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<b>Document Number</b>	QR2018
<b>Document Title</b>	Quality Report Cornflake production line 1
<b>Project Name</b>	Customer complaint Review
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## 1.0 Executive Summary

The purpose of this report is to document the results of the Engineering Study completed in order to assess the potential causes of customer complaint CAPA1261 for incorrect weights in Cornflake boxes coming from production lines 1, 2 & 3 in Business Unit1.

### 1.1 Process Parameters Established

**Table 1: Process Parameters Established**

Parameter	Products in scope	Operational Settings		
		Min	Nominal	Max
Weight	Cornflakes	N/A	500	N/A

## 2.0 References

### 2.1 Document References

**Table 2: Document References**

Document Number	Title
SOP1234	Validation Policy
SOP2111	CAPA Policy

### 2.2 Acronyms/Abbreviations/Definitions

**Table 3: Acronyms/Abbreviations/Definitions**

Acronyms/Abbreviations	Description
SOP	Standard Operating Procedure
CAPA	Corrective Action Preventative Action
Variable Data	Quantitative data e.g. weight, pressure, time, temperature
Minitab	Statistics Package
Process Capability	A measure of a process's ability to consistently deliver a product or service within the stated specifications

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### 3.0 Process Description

Currently cornflakes are manufactured from production lines 1, 2 & 3 in Business Unit1.The weighing process is validated and operating parameter used is target weight of 500g.

### 4.0 Scope

The scope is the weighing process used when filling cornflakes into boxes production lines 1, 2 & 3 in Business Unit1.

### 5.0 Objectives

The objectives of the study involved reviewing the data from the three most recent batches to determine the most likely potential cause for the complaints. The quality indicator used in cornflake box weight.

#### 5.1 Statistical Tools

The following Statistical tools /graphical analysis from Minitab will be used.

**Table 4: Statistical Trials**

Trial 1	Dot plot on data from each line
Trial 2	Time Series Plot on data from each line
Trial 3	Normality test on data from each line
Trial 4	Display Descriptive Statistics on data from each line
Trial 5	Compare data from the three lines using Boxplot.

#### 5.2 Sample Size Rational

A sample size of 25 boxes from each line was weighed to get variable data as part of the study.

