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

Date: May 1, 2024 Subject: Technical Report (TR) update NOSB Chair: Kyla Smith

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: Guidance Statement: Other: X

Statement of the Recommendation:

The NOSB voted unanimously to update the Technical Review templates for Handling and Crops/Livestock.

Rationale Supporting Recommendation:

The Materials Subcommittee engaged in the process of revising the Technical Review template in an effort to make the information requests clearer to the TR writers, reduce redundancy, and align the questions with those in the petition template. Additionally, the MS added questions to fulfill the directions of the Policy and Procedure Manuel's (PPM) assertion that "A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that materials impact on the environment, human health, and it's compatibility with organic principles." (Pg 28). The PPM is also clear that "[t]he decision to request a third-party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review" of the substance on hold (pg. 28). The PPM is instructive to the NOSB process of evaluating materials, giving an extensive list of sources needed for the NOSB to write recommendations. The PPM instructs Board members to "[r]ead the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, public or board comments from the optional petition discussion document, and recommendations of a contracted panel of experts when utilized." (Pg 26). The PPM recognizes that Subcommittees must cast a wide net to gather enough information to "prepare a written review of the substance according to the OFPA criteria" (Pg 26).

NOSB Vote:

Motion to accept the changes to the Technical Reports (TR) templates Motion by: Mindee Jeffery Seconded by: Nate Lewis Yes: 14 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Motion Passed

National Organic Standards Board Materials/GMO Subcommittee Proposal - Technical Review template update February 13, 2024

Intro/Background:

The Materials Subcommittee (MS) is proposing updates to the Technical Review (TR) templates to better align with the petition process and OFPA criteria and to directly address excluded methods.

The NOSB Policy and Procedures Manual defines a technical review as follows: "Technical Review - A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB." According to the PPM, "A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles." The two revised TR templates, one for Handling and one for Crops/Livestock are included as Appendices to this proposal. Also included as appendices are the two versions with redlining.

Discussion:

The Materials Subcommittee submitted a <u>discussion document</u> on the TR updates for comment at the Spring 2023 meeting. Public commenters were supportive of the initiative to reorganize the flow of questions, reduce redundancy, and suggested additional questions for ancillary substances, nanoparticles, and excluded methods. The suggested changes were incorporated into the templates, and in January 2024, the MS voted unanimously in support of the versions of the TR templates included in the appendices.

Questions to stakeholders:

Do the proposed revisions to the technical report (TR) templates for Handling and Crops/Livestock raise any concerns or challenges for stakeholders that create and/or use TRs?

Subcommittee Vote:

Motion to accept the technical Report template updates for Handling and Crops/Livestock. Motion by: Mindee Jeffery Seconded by: Nate Lewis Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Appendix A1 - Redlined version of TR template: Handling Appendix A2 - New version of TR template: Handling Appendix B1 - Redlined version of TR template: Livestock/Crops

Appendix B1 - New version of TR template: Livestock/Crops

Handling/Processing

Identification of Petitioned Substance			
Chemical Names	CAS Numbers		
List all chemical names	List CAS numbers		
List an chemical names	List CA3 Humbers		
Other Name:			
List other names	Other Codes:		
	List other codes (e.g., INS number, E number,		
Trade Names:	etc.)		
List trade names			
	Summary of Petitioned Use		
For petitions to add or amend a subst on the National List, summarize the a	ance, describe the petitioned use of the substance. For substances curre illowed uses under the USDA organic regulations (7 CFR Part 205).		
Char	cacterization of Petitioned Substance		
Composition of the Substance:			
Describe Composition of the Substance	ce		
Source or Urigin of the Substance:	f the exclusion of the head descend in some day 11, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,		
Drieny describe the source or origin o	i the substance (to be addressed in more detail below under		
Evaluation Questions 1 through 4).			
Properties of the Substance			
Describe Physical and Chemical Prop	verties of the Substance		
,			
Specific Uses of the Substance:			
Describe Specific Uses of the Substand	ce - primary focus should be given to describing the petitioned use of		
the substance as it relates to organic h	andling; secondary focus should be given to providing general		
information on other uses of the petiti	ioned substance in agricultural handling/processing.		
Approved Legal Uses of the Substan			
Describe the Status of the Petitioned S	Substance under applicable Federal Regulations (i.e., EPA, FDA,		
USDA (including APHIS or FSIS), NII	EHS, etc.)		
Action of the Substances			
Action of the Substance: Describe Action of the Substance for	cus should be given to describing mode of action of the substance		
when used as netitioned	tus should be given to describing mode of action of the subsidice,		
when used as pendoned.			
Combinations of the Substance			
	nce – focus should be given to describing whether the petitioned		
Describe Combinations of the Substance – focus should be given to describing whether the petitioned			
Describe Combinations of the Substar substance is a precursor to, componer	substance is a precursor to, component of, or commonly used in combination with a substance(s) identified		
Describe Combinations of the Substar substance is a precursor to, componer on the National List. Any known syne	ergistic effects (either positive or negative) with other substances on		
substance is a precursor to, componer on the National List. Any known syne the National List should be identified	ergistic effects (either positive or negative) with other substances on .		
Describe Combinations of the Substar substance is a precursor to, componer on the National List. Any known syne the National List should be identified	ergistic effects (either positive or negative) with other substances on		
Describe Combinations of the Substar substance is a precursor to, componer on the National List. Any known syne the National List should be identified In addition, information should be pr	ergistic effects (either positive or negative) with other substances on ovided on whether any additional ingredients (e.g., inert ingredients,		
Describe Combinations of the Substar substance is a precursor to, componer on the National List. Any known syne the National List should be identified In addition, information should be pr stabilizers, preservatives, carriers, ant	ergistic effects (either positive or negative) with other substances on ovided on whether any additional ingredients (e.g., inert ingredients, i-caking agents, or other materials) are generally added to		

Technical Evaluation Report Compiled by (Name of Contractor) for the USDA National Organic Program

