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Operational Prerequisite Programme Training Guide

Operational Prerequisite Programmes

Operational prerequisite programmes are put in place for significant hazards that are not controlled in the HACCP plan at Critical Control Points.

ISO 22000 Requirement for Prerequisite programmes

When selecting and/or establishing PRP(s), the food safety team will need to consider and utilize appropriate information such as statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards.

Prerequisite programmes will need to be appropriate, implemented across the entire production system and be approved by the food safety team.

Operational Prerequisite Programmes

An operational PRP is defined in ISO 22000 as a prerequisite (PRP) identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

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Identifying Operational Prerequisite Programmes

Use our unique HACCP Calculator ISO 22000 to help identify your Operational PRPs:

- **Use the simple steps to assessing Hazard significance generating a rating of 1 – 9**
- **The calculator automatically highlights significant hazards which require critical control point assessment**
- **Significant Hazards that are not included in your HACCP plan should be controlled by Operational Prerequisite programmes**

Refer to the HACCP Training Guide - ISO 22000 Module 2014, ISO 22000 HACCP Calculator Instructions and the HACCP Calculator to assist in your assessment.

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Identifying Operational Prerequisite Programmes

We will now go through the steps to identifying Operational Prerequisite Programmes.

Refer to the HACCP Training Guide - ISO 22000 Module 2014, ISO 22000 HACCP Calculator Instructions and the HACCP Calculator to assist in your assessment.

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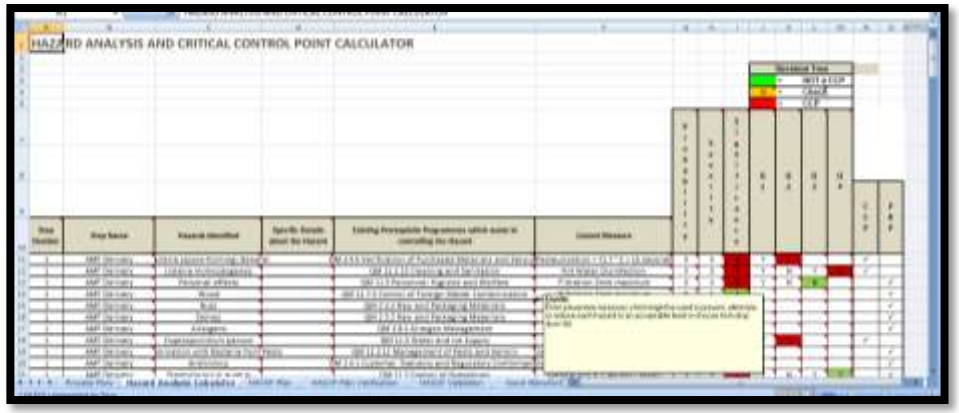
Hazard Assessment

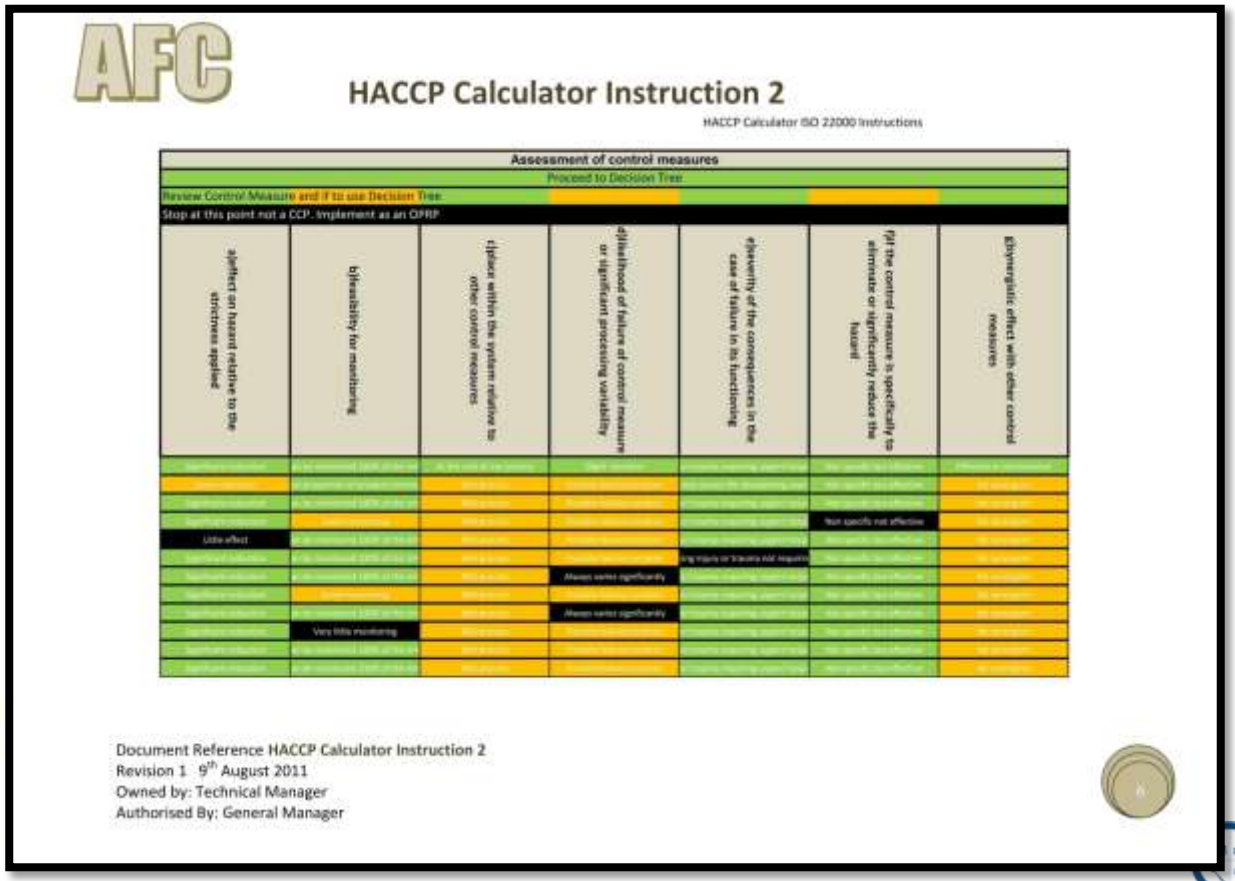
7.4.3 Hazard assessment

A hazard assessment should be conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met.