#### 5.3 Sampling Plan

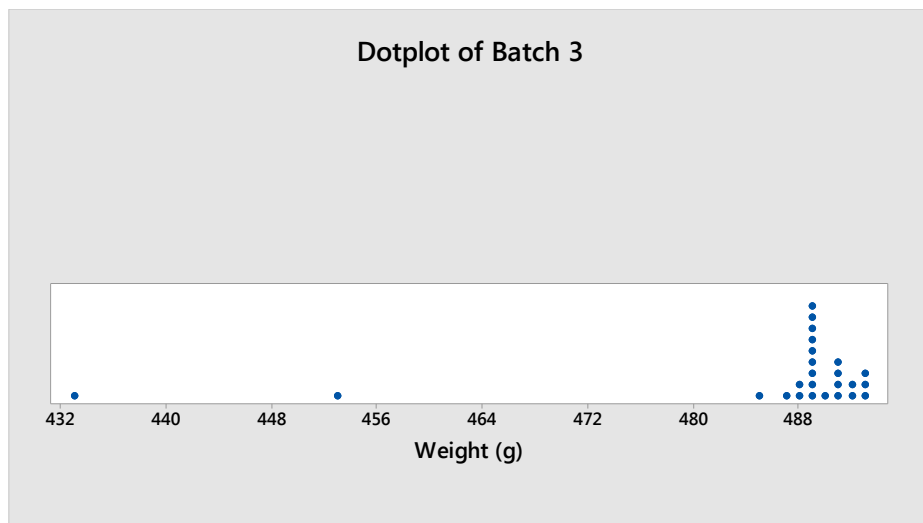
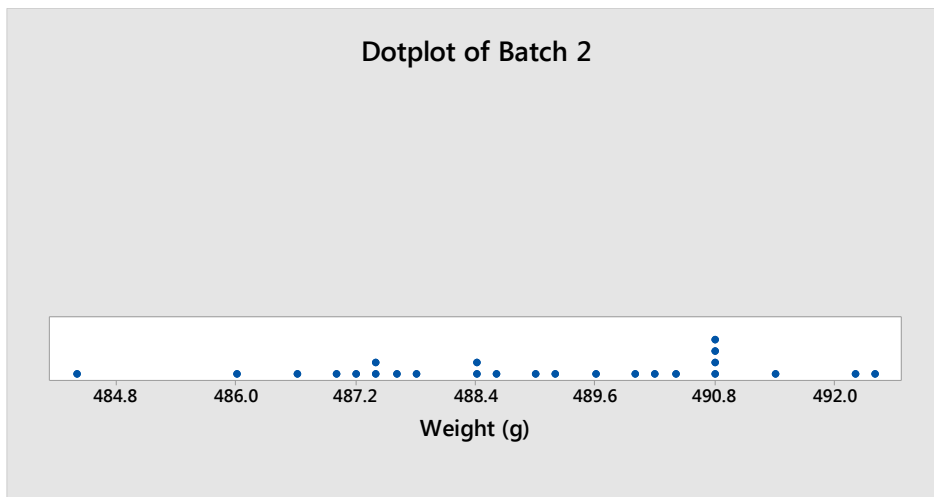
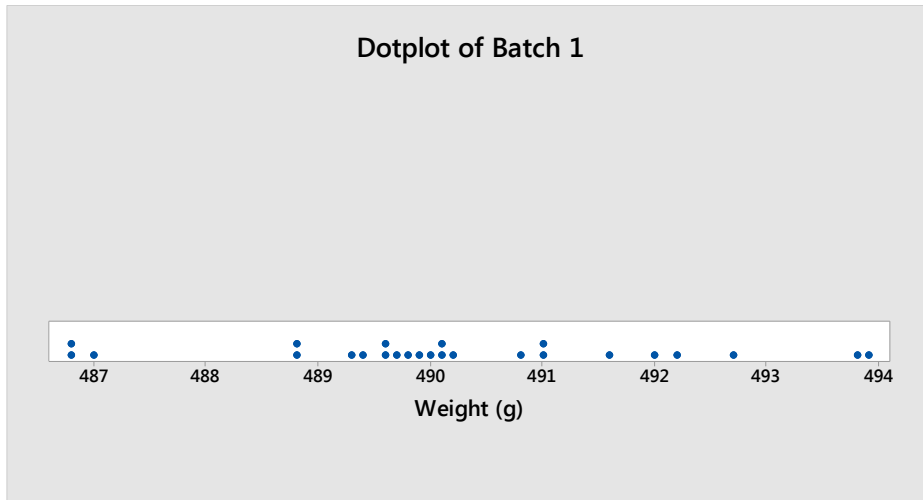
- 25 boxes will be weighed from line 1 and be called batch 1.
- 25 boxes will be weighed from line 2 and be called batch 2.
- 25 boxes will be weighed from line 3 and be called batch 3.

## 6.0 Results

<b>Weights of Boxes of Cornflakes in grammes (g)</b>			
<b>Time Order</b>	<b>Batch 1</b>	<b>Batch 2</b>	<b>Batch 3</b>
1	489.41	491.34	490.93
2	489.67	486.09	490.76
3	487.04	489.51	488.23
4	490.96	488.60	488.79
5	493.85	486.91	432.50
6	489.97	487.77	484.88
7	489.30	490.02	489.89
8	492.65	490.89	489.47
9	486.81	488.41	491.55
10	489.75	490.23	490.64
11	489.57	490.73	491.63
12	489.55	490.41	488.60
13	491.61	490.77	489.22
14	486.82	490.84	488.85
15	488.79	484.42	493.23
16	490.97	488.34	489.33
17	489.92	487.41	487.74
18	490.20	492.29	492.87
19	490.84	492.30	487.33
20	492.24	487.48	452.50
21	493.81	489.25	493.08
22	490.05	487.63	491.05
23	492.03	489.00	488.91
24	488.77	486.64	488.65
25	490.12	487.24	488.75

