

National Organic Standards Board (NOSB)
Crops Committee
List 4 Inerts in Pesticide Formulations
Discussion Document
November 2008

Background:

The National Organic Program (NOP) regulations currently allow the use inert ingredients in pesticide formulations that were previously classified by the EPA

As List 4A- Minimal Risk Inert Ingredients and List 4B- Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect the public health or the environment.

In accordance with the Food Quality Protection Act, in 2006 the EPA completed reassessments of inert ingredients used in pesticide products to ensure that such products met human health-based safety standards. Subsequent to that time, the EPA officially notified the NOP that the Inerts List system (Lists 3 and 4) referenced in the NOP regulations in §205.601 and 205.603 is now considered obsolete and no longer in effect.

The NOP needs to amend it's regulations to be in alignment with the modifications the EPA has made to it's regulations. In the meantime, the EPA has agreed to allow the NOP to continue the List 4 designation of allowed materials (as referenced in the August 2004 EPA List 4) while the NOP determines the best way to amend the regulations. The EPA reassessments have removed some materials from their list of minimal risk ingredients (List 4B), which are now prohibited under the NOP. The potential exists for the EPA to add new materials to their list of minimal risk ingredients as well. The EPA minimal risk ingredients can be found in 40 CFR 180.950 – *Tolerance exemptions for minimal risk active and inert ingredients* (attached at the end of this document). As the originator and maintainer of the National List of Allowed and Prohibited Substances in organic production and handling, the NOSB needs to work in concert with the NOP and EPA to accomplish the task of amending NOP inert ingredient regulations as they pertain to the National List.

Current Regulatory Language

§205.601....

m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(2) EPA List 3—Inerts of Unknown Toxicity allowed:

(i) Glycerine Oleate (Glycerol monooleate) (CAS #s 37220–82–9)—for use only until December 31, 2006.

(ii) Inerts used in passive pheromone dispensers.

(n) Seed preparations. Hydrogen chloride (CAS # 7647–01–0)—for delinting cotton seed for planting.

§205.603....

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

Plan of Action:

The NOSB will begin public discussion of these matters at their November 2008 meeting. Public comment is invited to comment on the possible solutions described below.

Public comment is heavily encouraged to identify the number and nature of synthetic materials deemed to be vital in pesticide formulations used in organic farming.

Possible solution options:

- 1)The NOP has suggested that a substitution of the language in the rule currently as List 4 with the new regulatory reference for 40 CFR 180.950 the minimal risk ingredients (significant correlation to List 4A).
- 2)Adopt the original 2004 List 4A inerts (Attachment 1) as an itemized list, with ongoing re-assessment through the sunset process.
- 3) Adopt the minimal risk ingredients currently in 40 CFR 180.950 (significant correlation to List 4A). This would entail a one time adoption of materials currently on this list with ongoing re-assessment through the sunset process.
- 4) Eliminate blanket inerts lists and adopt a policy of requiring inerts in pesticides to be petitioned individually.
- 5) Inerts (List 3) currently used in passive pheromone dispensers would be petitioned individually and be subject to regular sunset re-evaluations.

Upon taking the subject under advisement, a final NOSB recommendation could potentially be presented at the Spring 2009 meeting. Considering that the NOSB recommendation will need to be vetted through the EPA, a posting for public comment and NOSB adoption might be more realistically accomplished at the Fall 2009 meeting. Simultaneous to the NOSB review, an Advanced Notice of Proposed Rulemaking (ANPR) would be an important step prior to whichever meeting timetable is selected. Following the vote by the NOSB on a final recommendation on inert ingredients to be included on the National List, proposed rulemaking should proceed.

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

Unless specifically excluded, residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCa section 408, if such use is in accordance with good agricultural or manufacturing practices.

(a) *Commonly consumed food commodities.* Commonly consumed food commodities means foods that are commonly consumed for their nutrient properties. The term commonly consumed food commodities shall only apply to food commodities (whether a raw agricultural commodity or a processed commodity) in the form the commodity is sold or distributed to the public for consumption.

(1) Included within the term commonly consumed food commodities are:

(i) Sugars such as sucrose, lactose, dextrose and fructose, and invert sugar and syrup.

(ii) Spices such as cinnamon, cloves, and red pepper.

(iii) Herbs such as basil, anise, or fenugreek.

(2) Excluded from the term commonly consumed food commodities are:

(i) Any food commodity that is adulterated under 21 U.S.C. 342.

(ii) Both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat.

(iii) Alcoholic beverages.

(iv) Dietary supplements.

(b) *Animal feed items.* Animal feed items means meat meal and all items derived from field crops that are fed to livestock excluding both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat. Meat meal is an animal feed composed of dried animal fat and protein that has been sterilized. Other than meat meal, the term animal feed item does not extend to any item designed to be fed to animals that contains, to any extent, components of animals. Included within the term animal feed items are:

(1) The hulls and shells of the commodities specified in paragraph (a)(2)(ii) of this section, and cocoa bean.

(2) Bird feed such as canary seed.