ISO 22000 Implementation
Classification of Control Measures

The ISO 22000 HACCP Calculator can be used to help select and categorize control measures:



AFC

HACCP Calculator Instruction 2

HACCP Calculator ISO 22000 Instructions

Assessment of control measures						
Proceed to Decision Tree						
Review Control Measure and if to use Decision Tree						
Stop at this point not a CCP. Implement as an OPRP						
a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the hazard	g)synergistic effect with other control measures
					Non specific not effective	
Little effect						
			Always varies significantly			
			Always varies significantly			
	Very little monitoring					

Document Reference HACCP Calculator Instruction 2
Revision 1 9th August 2011
Owned by: Technical Manager
Authorised By: General Manager

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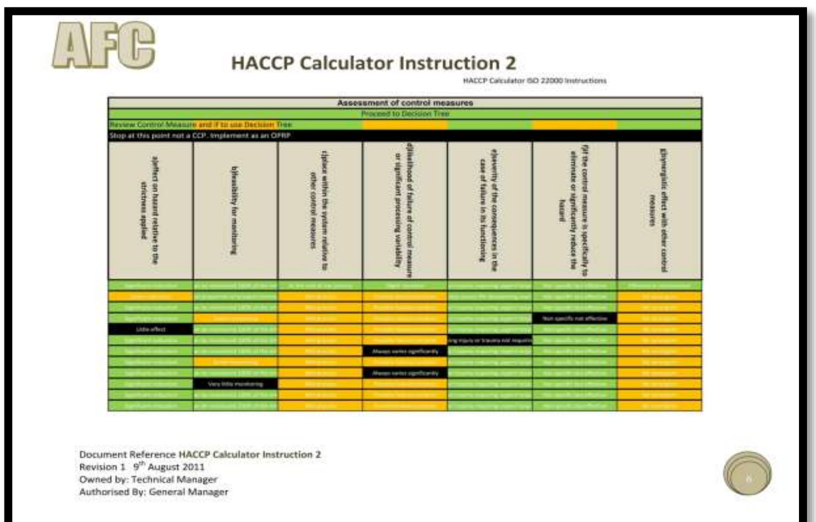
ISO 22000 Implementation Classification of Control Measures

Control measures will not be subject to the next stage and determining if they are critical control points if the food safety team decides based on their assessment as per Clause 7.4.4 that this is not necessary or feasible. These control measures will be part of the Operational Prerequisite Programme Plan.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HACCP Calculator Instruction 2

HACCP Calculator ISO 22000 Instructions

Assessment of control measures

Proceed to Decision Tree

Review Control Measure and if to use Decision Tree

Stop at this point not a CCP. Implement as an OPRP

a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the hazard	g)synergistic effect with other control measures
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	Non specific not effective	[illegible]
Little effect	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	Always varies significantly	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	Always varies significantly	[illegible]	[illegible]	[illegible]
[illegible]	Very little monitoring	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Document Reference HACCP Calculator Instruction 2
Revision 1 9th August 2011
Owned by: Technical Manager
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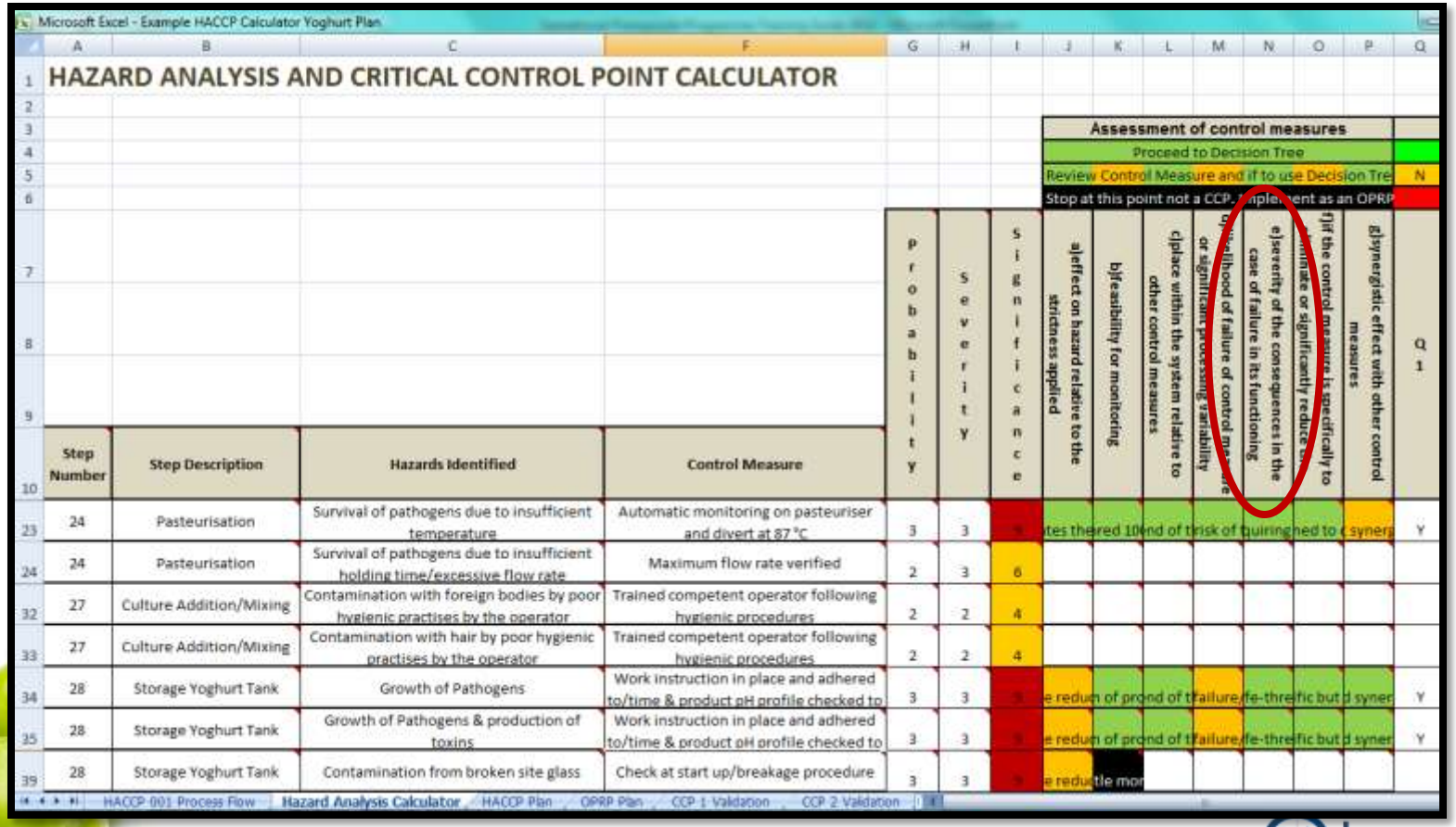
ISO 22000 Selection and Categorization of Control Measures

