





## COMPANIES

### Livestock Products

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## PRODUCTS


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## In an Organic Nutshell:

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- the National Organic Regulations require the following for materials
- ❖ Land used for organic production must be free from *prohibited materials* for 3 years before organic harvest
- ❖ As a rule, only *natural* materials may be used for crop & livestock production.
- ❖ Exceptions to that rule—both allowed synthetics and prohibited naturals—are on the *National List*.
- ❖ Agricultural commodities must be produced and handled without *The Big Three Excluded Methods* (GMOs), Sewage Sludge, Irradiation
- ❖ Processed Food and Formulated Feed needs to be composed of *organic* ingredients, again with exceptions on the *National List*.

## Definition of synthetic

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- A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.
- *USDA: 7CFR 205.1*

## Why doesn't 'Organic' always mean 'allowed for Organic' with inputs?

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- ❖ The NOP is a *food* labeling claim
- ❖ USDA jurisdiction over input labels not established
- ❖ Fertilizers, Soil Amendments: States determine what can be sold as 'organic'
- ❖ Feed: FDA regulated; labeling enforced by states
- ❖ Pesticides / External Parasiticides: EPA recognizes 'for organic production.'
- ❖ Animal Drugs: US Food and Drug Administration





## Agencies that Regulate Inputs

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- ❖ Feed and Fertilizer: State Control Officials
- ❖ Animal Drugs & Feed Additives: US Food & Drug Admin.
- ❖ Pesticides / External Parasiticides / Anti-microbials: US Environmental Protection Agency







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## Another definition of Organic.....



- *Organic fertilizer:* - A material containing carbon and one or more elements other than hydrogen and oxygen essential for plant growth.
- (Association of American Plant Food Control Officials Official Publication 2006 — in effect since 1973)

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## BUYER BEWARE!



- Fertilizer that does not comply with the NOP rule can legally be labeled as 'organic fertilizer' in most states (e.g. sludge, urea)
- Feed additives, feed supplements, and various other formulations that are prohibited in organic production are also sometimes mislabeled as 'organic.' (non-organic carriers)

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## What does all this mean?



- ❖ Some products that are all agricultural may be eligible to be "certified organic"
- ❖ NOP does not regulate other organic claims yet, but may decide to do so in future
- ❖ States continue to regulate organic input claims, most to existing state rules, but some are starting to enforce the NOP definition
- ❖ Since not all ingredients are on the label, it is not possible to tell what complies simply by looking at the ingredients

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## How Can You Be Sure an Input is OK?



- ❖ Include *all* inputs (feed ingredients, medications, cleaners, parasiticides, production aids) in your organic system plan.
- ❖ Get all the information on the composition of an input. It is not always possible to tell by looking at the label.
- ❖ The certifier needs to approve materials on the organic system plan—if not they need to tell you why not.
- ❖ Look for the OMRI Listed® seal—still need to get approval from the certifier, but most of the homework has been done

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## What is the National List?


- ❖ Part of the NOP regulations 7CFR 205.600 *et seq.*
- ❖ For Crops and Livestock, List of "exceptions"
  - - all naturals are allowed, unless they listed as prohibited
  - -all synthetics are prohibited, unless they are on the list as allowed
- ❖ For Processing and Handling, List of Allowed Non-organic Ingredients, whether natural or synthetic





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## Examples of synthetic substances on USDA National List "As disinfectants, sanitizer, and medical treatments" in organic dairy production

- ❖ Alcohols: ethanol and isopropanol
- ❖ Aspirin
- ❖ Biologics / Vaccines
- ❖ Glycerine & Chlorhexidine as teat dips
- ❖ Iodine, Chlorine products
- ❖ Oxytocin for post-parturition therapeutic applications
- ❖ Ivermectin with additional restrictions







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Examples of synthetic substances on USDA National List “As topical treatment, external parasiticide or local anesthetic” in organic livestock production



- ❖ Copper sulfate & Hydrated Lime
- ❖ Mineral oil (external use only)
- ❖ Iodine, Chlorine products
- ❖ Lidocaine and procaine

