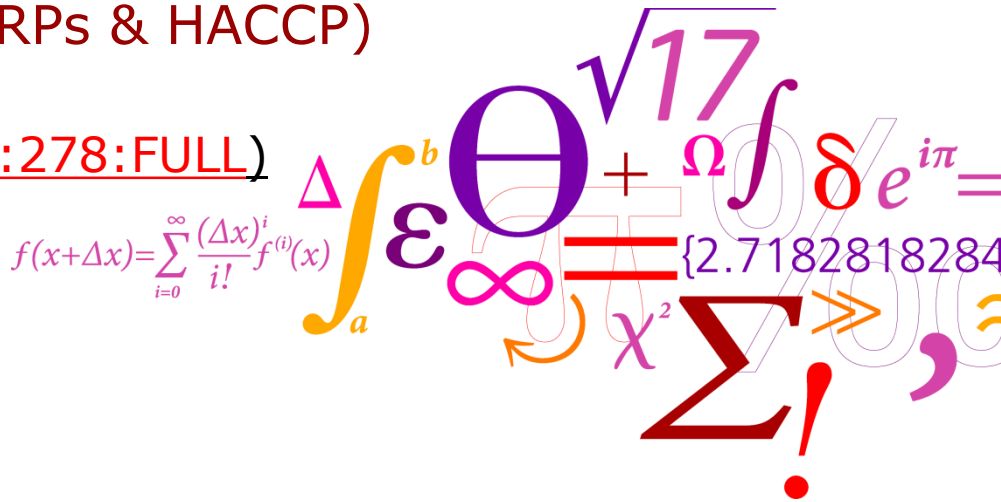
# Quality Risk Management & food safety management

by Tina Beck Hansen

- Quality Risk Management
(http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q9/Step4/Q9_Guideline.pdf)
ICH harmonized guideline

- Food safety management (PRPs & HACCP)
(http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:C:2016:278:FULL)
EU commission notice

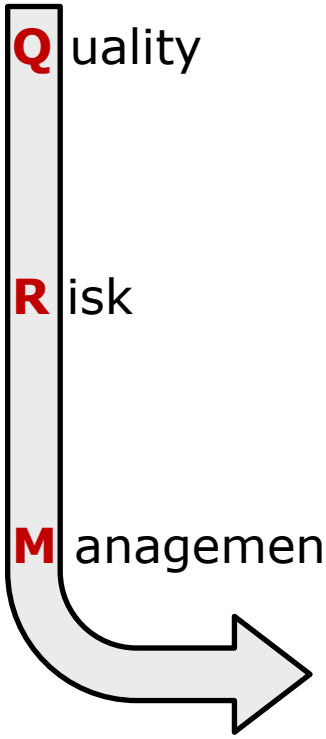



DTU Food
National Food Institute

# Quality Risk Management (QRM)

- What is QRM?
- The risk concept
- Example – drying process
- The typical QRM process
- Risk management tools

# What is QRM?



**Q**uality

Degree to which a set of inherent properties of a product, system or process fulfils *requirements*

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**R**isk

Combination of the *probability* of *occurrence* of harm and the *severity* of that harm

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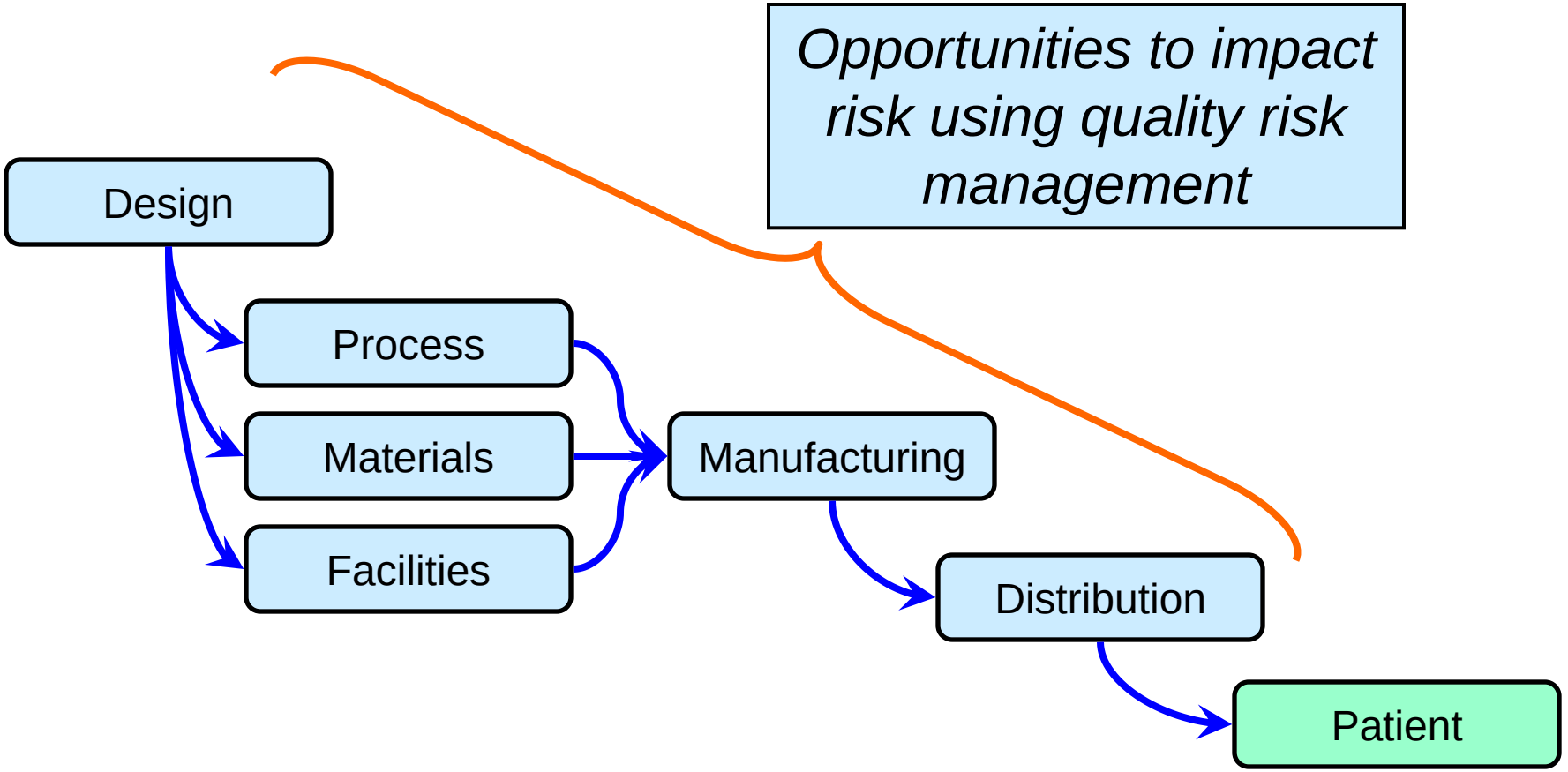
**M**anagement

