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## Process Validation: An Essential Step in Establishing a Rendering HACCP System

Rendering processes in Europe are approved in accordance with strict hygiene principles that use hazard analysis and critical control point (HACCP) systems to deliver the objectives of producing safe products for a wide variety of uses. The principles of HACCP systems are, of course, well known and will not be repeated here. What is not so clear is how some of the critical control points (CCPs) are either established or applied. This article will discuss the main elements that contribute to the HACCP-based approval regime laid down in the European Union (EU) animal by-products regulation (ABPR).<sup>1</sup>

### Process Evaluation

Most of the information about processing parameters used in Europe today originated from research into the inactivation by rendering of bovine spongiform encephalopathy (BSE) and scrapie (transmissible spongiform encephalopathies, or TSEs) conducted in the United Kingdom between 1990 and 1994. The work was well publicized (Taylor et al.<sup>2,3</sup>) and the author was a member of the research and publication teams.

However, as a prelude to the actual TSE inactivation tests, a series of process evaluations were completed to confirm the real process parameters for a range of generic process systems to be evaluated. This preliminary work was necessary to confirm the following for process systems having the characteristics of type (batch or continuous), pressure (atmospheric, above, vacuum), and fat level (defatted, natural fat, added fat). Also, the particle size of raw material was confirmed for each system. Thereafter, the following characteristics were determined for each process under consideration: minimum transit time under normal and maximum throughputs; minimum and maximum times during the transit profile; and the proportion of fat present.

### Processing Profiles

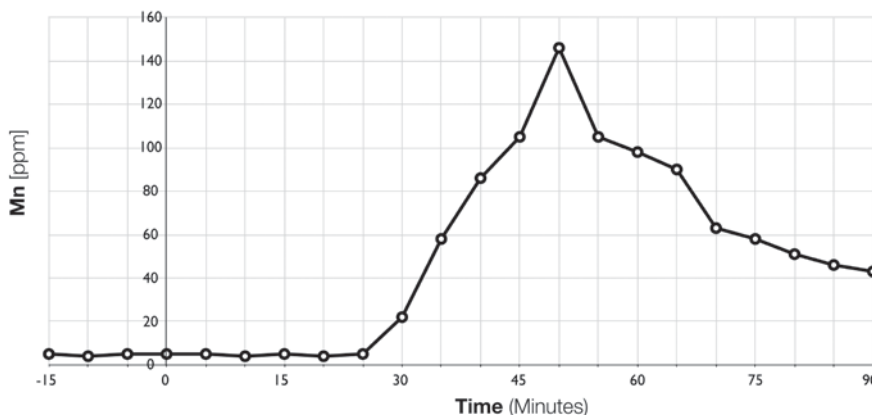
An insoluble marker was developed to be able to determine the minimum residence times in continuous rendering cookers. Manganese dioxide (MnO<sub>2</sub>) was chosen as it is heat stable and can be prepared into a suitable form (as a briquette) for introduction into the rendering process. Importantly, manganese is present in animal by-products at rather low levels and would therefore not interfere with the test itself. Manganese briquettes are prepared by dry mixing of one part Blue Circle's Portland cement with two parts sand and one part industrial grade MnO<sub>2</sub>. Water is added to make a paste that is molded into 30 to 40 millimeter (mm) spheres. The spheres are dusted with powdered

MnO<sub>2</sub> and then heated in oven for approx 18 hours at 100 degrees Celsius (C) to produce the dry MnO<sub>2</sub> briquettes.

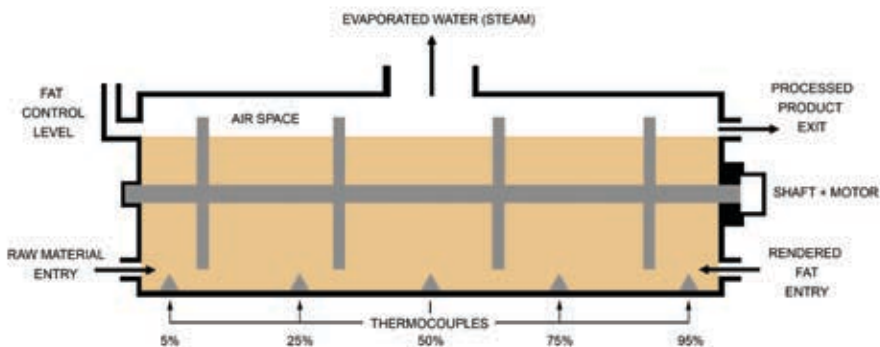
The dry briquettes are approximately the same size as the maximum raw material particle size, and when introduced into the process at the crusher stage will be broken down into smaller particles and even dust. The range of particle sizes produced is considered to represent the typical range of particle sizes passing through a cooker.

