**Sample Checklist for Retail Establishment Challenge Study for Extended Shelf Life or Holding Outside Temperature Control – Product not to be packaged**

**Section 1.0 – Laboratory Selection**

|  |  |  |
| --- | --- | --- |
| YES | NO | Does laboratory selection meet appropriate criteria from Section 1.0 of NACMCF document? (See Table 1 in the NACMCF document) |

**Section 3.0 – Factors related to tested product**

|  |  |
| --- | --- |
| **Critical Physical Property** | **Range for Product** (indicate NA if not applicable) |
| Water activity (aw) |  |
| pH |  |
| Salt content |  |
| Moisture |  |
| Other (including nitrites or inhibitors): |  |
| **Intended Conditions for Storage** | **Range for Product** (indicate NA if not applicable) |
| Storage temperature |  |
| Storage shelf life |  |
| Shelf life duration during challenge study |  |

|  |  |  |
| --- | --- | --- |
| YES | NO | Was product prepared and tested at intended conditions of use? |

**Section 4.0 – Organism Selection**

**Use Table 2 and Appendix C from NACMCF document to determine answers**

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathogen** **(Expand rows as needed)** | **Growth in the aw of food being tested?** | **Growth in the pH of food being tested?** | **Concern in the food product category?** |
|  | YES | NO | YES | NO | YES | NO |
|  | YES | NO | YES | NO | YES | NO |

**Section 9.0 – Sample Considerations**

|  |  |  |
| --- | --- | --- |
| How many samples were analyzed initially and at required time intervals? \_\_\_\_\_\_\_\_\_\_ | | |
| YES | NO | Was sample replicated as required (2+ for most pathogens, 5+ for *C. botulinum*) |
| YES | NO | Does lab provide sample preparation information that is appropriate for food being tested? |
| YES | NO | Does lab provide information on enumeration of pathogens/measurement of toxins conducted using validated methods in a qualified lab? (NACMCF Appendix A)? |

**Section 10.0 – Duration of Study and Sampling Intervals**

|  |  |  |
| --- | --- | --- |
| YES | NO | Does growth inhibition study provide adequate safety margin for shelf life? |
| YES | NO | Were at least 5 to 7 sampling intervals done during challenge study? |
| Maximum shelf life allowed based on study and safety margin: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

**Section 11.0 – Interpreting Test Results** (note that a product does not support pathogen growth if growth does not exceed the initial inoculum level by the limits listed below throughout the intended shelf life of the product and across replicate trial)

* **Most foodborne pathogens: 1-log increase above the initial inoculum level**
* ***S. aureus*: 3-log increase above the initial inoculum level**
* ***C. botulinum*: No toxin should be detected in the product**

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathogen (Expand rows as needed)** | **Initial Inoculum level (CFU/g)** | **Highest Growth Level (CFU/g)** | **Total Growth (CFU/g)** |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| YES | NO | Do results of study meet PASS/FAIL criteria in Section 11 of NACMCF document? |

|  |
| --- |
| **COMMENTS ON AREAS OF STUDY THAT DO NOT MEET NACMCF CRITERIA (expand rows as needed)** |
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