



VIII

Non Conformity Management

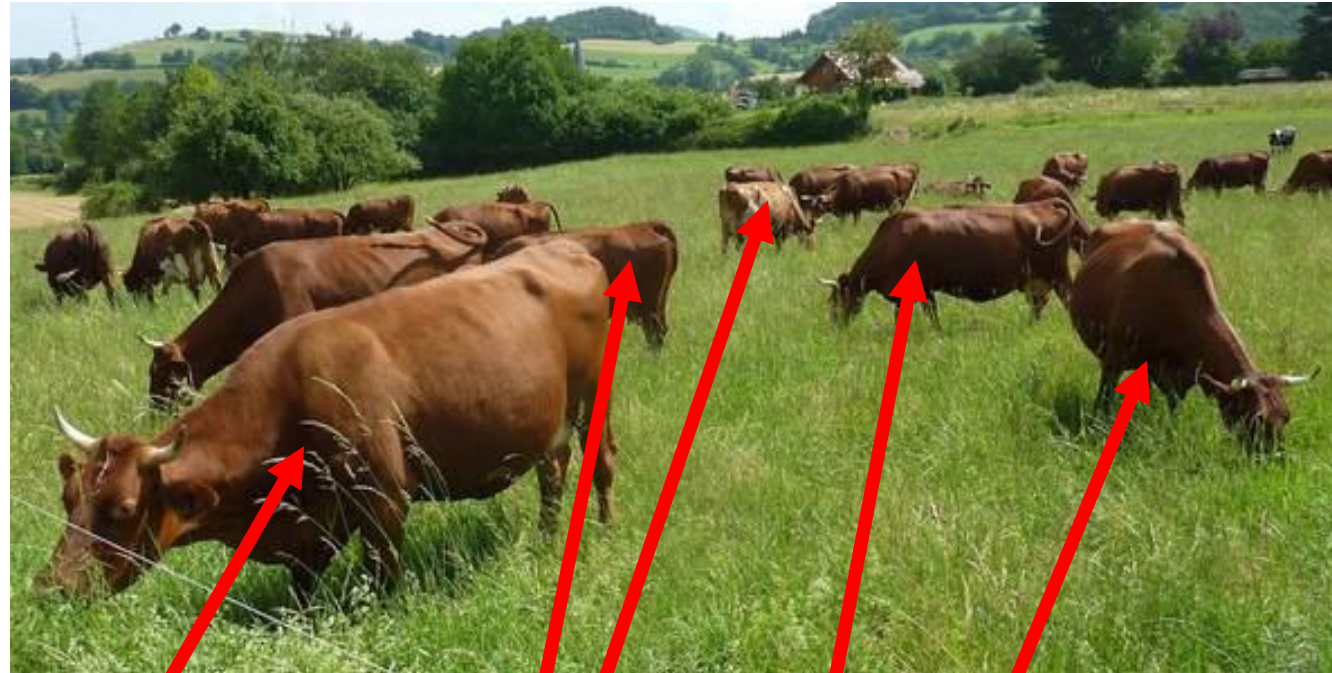
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What has to be recorded?

To record conformities in milk production every single day is apparently unefficient.

Everybody agrees that recording non conformities is acceptable.



- Rose: healthy
- Margie: healthy
- Bella: healthy
- Ella: healthy
- Annie: sick
-



Why recording conformities is often recommended?

*“In large food production businesses, the **high number of employees** makes it necessary to keep **comprehensive records**, in order to assure effective food safety management.”*





Why recording conformities is often recommended?

*“In large food production businesses, the **high number of employees** makes it necessary to keep **comprehensive records**, in order to assure effective food safety management.”*

But is it suitable for small scaled food production?

NO





Why recording conformities is often recommended?

“In farmhouse and artisan cheese dairies, as only one or a few people control all the processes, it may be sufficient to record only non-conformities and the measures taken to correct them.”

See “page 8 of the European Guide”





What is a non conformity?

A deviation from a specification, a standard or an expectation

To notice a non conformity you need a specification for your cheese





How to write a specification?

