Exercice 1 :

You are the quality manager in a medium-sized dairy company that produces **stirred fruit yogurt**. Here is the simplified manufacturing flow diagram:

1. Reception of raw milk (tank trucks)
2. Refrigerated storage (4°C)
3. Skimming / Standardization (adjusting fat and protein content)
4. Enrichment (adding milk powder)
5. Heat treatment (95°C for 5 minutes)
6. Cooling (to 42°C, inoculation temperature)
7. Inoculation (with *Streptococcus thermophilus* and *Lactobacillus bulgaricus*)
8. Incubation (maintained at 42°C for 4 hours until pH 4.6)
9. Stirring and Cooling (stopping acidification)
10. Addition of fruit preparation (pasteurized strawberry jam)
11. Packaging into pots
12. Cold storage (≤ 6°C)

Question 1:
For each step, identify a **potential hazard** (biological, chemical, or physical) and briefly justify why it is significant.

Step	Potential Hazard	Justification
Reception of raw milk		
Addition of fruit preparation		
Heat treatment (95°C)		

Question 2:
Among the hazards listed above, which one would justify the implementation of a **CCP (Critical Control Point)** in your opinion? Why couldn't it be managed solely by Good Hygiene Practices (prerequisites)?

Part B: Definition of Limits and Monitoring
During the analysis, you identified that the **incubation** step is crucial, not to eliminate a hazard, but to **create an unfavorable environment for pathogens** (through acidification).

- The rapid acidification by the lactic acid bacteria lowers the pH.
- A pH ≤ 4.6 reached in less than 4 hours prevents the growth of most pathogenic bacteria (*Listeria, Salmonella, Staphylococci*).

Question 3:
You define this point as an **oPRP (operational Prerequisite Program)** or a CCP depending on your analysis. If you define it as a CCP, propose:

- The **critical limit** to monitor.
- The **monitoring frequency**.
- The **corrective action** if the limit is not reached within the allotted time.

Question 1: Potential Hazards by Step

Step	Potential Hazard	Justification
Reception of raw milk	**Biological**: Pathogenic bacteria (*Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7).	Raw milk is an excellent culture medium. These bacteria can come from the animal (mastitis, fecal contamination) or the farm environment. This is a significant hazard because it can affect consumer safety if the heat treatment is insufficient.
Addition of fruit preparation	**Physical**: Foreign bodies (fragment of pits, seeds, pieces of plastic from packaging). **Chemical**: Pesticide residues, mycotoxins (if fruits are moldy).	Fruit preparations are complex ingredients. Physical hazards can injure the consumer. Chemical hazards are significant because they are not eliminated by pasteurization and are often invisible.
Heat treatment (95°C)	**Biological**: Survival of vegetative pathogenic bacteria.	This is the barrier step to destroy pathogens. If the temperature is not reached (e.g., 92°C) or the time is insufficient (e.g., 3 min), pathogens like *Listeria* or *Salmonella* can survive and end up in the finished product.

Question 2: Identification of the CCP

Heat treatment is a CCP (Critical Control Point).

- **Why CCP and not just GHP?**
    - It is a **specific technological step** with precise parameters (time/temperature).
    - Its objective is the **destruction** of microbiological hazards.
    - If it fails, the finished product will be dangerous, and no other step in the process (except perhaps acidification, which is not a destruction process) can make it safe.

- It requires **continuous monitoring** (temperature recording) and immediate corrective actions in case of deviation, which goes beyond the scope of basic Good Hygiene Practices (which are framework conditions).

Part B: Definition of Limits and Monitoring (Incubation)

Question 3: Definition of Limits (considering incubation as a CCP)

If we consider incubation as a CCP (or even an oPRP, the logic is similar), we define:

- **Critical Limit:** Achieve a pH ≤ 4.6 within a maximum of 4 hours after inoculation. *(Justification: Below pH 4.6, most pathogens cannot grow. The timeframe is crucial to prevent them from having time to proliferate or produce toxins).*
- **Monitoring Frequency:** Continuous (automatic recording by a pH probe with an alarm) or discontinuous (manual check every 30 minutes to 1 hour by the operator, recorded on a monitoring sheet).
- **Corrective Action:**
    1. **If the pH is not reached on time:** Extend the incubation and monitor the evolution.
    2. **If after 6 hours the pH is still not at 4.6:** Isolate the batch (quarantine).
    3. **Analyze the batch:** Perform microbiological analyses (search for *Listeria*, *Salmonella*, *Staphylococcus aureus* and count spoilage flora).
    4. **Decision:** Based on the results, either destroy the batch, redirect it to a use where it will undergo another cooking process (if possible), or downgrade it.
    5. **Action on the process:** Check the activity of the starter cultures, the incubation temperature, the absence of cleaning residues, and recalibrate the pH meter.

Exercise 2: Acidified Mayonnaise

a. Three essential PRPs for an egg-based product

Prerequisite Programs (PRPs) are the basic conditions that must be in place before implementing HACCP. For a product containing egg, three critical PRPs are:

1. **Temperature control (Cold chain management):**
    - *Justification:* Although pasteurized, egg yolk may contain survivors if the pasteurization was not perfect. Maintaining a temperature ≤ 4°C throughout the supply chain (storage, production) prevents the growth of any residual or contaminating pathogens (e.g., *Listeria*).
2. **Cleaning and disinfection (C&D) of food contact surfaces:**

- *Justification:* After the egg is pasteurized and the product is acidified, there is no further cooking step. If the mixture contacts a dirty surface (tank, pipe, mixer), **recontamination** by pathogens like *Listeria* or *Salmonella* can occur.