Systematic process for the assessment, control, communication and review of risks to the quality of the pharmaceutical product across the *lifecycle*

From ICH Q9

# Product lifecycle – the link to patient risk




From Ian R. Thrussel, WHO 2009

# The concept of risk

- **As an individual:**
  - Risk is a cognitive and emotional response to expected loss

- **As an technician:**
  - Risk is based on the expected likelihood of an event occurring combined with the consequences of that event if it occurred

**RISK (QRM)**

*The combination of the probability of occurrence of harm and the severity of that harm*

# The concept of risk – harm & hazard

**HARM**

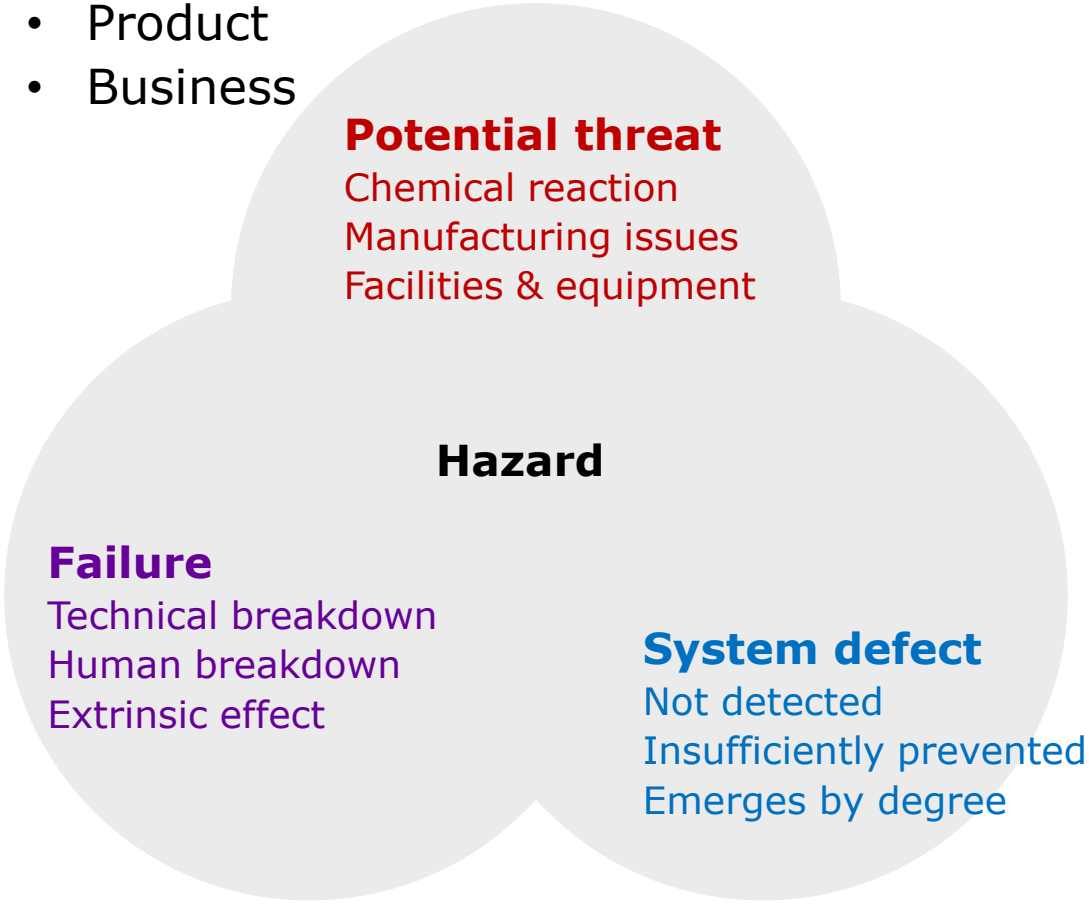
*Damage to health, including the damage that can occur from loss of product quality or availability*

