HACCP Plan Examples

Example #1: Company that makes beverages. Hired a consultant to develop their HACCP plan.

HACCP Plan (25 pages)

- Title page
- Table of Contents
  - Team & Responsibilities
  - HACCP plan per product (type)
  - Flow diagrams per product (type)
  - Product listing & packaging (page 25)
  - Certifications
  - Revision log
  - Supplemental data sheets

What's missing?

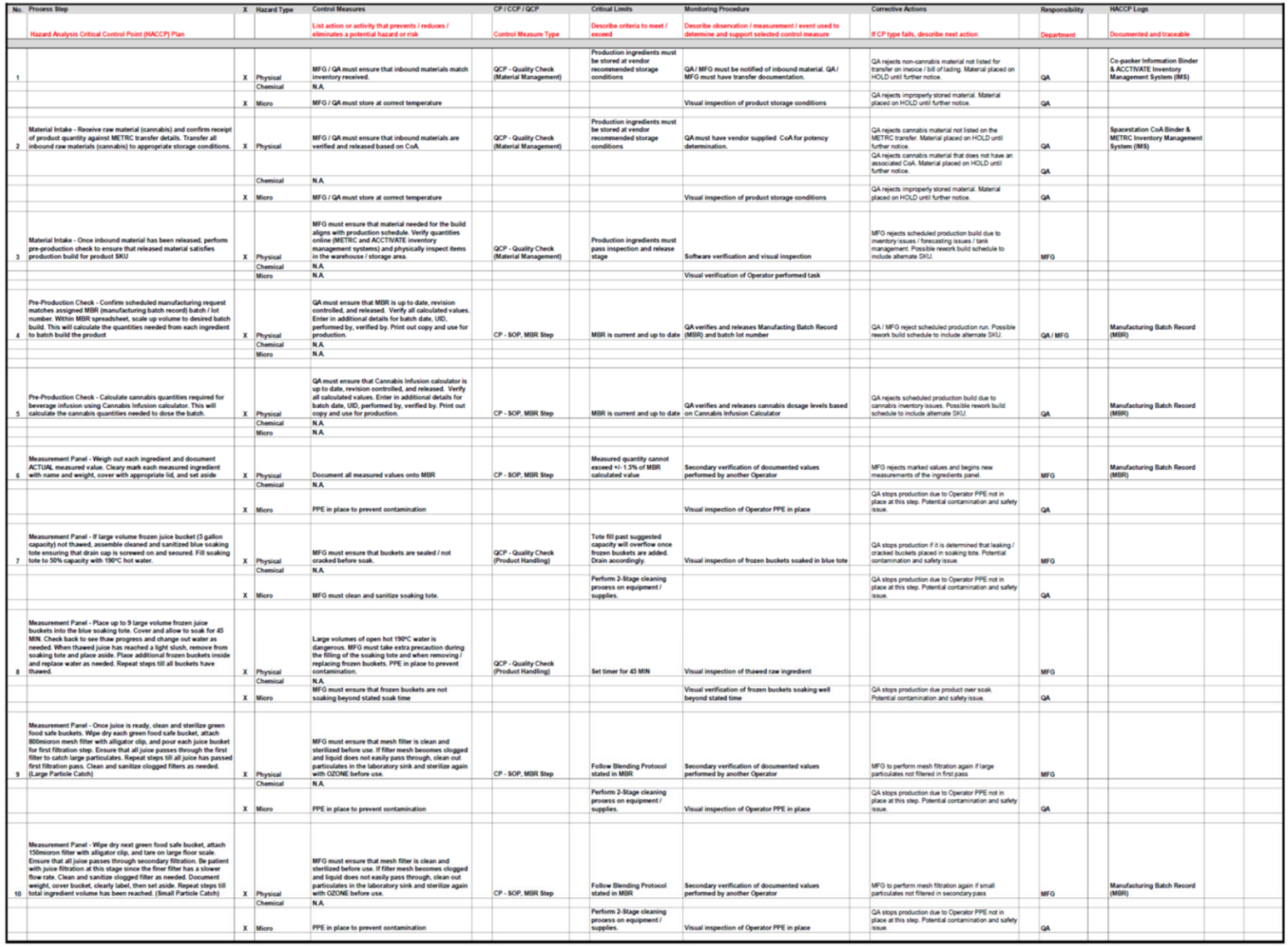
- Product(s) description
- SOPs
- PRPs
- Records
  - Critical Limits
  - Corrective Action
  - Calibration
  - Training

Page 4

Yes, it was printed in a size 8 font or smaller!

