Corbion *Listeria* Control Model

Best Practices

Introduction

The Corbion *Listeria* Control Model helps processors to develop Ready-to-Eat meat products and refrigerated foods, by predicting the growth of *Listeria monocytogenes* in specific food matrixes. It has been developed using a data set of over 2500 individual growth curves of statistically-designed experiments and expands upon prior models that have been used successfully for many years by both large and small meat/food companies.

The applicability of a predictive growth model depends on the amount of environmental parameters taken into account. The Corbion *Listeria* Control Model enables you to model growth according to eight food parameters; storage temperature, moisture content, pH, Sodium Chloride, Potassium Chloride, Sodium Nitrite, water activity and Corbion product. The levels of these parameters are based on total product formulation.

Appropriate use of the model increases the relevance of challenge studies and can aid in their design. We advise you to apply the guidelines in this document when using this model. If you have any questions or remarks, feel free to contact Corbion via your local representative or www.corbion.com/contact. Our experts are eager to help you.

About the model results

For a specific set of food characteristics *Listeria* challenge studies show variation at each point in time. Variation in *Listeria* growth is caused by study specific and processor specific situations, such as difference in *Listeria* strains, general production variation and different pre-cultivation methods. This variation can be represented by a normal distribution (Figure 1).

The Corbion *Listeria* Control Model uses the variation of the data set to show a graph with four growth lines -two red lines for the control and two blue lines for the situation after addition of a Corbion product. A grey area surrounds the blue line (Figure 2) visually representing the normal distribution of *Listeria* growth variability. The solid growth curves represent the so-called 'best fit' lines, while the dotted lines are the corresponding 95% lines. The best-fit line, 95% line and the grey area enables a direct comparison between the model's data set and individual *Listeria* challenge tests.

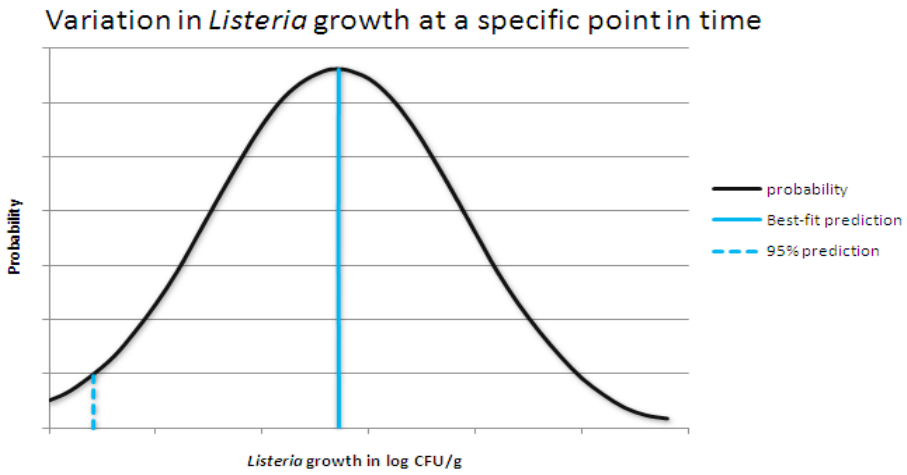

Figure 1

Descriptive image of a normal distribution curve representing variation in Listeria growth. The distribution curve correlates with specific food characteristics observed at a specific point in time.

The Corbion *Listeria* Control Model generates the 'best-fit' line by connecting the most probable *Listeria* counts for every point in time. The best-fit line therefore represents the most probable *Listeria* growth for the specific food characteristics entered into the model (figure 1).

According to the data set, 95% of the growth is expected to be slower than the 95% line. If the model's data represent your situation, you should expect that in 95% of the cases where Listeria is present, growth occurs on the dotted line, or later.

The grey shading which surrounds the best fit line represents 95% of the distribution within the bell shaped curve in Figure 1. It is darkest near the best fit line and lightens as it moves further from the line. The grey area above this best fit line indicates growth more rapidly than the best fit line. Grey shading below the best fit line indicates slower growth then the best fit line. Chances of *Listeria* growth occurring outside the grey area are minimal.

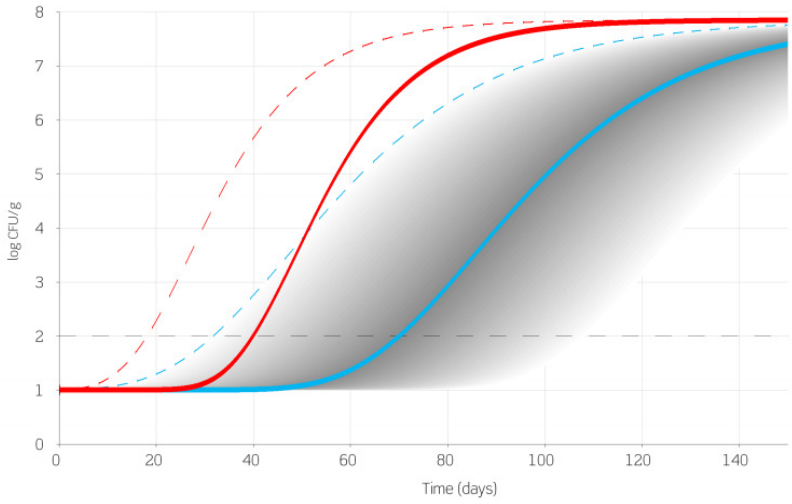

Figure 2
Example of *Listeria* growth graph as shown by the Corbion *Listeria* Control Model.