**HAZARD (QRM)**

*The potential source of harm*

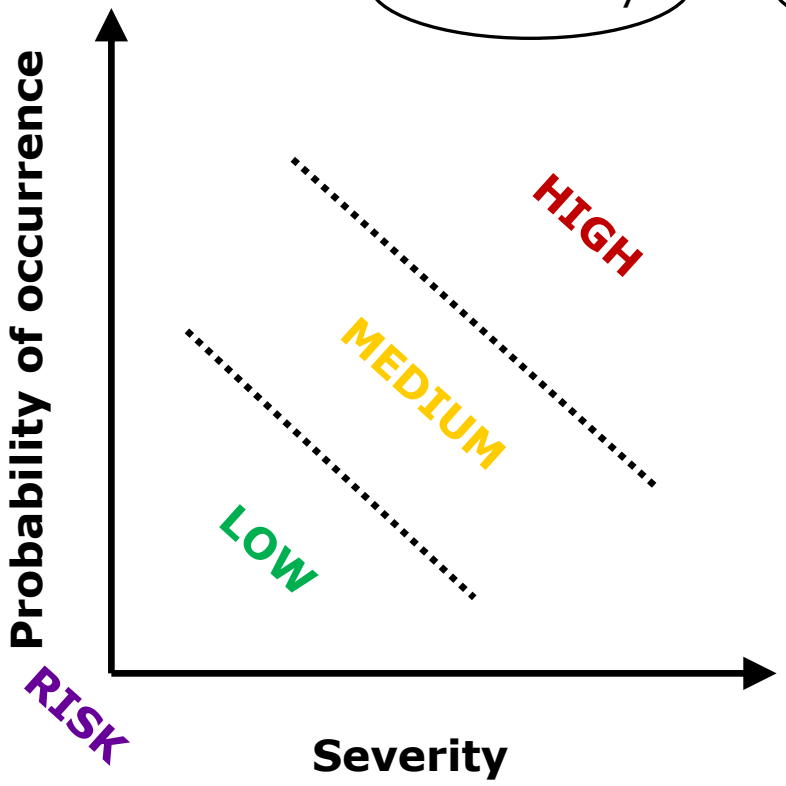
Anything with potential to cause harm to

- Patients/consumers
- Product
- Business



# The concept of risk – occurrence & severity

Probability X Severity = **RPN: Risk Priority Number**




Sometimes…….

X Detectability

# Info on severity, probability and detectability?

- **Severity (S)**
  - Link to end-product functional failure
  - Medical Department involvement

- **Probability (P)**
  - Use historical data
  - Similar processed products

- **Detectability (D)**
  - Method validation studies
  - Historical data

From ICH Q9 Briefing pack II, 2006

# Severity = consequences of failure

- **10 Extreme**
  - Predicted to cause severe impact on quality
- **7 High**
  - Predicted to cause significant impact on quality
- **3 Moderate**
  - Predicted to cause minor impact on quality
- **1 Low**
  - Predicted to have no/minor impact on quality of the product

From ICH Q9 Briefing pack II, 2006

# Probability = likelihood failure will happen

- **8 Regular failures**
  - Expected to happen regularly
- **4 Repeated failures**
  - Expected to happen in a low frequency
- **2 Occasional failures**
  - Expected to happen infrequently
- **1 Unlikely failures**
  - Unlikely to happen

From ICH Q9 Briefing pack II, 2006

# Drying process – defining severity and probability

| Ranking | Severity (S) | Probability (P) |
|---|---|---|
| 10 | Death | More than once a day |
| 9 | ↓ | 3 – 4 times a week |
| 8 | Permanent injury | Once a week |
| 7 | ↓ | Once a month |
| 6 | Temporary injury | Once in three months |
| 5 | ↓ | Once in half – one year |
| 4 | Reported / dissatisfied | Once a year |
| 3 | ↓ | Once in 1 – 3 years |
| 2 | Notice / no report | Once in 3 – 5 years |
| 1 | ↓ | Less than once in 5 years |

From ICH Q9 Briefing pack II, 2006

# Problem: Drying process – infant formula

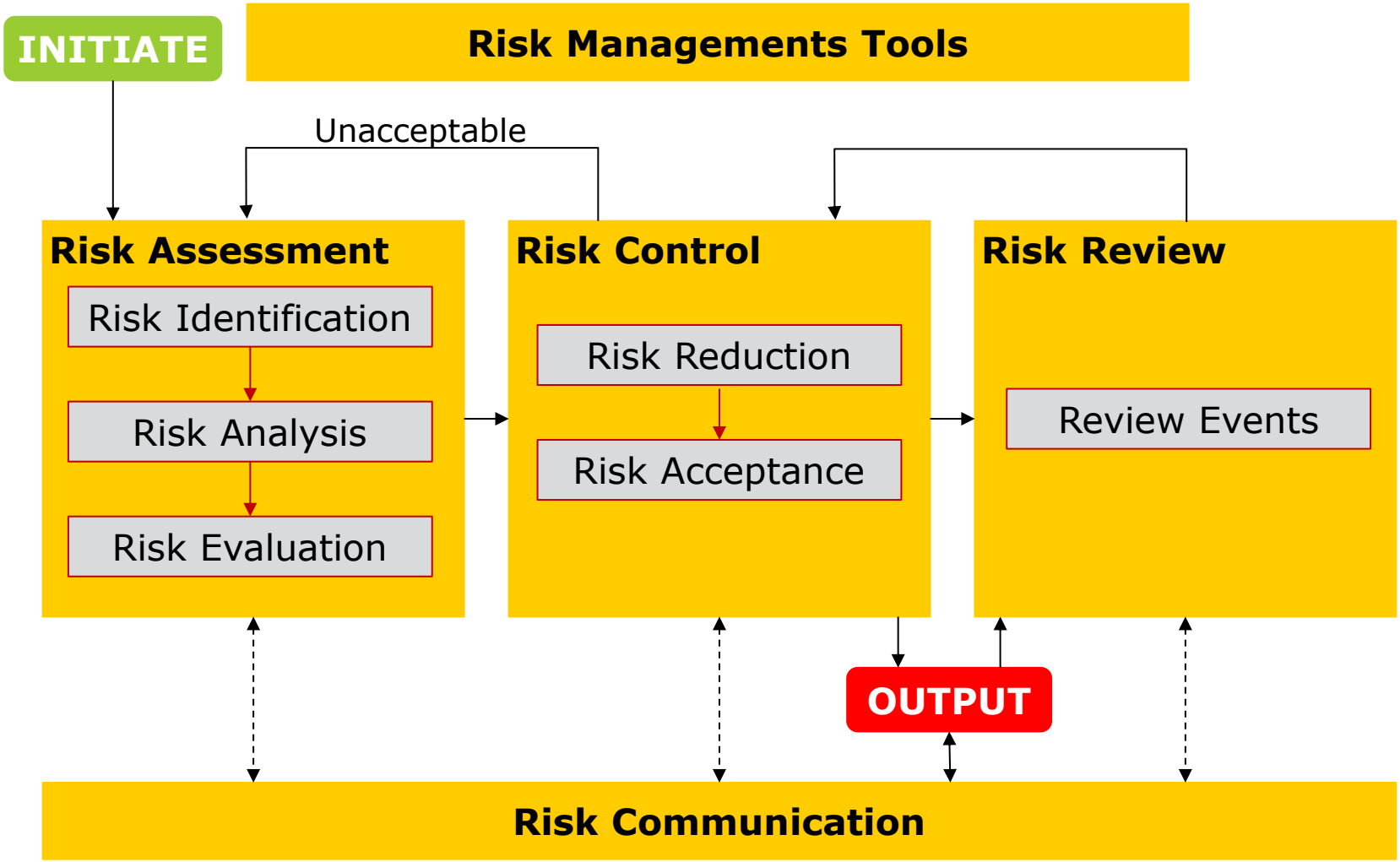
| Process | Mode of failure | Potential cause | S | P | RPN = SxP |
|---|---|---|---|---|---|
| 1. Set up | | | | | |
| 2. Start drying | | | | | |
| 3. Maintain temperature | | | | | |

