COCOA PROCESSING EXPECTATIONS

	Issued by:	Reviewed by:
Name:	Peter McClure	Dave Lillie
Function:	Food Safety	Global Auditing

TABLE OF CONTENTS

1.0 OBJECTIVE

All facilities which manufacture or handle cocoa beans, cocoa nibs, cocoa liquor, cocoa powder or cocoa butter for Mondelēz International shall have effective processing conditions in place to control the food safety risks.

Additional processing conditions as outlined in other Policy and Standards documents applicable to suppliers. Programs covered in these documents include but are not limited to: Good Manufacturing Practices (GMPs), Hazard Analysis and Critical Control Points (HACCP), Extraneous Matter Management, Infrastructure, Traceability, Allergen Management (if applicable), Pathogen Environment Monitoring, Hygienic Zoning, Calibration.

2.0 PURPOSE

Mondelēz International has identified that *Salmonella* may present a potential biological hazard in incoming raw cocoa beans. Thermal processing can be an effective control mechanism. To be effective, the process must consistently deliver a minimum degree of lethality.

3.0 SCOPE

The cocoa processing expectations apply globally to all suppliers/external manufacturers supplying processed cocoa products to any Mondelēz International processing facility. This document addresses the minimum requirements expected. This document is based on current knowledge with respect to ensuring food safety by processing and handling. It will be amended as necessary when new data are available. In the meantime, this document shall be used to provide examples of processes that would ensure safe products for consumer use.

4.0 RESPONSIBILITY

All facilities supplying processed cocoa products must ensure that instructions are developed, documented, communicated, and followed in order to meet the minimum processing standards outlined by this document. This document is an addendum to Mondelēz International Global Supplier Expectations/External Manufacturer Quality Requirements and Mondelēz International HACCP Standard.

5.0 REQUIREMENTS

5.1 Critical Control Points (CCP)

One of the Critical Control Points (CCP´s) described below in 5.1-A and 5.1-B shall be applied to control biological hazards (*Salmonella*) in raw cocoa beans and nibs.

Critical limits and validation documentation for each process must be on file at the plant with the HACCP plan. Records of thermal process validation and verification activities, including critical limits applied shall be made available to Mondelēz International during audits or upon request. CCP limits must not be changed without consulting Mondelēz International Corporate Quality/Food Safety.

The Mondelēz CCP models applied to raw cocoa beans and nibs, Models 9 and 10 described below, are designed to deliver a minimum 6 log reduction of *Salmonella*. No biological validation is required when these CCP models are validated in place using the critical limits outlined below.

In cases where the temperature described in the models below cannot be measured due to equipment design, the process shall be validated to meet the critical limit as follows: contact Mondelēz Food Safety and set up a specific validation study. The study must prove that the equipment will consistently deliver a minimum 6 log reduction of Salmonella. If Salmonella is not used in the validation study (e.g. for safety reasons), a surrogate organism with proven equivalent or higher heat resistance in beans/nibs compared to *Salmonella* may be used. Alternatively, a 2 log total viable count (TVC) reduction in the beans/nibs can be used as the performance criterion, as described below.

The basis for the 2 log TVC reduction target is that during the natural fermentation process used for cocoa beans, the numbers of spore-forming bacteria increase to high levels that survive the subsequent drying process. The microbial load of raw cocoa beans delivered to processing facilities is typically made up with approximately 50% of *Bacillus* spores (Lima *et al*., 2012; Barrile *et al*., 1971). The *D* values of *Bacillus* spores in lower moisture (3-4%) cocoa material are in the range of 6-15 minutes at 120°C (CCFRA, 1998). This heat process would deliver a predicted 3 fold (x3) higher kill of *Salmonella* under the same conditions (HACCP Model 10). Therefore, it can be assumed that a 2 log reduction in TVC will provide a more than adequate process to deliver the minimum 6 log reduction in *Salmonella* and includes a large margin of safety, based on the premise that the predominant microbes making up the TVC will be aerobic spore-forming bacteria.