For the test itself, some briquettes (approximately two kilograms of briquettes per ton of raw material feed) are introduced as a single batch in a paper bag into the raw material feed as close to the cooker as possible. Samples of cooked material greaves are taken

**Figure 1. Manganese Profile in Continuous Process Operating at 12.5 Tons Per Hour**



**Figure 2. Diagrammatic Representation of a Continuous, Atmospheric, Added Fat System Showing Thermocouple Positions**



at recorded times over a time period, including up to three samples before the briquettes are added to provide a background level. Samples of the material exiting the cooker are sent to a laboratory for analysis of manganese and on receipt of the results a graph can be plotted over a time period. The time taken to detect the first significant traces of manganese (greater than two times the average background level over three consecutive times) provides a measurement of minimum process time, as shown in Figure 1.

With continuous systems, residence time is affected by raw material feed rate, assuming that fat recycle level is constant. To illustrate the different minimum residence times achieved by different raw material feed rates, three examples of different feed rates are shown in Table 1. The information gained here will be applied again later on, but from a practical point of view, the operator will want to choose the maximum feed rate for his plant that can meet the validation criteria. Here a period of trial and error is needed to ascertain the optimum conditions.

### Temperature

Accurately measuring temperature in continuous cookers has been a challenge for engineers, with much of the early work involving trial and error. Eventually, it was decided to use thermocouples housed in sleeves introduced through the wall of the cooker. The design of these units was such that the contact with the temperature of the material being processed was maximized while minimizing the possibility of physical damage or the effect of the steam jacket on the temperature.

To achieve the temperature profile information in the correct format, the thermocouples are placed at positions along the length of the cooker that can be recorded as percent flow along the cooker, starting with the entrance at zero percent and the exit at 100 percent. Ideally, five thermocouples are employed, one close to the entry point, one close to the exit, and the other three spaced along the cooker. Figure 2 shows a diagrammatic representation showing thermocouple position in relation to percent flow. Normally the thermocouples are linked to a data recorder, so continuous measurement records can be kept of both

the validation tests and subsequent day-to-day operations as part of the HACCP system.

The actual temperature profile can now be measured over a period of time. In the example shown in Figure 3, average values are shown in relation to the thermocouple positions. In the actual validation test period, actual temperature values are used to determine the operating criteria.

### Inactivation Experiments

Full details of how the experimental protocols were developed, including a discussion of the preliminary studies,

are available in Woodgate<sup>4</sup> and will not be repeated here. The TSE inactivation studies reported by Taylor et al. were the source of the specific time and temperature conditions that have since been applied to EU rendering systems. These key process parameters are cited in Annex V, Chapter III of the EU ABPR. An example, shown in Table 2, gives the minimum profile for the example system described earlier on: continuous, atmospheric, added fat system (EU Method 4).

This profile can also be represented

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**Table 1. Example of the Relationship Between Raw Material Feed Rate and Minimum Residence Time**

Feed Rate (tons/hour)	Minimum Residence Time (minutes)
10	35
12.5	28
15	22

**Table 2. Continuous, Atmospheric, Added Fat System: Time and Temperature Profile**

Temperature Above	For a Minimum Time of
100°C	16 minutes
110°C	13 minutes (of the 16 minutes)
120°C	8 minutes (of the 16 minutes)
130°C	3 minutes (of the 16 minutes)

**Table 3. Validation Approval Conditions for a Typical Rendering Process in the EU, Including Microbiological Criteria**