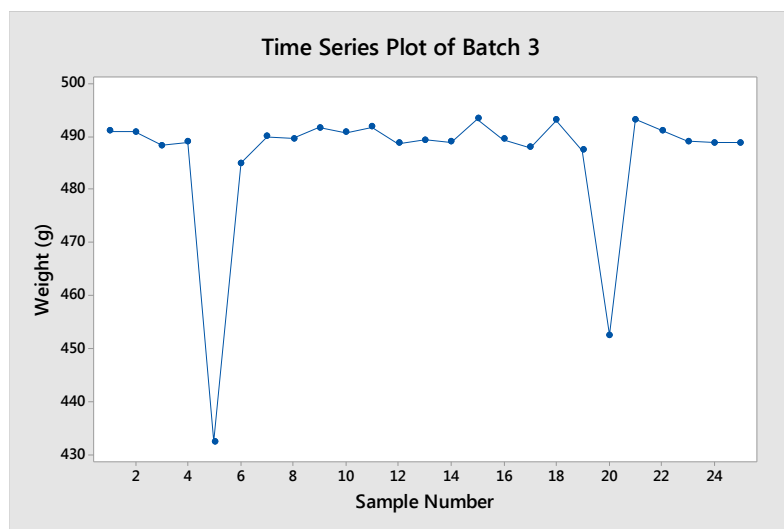
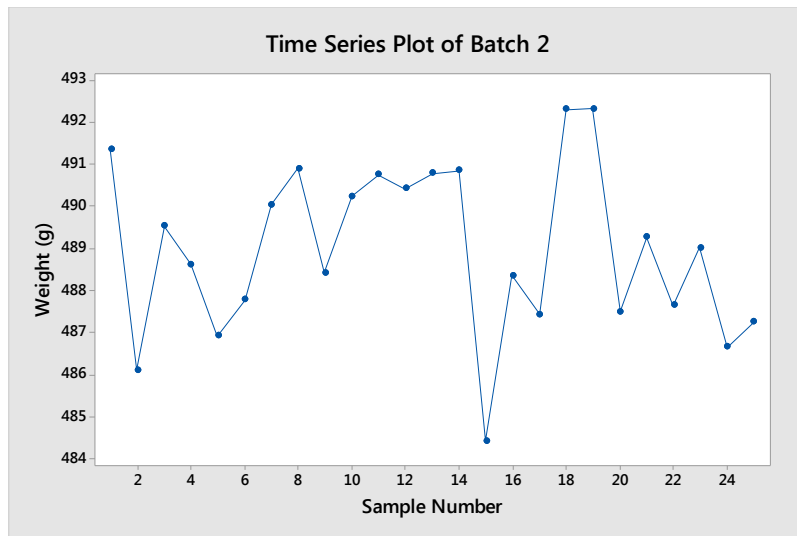
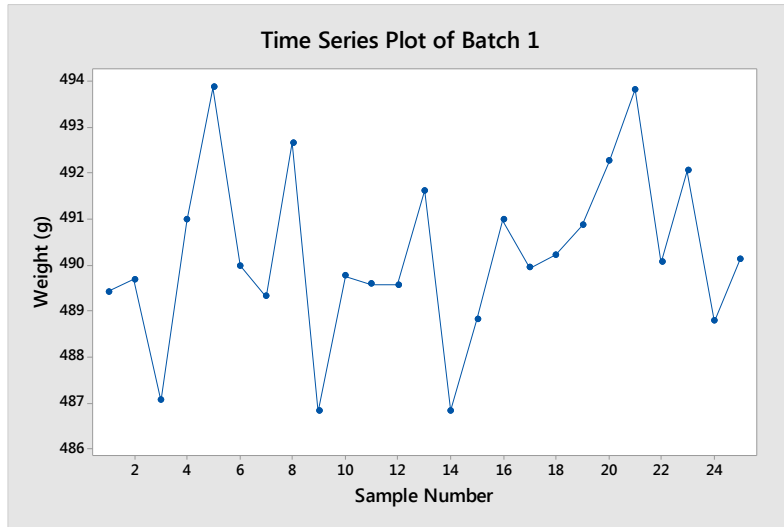
**Figure 1: Data on box weights Batch 1, 2 & 3**

Figure 1 shows the weights for the three batches 1, 2 & 3 of cornflake boxes.



