

European regulation of organic animal treatments

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Abstract

European Union organic farming regulations place an emphasis on prophylaxis in agriculture to ensure animal health. The veterinary treatments in organic animal husbandry are largely defined in Articles 23 and 24 of EC regulation No. 889/2008. Very few substantial changes are apparent in this regulation as compared to its predecessor. Veterinarians may use any effective medicines appropriate for the indication and animal species. Where possible, effective homeopathics, phytotherapeutics or the like should have priority.

Among others, the main problems of implementing these regulations into daily farm practice emerge from the prohibition of preventive treatment, the doubled withdrawal period and the restriction of the number of treatments. The dilemma is that these rules, mainly created to protect consumers and environment against pharmaceutical residues, may potentially prevent an early effective treatment of livestock because they could have an adverse economic effect for the farmer.

Unambiguous sentences are needed. The regulations should be directed towards definition and guarantee of good animal health. A revision of EC No 889/2008 should then thoroughly consider the feasibility of the rules and their impact on animal welfare.

A clarification and discussion of animal treatment guidelines for organic farming would seem at this time to be useful for farmers, veterinarians, control boards, and not least, for the well-being of livestock.

Keywords: organic husbandry, veterinary medicinal products, animal health

Zusammenfassung

Europäische Regelung zur Tierbehandlung im Ökologischen Landbau

Die Europäische Union betont in den Richtlinien zur ökologischen Tierhaltung besonders die Krankheitsverhütung zur Erhaltung der Tiergesundheit. Hauptsächlich in den Artikeln 23 und 24 der neuen EG Richtlinie Nr. 889/2008 sind die Regelungen zu tierärztlichen Behandlungen festgelegt. Die Neufassung hat hier gegenüber der Vorläufer Richtlinie keine wirklichen Veränderungen mit sich gebracht. Tierärzte können jede für das Tier und die Indikation wirksame Medikation anwenden. Wo es möglich ist, soll den Homöopatika, Phytotherapeutika und Ähnlichem der Vorrang eingeräumt werden.

In der täglichen betrieblichen Praxis ergeben sich unter anderem Probleme besonders mit dem Verbot der präventiven Behandlung, der verdoppelten Wartezeit und den Vorschriften zur maximalen Anzahl der Behandlungen. Diese Regelungen, hauptsächlich geschaffen, um Verbraucher und Umwelt vor Medikamentenrückständen zu bewahren, könnten jedoch dazu führen, dass zum Schaden des Nutztieres eine rechtzeitige effektive Behandlung unterbleibt, da der Landwirt andernfalls ökonomische Nachteile zu tragen hätte.

Hier sind klar formulierte, eindeutige Sätze notwendig. Die Regelungen sollten darauf abzielen, die gute Tiergesundheit zu definieren und sicherzustellen. Eine Revision der Durchführungsverordnung 889/2008 muss dann die praktische Umsetzbarkeit und insbesondere die Auswirkungen auf das Wohlbefinden der Tiere durchgängig beachten.

Für die Landwirte, Tierärzte, Kontrollstellen und letztendlich für das Wohlbefinden der Nutztiere ist es jetzt an der Zeit, die Diskussion über eine Revision der Richtlinien zur Tierbehandlung im Ökolandbau zu beginnen.

Schlüsselwörter: ökologische Tierhaltung, Tierarzneimittel, Tiergesundheit

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Introduction

Causal relationship between health and husbandry must be considered in making animal-appropriate husbandry recommendations. For European Organic Farming, the objectives for animal husbandry were initially aligned in the year 2000, when the EC regulations [Council Regulation (EC) No 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No 2092/91] concerning livestock production came into force. Appendix I B No 5: "Disease prevention and veterinary treatment" states that animal health is based on principles like the choice of appropriate breeds and of animal-fair husbandry practices, high-quality feeds, regular use of outdoor-runs and pasturage. The new regulation (EC) No 834/2007, in force since January 1, 2009, additionally mentions hygienic conditions. These principles should limit animal health problems to a minimum. The remaining problems should be controlled mainly by preventive health care.

At the moment, this remains a goal rather than a reality. Up until now, no constant improved flock and herd health could be shown in organic farming. Outdoor husbandry, for example, raises the risk of endoparasites, livestock infections and even zoonotic infections. Thus, the level of bio-security may be lower than that of conventional farming (Bennedsgaard et al, 2003; Conraths et al, 2005; Hovi et al, 2003; Schnieder 2003; Kijlstra et al, 2008b; Kijlstra et al, 2008a).