# How to proceed?

- Take action when RPN is over a defined unacceptable limit
- Take action when the severity is over an unacceptable limit

| Process | Mode of failure | Potential cause | S | P | RPN | Recommended action | S | P | RPN |
|---|---|---|---|---|---|---|---|---|---|
| 1. Set up | | | | | | | | | |
| 2. Start drying | | | | | | | | | |
| 3. Maintain temp. | | | | | | | | | |

# The typical QRM process




From ICH Q9

# Risk Management Tools

- Basic risk management facilitation methods
  - Flowcharts
  - Check sheets
  - Process mapping
  - Cause and effect diagrams (Ishikawa/fish bone)
- Failure Mode Effects Analysis (FMEA)
  - Break down large complex processes into manageable steps
- Failure Mode, Effects and Criticality Analysis (FMECA)
  - FMEA & links severity, probability & detectability to criticality
- Fault Tree Analysis (FTA)
  - Tree of failure modes combinations with logical operators
- Hazard Analysis and Critical Control Points (HACCP)
  - Systematic, proactive and preventive method on criticality
- Hazard Operability Analysis (HAZOP)
  - Brainstorming technique
- Preliminary Hazard Analysis (PHA)
  - Possibilities that the risk event happens
- Risk ranking and filtering
  - Compare and prioritize risks with factors for each risk
- Supporting statistical tools

Risk Identification

Risk Evaluation

Risk Control

From ICH Q9

# Appropriate tool dependents on hazard

| System | Process | Product |
| --- | --- | --- |
| **Facility & people**<br>• Operators<br>• Environment<br>• Equipment<br>• IT<br><br>**Organisation**<br>• Quality system<br>• Controls<br>• Documentation | **Production line**<br>• Process operations<br>• Quality parameters | **Safety & efficacy**<br>• Quality attributes<br>• Specifications |

# Linking type of hazard with tool: example

| **Tool** | **System** (facility & people) | **System** (organisation) | **Process** | **Product** (safety & efficacy) |
|---|---|---|---|---|
| Flow charts | | | X | |
| Check sheets | X | | | X |
| Process mapping | | | X | |
| Cause & effect | | | X | X |
| FMEA/FMECA | | X | X | |
| FTA | | | X | X |
| HACCP | | X | X | |
| HAZOP | X | | X | |
| PHA | X | X | X | |
| Risk ranking | X | X | X | |
| Statistical tools | | | | X |

Summarized from ICH Q9

# Food safety management

- Food safety in the food control system
- Food safety management through own-check
- PRP versus HACCP
- HACCP in food legislation
- The 7 principles of HACCP
- Hazard analysis
- Control measures, CCPs and oPRPs
- HACCP plan

# Food safety management?

# What is a (foodborne) hazard?

**HAZARD**

*A biological, chemical, or physical **agent** in, or condition of, food with the potential to cause an adverse health effect*

# Hazards - examples

## Chemical hazards

- Environmental pollutions (*e.g.* lead, mercury)
- Production aids (*e.g.* pesticides, nitrate, cleaning materials)
- Compounds formed during cooking (*e.g.* acrylamide, mutagens)
- Naturally occurring toxins in food (*e.g.* lectin and solanine)
- Migration from plastic utensils and packaging material
- Allergens

## Physical hazards

- Pieces from utensils or humans (*e.g.* nails, jewelleries)
- Pieces from broken ??????