The parameters used during validation, taking into account variability of critical monitoring devices, will then become the critical limits for that equipment. The monitoring activities will also need to be adjusted to that piece of equipment. All respective data shall be available at the respective plant.

Note: Cocoa bean/nib saturated steam heat treatment is the preferred option for cocoa bean/nib processing.

Note: Moisture of the beans/nibs must be within the specification for the product. When beans/nibs are pre-dried to lower moisture prior to treatment, please contact Mondelēz International Food Safety.

5.1- A. Cocoa bean/nib steam treatment [HACCP Model 9]

CCP ID: Time and Temperature to reduce 6 logs of *Salmonella* Typhimurium*, Salmonella* Enteritidis*, Salmonella* Senftenberg. (Moisture is not part of the CCP as this process uses saturated steam).

Process Step: Steam treatment of cocoa beans/nibs

Hazard: Biological (*Salmonella – various strains based on available data and strains involved in outbreaks related to dry foods*)

Critical Limit: Controllable conditions required to ensure the bean/nib temperature reaches 80°C (176°F) by using saturated steam. The chosen critical parameters must be validated to achieve this temperature.
Note: Technically superheated steam is used for this treatment. i.e. saturated steam pressurized to avoid condensation in the pipes & allow for rapid heat transfer by condensation.

The minimum applicable temperature is 80°C (176**°**F). Time is instantaneous. The device controlling the process is commonly pressure and this correlates directly with temperature.

Monitoring Activity/Frequency: Parameters above shall be monitored and recorded automatically for each batch. The system shall stop the process if the critical limits are not met. Data must be reviewed at a frequency sufficient to demonstrate control.

5.1- B. Cocoa nib heat treatment [HACCP Model 10]

CCP ID: Time, temperature and moisture to reduce 6 logs of *Salmonella* Eastbourne and *Salmonella* Napoli. Moisture is part of the CCP as the process does not use saturated steam.

Process Step: Heat treatment of cocoa nibs

Hazard: Biological (*Salmonella – strains involved in outbreaks related to dry products, chocolate*)

Critical Limit:

Time/Temperature/Moisture as follows:

If moisture 1.0 - 2.5 %, then:		If moisture above 2.5%, then:	
Min. Temperature	Min. Time	Min. Temperature	Min. Time
120°C (248°F)	11.70 min.	110°C (230°F)	4.40 min.
130°C (266°F)	4.93 min.	120°C (248°F)	2.04 min.
140°C (284°F)	2.08 min.	125°C (257°F)	1.39 min.
		130°C (266°F)	0.95 min.
		140°C (284°F)	0.44 min.
z = 26.67 C^o (48.08 F^o)		z = 30.03 C^o (54.06 F^o)	

(lowest applicable temperature is 90°C/194°F)

Note: Applicable moisture refers to the level (%) after roasting/alkalization, before cooling/water removal and discharge, once the CCP limit is met.

Equivalent time/temperature parameters can be calculated using z values and cumulative lethality may be applied above the minimum temperatures specified

5.2 Monitoring Activity/Frequency:

Temperature – Batch systems: Critical product temperature, at the coldest point or measured in a location representative of the entire batch, is recorded to a permanent record such as a temperature chart or a digital recording device.
Temperature readings can be manually recorded, provided the system has the following:

- an alarm set at the critical limit;
- the start and end times of the holding period are noted;
- a correction to the hold time is made in case the temperature drops below the critical limit.

Temperature – Continuous systems: Temperature shall be recorded to a continuous record, such as a temperature chart or a digital recording device. The recording frequency depends on the speed at which the process variable changes, the monitoring frequency, and the robustness of the control system particularly if there are automatic alarms and reactions to alarms.

Temperature (processes with holding tube): Temperature of the product at the end of the holding tube* shall be continuously recorded on a temperature chart. If the required holding time is instantaneous (0.5 seconds or less), then the temperature sensor can be located after the heat exchanger.
*If the holding tube is heated, the temperature shall be recorded at the coldest spot of the tube.