Animal health problems are usually diverse, with a greater variation in the health status of individual organic farms than between conventional and organic systems (Sundrum 2004). Good animal health presumably relies strongly on the personal priorities and skills of the farmer and correlates with other farm features like labour capacity, personal interest, indoor and outdoor surface areas and available equipment.

The restrictions on number of treatments and rejection of prophylactic practices may also contribute to inadequate animal health management in organic farming. Van der Meulen et al (2007) maintain that the use of chemotherapeutics is currently inevitable to prevent animal suffering or distress in organic husbandry.

In some cases, veterinarians appear to have serious deficits in knowledge of strategic medical solutions for organic herds. Some veterinarians demonstrate a certain scepticism concerning organic farming, while others are unsure about therapy restrictions. And in some cases, interaction between farmers and veterinarians is unsatisfactory (Hertzberg et al, 2003; Hammarberg 2001; Hovi et al, 2003; Leeb et al, 2000; Sundrum 2004; Vaarst et al, 2003). The reason for that could be that some issues within the EU regulation are prescribing or recommending detailed treatment restrictions which seems to be in con-

trast to current pharmacological knowledge and thus are difficult to communicate to veterinarians.

The following paper aims to address some of the problems, fill some gaps in information and clarify misunderstandings arising from the EC organic regulations, and further to promote scientific discussion on the topic.

Regulations and Problems

The following six topics are most important in the debate on the current EC organic animal treatment regulations.

1 Treatment Requirement

Sick animals must be treated immediately. Thus a farmer violates the law if he chooses not to treat sick livestock [(EC) No 889, Art. 24(1)]. But there is no gold standard which defines the degree of illness, which requires a treatment. The decision is in the farmer's responsibility, depending only on personal awareness, skills and experiences.

2 Complementary Medicines Favoured

Organic farming favours complementary medicines [(EC) No 889, Art. 24(2)], because they are said to support the natural defence mechanisms in the organism without leaving chemical residues in dung and food. Phytotherapeutic and homeopathic products and trace elements are to be preferred *provided that their therapeutic effect is effective for the species of animal and the illness*. This sentence in the new regulation resolves all uncertainties of former versions: the remedy used must guarantee its effectiveness for the illness being treated.

Should the effectiveness of the medication be doubtful, then generally used, veterinary medications are to be chosen *to avoid suffering or distress of the animal* [(EC) No 889, Art. 24(3)]. These pharmaceuticals must be used as there is no alternative option (apart from culling!). The farmer is not permitted to choose ineffective products if suffering or distress impends. Instead of stipulating that a certain sort of drug is to be used, the most effective method to cure should get mandatory in a revision of regulations to avoid suffering or distress of the animal. This could still all concerns and it would be in accordance with the principles of Good Veterinarian Practice (GVP).

The efficacy of homeopathics in livestock has not been officially verified, and in Sweden, for example vets are not allowed to prescribe these remedies (Hammarberg 2001). On the other hand, hints on sensible homeopathic treatment are published increasingly (Enbergs et al, 2007; Fidelak et al, 2004; Ivmeyer et al, 2008; Klocke et al, 2010; Schütte 2003).

It is commonly believed that only complementary and alternative medicine (CAM) has to be used in the treatment of organic livestock. This cannot be confirmed by the EC regulation since concerns could arise that sick animals are not always treated in an appropriate way (Hammarberg 2001). The new regulations take account of this and place the priority on animal welfare. The use of chemotherapeutics is justified as it is yet the substantiated method to prevent animals from suffering or distress if falling seriously ill. The use of chemical medicines is, however, to be limited to the indispensable minimum. The principles of GVP contain a similar passage.

In consequence, irritations may follow if farmers insist to demand alternative treatments from the veterinarian. Strictly speaking, the veterinarian has few opportunities to use alternative remedies in terms of evidence based medicine. This discrepancy raises the question of the conditions under which alternative medicine can be used at all. The regulation seems to encourage farmers to use these therapies as far as possible while they don't have medical skills for the assessment of disease severity. Certainly they will recognize live threatening conditions, but most of the livestock disease requires intensive veterinary diagnostics for detection. A revision of regulations should clarify this point.