(3) Any feed component of a medicated feed meeting the definition of an animal feed item.

(c) *Edible fats and oils.* Edible fats and oils means all edible (food or feed) fats and oils, derived from either plants or animals, whether or not commonly consumed, including products derived from hydrogenating (food or feed) oils, or liquefying (food or feed) fats.

(1) Included within the term edible fats and oils are oils (such as soybean oil) that are derived from the commodities specified in paragraph (a)(2)(ii) of this section when such oils are highly refined via a solvent extraction procedure.

(2) Excluded from the term edible fats and oils are plant oils used in the pesticide chemical formulation specifically to impart their characteristic fragrance and/or flavoring.

(d) [Reserved]

(e) *Specific chemical substances.* Residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCa section 408, if such use is in accordance with good agricultural or manufacturing practices.

Chemical	CAS No.
Acetic acid, sodium salt	127-09-3
Alpha-cyclodextrin	10016-20-3
Amylopectin, acid-hydrolyzed, 1-octenylbutanedioate	113894-85-2
Amylopectin, hydrogen 1-octadecenylbutanedioate	125109-81-1
Animal glue	None
Ascorbic acid (vitamin C)	50-81-7
Beeswax	8012-89-3
Benzoic acid, sodium salt	532-32-1
Beta-cyclodextrin	7585-39-9
Carbonic acid, monopotassium salt	298-14-6
Carbonic acid, monosodium salt (sodium bicarbonate)	144-55-8
Carnauba wax	8015-86-9
Carob gum (locust bean gum)	9000-40-2
Castor oil	8001-79-4
Castor oil, hydrogenated	8001-78-3
Cellulose	9004-34-6
Cellulose acetate	9004-35-7

Cellulose, carboxy methyl ether, sodium salt	9004-32-4
Cellulose, 2-hydroxyethyl ether	9004-62-0
Cellulose, 2-hydroxypropyl ether	9004-64-2
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3
Cellulose, methyl ether	9004-67-5
Cellulose, mixture with cellulose carboxymethyl ether, sodium salt	51395-75-6
Cellulose, pulp	65996-61-4
Cellulose, regenerated	68442-85-3
Citric acid	77-92-9
Citric acid, 2-(acetyloxy)-, tributyl ester	77-90-7
Citric acid, calcium salt	7693-13-2
Citric acid, calcium salt (2:3)	813-94-5
Citric acid, dipotassium salt	3609-96-9
Citric acid, disodium salt	144-33-2
Citric acid, monohydrate	5949-29-1
Citric acid, monopotassium salt	866-83-1
Citric acid, monosodium salt	18996-35-5
Citric acid, potassium salt	7778-49-6
Citric acid, triethyl ester	77-93-0
Citric acid, tripotassium salt	866-84-2
Citric acid, tripotassium salt, monohydrate	6100-05-6
Citric acid, sodium salt	994-36-5
Citric acid, trisodium salt	68-04-2
Citric acid, trisodium salt, dihydrate	6132-04-3
Citric acid, trisodium salt, pentahydrate	6858-44-2
Coffee grounds	68916-18-7
Dextrins	9004-53-9
1,3-Dioxolan-2-one, 4-methyl-(propylene carbonate)	108-32-7
Fumaric acid	110-17-8
Gamma-cyclodextrin	17465-86-0

Gellan gum	71010-52-1
D-Glucitol (sorbitol)	50-70-4
Glycerol (glycerin) (1,2,3-propanetriol)	56-81-5
Guar gum	9000-30-0
Humic acid	1413-93-6
Humic acid, potassium salt	68514-28-3
Humic acid, sodium salt	68131-04-4
Lactic acid, n-butyl ester	138-22-7
Lactic acid, n-butyl ester, (S)	34451-19-9
Lactic acid, ethyl ester	97-64-3
Lactic acid, ethyl ester,(S)	687-47-8
Lanolin	8006-54-0
Lecithins	8002-43-5
Lecithins, soya	8030-76-0
Licorice Extract	68916-91-6
Maltodextrin	9050-36-6
Paper	None
Potassium chloride	7447-40-7
2-Propanol (isopropyl alcohol)	67-63-0
Red cabbage color, expressed from edible red cabbage heads via a pressing process using only acidified water	None
Silica, amorphous, fumed (crystalline free)	112945-52-5
Silica, amorphous, precipitated and gel	7699-41-4
Silica gel	63231-67-4
Silica gel, precipitated, crystalline-free	112926-00-8
Silica, hydrate	10279-57-9
Silica, vitreous	60676-86-0
Soap (The water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid)	None
Sorbic acid, potassium salt	24634-61-5
Soapbark (Quillaja saponin)	1393-03-9

Sodium alginate	9005-38-3
Sodium chloride	7647-14-5
Syrups, hydrolyzed starch, hydrogenated	68425-17-2
Ultramarine blue (C.I. Pigment Blue 29)	57455-37-5
Urea	57-13-6
Vanillin	121-33-5
Xanthan gum	11138-66-2