1. Each step has details about what is done at each step.
2. Hazards are listed as Physical, Chemical and Micro (no specifics)
3. Control Measures are classified as CP/CCP/QCP
4. Critical Limits are statements about what 'must' be done (no specifics)
5. Metrics (listed at the end of each plan)
   Process steps: 51
   CCP: 4
   QCP: 30
   CP: 17

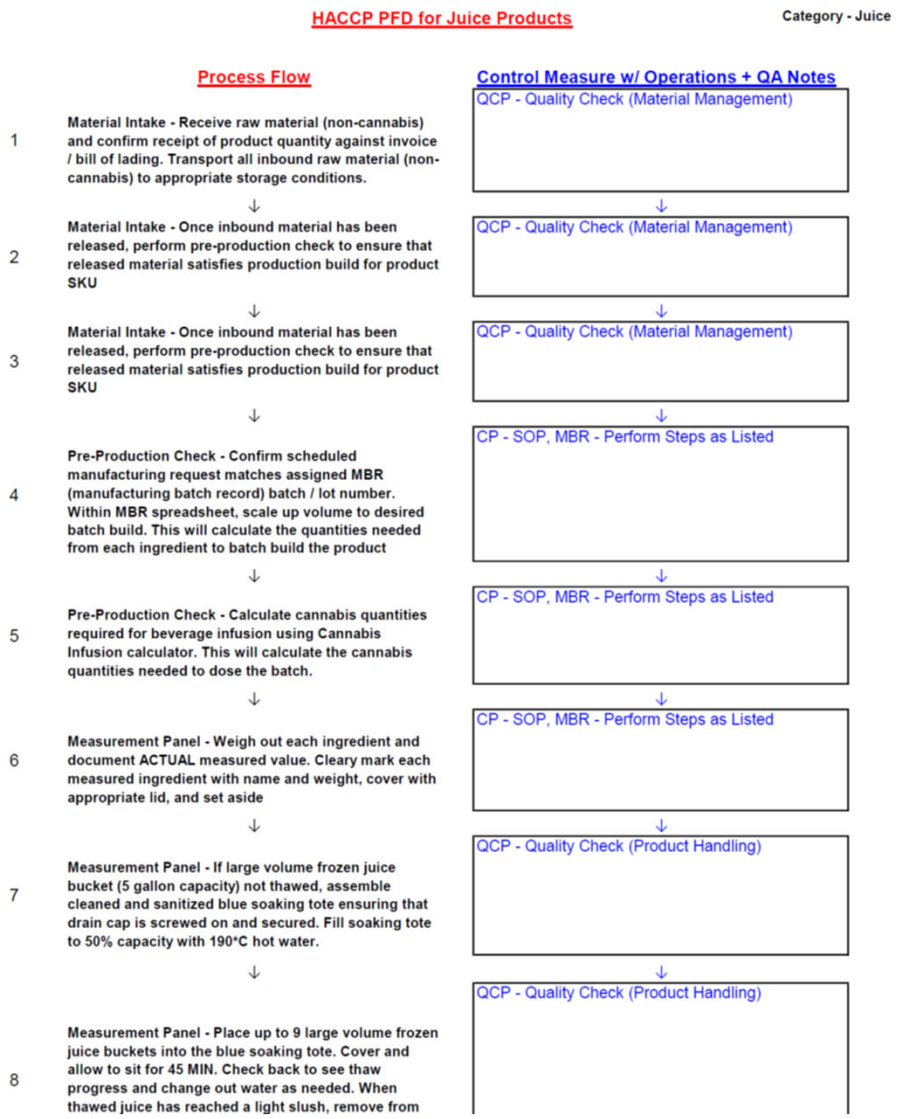
but I still don't know what their Hazards are or how they're controlling them!!



