Root Cause Investigations for CAPA

Lassi Eronen, Marketing Manager

Agenda

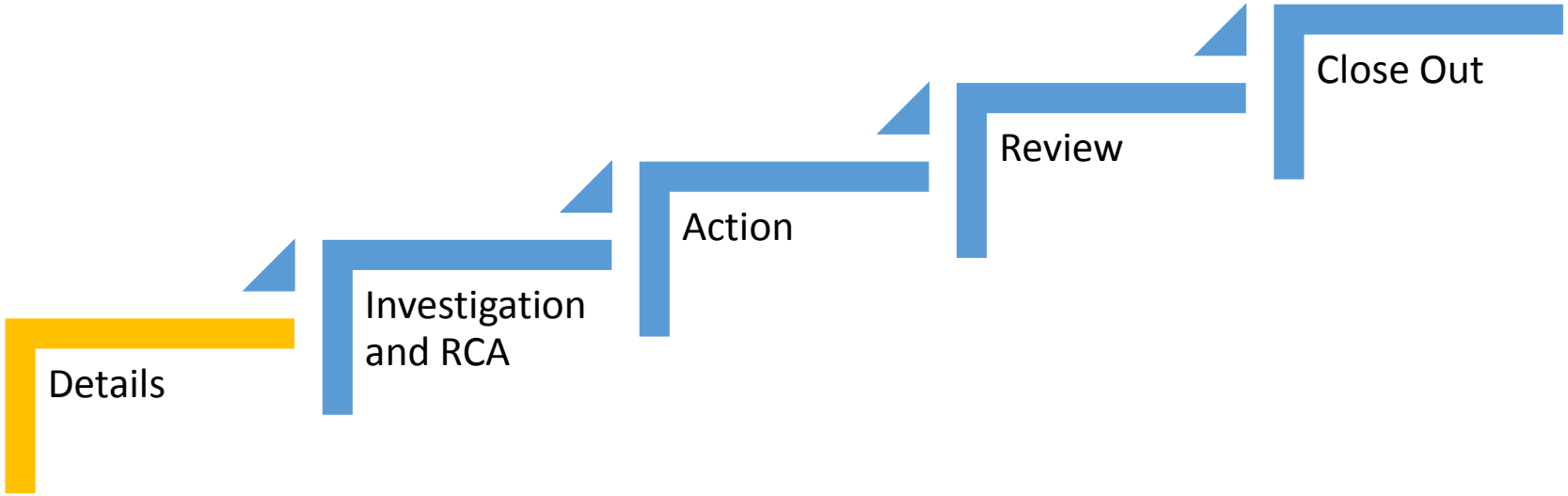
- Quick overview of the CAPA workflow
- Using the Causes list
- Using different RCA techniques with Safefood 360°
- Using the query tool for statistical analysis of root causes

Getting to the bottom of it

Why is root cause analysis needed?

- Historically RCA has been viewed as optional – a nice to have
- Latest BRC versions require you to conduct a proper root cause analysis
- Like Einstein said ” If I had an hour to solve a problem I'd spend 55 minutes thinking about the problem and 5 minutes thinking about solutions.”
- If you spend time – no matter how little in the end – about defining the root causes of your problems, you will end up creating more lasting change

