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1. Executive summary

Mastitis is one of the most prevalent diseases in organic dairy cattle production. Developing novel approaches to mastitis control by combining effective preventive herd health management strategies and alternative safe treatments, will contribute to reduce antibiotic use in organic dairy farms.

Essential oil treatments to control mastitis in dairy cows can be used, for their antibacterial or anti-inflammatory effects. According to organic principles, phytotherapeutics should be preferred to antibiotics to insure animal health, when prevention is not enough. However, there is no clear authorization to the use Essential Oils (EOs) as a Veterinary Medicinal Product (VMP).

In the RELACS project, trials on 34 farms are ongoing to measure on-farm effectiveness to control mastitis in dairy cows. The efficacy of EOs treatment is measured for clinical healing, cell healing, and bacteriological healing.

If the efficacy of EO treatment is the same or better than antibiotic treatment, the cost of use of EO is lower than that of antibiotics (AB). EO use requires an additional workload compared to the use of antibiotics (i.e. preparation, duration and observation).

There are no significant difference in the socio-economic impact of the two treatments: EOS vs AB. The major impact is on the environment (diffusion of antibiotics residues in manure), human health and animal health and welfare. Antibiotic resistant pathogens are a major challenge in veterinary and human medicine.

The main challenge for implementing alternative livestock production methods that replace antibiotics, will be to train veterinarians and farmers on the use of EOs, and to clarify the regulatory status (Maximum Residue Limits, health plan, specific regulatory statuses for herbal plants, low concern natural substance/product).

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2. EU legislative background on the use of Essential Oils in animal health

Mastitis is one of the most prevalent diseases in organic dairy cattle production. Developing novel approaches to mastitis control by combining effective preventive herd health management strategies and alternative safe treatments will contribute to reduce antibiotic use in organic dairy farms. Within RELACS, a strategy fostering refinement of farmers' innovation capacity related to non-antibiotic mastitis control by external application of essential oils (EO) is studied. Essential oils are widely used by French farmers for their antibacterial or anti-inflammatory effects, sometimes with the advice of their veterinarians.

According to organic principles, phytotherapeutics should be preferred to antibiotics for securing animal health, when prevention is not enough.

However, there is no clear authorization for the use of EOs as a Veterinary Medicinal Product (VMP). Where there is a therapeutic claim associated with the use of herbal products, the VMP status is required: the product must be registered (Market Authorization - MA) and the maximum residues levels (MRL) must be established. Self-medication by the farmer on animals is not allowed.

2.1 EU legislative background for veterinary treatments

2.1.1 EU Horizontal legislation on veterinary drugs

The use of plant extracts or essential oils for the treatment or prevention of animal diseases is based on several regulations at EU level:

- Regulation (EU) 2019/6 on veterinary medicinal products (VMP), which requires a market authorisation (MA) for the product and a prescription by a veterinarian to use the product. Self-medication by farmers on the animals is not allowed. In some cases, a veterinarian can give a prescription for products without MA (but MRL status is required, see below), provided that a withdrawal period is applied. The withdrawal period is the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal. For organic products, this withdrawal period is doubled. In contrast to homeopathy, a specific regulation of veterinary herbal medicinal products is missing from the recent regulation. It is only mentioned in the preamble (12) that: There is insufficient information to date on traditional herbal products used to treat animals in order to allow the setting up of a simplified system. Therefore, the possibility of introducing such a simplified system should be examined by the Commission based on the information provided by the Member States on the use of such products on their territory.
- Regulation (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits (MRL) in foodstuffs of animal origin. It is mandatory to establish MRL status for any pharmacologically active substance intended for use in the EU in veterinary medicinal products which are to be administered to food-producing animals. It is not possible to have MA without this MRL status, but it is possible to haver MRL status without MA.

In regulation (EU) 37/2010, substances must be registered in a list (a board) to acquire a status:

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- substance with MRL approved
- substance with MRL banned
- Substance with MRL not required

2.1.2 Veterinary treatments in the EU Organic Regulation

Extract from Annex II of Organic Regulation (EC) No 2018/848 on organic production:

- Animal health management should mainly be based on **the prevention of disease**. In addition, specific cleaning and disinfection measures should be applied. The preventive use of chemically synthesised allopathic medicinal products, including antibiotics, should not be permitted in organic production. In the event of sickness or injury of an animal requiring immediate treatment, the use of such products should be limited to the minimum necessary to re-establish the well-being of the animal. In such cases, in order to guarantee the integrity of organic production for consumers, the official withdrawal period after use of such medicinal products as specified in the relevant Union legislation should be double the normal withdrawal period and have a minimum duration of 48 hours;
- 'Preventive measures' means measures that are to be taken by operators at every stage of production, preparation and distribution in order to ensure the preservation of biodiversity and soil quality, **measures for the prevention and control of pests and diseases and measures** that are to be taken to avoid negative effects on the environment, animal health and plant health;
- 'veterinary treatment' means all courses of a curative or preventive treatment against an occurrence of a specific disease;
- the application of animal husbandry practices which enhance the immune system and strengthen the natural defence against diseases, including regular exercise and access to open air areas and pastures.
- (1.5.2.2) Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, **when the use of phytotherapeutic, homeopathic and other products is inappropriate.** In particular, restrictions with respect to courses of treatment and withdrawal periods shall be defined.
- (1.5.2.3) Feed materials of mineral origin authorised pursuant to Article 24 for use in organic production, nutritional additives authorised pursuant to Article 24 for use in organic production, **and phytotherapeutic and homeopathic products shall be used in preference to treatment with chemically synthesised allopathic veterinary medicinal products, including antibiotics, provided that their therapeutic effect is effective for the species of animal and for the condition for which the treatment is intended.**

2.1.3 Feed additive regulation

Some EOs are and can be registered as food or feed additive under the regulation (CE) n°1831/2003. In this case, they cannot claim to be healing, they just have a food function, and are therefore no curative product for the animals.

