



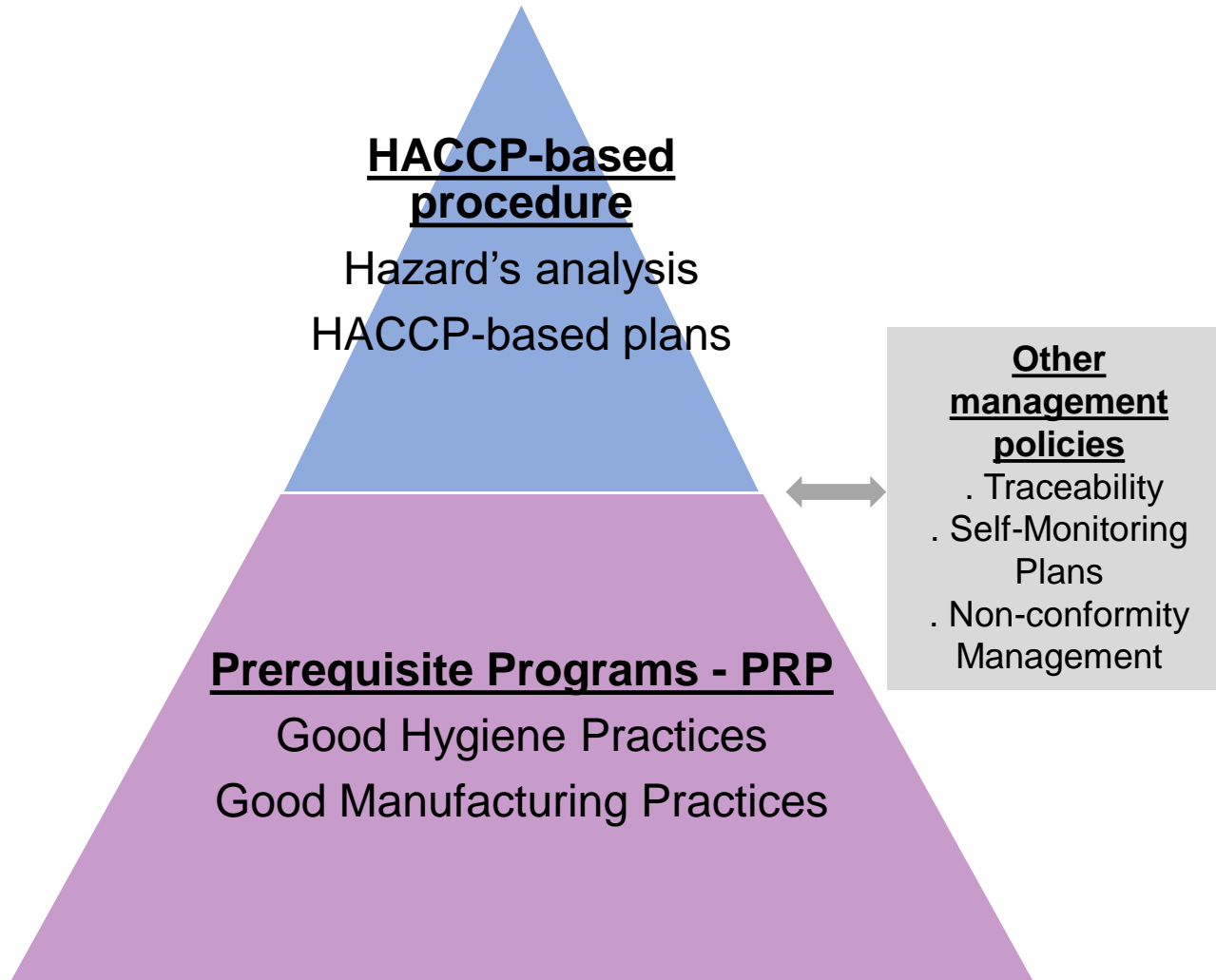
VII

Self-Monitoring

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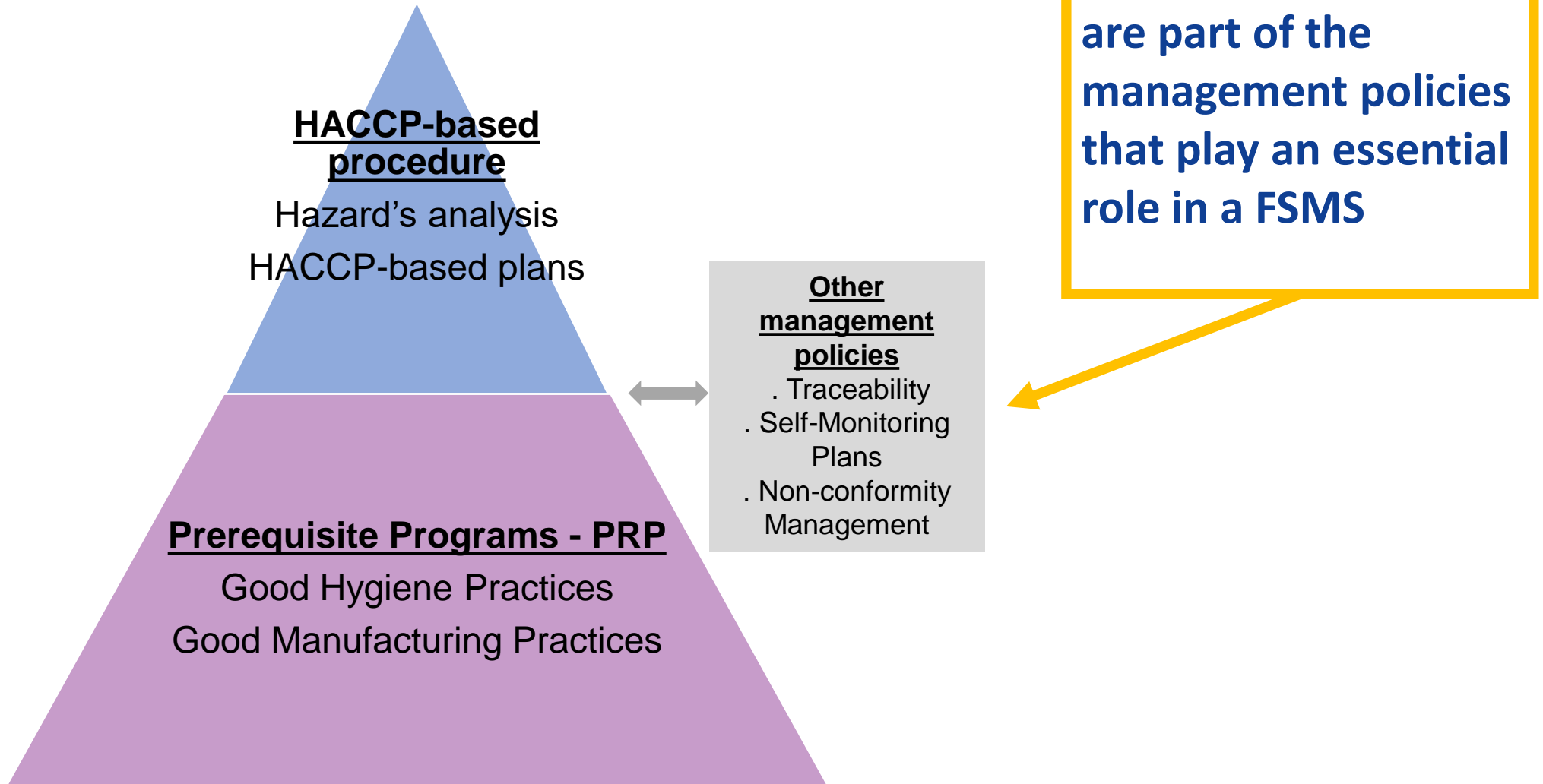


FSMS in resume





FSMS in resume





Control hazards by self monitoring measures at all stages:

- GHP
- GMP
- HACCP based plans
- Staff training
- Analysis during production process
- Analysis of products to verify FSMS
- Traceability
- Non Conformity Management