## Biological hazards

- Bacteria
- Moulds, yeasts and algae
- Viruses
- Parasites

# Food safety management in the control system

§

Ministeriet for Fødevarer, Landbrug og Fiskeri
Fødevarestyrelsen

**Hazards** → **Policy & legislation** → **Food control system**

**Own-check**
- PRPs
- HACCP

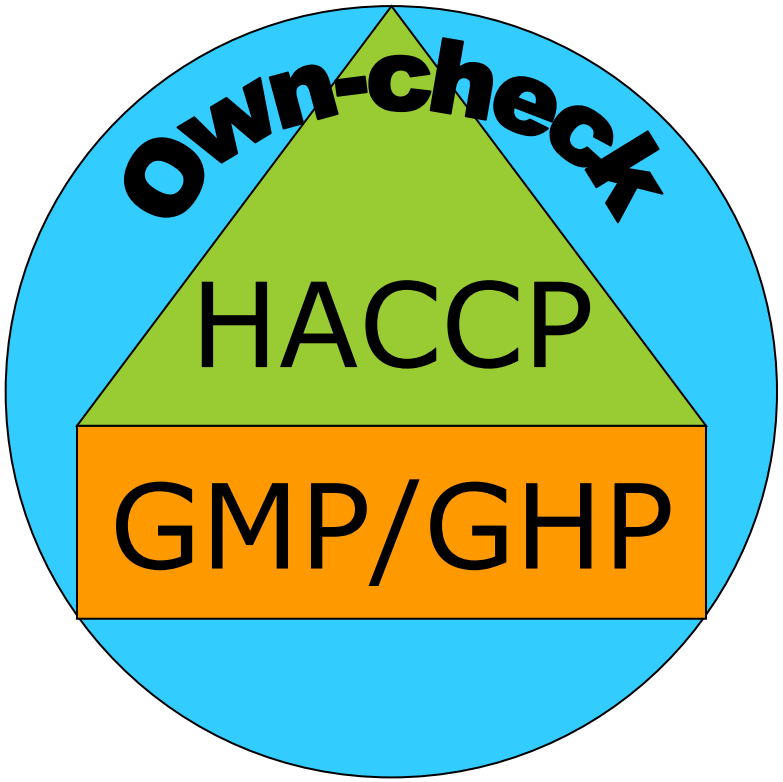
**Certification**
- ISO 22000
- BRC & IFS
- FSSC

**Public control authority**
- inspection
- smiley

# What is own-check?

- The preventive and systematic actions food business operators take to ensure that:
  - They follow the regulations related to food production
  - Food products do not pose a risk to humans

- Daily routine procedures and monitoring system



# Prevention of hazards?

- Prevent contamination
- Prevent spreading
- Prevent formation

**GENERAL**

vs.

**TARGETED**

# The general preventions – *good practices*

**GHP – Good Hygienic Practice**

*The control of contamination routes*

**GMP – Good Manufacturing Practice**

*The control of the operation*

PRP

# The targeted preventions – *systematic control*

Systematic and science-based approach for

- *identification*
- *assessment*
- *control*

of the hazards linked to the ***specific*** *production* of food

HACCP

# HACCP prerequisites (PRPs): GMP/GHP

- ***Personnel*** *(disease control, cleanliness, education, training, supervision)*
- ***Plants and grounds*** *(grounds, plant design and construction)*
- ***Sanitary operations*** *(general maintenance, substrates used for cleaning, pest control, sanitation of food-contact-surfaces, storage and handling)*
- ***Sanitary facilities and controls*** *(water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, rubbish and offal disposal)*
- ***Equipment and utensils*** *(maintenance, hygienic design)*
- ***Processes and controls*** *(raw materials, manufacturing operations, labelling, traceability)*
- ***Warehousing and distribution*** *(ventilation, temperature)*

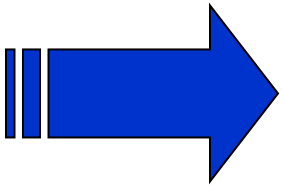
From: http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110977.htm

# What is HACCP?

- First of all HACCP is an abbreviation ……
- HACCP stands for a science-based system for identification, evaluation and control of hazards involved in food production
- The HACCP system is meant to ensure that food products are not a risk to human health
- In practice, HACCP takes place as a daily monitoring of CCPs and a periodic control of the system

*Hazard Analysis and Critical Control Points* (HACCP) is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-point testing.

(HACCP Guidance document, EU)



**HACCP plan**

# HACCP in the EU Food Legislation

- Regulation no. 178/2002 – the General Food Law
- Reg. no. 882/2004 – on official control
- Reg. no 852/2004 – on hygiene of foodstuffs

# HACCP in EU Food Legislation

- The EU food law places full responsibility for safe food on the food business operators
- In accordance with EU law all food businesses are, therefore, obliged to implement own-check systems (FSMS)
- This own-check system must build on the **principles of HACCP**
- The authorities should through public control systems make regular audits of the food businesses to ensure that own-check systems are running in accordance with regulations

# HACCP principles

1. Conduct a **hazard analysis**
2. Determine the **Critical Control Points (CCP)**
3. Establish **critical limit(s)**
4. Establish a system to **monitor** control of the CCP
5. Establish the **corrective action** to be taken when monitoring indicates that a particular CCP is not under control
6. Establish procedures for **verification** to confirm that the HACCP system is working effectively
7. Establish **documentation** concerning all procedures and records appropriate to these principles and their application

(from Codex Alimentarius, 2003)

# HACCP based procedures - steps

**INITIATE**

1. Management decision
2. Assemble HACCP team

**PLAN**

3. Describe product
4. List raw materials and contact materials
5. Construct and confirm flow diagram (FD)
6. List all potential hazards, conduct hazard analysis, identify control measures
7. Select CCPs on FD
8. Plan critical limits for CCPs
9. Plan monitoring
10. Plan corrective actions
11. Plan verification procedures
12. Plan documentation and record keeping