Cooker Identity	Cooker No. 4	CCP	Monitoring
Raw material particle size	Maximum 30 mm	1	Daily
Raw material feed rate	Maximum 12.5 tons/hour (setting 6 pump rate)	2	Continuous (daily audit)
Fat addition rate	Not to exceed 3 tons/hour (minimum 50% on level control)	3	Continuous (daily audit)
Exit temperature (thermocouple 5)	Minimum 135°C	4	Continuous – data recorded
Microbiological criteria	Absent: Clostridia, Salmonella Limit: Enterobacteriaceae	5	Dispatch samples

**Table 4. Noncompliance and Corrective Actions**

CCP	Corrective Action
1	Replace any worn anvils or breakers to ensure minimum particle size. Reprocess processed animal proteins (PAP)/meat and bone meal (MBM) produced under noncompliant conditions.
2	Ensure maximum feed rate is not exceeded. (In practice, control with safety margin.) Reprocess PAP/MBM produced under noncompliant conditions.
3	Ensure maximum fat addition rate is not exceeded (control with safety margin).
4	Ensure that exit temperature does not fall below minimum temperature. Establish "action zone." Stop raw material feed if enter action zone and allow temperature to rise before recommencing raw material feed. Reprocess PAP/MBM produced under noncompliant conditions.
5	Noncompliant PAP/MBM produced may be subject to recall and reprocessing.

graphically (Figure 4) showing the minimum temperature and time requirements more clearly. The graph will be required after the validation test to lay over the actual test to check whether the process has achieved the required temperature profile.

### Process Approval

Now that the preliminary work has been completed, the process can be validated to operate at or above the approval standards. The process should be operating at steady state during the test according to the desired conditions of particle size, raw material feed rate, fat recycle rate, and steam pressures to achieve the required temperatures. The key test is the marker flow rate test. The marker test is completed under typical operating conditions that are all recorded for use afterwards. The data recorded is then applied when the results of the manganese marker trials are able to be plotted against time.

Step 1: Determine the minimum residence time under trial conditions (Figure 1).

Step 2: Plot the temperature profile under the trial conditions (Figure 3).

Step 3: Plot temperature profile against minimum residence time (on X axis). For this, zero percent equals two minutes, and 100 percent equals minimum residence time (26 minutes) (Figure 5 blue line).

Step 4: Overlay the red line (from Figure 4) to produce a final graph with two lines (Figure 5).

If the blue line in Figure 5 shows that the temperatures (at the relevant times) exceed the minimum red line temperatures, then the validation test can be regarded as a success. If, however, the blue line does not exceed the red line, the validation test is regarded as a failure. In those circumstances, a repeat is required and normally one or more of the key factors is varied to ensure success. The main parameters altered include raw material feed rate (reduced) or steam pressure (increased) to raise the temperature profile. As a result of a successful validation, the key process criteria associated with that test are set as the CCPs that become central to the approval certificate for that process. A typical validation approval issued by

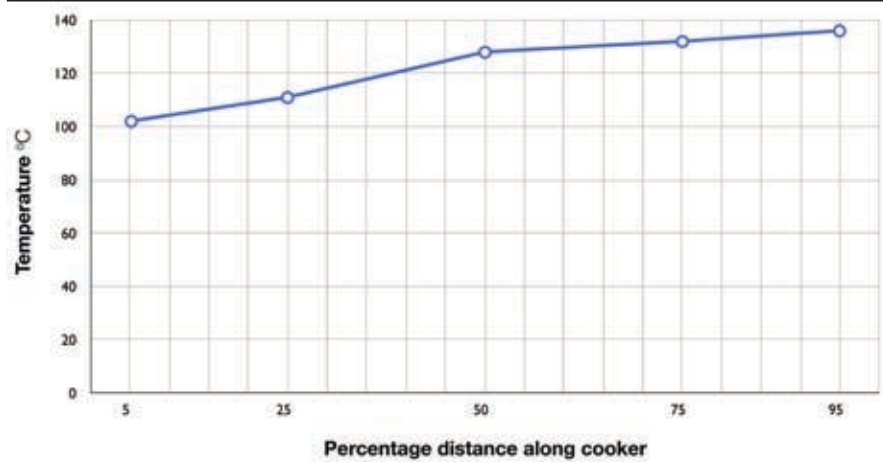
the competent authority is shown in Table 3. Some of the parameters, such as raw material feed rate or fat addition level, are set in practical terms such as pump settings and fat level control respectively.