e) Assess the severity of the consequence(s) in the case of failure in its functioning:



Microsoft Excel - Example HACCP Calculator Yoghurt Plan

HAZARD ANALYSIS AND CRITICAL CONTROL POINT CALCULATOR

Assessment of control measures

Proceed to Decision Tree

Review Control Measure and if to use Decision Tre — N

Stop at this point not a CCP, ...plement as an OPRP

Step Number	Step Description	Hazards Identified	Control Measure	Probability	Severity	Significance	a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce ...	g)synergistic effect with other control measures	Q 1
23	24	Pasteurisation	Survival of pathogens due to insufficient temperature	Automatic monitoring on pasteuriser and divert at 87 °C	3	3	9	...tes thered 10...	...end of t...	...risk of ...	...quiring...	...ned to c...	syner...	Y
24	24	Pasteurisation	Survival of pathogens due to insufficient holding time/excessive flow rate	Maximum flow rate verified	2	3	6							
32	27	Culture Addition/Mixing	Contamination with foreign bodies by poor hygienic practises by the operator	Trained competent operator following hygienic procedures	2	2	4							
33	27	Culture Addition/Mixing	Contamination with hair by poor hygienic practises by the operator	Trained competent operator following hygienic procedures	2	2	4							
34	28	Storage Yoghurt Tank	Growth of Pathogens	Work instruction in place and adhered to/time & product pH profile checked to	3	3	9	...e redu...	...m of p...	...rond of t...	...failure,	...fe-threa...	...fic but d	syner...	Y
35	28	Storage Yoghurt Tank	Growth of Pathogens & production of toxins	Work instruction in place and adhered to/time & product pH profile checked to	3	3	9	...e redu...	...m of p...	...rond of t...	...failure,	...fe-threa...	...fic but d	syner...	Y
39	28	Storage Yoghurt Tank	Contamination from broken site glass	Check at start up/breakage procedure	3	3	9	...e redu...	...tle mor...						

HACCP 001 Process Flow | Hazard Analysis Calculator | HACCP Plan | OPRP Plan | CCP 1 Validation | CCP 2 Validation

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ISO 22000 Selection and Categorization of Control Measures

So now you will have assessed the control measures as per ISO 22000 Clause 7.4.4.
Based on this assessment of control measures there are 3 results:

1. **Proceed to Decision Tree**
2. **Review Control Measure and if to use Decision Tree**
3. **Stop at this point not a CCP. Implement as an OPRP or consider alternative control measures.**

Assessment of control measures	
Proceed to Decision Tree	
Review Control Measure and if to use Decision Tre	N
Stop at this point not a CCP. Implement as an OPRP	

a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the	g)synergistic effect with other control measures	Q 1

