



**CCOF**  
*Certification Services, LLC*

# **IMPORTANT!**

**Organic livestock certification changes enclosed.  
Including: New Allowed Medications, Excipients,  
Changes to the National List & Re-evaluated Materials**

**Please read carefully. Your organic practices and  
certification may be affected.**

**Thank you for your support of  
organic production and CCOF.**

**Please contact us if you have any questions.**

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# CCOF

Organic Certification Trade Association Education & Outreach Political Advocacy

## Livestock News: Medicinal Substances Regulation Changes - December, 2007

Over the last few months, National Organic Program (NOP) livestock regulations that cover medicinal products have changed significantly. Additionally, CCOF has re-evaluated our interpretation regarding the allowance of certain livestock products. Please see below for important updates that may affect your operation.

### Products Added to the National List, NOP 205.603

On December 12, 2007, a Final Rule was published in the Federal Register allowing new synthetic substances for use as specific medical treatments in organic livestock production. Many of these substances require a withdrawal period before an animal may be sold or milked as "organic". The following nine synthetic substances have been added to the National List and may now be used with the following requirements/conditions:

- **Atropine** – allowed only under order of a licensed vet. 56 day withdrawal for slaughter animals, 12 day withdrawal for dairy animals
- **Butorphanol** - allowed only under order of a licensed vet. 42 day withdrawal for slaughter animals, 8 day withdrawal for dairy animals
- **Flunixin** - withdrawal period two times that required by FDA
- **Furosemide** - withdrawal period two times that required by FDA
- **Magnesium hydroxide** - allowed only under order of a licensed vet.
- **Peroxyacetic/ Peracetic acid** - for sanitizing facilities & equipment

- **Poloxalene** - for emergency treatment of bloat
- **Tolazoline** - allowed only under order of a licensed vet. Allowed only to reverse the effects of sedation and analgesia caused by Xylazine. 8 day withdrawal for slaughter, 4 day withdrawal for dairy
- **Xylazine** - allowed only under order of a licensed vet and only in an emergency. 8 day withdrawal for slaughter animals, 4 day withdrawal for dairy animals

**While these substances have been added to the National List, this is not a blanket approval for use.** Each product must be reviewed in the context of your Organic System Plan and specifically approved for your use. Please note that you must be able to demonstrate compliance with withdrawal times for those materials that have specific withdrawal requirements.

**If there is a product that you would like to use, such as Banamine, that contains one of these substances, please submit a Material Review Request Form (MRRF) to CCOF.** Remember that all products must be listed in your Organic System Plan before use.

### Products not added to the National List:

The NOP decided the following substances may not be allowed for organic livestock production as they were not authorized by the FDA for use as a medical treatment for livestock. The following synthetic substances cannot be used by organic

livestock producers as medical treatments:

- Activated charcoal
- Bismuth subsalicylate
- Calcium propionate
- Kaolin pectin
- Mineral oil
- Propylene glycol

Please note that all synthetic forms of these substances remain prohibited. If you wish to use a product containing a non-synthetic form of one of these substances, please be sure to include documentation from the manufacturer disclosing the non-synthetic source when you submit the MRRF to CCOF.

### Reevaluated Products:

Based on input from industry experts and further investigation by CCOF, we have reevaluated the following products and determined that they may be acceptable for use in organic livestock production, depending on your overall health care management plan:

- Immunoboost, manufactured by Bioniche Animal Health USA, may be used as a biologic
- Calf 180, manufactured by Crystal Creek, may be used as a medical treatment
- Calcium Borogluconate, multiple manufacturers, may be used as an electrolyte

If you previously submitted a MRRF for one of the above products that was denied by CCOF, and still wish to use these products as part of your healthcare plan, please resubmit the MRRF to CCOF for evaluation.

## **Medicines vs. Feed Supplements**

Please remember that when you are requesting review of a product by CCOF, you must indicate the reason for use. For example, is it a feed supplement, a treatment for milk fever, a vaccine, or something else? Whether or not a product will be allowed for your use will depend on the situation in which you plan to use it. As a reminder:

- Feed Supplement & Additive: a material added to the feed consumed by livestock for nutritional purposes, such as vitamins and minerals.
- Medical product: a product used to treat a specific illness, for a specified period of time, on a non-routine basis. If you use a product approved for medicinal use only, you must record the illness being treated and the time period of treatment.

### **Excipients: NOP 205.603(f)**

In addition to the changes above, the December 12, 2007 Final Rule includes a new section allowing excipients in animal drugs under certain conditions. According to the Animal Medicinal Drug Use Clarification Act, excipients are “any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.”