It is inevitable to define stages of disease which may be treated by alternative methods in terms of a first treatment line under expert control (complementary metaphylaxis). Since (1) the therapy decision remains in the hands of veterinarians, (2) good veterinarian practice and human ethical comprehension prioritize animal welfare as the primary therapy target rather than the method to achieve this and (3) the farmer is not allowed to use non-registered drugs for treatment, the regulation should focus on the interaction between veterinarian and farmer rather than to provide therapy instructions aiming on farmer decisions.

For these purposes, in complementary medicine educated veterinarians are needed to include their experiences into the health control system of organic farms.

Apart from the lack of efficacy proof of CAM-methods, the experience of the therapist can also play a role on determining the effectiveness of alternative medical treatments. While advanced training in alternative medicine is available for veterinarians, it is costly and time-consuming.

Farmers already broadly apply various forms of complementary medicine themselves. Although scientific evidence is not yet available, in the perception of farmers many remedies and concepts have shown their efficacy (Leon et al, 2006). It is not legal for farmers to use unlicensed agents instead of treating their animals with licensed veterinary medicinal products. Ingredients not listed in Council Regulation EC No 37/2010, defining the Maximal Residues Limits in foodstuffs of animal origin, are not allowed in food

producing animals. Without a prescription, homeopathics are only permitted above the D4 - Dilution (1:10000).

Therefore, the regulations should ensure to choose the best therapy method for a respective disease regarding cure chance in relation to seriousness and consumer's protection independent of the contents of the drugs. Thus, the emphasis should be put on therapy success chances rather than on the contents of the drugs. In case of evidence of efficacy provided by non-chemical drugs, these should be preferred. Measures should be taken to improve education of veterinarians in CAM methods to provide the basis of further clinical research on these methods.

3 Preventive Treatment is Prohibited

The use of chemically synthesized allopathic veterinary medical products or antibiotics for preventive treatment is prohibited in according to the current regulation [(EC) No 889, Art. 23(1)]. But medications are allowed (on an individual basis!) if needed to avoid suffering or distress of the animal [Art. 24(3)]. According to this paragraph, obviation of disease progression (metaphylaxis) with conventional medications is allowed. Until now the regulation does not introduce the term of metaphylaxis which considers the treatment of animals under higher risk of disease with the aim of preventing disease outbreak or health depression.

It has to be discussed whether these strategies are suitable to maintain health in organic herds because they are often accompanied by an increase of chemical drug application. On the other hand individualized metaphylactic measures should be able to improve animal health state and lead to reduction of acute disease conditions and are therefore in accordance to animal welfare issues.

As examples the following conditions may get discussed:

- The drying off with antimicrobial mastitis syringes is not considered a preventive measure if a high risk of mastitis infection is documented. In cases of subclinical chronic mastitis, it is considered a therapeutic treatment. More new udder infections at calving were found in untreated cows.
- The preventive treatment of newly bought calves with antibiotics may also be therapeutic if the probability is high that the animal is already within the incubation period of crowding disease (enzootic bronchopneumonia).
- Treating piglets against postnatal anaemia, a consequence of the lack of natural soil in feeding, with injections of iron supplements could be regarded as metaphylactic or preventive.

This paragraph means also that a systematic or strategic approach to treatment is apparently not consistent with organic rules. Such an approach could be, for example,

a tactical combating of endoparasites like routine anthelmintic treatments to interrupt the parasite's lifecycle before the treated animal shows signs of infection. It is to put up for discussion if the organic farmer really should do without strategic treatment.

Organic farmers must be particularly alert to the health status of their animals. If a chemical-synthetic treatment begins too late, the objective of reduced medicine use is defeated because treatments often must be longer and more intensive. In many cases, no complete recovery is then possible.

A general ban of foresighted treatment is adverse to GVP principles and is not in accordance with the high priority of animal welfare in organic husbandry.

In the future probably a lot of exceptions by the control boards will follow the ban of preventive treatment. For example, the term "preventive" is to be defined exactly. Perhaps it would be advisable to resume the discussion in this point, otherwise interpretation of the Article 23 (1) within the EU members will be ambiguous. In consequence the regulation could lose its authority.