**Validation**

**HACCP plan**

**IMPLEMENT**

13. Write operating procedures
14. Run trial test and evaluate
15. Run trial verification

**OPERATE**

16. Start use of system
17. Conduct verification

# What is principle 1 – Hazard analysis?

**Aim:**

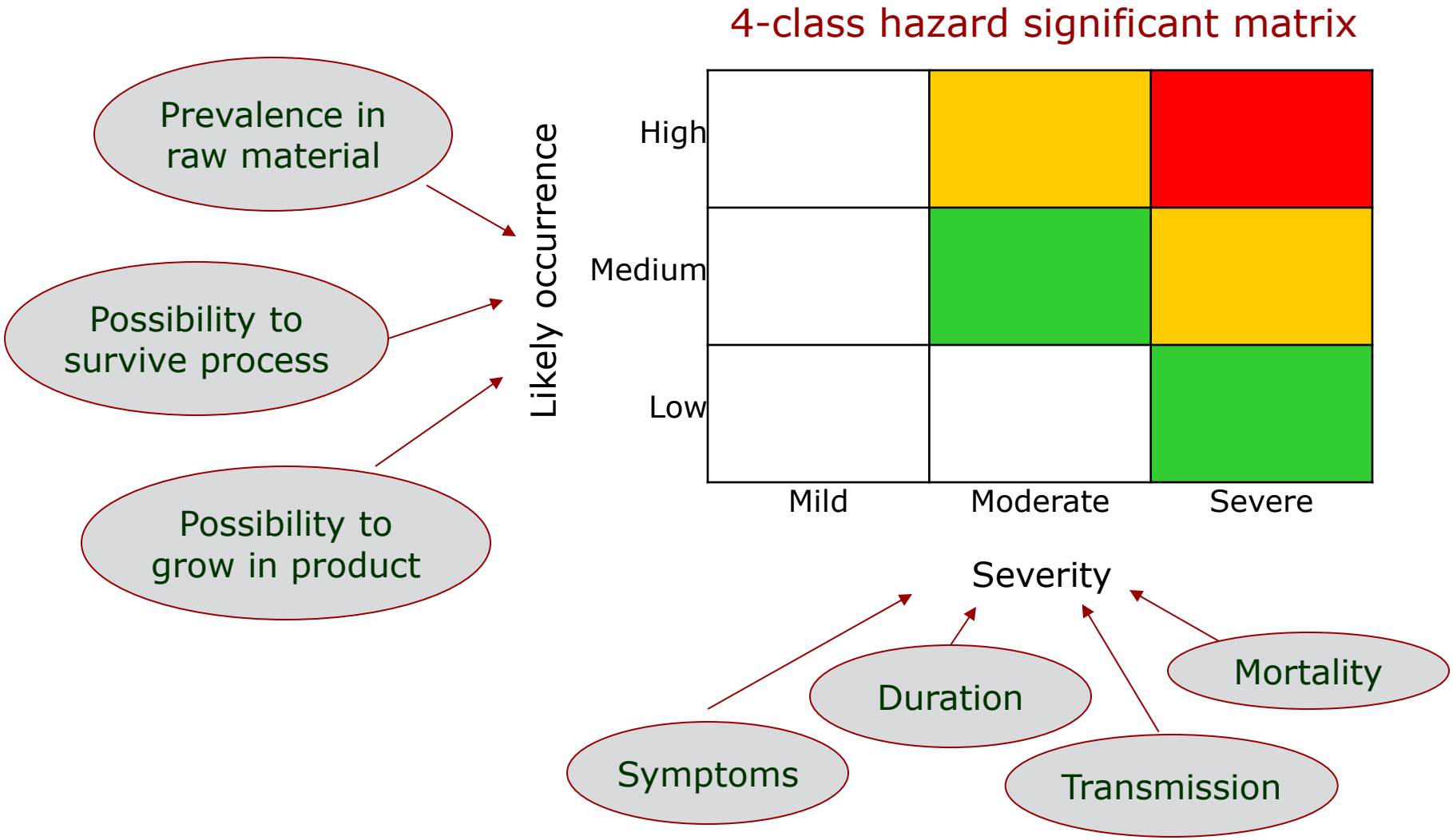
To assess whether a certain hazard is of such a nature that its elimination or reduction to acceptable level is essential to the production of a safe product.

**Questions to consider:**

1) Likely occurrence of hazards and severity of their adverse health effects
2) Evaluation of the significance of hazards
3) Survival or growth of microbial hazards and formation of chemical hazards
4) Possible toxin production and persistence
5) Contamination or recontamination

A. Hazard identification
B. Hazard significance
C. Control measures

# HACCP principle 1 – Hazard ranking



# Defining hazard severity

| Severity categories | Description |
|---|---|
| SEVERE | *Microbial* contaminants causing life-threatening illness. *Chemical* contaminants or *foreign bodies* causing life-threatening or permanent illness or injury. |
| MODERATE | *Microbial* contaminants causing chronic illness. *Chemical* contaminants or *foreign bodies* causing temporary illness or injury. |
| MILD | *Microbial* contaminants causing moderate illness. *Chemical* contaminants or *foreign bodies* causing discomfort, nausea, etc. |

From: De Silva, 2007

# What are control measures?

**CONTROL MEASURE**

*Any **action and activity** that can be used to prevent or eliminate a food safety hazard or reduce its impact or occurrence to an acceptable level*

# HACCP principle 1 – summary of hazard analysis

| Hazard | Source of hazard | Likely occurrence | Severity | Significance | Control measure |
|---|---|---|---|---|---|
| *List of all identified foodborne hazards;*<br><br>Biological<br>Chemical<br>Physical | *For each hazard indicate where the hazard comes from;*<br><br>Raw material<br>Packaging material<br>Process environment<br>Human contact | *Evaluate whether the occurrence of the hazard is;*<br><br>LOW<br>MEDIUM<br>HIGH | *Evaluate whether the consequence of the hazard is;*<br><br>MILD<br>MODERATE<br>SEVERE | *Indicate significance level of the hazard using the matrix;*<br><br>'white'<br>'green'<br>'yellow'<br>'red' | *Identify all possible control measures for the hazard;*<br><br>High temp.<br>Low pH<br>Low $a_w$<br>Etc. |

# What is principle 2 – critical control points?

**CONTROL MEASURE**

*Any **action and activity** that can be used to prevent or eliminate a food safety hazard or reduce its impact or occurrence to an acceptable level*

**CCPs**

**oPRPs**

# Definitions in "plain English"

***CCPs*** are the points (or steps) at which control measures must be applied.

***CCPs*** are points that are critical or essential to safety. They are the points where control measures can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

***oPRPs*** are used to reduce the likelihood that products will be exposed to hazards, that they will be contaminated, and that hazards will proliferate.