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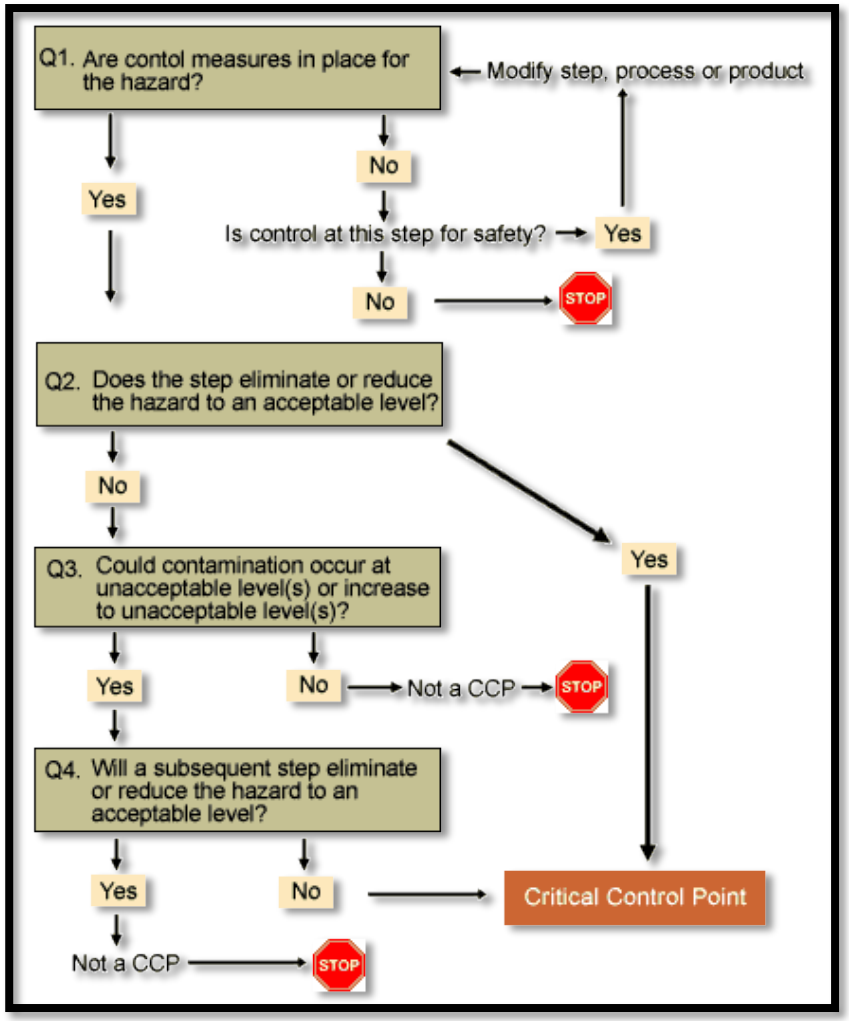
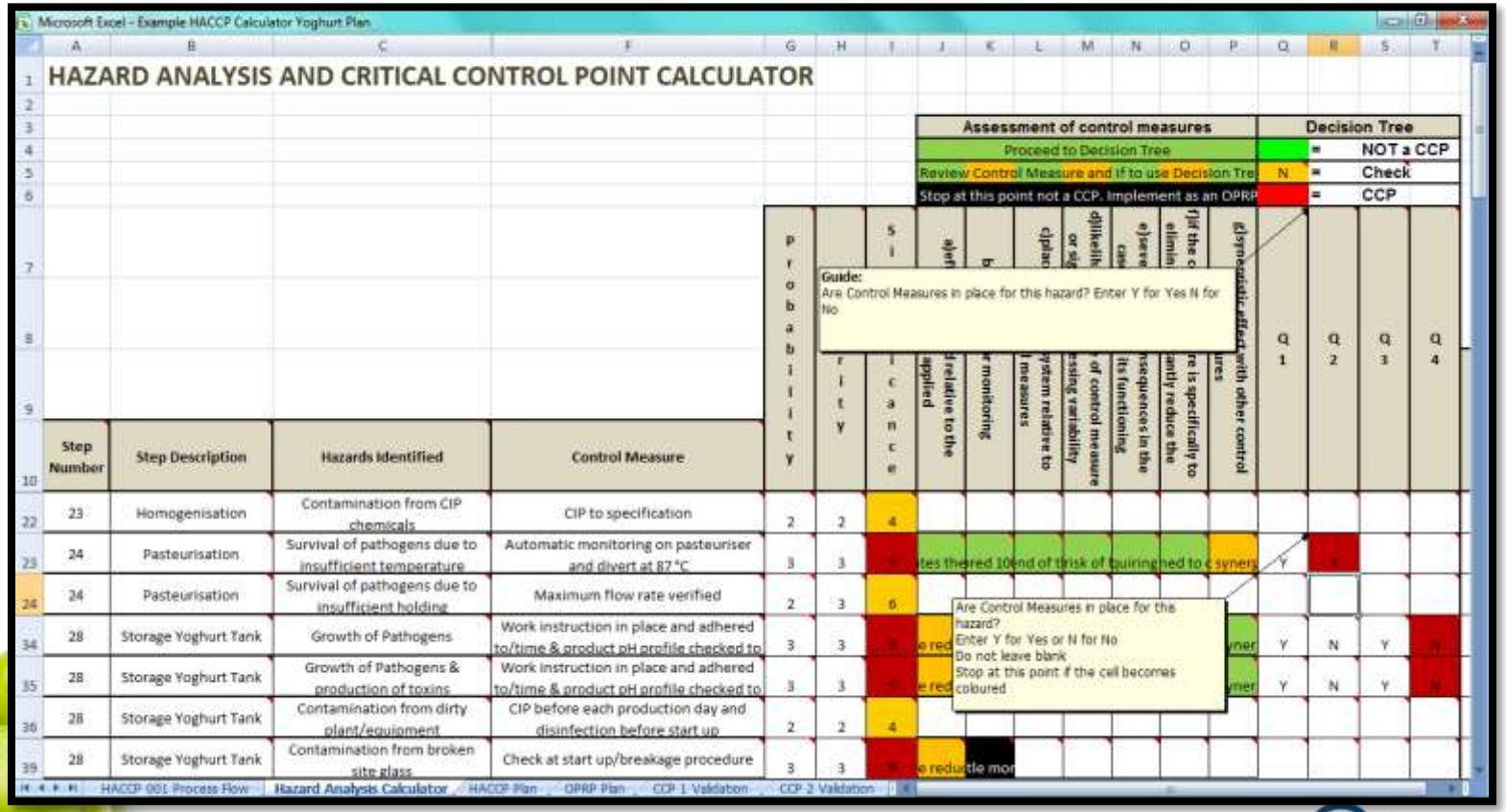
HACCP Decision Tree

Now in order to decide if a Hazard control is a Critical Control Point and in the HACCP plan we use the decision tree to help us.