Process step to monitor	Parameter	Target value
Milk storage	Storage temperature	6-8 °C

Maturation with inoculation	Kind of culture	Mesophilic starter culture
	Amount of culture	0,8-1 %
	Organoleptic inspection	culture defined
	Inoculation temperatur	31 °C
	Pre-maturing duration	30 min
	Degree of acidification at the end of pre-maturing	6.55 pH

A specification defines a set of requirements (Parameter and target values).

This can include a high number of different values.



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A specification can include different parameters.

Only parameters with an impact on food safety are relevant for your Food Safety Management System

Parameters with an impact on food safety



How to write a specification?

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A specification can include different parameters.

Only parameters with an impact on food safety are relevant for your Food Safety Management System

Parameters with an impact on food safety

Parameters with **no impact on food safety**



How to write a specification?

section V- HACCP-based Plans ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Maturation with inoculation	M, C: Improper process parameters can allow growth of pathogenic bacteria.	Maintain correct temperature, time and dose of cultures. Add cultures as soon as possible. (3)	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Adjust production parameters: time, temperature, type and dose of cultures.
	M: Contamination of milk during inoculation due to poor quality of starter bacteria or inadequate handling by the cheesemaker.	Use only starters of known origin (including homemade starters) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject starters of suspect odour, colour or appearance. (3)	Visual and organoleptic inspection of direct or bulk starters	Reject inactive starters or those with suspect or damaged packaging. Adjust bulk starter preparation procedure.
Addition of the coagulant	M, C: A coagulant can be contaminated due to bad handling or storage. Coagulants can contaminate milk with pathogenic bacteria or chemical compounds	Use only coagulants of known origin (including homemade coagulant) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject coagulants of suspect odour, colour or appearance. (4)	Visual and organoleptic inspection of coagulants.	Reject coagulants of suspect quality, abnormal appearance or smell, or those with suspect or damaged packaging. Amend handling and storage procedures. Change the supplier.
Curd Treatments (cutting, ladling, stirring, washing, draining, moulding, pressing).	M: Contamination of the curd by the hands and arms of the cheesemaker.	Ensure food handlers have clean hands/arms. Where necessary use protective gloves to cover skin lesions. (5)	Visual inspection.	Wash hands/arms. Change torn gloves. If it is a recurrent issue review training of cheesemaker.

Sensory evaluation is a very important part of the checking and monitoring procedure