***oPRPs*** are also used to reduce the likelihood that the processing environment will be exposed to hazards, that it will be contaminated, and that hazards will proliferate in that environment.

Visual observations

Sensory evaluations

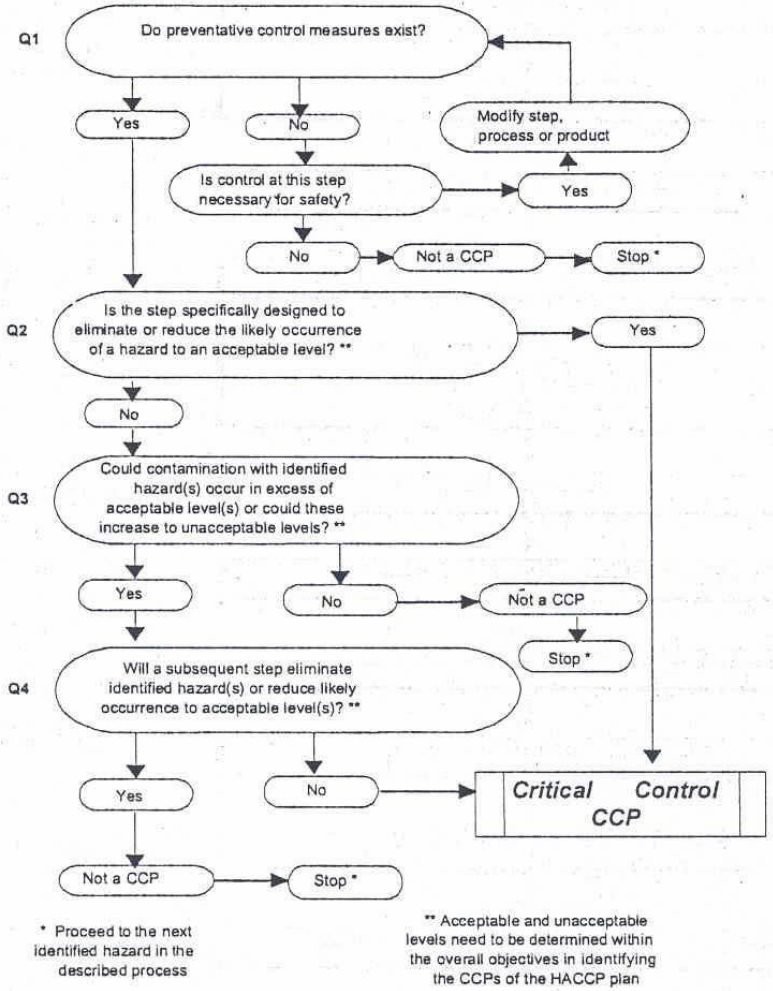
Measurements

Tests

From: http://www.praxiom.com/iso-22000-definitions.htm

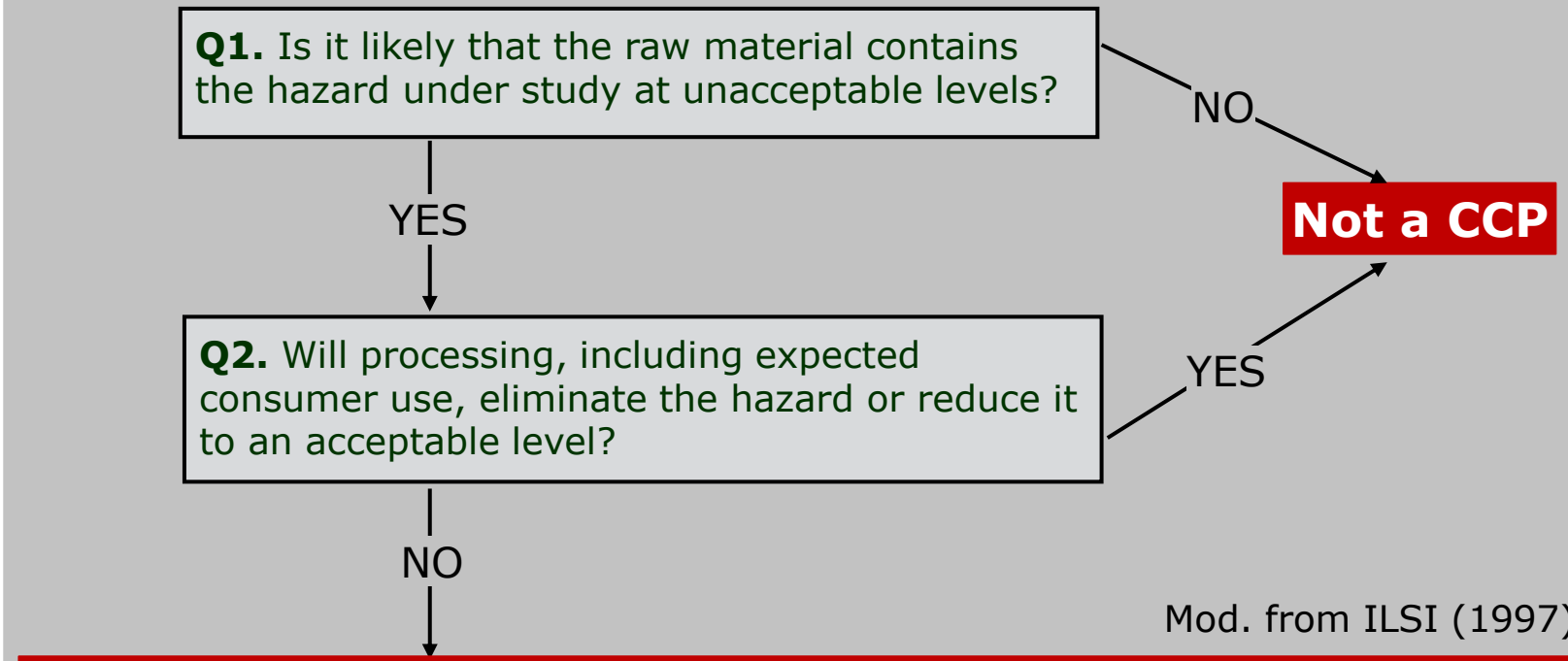
# HACCP – determine CCPs/oPRPs

- Logical and transparent approach
- Decision tree
- Applied for each hazard
- An example from the old guidance document
- Two new examples added in the revised document
- Training needed!

