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FROM : **OFFICE OF THE DIRECTOR**

SUBJECT : **U.S. DEPARTMENT OF AGRICULTURE'S ORGANIC REGULATIONS
FINAL RULE ON THE NATIONAL LIST OF ALLOWED AND
PROHIBITED SUBSTANCES (NATIONAL LIST)**

DATE : **March 12, 2019**

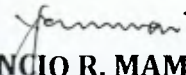
We have attached herewith the summary of the final rule amending §§ 205.600 through 205.607 of the USDA organic regulations (five pages). The following are the notable changes in the Final Rule:

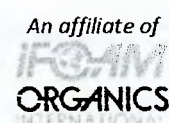
1. use restrictions for seventeen substances allowed for organic production or handling on the National List.
2. additional sixteen new substances on the National List to be allowed in organic production or handling.
3. prohibit the use of rotenone in organic crop production.
4. removes ivermectin as an allowed parasiticide for use in organic livestock production, and
5. allow the use of parasiticides in fiber bearing animals.

This rule was fully implemented on 28 January 2019 except that the amendments for the substances ivermectin, flavors, cellulose, and glycerin will be implemented on 27 December 2019.

In this respect, we would like to request your office to distribute this final rule to all USDA Organic Agriculture certified Micro Small and Medium Enterprises (MSMEs) under your respective jurisdiction who will likely be affected by the new regulations.

Should you have any inquiries, please do not hesitate to contact Mr. Rodolfo N. Panganiban at DA truck line (02) 9288751 local 3308 or email at rnpanganiban@gmail.com.


VIVENCIO R. MAMARIL PhD
Director IV



TITLE : NATIONAL ORGANIC PROGRAM; AMENDMENTS TO THE NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES (CROPS, LIVESTOCK AND HANDLING)

TECHNICAL BARRIER TO TRADE NOTIFICATION : G/TBT/N/USA/1334/Add. 2

IMPLEMENTATION DATES : Implemented on 28 January 2019 except the amendments for the substances ivermectin, flavors, cellulose, and glycerin which will be implemented on 27 December 2019.

This final rule amends the National List Allowed and Prohibited Substance's §§ 205.600 through 205.607 of the USDA organic regulations. The National List Allowed and Prohibited Substance (national List) identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling.

The following provides an overview of the final rule additions and amendments to designated sections of the National List regulations.

Substance	Particulars
§205.601 Synthetic substances Allowed for Use in Organic Crop Production	
1. Hypochlorous Acid (generated from electrolyzed water)	As a chlorine material allowed for use as an algicide, disinfectant, and sanitizer, including irrigation cleaning system
2. Magnesium Oxide	Use in controlling the viscosity of clay suspension agent for humates;
3. Squid byproducts from food waste processing only	Use in organic crop production. The pH can be adjusted with sulfuric, citric or phosphoric acid. The acid amount shall not exceed the minimum needed to lower pH to 3.5.
4. Micronutrients	Not to be used as a defoliant, herbicide, or desiccant. Micronutrients made from nitrates or chlorides are not allowed. This amendment removes the restriction on documenting micronutrient deficiency that was imposed by allowing soil testing as the only method for demonstrating soil micronutrient deficiency.
§205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production	

1. Rotenone (CAS#83-79-4)	Prohibited for use in organic crop production
§205.603 Synthetic Substance Allowed for Use in Organic Livestock Production	
1. Activated Charcoal	It must come from vegetative sources. Used as therapeutic treatment on as-needed basis with mammalian livestock in cases of suspected ingestion of toxic plants and control of diarrhea caused by moldy silage.
2. Calcium Boroglyconate	Used for treatment of milk fever only
3. Calcium Propionate	Used for treatment of milk fever only
4. Chlorhexidine	Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness
5. Hypochlorous Acid	It must be generated from electrolyzed water. For use in disinfecting and sanitizing equipment and facilities in organic livestock production.
6. Kaolin Pectin	For use as an adsorbent, antidiarrheal, and gut protectant
7. Mineral Oil	For relief of intestinal compaction. For use as a topical treatment, external parasitic, or local anesthetic. prohibited for use as a dust suppressant
8. Nutritive Supplements (injectable vitamins, trace minerals and electrolytes)	Allowed to use individually or in combination and be administered or ordered by a licensed veterinarian.
9. Parasiticides, Fenbendazole, and Moxidectin	Parasiticides— prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic. Fenbendazole (CAS #43210- 67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species. Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