Time (continuous process):
If time is not directly measured but expressed as flow rate, a verified correlation shall be available to correlate time to that measurement (e.g. minutes to volume). The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP plan.
Flow rate setting shall be recorded and checked at the beginning of the process run, at the start-up of each shift, after adjustments and at the end of the run in case of changeover or it is technically not possible to exceed the time requirements (this must be documented).

Moisture: There are two ways to verify the appropriate moisture content for effective pathogen reduction in cocoa nib heat treatment:

1. Water addition (volume) is measured and recorded for each batch, or
2. Moisture is measured at the end of the heating process, at a minimum frequency of once per shift.

When using option 1, the moisture of the nibs at the exit of the roaster must be measured during the validation study in order to determine which set of temperature/time parameters will be used for processing.

Note: The correlation of worst case processing conditions (minimum water addition and maximum weight of nibs) vs. moisture of nibs at the end of the heating process (roasting/alkalization) must be documented and filed with the HACCP plan. The correct water-to-product ratio must be applied to ensure that the water is above a minimum level and product below a maximum load, so that it is consistent with the ratio used in the validation study.

5.3 Corrective Action Activity

Under processed product shall be automatically diverted and/or reprocessed to meet critical limit conditions or product shall be identified, placed on Category I hold and further actions agreed or product will be discarded. Equipment/pipework that has been utilised to produce/handle these under processed products after the thermal process must be cleaned and disinfected before resuming adequate processing. The system divert shall be reflected by the frequency pen marking on the temperature chart or documented on digital recording device.

In cases where deviations from critical limits are detected during a record review, after finished product is produced, all affected product shall be placed on hold to prevent release and the designated Mondelēz International Function contact shall be notified to determine disposition. Hold & Release documentation is required.

5.4 Monitoring and Corrective Action Responsibility

Designated trained employee.

5.5 Record Location

All records must have a designated location. Examples of records include temperature charts and calibration log, Hold and Release Records, Corrective Action Records, Validation and Verification Records, Traceability Records, Moisture Measurements or Water Added and Maximum Weight of Nibs.

5.6 Minimum CCP Verification Activities

Processing records must be initially reviewed and signed by the attending technician, and countersigned by a designated and trained employee at least daily or prior to release of product to Mondelez International.

Regular verifications are required to show that the critical limits from the validation are met and that the system has not changed.

5.7 HACCP Plan Verification Activities

Examples of HACCP Plan Verification Activities include:

A. A designated plant employee review records daily or prior to release of product to Mondelez International;
B. Alarm operation must be verified at a frequency sufficient to demonstrate control;
C. Verification of the diversion system shall be done daily: verify that the divert valve opens path to divert material when critical limit is reached and verify that divert valve remains open until the minimum critical limit is reached;
D. All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control, as outlined in SQE/EMQR;
E. The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP plan;
F. Comparison of temperature readings from the heating vessel, from temperature probes placed in the heating vessel or in product, with readings obtained during the validation at a minimum frequency of every two years, to verify that temperatures achieved in the heating system match with temperatures measured during the validation, using the same volume of nibs/beans as used in the validation.

6.0 PROCESS VALIDATION

6.1 Introduction

A validation study shall be performed to demonstrate that, under particular controlled conditions, the process will consistently deliver the minimum lethality needed to effectively control *Salmonella* on the incoming raw cocoa beans/nibs. The minimum lethality required by Mondelēz International is six logs reduction of *Salmonella*.

The validation should include the review of historical microbiological data (if available).

6.2 Study Requirements

A process validation study is used to determine whether cocoa bean/nib processing can consistently deliver a process adequate to reduce six logs of *Salmonella*.

There are also situations where a re-validation is required:

- When there is a system failure resulting in process deviations that cannot be identified;
- Whenever there is a change in the design of the processing equipment or conditions used - only that part of the system affected by the change needs to be re-validated – this includes where nib moisture content is lower than specified e.g. through pre-drying;
- Where Mondelēz International updates the target organism or log reduction target required, based on new information.