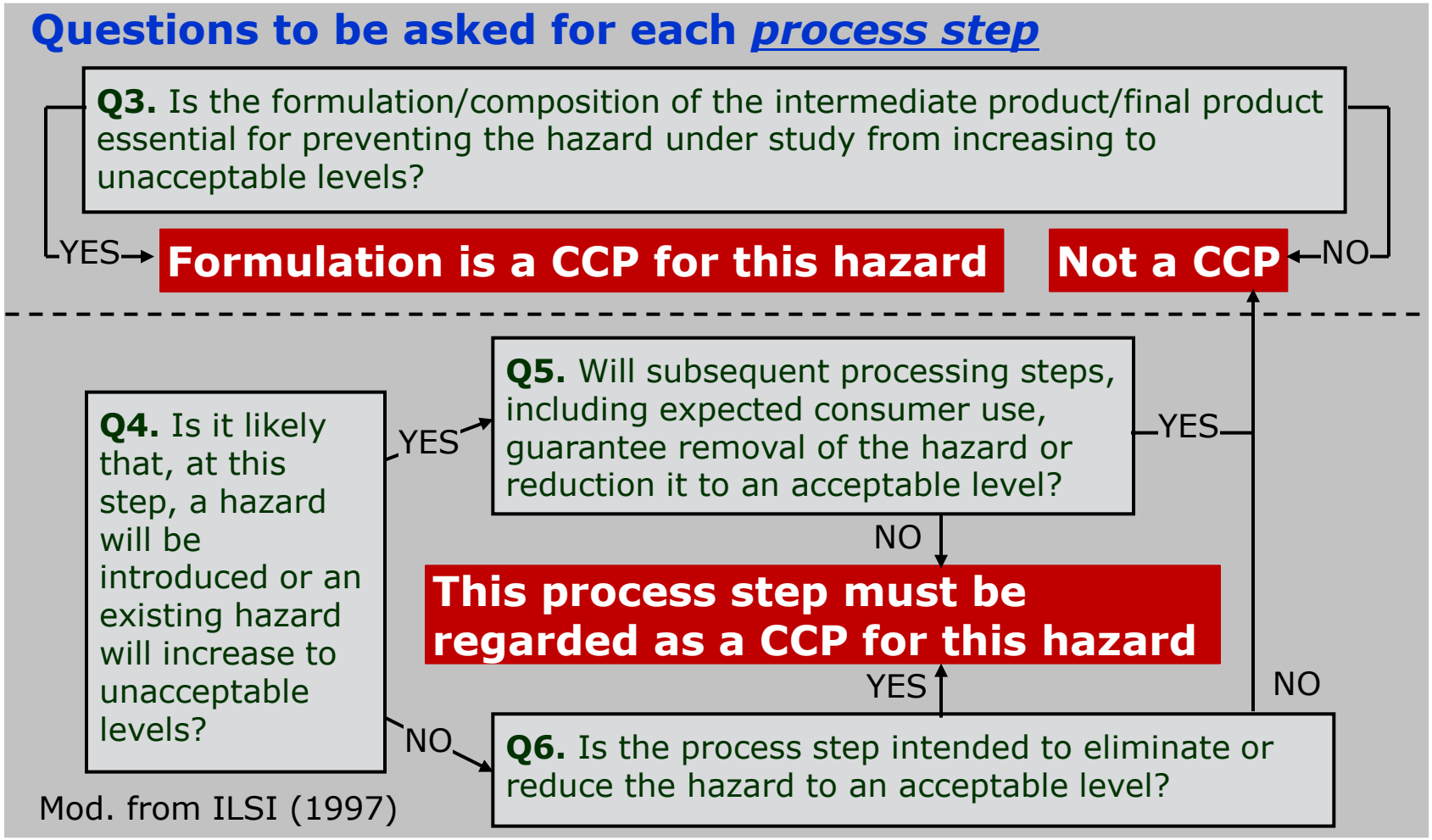


# HACCP – example of CCP/oPRP decision tree

## Questions to be asked for each *raw material* and *contact material*



# HACCP – example of CCP decision tree



# Contents of a HACCP plan

| Hazard analysis output | | | | Critical Control Point output | | | | |
|---|---|---|---|---|---|---|---|---|
| Point of control | Hazard | Condition leading to hazard | Control measure | CCP parameter | Critical limit | Target value | Monitoring | Corrective action |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

# Example for pasteurization step

Example:

- Sous-vide cooked roast beef
- Shelf-life of 3 weeks at <5°C
- Intended for cold use in sandwiches

| Point of control | Hazard | Condition leading to hazard | Control measure | CCP parameter | Critical limit | Target value | Monitoring | Corrective action |
|---|---|---|---|---|---|---|---|---|
| Low tempe-rature pasteuri-zation | *Listeria monocy-togenes* | Survival of treatment | Heat | Time and tempe-rature | A pasteuri-zation value of 20 min at 62°C in the centre of the thickest product | 63°C in centre for 20 min. | Tempe-rature and time measure-ment in centre of the thickest product | Prolong pasteuri-zation until critical limit is met |