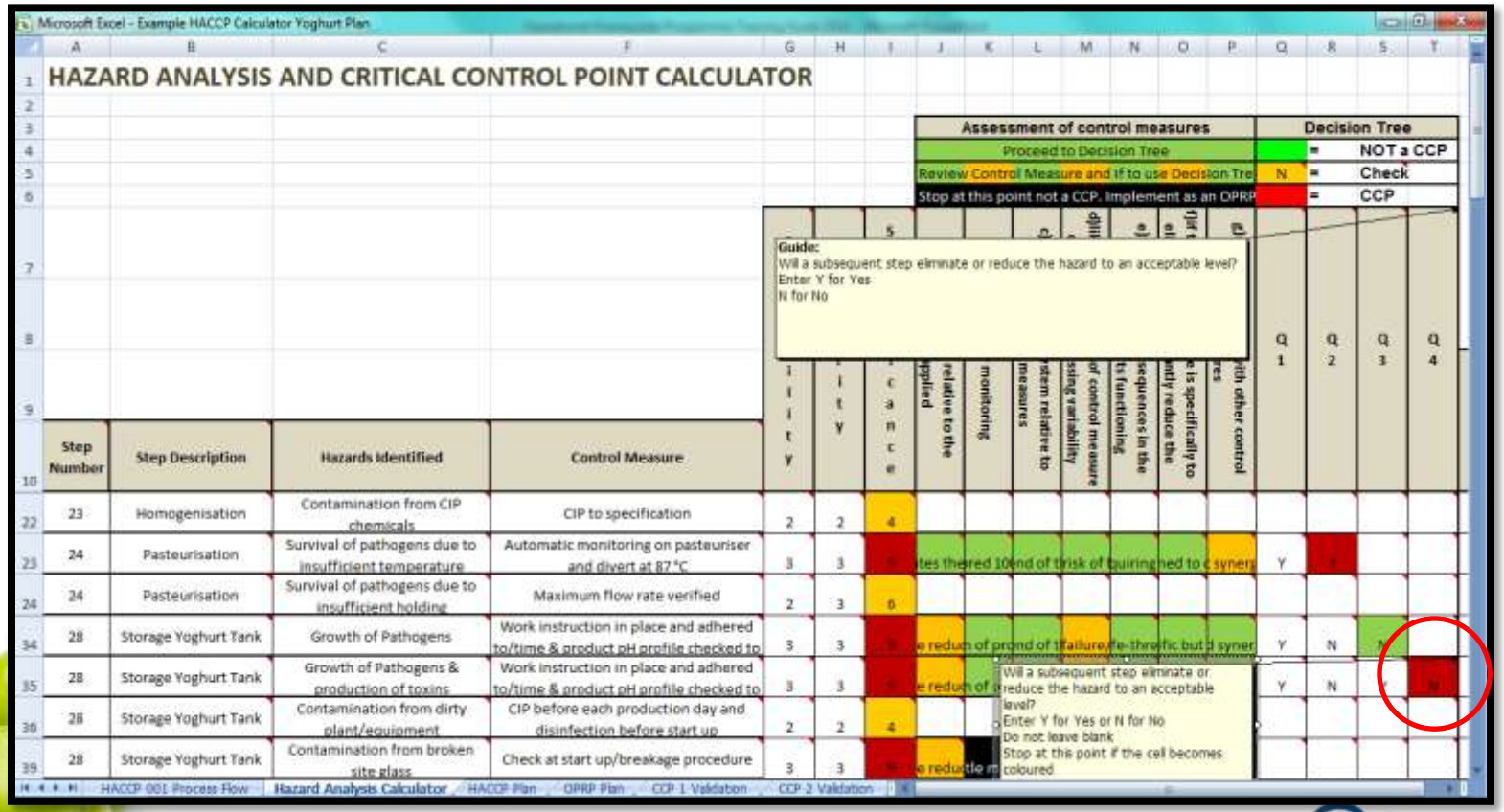
Determine the Critical Control Points (CCPs)

Q1 Are control measures in places for the hazard? Enter Y or N in the appropriate box.



Determine the Critical Control Points (CCPs)

A red cell indicates a CCP.



Microsoft Excel - Example HACCP Calculator Yoghurt Plan

HAZARD ANALYSIS AND CRITICAL CONTROL POINT CALCULATOR

Assessment of control measures	Decision Tree	
Proceed to Decision Tree	=	NOT a CCP
Review Control Measure and if to use Decision Tree	N =	Check
Stop at this point not a CCP. Implement as an OPRP	=	CCP

Guide:
Will a subsequent step eliminate or reduce the hazard to an acceptable level?
Enter Y for Yes
N for No

Step Number	Step Description	Hazards Identified	Control Measure	Severity	Probability	Significance	Q1	Q2	Q3	Q4
23	Homogenisation	Contamination from CIP chemicals	CIP to specification	2	2	4				
24	Pasteurisation	Survival of pathogens due to insufficient temperature	Automatic monitoring on pasteuriser and divert at 87 °C	3	3		Y			
24	Pasteurisation	Survival of pathogens due to insufficient holding	Maximum flow rate verified	2	3	6				
34	28	Storage Yoghurt Tank	Growth of Pathogens	Work instruction in place and adhered to/time & product pH profile checked to	3	3		Y	N	N	
35	28	Storage Yoghurt Tank	Growth of Pathogens & production of toxins	Work instruction in place and adhered to/time & product pH profile checked to	3	3		Y	N		N
36	28	Storage Yoghurt Tank	Contamination from dirty plant/equipment	CIP before each production day and disinfection before start up	2	2	4				
39	28	Storage Yoghurt Tank	Contamination from broken site glass	Check at start up/breakage procedure	3	3					

Will a subsequent step eliminate or reduce the hazard to an acceptable level?
Enter Y for Yes or N for No
Do not leave blank
Stop at this point if the cell becomes coloured

HACCP 001 Process Flow | Hazard Analysis Calculator | HACCP Plan | OPRP Plan | CCP 1 Validation | CCP 2 Validation

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ISO 22000 Implementation
Classification of Control Measures

The food safety team have now decided if control measures are to be part of Operational Prerequisite Programmes or the HACCP plan.

<u>Critical Control Points</u> identified are included in the HACCP plan.

<u>Significant hazards</u> that are not CCP's should be controlled by Operational Prerequisite Programmes.

Other hazards identified in the <u>Preliminary Hazard List</u> should be controlled by Prerequisite programmes.

See the summary in the columns U – W on the next slide.