51 52				
52 53	Status			
54				
55	Historic Use:			
56	Describe historic use of the substance in organic agricultural production (if no historic use in organic			
57	agricultural production, please describe historic use in conventional agricultural production).			
58				
59	Organic Foods Production Act, USDA Final Rule:			
60	Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990			
61	(OFPA) or the USDA organic regulations, 7 CFR Part 205.			
62 62	International			
63 64	International			
65	Describe the status of the substance among international organizations. Specifically, the report should			
66	address whether the petitioned substance is allowed or prohibited for use in other international organic			
67	standards such as:			
68				
69	Canada , Canadian General Standards Board –			
70				
71	CAN/CGSB-32.310- Organic production systems-General principles and management standards			
72	CAN/CGSB-32.311-2015, Organic Production Systems Permitted Substances List			
73	http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172			
74	CODEX Alimentarius Commission Cuidelines for the Production Processing Labelling and			
75 76	Marketing of Organically Produced Foods (CL 32-1999)			
70	http://www.fao.org/docrop/005/22722F/2272E00 HTM			
78	Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".			
79	,			
80	European Economic Community (EEC) Council Regulation – EC No. 834/2007 and 889/2008			
81	<u> http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889</u>			
82				
83	Japan Agricultural Standard (JAS) for Organic Production			
04 85	<u>http://www.maii.go.jp/e/jas/specific/criteria_o.ntmi</u>			
85	International Federation of Organic Agriculture Movements (IFOAM)			
87	http://www.ifoam.bio/en/ifoam-norms			
88				
89				
90	Evaluation Questions for Substances to be used in Organic Handling			
91				
92	[combination of old #1, 2 &3 – word smithed and added D, E and F]			
93	Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the			
94	petitioned substance. Further, describe any chemical change that may occur during manufacture or			
95	tormulation of the petitioned substance when this substance is extracted from naturally occurring plant,			
90 07	animal, or mineral sources (7 U.S.C. § 0502 (21)). (A) Describe in the substance is extracted from naturally			
98	manufacture or formulate the petitioned substance. Include any chemical changes that may occur			
99	during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is			
100	agricultural or Non-agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7			
101	U.S.C. §6502(21); NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms			
102	contain nanoparticles? (E) Does the substance in its raw or formulated forms contain ancillary			
103	substances (F) Is the substance created using Excluded Methods?			
104				

105	Data Required: The response must describe the processes used to manufacture or formulate the substance,					
106	including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing					
107	methods which are not included in the petition, if any, should be presented. The response must also					
108	describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all					
109	manufacturing or formulation processes. For the purposes of this response, a chemical change could be the					
110	addition or deletion of one atom to the substance's molecular structure or other description of chemical					
111	modification.					
112	(A)	If the substance is extracted from a natural material, information should be provided on any				
113		materials and methods used to extract, separate, isolate, or withdraw the substance, including any				
114		solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the				
115		substance is created by a naturally occurring biological process, those process(es) must be				
116		described in detail.				
117						
118		For the purposes of this response, naturally occurring biological processes are processes that				
119		include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation,				
120		various metabolic processes, and photosynthesis.				
121						
122	(B)	The response must describe the processes used to manufacture or formulate the substance,				
123		including a discussion of all precursors and/or feedstocks. A description of alternate				
124		manufacturing methods and the extent of their commercial use which are not included in the				
125		perition, if any, should be presented. The response must also describe, in detail, any chemical				
120		formulation processes. If any synthetic materials used in the production or sytraction of a				
127		substance remain in the final product, describe them				
120		substance remain in the final product, describe them.				
129		For the nurneses of this response a chemical change involves a process (i.e., chemical reaction)				
130		whereby a substance is transformed into one or more other distinct substances. This may include				
132		the addition or deletion of one atom to the substance's molecular structure or other description of				
133		chemical modification				
134						
135		Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or				
136		catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-				
137		reduction, polymerization, etc., obtained through process units such as compressors, cracking				
138		towers, heat exchangers, mixers, reactors, pumps, etc.				
139						
140	(C)	Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22)				
141		NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as				
142		agricultural or non-agricultural.				
143						
144	(D)	Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are				
145		they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP?				
146		(Policy Memo 15-2)				
147						
148	(E)	Ancillary Substances: Does the substance in its raw or formulated forms contain ancillary				
149		substances as defined by the NOSB in the 2016 recommendation?				
150		(https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Propo				
151		sal%20NOP.pdf)				
152						
153	(F)	Excluded Methods:				
154		i. Is the substance created using excluded methods? This includes but is not limited				
155		to the following list of techniques found to be "excluded methods" by the NOSB:				
156		Targeted genetic modification (TagMo), Synthetic gene technologies, Genome				
157		engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant				
158		breeding techniques, Synthetic Biology, cloned animals and offspring, plastid				
159		transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed				

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	using invitro nucleic acid techniques, induced mutage vitro nucleic acid techniques, cell and protoplast fusio	enesis developed through in on (NOP policy Memo 13-1).
ii.	If the substance is manufactured from agricultural rav materials derived from genetically engineered crop, or	v materials, are those r crops resulting from
	excluded methods?	Lange and the table in the second
111.	the substance is manufactured from other biological those produced by fermentation or enzymatic action – materials, derived from genetically engineered organi resulting from excluded methods?	- are those biological sms, or crops organisms
[old #4] Evaluation Qu manufactured by a che	stion #2: Discuss whether the petitioned substance i nical process, or created by naturally occurring biolo	is formulated or gical processes (7 U.S.C. §
6502 (21)). Discuss whe	her the petitioned substance is derived from an agric	cultural source. Specify
whether the petitioned	Substance is categorized as generally recognized as s	ate (GRAS) when used
describe the regulatory	status.	or categorized as GKA5,
Data Required: For the	purposes of this response, chemical processes are proc	cesses include, but are not
limited to, acid base rea	tions, calcification, thermal or catalytic cracking, ester	ification, hydrogenation,
mixing of substances or	elements, oxidation reduction, polymerization, etc., of	otained through process units
such as compressors, cr	cking towers, heat exchangers, mixers, reactors, pump	os, etc.
-		
If the substance is extra	ed from a natural material, information should be pro	ovided on any materials and
methods used to extrac	separate, isolate, or withdraw the substance, includin	ig any solvents used, acid
base extraction method	or mechanical or physical separation methods.	
If the substance is create	1 by a naturally occurring biological process, those pr	ocess(es) must be described
in detail. For the purpe	es of this response, naturally occurring biological proc	cesses are processes that
include but are not limi	ed to, aerobic and anaerobic digestion, decomposition	, fermentation, various
metabolic processes, an	-photosynthesis.	
Information should be j	ovided on whether the substance has been chemically	y modified from the source
or origin of the substan	; including whether the substance has been isolated t	rom a natural source in a
torm that does not occu	in nature, and whether any synthetic materials used i	in the production or
extraction of a substance	may remain in the final product.	
		1
For the purposes of this	esponse, an agricultural source is any agricultural con	mmodity or product,
whether raw or process	d, including any commodity or product derived from	livestock that is marketed in
the United States for hu	nan or livestock consumption.	
D 1 1		
Purpose and necessity	<u>t the substance</u>	
	ation #2. If the substance is a surthatic substance of	warride a list of warranthatis
[010 #5] Evaluation Qu	<u>stion #3:</u> If the substance is a synthetic substance, p	tovide a list of nonsynthetic
tochnical function or n	repetitioned substance (7 CFR 205.000(D)(1)). Descri	7 CER 205 600(b)(4))
reclinical function of p	rpose of the petitioned substance is a preservative (7	CFR 203.000(D)(4)).
Data Required The rec	onco must discuss whether non-synthetic or natural s	ources of the potitioned
substance ovist and are	vailable. The report contractor should examine the of	foct form function quality
and quantity of the nati	cally sourced version of the potitioned substance in co	marison to manufactured
vorsions The following	information on any naturally coursed vorsions should	the provided in the report.
versions. The following	anormanon on any naturany sourced versions should	a de provideu in die report.
litoratura inclu	ing product or practice description on performance a	nd tost data:
• nome and add	se of the manufacturer(s) if applicables and	
• name and dddr	so or the manufacturer(s), if applicable; and,	