3. **Personal hygiene:**
    - *Justification:* Humans are major vectors for *Staphylococcus aureus* (via hands, skin) and fecal bacteria. Hand washing, wearing gloves, and hairnets are imperative to prevent manual contamination.

(Other possible answers: Equipment maintenance, staff training, allergen control if garlic is considered an allergen).

b. Primary biological hazard and its significance

Hazard: *Salmonella* spp.

Justification for its significance:

- **Raw material:** Eggs, even pasteurized, are historically linked to this hazard. A minor failure in the supplier's pasteurization process could introduce *Salmonella*.
- **Finished product:** Mayonnaise is a "sensitive" product; it is not cooked and is stored chilled. The only barrier to *Salmonella* survival is acidity (low pH).
- **Severity:** *Salmonella* causes severe foodborne illnesses (salmonellosis), which can be fatal in vulnerable populations.
- **Control:** Since cooking is not possible, pH is the sole control factor. If the pH is too high, *Salmonella* can survive and multiply.

*(*Listeria monocytogenes* could also be cited, especially for products with a long refrigerated shelf life).**

c. Justification of the "Acidification/Mixing" step as a CCP

The "Acidification/Mixing" step is a **Critical Control Point (CCP)** for the following reasons:

1. **It is the last control step:** Once the mix is made and packaged, there is no subsequent step (no cooking, no freezing) to destroy or inhibit pathogens.
2. **The factor is measurable:** pH can be measured in real-time (or by sampling). It is an objective measurement.
3. **Direct link to safety:** pH is the only factor guaranteeing the microbiological safety of the finished product. If the target pH is not achieved, the product is **unsafe**.
4. **Critical limits are applicable:** A precise limit ($pH \leq 4.0$) and tolerance can be defined.

5. **Codex Alimentarius definition:** It is a step where a control measure (adding acid) is essential to prevent, eliminate, or reduce a hazard to an acceptable level. Here, it **prevents** the growth of pathogens.

d. Calculation of the Critical Limit

1. Calculate the required molar concentration of H^+

- **Formula:** $[H^+] = 10^{-pH}$
- **Application:** Target pH of the pre-mix = 2.8
  $[H^+] = 10^{-2.8}$
- **Result:** $[H^+]$ = **1.58×10^{-3} mol/L** (or 0.00158 mol/L).

2. Calculate the mass of pure acetic acid needed for 200 L

Reasoning: To simplify the exercise, we assume acetic acid (a weak acid) behaves like a strong acid and releases 1 H^+ per molecule. Therefore, we need 1.58 × 10⁻³ moles of acetic acid per liter.

- **Moles needed for 200 L:**
  n = $[H^+]$ × Volume
  n = (1.58×10^{-3} mol/L) × 200 L
  n = **0.316 moles** of acetic acid.
- **Convert moles to mass:**
  - Molar mass (M) of CH_3COOH = 60 g/mol.
  - Formula: mass = n × M
  - mass = 0.316 mol × 60 g/mol
  - mass = **18.96 g**.

Final answer: Approximately **19 g of pure acetic acid** are needed to prepare 200 liters of pre-mix solution at pH 2.8.

*(**Teaching note:** In reality, vinegar (diluted acetic acid, often 8% or 10%) is used. The calculation would be different: you would need to divide this mass by the vinegar concentration. E.g., if using 10% vinegar (100g/L), you would need ~190 mL of vinegar for 200L of water. This seems very small, highlighting the importance of precise dosing).*

e. Deviation and Corrective Action

1. Compliance with the Critical Limit

- **Critical Limit (CL) for the finished product:** pH ≤ **4.0**.

- **Measured value:** pH = **4.4**.
- **Conclusion: NO**, this batch is non-compliant. The measured value (4.4) is higher than the critical limit (4.0). The product cannot be commercialized as is because it lacks the necessary acidic barrier against pathogens.

2. Immediate corrective actions (Segregation and Correction)

- **On the product:**
    1. **Quarantine:** Immediately label the batch as "NON-CONFORMING - BLOCKED".
    2. **Decision on product disposition:**
        - **Option A (Rework):** If technically possible (accessible tank), add more acid to lower the pH below 4.0 and re-check.
        - **Option B (Downgrade):** Sell the batch to another industry for a use that requires cooking (e.g., pizza sauce), which would destroy the pathogen.
        - **Option C (Destruction):** If neither of the above options is possible, the product must be destroyed.
- **On the process:**
    1. **Stop the line:** Suspend production immediately.
    2. **Find the immediate cause:** Check the vinegar doser (is it clogged? misadjusted?), check the incoming vinegar batch (is it less concentrated than usual?), check the pH meter (is it properly calibrated?).
    3. **Correction:** Re-calibrate the doser, adjust the recipe, re-calibrate the measuring instrument.
    4. **Re-validation:** Run a test batch and verify the pH before resuming full production.

3. Root cause analysis (Preventive approach)

To prevent recurrence, use a method like the **"5 Whys"** or a **Fishbone (Ishikawa) diagram**.

Example using the 5 Whys:

1. **Why was the pH 4.4?**
   → Because the vinegar doser dispensed too little acid.
2. **Why did the doser dispense too little?**
   → Because it was partially clogged.

3. **Why was it clogged?**
   → Because it wasn't cleaned properly after the last production run.

4. **Why was the cleaning incorrect?**
   → Because the operator did not follow the cleaning procedure (SOP).

5. **Why didn't the operator follow the procedure?**
   → Because they were not trained on this new machine, or the procedure was not posted nearby.

Preventive actions to implement (CAPA):

- Update the operator's training records.
- Post the cleaning procedure (SOP) next to the machine.
- Add a visual inspection of the doser to the pre-startup checklist.