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Validation of CCP's and Operational Prerequisite Programmes

HACCP Validation - CCP 1

Product Category	Pasteurisation		
Step Number	24		
Hazard	Survival of pathogens		
Control Measure	Minimum pasteurisation temperature of 87 °C is applied		
Validation Methods	Applicable		Comments
	Yes	No	
Third Party Scientific Validation	✓		* CODEX guidance
Historical Knowledge	✓		
Simulated Production Conditions			
Collection of Data in normal production			
Admissible in industrial practices	✓		
Statistical Programmes			
Mathematical Modelling			
Conclusion			
Internal Validation Required?		✓	
Comments	Minimum requirements for the pasteurisation of milk are 71.7 °C for 15 seconds. This plant holds product for 300 seconds.		
CCP Confirmed	✓		
Authorised by(Name):			
Signature:			

*CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS CAC/RCP
Process management
Performance criteria
As C. burnettii is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurization is designed to achieve at least a 5 log reduction of C. burnettii in whole milk (4% milkfat).
Process criteria
According to validations carried out on whole milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to heating every particle of the milk to 72 °C for 15 seconds (continuous flow pasteurization) or 63 °C for 30 minutes (batch pasteurization).

HACCP Validation - OPRP 2

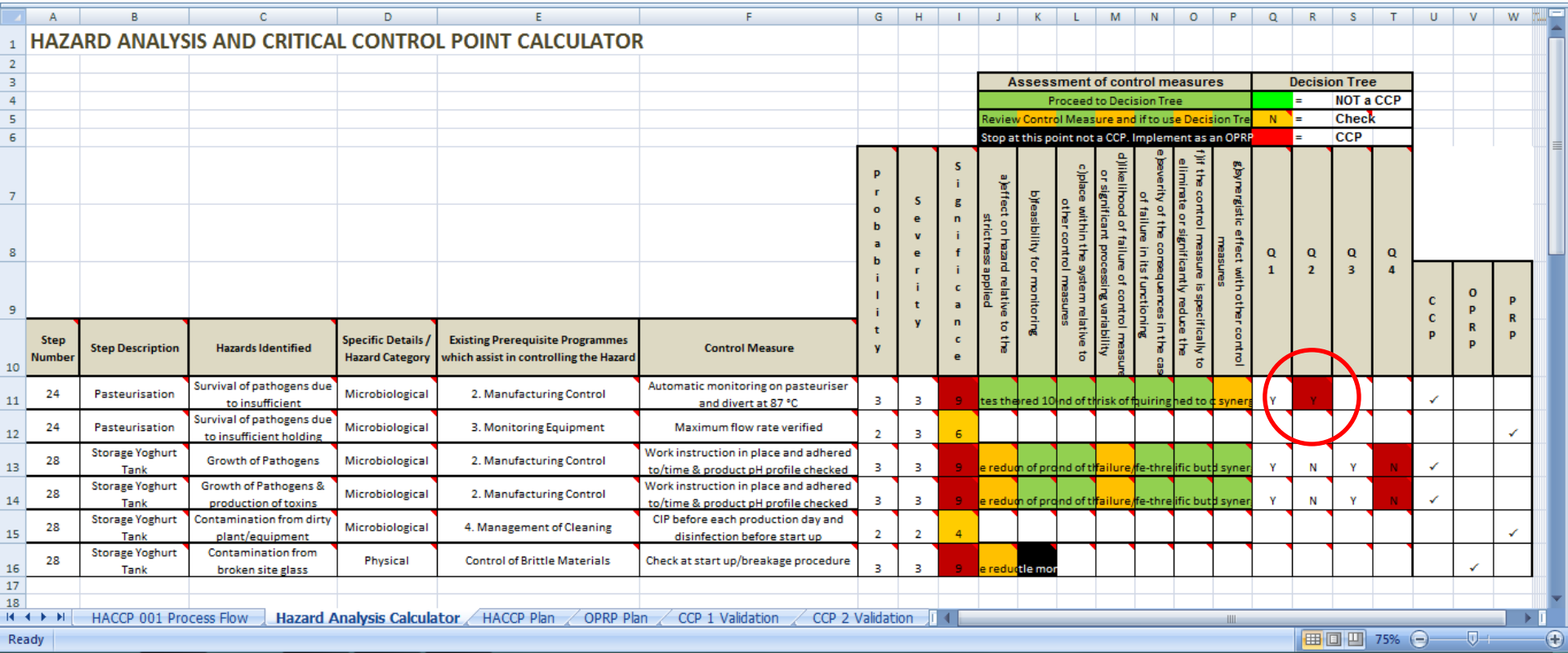
Product Category	Storage Yoghurt Tank		
Step Number	28		
Hazard	Contamination from glass/perspex		
Control Measure	Checking the Safety Glass		
Validation Methods	Applicable		Comments
	Yes	No	
Third Party Scientific Validation			
Historical Knowledge			
Simulated Production Conditions			
Collection of Data in normal production			
Admissible in industrial practices	✓		Lighting Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakage.
Statistical Programmes			
Mathematical Modelling			
Conclusion			
Internal Validation Required?		✓	
Comments	Prerequiste controls are sufficient to reduce the liklihood of contamination. The significance of the hazard is reduced by product		
OPRP Confirmed	✓		
Authorised by(Name):			
Signature:			

PRP Verification required	Start up checks to ensure safety glass is intact prior to start up - YGR 005 Yogurt Pasteurizer Log
PAS 220:2008 10.4 Physical contamination Where glass and/or brittle material are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place.	✓
Glass breakage records shall be maintained.	✓
Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.	✓

ISO 22000 HACCP - CCP Example

Q2 Does the step eliminate or reduce the hazard to an acceptable level?