No.	Process Step	X	Hazard Type	Control Measures	CP / CCP / QCP	Critical Limits	Monitoring Procedure	Corrective Actions	Responsibility	HACCP Logs
	Hazard Analysis Critical Control Point (HACCP) Plan			List action or activity that prevents / reduces / eliminates a potential hazard or risk	Control Measure Type	Describe criteria to meet / exceed	Describe observation / measurement / event used to determine and support selected control measure	If CP type fails, describe next action	Department	Documented and traceable
1		X	Physical	MFG / QA must ensure that inbound materials match inventory received.	QCP - Quality Check (Material Management)	Production ingredients must be stored at vendor recommended storage conditions	QA / MFG must be notified of inbound material. QA / MFG must have transfer documentation.	QA rejects non-cannabis material not listed for transfer on invoice / bill of lading. Material placed on HOLD until further notice.	QA	Co-packer Information Binder & ACCTIVATE Inventory Management System (IMS)
			Chemical	N.A.						
		X	Micro	MFG / QA must store at correct temperature			Visual inspection of product storage conditions	QA rejects improperly stored material. Material placed on HOLD until further notice.	QA	
2	Material Intake - Receive raw material (cannabis) and confirm receipt of product quantity against METRC transfer details. Transfer all inbound raw materials (cannabis) to appropriate storage conditions.	X	Physical	MFG / QA must ensure that inbound materials are verified and released based on CoA.	QCP - Quality Check (Material Management)	Production ingredients must be stored at vendor recommended storage conditions	QA must have vendor supplied CoA for potency determination.	QA rejects cannabis material not listed on the METRC transfer. Material placed on HOLD until further notice.	QA	Spacestation CoA Binder & METRC Inventory Management System (IMS)
								QA rejects cannabis material that does not have an associated CoA. Material placed on HOLD until further notice.	QA	
			Chemical	N.A.						
		X	Micro	MFG / QA must store at correct temperature			Visual inspection of product storage conditions	QA rejects improperly stored material. Material placed on HOLD until further notice.	QA	
3	Material Intake - Once inbound material has been released, perform pre-production check to ensure that released material satisfies production build for product SKU	X	Physical	MFG must ensure that material needed for the build aligns with production schedule. Verify quantities online (METRC and ACCTIVATE inventory management systems) and physically inspect items in the warehouse / storage area.	QCP - Quality Check (Material Management)	Production ingredients must pass inspection and release stage	Software verification and visual inspection	MFG rejects scheduled production build due to inventory issues / forecasting issues / tank management. Possible rework build schedule to include alternate SKU.	MFG	
			Chemical	N.A.						
			Micro	N.A.			Visual verification of Operator performed task			
4	Pre-Production Check - Confirm scheduled manufacturing request matches assigned MBR (manufacturing batch record) batch / lot number. Within MBR spreadsheet, scale up volume to desired batch build. This will calculate the quantities needed from each ingredient to batch build the product	X	Physical	QA must ensure that MBR is up to date, revision controlled, and released. Verify all calculated values. Enter in additional details for batch date, UID, performed by, verified by. Print out copy and use for production.	CP - SOP, MBR Step	MBR is current and up to date	QA verifies and releases Manufacting Batch Record (MBR) and batch lot number	QA / MFG reject scheduled production run. Possible rework build schedule to include alternate SKU.	QA / MFG	Manufacturing Batch Record (MBR)
			Chemical	N.A.						
			Micro	N.A.						
5	Pre-Production Check - Calculate cannabis quantities required for beverage infusion using Cannabis Infusion calculator. This will calculate the cannabis quantities needed to dose the batch.	X	Physical	QA must ensure that Cannabis Infusion calculator is up to date, revision controlled, and released. Verify all calculated values. Enter in additional details for batch date, UID, performed by, verified by. Print out copy and use for production.	CP - SOP, MBR Step	MBR is current and up to date	QA verifies and releases cannabis dosage levels based on Cannabis Infusion Calculator	QA rejects scheduled production build due to cannabis inventory issues. Possible rework build schedule to include alternate SKU.	QA	Manufacturing Batch Record (MBR)
			Chemical	N.A.						
			Micro	N.A.						