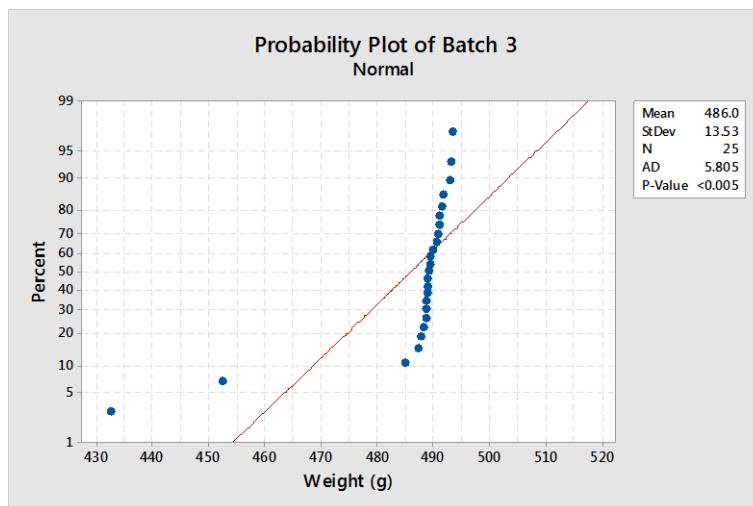
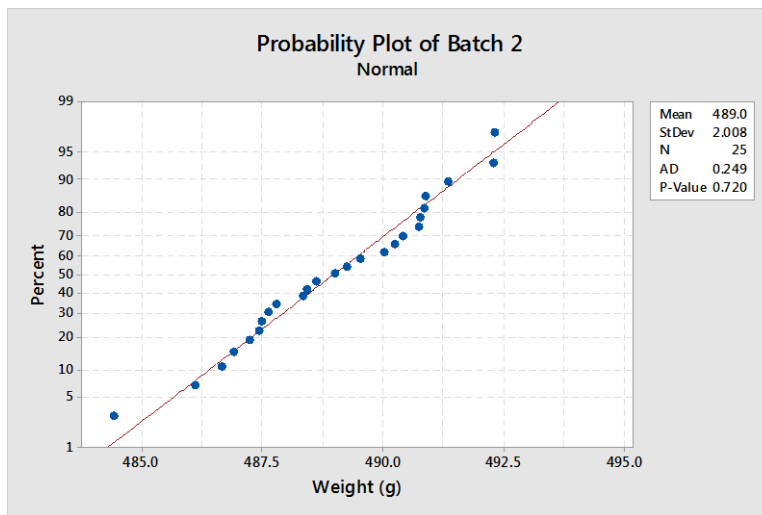
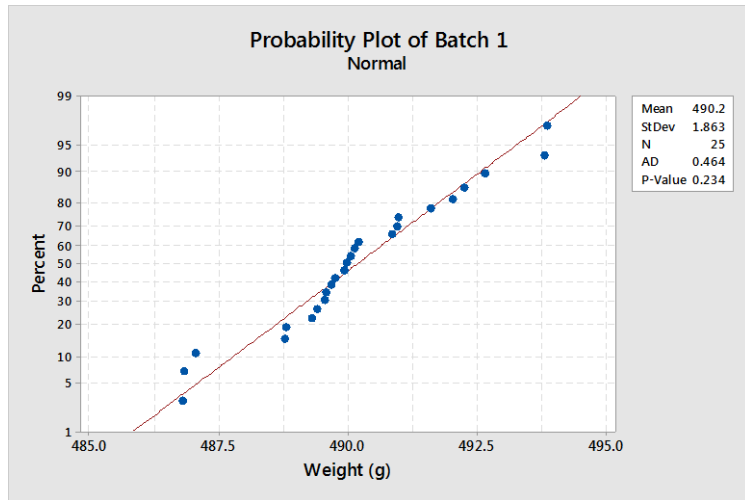
**Figure 2: Dot Plot Batch 1, 2 & 3**

Figure 2 shows the dot plot data for weights for the batches 1, 2 & 3 of cornflake boxes.



**Figure 3: Time Series Plot Batch 1, 2 & 3**

Figure 3 shows the Time Series Plot data for weights for the batches 1, 2 & 3 of cornflake boxes.



**Figure 4: Normality Test Batch 1, 2 & 3**

Figure 4 shows the Normality Test data for weights for the batches 1, 2 & 3 of cornflake boxes.



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### Descriptive Statistics: Batch 1 Statistics

Variable	N	N *	Mean	SE Mean	StDev	Variance	CoefVar	Minimum	Q1	Median	Q3
Batch 1	25	0	490.19	0.373	1.86	3.47	0.38	486.81	489.36	489.97	491.29

Variable	Maximum	Range	Mode	N for Mode	Skewness	Kurtosis
Batch 1	493.85	7.04	*	0	0.11	0.09

### Descriptive Statistics: Batch 2 Statistics

Variable	N	N *	Mean	SE Mean	StDev	Variance	CoefVar	Minimum	Q1	Median	Q3
Batch 2	25	0	488.98	0.402	2.01	4.03	0.41	484.42	487.45	489.00	490.75

Variable	Maximum	Range	Mode	N for Mode	Skewness	Kurtosis
Batch 2	492.30	7.88	*	0	-0.23	-0.45

### Descriptive Statistics: Batch 3 Statistics

Variable	N	N *	Mean	SE Mean	StDev	Variance	CoefVar	Minimum	Q1	Median	Q3
Batch 3	25	0	485.98	2.71	13.53	183.16	2.78	432.50	488.42	489.22	490.99

Variable	Maximum	Range	Mode	N for Mode	Skewness	Kurtosis
Batch 3	493.23	60.73	*	0	-3.44	11.65

**Figure 5: Descriptive Statistics Batch 1, 2 & 3**

Figure 5 shows the Descriptive Statistics data for weights for the batches 1, 2 & 3 of cornflake boxes.