Yes - Y is entered into the box which turns red. We stop at this point as it is a critical control point



HAZARD ANALYSIS AND CRITICAL CONTROL POINT CALCULATOR

Assessment of control measures			
Proceed to Decision Tree		=	NOT a CCP
Review Control Measure and if to use Decision Tre	N	=	Check
Stop at this point not a CCP. Implement as an OPRP		=	CCP

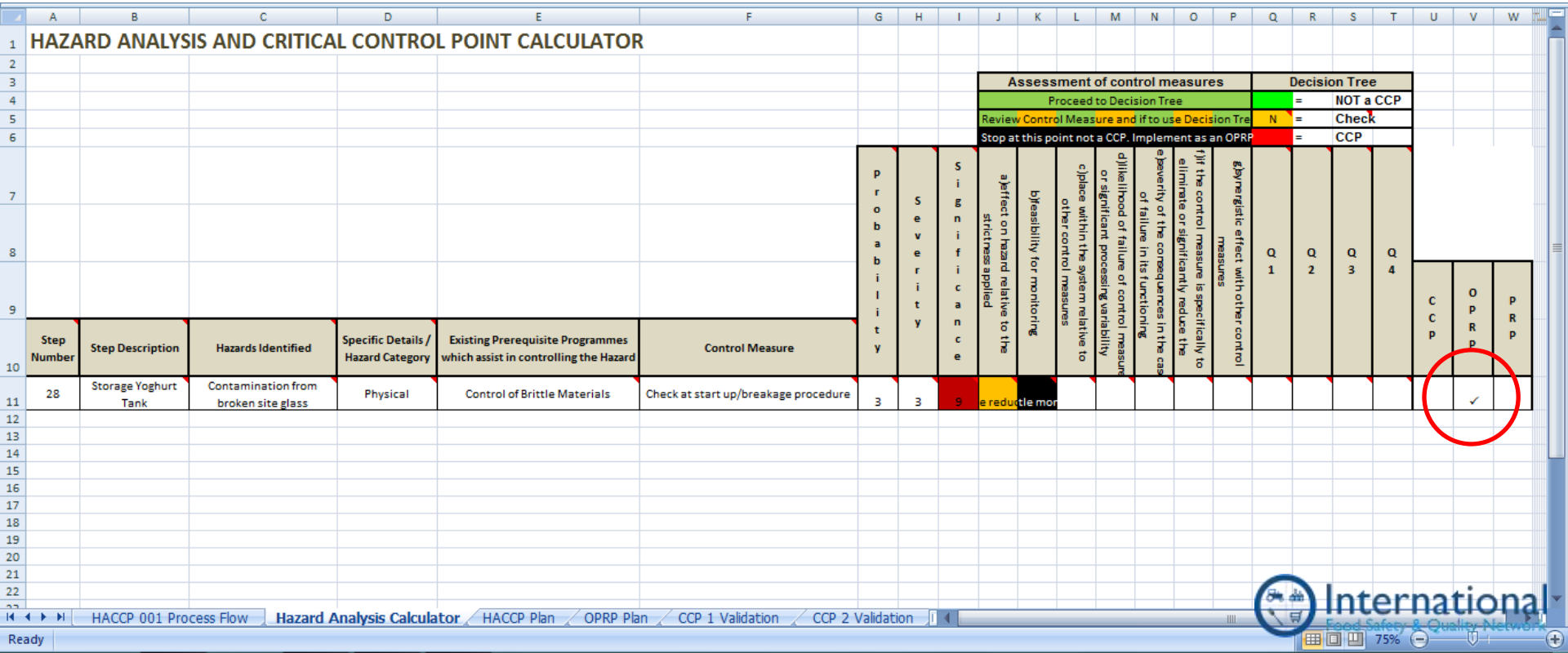
Step Number	Step Description	Hazards Identified	Specific Details / Hazard Category	Existing Prerequisite Programmes which assist in controlling the Hazard	Control Measure	Probability	Severity	Significance	a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the	g)synergistic effect with other control measures	Q 1	Q 2	Q 3	Q 4	CCP	OPRP	PRP
24	Pasteurisation	Survival of pathogens due to insufficient	Microbiological	2. Manufacturing Control	Automatic monitoring on pasteuriser and divert at 87 °C	3	3	9	tes the red 10	nd of th risk of	quiring	hed to c synerg				Y	Y			✓		
24	Pasteurisation	Survival of pathogens due to insufficient holding	Microbiological	3. Monitoring Equipment	Maximum flow rate verified	2	3	6														✓
28	Storage Yoghurt Tank	Growth of Pathogens	Microbiological	2. Manufacturing Control	Work instruction in place and adhered to/time & product pH profile checked	3	3	9	e reduc	n of pr	nd of th	failure	fe-thre	ific but	d syner	Y	N	Y	N	✓		
28	Storage Yoghurt Tank	Growth of Pathogens & production of toxins	Microbiological	2. Manufacturing Control	Work instruction in place and adhered to/time & product pH profile checked	3	3	9	e reduc	n of pr	nd of th	failure	fe-thre	ific but	d syner	Y	N	Y	N	✓		
28	Storage Yoghurt Tank	Contamination from dirty plant/equipment	Microbiological	4. Management of Cleaning	CIP before each production day and disinfection before start up	2	2	4														✓
28	Storage Yoghurt Tank	Contamination from broken site glass	Physical	Control of Brittle Materials	Check at start up/breakage procedure	3	3	9	e reduc	tle mor											✓	

HACCP 001 Process Flow | Hazard Analysis Calculator | HACCP Plan | OPRP Plan | CCP 1 Validation | CCP 2 Validation

Ready 75%

ISO 22000 HACCP - OPRP Example

So let's look an example where a control measure is categorised not as a critical control point but an Operational Prerequisite Programme.



HAZARD ANALYSIS AND CRITICAL CONTROL POINT CALCULATOR

Assessment of control measures			
Proceed to Decision Tree		=	NOT a CCP
Review Control Measure and if to use Decision Tre	N	=	Check
Stop at this point not a CCP. Implement as an OPRP		=	CCP