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214	• types of products the substance is currently used in.			
215	The response must explain why the primary function of the substance is or is not as a preservative.			
217	[old #6] Evaluation Question #4: Specify whether the petitioned substance is categorized as generally			
218	recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR			
219	205.600(b)(5)). If not categorized as GRAS, describe the regulatory status. Describe whether the			
220	petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive			
221	values lost in processing (except when required by law). If so, now? (7 CFR 205.600(b)(4)).			
222	Date Required: The response must indicate whether or not the substance has been determined to be CRAS			
223	by EDA This information may be found in 21 CER Parts 182 184 and 186. If not determined to be CRAS			
225	by FDA, indicate whether it appears on FDA's "CRAS Notice Inventory" available at			
226	http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing-			
227				
228	The response should cite the FDA regulatory citation confirming GRAS status or whether FDA has			
229	provided a response letter of no objection to a manufacturer's notification of GRAS status. When			
230	replacement or improvement of nutrients is required or allowed by regulation, the report evaluators			
231	should cite the appropriate regulations.			
232				
233	<u>loid #71</u> Evaluation Question #5: Describe whether the primary technical function or purpose of the			
234	petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a			
233	the food or feed when the notitioned substance is used (7 CER 205 600(b)(3))			
230	the food of feed when the petitioned substance is used (7 CFR 205.000(b)(5)).			
238	Data Required: The response must explain why the primary function of the substance is or is not as a			
239	preservative. The response must indicate whether the use of the petitioned substance affects the levels of			
240	nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product.			
241	Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.			
242				
243	Environment and human health effects			
244				
245	old #8] Evaluation Question #6: Describe whether the petitioned substance will be used primarily to			
240	hy law) and how the substance regreates or improves any of these food/food characteristics (7 CEP			
248	$\frac{205.600(b)(4)}{201}$ List any reported residues of heavy metals or other contaminants in excess of FDA			
249	tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).			
250	Dete Descripted, W/here works constant or increased of autoinstatic rescuired or allowed has resculation, the			
251	report evaluators should gite the appropriate regulations. The response must indicate whether the			
252	petitioned substance may contain residues of substances that exceed EDA's Action I evels for Poisonous or			
255	Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found			
255	in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels			
256	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-			
257	poisonous-or-deleterious-substances-human-food-and-animal-feed See the latest edition of Food Chemicals			
258	Codex (National Research Council) for accepted reference standards for metals and other contaminants in			
259	food ingredients in the U.S.			
260				
261	[old #9] Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the			
262	food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)). Discuss and summarize			
263	findings on whether the manufacture and use of the petitioned substance may be harmful to the			
264	environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).			
265				
266	Data Required: The response must indicate whether the use of the petitioned substance affects the levels of			
267	nutrients (e.g., proteins, carbohydrates, tats, vitamins, and minerals) commonly found in the food product.			
268	Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients. In			
269	consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe			
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270 271 272 273 274	the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (<i>e.g.</i> , predators and parasitic hymenoptera), pollinators, bats and birds.
275	[old #10] Evaluation Question #8: List any reported residues of heavy metals or other contaminants in
276 277 278 279	excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5))Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).
280	Data Required: The response must indicate whether the petitioned substance may contain residues of
281 282 283 284	substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. These action levels can be found at https://www.fda.gov/food/guidanceregulation/ucm077969. See the latest edition of Food Chemicals
285	Codex (National Research Council) for accepted reference standards for metals and other contaminants in
286 287	food ingredients in the U.S. Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.
288 289 290	Alternatives
290	[old #3] Evaluation Question #9. Discuss and summarize findings on whether the manufacture and use
292	of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1)
293 294 295	(A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)). Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).
296 297 298 299	Data Required : In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (<i>e.g.</i> , predators and
300	parasitic hymenoptera), pollinators, bats and birds.
301 302 303 304 305	The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:
306	• literature, including product or practice description, on performance and test data:
307	• name and address of the manufacturer(s), if applicable; and,
308 309	• types of products the substance is currently used in.
 310 311 312 313 314 315 	[old #12] Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)). Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the NOP regulations.
316	Data Required. Describe reported health effects and causation that may be attributed to the use of the
 317 318 319 320 	petitioned substance and/or its breakdown products. The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:
321 322	• A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;
323 324	• Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.

Technical Evaluation Report	Name of Material	Handling/Processing
 A comparison of reported (natural) product to the pe A comparison of reported substitute non-synthetic (r Literature, including prode Types of products and ran 	risks to human health associated with t titioned substance; environmental effects (both aquatic and atural) product to the petitioned substa uct or practice description, on performa ge of uses for the alternative substance	he substitute non-synthetic d terrestrial) associated with the ince; ince and test data; and
[old #13] Evaluation Question #11 petitioned substance unnecessary that could be alternatives for the J	<u>:</u> Describe any alternative practices th (7 U.S.C. § 6518(m)(6)). Provide a list o petitioned substance (7 CFR 205.600(b)	nat would make the use of the of organic agricultural products (1)).
Data Required: The response to th availability of an alternative practi	is request for development of technical ce(s) to the use of the petitioned substar	information must describe the nce. Many research based
alternative practices may be found https://attra.ncat.org/; these reso practices. When assessing alternati	at: <u>http://eorganic.info/, https://www</u> irces should be consulted before exhau ve practices, the report should address:	w.sare.org/ , and sting search for alternative :
 Literature, including prac A comparison of the func petitioned substance; and 	tice description, on performance and te tion and effectiveness of the proposed a 7	st data; Ilternative practice to the
• Iypes of products product The list should be based upon a co recommended organic agricultural found at: <u>https://organic.ams.usd</u> https://www.sare.org/, <u>https://w</u> these resources should be consulte organic agriculturally derived alter	ed and scope of use of alternative pract mparison of the effect, form, function, q product with the petitioned substance. <u>a.gov/Integrity/default.aspx</u> , <u>http://e</u> <u>www.omri.org/</u> , <u>www.606organic.com</u> , d before exhausting search for alternati- rnatives by summarizing:	t ices. [uality, and quantity of the . Many organic products may be <u>organic.info/</u> , , and <u>https://attra.ncat.org/;</u> ve practices. Briefly describe the
• A comparison of the effect agricultural product to the	, form, function, quality, and quantity o petitioned substance;	of the substitute organic
 Commercial availability of A comparison of reported product to the petitioned s 	substitute organic products, both domo risks to human health associated with t ubstance;	estically and globally he substitute organic agricultura
A comparison of reported substitute organic agricult	environmental effects (both aquatic and ural product to the petitioned substance	l terrestrial) associated with the
 Any literature, including p The name and address of t Types of products and ran 	roduct description, on performance and he supplier/manufacturer, if applicable ge of uses for the alternative substance.	d test data; e; and
[old #11] Evaluation Question #12 may be used in place of a petition substances that may be used in pl there are any alternative practices U.S.C. § 6518(m)(6)).	<u>2:</u> Describe all natural (non-synthetic) of ed substance (7 U.S.C. § 6517(c)(1)(A)(i ace of the petitioned substance (7 U.S. that would make the use of the petitic	substances or products which i i)). Provide a list of allowed C. § 6518(m)(6)). Describe if oned substance unnecessary (7
Data Required: The response mus which could be substituted for peti https://organic.ams.usda.gov/Int https://www.omri.org/, www.60 consulted before exhausting search	t describe the availability of a non-synth tioned substance. Many natural substa egrity/default.aspx, http://eorganic.in Gorganic.com, and <u>https://attra.ncat.e</u>	netic or natural substance(s) Inces may be found at: fo/, https://www.sare.org/, https://www.sare.org/, ion should address:
A comparison of the effect (natural) product with the	, form, function, quality, and quantity o petitioned substance;	of the substitute non-synthetic

