 6.70 |
| 149 | 65 | 259.2 | 4.32 |
| 158 | 70 | 124.5 | 2.08 |
| 167 | 75 | 42.8 | 0.71 |
| 176 | 80 | 28.0 | 0.47 |
| 185 | 85 | 9.3 | 0.16 |
| 194 | 90 | 6.1 | 0.10 |
| 203 | 95 | 4.0 | 0.07 |
| 212 | 100 | 2.6 | 0.04 |

| 7.0 log Reduction | | | |
|---|---|---|---|
| Temp ºF | Temp ºC | Seconds | Minutes |
| 143.6 | 62 | 562.8 | 9.38 |
| 149 | 65 | 362.7 | 6.05 |
| 158 | 70 | 174.5 | 2.91 |
| 167 | 75 | 59.9 | 1.00 |
| 176 | 80 | 39.2 | 0.65 |
| 185 | 85 | 13.0 | 0.22 |
| 194 | 90 | 8.5 | 0.14 |
| 203 | 95 | 5.6 | 0.09 |
| 212 | 100 | 3.7 | 0.06 |

*Columns one and two are the minimum internal temperatures in Fahrenheit or Celsius that is required to obtain a 5.0 or 7.0 $log_{10}$ reduction respectively. Columns three and four are the minimum processing times in seconds or minutes after minimum temperature is reached. Calculations were performed using the following: reference temperature of 62 °C, 71°C or 82°C depending on the temperature calculated; z-value of 15.72 °C or 27.2 °C depending on the reference temperature, and; D-value of 1.34°C, 0.2°C or 0.04°C depending on the reference being calculated* (Woerner et al., 2014).

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