6	Measurement Panel - Weigh out each ingredient and document ACTUAL measured value. Cleary mark each measured ingredient with name and weight, cover with appropriate lid, and set aside	X	Physical	Document all measured values onto MBR	CP - SOP, MBR Step	Measured quantity cannot exceed +/- 1.5% of MBR calculated value	Secondary verification of documented values performed by another Operator	MFG rejects marked values and begins new measurements of the ingredients panel.	MFG	Manufacturing Batch Record (MBR)
			Chemical	N.A.						
		X	Micro	PPE in place to prevent contamination			Visual inspection of Operator PPE in place	QA stops production due to Operator PPE not in place at this step. Potential contamination and safety issue.	QA	
7	Measurement Panel - If large volume frozen juice bucket (5 gallon capacity) not thawed, assemble cleaned and sanitized blue soaking tote ensuring that drain cap is screwed on and secured. Fill soaking tote to 50% capacity with 190°C hot water.	X	Physical	MFG must ensure that buckets are sealed / not cracked before soak.	QCP - Quality Check (Product Handling)	Tote fill past suggested capacity will overflow once frozen buckets are added. Drain accordingly.	Visual inspection of frozen buckets soaked in blue tote	QA stops production if it is determined that leaking / cracked buckets placed in soaking tote. Potential contamination and safety issue.	MFG	
			Chemical	N.A.						
		X	Micro	MFG must clean and sanitize soaking tote.		Perform 2-Stage cleaning process on equipment / supplies.		QA stops production due to Operator PPE not in place at this step. Potential contamination and safety issue.	QA	
8	Measurement Panel - Place up to 9 large volume frozen juice buckets into the blue soaking tote. Cover and allow to soak for 45 MIN. Check back to see thaw progress and change out water as needed. When thawed juice has reached a light slush, remove from soaking tote and place aside. Place additional frozen buckets inside and replace water as needed. Repeat steps till all buckets have thawed.	X	Physical	Large volumes of open hot 190°C water is dangerous. MFG must take extra precaution during the filling of the soaking tote and when removing / replacing frozen buckets. PPE in place to prevent contamination.	QCP - Quality Check (Product Handling)	Set timer for 45 MIN	Visual inspection of thawed raw ingredient		MFG	
			Chemical	N.A.						
		X	Micro	MFG must ensure that frozen buckets are not soaking beyond stated soak time			Visual verification of frozen buckets soaking well beyond stated time	QA stops production due product over soak. Potential contamination and safety issue.	QA	
9	Measurement Panel - Once juice is ready, clean and sterilize green food safe buckets. Wipe dry each green food safe bucket, attach 800micron mesh filter with alligator clip, and pour each juice bucket for first filtration step. Ensure that all juice passes through the first filter to catch large particulates. Repeat steps till all juice has passed first filtration pass. Clean and sanitize clogged filters as needed. (Large Particle Catch)	X	Physical	MFG must ensure that mesh filter is clean and sterilized before use. If filter mesh becomes clogged and liquid does not easily pass through, clean out particulates in the laboratory sink and sterilize again with OZONE before use.	CP - SOP, MBR Step	Follow Blending Protocol stated in MBR	Secondary verification of documented values performed by another Operator	MFG to perform mesh filtration again if large particulates not filtered in first pass	MFG	
			Chemical	N.A.						
		X	Micro	PPE in place to prevent contamination		Perform 2-Stage cleaning process on equipment / supplies.	Visual inspection of Operator PPE in place	QA stops production due to Operator PPE not in place at this step. Potential contamination and safety issue.	QA	
10	Measurement Panel - Wipe dry next green food safe bucket, attach 150micron filter with alligator clip, and tare on large floor scale. Ensure that all juice passes through secondary filtration. Be patient with juice filtration at this stage since the finer filter has a slower flow rate. Clean and sanitize clogged filter as needed. Document weight, cover bucket, clearly label, then set aside. Repeat steps till total ingredient volume has been reached. (Small Particle Catch)	X	Physical	MFG must ensure that mesh filter is clean and sterilized before use. If filter mesh becomes clogged and liquid does not easily pass through, clean out particulates in the laboratory sink and sterilize again with OZONE before use.	CP - SOP, MBR Step	Follow Blending Protocol stated in MBR	Secondary verification of documented values performed by another Operator	MFG to perform mesh filtration again if small particulates not filtered in secondary pass	MFG	Manufacturing Batch Record (MBR)
			Chemical	N.A.						
		X	Micro	PPE in place to prevent contamination		Perform 2-Stage cleaning process on equipment / supplies.	Visual inspection of Operator PPE in place	QA stops production due to Operator PPE not in place at this step. Potential contamination and safety issue.	QA	