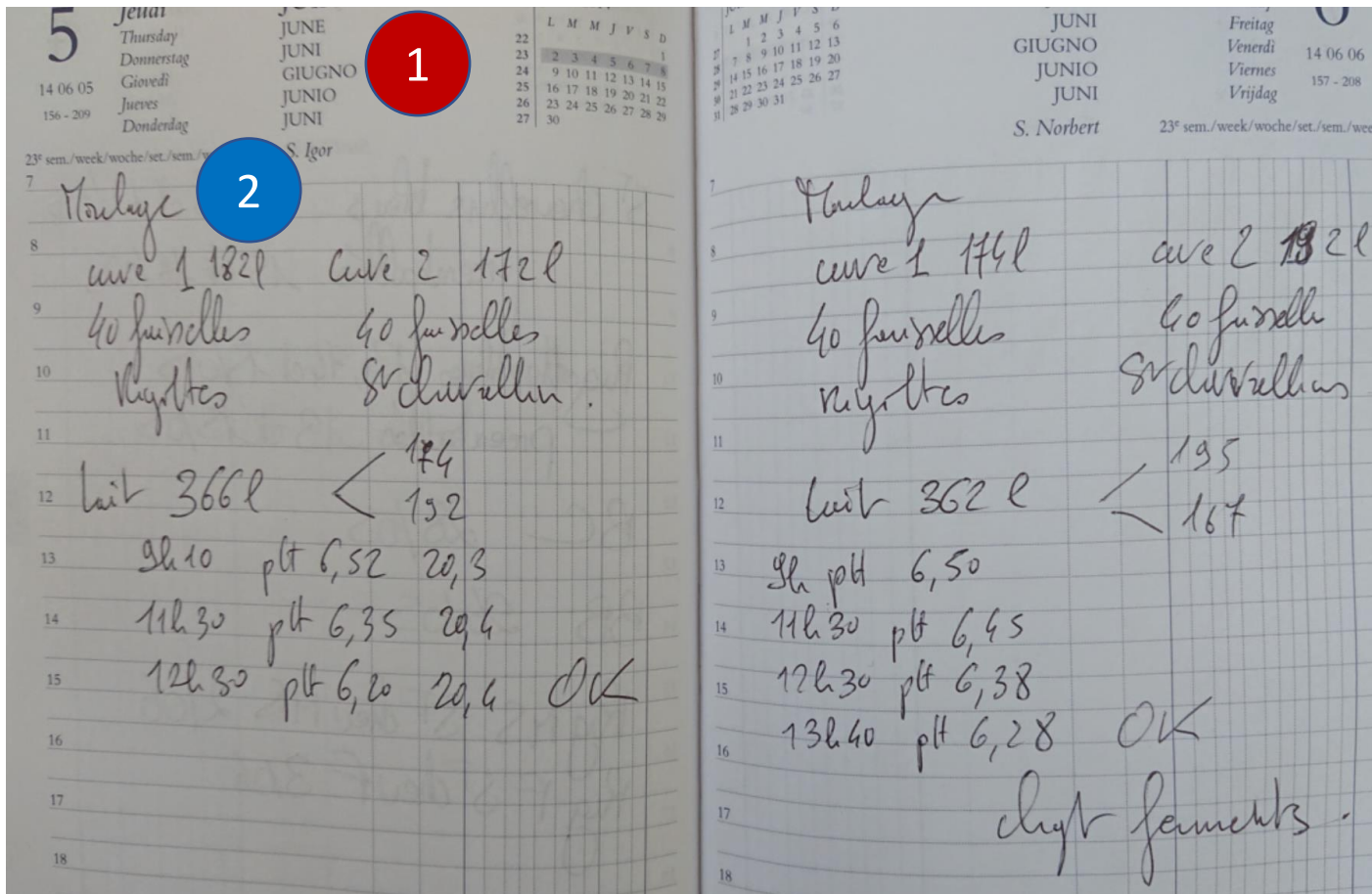
Do we have to record all non-conformities?

No, only **non-conformities with an impact on food safety** have to be recorded. The HACCP-based plans in section V help to find the relevant parameters. The values set as target value depend on the cheesemakers experience.

Process step to monitor	Parameter	Target value	Corrective action
Milk storage	Storage temperature	6-8 °C	Milk is pasteurised immediately before processing or batch in-question has to be highlighted and prior to sale put under end-product control. The refrigeration unit has to be checked.
Maturation with inoculation	Kind of culture	Mesophilic starter culture	
	Amount of culture	0,8-1 %	
	Organoleptic inspection	culture defined	In case of abberation the culture has to be replaced by a backup
	Inoculation temperatur	31 °C	
	Pre-maturing duration	30 min	
	Degree of acidification at the end of pre-maturing	6.55 pH	



Example 1: How can we record non-conformities?