Example: self monitoring measures to control *Listeria monocytogenes*

- GHP -> regular inspection and maintenance of milking machine
- GMP -> acidification of a product
- HACCP based plans -> monitoring of acidification
- Staff training -> training of milking staff
- Analysis during production process -> monitoring smear water, testing processing areas and equipment for *L. monocytogenes*, product testing with n=1
- Analysis of products to verify FSMS -> product testing with n=5
- Traceability -> record keeping systems which enables tracing back and forward
- Non Conformity Management -> suspension of distribution and product withdrawal or recall



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All measures in the Food Safety Management System together make sure that food safety hazards are eliminated, prevented or reduced to an acceptable level.



Considerations when making a sampling plan

- Purpose of collecting a sample
- Effectiveness of sampling
- Bottleneck management





Purpose of collecting a sample -1

- What is the objective of the analysis?
 - To demonstrate the efficiency and effectiveness of the FSMS (validation and verification)
 - To assess the acceptability of a certain batch or a process

→ Product testing (n=5) appropriate against microbiological criteria in Annex I of Regulation 2073/2005.

→ Frequency not prescribed in regulation: responsibility of the producer





Purpose of collecting a sample - 2

- What is the objective of the analysis?
 - To control the production process

→ Testing procedures (frequency and number of samples (n)) should be based on producer's assessment.

Except for a few type of products for which minimum frequencies of testing are fixed in the regulation (e.g. milk as primary material).





Effectiveness of sampling - right place and moment

- Sampling can be done during the whole production process, not only on finished product
- Method depends on what the producer wants to check, e.g.:
 - Effectiveness of change in disinfection – check total bacterial count on disinfected material/surface
 - Absence of Listeria on washed rind cheese – test smear water
 - Effectiveness of pasteurisation – check pasteurised milk for alkaline phosphatase or Enterobacteriaceae





Effectiveness of sampling – do it correctly

Important:

- Use a method which identifies organisms appropriate to process or product
- Use an aseptic sampling technique to avoid cross contamination
- Make sure the sample arrives at the laboratory in undamaged condition and at right temperature
- Follow instructions supplied with commercial sampling kits



Effectiveness of sampling – do it clever

Reduce number of samples and costs by using other sampling and testing procedures like pooling samples together, using of alternative sampling sites and using of trend analyses if competent authority agrees.





'Bottleneck' management

Every hazard has its most important source of contamination. It can be more effective to monitor those sources by process or environmental controls than by end-product testing.

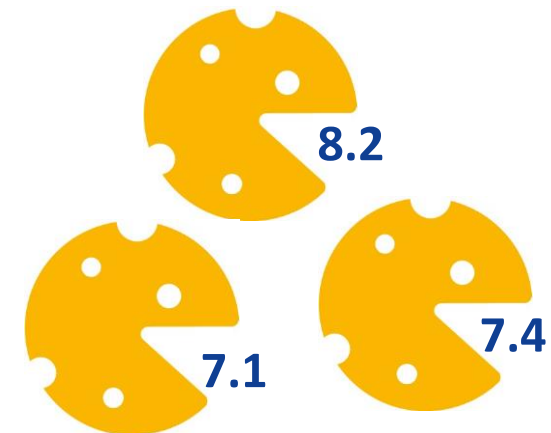




Important!

Before sampling be sure that:

- You can interpret the outcome of the analysis correctly
 - type of sample (product, environment, method, ...)
 - limits (legal requirements, own target value, ...)
- You know what you need to do when there is a positive finding:
 - non conformity management
 - corrective actions
 - preventive actions





Tools available for this section



- 7.1 Presentation Difference between ‘Sampling during production process or for validation’
- 7.2 Fact sheet Statistics of microbiological sampling
- 7.3 Exercises Statistics of microbiological sampling
- 7.4 Training How to set up a sampling plan
- 7.5 Fact sheet Sampling strategies
- 7.6 Hazard prevention plan
- 7.7 Instruction sheet for group work milk testing
- 9.2 List of shelf life studies

Example 1: Annual Sampling Plan
Difference between „Testing during the process“ and „Validation“

