

# Teat dipping and future regulations

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In most industrialised countries, such as the USA and Western Europe, bovine mastitis is still a relevant economical problem in dairy production, averaging \$200 loss per cow per year in the US.

The need to control mastitis is not only driven by the animal health and productivity concerns, but also by the consumer of milk and dairy products.

Usually, the milk price is directly linked to somatic cell count (SCC) and bacterial count. Therefore, the national average SCC is a strong indicator of the milk quality and productivity in a country. This average has been decreasing drastically during the last decade in Europe.

The national average is less than 300,000 SCC/ml milk in most western European countries and about 350,000 SCC in the USA.

## Mastitis infections

Mastitis is an inflammation of the mammary gland, in major cases due to an intra-mammary infection (IMI) caused by micro-organisms, most likely bacteria.

Although, most IMI are due to Staphylococcus aureus, streptococcus species and coliforms, more than 100 species have been identified to be involved in mastitis infections.

Due to common intensive dairy production and the nature of the disease epidemic, mastitis is a very contagious disease.

It can be transmitted easily from one cow to another through the milking practices or directly from the environment (housing, litter, pasture).

This is due to the fact that a cow under



treatment is still contagious and that sub-clinical mastitis is rarely identified on time.

The current practices to prevent and/or control mastitis might be summarised as follows:

### ● Vaccination.

The practice of vaccination is very complex in mastitis prevention. As stated above

more than 100 species are involved in IMI, and it is known that vaccination would activate the immune system for one or few specific antigen.

This routine is more applied to environmental mastitis with high prevalence on farm such as Staphylococcus and E. coli, and may be very helpful in case of predominant IMI

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**Table 1. Comparison chart between medicinal and biocidal regulatory requirements.**

		Medicinal teat dip	Biocidal teat dip
Product	Label claim Quality of the active substance	Mastitis prevention European Pharmacopoeia	Teat disinfection Up to the manufacturers specifications
Manufacturing of the product	Manufacturing of the active substance Other excipients	GMP Pharma (*) European Pharmacopoeia + GMP manufacturing GMP Pharma (*)	None, no quality requirements None, no quality requirements
	Manufacturing of the finished product Batch release of the finished teat dip	According to GMP Pharma (*) by industrial pharmacist	None, no quality requirements None
	Batch traceability and recall	According to GMP Pharma (*) by industrial pharmacist	None
Consumer safety	Residue safety/ Pharmacokinetics User safety Pharmacovigilance	MRL Listing of all excipients** Toxicity testing Yes, at European level	None Toxicity testing None
Animal safety	Residue safety	MRL Listing of all excipients Animal testing	None None
	Tolerance in the target species Pharmacovigilance	Yes, at European level	None
Efficacy	Teat dip efficacy in-vitro Teat dip efficacy in-vivo	EN testing*** Clinical trials	EN testing None

(\*) GMP: Good Manufacturing Practices inspected and authorised by the Ministry of Health.

(\*\*) Established maximum residue limit or inclusion in annex II of the council regulation EECN° 2377/90

(\*\*\*) European Norms for antiseptic and disinfectant in vitro testing, EN 1040 and EN 1656

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on farm from a known identified germ, to reduce the infection pressure at the herd level.

#### ● **Antibiotherapy.**

Whether dry cow therapy or punctual post-infection antibiotherapy, antibiotics are widely used in the fight against mastitis.

However, one should ensure the use of an appropriate antibiotic in terms of spectrum and potential resistance.

In case of recidivism or persistent infection, the farmer should not hesitate to ask for an antibiogram test in order to identify the specific germ involved in the persistent IMI.

Antibiogram testing is very useful to find

the appropriate antibiotic family able to eradicate the infection.

Efficient anti-biotherapy is very useful when the infection has been identified and the cow isolated.

However, it is better to prevent the new IMI with all means in order not to reach the ultimate step of antibiotherapy and to avoid unnecessary treatment costs and milk production loss.

Therefore, anti-biotherapy should be preceded by stringent prevention methods to avoid cross contamination and epidemical mastitis on farms.