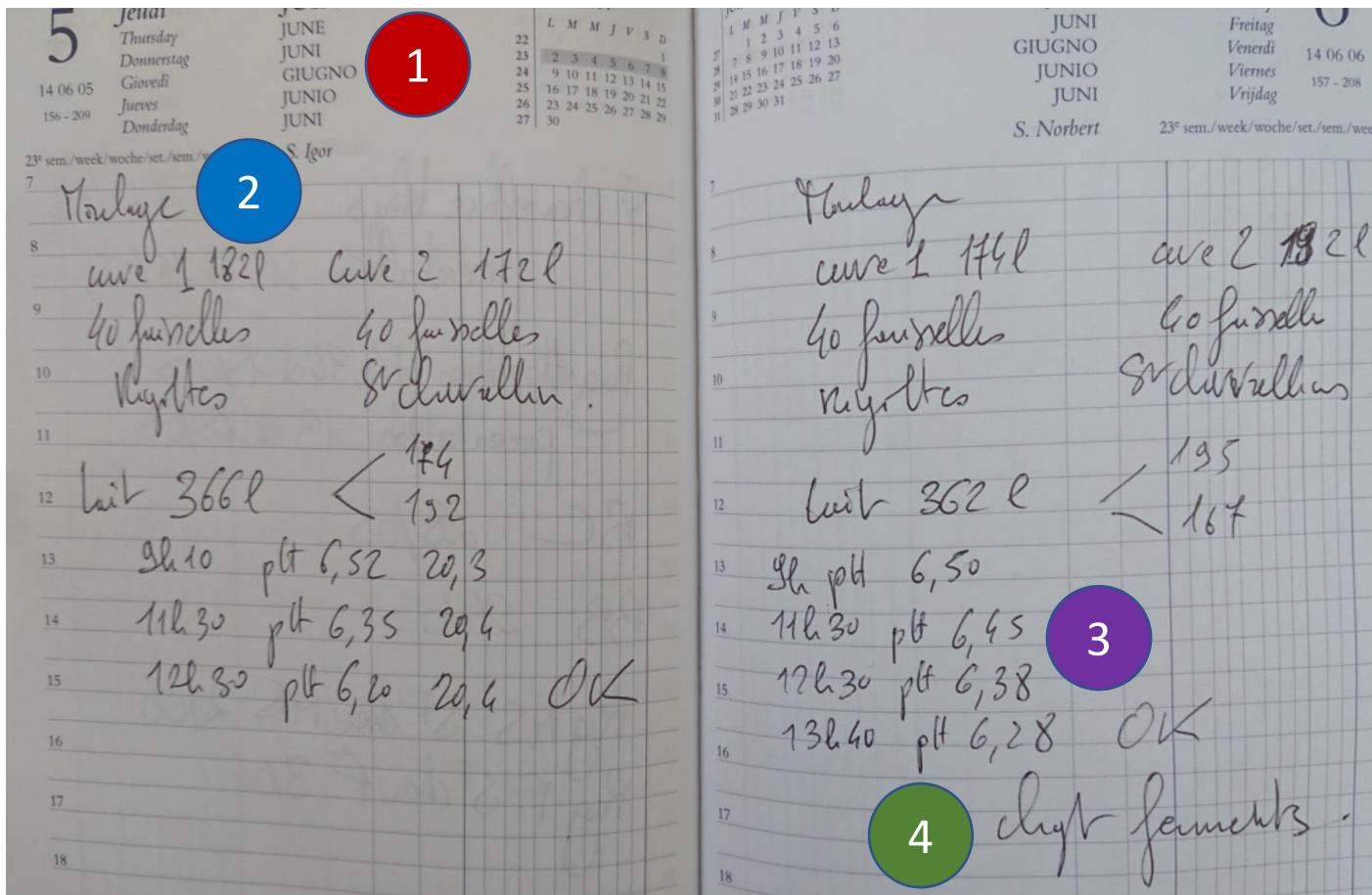
A agenda can be used as a very simple tool for documentation.

- Date 1
- Product 2

If non-conformities occur the **non-conformity** and the **corrective actions** have to be recorded here too.



Example 1: How can we record non-conformities?



A agenda can used as a very simple tool for documentation.

- Date 1
- Product 2
- Non conformity 3
"slow acidification"
- Corrective action 4
„Next production: Replacement and use of a new starter"



Example 2: How can we record non-conformities?

Date	Product	Non Conformity	Corrective actions
July 9th, 2018	Semi Hard Cheese	Storage temperature was too high (14 °C)	Milk has been pasteurised immediately before processing. The refrigeration unit has been checked.
July 9th, 2018	Semi Hard Cheese	Bulk starter had a yeasty smell	Starter has been rejected and replaced by a direct starter.

A non-conformance report must include at a minimum the following informations:

- Date
- Product
- Non conformity
- Corrective action



Example 3: How can we record non-conformities?

Date: July 9th, 2018 Name of the product: Semi Hard Cheese

Process step to monitor	Parameter	Target value	Correction value	Corrective action
Milk storage	Storage temperature	6-8 °C	14 °C	Milk has been pasteurised immediately before processing. The refrigeration unit has been checked.