rechnical Evaluation Report	Name of Material	Handling/Processing
 Commercial availability of globally. 	f substitute non-synthetic (natural) prod	lucts, both domestically and
 A comparison of reported risks to human health associated with the substitute non-synthetic 		
(natural) product to the petitioned substance:		
A comparison of reported	environmental effects (both aquatic and	d terrestrial) associated with the
substitute non synthetic (r	natural) product to the petitioned substa	ince;
 Literature, including prod 	uct or practice description, on performa	ince and test data; and
Types of products and ran	ge of uses for the alternative substance;	-and,
The response to this request for de	velopment of technical information mu	st describe the availability of an
alternative practice(s) to the use of	the petitioned substance. Many researce	ch-based alternative practices
may be found at: http://eorganic.i	info/, <u>https://www.sare.org/</u> , and <u>http</u>	os://attra.ncat.org/; these
resources should be consulted before	ore exhausting search for alternative pra	actices. Briefly describe
alternative practices by summarizi	ng:	
Literature, including prac	ctice description, on performance and te	est data;
• A comparison of the func	tion and effectiveness of the proposed a	alternative practice to the
petitioned substance; and	l,	
Types of products product	ced and scope of use of alternative pract	tices.
Evaluation Information #13: Prov	vide a list of organic agricultural produ	icts that could be alternatives f
the petitioned substance (7 CFR 2	.05.600(b)(1)).	
I I I I I I I I I I I I I I I I I I I		
Data Required: The list should be	based upon a comparison of the effect,	form, function, guality, and
quantity of the recommended orga	nic agricultural product with the petitic	oned substance. Many organic
products may be found at: https://	/organic.ams.usda.gov/Integrity/defau	ilt.aspx. http://eorganic.info/-
products may be found at: <u>https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.into/</u> ,		
neps://www.sare.org/, neps://v	www.omrl.org/- www.buborganic.com	. and https://attra.ncat.org/;
these resources should be consulted	<u>www.omfl.org/, www.6060rganic.com</u> , d before exhausting search for alternati	, and <u>https://attra.ncat.org/;</u> ve.practices. In developing the
these resources should be consulte list, the following should be considered	vww.omn.org/www.oooorganic.com, vd before exhausting search for alternati lered:	, and <u>https://attra.ncat.org/;</u> ve practices. In developing the
these resources should be consulte list, the following should be consid	www.omnl.org/www.ouoorganic.com, ad before exhausting search for alternati lered:	, and <u>https://attra.ncat.org/;</u> ve practices. In developing the
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432 433

References

- All citations listed in the report must be included in references section using MLA format.
- A minimum of 20 current scientific references must be cited in the report to provide adequate scientific
- 436 credibility and thorough review. Citation using MLA format must be included appropriately within the
- 437 text to avoid plagiarism.

Appendix A2: TR Template updated - Handling/Processing

Name of Material

Handling/Processing

Identification of Petitioned Substance				
Chemical Names:	CAS Numbers:			
List all chemical names	List CAS numbers			
Other Name:				
List other names	Other Codes:			
	List other codes (e.g., INS number, E number,			
Trade Names:	etc.)			
List trade names	,			
S	ummary of Petitioned Use			
For petitions to add or amend a substanc on the National List, summarize the allow	e, describe the petitioned use of the substance. For substances cur wed uses under the USDA organic regulations (7 CFR Part 205).			
Charact	erization of Petitioned Substance			
Composition of the Substance:				
Describe Composition of the Substance				
Source or Origin of the Substance:				
Briefly describe the source or origin of th	e substance (to be addressed in more detail below under			
Evaluation Questions 1 through 4).				
Properties of the Substance				
Describe Physical and Chemical Properti	as of the Substance			
Describe i hysical and chemical i toperu				
Specific Uses of the Substance:				
Describe Specific Uses of the Substance -	primary focus should be given to describing the petitioned use of			
the substance as it relates to organic hand	lling; secondary focus should be given to providing general			
information on other uses of the petition	ed substance in agricultural handling/processing.			
1.	0 0 1 0			
Approved Legal Uses of the Substance:				
Describe the Status of the Petitioned Subs	stance under applicable Federal Regulations (i.e., EPA, FDA,			
USDA (including APHIS or FSIS), NIEHS	5, etc.)			
Action of the Substance:				
Describe Action of the Substance – focus	should be given to describing mode of action of the substance,			
when used as petitioned.				
Combinations of the Culture				
<u>Complications of the Substance</u>	focus should be given to describing whether the restition of			
Describe Combinations of the Substance	- nocus should be given to describing whether the petitioned			
substance is a producer to component of	i, or commonly used in combination with a substance(s) identified			
substance is a precursor to, component o	etic offacts (aither positive or pagative) with other substances on			
substance is a precursor to, component o on the National List. Any known synergi the National List should be identified	stic effects (either positive or negative) with other substances on			
substance is a precursor to, component o on the National List. Any known synergi the National List should be identified.	istic effects (either positive or negative) with other substances on			
substance is a precursor to, component o on the National List. Any known synergi the National List should be identified. In addition, information should be provid	istic effects (either positive or negative) with other substances on ded on whether any additional ingredients (e.g., inert ingredients			
substance is a precursor to, component o on the National List. Any known synergi the National List should be identified. In addition, information should be provid stabilizers, preservatives, carriers, anti-ca	istic effects (either positive or negative) with other substances on ded on whether any additional ingredients (e.g., inert ingredients, iking agents, or other materials) are generally added to			