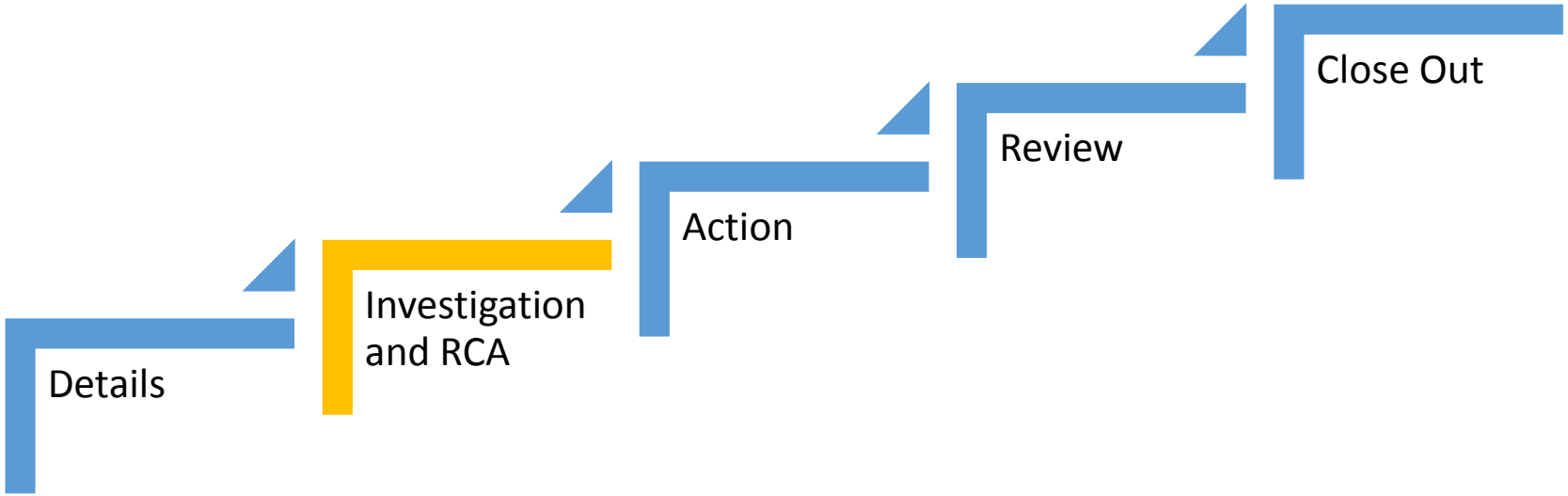
CAPA workflow



What is the problem?

- Is there really a problem?
- What is it?
- Who is involved?
- When is it happening?
- Is it severe?
- What is the extent of it?

CAPA workflow



Root cause or causal factor?

- Only by attacking the root cause you can prevent the issue from occurring again

Root cause or causal factor?

Different techniques

Name	Complexity	Use	Information
5 Why's	Simple	Day-to-day investigations	
Fishbone Technique	Moderate	Investigations of any kind	
Kepner Tregoe Root Cause Analysis	Complex	Severe or multifaceted issues	View link

Root Cause with Fisbone -

https://workflowy.com/#/0850b03ff75b

workflowy+ Search Completed: Visible Help Save now

Home >

Root Cause with Fisbone

- Problem: Cooker temperature was out of specification
  - Equipment
    - Cooker
      - Controller
    - Pipes
  - Environment
  - Staff
  - Policies
    - Maintenance
      - Scheduled for once a year
    - Training
      - Not part of onboarding training for maintenance staff

Benefits of the fishbone technique

- Extremely easy and straightforward
- It is multidimensional compared to 5 Why technique which leads into a rather singular conclusion about the root cause