Determining safety levels

During the process of food product development, safety margins should be incorporated into the product shelf life. The exact size of the margins depends on:

- Company policy regarding shelf life and safety
- Variations between batches of food products
- Your *Listeria* challenge studies
- Local regulations and policy

Company policy regarding shelf life and safety should be determined prior to usage of this model. This includes a corporate guideline of shelf life definition related to safety testing of a product. We advise to include these best practices guidelines into the company policy.

Local regulations and policy should be known prior to product development, and can be used to set a target shelf life and product formulation.

Variations between batches of food products

By taking into account variations between food product batches, 'worst case scenarios' can be simulated wherein *Listeria* growth is highest. The guidelines below describe how to calculate variations and how these should be entered into the model.

Table 1 can be used to simulate minimal inhibition of *Listeria* growth within the variation of a food product.

Table 1
Guidelines to apply measurements of the standard deviation (SD), based on the average (avg) variation. Formulation levels in the model is based on total formulation.

Factor	Enter Value
Growth vs. no growth Allowing higher maximum outgrowth levels increases predicted shelf life, therefore decreasing estimated safety levels.	Consider conditions where no growth (i.e. less than 0.5 log) occurs during the product shelf life.
Temperature Higher storage temperatures promote the growth of *Listeria*. Storage temperature can fluctuate and cannot always be controlled by the food producer.	Enter highest storage temperature found in the distribution chain.
Moisture level Growth will generally be reduced at lower moisture levels, measure to the nearest 0.2%.	avg +2SD
Sodium nitrite levels Growth will generally be reduced at higher nitrite levels. Measure ingoing levels to the nearest 10ppm.	avg -2SD
pH Growth will be reduced at lower pH values, measure to the nearest 0.1 units.	avg +2SD
Salt (NaCl and KCl) Growth will generally be reduced at higher levels, measure to the nearest 0.1%.	avg -2SD
Corbion product Food products have a background level of lactate up to 1.0%. Potential for variation is included in the model calculations. However, it is important to be sure the amounts added to products are accurate.	avg -2SD

An average and standard deviation based on 30 or more different lots of production is desired. A minimum of five to ten values is required to get a representative value of variations.

If no data on variation is available, the cooking yield of a product and the 95% line can function as a measure of variation. The 95% line is a measure of variation of the data set used for the model. This can be held as a substitute when variation in food products are unknown.

Your *Listeria* Challenge Studies

The Corbion *Listeria* Control Model is based on a large amount of data, which does not always represent producer specific situations. On the other hand, a producer's specific *Listeria* screening data sets are less extensive and do not reveal the full variation of your situation. Therefore a balance must be found between the predictions of the model and producer specific data and experience.

The general rule is to start with the model and benchmark the prediction with data and experience. The benchmark can be used to adjust a product formulation in such a way that a more desirable *Listeria* growth is predicted. If your challenge data is consistently close to the best-fit line, you can assume the model's variation is equal to your variation. By using the 95% line, predicted *Listeria* growth is higher, after all: 95% of growth is expected to be slower than the 95% line. Adjusting the product formulation according to this line, results in a product with a higher safety margin.

The choice of using the 95%, the best-fit line or somewhere in between as a benchmark, should be ideally standardized and made by the processor. The consistency and amount of Listeria screening data are important factors to consider: large data sets with consistent results are a good basis for a solid benchmark.

In some cases processor specific situations, such as a difference in *Listeria* strains and different pre-cultivation methods, can cause a difference between your data and LCM prediction. If a structural difference is seen between your own *Listeria* challenge data and the model's results, the model's prediction can be adjusted accordingly.

Using the advanced settings in the model, the lag time can be adjusted in three ways.

- -Calculate a correction factor
- -Set a fixed lag time (in days)
- -Use no lag time

For more information on how to apply these factors, please read the user guidelines (available in the model).

Remarks

Listeria control is a continuous effort utilizing sanitation solutions such as SSOP (Sanitation Standard Operating Procedures) and HACCP programs (Hazard Analysis and Critical Control Points). The Corbion *Listeria* Control Model assists in this effort and can shorten the product development cycle. When applied correctly, Corbion products inhibit *Listeria monocytogenes* growth, but cannot remediate high levels of contamination. Neither this model, nor the use of Corbion solutions should be used in lieu of good sanitation practices!

Corbion cannot be held responsible for the presented results. Use of the model implies you accept the terms and conditions, as set forth on the website of the model. Please go to our website for the terms of agreement.

For further assistance in applying the model, please contact your local Corbion representative.