4 Restrictions on Growth Promoters and Hormones

Growth promoters and hormones are restricted in organic farming [(EC) No 889, Art. 23(2)]. The regulation probably means that hormones may only be given in the context of a therapeutic veterinary treatment of single animals. Routine induction or synchronization of estrus or injections of Oxytocin to ease milking are still prohibited. But following the regulation text: "... the use of hormones ... or for other purposes ... is prohibited." will lead to the consequence, that the use of hormones is not allowed at all. This sentence needs a revision. Otherwise each treatment with hormones (for example cortisol) stays banned. This is adverse to GVP principles and any pharmaceutical knowledge.

5 Legal withdrawal period doubled

"The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, is to be twice the legal withdrawal period or, in a case in which this period is not specified, 48 hours" [(EC) No 889, Art. 24(5)].

The doubling of the withdrawal period and the 48 hours rule only concern allopathic veterinary remedies, thus everything that is not ranked homeopathic, including phytotherapeutics. The 70 plants registered were examined intensively and possible residues were classified as without risk for humans (EC No 37/2010). The 48-hours rule also holds for medicinal products with a legal withdrawal period of zero days. This includes, for example the use of

sodium chloride (NaCl) and glucose infusion solutions. Experts have termed this ruling absolutely useless (Tiergesundheit im Ökolandbau: Rechtliche Grundlagen, 2006).

The doubled withdrawal period is also problematic for the owners of „minor species“, like goats. In Germany the legal withdrawal time has to be doubled and is at least 28 days on meat and 7 days on milk, if the medicine used is not registered for the species which is treated ("Umwidmung"). That means, for example, a 56-day ban after treating an organic kid with an ointment licensed only for sheep.

The doubled withdrawal period is particularly difficult in connection with mastitis treatments. A total of 85 % of the mastitis treatments in organic farms were allopathic (Brinkmann et al, 2007) and at least 14 % of organic farmers usually treat with intramammary syringe at drying-off (Rahmann et al, 2004). In organic husbandry, milk of treated cows usually has to be withdrawn for 10 days; but if the birth takes place too early, the withdrawal period is up to 94 days, depending on the remedy. In reality, the withdrawal of milk for more than 4 to 6 weeks after parturition has to be questioned.

The correct doubling of the withdrawal period is hardly to survey as elimination of pharmaceuticals follows various exponential equations. And it is impossible to detect whether a 48-hour delay was considered after giving a medication without detectable residues (i.e. NaCl solution). Only recording done by the farmer himself could be evaluated by the control authority. The constant documentation of these kinds of animal treatments and reliable adherence to the withdrawal period of at least 48 hours may be challenged.

But the doubling of the legal withdrawal period for chemical drugs in organic farming was enacted to improve consumer protection. The fact that traces of antibiotics or metabolites can be expected within legal withdrawal periods increases the consumer's confidence in organic products, after prolonging the withdrawal period.

In any case the 48 hours rule including pharmaceutical products consisting of only physiological ingredients such as saline, bicarbonate, glucose should be omitted from the regulation, as it is in the Swiss organic regulations (Hertzberg et al, 2003). Same revision for licensed phytotherapeutics would be sensible. Single doubling after "Umwidmung" should be enough.

6 Restriction on Number of Treatment Courses

The number of treatment courses with *chemically-synthesized allopathic veterinary medicinal products or antibiotics* is restricted, if milk, eggs and meat is ought to be marketed as organic products [(EC) No 889, Art. 24(4)]. For fattening pigs and fowl the regulation allows only one

treatment course in hole life. A cow and its milk only get disqualified as "organic" with the fourth treatment course per year. This regulation does not apply to vaccinations and treatments against parasites. A treatment course covers the period of the first application of chemical-synthetic medicine within a therapy, up to the recovery of the animal. In case of a relapse of the same illness, a second treatment may be summarized with the first treatment to one treatment course.

A problem emerging in daily practice is awareness of previous treatment courses with the purchase of, for example, a group of weaned piglets. Another unsolved problem is medication in the castration of male piglets. Both, anaesthesia and pain control after the operation must be counted regarding legislation. Another question is raised according to pharmaceuticals with exclusive topical effectiveness. The correct documentation of these treatments may be questioned.

The paragraph is being discussed increasingly critically because farmers could place considerations of financial loss ahead of animal welfare issues if they underestimate the extent of the disease (Tiergesundheit im Ökolandbau: Rechtliche Grundlagen, 2006). Such decisions are diametrically opposed to the intentions of organic livestock production.