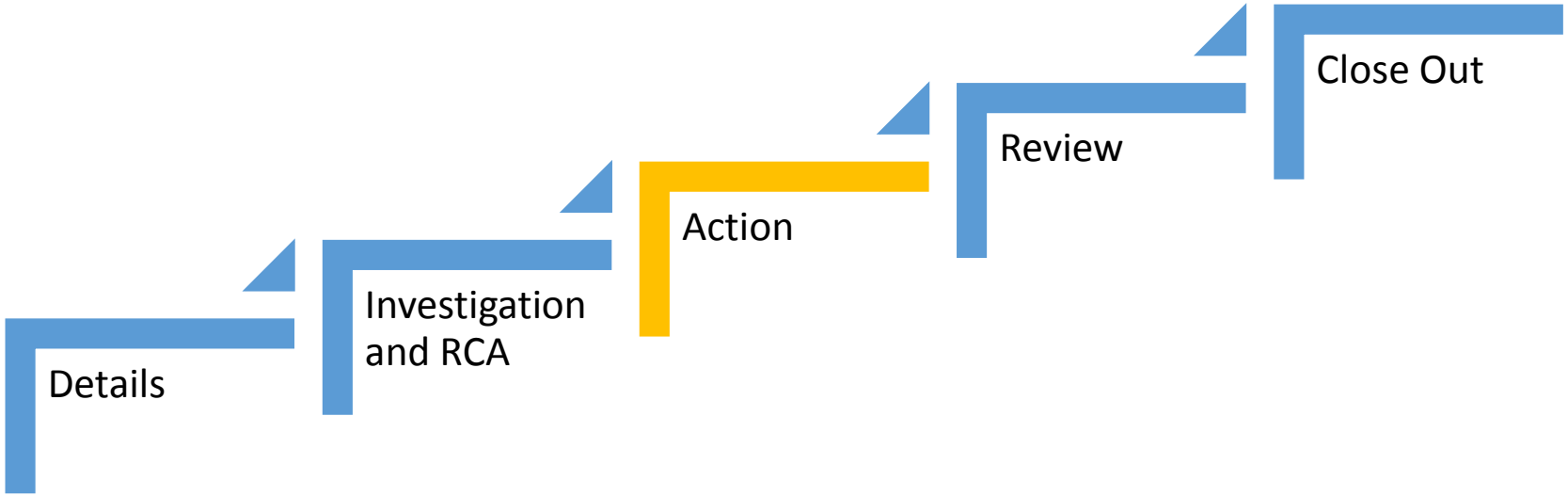
Assign the Corrective Action a Cause

- Categorizing records based on causes will help you later create useful statistical analysis

Investigation / Root Cause Analysis

Date	05/05/2015
Root Cause	Poor Communication
Report	As part of the RCA we found there was no communication between production and QA.

CAPA workflow



Actions

- Assign relevant actions based on the investigation
- Establish a weekly / bi-weekly / monthly improvement meeting where you review and monitor open corrective actions

Using the query tool for statistical analysis

Example: How to build a treemap showing causes and nonconformances in one chart