Maturation with inoculation	Kind of culture	Mesophilic starter culture		
	Amount of culture	0,8-1 %		
	Organoleptic inspection	culture defined	yeasty-smelling	Starter has been rejected and replaced by a direct starter
	Inoculation temperatur	31 °C		
	Pre-maturing duration	30 min		
	Degree of acidification at the end of pre-maturing	6.55 pH		

A non-conformance report must include at a minimum the following informations: Date, Product, Non conformity, Corrective action



Conclusion

- To record only non-conformities make an evaluation easier.
- To have a non-conformance report allows you to record all non-conformities in one place (Example 1 and 2). Specification must be provided elsewhere.
- To combine specification and non-conformance report (Example 3) makes a product-related evaluation easier.
- The cheesemaker can decide which kind of documentation is more suitable for him.
- **The non-conformance report has to be stored.**



Recall and Withdrawal



Difference between recall and withdrawal

Issue identified with product

Does this issue pose a food safety risk?

- **No**, the issue does not pose a food safety risk
 - e.g. underweight, quality defect (like texture or colour), breach of process hygiene microbiological criterion

→ **Product is safe**

- **Yes**, the issue poses a food safety risk
 - e.g. breach of food safety microbiological criterion, chemical contamination, allergen not declared, physical contamination

→ **Product is unsafe**



Issue identified with product

→ Product is safe

- It *may* be withdrawn (for commercial reasons)
- Follow guidance of Non-Conformity Management

→ Product is unsafe

- Follow decision tree (Section VIII of the Guide)
 - Unsafe product is still under the control of the producer:
Suspend distribution
 - Unsafe product has not yet reached final customer:
Withdraw
 - Unsafe product may have reached final customer:
Recall
- Follow guidance of Non-Conformity Management



Issue identified with product

→ Product is safe

- It *may* be withdrawn (for commercial reasons)
- Follow guidance of Non-Conformity Management



→ Product is unsafe

- Follow decision tree (Section VIII of the Guide)
 - Unsafe product is still under control of producer:
Suspend distribution
 - Unsafe product has not yet reached final customer:
Withdraw
 - Unsafe product has reached final customer:
Recall
- Follow guidance of Non-Conformity Management



Tools available for Non Conformity Management



- 8.1 Questions for Discussion Recall -Withdrawal
- 8.2 Fact sheet Sources of contamination
- 8.3 Fact sheet Growth limits of pathogens
- 8.4 Example of Registration non-conformities 2
- 8.5 Example of Registration non-conformities 3

Registration of non conformities and corrective measures

Date	Product	Non Conformity	Corrective Measure

Salmonella

Possible Sources	Pasteurised Products	Raw Milk Products
Milk Production, Transportation & Storage		
Mastitis & Animal Health	X	*

		**

Growth Limits for Food Pathogens (pH)

Organism	Minimum	Optimum
Enterohemorrhagic <i>E. coli</i>	4.40	6.00-7.00
<i>Salmonella</i>	4.20	7.00-7.50
<i>Listeria monocytogenes</i>	4.39	7.00
Coagulase-Positive Staphylococci	4.00	6.00-7.00
Formation of Staphylococcal Enterotoxin	4.50	7.00-8.00

Example 2: How can we record non-conformities?

Date: July 9th, 2018 Name of the product: Semi Hard Cheese

Process step to monitor	Parameter	Target value	Correction value	Corrective action
Milk storage	Storage temperature	8-10 °C	14 °C	Milk is pasteurised in advance to processing or batch in-question has to be highlighted and prior to sale put under end-product control.
Maturation with inoculation	Kind of culture	Mesophilic starter culture		
	Amount of culture	0.8-1%		
	Organoleptic inspection	culture defined	yeasty-smelling	Starter has been rejected and replaced by a direct starter
	Inoculation temperature	31 °C		
Pre-maturing duration	30 min			
	Degree of acidification at the end of pre-maturing	6.55 pH		

A non-conformance report must include at a minimum the following informations: Date, Product, Non conformity, Corrective action

Withdrawal versus recall – discussion:

... false?
 ... dairy product which breaches a process hygiene criterion must be recalled if it has already been placed on the market.