

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

Date: December 2, 2011

Subject: Petition to add Indole-3-butyric acid (IBA) to the National List §205.601

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X
Guidance Statement
Other

Statement of the Recommendation (Including Recount of Vote):

The Board determined that the material is synthetic (Motion: John Foster, Seconded: Colehour Bondera- No: 0, Yes: 14) and rejected the petition to add the material to 205.601 of the National List. (Motion John Foster, Second Tina Ellor- No 12, Yes 2).

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

The petition failed evaluation criteria 2 (essential) and criteria 3 (compatibility) and the environmental impacts may be greater than indicated raw depending on materials used, manufacturing process and method of use.

NOSB Vote:

Moved: John Foster		Second: Tina Ellor		
Yes: 2	No: 12	Abstain: 0	Absent: 0	Recusal: 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November, 2011

Substance: Indole-3-butyric acid (IBA) CAS#133-32-4

Committee: Crops Livestock Handling Petition is for: IBA as a plant growth regulator

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 <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> | No <input checked="" 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 type="checkbox"/> |

B. Substance Fails Criteria Category: 2 and 3 **Comments:** There has not been shown to be a demonstrated need for IBA in organic production. Synthetic materials to achieve propagation and to regulate plant growth is inconsistent with organic production. In addition, although #1 is checked yes, environmental impacts may be greater than indicated in the review depending on the raw materials used and the manufacturing process. In addition, although the most common probable use of IBA would be point application by dipping plant cuttings in powder dust or solution to promote rooting, the petition requests a broader use. Area application would present a different more complex risk.

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):

Classification of the material: Synthetic Non-synthetic _____ Absent: _____ Abstain _____

Motion by: Barry Flamm Seconded: Tina Ellor Yes: 6 No: _____ Absent: 1 Abstain: _____

Recommended Committee Action & Vote Motion to list under 205.601(k)

Motion by: Barry Flamm Seconded: Tina Ellor Yes: 1 No: 4 Absent: _____ Abstain: _____

Crops	Agricultural		Allowed ¹	
Livestock	Non-Synthetic		Prohibited ²	
Handling	Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>
No restriction	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. _____ Describe why material was rejected: Failed Categories 2&3 and concerns under category 1 _____

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up _____

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance:

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]			N/A	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		Petitioner stated IBA is a technical grade synthesized substance from many sources. 186 products containing IBA are available in US. IBA is manufactured world wide. Thus, there might be different manufacturing procedures. (TR 227)
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 282- IBA is biosynthesized in natural plants and produced by soil bacteria. It is non-toxic to avian wildlife, plants, but slightly toxic to fish and aquatic, and invertebrates and should not cause adverse effects to mammalian wildlife. EPA says IBA does not persist in the environment. TR 221 EPA also waved most tox requirements. TR 252-255 – IBA has typical hormonal dose-response pattern. TR 287- PAN data base shows no evidence of harmful effects to environment, except slight toxicity to fish.
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		TR 238- Indole (CAS#120-72-9) butyrolactone(CAS# 96-48-0) and Sodium Hydroxide (CAS# 1310-73-2) was on list 4B.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			TR 246- potentially reacts with strong oxidizers. TR 249- 250 synergistic with other chemicals and bacteria
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		TR 44- There are two general groups of application methods in terms of toxic effect and environmental consequence. 1) point application: dipping plant cuttings in powder,dust or solution. 2) Area application/ broad cast: foliar spray, turf, and adding to springler system. The risks are greater under group 2.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See # 3 above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See # 3 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		See # 3 above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		EPA says no known risks to human health and has granted an exemption for tolerance of residue. IBA is an "acute health hazard" under Section 311/312 Hazard class of SARA Title III Rules (MSDA-IBA,2007)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			N/A	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			N/A	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			N/A	

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance:

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			Petitioner stated IBA is a technical grade synthesized substance
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			Petitioner/TR
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		However, IBA does occur naturally in a variety of plants.
4. Is there a natural source of the substance? [§205.600 b.1]			N/A	
5. Is there an organic substitute? [§205.600 b.1]			N/A	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			N/A	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		IBA occurs naturally, but there is not any commercially available extraction process. The most commonly used auxin for inducing adventitious rooting is IAA, but the availability of natural sources is unclear.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			N/A	
9. Is there any alternative substances? [§6518 m.6]		X		TR 392- 398 Researchers have evaluated the effects of several alternative materials containing growth hormones.(Not clear if these would provide the same response as an auxin.)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR 499 Successful rooting from stem cuttings depend on many factors: timing, types of cutting, light, temperature, moisture and 10 other factors including plant hormones.(which may be produced naturally by the plant tissues- BF)

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance:

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			N/A	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		TR 381- European and N. American regulations do not allow synthetic products to obtain organic propagation. It does not fit any of the allowed categories for approving synthetic inputs: 6517c1(B)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		IBA is biosynthesized in natural plants and produced by soil bacteria. There is no evidence that chemical properties of synthetic IBA are different from natural sources, but the manufactured IBA contains impurities.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			N/A	
5. Is the primary use as a preservative? [§205.600 b.4]			N/A	
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]			N/A	
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;				
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		

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NOSB Evaluation Criteria for Substances Added To the National List

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: Name

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. <u>Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?</u>				
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?				
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?				
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?				
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);				
b. Number of suppliers and amount produced;				
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;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

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