A checklist has been attached to provide minimum requirements for validation study reports. Validation reports shall be available for review.

The critical parameters shall be monitored under “worst case” conditions, e.g. lowest zone temperatures, coldest location. Where applicable, temperature profiles are to be collected at various points throughout the process. Temperature profiles shall be collected and reviewed.

A review of the design of the equipment and the heat distribution shall take place, including the location of the probes (e.g. coldest spot), except for Barth roasters, debacterizers, and deodorizers where this is not necessary.

For processes that include water addition, the homogenous distribution of the water must be ensured.

Cumulative lethalities will be calculated from the temperature data, and the cumulative lethalities compared against the critical limits of the appropriate HACCP CCP Model(s).

Three controlled runs shall be conducted for the validation study. The start-up process shall also be defined and validated to ensure critical limits are met.

Note: In cases where time/temperature/moisture cannot be measured due to equipment design, the process shall be validated to meet the critical limit as follows: The validation study shall prove that the equipment will consistently deliver either:

- a 6 log *Salmonella* reduction on cocoa beans/nibs or 6 log reduction of an appropriate surrogate organism (with equivalent or higher heat resistance than *Salmonella* under same conditions of heating), using worst case conditions, and minimum of three controlled runs;

or

- a 2 log TVC reduction of the cocoa beans/nibs. Records of time/temperature/moisture (water added at start and weight of nibs or % moisture at end of roasting/alkalization)/TVC measurements from 30 different batches shall be provided. Verification that mesophilic spores make up a significant % of bacteria present on cocoa beans/nibs shall be carried out on a minimum of 3 batches of these raw materials using a recognised method for enumeration of mesophilic spores.

Recognised methods for enumeration of mesophilic spores include the APHA Compendium of Methods for the Microbiological Examination of Foods (APHA, 2015) and BS 4285-3.3 (1986).

The parameters used during validation will then become the critical limits for that equipment. The monitoring activities will also need to be adjusted to that piece of equipment.
All respective data shall be available at the respective plant.

6.3 Description of the Process

The validation study shall describe:

The process e.g. type and brand of processing equipment, batch vs. continuous, processing conditions, description of zones, type of temperature sensors, location of the temperature sensors, water/steam injection, divert or shutdown features.

6.4 Data Collection

For thermal processes, temperature and humidity data shall be collected using calibrated temperature and humidity measuring sensors.

6.5 Lethality Computation

For thermal processes, *Salmonella* heat resistance values are provided in the respective CCP models of the Mondelēz International HACCP standard.

The following thermal process equation may be used to calculate equivalent time/temperatures (critical limits) when actual temperatures applied are different than those stated in the CCP Models:

$$F = F_R \, 10^{\frac{T_R - T}{z}}$$

T = temperature
F = the time required at actual applied temperature T
F_R = the time required at given T_R i.e. the time/temp. stated in Model CCP
z = the z-value is the increase/decrease in temperature required to decrease/increase time by a factor of 10

Calculation Example: Reference Model CCP: - Cocoa Nib Heat Treatment
Hazard: *Salmonella*

Critical Limit: 120°C for 2.04 min. (moisture above 2.5%)
What is the equivalent time (F) at 130°C?

T = 130°C
F = ?
F_R = 2.04 min. (reference Model CCP)
TR = 120°C (reference Model CCP)
z = 30.03°C (reference Model CCP)

$$F_{at\ 130°C} = 2.04 \times 10^{\frac{120°C - 130°C}{30.03°C}}$$

$$F_{at\ 130°C} = 0.95 \text{ min.}$$

Accumulated lethality values for the run are calculated by summing of the cumulative lethality values measured at each probe.

6.6 Validation Study Report Minimum Content

The following provides guidance on the minimum content of a Validation Study Report:

DESIGN STUDY REPORT MINIMUM CONTENT

☐ **CCP Model (reference to Mondelēz International HACCP Standard) applied:**

Process Description

- Type and brand of equipment (attach diagram), including batch or continuous process
- Processing conditions - variable parameters and fixed parameters
- Heating medium
- Type and location of temperature sensors
- Divert or shutdown features
- Humidity/moisture measuring device
- Product description

☐ **Establishment of Worst Case Conditions - Time** (Continuous Process)

- Describe method and results to determine maximum flow rate and hence minimum residence time (within the selected zone).