There is no rationale to give a certain number of treatment courses for qualification the products as organic. The damage for animal welfare (in terms of increased potential of not adequately treated animals) followed by practicing this regulation is much higher than the consumer's protection and confidence in organic animal production.

Instead of summarizing (with significant documentation and monitoring effort) the treatment cycles, a systematically performed control of residues could confirm the premium quality of organic food and help to gain confidence and earn an adequate price.

The principle of product quality enhancement in terms of residue free products of high quality should be considered rather than limiting the health control and management system on basis of living animals. Under practical conditions farmers are not able to maintain organic production e.g. after castration of piglets which requires anaesthetic and antiphlogistic treatment and thus more than the allowed one medication per lifetime.

The Article 24(4) leads to "solutions" where the farmers could try to practice ways to ensure the maintenance of organic status (1) by neglecting treatment documentation or (2) by using inadequate treatment measures without consulting a veterinarian or (3) by omitting required treatments at all.

In consequence, the control of food leaving the farm accompanied by measures to decrease risk for human (like doubled withdrawal period) should result in higher efforts

for healthy animals to avoid penalties and fit to the intention of organic production.

Also stepwise penalties for lower qualities (avoiding total loss by adequate therapies) may be a suitable means to achieve this goal. For instance, the milk quality improved 80 % within two years after payment was linked to a lower limit for germs/ml, controlled by the creamery (Suhren et al, 1996). A forward-looking issue under dispute is the granting of good health awards without penalizing effective treatment of animals where necessary. One approach to bridging this gap could be the definition of individual goals with animal health plans on each organic farm, including independent monitoring (Vaarst et al, 2006). The control of residues will guarantee the required consumer-friendly production process.

An overall critique of the whole regulation can be voiced with regard to the lack of precise phrasing. The only term defined is "Veterinary medicinal product" meaning: "Any substance or combination of substances presented for treating or preventing disease in animals..." [2001/82/EC]. But many terms are left undefined, for example, "allopathic veterinary medicinal product"; "chemically-synthesized allopathic veterinary treatment"; "antibiotics"; "hormones or similar substances"; "phytotherapeutic products"; "homeopathic products" and "artificial aids for growth promotion purposes".

Another need of review appears to be the list of products for cleaning and disinfection (Annex VII), as no effective disinfectant against persistent parasites eggs is allowed in organic farming, while extremely toxic Formaldehyde is listed.

Enhanced pharmacological expert knowledge would be useful to harmonize the regulations.

Conclusion

Revision and clarification of the guidelines for animal treatments are essential for farmers, veterinarians and control authorities and control bodies. The problems round the use of chemical-synthetic animal drugs in the daily practice of organic farming have to be discussed critically. The new Council regulation (EC) No 834/2007 defines only goals, while the detailed rules for application are fixed in (EC) No 889/2008. A revision of these regulations should thoroughly consider their feasibility and their impact on animal welfare.

Organic farming could be compromised by losing its reputation for reliability. If organic husbandry does not pick up and implements the facts about the interaction of outdoor keeping, animal health and adequate medical treatment, the problem will increase.

The correlation between costly labour and animal health and welfare should be scientifically proved and communi-

cated to the consumer. Better understanding would improve the perception of organic production processes and explain the required pricing. In the future, the objective of "less drugs" in organic animal farming should be reached by long-term adaptation of hygiene, feed and husbandry-methods. Mandatory animal health plans, herd management and other preventive measures could be useful tools, as well as a system of "reward or loss" in relation to defined animal health parameters, without penalizing effective treatment. This could possibly include bonus payments for well performing animal welfare practices indicated by animal specific outcomes.

Organic farming should try to reach an exemplary good animal health status by improving management rather than by drugs. But denying the necessity of chemical veterinary treatments will not help. Animal welfare has to be the major objective in organic farming.

General outline for a revision

- The term of metaphylaxis should be introduced to the regulation as a suitable measure to improve animal health on herd level.
- Regulations should ensure the best treatment measures.
- Regulations should avoid antagonisms between economic and welfare aspects rather than lead to decision challenges the farmer is faced with.
- Detailed paragraphs consisting of exact figures lacking of scientific rationale should be omitted from the regulation, such as the 48h rule and the limitation of treatment cycles.
- Instead, measures on herd level should be practiced to improve animal health and product quality.
- Animal health management should be linked to improvement concepts of the farm. Animal health plans and control of success could get mandatory in organic farming.

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