The regulation further states that excipients are allowed for use in animal drugs only if the excipient is:

- FDA listed as Generally Recognized As Safe (GRAS);
- Approved by the FDA as a food additive; or
- Included in the FDA review and approval of a New Animal Drug Application (NADA) or New Drug Application (NDA).

**Before this amendment was made to the NOP regulations,** CCOF had allowed any material to be used as an excipient. From now on, we must be able to verify that all excipients meet one of the three requirements listed above before we can approve a medical product. When you submit a MRRF for a medical product that contains any excipients (often listed as “other” or “non-active” ingredients) you will need to provide documentation from the manufacturer that the excipient is GRAS, an approved food additive or included on the NADA or NDA.

### **Milk Replacers no longer allowed:**

As of October 16, 2007 milk replacers are no longer allowed for organic calves. Milk replacers were previously listed as allowed for emergency use only. They have since passed their “sunset” date and have been removed from the list of allowed substances. If you were using milk replacers for your organic calves, please revise your Organic System Plan to show that you will comply with the new regulations by using only organic milk to feed organic calves.

### **Upcoming Changes:**

**We at CCOF recognize that the continual changes to livestock regulations may cause confusion and frustration.** We are doing our best to keep you informed of the changes as they happen and to stay on top of current issues in the industry. While we do not anticipate further changes to medication regulations in the near future, we do anticipate the publication of pasture regulations soon.

At this time, we do not know how specific the pasture requirements will be or how the regulation may be worded. We continue to strongly recommend that you take steps to ensure that your operation will meet the 120 days/ 30% recommendations agreed to by the Associations of Organic Dairy Producers. As soon as new pasture requirements are published, we will inform you of the details.

**A complete copy of the National Organic Program standards is available by mail from CCOF at any time and online at :**  
**[www.ccof.org/standards.php](http://www.ccof.org/standards.php)**

**MRRF forms are also available online at:**  
**[www.ccof.org/forms.php](http://www.ccof.org/forms.php)**

**Please do not hesitate to contact certification staff at CCOF if you have any questions.**



# CCOF

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## Materials Review Request Form

**It is your responsibility to verify all input materials are allowed before you use them. Only materials included on your Organic System Plan and approved by CCOF may be used.**

Materials that have been identified as compatible with organic production can be found on the Products List published by the Organic Materials Review Institute (OMRI), [www.omri.org](http://www.omri.org), or Washington State Dept. of Ag. (WSDA), [www.agr.wa.gov/FoodAnimal/Organic/MaterialsLists.htm](http://www.agr.wa.gov/FoodAnimal/Organic/MaterialsLists.htm). For materials not on either of these lists, CCOF will review the material for CCOF clients on a case by case basis to determine compliance with National Organic Program and international standards.

### A. INSTRUCTIONS

If you wish to use a material NOT on either the OMRI or WSDA brand name products lists, please follow these instructions:

1. Complete a separate form for each product.
2. Complete the product and use information (Section B) below.
3. Attach at least one of the following:
  - A copy of the label showing 100% of all ingredients;
  - Or, a copy of the MSDS (Material Safety Data Sheet). Only adequate if 100% of ingredients disclosed;
  - Or, a current statement from the manufacturer including a complete ingredient list. Only adequate if 100% of ingredients disclosed;
4. For all "inert" or "other" ingredients shown on product label or MSDS provide:
  - A statement from the manufacturer that either discloses all inerts, or, for pesticide products, a statement of which EPA list of inert ingredients they are on.
5. Fax or mail this form with all attachments to CCOF. CCOF will notify you of the results.

### B. PRODUCT INFORMATION

Reason for use:	
Date:	CCOF operation requesting review:
Material manufacturer:	Name and formulation of product:

Note: If product is approved for your use, you must update your OSP to include the brand name.

### C. FOR CCOF USE ONLY:

- Client named above may use this product with no restrictions.
- Client named above may use this product with the restrictions listed below.
- Insufficient information to determine compliance. Client named above must cease and desist use.
- Above material is **prohibited**, use of this product will constitute a non-compliance.

**Restrictions:**  NOP  EEC 20/9291 (EU)  IFOAM  USDA/MAFF (Japan)

**Reviewer:**

**Date:**

CCOF has reviewed this material for use by the client named above based on the information provided. This document does not allow nor encourage the commercial use of CCOF's name or seal in association with this material, nor does it imply endorsement of the material or manufacturer.

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