

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: October 28, 2010
Subject: Tall Oil
Chair: Daniel G. Giacomini

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other Not to list Tall oil (CAS# 8002-26-4) on the National List §205.601.

Statement of the Recommendation (Including Recount of Vote):

The recommendation is to list Tall Oil (CAS# 8002-26-4) on the National List 205.601 FAILED by a vote of 14 no to 0 yes. Tall Oil was classified as synthetic by a vote of 14 yes, and 0 no.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Substance fails criteria categories 1,2, and 3. Even though Tall Oil is being petitioned as an inert, it also has insecticidal properties and so fails the environmental impact criteria. There are alternatives, therefore it fails the essentiality criteria, and because of its insecticidal properties, it fails is not compatible or consistent with organic or sustainable agriculture. Please see the Crops Committee recommendation, attached.

NOSB Vote: The motion before the board was to consider Tall oil (CAS# 8002-26-4) synthetic.

| | | | | |
|--------------------------|--------------|---------------------------|------------------|-------------------|
| Moved: Tina Ellor | | Second: Jeff Moyer | | |
| Yes: 14 | No: 0 | Abstain: 0 | Absent: 0 | Recusal: 0 |

NOSB Vote: The motion before the board was to list Tall Oil (CAS# 8002-26-4) on the National List §205.601.

| | | | | |
|--------------------------|---------------|---------------------------|------------------|-------------------|
| Moved: Tina Ellor | | Second: Jeff Moyer | | |
| Yes: 0 | No: 14 | Abstain: 0 | Absent: 0 | Recusal: 0 |

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

| | |
|---------------------------------------|---|
| For NOSB Meeting: October 2010 | Substance: Tall Oil CAS# 8002-26-4 |
|---------------------------------------|---|

Committee: Crops Livestock Handling Petition is for: Distillated Tall Oil to be included on the National List § 205.601

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | | |
|--|-----|--|-----|-------------------------------------|
| 1. Impact on Humans and Environment | Yes | No <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes | No <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes | No <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes | No <input type="checkbox"/> | N/A | <input checked="" type="checkbox"/> |

B. Substance Fails Criteria Category: 1, 2, and 3; **Comments:** Even though Tall Oil is being petitioned as an inert, it also has insecticidal properties so the committee felt that it failed the environmental impact category. There are alternatives; therefore the committee does not feel it was essential, and the committee determined that it is not compatible or consistent with organic or sustainable agriculture.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):

__ Tall Oil be classified as synthetic for crop production _____

Classification of the material: Synthetic 6 Non-synthetic 0 Absent: 1 Abstain 0

Motion by: Keven Englebert; Secoded: Tina Ellor

Recommended Committee Action & Vote (State Actual Motion): To add Tall oil to the national list § 205.601 as a synthetic for use in crop production.

Motion by: Kevin Englebert; Secoded: Jeff Moyer Yes: 0; No: 6; Absent: 1; Abstain: 0;

| | | | | | |
|----------------|-------------------------------------|---|-------------------------------------|-------------------------|-------------------------------------|
| Crops | <input checked="" type="checkbox"/> | Agricultural | | Allowed ¹ | |
| Livestock | <input type="checkbox"/> | Non-Synthetic | | Prohibited ² | |
| Handling | <input type="checkbox"/> | Synthetic | <input checked="" type="checkbox"/> | Rejected ³ | <input checked="" type="checkbox"/> |
| No restriction | <input type="checkbox"/> | Commercially Un-Available as Organic ¹ | | Deferred ⁴ | |

1) Substance voted to be added as "allowed" on National List to § 205._____ with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205._____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205.601__ Describe why material was rejected: __ Substance has insecticidal properties despite being petitioned as an inert. The CC felt that it failed categories 1, 2, and 3: adverse environmental impacts, non-essential, and inconsistent with organic and sustainable agriculture.