Technical Evaluation Report Compiled by (Name of Contractor) for the USDA National Organic Program

r		
Status		
	Historia Hast	
	<u>Ensionic Use:</u>	
	agricultural production place describe biotoric use in conventional agricultural production.	
	agricultural production, please describe historic use in conventional agricultural production).	
	Organic Foods Production Act USDA Final Rule	
	Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 19	
	(OFPA) or the USDA organic regulations. 7 CFR Part 205	
	(errif) of the cobin ofganic reganitions), " errif are 200.	
	International	
	Describe the status of the substance among international organizations. Specifically, the report should	
	address whether the petitioned substance is allowed or prohibited for use in other international organic	
	standards such as:	
	Canada	
	CAN/CG5B-32.310- Organic production systems-General principles and management standards	
	CAN/CCSR 22 211 Organia Draduction Systems Dormittad System and List	
	CAIN/ CG5D-52.511, Organic Froduction Systems-Permitted Substances List	
	<u>1111p.//www.nispection.gc.ca/100u/0rganic-products/stanuarus/eng/150050001905//15005080/51/2</u>	
	CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and	
	Marketing of Organically Produced Foods (GL 32-1999)	
	http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM	
	Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".	
	European Economic Community (EEC) Council Regulation – EC No. 834/2007 and 889/2008	
	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R1165&from=EN#d1e32-48-1	
	Japan Agricultural Standard (JAS) for Organic Production	
	http://www.matt.go.jp/e/jas/specific/criteria_o.html	
	IFUAINI-Organics International	
	<u>intp://www.itoani.bio/en/itoani-norms</u>	
	Evaluation Questions for Substances to be used in Organic Handling	
	L'analistic Questions for Substances to be used in Organic Humaning	
	Classification of the substance	
	Evaluation Question #1: (A) Describe if the substance is extracted from naturally occurring plant	
	animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formula	
	the petitioned substance. Include any chemical changes that may occur during manufacture or	
	formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or Non-	
	agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. §6502(21);	
	NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms contain nanoparticle	
	(E) Does the substance in its raw or formulated forms contain ancillary substances (F) Is the substance	
	created using Excluded Methods?	

[Insert date transmitted to NOP]

104 105		
106		
107		
108 109	Data Ro	equired:
110	(A)	If the substance is extracted from a natural material, information should be provided on any
111		materials and methods used to extract, separate, isolate, or withdraw the substance, including any
112		solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the
113		substance is created by a naturally occurring biological process, those process(es) must be
114		described in detail.
115		
116		For the purposes of this response, naturally occurring biological processes are processes that
110		include but are not limited to, aerobic and anaerobic digestion, decomposition, termentation,
118		various metabolic processes, and photosynthesis.
119	(B)	The response must describe the processes used to manufacture or formulate the substance
120	(D)	including a discussion of all procursors and /or foodstocks. A description of alternate
121		manufacturing methods and the extent of their commercial use which are not included in the
122		petition if any should be presented. The response must also describe in detail any chemical
123		changes effected on any naturally occurring precursor or feedstock by all manufacturing or
125		formulation processes. If any synthetic materials used in the production or extraction of a
126		substance remain in the final product, describe them.
127		I I I I I I I I I I I I I I I I I I I
128		For the purposes of this response, a chemical change involves a process (i.e., chemical reaction)
129		whereby a substance is transformed into one or more other distinct substances. This may include
130		the addition or deletion of one atom to the substance's molecular structure or other description of
131		chemical modification.
132		
133		Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or
134		catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-
135		reduction, polymerization, etc., obtained through process units such as compressors, cracking
136		towers, heat exchangers, mixers, reactors, pumps, etc.
13/		Provident the information provided on (A) and (D) the definition of complexitient $7 \text{ LLC} \subset 8 (E02)(22)$
138	(C)	Dased on the information provided on (A) and (b), the definition of synthetic at 7 U.S.C. § 6502 (22)
139		nor Guidance 5055-1 and NOr Guidance 5055-2, describe if the substance can be classified as
140		agricultural of non-agricultural.
142	(D)	Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are
143	(2)	they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP?
144		(Policy Memo 15-2)
145		
146	(E)	Ancillary Substances: Does the substance in its raw or formulated forms contain ancillary
147		substances as defined by the NOSB in the 2016 recommendation?
148		(https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Propo
149		sal%20NOP.pdf)
150		
151	(F)	Excluded Methods:
152		i. Is the substance created using excluded methods? This includes but is not limited
153		to the following list of techniques found to be "excluded methods" by the NOSB:
154		Targeted genetic modification (TagMo), Synthetic gene technologies, Genome
155		engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant
156		breeding techniques, Synthetic Biology, cloned animals and offspring, plastid
157		transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

Technical Evaluation Report	Name of Material	Handling/Processing
ii.	using invitro nucleic acid techniques, induced mutag vitro nucleic acid techniques, cell and protoplast fusio If the substance is manufactured from agricultural ra materials derived from genetically engineered crop, o excluded methods?	enesis developed through in on (NOP policy Memo 13-1). w materials, are those or crops resulting from
iii.	If the substance is manufactured from other biologica those produced by fermentation or enzymatic action- materials, derived from genetically engineered organ resulting from excluded methods?	ıl raw materials – such as – are those biological isms, or crops organisms
Evaluation Question #2 recognized as safe (GRA 205.600(b)(5)). If not cat	Specify whether the petitioned substance is catego S) when used according to FDA's good manufactur gorized as GRAS, describe the regulatory status.	orized as generally ring practices (7 CFR
Purpose and necessity of	<u>f the substance</u>	
Evaluation Question # substance is a preservat	<u>:</u> Describe whether the primary technical function o ive (7 CFR 205.600(b)(4)).	or purpose of the petitioned
Data Required: The res preservative.	ponse must explain why the primary function of the s	substance is or is not as a
Evaluation Question #4 or improve flavors, colo If so, how? (7 CFR 205.6	Describe whether the petitioned substance will be rs, textures, or nutritive values lost in processing (ex 00(b)(4)).	e used primarily to recreate «cept when required by law).
Data Required: When report evaluators should	placement or improvement of nutrients is required o cite the appropriate regulations.	r allowed by regulation, the
Evaluation Question #5 feed when the petitione	Describe any effect or potential effect on the nutri d substance is used (7 CFR 205.600(b)(3)).	tional quality of the food or
Data Required: The resp nutrients (e.g., proteins, Effects may include incr	onse must indicate whether the use of the petitioned carbohydrates, fats, vitamins, and minerals) common easing or decreasing the amount and/or bioavailabili	substance affects the levels of ly found in the food product. ty of the nutrients.
Environment and huma	n health effects	
Evaluation Question #6 FDA tolerances that are	List any reported residues of heavy metals or othe present or have been reported in the petitioned sub	r contaminants in excess of ostance (7 CFR 205.600(b)(5)).
Data Required: The resp substances that exceed F the most part, these action contaminants are address fda-guidance-documents/ <u>c</u> animal-feed See the latest reference standards for p	onse must indicate whether the petitioned substance DA's Action Levels for Poisonous or Deleterious Sub- in levels will relate to residues found in agricultural p sed through FDA's action levels. <u>https://www.fda.gov// uidance-industry-action-levels-poisonous-or-deleterious-su-</u> edition of Food Chemicals Codex (National Research netals and other contaminants in food ingredients in	may contain residues of stances in Human Food. For products. Heavy metals or <u>regulatory-information/search- ubstances-human-food-and-</u> Council) for accepted the U.S.