In addition to the physical validation criteria (steps 1-4 above), microbiological samples are taken at the time of the

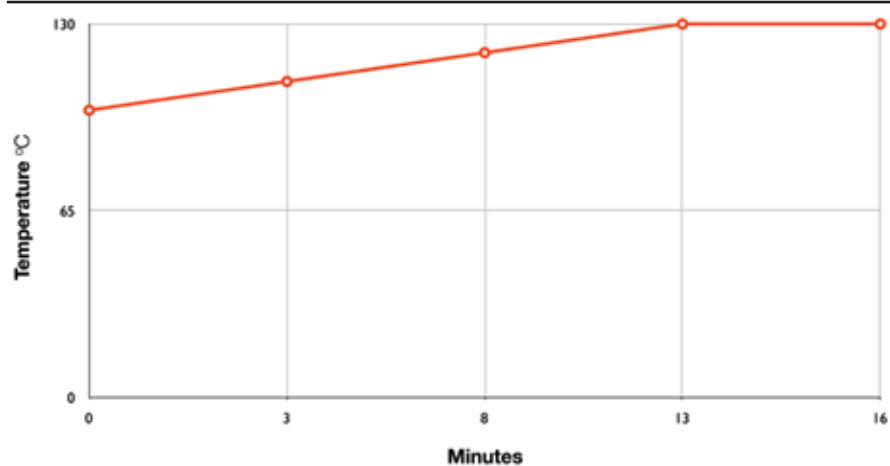
validation test and at other times in accordance with EU rules. Each of these microbiological species are determined on samples produced on an ongoing basis (normally hygiene samples taken “in-house” and official samples taken from dispatch loads).

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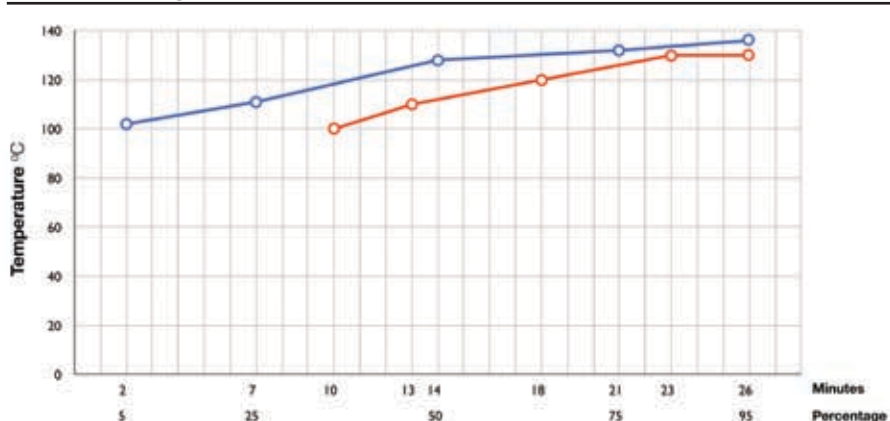
**Figure 3. Temperature Profile in a Continuous, Atmospheric, Added Fat System**



**Figure 4. Temperature Profile Over Minimum Residence Time Period**



**Figure 5. Final Validation Graph Showing Actual Temperatures with the Minimum Requirements**



Of course, when using a HACCP system, it is necessary to lay down the corrective actions following any breach of a CCP. Noncompliance and corrective actions for each CCP are in Table 4.

### **Conclusion**

It is possible to validate a rendering process according to the procedure described and to lay down the CCPs to ensure that the specific validation conditions are met. Following the validation and approval, operation of the plant according to HACCP principles should ensure that the approval standards are continuously met. Revalidations should, in practice, only be required if or when there are significant changes to the process such as a replacement, new cooker unit, or a redesign of the plant layout. **R**

### References

1. Regulation No. 1774/2002. 2002. *Official Journal of the European Communities* 10.10.2002:L273/1.
2. Taylor, D. M., S. L. Woodgate, and M. J. Atkinson. 1995. Inactivation of the bovine spongiform encephalopathy agent by rendering procedures. *Veterinary Record* 137:605-610.
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4. Woodgate, S.L. 1994. Rendering systems and BSE de-activation. *Livestock Production Science* 38:47-50.