Review their flow diagram (5 pages)

-- again, too much detail



HACCP PFD for Juice Products

Category - Juice

	Process Flow	Control Measure w/ Operations + QA Notes
1	Material Intake - Receive raw material (non-cannabis) and confirm receipt of product quantity against invoice / bill of lading. Transport all inbound raw material (non-cannabis) to appropriate storage conditions.	QCP - Quality Check (Material Management)
2	Material Intake - Once inbound material has been released, perform pre-production check to ensure that released material satisfies production build for product SKU	QCP - Quality Check (Material Management)
3	Material Intake - Once inbound material has been released, perform pre-production check to ensure that released material satisfies production build for product SKU	QCP - Quality Check (Material Management)
4	Pre-Production Check - Confirm scheduled manufacturing request matches assigned MBR (manufacturing batch record) batch / lot number. Within MBR spreadsheet, scale up volume to desired batch build. This will calculate the quantities needed from each ingredient to batch build the product	CP - SOP, MBR - Perform Steps as Listed
5	Pre-Production Check - Calculate cannabis quantities required for beverage infusion using Cannabis Infusion calculator. This will calculate the cannabis quantities needed to dose the batch.	CP - SOP, MBR - Perform Steps as Listed
6	Measurement Panel - Weigh out each ingredient and document ACTUAL measured value. Cleary mark each measured ingredient with name and weight, cover with appropriate lid, and set aside	CP - SOP, MBR - Perform Steps as Listed
7	Measurement Panel - If large volume frozen juice bucket (5 gallon capacity) not thawed, assemble cleaned and sanitized blue soaking tote ensuring that drain cap is screwed on and secured. Fill soaking tote to 50% capacity with 190°C hot water.	QCP - Quality Check (Product Handling)
8	Measurement Panel - Place up to 9 large volume frozen juice buckets into the blue soaking tote. Cover and allow to sit for 45 MIN. Check back to see thaw progress and change out water as needed. When thawed juice has reached a light slush, remove from	QCP - Quality Check (Product Handling)

Conclusion

They hired a consultant to write this up for them, but the team was not involved in the development.

Nobody at the plant understood what their hazards were, much less their control measures or CCPs

The HACCP plan was incomplete (but overwhelming)

Too much detail in the HACCP plan, but no discussion about specific hazards

Another juice example

HACCP Plan
for Juice Products
3 pages
8 steps

- No flow diagram
- No product description
- Note headers
- General

1). Process Step	2). Food and Safety Hazard: Biological Chemical Physical	3). Reasonably Likely to Occur	4). Bases of column 3 Decision	5). If "Yes" in column 3, what steps to reduce/Control Point	6). Critical Control Point
Juice	**Chemical-** Possible pesticide	Yes	Much of the juice made in the US contains several pesticides	Purchasing juice that should be pesticide free ; All products are lab tested and if unauthorized pesticides are detected the batch is destroyed	Lab testing
Storing Juice	**Biological-** Temp range deviation and microbial growth	No	Regular monitoring of temperatures at acquisition and while in storage; large freezer holds temperature for several days if power is lost; food safety standard practices are used with storing and thawing of juice and concentrates	N/A	All products are pasteurized before being sold

Do you want to test the product upon receipt or purchasing? Or ask your supplier to assure there are no pesticides?

Page 2

Blending Juice	**Biological-** Temperature range deviation and Contamination	No	Temperature is checked while blending; use of clean equipment and supplies; Staff clean\sanitize equipment after and before use; all bottles are pasteurized prior to being released for sale	N/A	All products are pasteurized before being sold
Bottling Juice	**Biological-** Microbial growth **Physical-** Debris contamination	No	All equipment is self contained and moved to freshly cleaned and sanitized bottles; Staff clean\sanitize equipment after and before use; all bottles are pasteurized prior to being released for sale	N/A	All products are pasteurized before being sold
Cannabis	**Biological-** Potency	No	Very low doses of cannabis are in the finished product; All cannabis added is measured before being added to the product	N/A	Lab testing

Page 3

- where's the pasteurization step??