- This is a particularly useful chart type because it allows you to group multiple variables into one chart and allow you to visualize the connection

Export the dates, NC categories and causes

Title [CAPA] Root causes & nonconformance categories

Tables

- AuditProgram
- AuditProgramAuditor
- AuditInternalRecord
- AuditRecordChecklistDetails
- BatchingRecord
- BatchingRecordRecipe
- Brand
- Cause
- Checklist
- ChecklistDetails
- CleaningStandardRecord
- CleaningStandardRecordTask

Columns

Expression	Title
CorrectiveAction Date	CorrectiveAction Date
CorrectiveAction Nonconformance	CorrectiveAction Nonconformance
CorrectiveAction Cause	CorrectiveAction Cause

[Add new column]

Conditions

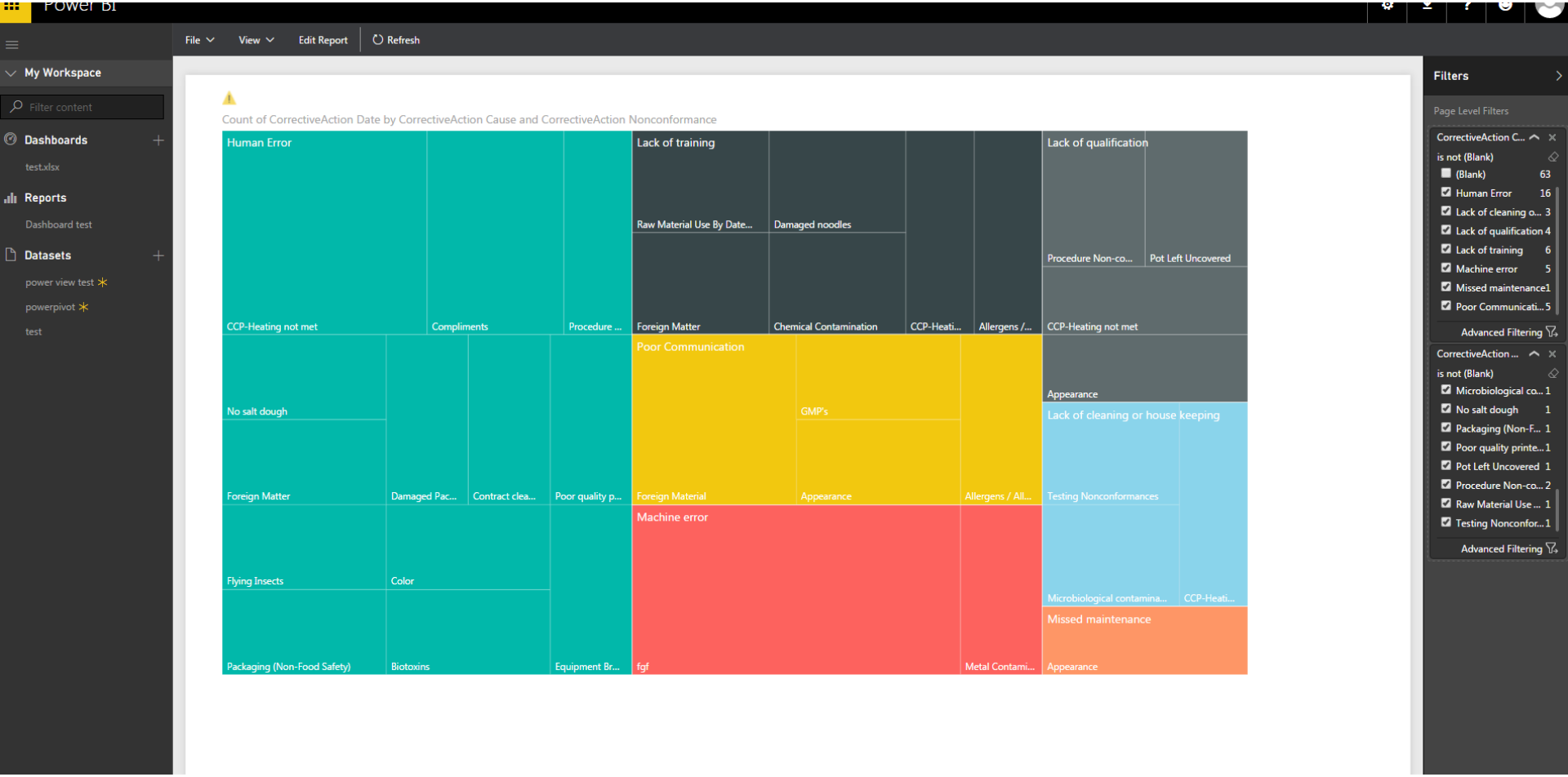
Select records where all of the following apply