209 210 211 212	<u>Evaluation Question #7:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).
213 214 215 216	Data Required : In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both torrestrial and aquatic systems and effects on arthropod natural enemies (<i>a.e.</i> , predators and
210 217 218	parasitic hymenoptera), pollinators, bats and birds
219 220 221	Evaluation Question #8: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).
222 223 224 225	Data Required : Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.
226 227	Alternatives
228 229 230	<u>Evaluation Question #9</u> : Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).
231 232 233 234	Data Required : The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:
235 236 237 238	 literature, including product or practice description, on performance and test data; name and address of the manufacturer(s), if applicable; and, types of products the substance is currently used in.
239 240 241 242 243	<u>Evaluation Question #10</u> : Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the NOP regulations.
244 245 246	Data Required : The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:
247 248 249	 A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance; Commercial availability of substitute non-synthetic (natural) products, both domestically and
249 250 251	 Commercial availability of substitute non-synthetic (natural) products, both domestically and globally. A comparison of reported risks to human health associated with the substitute non-synthetic
252 253	 (natural) product to the petitioned substance; A comparison of reported environmental effects (both aquatic and terrestrial) associated with the
254 255	substitute non-synthetic (natural) product to the petitioned substance;Literature, including product or practice description, on performance and test data; and
256 257	Types of products and range of uses for the alternative substance
258 259 260	Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).
261 262 263	Data Required: The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: <u>https://organic.ams.usda.gov/Integrity/default.aspx</u> , <u>http://eorganic.info/</u> ,

	https://www.sare.org/, <u>https://www.omri.org/</u> , <u>www.606organic.com</u> , and <u>https://attra.ncat.org/</u> ; these resources should be consulted before exhausting search for alternative practices. Briefly describe the organic agriculturally derived alternatives by summarizing:
	 A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance:
	 Commercial availability of substitute organic products, both domestically and globally.
	 A comparison of reported risks to human health associated with the substitute organic agricultural
	product to the petitioned substance:
	 A comparison of reported environmental effects (both aquatic and terrestrial) associated with the
	substitute organic agricultural product to the petitioned substance;
	• Any literature, including product description, on performance and test data:
	• The name and address of the supplier/manufacturer, if applicable; and
	 Types of products and range of uses for the alternative substance.
	Types of produces and range of uses for the uncernance substance.
	Evaluation Question #12: Describe if there are any alternative practices that would make the use of the
	petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).
	Data Required : The response to this request for development of technical information must describe the
	availability of an alternative practice(s) to the use of the petitioned substance. Many research-based
	https://attra.pcat.org/: these recources should be consulted before exhausting search for alternative
	practices Briefly describe alternative practices by summarizing:
	Literature including practice description on performance and test data:
	 A comparison of the function and effectiveness of the proposed alternative practice to the
	petitioned substance: and
	 Types of products produced and scope of use of alternative practices
	Types of produced and scope of doe of distributive practices.
Γ	Report Authorship
	The following individuals were involved in research, data collection, writing, editing, and/or final
	approval of this report:
	Name, Title, Organization
	Name, Title, Organization
	Name, Title, Organization
	All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing
	Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.
г	
Ļ	References
	All citations listed in the report must be included in references section using MLA format.
	A minimum of 20 current scientific references must be cited in the report to provide adequate scientific
	andibility and therough ravious Citation using MIA format must be included anneopriately within the text
	credibility and thorough review. Citation using MLA format must be included appropriately within the text

Crops or Livestock

Identif	ication of Petitioned Substance
Chemical Names:	CAS Numbers:
List all chemical names	List CAS numbers
Other Name:	
List other names	Other Codes:
Trada Namoo	List other codes
List Trade Names	
Si	ummary of Petitioned Use
For petitions to add or amend a substance on the National List, summarize the allow	e, describe the petitioned use of the substance. For substances curre ved uses under the USDA organic regulations.
Characte	erization of Petitioned Substance
Composition of the Substances	
Describe Composition of the Substance	
Describe composition of the Substance	
Source or Origin of the Substance:	
Briefly describe the source or origin of the	e substance (to be addressed in more detail below under
Evaluation Questions 2 and 3).	
Descention of the Carbon sec	
Properties of the Substance:	as of the Substance
Describe i hysicai and Chemicai i ropertie	es of the Substance
Specific Uses of the Substance:	
Describe Specific Uses of the Substance -	primary focus should be given to describing the petitioned use of
the substance; secondary focus should be	given to providing general information on other uses of the
petitioned substance in agricultural crop	or livestock production.
Approved Legal Lloss of the Substances	
Describe the Status of the Patitioned Sube	tance under applicable Federal Regulations (i.e., FPA, FDA
USDA (including APHIS or FSIS). NIEHS	<i>b</i> , etc.)
	, ;
Action of the Substance:	
Describe the Mode Action of the Substand	ce – focus should be given to describing the mode of action of the
substance, when used as petitioned.	
Combinations of the Substance:	(constructed by strength 1, 11), 1, 2, 3, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4,
Describe Combinations of the Substance -	- rocus snould be given to describing whether the petitioned
on the National List	, or commonly used in combination with a substance(s) identified
on the Inational List.	
	led on whether any additional ingredients (e.g. inert ingredients
In addition, information should be provide	
In addition, information should be provid stabilizers, preservatives, carriers, anti-ca	king agents, or other materials) are generally added to
In addition, information should be provid stabilizers, preservatives, carriers, anti-ca commercially available forms of the petiti	king agents, or other materials) are generally added to ioned substance.