Products: Lactic cheese (raw milk) and Yogurt (pasteurised milk)
Milk: Goat milk
Quantity: 36.000 litres / year
Production time: May to November

Organism	Time of the investigation	Standard value	1st quarter	2nd quarter	3rd quarter	4th quarter
<i>Escherichia coli</i>	Products placed on the market during their shelf life		No production	Yogurt		
Cocci-fermenting staphylococci	at the time during the manufacturing process when the number of staphylococci is expected to be highest		No production	Lactic cheese	Yogurt	Lactic cheese
<i>Listeria monocytogenes</i>	before the food has left the immediate control of the food business operator, who has produced it	See Section VII + or documents of the cheesemaker	No production	Lactic cheese		
<i>Salmonella</i>	Products placed on the market during their shelf-life		No production	Lactic cheese		

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Training Exercise: „Microbiological Game“
Mean for Learning

Two possible classroom based exercises are outlined below in order for the trainer to be able to facilitate microbiological sampling.

The exercise takes the form of a game called „Microbiological Bqg“. It can be linked to HACCP (especially surface controls, self-monitoring and non-compliance management). It is important for the trainer to convey the message that effective HACCP based risk management is a way of ensuring consumer safety through increased sampling done...

Exercise 1
The trainer should ask their trainees to pick one number between 1 and 200 and write it on a piece of paper.
The trainer should pick ten numbers between 1 and 200 and write them on a piece of paper.
The trainer should find the numbers that the numbers represent the number of 25g units of cheese made by a small producer. The batch consists of 20 25g cheeses. The trainer should ensure that, unknown to the trainees, the batch is contaminated with a prevalence of 10% (i.e. 10% of the samples will show the contamination).
The trainer should begin reading out the numbers and the trainees should call „Yogurt“ if called.
The trainer should begin reading out the numbers and the trainees should call „Cheese“ if called.

Exercise 2
The trainer should ask their trainees to pick the numbers between 1 and 400 and write them on a piece of paper.
The trainer should pick twenty numbers between 1 and 400 and write them on a piece of paper.
The trainer should find the numbers that the numbers represent the number of 25g units of cheese made by a small producer. The batch consists of 2 25g cheeses. 100g of cheese should be taken for the inspection. The batch is contaminated with a prevalence of 5% (i.e. 5% of the samples will show the contamination).
The trainer should begin reading out the numbers and the trainees should call „Yogurt“ if called. The game continues until all twenty numbers have been read out.
The trainer should ask the students to consider the proportion of the students who identified the contamination and the proportion who missed it. The trainer should then consider how many students identified the contamination in 10 or more samples.

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Means of Analysis
Difference between „testing during the process“, „environmental testing“ and „product testing for validation“

How to control the hazards in cheese and dairy products?

Producers can only assure food safety by the use of a food safety management system. Reliance on end-product testing alone is not sufficient and ineffective.

- **Self monitoring:** Analysis during the production process to control the production process
- **Validation:** Verification and validation of the food safety management system

Monitoring of linear water
Product testing with mTS
Product testing with mTS

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The Limitations of Microbiological Sampling

Microbiological sampling can be used to verify effectiveness of food safety management systems such as the adapted HACCP-based system outlined in the Guide to Good Hygiene Practices in the production of various cheese and dairy products.

It is important to stress however that there are limitations to the effectiveness of using food safety management solely on testing and this was the reason that HACCP was first developed in the 1960s to ensure that foods developed for the space programme would be safe for astronauts to eat.

The certainty of finding a contaminant during microbiological sampling can be calculated using a statistical function called „hypergeometric distribution“. Without showing the complicated equations to calculate it, we can look at certainty in the example shown below.

Find one contaminant with a single sample.

This grid below is made up from 100 squares, 95 of them are green and 5 of them are red. We can say that the red squares have a prevalence of 5%. These represent unsatisfactory (unsafe) food items contaminated with a low level pathogen, 100% non-contaminated samples.

There is a number of non-conformities, but let us imagine a mark...
In order to a single square from the 100, the certainty and therefore identify that the batch contains a non-conformity they will not detect the non-conformity with one