Shipping Final Product	**Physical-** Breakage	No	All final products are stored and shipped in individual bottles and placed in special bottle cases to prevent breakage		Distributor Company Blackbird inspects cases for breakage/leakage before shipping to customers
Receiving Juice	**Biological-** Temperature range deviation/microbial growth	No	Juice is shipped in refrigerated trucks and temperature is collected at delivery to ensure the juice is in temperature range		All products are pasteurized before being sold
Cannabis Storage	**Biological-** Microbial growth and potency impact	No	Cannabis oil is stored in a locked cool dark place; all products are laboratory tested prior to being released to our consumers		All products are pasteurized before being sold


A few things to think about

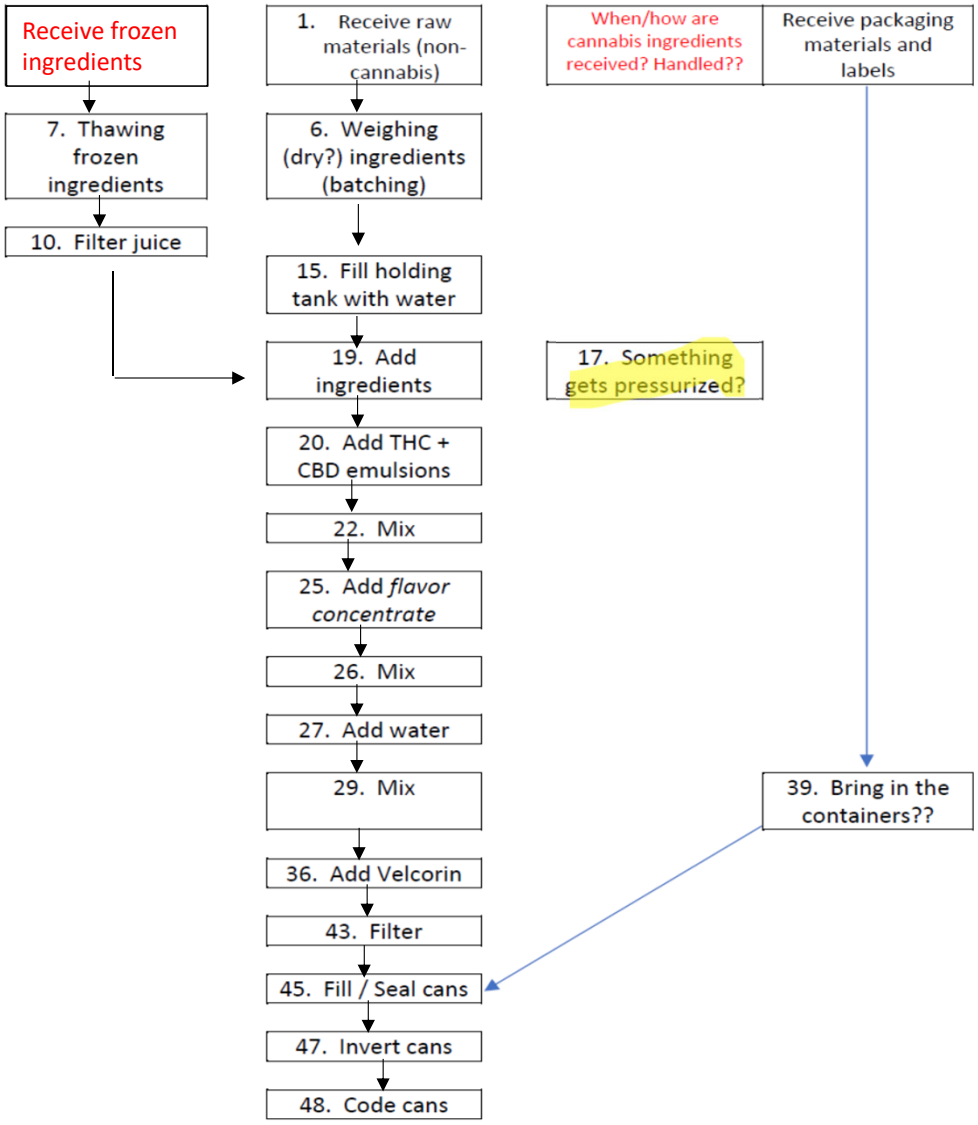
Product description – frequently overlooked

- The HACCP team and the inspector needs to understand what the product is, how it's made (ingredients + process steps), what kind of container it's in and how it is intended to be shipped and consumed.
  - Ingredients may determine the type of product it is (acid/acidified; low Aw, etc.)
  - Shelf stable vs perishable
  - Glass vs plastic container
  - Single serve, RTE/RTD or to be portioned out

  - Try to focus on safety concerns, with cannabis products, regulatory issues will be important too, but may be addressed separately?