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Tina Ellor
Committee Chair

September 9, 2010
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance – Tall Oil

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|---|-----|----|------------------|--|
| 1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] | | | X | TR lines 194-208—environmental contamination associated with the Kraft papermaking process. |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | X | | | TR lines 194-208—environmental contamination associated with the Kraft papermaking process. |
| 3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i] | X | X | | No: TR lines 220-250—low concern for potential risk Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties. |
| 4. Does the substance contain List 1, 2, or 3 inert? [§6517 c (1)(B)(ii); 205.601(m)2] | X | | | It was (is?) on the EPA List 3 Inert Substances of Unknown Toxicity |
| 5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1] | | X | | TR lines 256-278 |
| 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] | X | X | | No: TR lines 283-341 Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties. Insecticidal activity cause unintentional adverse biological interactions. |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | X | X | | No: TR lines 346-412 Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties. The insecticidal properties may be detrimental to soil organisms, especially insects. |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | X | | | TR lines 417-431—Tall oil rosin may cause dermal sensitivity |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | X | | TR lines 436-457 |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4] | | X | | TR lines 462-481 |
| 11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3] | | | X | |
| 12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5] | | | X | Tall oil is GRAS as an indirect food additive (<i>Handbook of Preservatives</i> by Ash and Ash, Synapse Information Resources 2004, page 555) and http://edocket.access.gpo.gov/cfr_2008/aprqr/21cfr186.1557.htm |
| 13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5] | | | X | |

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance – Tall Oil

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|--|-----|----|------------------|---|
| 1. Is the substance formulated or manufactured by a chemical process? [6502 (21)] | X | | | TR lines 129-146 |
| 2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)] | X | | | TR lines 172-181 |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | X | | TR lines 186-189. It is an extract of trees, which are natural products, but it is not clear whether tall oil would exist in nature without the pulping and extraction process. |
| 4. Is there a natural source of the substance? [§205.600 b.1] | | | X | TR 186-189—Tall oil products are materials extracted from wood pulp, especially pine tree wood, which is a renewable natural resource. During the process of pulping coniferous trees to make paper, sodium salts of chemicals (tall oil soaps) occurring naturally in the trees are produced as a co-product. When acidulated, this soap becomes Crude Tall Oil (US EPA, 2009). |
| 5. Is there an organic substitute? [§205.600 b.1] | | | X | Vegetable oil TR line 500. |
| 6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6] | | | X | |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | X | | | TR lines 486-491—animal tallow, terpene extracts from soft woods |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | | | X | |
| 9. Is there any alternative substances? [§6518 m.6] | X | | | TR lines 496-501, 486-491. Vegetable oils, white mineral oils |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | X | | | TR lines 506-511 |

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance – Tall Oil

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|--|-----|----|------------------|--|
| 1. Is the substance compatible with organic handling? [§205.600 b.2] | | | X | |
| 2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)] | | X | | TR lines 157-167 and 331-341. Tall oil has insecticidal properties although it is being petitioned as an inert. Because of its unintentional effects on non-target insects and therefore biodiversity, the CC felt that it is incompatible with organic farming. |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | | X | | TR lines 157-167 and 331-341. Tall oil has insecticidal properties although it is being petitioned as an inert. Because of its unintentional effects on non-target insects and therefore biodiversity, the CC felt that it is incompatible with sustainable agriculture. |
| 4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3] | | | X | |
| 5. Is the primary use as a preservative? [§205.600 b.4] | | | X | |
| 6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4] | | | X | |
| 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: | | X | | |
| a. copper and sulfur compounds; | | X | | |
| b. toxins derived from bacteria; | | X | | |
| c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? | | X | | |
| d. livestock parasiticides and medicines? | | X | | |
| e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners? | | X | | |

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance – Tall Oil

| Question | Yes | No | N/A | Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown) |
|--|-----|----|-----|---|
| 1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling? | | | X | |
| 2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling? | | | X | |
| 3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling? | | | X | |
| 4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling? | | | X | |
| 5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions); | | | X | |
| b. Number of suppliers and amount produced; | | | X | |
| c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; | | | X | |
| d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or | | | X | |
| e. Are there other issues which may present a challenge to a consistent supply? | | | X | |