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Examples of synthetic substances on USDA National List “As feed additives” or “As feed supplements” in organic dairy production



- ❖ Trace Minerals (FDA Approved)
- ❖ Vitamins (FDA Approved)
- ❖ Milk replacers without antibiotics & not from BST treated animals, emergency use only
- ❖ Cannot be provided in amounts above those needed for adequate nutrition and health maintenance [205.237(b)(2)]

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Nonsynthetic substances prohibited for organic livestock production

- ❖ Strychnine [National List]
- ❖ Manure used as feed [205.237(b)(2)]
- ❖ Hormones for growth promotion [205.238(c)(3)]
- ❖ Animal drugs administered in the absence of illness or that violate the Federal Food Drug and Cosmetic Act [205.238(c)(6)]






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### Filing a Petition

- What is it? Chemical, common name & CAS #
- Action sought: Allowing, Prohibiting, or Amending?
- Intended Use: Crop, Livestock Processing?
- Manufacturer(s); Sources & Manufacturing Processes
- Regulatory status: EPA, FDA, State?
- Organic status: EU, Private standards
- Safety information: MSDS, NIEHS Reports

*Abridged from 7 USC 6518(m)*






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### Filing a Petition

- Why is it necessary or unnecessary?
- What are the alternatives?
- What are the benefits over the alternatives?
- Research on the petitioned substance that addresses the evaluation criteria.

*Abridged from 7 USC 6518(m)*






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### Evaluation Criteria

<ul style="list-style-type: none"> <li>• Potential detrimental chemical interactions.</li> <li>• Toxicity and mode of action.</li> <li>• Environmental contamination during manufacture, use, misuse or disposal.</li> <li>• Human health effects.</li> </ul>	<ul style="list-style-type: none"> <li>• Biological and chemical interactions in the agroecosystem.</li> <li>• Alternatives to using the substance including practices.</li> <li>• Compatibility with a system of sustainable agriculture.</li> </ul>
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*Abridged from 7 USC 6518(m)*







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## Petitions and NOSB Recommendations



- ***PLEASE NOTE:***
- *“Substances on this site may not be used in organic production or handling before the effective date of any final rule adding the substance to the National List.”*
- [Http://www.ams.usda.gov/nop/NationalList/PetitionedSubstancesDatabase.htm](http://www.ams.usda.gov/nop/NationalList/PetitionedSubstancesDatabase.htm)

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## NOSB Recommended Animal Drugs



- NOSB has completed review and made recommendations on 26 Livestock Petitions since 2000
- Only one—methionine for poultry feed—has been accepted
- There are 25 Recommendations—Mostly Animal Drugs for Dairy Cows—that have not been accepted by the NOP

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## NOSB Recommended Animal Drugs



- July 17, 2006 NOP Proposed adding some of the recommended materials
- Only Peracetic acid was consistent with the NOSB's recommendation
- Excipients close to the NOSB's recommendation

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*Seven animal drugs permitted by FDA discretion and recommended by the NOSB were not proposed for addition to the National List by the NOP*



- activated charcoal
- calcium borogluconate
- calcium propionate (for milk fever)
- kaolin pectin
- magnesium oxide
- mineral oil
- propylene glycol

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*One parasiticide recommended by the NOSB was not proposed for addition to the National List by the NOP*


- Moxidectin
  - considered a macrolide antibiotic
  - Ivermectin is also a macrolide antibiotic & is on the National List





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*Five did not include the NOSB recommended Extended Withdrawal in the NOP's Proposal:*

- Butorphanol
- Flunixin
- Furosemide
- Tolazoline
- Xylazine







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*The NOP's Proposed to add veterinary supervision to the NOSB's recommendation to these three:*


- Atropine
- Bismuth subsalicylate
- Magnesium hydroxide



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*The NOP's Proposal did not include an emergency use limitation included in the NOSB's recommendation:*

- Poloxalene
- Tolazoline
- Xylazine



## Contact OMRI

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