Registration dossier for EO *origanum* and *litsea*, as feed additive, are ongoing (regulation (CE) n°1831/2003).

In France, EO *litsea* is registered as a feed "dietary supplement".

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2.2 Economic impact of use EOs as alternatives to antibiotic

2.2.1 Impact assessment method

To quantify the economic impact of the alternatives EOs (*Origanum* and *Litsea*) to antibiotic use, we compared essential oil treatment with antibiotic treatment to treat light to moderate clinical mastitis cases.

When farmers identify a mastitis case, they would either carry out:

- An essential oil treatment: Two EOs (*Origanum* and *Litsea*) are applied individually, one after the other. They are diluted in organic sunflower oil (10% EO, 90% vegetable oil). 2.5 ml of each mixture is applied to the skin of the udder, two times a day after milking, for seven days.
- An antibiotic treatment: MASTIJET® (antibiotic Suspension - Tétracycline, Bacitracine, Néomycine, Prednisolone), broadly used by French veterinarians. This antibiotic is given twice a day during two days.

Through a series of farmers meetings, on-farm trials, and French **farmers' experience from groups of farmers (Adage 35** and **Fevec**), we identified a series of potential costs/expenses/additional workload that could result from the use of these alternatives. To determine the potential cost for the farmer, we compared with Alexandre Fauriat, veterinarian in the project RELACS, the terms of use between essential oils and antibiotic.

2.2.2 Origin of raw material

EO *Litsea* is produced mainly in Asia (and USA or Oceania), and available as an organic product.

EO O*riganum* is produced in Europe and available as an organic product.

EOs can be purchased easily in pharmacy, in veterinarians' pharmacy, in food shop, in cosmetics shop, and directly from EO producers.

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2.2.3 Assessment of the cost of EO use in mastitis control

	Essential Oils	Antibiotics
	Practices and cost	Practices and cost
Number of applications	two/day	two/day with Mastijet® AB
Length of treatment	7 days	2 days
Application EO Litsea (2,5 ml*2 times / day) ml	2,8 €	
Application EO Origanum (2,5 ml*2 times / day) ml	4,8 €	
Sunflower oil for the two applications ml (dilution 90%)	0,5 €	
Total direct costs	**8,1 €**	**18,1**

The cost of EOs can be reduced. We assessed the cost based on a purchase by the farmer in a pharmacy, in small quantities. If each farmer buys their own EOs, it is more expensive. If farmers organise a group order together with the vets, it would less expensive. The cost of the antibiotic treatment is based on the main product used in France. With this product, in France the cost of an antibiotic treatment for mastitis control is around 18.1 € whereas the cost of treatment with EOs is estimated around 8.1 €.

The use of EO is cheaper, if the treatment is efficient. EO should be considered as an alternative that should help to reduce the use of antibiotics, and not as a direct alternative to antibiotics.

2.2.4 Increased workload

The use and therefore application of EOs requires time for observation which is higher than when applying antibiotics. The length of treatment is seven days with EO treatment, whereas it lasts only two days with AB treatment.

If farmers use EO treatments as a veterinary medicinal products, the veterinarian must do an extemporaneous preparation and must train the farmers. However, once this is done, the application should not require a lot of time from the farmer, and the cost attached to the increase of workload would not be significant.

A withdrawal period after the use of EOs to treat a mastitis applies: seven days prior to the consumption of meat and 14 day prior to the consumption of milk.

If EOs are used for prevention, there is no withdrawal period.

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3. Conclusion

In the RELACS project, trials in 34 farms are ongoing to measure on-farm effectiveness to control mastitis on dairy cows. The efficacy of EO treatments is measured as its result in clinical healing, cell healing, and bacteriological healing.

If the efficacy of EO treatments is the same or better than that of antibiotic (AB) treatment, the cost of use of EO is lower than that of AB. EO use requires an additional workload compared to the use of antibiotics (i.e. preparation, duration and observation).

There are no great socio-economic impact between the 2 treatments, EOS vs AB. The major impact is on the environment (diffusion of antibiotics residues in manure), the human health and animal health and welfare. Antibiotic resistant pathogens are a major challenge in veterinary and human medicine.

The main challenge for implementing alternative livestock production methods replacing antibiotics will be to train veterinarians and farmers on the use EOs, and to clarify their regulatory status (MRL-Maximum Residue Limit, health plan, specific regulatory statuses for herbal plants, low Concern Natural substance/product).