10. Ivermectin	This parasiticide is no longer allowed for use in organic livestock production.
11. Propylene glycol	Use as a remedy for ketosis in ruminants
12. Acidified Sodium Chlorite	For use as a teat dip when used as a disinfectant, sanitizer, or medical treatment.
13. Xylazine	To be used for sedation of animals when necessary to perform non-emergency health care procedures. This includes the following requirements: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
14. Zinc Sulfate	For use in hoof and foot treatments only
15. Lidocaine	Annotation was amended to reduce the withholding periods for lidocaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk.
16. Procaine	Like Lidocaine, the annotation was amended to reduce the withholding periods for procaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk.
17. Methionine	For use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds
18. Excipients	To be use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.
§ 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as “Organic” or “Made With Organic (Specified Ingredients or Food Group(s)).”	
1. Alginic Acid	Reclassified alginic acid from a non-synthetic substance to a synthetic substance
2. Flavors	Revised the annotation of flavors to change the allowance for nonorganic flavors to require the use of organic flavors when they are commercially available
3. Cellulose	For use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

4. Chlorine materials	<p>This rule clarifies what chlorine levels are permitted for use in water in direct contact with food versus in water used as an ingredient in food.</p> <p>Chlorine materials intended for disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).</p>
5. Hypochlorous Acid (generated from electrolyzed water)	Allowed for use as a disinfectant and sanitizer in organic handling.
6. Potassium Lactate	Use as an antimicrobial agent and pH regulator only.
7. Sodium Lactate	Use as an antimicrobial agent and pH regulator only.
8. Glycerin	This rule changes the classification of glycerin from an allowed synthetic substance to an agricultural product that must be an organic product unless such organic products are not commercially available.
§ 205.606 Nonorganically Produced Agricultural Products Allowed as Ingredients in or on Processed Products Labeled as "Organic."	
1. Colors Derived From Agricultural Products	<p>This rule amends the USDA organic regulations to replace the Chemical Abstract Services (CAS) numbers included in the annotation of each color.</p> <p>The binomial nomenclature of the agricultural source of the color extract were as follows:</p> <ol style="list-style-type: none"> 1. Beet juice extract color—derived from <i>Beta vulgaris L.</i>, except must not be produced from sugarbeets. 2. Beta-carotene extract color— derived from carrots (<i>Daucus carota L.</i>) or algae (<i>Dunaliella salina</i>). 3. Black currant juice color—derived from <i>Ribes nigrum L.</i> 4. Black/purple carrot juice color— derived from <i>Daucus carota L.</i> 5. Blueberry juice color—derived from blueberries (<i>Vaccinium spp.</i>). 6. Carrot juice color—derived from <i>Daucus carota L.</i>

7. Cherry juice color—derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.
8. Chokeberry, aronia juice color— derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.
9. Elderberry juice color—derived from *Sambucus nigra* L.
10. Grape juice color—derived from *Vitis vinifera* L.
11. Grape skin extract color—derived from *Vitis vinifera* L.
12. Paprika color—derived from dried powder or vegetable oil extract of *Capsicum annuum* L.
13. Pumpkin juice color—derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne.
14. Purple sweet potato juice color— derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.
15. Red cabbage extract color— derived from *Brassica oleracea* L.
16. Red radish extract color—derived from *Raphanus sativus* L.
17. Saffron extract color—derived from *Crocus sativus* L.
18. Turmeric extract color—derived from *Curcuma longa* L.

The use of binomial nomenclature in § 205.606(d) clarifies which agricultural sources may be used to derive the color extract. Varieties or cultivars of the same species may be used as sources for a color extract unless otherwise excluded in the annotation. Agricultural sources with the same genus but not the same species will not be eligible for use as a source for a color.