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| FORM C – FCMS Review Form | |
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| Business Name: |  |
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| Approval Number: |  |
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| Officer: |  |
|  |  |
| Date of Initial Completion: |  |

**PREPARATION AND PREREQUISITE PROGRAMMES**

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| **What evidence is there of management commitment to the FCMS?** |  |
| **What is the scope of the FCMS?**  **Has a linear or modular approach been taken?**  **How many HACCP studies are there?**  **Are all products covered by the FCMS?** |  |
| **Does the FCMS include a documented prerequisite programme?** |  |
| **Does the FCMS include process controls? E.g. master manufacturing instructions, traceability, and product recall.** |  |

**HACCP Step 1: HACCP Team**

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| **Who was on the team?** |  |
| **Are all appropriate disciplines represented?** |  |
| **What is the level of knowledge? (Evidence of training, qualifications, experience, etc)** |  |
| **Do any processes require specialist knowledge?** |  |
| **Has external expertise been sought where necessary?** |  |

**HACCP Steps 2 and 3: Product Description and Intended Use**

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| **Are all products and processes covered by product descriptions?** |  |
| **Has the product been described in safety terms?**  E.g. does it cover composition,  characteristics (e.g. aw, pH), processing (drying, heating, freezing etc.) packaging (e.g. MAP), storage conditions (e.g. chilled, frozen), shelf-life, intended customers and use etc, micro/chemical criteria?  Has the epidemiological history of the product/process been referenced? Have the principle hazards been specified? Have the controlling factors/measures been identified in general terms? |  |

**HACCP Steps 4 and 5: Process Flow Diagram**

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| **Is the process flow diagram (PFD) accurate and adequate?** |  |
| **Has the PFD been verified for accuracy and by whom?**  **How was it verified? Is this documented?** |  |
| **Are inputs, process/storage activities and outputs included in the flow diagram?** (Including Rework).  (The PFD should be verified by ‘walking the line’ during the reality check inspection.) |  |
| **Have CCPs been mapped onto the PFD?** |  |

**HACCP Step 6: Hazard Identification and Analysis**

It is suggested that elements of the PFD are sampled on both an elective and random basis and the officer carries out and documents Step 6 according to the structured approach in the guidance.   
A chart for recording is included at the end of this form.

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| **Have all relevant hazards been identified?**  **Have the hazards been specifically identified by type/source or have they been generalised?**  **What method was used to identify the hazards?**  **Were the contributory factors considered used i.e. P.I.I.M.S/P.I.I.G.S?** |  |
| **How did the team assess the likelihood of occurrence and severity?** (Rating system?) |  |
| **What information sources were utilised?** (e.g. legislation, industry guidance, scientific data, trade associations, own experiments/data) |  |
| **Have appropriate control measures been identified for each hazard?** |  |
| **Will the control measures control the hazards and how was this validated?** |  |

**HACCP Step 7: Determine the Critical Control Points**

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| **How were the CCPs identified?**  By expert judgement?  By the use of a decision tree? (Has the decision tree been used correctly?)  By the use of consultants? |  |
| **Have all necessary CCPs been identified?** |  |
| **Have any controls been incorrectly identified as CCPs?** |  |
| **How are the hazards which are not controlled by CCPs addressed?**  Prerequisites, Operational Prerequisites, Standard Operating Procedures etc. |  |

**HACCP Step 8: ESTABLISH CRITICAL LIMITS (ALL CCPs)**

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| **Have critical limits been established for each CCP?**  How do they differ from operational limits/target levels? |  |
| **How were the critical limits established?**  (Experimental data, legal requirements, literature references, etc)? |  |
| **Are the critical limits realistic, measurable or observable?**  (E.g. time, temperature, pH, aw, visual appearance etc.) |  |
| **What validation exists that the critical limits control the identified hazards?** |  |

**HACCP Step 9: ESTABLISH MONITORING SYSTEM**

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| **Do monitoring procedures cover all CCPs?** |  |
| **Has the reliability of monitoring procedures been assessed where appropriate?** |  |
| **Is monitoring frequent enough to detect loss of control?** |  |
| **Do procedures ensure monitoring equipment calibrated appropriately?** |  |
| **Is monitoring restricted to appropriately identified and trained personnel?**  **Do monitoring procedures specify who/what/when/how?** |  |

**HACCP Step 10: ESTABLISH CORRECTIVE ACTIONS**

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| **Have the corrective actions been properly defined such that control is regained?** |  |
| **Do the corrective actions prevent all non-conforming product entering the food chain?**  (Including production since last satisfactory CCP check if appropriate) |  |
| **Has the authority for corrective action been assigned?**  **Do corrective actions address past, present and future loss of control?** |  |

**HACCP Step 11: VALIDATION, VERIFICATION AND REVIEW PROCEDURE**

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| **How has the HACCP system been validated?**  E.g. process capability studies, product testing etc. |  |
| **What verification procedures are in place?**  E.g. management checks, internal audits, external audits, sampling, calibration etc. |  |
| **Who is responsible for verification?** |  |
| **Are all CCPs covered by the verification programme?** |  |
| **What review arrangements are in place for the HACCP? (All Steps to be considered)** |  |

**HACCP Step 12: ESTABLISH DOCUMENTS AND RECORDS**

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| **Are the FCMS procedures adequately documented?**  E.g. Hazard analysis, CCP determination, CL determination, sampling plans etc. |  |
| **How is the documentation controlled with regard to update and issues, etc.?** |  |
| **Are records adequate to demonstrate that CCPs/OPPs are being effectively monitored and under control (including corrective actions)?** |  |
| **Are validation, verification and review procedures documented?** |  |

**Record of Review**

The FCMS review should be reviewed at each inspection cycle and updated electronically – a record of the review and summary of any changes should be detailed below. In the event of significant changes to the HACCP system a new checklist should be completed.

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| **Date of Review** | **Summary of Amendments** |
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| **END OF FORM** | |