☐ **Establishment of Worst Case Conditions - Temperature**

- Describe method and results to determine appropriate location of temperature probes (coldest location).

☐ **Establishment of Worst Case Conditions – Other e.g. moisture, pressure**

- Describe method and results to determine worst case for any other parameters identified as necessary for monitoring.

☐ **Process Capability Study**

- Set target parameters to ensure process variability remains above critical limit (6 log reduction) supported by Engineering

☐ **Corrective Action**

- Describe corrective action design features (e.g. alarm, automated divert or shutdown) and the parameters which trigger them.

☐ **Adequacy of Start Up for Continuous Process**

- Describe assessment of start-up process to demonstrate at least a 6 log reduction is achieved during the start-up phase - confirm the process is documented, complete and available on-site, and records monitoring start up conditions are available.

☐ **Monitoring Records**

- Attach examples (completed) of monitoring records (log sheets) and calculated log reduction to demonstrate actual practices are in line with design assessment.

7.0 PREVENTION OF CROSS CONTAMINATION (SPECIFIC REQUIREMENTS)

The facility must maintain hygienic zoning practices in place to ensure separation of processed and unprocessed cocoa products to mitigate the potential for cross contamination. Dedicated and separated storage areas must be maintained when a processing step is maintained as a CCP to mitigate microbiological contamination.

The following barriers are expected to be found in a cocoa facility:

- Structural separation of the area by design (e.g. separate building, by physical barriers and compartmenting) or use of closed systems (e.g. tanks and pipes),
- Well defined and controlled traffic patterns of people, materials and equipment (e.g. movement of equipment, internal transport etc.)
- Traffic restriction shall be in place between areas with processed material and non-processed material, e.g. sluice with hand washing and sanitation device.
- Appropriate air filtration and air flow controls.
- Separate drains or drains that do not flow into production areas where processed materials are being handled.

7.1 Air Requirements

Please reference relevant Mondelēz Policy and Standards documents relevant to suppliers to determine appropriate air quality standards.

- No air filtration is required in raw area.
- In general, raw area shall have negative air pressure in relation to controlled area. The source of air for plant and product cooling shall not come from raw area.
- Relative room pressure shall either be positive (to prevent ingress of microorganisms from raw area) or neutral in relation to adjacent areas where a contamination by air is unlikely to occur. Where there is positive air pressure in the controlled area, the air flow shall be monitored at a frequency to demonstrate control e.g. monthly.
- When adequate air filtration is installed in the controlled area, air sampling is not required.

7.2 Water Requirements

In addition to the water testing program described in the relevant Policy and Standards documents, cocoa processing facilities shall perform tests for *Salmonella* on recirculated water circuits as part of their corrective actions if APC and coliform values are out of standard. Sample size shall be 900ml total. Additional corrective actions must be taken in case positive results are found.

8.0 PATHOGEN ENVIRONMENTAL MONITORING (please refer to SQE or EMQR)

All facilities that process cocoa products must have an effective program for pathogen environmental monitoring to verify the effectiveness of controls for preventing cross-contamination. Please refer to the SQE or EMQR for a general description of the pathogen environmental monitoring program.

In general, pathogen environmental monitoring must be conducted in the processed zones where processed product is exposed to the environment. Swabs shall be taken from non-product contact surfaces including floors, drains, wheels/legs of equipment, control panels, equipment exterior, etc.

9.0 INCOMING RAW MATERIAL

Products and ingredients used in products will meet the specifications prescribed by Mondelēz International. It is expected that cocoa beans/nibs/butter are tested for their quality on a regular basis, according to local legislation.