#### ● **Biosecurity and good hygiene practices.**

The biosecurity on farm goes from the selection of animals to the housing and cow

comfort, involving in most cases, barn and litter disinfection, milking machine and cluster cleaning and disinfection, pre-milking preparation and post-milking teat dipping.

The last two routines being part of prevention therapy are commonly referred to as teat dipping.

Teat dipping products are chemical solutions usually containing a blend of an active substance and emollients:

#### ● **State of the art.**

The most common active substances used are iodine (70% market share in the US and 60% in Europe), and chlorhexidine (10-15%).

Many other active substances with lower market share might be found on the European market – lactic acid, chlorine dioxide, sulphonic acid, hydrogen peroxide.

In the USA it is common to dip or spray the cow teats before and after each milking, while in Europe teat dipping or spraying is usually done only after milking.

The pre-milking udder preparation in Europe consists of dry or wet paper wiping, udder cleaning using an udder wash or dipping followed by wiping using a foaming udder wash.

The pre-milking routine is very important with regard to milk quality and bulk bacterial and cell count and prevention from environmental bacterial infections, injected into the teat canal during the milking process.

The post-milking dipping is known to reduce the new IMI at the herd level by at least 50%.

#### ● **Regulatory status of teat dipping products in Europe.**

While in the USA, teat dips are considered a drug and submitted to FDA listing and FDA establishment registration, the situation is hardly harmonised in Europe.

The gap in this harmonisation comes from the fact that the classification of teat dipping products in Europe is based on the function and not on the presentation allowing room for 'borderline' products.

It is much easier in a harmonisation process to use a classification by presentation, for example a shampoo is a cosmetic, a fly repellent is a biocide and a teat dip is a medicine. The classification by function goes further than the presentation/form or the composition, and therefore depends on the manufacturer's label claim in many countries, giving room for confusion and consumer safety exposure.

#### ● **Medicinal teat dips.**

Any product used to prevent or cure a disease is classified as a medicine according to European regulations for veterinary products (EEC 2001/82).

Therefore, teat dips used to prevent mastitis are considered medicinal and should be submitted to a veterinary medicine marketing authorisation.

Furthermore, in some European countries, teat dips are medicinal only by presentation

or when they contain a limit level of iodine or chlorhexidine (UK and Germany).

In some other countries, teat dips may be freely sold if there is no mastitis prevention claim.

However, it would be hard to believe that teat dips are used twice a day by the farmer without any therapeutic reason. It is also risky for animal, user and consumer safety to apply a chemical product on a routine basis, especially when the chemical comes into contact with the skin and food, when it has pharmacokinetic and pharmacodynamic activities and with no control on safety, clinical efficacy or manufacturing quality.

#### ● Biocidal teat dips.

A biocide is an active chemical used to inhibit or destroy germs, usually on hard surfaces.

Some European countries include in this category chemicals used on a healthy skin as well. These are defined as 'antiseptics' from the medicinal point of view.

Therefore, teat dips are still considered as a 'borderline' product category in many EU member states. They may be regulated under both medicinal and biocidal regulation.

However, biocidal teat dips are not allowed to claim any efficacy against mastitis or even against pathogenic bacteria responsible for mastitis infections.

Table I on page 23 compares both medi-



nal and biocidal classification in regards of quality, safety and efficacy.

## Conclusion

It is obvious that manufacturing a medical teat dip is more costly in terms of GMP guidelines and raw material selection (according to European Pharmacopoeia).

However, this regulation reduces the risk to the user, the consumer and the animal and obliges the actual clinical efficacy of a teat dip to be demonstrated.

Ensuring the teat dip is sold under the biocidal directive already improves the actual situation in many European countries, but does not assess the actual exposure of the animal, the user and the milk consumer, or the actual clinical efficacy on the cow. Therefore, the authorities should be careful that the claims made on labels and marketing

material correspond to the registration category made by companies.

When European harmonisation places these products as medicinal in all EU member states, false competition will be avoided and the safety of the milk chain will be improved. Moreover, as teat dips are involved in the milking process on a daily basis, the production of teat dips should be strictly controlled in order to avoid accidents and to protect users/consumers and animal health.

One should not forget that milk is the most consumed food product in Europe. ■

## References

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