

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to classify Indole-3-butyric acid (CAS#133-32-4) (IBA) as synthetic.

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

The petitioner stated that the substance (IBA) is a technical grade synthesized substance from many commercial sources.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Motion to list Indole-3-butyric acid (CAS#133-32-4) (IBA) as petitioned on §205.601 for the purpose of plant propagation via dipping.

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

The committee found that IBA is not essential and is not compatible with organic production, and therefore voted to not add it to the National List .

Committee Vote:Moved: Seconded: Yes: No: Abstain: Absent: Recuse:

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Indole-3-butyric acid (IBA) CAS#133-32-4**

January 29, 2013

Summary of Proposed Action:

Indole-3-butyric acid (IBA) CAS#133-32-4 was petitioned in 2009 and was reviewed in 2011 by the NOSB, which voted to not add it to the National List. The petitioner re-petitioned the substance in 2012, this time with a use restriction to rooting cuttings. Besides the use restriction, no new information accompanied the re-petition.

IBA is a plant hormone in the auxin family and is an ingredient in many commercial horticultural plant rooting products. IBA is not soluble in water and it is typically dissolved in 75% or purer alcohol for use in plant rooting, making a solution of between 10,000 to 50,000 ppm. This alcohol solution is then diluted with distilled water to the desired concentration. IBA is also available as a salt, which is soluble in water. This compound had been classified as synthetic; however, it was reported that the compound was isolated from leaves and seeds of maize and other species.

IBA is used to promote strong rooting and root growth, which users say has the benefit of minimizing the period of time in which young planting stock is susceptible to disease and pest pressure, thereby minimizing additional pest and disease control measures and crop losses. It also provides for propagation of seedless annual crops and some perennial crops impossible or nearly so without such support. Additionally, unique flavors of individual plants (e.g. mint, basil) can be precisely propagated whereas propagation by seed creates variability in flavors of sexually propagated stock. Proponents of IBA's inclusion on the National List say it would also allow propagation materials to be sold as organic within a 12-month time frame, thus further developing the supply to build the market for organic perennial planting stock on a regular basis. Its utility in the ornamental crop sector is widespread and may encourage ornamental nurseries to work toward developing organic crop production systems. Five growers provided their written support as part of the petition packet in favor of the including of the material to facilitate the production of organic herbs, strawberries, herb transplants, and other crops, and they appear to have a real interest in the inclusion of IBA on the National List.

IBA's status as a production aid (as opposed to pest control or disinfectant, for example) places it in uncertain territory relative to the National List and makes it difficult to categorize. Additionally, there was little call from organic growers for the material to be placed on the National List and the Crops Subcommittee would like to hear additional comments from the organic growing community as to need and compatibility of the material.

The committee found that it is not essential and is not compatible with organic production.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)

Satisfied?

- | | Criteria |
|--|--|
| 1. Impact on Humans and Environment
<input type="checkbox"/> N/A | x Yes <input type="checkbox"/> No |
| 2. Essential & Availability Criteria
<input type="checkbox"/> N/A | <input type="checkbox"/> Yes x No |
| 3. Compatibility & Consistency
<input type="checkbox"/> N/A | <input type="checkbox"/> Yes x No |
| 4. Commercial Supply is Fragile or Potentially Unavailable
x N/A
as Organic (only for § 205.606) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Substance Fails Criteria Category: [2, 3] Comments: There has not been shown to be a demonstrated need for IBA in organic production. The majority of the subcommittee found that synthetic materials to achieve propagation are 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.

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria

Citation

Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Classify IBA as synthetic.

Motion by: John Foster Seconded by: Harold Austin

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse:0

Listing Motion: List IBA (CAS# 133-32-4) as petitioned on §205.601 for the purpose of plant propagation via dipping.

Motion by: John Foster Seconded by: Harold Austin

Yes: 3 No: 5 Absent: 0 Abstain: 0 Recuse:0

Crops	x	Agricultural	<input type="checkbox"/>	Allowed¹	<input type="checkbox"/>
Livestock	<input type="checkbox"/>	Non-synthetic	<input type="checkbox"/>	Prohibited²	<input type="checkbox"/>
Handling	<input type="checkbox"/>	Synthetic	x	Rejected³	x
No restriction	<input type="checkbox"/>	Commercial unavailable as organic	<input type="checkbox"/>	Deferred⁴	<input type="checkbox"/>

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

²Substance to be added as “prohibited” on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

⁴Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair

January 29, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Indole-3-butyrac acid (IBA)

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		TR 227- Petitioner stated IBA is a technical grade synthesized substance from many sources.186 products containing IBA are available in US. IBA is manufactured worldwide. Thus, there might be different manufacturing procedures. TR 240 Isopropyl ether is listed as "UN1159 Flammable Liquid" by U.S. DOT. The health effects are listed in 240 OSHA as "Irritation-Eye, Nose, Throat, Skin --- Mild (HE15)."
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 282- IBA is synthesized 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 waived 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.

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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) were on EPA inerts 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: "The stimulating effect of IBA is synergistic with other chemicals and bacteria."
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		TR 262-264: The literature about IBA's potentially detrimental chemical interaction with other substances used in organic crop or livestock production is scarce.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		TR 272-274: The literature about potential detrimental physiological effects is limited. Instead, indole derivatives including IBA possess fungicidal activity against some plant pathogenic fungi (Abdel-Aty, 2010). (Nothing stated about effects on beneficial fungi.)
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		TR 303-313: EPA says no known risks to human health and has granted an exemption for tolerance of residue, but has waived many data requirements. 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	

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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: Indole-3-butyric acid (IBA)

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			
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			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			TR 294-296
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		TR 62, 142-155: 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. Are there any alternative substances? [§6518 m.6]	X			TR 314-500 identifies many substances and practices.

10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR 314-500 identifies many substances and practices. 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)
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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: Indole-3-butyric acid (IBA)

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	X		TR 381- European and N. American organic regulations do not allow use of synthetic products for propagation. It does not fit any of the allowed categories for approving synthetic inputs: 6517c1(B). However, proponents say it does promote healthy plant tissue thereby reducing needs for further intervention measures.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		IBA is produced in plants and 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		X		

categories:				
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		

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 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:** Indole-3-butyric acid (IBA)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. <u>Is the comparative description provided</u> 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			x	

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:			x	
a. Regions of production (including factors such as climate and number of regions);				
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	

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