[Add new condition]

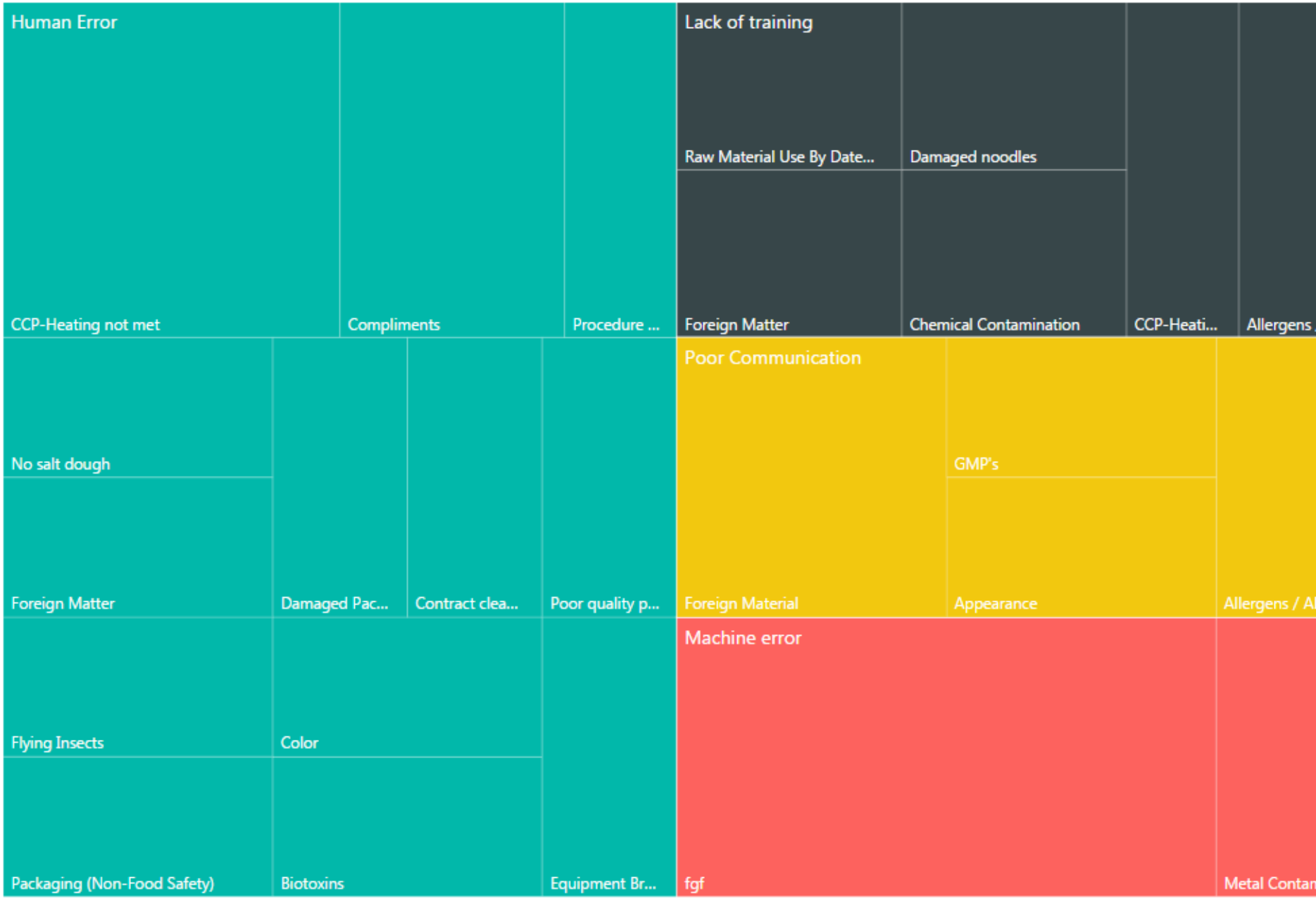
Clear Execute

Check the data

	A	B	C	D
1	CorrectiveAction Da	CorrectiveAction Nonconformanc	CorrectiveAction Cause	
2	04/02/2015		Human Error	
3	19/08/2014	Packaging (Non-Food Safety)	Human Error	
4	13/08/2014	Flying Insects	Human Error	
5	13/03/2015	CCP-Heating not met	Human Error	
6	02/03/2015		Lack of training	
7	20/11/2014		Machine error	
8	24/11/2014	Foreign Material	Poor Communication	
9	23/10/2015	Appearance	Lack of qualification	
10	05/05/2015	Procedure Non-conformance	Lack of qualification	
11	17/09/2015	Compliments	Human Error	
12	19/05/2015	CCP-Heating not met	Human Error	
13	27/04/2015	Procedure Non-conformance	Human Error	
14	16/09/2015	No salt dough	Human Error	
15	27/05/2015		Human Error	
16	23/06/2015		Human Error	
17	01/09/2015		Human Error	
18	24/06/2015		Human Error	


Power BI
File
View
Edit Report
Refresh
My Workspace
Filter content
Dashboards
test.xlsx
Reports
Dashboard test
Datasets
power view test
powerpivot
test
Count of CorrectiveAction Date by CorrectiveAction Cause and CorrectiveAction Nonconformance
Human Error
CCP-Heating not met
Compliments
Procedure ...
Lack of training
Raw Material Use By Date...
Damaged noodles
Foreign Matter
Chemical Contamination
CCP-Heati...
Allergens /...
Lack of qualification
Procedure Non-co...
Pot Left Uncovered
CCP-Heating not met
No salt dough
Foreign Matter
Damaged Pac...
Contract clea...
Poor quality p...
Poor Communication
GMP's
Foreign Material
Appearance
Allergens / All...
Appearance
Lack of cleaning or house keeping
Testing Nonconformances
Microbiological contamina...
CCP-Heati...
Flying Insects
Color
Packaging (Non-Food Safety)
Biotoxins
Equipment Br...
Machine error
fgf
Metal Contami...
Missed maintenance
Appearance
Filters
Page Level Filters
CorrectiveAction C...
is not (Blank)
(Blank) 63
Human Error 16
Lack of cleaning o... 3
Lack of qualification 4
Lack of training 6
Machine error 5
Missed maintenance 1
Poor Communicati... 5
Advanced Filtering
CorrectiveAction ...
is not (Blank)
Microbiological co... 1
No salt dough 1
Packaging (Non-F... 1
Poor quality printe... 1
Pot Left Uncovered 1
Procedure Non-co... 2
Raw Material Use ... 1
Testing Nonconfor... 1
Advanced Filtering

Count of CorrectiveAction Date by CorrectiveAction Cause and CorrectiveAction Nonconformance



Q&A

Thanks for listening! It’s time for your questions.