10.0 SPECIAL CASES

<u>De-odorization of cocoa butter</u>
Based on published literature (Krapf and Gantenbein-Demarchi, 2010) *Salmonella* is less heat resistant in cocoa butter compared with cocoa mass. Therefore, the model “cocoa nib heat treatment” applying moisture values >1% is used for de-odorization, thereby adding an additional safety margin.

Appendix A - REFERENCE DOCUMENTS

Supplier Quality Expectations (SQE)
External Manufacturer Quality Requirements (EMQR)
Supplier HACCP Standard

Appendix B - SCIENTIFIC BASIS AND REFERENCES

- Leatherhead Food Research Association. 1990. Effect of moisture level on the heat resistance of *Salmonella* in cocoa liquor, Research Report No. 666, April 1990.

Note: Since the critical limits are based on a cocoa liquor study it could also be used for heat treatment of cocoa liquor. However, based on the fact that this heat treatment is more difficult to control, it is not recommended to be used.

- American Public Health Association (APHA) 2015 Compendium of Methods for the Microbiological Examination of Foods, section 8, Mesophilic Aerobic Plate Count.. https://ajph.aphapublications.org/doi/book/10.2105/MBEF.0222
- Barrile, J.C., Ostovar, K. and Keeney, P.G. 1971 Microflora of cocoa beans before and after roasting at 150°C, J. Milk Food Technol., 34, 369-371.
- BS 4285 1986 Microbiological examination for dairy purposes. Part 3 Methods for detection and/or enumeration of specific groups of microorganisms. Section 3.3 Enumeration of aerobic bacterial spores
- Campden Food and Drink Research Association (CFDRA) 1992. Food Pasteurization Treatments. Technical Manual No. 27, April 1992.
- Campden Food Research Association (CFRA) study “Determination of the heat resistance of *Bacillus* spp. in Cocoa mass” October 1998.
- Doyle, M.E. and Mazzotta, A.S. (2000) “Review of studies on the thermal resistance of salmonellae”, J. Food Prot. 63 (6): 779.
- KJS Memo sent out 21.12.98 from N. Becsey, U. Dreier, F. Kley
- Krapf, T. and Gantenbein-Demarchi, C. (2010) Thermal inactivation of *Salmonella* spp. during conching. LWT – Food Science and Technology 43: 720-723
- Lima, J.R., van der Velpen, V., Wolkers-Rooljackers, J., Kamphuls, H.J., Zwietering, M.H. and Nout, M.J.R 2012 Microbiota dynamics and diversity at different stages of industrial processing of cocoa beans into cocoa powder. Appl. Env. Microbiol., 78 (8), 2904-2913.
- Ch. Stehli, C. Gantenbein-Demarchi, K. Benz (2002) Lebensmitteltechnologie 35 (Nr. 7-8): 258pp. „Sporeninaktivierung auf Kakaobohnen“
- Steam Information by Spirax Sarco

Note: In confectionery products *Salmonella* has been recognized as main pathogen of concern. (ICMSF “Microorganisms in Food 2: Sampling for Microbiological Analysis”2nd edition, 1986)

Appendix C - CONTACT INFORMATION

Mondelēz International
Food Safety,
Linden 4, Bournville Place,
Bournville,

Birmingham,
West Midlands,
UK
Phone: + 44 7824 550360

Revision Log:		
Date Revised:	**Supersedes:**	**Summary of Revision:**
16 APR 14	16 DEC 13	Added watermark, CCP (Chapter 5): added preferred processing option, Chapter 7.1 referenced SQE / EMQR for air filtration
19 FEB 19	16 APR 14	Removed reference to SQE and EMQR in section 1 due to changes in One Quality system. Added that 6 log reduction in *Salmonella* is primary target earlier in CCP section and also added on use of a suitable surrogate for validation. Added basis for 2 log reduction, where sporeformers are considered to be the dominant forms present on raw cocoa beans and reference for this basis. Added references for 2 log TVC reduction. Clarified when moisture measurements must be made and options for this. Added frequency for heating system temperature measurement verifications. Added scenarios where re-validation is required. Added requirement to monitor air flow when controlled area is under positive pressure