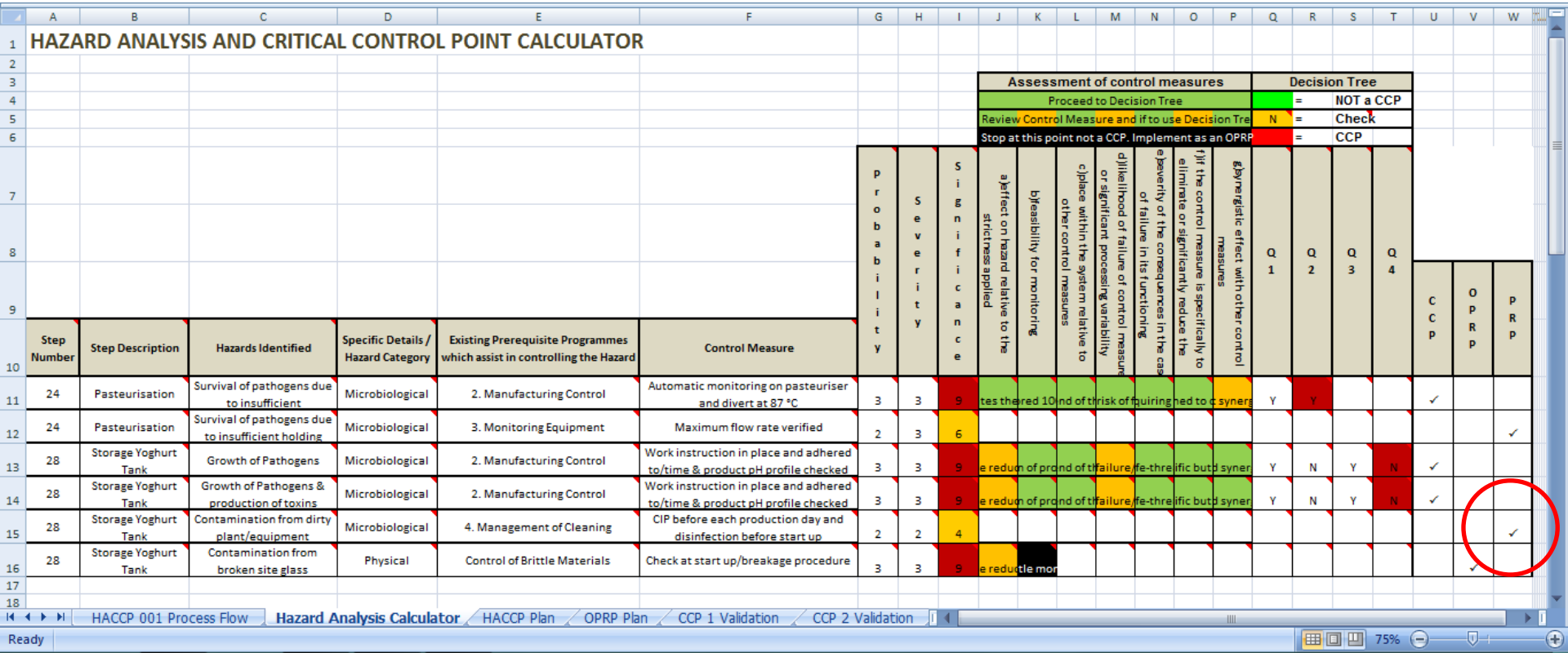
Step Number	Step Description	Hazards Identified	Specific Details / Hazard Category	Existing Prerequisite Programmes which assist in controlling the Hazard	Control Measure	Probability	Severity	Significance	a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the	g)synergistic effect with other control measures	Q 1	Q 2	Q 3	Q 4	CCP	OPRP	PRP
28	Storage Yoghurt Tank	Contamination from broken site glass	Physical	Control of Brittle Materials	Check at start up/breakage procedure	3	3	9	e reductle mor												✓	

HACCP 001 Process Flow | Hazard Analysis Calculator | HACCP Plan | OPRP Plan | CCP 1 Validation | CCP 2 Validation

Ready

ISO 22000 HACCP - PRP Example

CIP daily and before use is implemented as a Prerequisite procedure.



HAZARD ANALYSIS AND CRITICAL CONTROL POINT CALCULATOR

Assessment of control measures			
Proceed to Decision Tree		=	NOT a CCP
Review Control Measure and if to use Decision Tre	N	=	Check
Stop at this point not a CCP. Implement as an OPRP		=	CCP

Step Number	Step Description	Hazards Identified	Specific Details / Hazard Category	Existing Prerequisite Programmes which assist in controlling the Hazard	Control Measure	Probability	Severity	Significance	a)effect on hazard relative to the strictness applied	b)feasibility for monitoring	c)place within the system relative to other control measures	d)likelihood of failure of control measure or significant processing variability	e)severity of the consequences in the case of failure in its functioning	f)if the control measure is specifically to eliminate or significantly reduce the	g)synergistic effect with other control measures	Q 1	Q 2	Q 3	Q 4	CCP	OPRP	PRP
24	Pasteurisation	Survival of pathogens due to insufficient	Microbiological	2. Manufacturing Control	Automatic monitoring on pasteuriser and divert at 87 °C	3	3	9	tes the	red 10	nd of th	risk of	quiring	ned to c	syner	Y	Y			✓		
24	Pasteurisation	Survival of pathogens due to insufficient holding	Microbiological	3. Monitoring Equipment	Maximum flow rate verified	2	3	6														✓
28	Storage Yoghurt Tank	Growth of Pathogens	Microbiological	2. Manufacturing Control	Work instruction in place and adhered to/time & product pH profile checked	3	3	9	e reduc	n of pr	nd of th	failure	fe-thre	ific but	syner	Y	N	Y	N	✓		
28	Storage Yoghurt Tank	Growth of Pathogens & production of toxins	Microbiological	2. Manufacturing Control	Work instruction in place and adhered to/time & product pH profile checked	3	3	9	e reduc	n of pr	nd of th	failure	fe-thre	ific but	syner	Y	N	Y	N	✓		
28	Storage Yoghurt Tank	Contamination from dirty plant/equipment	Microbiological	4. Management of Cleaning	CIP before each production day and disinfection before start up	2	2	4														✓
28	Storage Yoghurt Tank	Contamination from broken site glass	Physical	Control of Brittle Materials	Check at start up/breakage procedure	3	3	9	e reduc	tle mor											✓	

HACCP 001 Process Flow | Hazard Analysis Calculator | HACCP Plan | OPRP Plan | CCP 1 Validation | CCP 2 Validation

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That's the end of this training package

Thank you for attending