

# Tracking Sheet - Option Used For the Control of *E. Coli O157:H7* in Dry And Semi-dry Fermented Sausage

Instructions:

1. Complete a copy of part I of this form for each dry or semi-dry meat sausage made at the facility.
2. If the formulation/manufacturing processes is being changed as a result of the new requirements, a new label registration will be required. In this case, complete a copy of part II of this form as well; **AND**
3. Attach a copy of the registered label and detailed formulation/processing information which was provided to the labels section at the time of label registration..

<b>PART I</b> - to be completed individually for each dry or semi-dry meat sausage made at the facility					
1. Product name:					
2. Label Registration Number:					
3. Option/process controls currently used for the Control of <i>E. coli O157:H7</i> :					
Option #	Details regarding the Option				
1	Time x Internal Temp. combination is :    ___ ° C / ___ ° F X ___ Minutes				
2	Check off the process method which you are using under this option;				
<input type="checkbox"/>	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
<input type="checkbox"/>	70	21	≥5.0	≤ 55 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	≤ 55 mm	HOLD @ 90°F for ≥6 days
<input type="checkbox"/>	90	32	≤4.6	≤ 55 mm	HEAT (1hr @ 110°F then 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)
<input type="checkbox"/>	90	32	≥5.0	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)
<input type="checkbox"/>	96	36	≤5.0	≤ 55 mm	HEAT (128°F internal product temperature x 60 minutes) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ratio of ≤ 1.6:1)
<input type="checkbox"/>	110	43	≤4.6	≤ 55 mm	HOLD @ 110°F for ≥ 4 days
<input type="checkbox"/>	110	43	≤4.6	56 to 105 mm	HOLD @ 110°F for ≥ 4 days
<input type="checkbox"/>	110	43	≥5.0	56 to 105 mm	HOLD @ 110°F for ≥ 7 days
3	End Product Testing - <b>30 samples from each lot of finished product</b> must be tested for at least <i>E. coli O157:H7</i> and Salmonella				
What laboratory is being used:					

What is the official laboratory method used:

4		Check off the process method which you are using under this option			
√ <input type="checkbox"/>	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
<input type="checkbox"/>	70	21	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	56 to 105 mm	HOLD @ 90°F for 7 days then dry
<input type="checkbox"/>	90	32	≥5.0	56 to 105 mm	HOLD @ 90°F for 7 days then dry
<input type="checkbox"/>	110	43	≥5.0	≤ 55 mm	HOLD @ 110°F for 7 days then dry
<input type="checkbox"/>	110	43	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)

Under this option 15 samples of raw batter must be tested for each lot

What laboratory is being used:

What is the official laboratory method used:

5	Outside validation by a 3 <sup>rd</sup> party
---	---

When/where was the validation test conducted?

Have the testing results been accepted by the Food of Animal Origin Division and/or Food borne Pathogens Unit? YES  NO   
 (Until the results are forwarded and accepted, the operator cannot use them to justify manufacturing product under either Option 2 or 4)

What is the D reduction achieved?

If the reduction is less than 5D, 15 samples of raw batter must be tested for each lot;

What laboratory is being used:

What is the official laboratory method used:

PART II - To be completed if a change to the process is being made and the label is being re-submitted in order to register the new process.

1. Product name:
2. Previous Label Registration Number:
Date of label (re)submission:

Which option is being proposed for the control of E. coli O157:H7  
(indicate the option on the label submission request as well. Ensure that you also provide the following information for the option which you have selected.)

Option #	Details regarding the Option
1	Time x Internal Temp. combination is :    ___ ° C / ___ ° F X ___ Minutes
2	Check off the process method which you are using under this option;

√ <input type="checkbox"/>	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
<input type="checkbox"/>	70	21	≥5.0	≤ 55 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	≤ 55 mm	HOLD @ 90°F for ≥6 days
<input type="checkbox"/>	90	32	≤4.6	≤ 55 mm	HEAT (1hr @ 110°F then 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)
<input type="checkbox"/>	90	32	≥5.0	56 to 105 mm	HEAT (1hr @100°, 1hr @110°F, 1hr @120°F, then 7hrs @ 125°F)
<input type="checkbox"/>	96	36	≤5.0	≤ 55 mm	HEAT (128°F internal product temperature x 60 minutes) and DRY (at 55°F and 65% Relative Humidity to a Moisture Protein Ratio of ≤ 1.6:1)
<input type="checkbox"/>	110	43	≤4.6	≤ 55 mm	HOLD @ 110°F for ≥ 4 days
<input type="checkbox"/>	110	43	≤4.6	56 to 105 mm	HOLD @ 110°F for ≥ 4 days
<input type="checkbox"/>	110	43	≥5.0	56 to 105 mm	HOLD @ 110°F for ≥ 7 days

<b>3</b>	End Product Testing - <b>30 samples from each lot of finished product</b> must be tested for at least <b>E. coli O157:H7 and Salmonella</b>
----------	---

What laboratory is being used:
What is the official laboratory method used:

4		Check off the process method which you are using under this option			
√ <input type="checkbox"/>	Fermentation chamber temperature		pH at the end of fermentation process	Casing diameter	Subsequent process (dry, hold or cook)
	°F	°C			
<input type="checkbox"/>	70	21	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
<input type="checkbox"/>	90	32	≤4.6	56 to 105 mm	HOLD @ 90°F for 7 days then dry
<input type="checkbox"/>	90	32	≥5.0	56 to 105 mm	HOLD @ 90°F for 7 days then dry
<input type="checkbox"/>	110	43	≥5.0	≤ 55 mm	HOLD @ 110°F for 7 days then dry
<input type="checkbox"/>	110	43	≥5.0	56 to 105 mm	HEAT (1hr @ 110°F and 6 hrs @ 125°F)
<p><u>Under this option 15 samples of raw batter must be tested for each lot</u></p> <p>What laboratory is being used:</p> <p>What is the official laboratory method used:</p>					
5		Outside validation			
When/where was the validation test conducted?					
<p>Have the testing results been accepted by the Food of Animal Origin Division and/or Food borne Pathogens Unit? YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>(Until the results are forwarded and accepted, the operator cannot use them to justify manufacturing product under either Option 2 or 4)</p>					
What is the D reduction achieved?					
<p><u>If the reduction is less than 5D, 15 samples of raw batter must be tested for each lot:</u></p> <p>What laboratory is being used:</p> <p>What is the official laboratory method used:</p>					