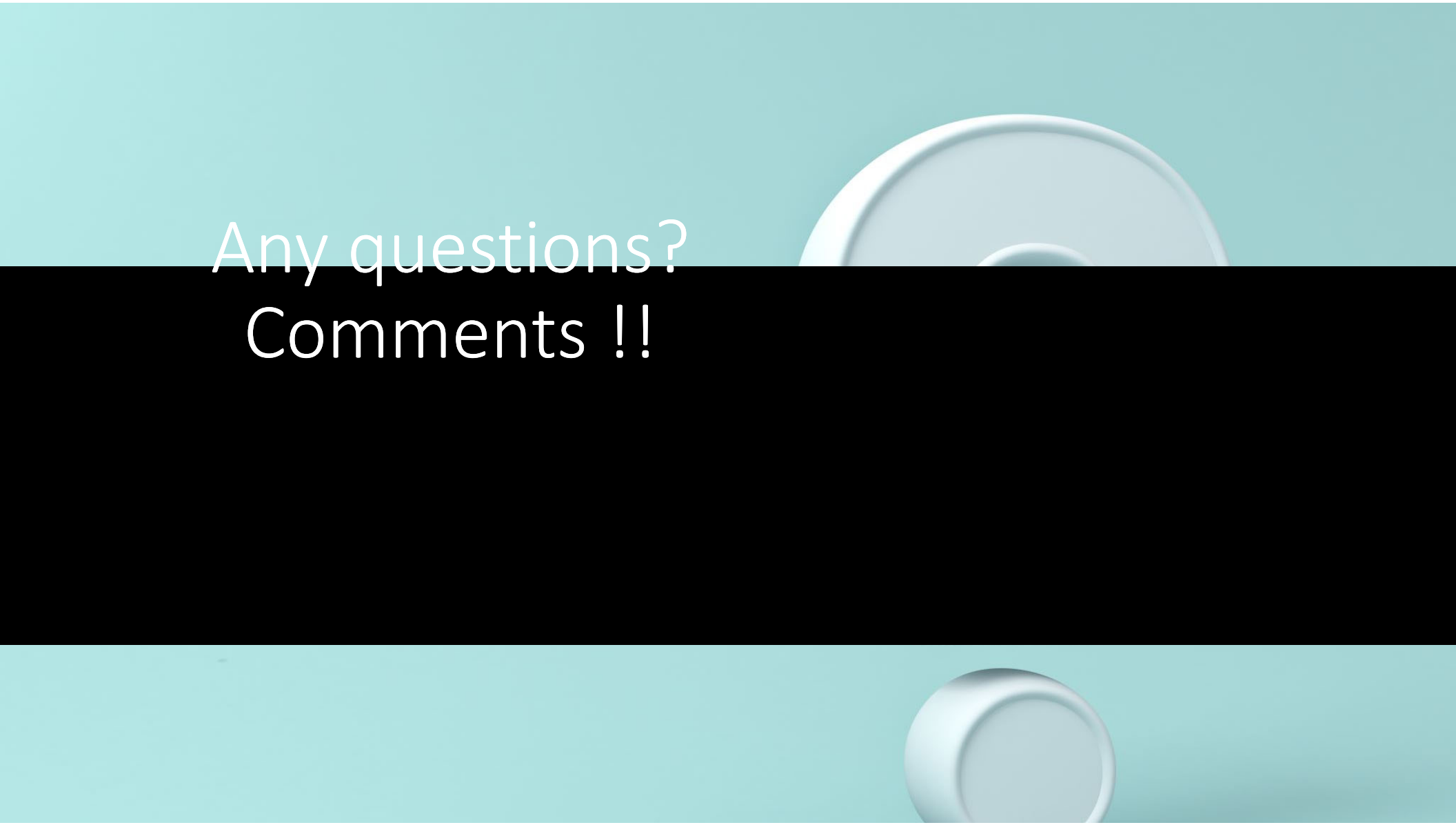
The flow diagram from the plan presented above went from 51 steps to this

- A few steps were missing
- Not sure where #17 fit into the flow



HACCP Plan example: Tincture

- Hazard Analysis
- Critical Limits, etc.


Any questions?
Comments !!