52	Status		
53			
54 55	<u>HISTORIC USE:</u> Describe historic use of the substance in organic agricultural production (if no historic	ric use in organic	
56 57	agricultural production, please describe historic use in conventional agricultural production	oduction).	
58	Organic Foods Production Act, USDA Final Rule:		
59 60 61	Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods (OFPA) or the USDA organic regulations, 7 CFR Part 205.	Production Act of 1990	
62 63	International		
64 65 66 67	Describe the status of the substance among international organizations. Specifically, address whether the petitioned substance is allowed or prohibited for use in other in standards such as:	the report should nternational organic	
68 69	Canada - Canadian General Standards Board Permitted Substances List. This list wa November 2015.	as updated in	
70	CAN/CGSB-32.310- Organic production systems-General principles and management	ent standards	
71 72	CAN/CGSB-32.311-2015 – Organic production systems - Permitted substances lists	3 <u>1s/internet/bio</u>	
72 73 74	org/lsp-psl-eng.html		
75 76 77	CODEX Alimentarius Commission, Guidelines for the Production, Processing, La of Organically Produced Foods (GL 32-1999) -	belling and Marketing	
78 79	Note: For Codex, the reference should be cited as "guidelines," rather than as "stand	lards".	
80	<u>http://www.codexalimentarius.org/standards/list_standards/en/?no_cache=1</u>		
81 82	<u>http://www.codexalimentarius.org/download/standards/360/exg_032e.pdf</u>		
82 83 84	European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 8	889/2008	
85 86	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:J	EN:PDF	
80 87	Japan Agricultural Standard (JAS) for Organic Production –		
88 89	<u>Intp.//www.intain.go.jp/c/jas/specific/criteria_o.intini</u>		
90 91	International Federation of Organic Agriculture Movements (IFOAM) – http://www.ifoam.bio/en/ifoam_norms		
92 93			
94	Evaluation Questions for Substances to be used in Organic Crop or Livest	tock Production	
95 96	Classification of the substance		
97	<u>Emportation of the substitute</u>		
98	[combination of old #2 & 3 – word smithed and added D and E]		
 99 100 101 102 103 104 105 	Evaluation Question #1: Indicate which category in OFPA that the substance falls substance contain an active ingredient in any of the following categories: copper compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, f seed, vitamins and minerals; livestock parasiticides and medicines and production netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipm Describe if the substance is extracted from naturally occurring plant, animal, or methods substance as writher in gradient that is not classified by the EPA as is set	<u>s under: (A) Does the</u> and sulfur ish emulsions, treated n aids including ent cleansers? (<u>A)</u> nineral sources. (B) Is	
105	Inset date report is transmitted to NOP!	Page 2 of 8	
		1 495 2 01 0	

106 107 108 109 110 111 112	concern- ingredie 180? (B) substance substance synthetic formulat	(i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert nt which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part Describe the most prevalent processes used to manufacture or formulate the petitioned ce. Include any chemical changes that may occur during manufacture or formulation of the ce. (C) Based on the manufacturing process description, discuss if the substance is classified as c or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033-1]. (D) Does the substance in its raw or ted forms contain nanoparticles? (E) Is the substance created using Excluded Methods?
113	Data Ree	quired:
114 115 116	(A) 1	- If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any
117 118 119	5 5 (solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.
120 121 122 123 124	l i	For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.
125 126 127 128 129 130 131	(B) i i i i i i i i i i i i i i i i i i i	The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.
132 133 134 135 136 137	l v t	For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.
138 139 140 141	((1 t	Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.
142 143 144 145 146 147	(C) 1 2 1 1	Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic. Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.
148 149 150	(D) I t (Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)
151 152 153 154 155 156 157 158	(E) 1	 Excluded Methods: Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

Technical Evaluation Report	[Name of Material]	Crops or Livestock
ii.	using invitro nucleic acid techniques, induced mutag vitro nucleic acid techniques, cell and protoplast fusio If the substance is manufactured from agricultural ra- materials derived from genetically engineered crop, o excluded methods?	enesis developed through in on (NOP policy Memo 13-1). w materials, are those or crops resulting from
iii.	If the substance is manufactured from other biologica those produced by fermentation or enzymatic action- materials derived from genetically engineered organi resulting from excluded methods?	l raw materials – such as – are those biological sms, or crops organisms
[old #1] Evaluation Qu	estion #2: Describe the most prevalent processes use d substance. Further, describe any chemical change	ed to manufacture or that may occur during
manufacture or formul occurring plant, animal Is the substance used in categories: [§6517(c)(1)(soaps, horticultural oils medicines and product covers, and equipment that are not classified b toxicological concern?	ation of the petitioned substance when this substance , or mineral sources (7 U.S.C. § 6502 (21)). For substance n production, and does it contain an active synthetic B)(i)]; copper and sulfur compounds; toxins derived s, fish emulsions, treated seed, vitamins and mineral ion aids including netting, tree wraps and seals, inse cleansers; or (ii) is used in production and contains so by the Administrator of the Environmental Protection	e is extracted from naturally nces classified as synthetic: ingredient in the following from bacteria; pheromones, s; livestock parasiticides and ect traps, sticky barriers, row synthetic inert ingredients n Agency as inerts of
Data Required: The resincluding a discussion of methods and the extent presented. The response occurring precursor or for response, a chemical chem	ponse must describe the processes used to manufactur of all precursors and/or feedstocks. A description of a of their commercial use which are not included in the e-must also describe, in detail, any chemical changes e reedstock by all manufacturing or formulation process ange involves a process (i.e., chemical reaction) where listinct substances. This may include the addition or d	re or formulate the substance Iternate manufacturing petition, if any, should be ffected on any naturally es. For the purposes of this by a substance is transformed eletion of one atom to the
[old #7] Evaluation Qu manufactured by a che 6502 (21)). Describe an substances used in orga	estion #3: Discuss whether the petitioned substance mical process, or created by naturally occurring biolo y known chemical interactions between the petition anic crop or livestock production or handling. (7 U.S	-is formulated or o gical processes (7 U.S.C. § ed substance and other 6.C. § 6518(m)(1)).
Data Required: For the limited to, acid base rea mixing of substances or such as compressors, cr	purposes of this response, chemical processes are pro ctions, calcification, thermal or catalytic cracking, este elements, oxidation-reduction, polymerization, etc., o acking towers, heat exchangers, mixers, reactors, pum	cesses include, but are not rification, hydrogenation, btained through process unit ps, etc.
If the substance is extract methods used to extract base extraction methods	cted from a natural material, information should be pr ;, separate, isolate, or withdraw the substance, includir 5, or mechanical or physical separation methods.	ovided on any materials and ng any solvents used, acid-
If the substance is created in detail. For the purpo include but are not limi metabolic processes, an	ed by a naturally occurring biological process, those process of this response, naturally occurring biological process of this response, naturally occurring biological proceed to, aerobic and anaerobic digestion, decomposition d photosynthesis.	:ocess(es) must be described :cesses are processes that 1, fermentation, various
Information should be p or origin of the substand form that does not occu	provided on whether the substance has been chemicall ce, including whether the substance has been isolated i r in nature, and whether any synthetic materials used	y modified from the source f rom a natural source in a in the production or
[Insert date report is transmitted	to NOP]	Page 4 of 8