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## 7.0 Conclusion

### Line 1

- The weighing completed on batch 1 has demonstrated that line 1 process is capable but is not centred on the target of 500g.
- The Dot Plot shows the highest cluster of results around 490g.
- The Times Series Plot shows the process varies from the highest (sample 5) to the lowest (sample 9) results in close proximity to each other and the difference between high and low is approx. 7g.
- The normality test shows that the data is normal with a P-Value of 0.234.
- The display descriptive statistics shows that the mean and the median are very close and the standard deviation is low which indicates that this is a capable process.  
The mean of 490.19 is skewed approx. 10g below the expected target of 500g.

### Line 2

- The weighing completed on batch 2 has demonstrated that line 2 process is capable but is not centred on the target of 500g.
- The dot plot shows the highest cluster of results around 488 and 490g.
- The Times series plot shows that the process varies from highest (sample 13) to lowest (sample 14) results in close proximity to each other and the difference between highest and lowest is approx. 8g.
- The normality test shows that the data is normal with a P-Value of 0.720.
- The display descriptive statistics shows that the mean and the median are very close and the standard deviation is low which indicates that this is a capable process  
The mean of 488.98 is skewed approx. 10g below the expected target of 500g.

### Line 3

- The weighing completed on batch 3 has demonstrated that line 3 process is not capable and is not centred on the target of 500g.
- The dot plot shows the highest cluster of results around 488g.
- The Times series plot shows that sample 5 is approximately 50g lighter than samples 4 and 6 and sample 20 is approximately 35g lighter than samples 19 and 21.
- The normality test shows that the data is not normal with a P-Value of <0.005.
- The display descriptive statistics shows that the mean and the median are wide apart and the standard deviation is high which indicates that this is a not a capable process.  
The mean of 488.98 is skewed approx.10g below the expected target of 500g.  
The maximum result is approximately 60g heavier than the minimum result.

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### Compare Lines, 1, 2 & 3

The process control characteristics of lines 1 and 2 are similar. They have similar means and standard deviation and both sets of data are normal.

The process control characteristics of line 3 show that it is operating differently to line 1 and line 2. The std dev of 13.53 is much higher than the std dev of 2.01 for line 2 and 1.86 for line 1. The samples 5 and 20 are outliers in the process.

#### 7.1 Summary

The data from the line 1 and 2 processes are normal as P-Value is above 0.05.

They are both capable but the mean is skewed approximately 10g below target.

The data from line 3 shows samples 5 and 20 as outliers. The mean is also skewed approximately 10g below target. It is not a capable process and the data is not normal as the P-value is below 0.05.

Sample 5 and 20 from line 3 were reweighed to determine if the recorded results were correct. The second set of results was equivalent to the first set.

This shows that line 3 is not a stable process and would indicate that there is an assignable cause for these results.

## 8.0 Recommendations

### Short term actions

#### Line 3

- Line 3 needs to be shut down until root cause for the process instability is determined.
- Line 3 is currently not operating as a stable process and the results for sample 5 and 20 strongly indicate that the customer complaints are coming from line 3. Sample 5 is approx. 53 g lighter than the mean and therefore would not meet customer expectation and would be classified as a reject.
- Line 3 needs urgent review to determine the root cause for these outliers and remediation is required to resolve this issue. Further sampling will be required after remediation to ensure the process is capable.
- The mean for line 3 needs to be shifted by approximately 10g so that it is closer to the target figure.
- Introduce an upper specification limit of 505g and lower specification limit of 495g to the process.
- In process sampling will be required for each completed batch before release.
- Increase sampling to 27 boxes out of each batch of 1000 (AQL 1.5% C=0 sampling plan).
- Batches will be required to meet PPK acceptance criteria of 1.0 or above to allow them to be released.

#### Line 1 & 2

- Line 1 and 2 are shown to be stable processes so can continue to run.
- The mean for lines 1 & 2 needs to be shifted by approximately 10g so that it is closer to the target figure.
- Increase sampling to 27 boxes out of each batch of 1000 (AQL 1.5% C=0 sampling plan).
- Introduce an upper specification limit of 505g and lower specification limit of 495g to the process.

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- Batches will be required to meet PPK acceptance criteria of 1.0 or above to allow them to be released.

**Long term actions**

- Operational (OQ) and process qualification (PQ) validation as per SOP1234 rev 16 will be required for all three lines. The OQ will establish the ability to produce acceptable product at the limits of the packing processing conditions. The PQ will provide a high degree of assurance that the packing processes will, under nominal processing conditions, consistently produce a product that meets predetermined specifications.
- This is to be completed as part the corrective action required for CAPA1261 and will provide data for statistically valid sampling criteria for in process sampling and batch release requirements.