

Series N°03

Exercise 1 :

1. **Hierarchy & legal scope:**

- **National regulation (ministerial decree)** – Legally binding, directly enforceable in that country.
- **Codex Alimentarius** – Not legally binding per se, but reference in WTO disputes.
- **ISO 22000** – Voluntary standard, no legal force unless referenced in legislation or contract.

2. **Is Codex strictly mandatory at national level?**

No. It is a **reference**; countries may adopt stricter measures if scientifically justified.

3. **Priority text for national market non-conformity**

National regulation (e.g., ministerial decree, food code, public health law).

Exercise 2 :

- **“Organic”** → Ethics / Regulatory (production method)
- **“Fair trade”** → Ethics/Service
- **“Preservative-free”** → Nutrition / Health
- **Recycled packaging** → Ethics / Environment/ Technology
- **Plastic fragment** → Health / Safety (physical hazard)

Plastic fragment: is a regulatory failure

Justification:

- The presence of a hard plastic fragment is a **Physical Hazard** (foreign body contamination).
- It is **strictly prohibited** by **Regulation (EC) No 178/2002** (General Food Law) Article 14: *"Food shall not be placed on the market if it is unsafe."*
- While it might be *unethical* to sell it knowing it's contaminated, the primary violation is **Legal Compliance (Safety)**. It is not merely an ethical issue like "misleading advertising"; it is a **public health risk**.

Exercise 3 :

Plan: n=5, c=2, m=10, M=100

Results: 5, 12, 85, 150, 30

1. Classification of each result

- **5 CFU/g:** $\leq m$ (10) $\rightarrow$ **Satisfactory**
- **12 CFU/g:** $> m$ but $\leq M$ ($10 < 12 \leq 100$) $\rightarrow$ **Acceptable**
- **85 CFU/g:** $> m$ but $\leq M \rightarrow$ **Acceptable**
- **150 CFU/g:** $> M$ (100) $\rightarrow$ **Unsatisfactory**
- **30 CFU/g:** $> m$ but $\leq M \rightarrow$ **Acceptable**

2. Is the batch accepted or rejected?

- **Acceptable results** $\leq c=2 \rightarrow$ Here, 3 acceptable (12,85,30) + 1 unsatisfactory (150) $\rightarrow$ actually:

Wait: unsatisfactory $> M$ counts as marginal? In 3-class plan:

- $\leq m$ = satisfactory
- between m and M = acceptable
- $\geq M$ = unacceptable

One unacceptable (150) $\rightarrow$ batch rejected immediately (even if $c=2$, any $> M$ = reject).

3. If one sample had >100 CFU/g, what would you decide?

If one sample >100 CFU/g $\rightarrow$ same $\rightarrow$ reject.

In a **3-class plan**, c refers to the **maximum number of samples allowed between m and M** . The **number of samples $> M$ must ALWAYS be ZERO**. A value over M indicates a gross hygiene failure or potential pathogen presence.

4. Why 3-class plan?

Because *E. coli* is a **hygiene indicator**, not a direct pathogen. 3-class allows marginal values between m and M .

Exercise 4 :

1. **Withdrawal** – from supply chain before reaching consumer.

Recall – from consumers.

Here, batch already sold to supermarkets & restaurants $\rightarrow$ must trigger **recall**.

2. **Traceability info urgently needed:**

- Downstream: which supermarkets, which restaurants, how much delivered.
- Upstream: smoked salmon batch number, supplier, production date.

3. **Can restaurant owner be sanctioned?**

Yes, if served after being notified of contamination.

Legal basis: **Hygiene Package (EC 852/2004)** – operator's **obligation of result** for food safety.

Exercise 5 :

1. **Classical sterilization (canning)** → **Not suitable** – destroys taste & vitamins (high temp, long time).
2. **Classical pasteurization** → Possible.
Time/temp: e.g., 72°C for 15 sec (HTST : High Temperature Short Time) or lower 60–65°C for longer.
But 30 days shelf life requires **refrigeration** + **strict hygiene** (pasteurization reduces but doesn't sterilize).
3. **Adding preservatives (E200–E299)**
 - Legal if within EU limits.
 - **Not ethical** if claiming “no chemical preservatives”.
 - **Not compliant** with request (request explicitly said “without adding chemical preservatives”).

Exercise 6 :

1. Penal & administrative risks

- **Penal:** Fines, imprisonment for director (food fraud / health risk).
- **Administrative:** Withdrawal of authorization, closure, mandatory recall, public naming.

A. Penal risks (criminal liability)

Risk	Explanation
Heavy fines	Can reach hundreds of thousands of euros (or local equivalent), often proportional to turnover.
Imprisonment	In many jurisdictions (EU, US, etc.), responsible managers can face prison time.
Corporate criminal liability	The company itself can be prosecuted, leading to closure or ban from food production.

B. Administrative risks

Risk	Explanation
License suspension or revocation	Health authorities can shut down the facility.
Mandatory destruction of the batch	The company pays for destruction, even if the batch is unsold.
Ban from export	The company may be barred from exporting to certain markets.
Blacklisting	Name published on official lists of non-compliant companies.
Increased inspections	Future production will face stricter, more frequent controls.

2. Deontology of Quality Manager

Must **refuse to market** non-compliant batch.

Ethical duty: protect consumer health > company profit.

Core ethical principles to apply

Principle	Application
Consumer safety first	Never sell food that does not comply with legal safety limits.
Transparency	Immediately inform top management and the competent authorities.
Professional integrity	Resist any pressure to bypass the law, even for financial reasons.
Regulatory compliance	Obey food law strictly; no exception for “small errors”.
Duty of care	Prevent potential harm before it occurs.

What the Quality Manager must NOT do

- Accept to sell the batch knowingly.
- Hide the non-conformity.
- Compensate” in the next batch (this is fraud).

What the Quality Manager MUST do

- Declare the non-conformity internally (written report).
- Block the batch from shipping.
- Propose legal solutions (rework, destruction, etc.).
- If management refuses, escalate to the food safety authority (whistleblowing).

3. Professional response to director

Dear Production Director,

I understand the financial concerns, but I cannot accept selling this batch. A 15% excess of nitrite above the legal limit is a clear violation of food safety regulations.

Legally and ethically, we must not release this product.

If we knowingly sell it, the company faces heavy fines, possible closure, and criminal charges for both the company and us as responsible managers.

I propose the following legal alternatives:

1. Rework – blend this batch with a compliant batch to bring nitrite levels below the limit (if technically possible).
2. Destruction – destroy the batch under official supervision.

3. Non-food use – use the meat for non-human purposes (e.g., pet food, if legally allowed).

I am ready to support any of these solutions. However, I cannot accept selling a non-compliant batch.

Please advise on which legal option we will implement. I will also document this non-conformity in our Food Safety Management System.