

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <b>November 2008</b>	Substance: <b>Ethylene for ripening of pears</b>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> Petition is for: <b>Inclusion of Ethylene for ripening of pears on the National List § 205.605(b)</b>																									
<b>A. Evaluation Criteria</b> (Applicability noted for each category; Documentation attached) <span style="float: right;"><b>Criteria Satisfied? (see B below)</b></span>																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
<b>B. Substance Fails Criteria Category:</b> _____ <b>Comments:</b> _____																									
<b>C. Proposed Annotation (if any):</b> <u>Amend 205.605 (b) Ethylene - to include post harvest ripening of pears.</u>																									
Basis for annotation: To meet criteria above: <input checked="" type="checkbox"/> Other regulatory criteria: _____ Citation: _____																									
<b>D. Recommended Committee Action &amp; Vote (State Actual Motion):</b> <u>Recommend Ethylene for ripening of pears for listing on §205.606(b).</u>																									
<i>Motion by: Steve DeMuri      Seconded: Julie Weisman      Yes: 4      No: 0      Absent: 2      Abstain: 0</i>																									
<table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;"></td> <td style="width: 25%;">Allowed<sup>1</sup></td> <td style="width: 25%; text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>Livestock</td> <td></td> <td>Non-Synthetic</td> <td></td> <td>Prohibited<sup>2</sup></td> <td></td> </tr> <tr> <td>Handling</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Synthetic</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Rejected<sup>3</sup></td> <td></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Commercially Un-Available as Organic<sup>1</sup></td> <td></td> <td>Deferred<sup>4</sup></td> <td></td> </tr> </table>		Crops		Agricultural		Allowed <sup>1</sup>	<input checked="" type="checkbox"/>	Livestock		Non-Synthetic		Prohibited <sup>2</sup>		Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected <sup>3</sup>		No restriction		Commercially Un-Available as Organic <sup>1</sup>		Deferred <sup>4</sup>	
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1) <b>Substance voted to be added as "allowed" on National List to § 205.605(b) with Annotation</b> (if any): <u>Amend 205.605 (b) Ethylene to read: "Ethylene—allowed for the post harvest ripening of pears and tropical fruit, and the degreening of citrus.</u>																									
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. 606 Describe why material was rejected: _____																									
4) Substance was recommended to be deferred because _____ _____ If follow-up needed, who will follow up _____																									
<b>E. Approved by Committee Chair to transmit to NOSB:</b>																									
<u>Julie Weisman</u> Committee Chair	<u>9/24/2008</u> Date																								

## NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

### Category 1. Adverse impacts on humans or the environment? Substance - Ethylene for ripening of pears

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		“The amount released to the atmosphere during manufacture or fruit treatment is miniscule when compared to the ethylene released from auto exhaust, petrochemical plants, or fires.” - Page 3 of the TAP. Ethylene can have a detrimental effect on horticultural plants if they are stored in areas with ethylene in the surrounding environment, such as in storage rooms or greenhouses. (Sherman 1985 article attached to TAP report)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		See above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		There is no concrete evidence of harm to the environment in the TAP. The petition claims no environmental harm. In 1999, the NOSB approved the use of synthetic ethylene for tropical fruit ripening and degreening of citrus.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		None mentioned in either the TAP or the petition.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		No detrimental chemical interactions with other materials mentioned in the petition or the TAP.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	Post harvest use.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	Post harvest use.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Not mentioned in the TAP or in the petition. The petition claims the EPA has designated ethylene a “biorational pesticide” - that it is of “natural origin and having limited or no adverse effects on the environment or beneficial organisms”. Ethylene in the atmosphere is decomposed by UV light
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		No mention of persistence or concentration of the material or breakdown products in the environment in either the petition or the TAP. Ethylene is readily decomposed in the atmosphere by UV light.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		The substance can be explosive at high temperatures in high concentrations. According to the TAP report, exposure to the gas causes dizziness and could cause suffocation from decreasing the amount of oxygen.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Adverse affects as defined by applicable Federal regulations not specifically mentioned in the TAP or the petition.
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]			X	Not GRAS because it is regulated by EPA, not by FDA. Page 2 of TAP report
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Not mentioned in the TAP or the petition. This is a gaseous material.

<sup>1</sup>If 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 - Ethylene for ripening of pears**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			According to the petition on page 3, and the TAP report on page 1, there are several methods of manufacture, but the predominant method involves the pyrolysis of hydrocarbon feedstocks, such as natural gas liquids or crude oil in tubular reactor coils installed in externally fired heaters. May also be produced from ethanol in fixed or fluid-bed reaction systems.
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		See above.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Ethylene is produced naturally by ripening fruits, but according to the petitioner and TAP report, a method of collecting the naturally produced substance has not been successfully commercialized. <b>The substance being petitioned is the synthetic manufactured form, not the naturally occurring form.</b>
4. Is there a natural source of the substance? [§205.600 b.1]	X			See above
5. Is there an organic substitute? [§205.600 b.1]			X	Synthetic substance
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			According to the petition, consumers miss out on several months of organic pears because without the use of ethylene, organic fruit of acceptable quality cannot be distributed. Pears do not ripen adequately or evenly on trees naturally. Reviewer contacts with industry members revealed that organic pear growers believe they are at a disadvantage vs. conventional growers without the ethylene tool, and produce inferior product for consumers. Without ethylene, fruit quality (ripeness) is widely variable.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		Naturally produced ethylene is common in a variety of fruits as part of the ripening process, but a method of collecting the naturally occurring form has not been commercialized.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		The petitioned form of ethylene is a synthetic material.
9. Is there any alternative substances? [§6518 m.6]		X		Only naturally produced ethylene from fruit, but this process has not been harnessed and commercialized.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Fruit (pears) could be ripened naturally, but it is uneven and requires more sorting, and there is a quality impact. Page 2 of the TAP.

<sup>1</sup>If 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 - Ethylene for ripening of pears**

Question	Yes	No	N/A <sup>1</sup>	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			Material is being petitioned for inclusion on §205.605(b) - synthetic, as a substance used in a post harvest (handling) situation, not for production.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Material is being petitioned for inclusion on §205.605(b) for post harvest handling of organic pears, not as a material to be used in production..
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			There is no affect on nutritional quality with the use of Ethylene, according to both the petition and the TAP report.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Primary use is a ripening agent, not a preservative.
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		The purpose is to enhance ripening, not to replace attributes that might have been lost during processing.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		Ethylene for pear ripening is being petitioned for inclusion on 205.605(b), for post-harvest handling, not for use in pear production systems.
a. copper and sulfur compounds;		X		Same as above
b. toxins derived from bacteria;		X		Same as above
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		Same as above
d. livestock parasiticides and medicines?		X		Same as above
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		Same as above

<sup>1</sup>If 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 - Substance - Ethylene for ripening of pears**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in <u>organic handling</u> ?			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
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 <b>form</b> to fulfill an essential function in a system of <u>organic handling</u> ?			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
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 <b>quality</b> to fulfill an essential function in a system of <u>organic handling</u> ?			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
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 <b>quantity</b> to fulfill an essential function in a system of <u>organic handling</u> ?			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
a. Regions of production (including factors such as climate and number of regions);			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
b. Number of suppliers and amount produced;			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
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	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).
e. Are there other issues which may present a challenge to a consistent supply?			X	Synthetic, non-agricultural substance being petitioned for inclusion on 205.605(b).