213 214 215 216 217 218	extraction of a substance may remain in the final product. The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions.
219 220 221 222 223	[combination of old #4 & 5] Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)). Discuss (A) the toxicity and mode of action of the substance; (B) the toxicity and mode of action of its breakdown products or any contaminants; and (C) their persistence and areas of concentration in the environment (7 U.S.C. §6518(m)(2)).
224 225 226 227 228 229 230 231 232 233 234 235 236	 Data Required: The response must describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned. (A) Describe whether the petitioned substance has been reported to have toxic effects and if its mode of action can cause adverse health and/or environmental effects. (B) Describe whether the petitioned substance contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time. (C) Describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.
237 238 239 240 241	[old #6] Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)). Discuss the probability of environmental contamination during manufacture, use, misuse or disposal of the substance (7 U.S.C. §6518(m)(3)).
242 243 244 245 246 247 248 249 250 251	Data Required : The response must describe whether the petitioned substance, its contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time. The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. Data or reports from U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available. This data may also be available through review of assessments performed per EPA, FDA, and/or NIEHS review.
251 252 253 254 255 256 257	[old #8] Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)). Discuss the effects of the substance on biological and chemical interactions in the agroecosystem. Include the physiological effects of the substance on soil, crops, livestock or other organisms (such as aquatic) that could be affected by the substance when used as petitioned. (7 U.S.C. §6518(m)(5))
257 258 259 260 261 262 263 264 265	Data Required : The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. This data may be available through review of assessments performed per EPA, FDA, and/or NIEHS review. Data or reports from other U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available. The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem.

266 267	The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae,
268 269	and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and
270 271	how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe
272 273	whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.
274 275	In addition, the response should describe the potential or actual impacts of the substances upon
276 277 278	endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.
278 279 280	[old #9] Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any
281	environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).
282 283	Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).
284	
285 286	Data Required: The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in
287	organic production or handling as applicable. Describe any common combinations of materials used with
288	the petitioned substance. Describe any substances resulting from these interactions and whether they may
289	cause adverse health and/or environmental effects either present in the substance or arising from the
290	degradation of the substance over time. Toxicity, mode of action, and persistence of the substance and its
291	breakdown products should be explained. Considering the information described in questions #1-6 and
292	any other relevant information, discuss if the petitioned substance and/ or its breakdown products can
293	cause harmful effects on the environment. Describe the biological, chemical and physical factors that may
294	be affected by the use of the substance and/ or its breakdown products.
295	
296	Harm to Human Health
297	[1] #10] Evolution Occastion #0. Describe any offects of the notitioned substance on hislorical or
298	<u>[010 #10]</u> Evaluation Question #6: Describe any effects of the petitioned substance on biological of
300	(including the salt index and solubility of the soil) grops and livestock (7 U.S.C. & 6518 (m) (5)).
301	Describe and summarize any reported effects upon human health from use of the petitioned substance
302 302	(7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).
303	Data Required: The response must describe the substances (the patitioned substance and / or its
305	by b
306	agro ecosystem. The effects of these substances, including toxicity, mode of action and environmental
307	persistence of the substance and its breakdown products should be explained.
308	personence of the substance and his breakdown produces should be explained.
309	The response should describe whether and how the petitioned substance affects the survival and/or
310	function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae,
311	and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt
312	concentration, solubility or other parameter. For crops, the response should also describe whether and
313	how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization,
314	or other parameters when used as petitioned. For livestock production, the response should also describe
315	whether and how the substance affects animal physiology by creating changes in behavior, fertility,
316	metabolism or other parameters.
317	
318	In addition, the response should describe the potential or actual impacts of the substances upon
319	endangered species, population, viability or reproduction of non-target organisms and the potential for
320	measurable reductions in genetic, species or eco-system biodiversity, if possible. Drawing upon responses

321 322 323	to above questions #1-7 and any other relevant information, describe the reported health effects that may be attributed to the petitioned substance and/or its breakdown products.
323 324	Necessity and Alternatives
325 326 327 328 329 330 331	[old #11] Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)). Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).
332 333 334 335	Data Required : Drawing upon responses to above questions #2-8, and any other relevant information, describe the biological, chemical and physical agents capable of causing harmful environmental effects and the causation, that may be attributed to the use of the petitioned substance and/or its breakdown products. The response must describe the availability of non-synthetic or natural substance(s), including organic
336 337	agricultural products, which could be substituted for petitioned substance. The examination should address:
338 339	• a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
340 341 242	 literature, including product or practice description, on performance and test data; name and address of the manufacturer(s), if applicable; and For livestock (and not food) food substances information on technical horrises to production of
342 343 344	• For livestock (and per food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.
348 349 350 351 352 353 354	 Data Required: Drawing upon responses to above questions #2.8 and any other relevant information, describe the reported health effects and causation that may be attributed to the petitioned substance and/or its breakdown products. The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the
355 356	petitioned substance.
357 358 359 360 361	 When assessing alternative practices, the report should address: Literature, including specific practice description, on performance and test data; A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and, Frequency or prevalence of use of alternatives, if known.
362 363 364	<u>Evaluation Question #11:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed
365 366	substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).
367 368 369	Data Required : The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:
370 371 372	 a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance; literature, including product or practice description, on performance and test data;
373 374 375	 Inclusive inclusive product of practice description, on performance and test data; name and address of the manufacturer(s), if applicable; and For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

	Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned
	substance unnecessary (7 U.S.C. § 6518 (m) (6)).
	Data Required: The response to this request for development of technical information must describe the
	availability of alternative practices, such as cultural, biological, and mechanical controls, to the use of the
	petitioned substance.
	1
	Alternative cultural methods including methods used to enhance crop health and prevent weed, pest, or
	disease problems without the use of substances. Examples include the selection of appropriate varieties
	and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by
	manipulating the microclimate with green houses, cold frames; or wind breaks.
	Other alternative practices may include, but are not limited to, crop rotation, mulching with fully
	biodegradable materials, mechanical cultivation, augmentation or introduction of predators or parasites of
	the pest species; development of habitat for natural enemies of pests; nonsynthetic controls such as lures.
	traps, and repellents; sanitation measures and management practices which suppress the spread of disease
	organisms.
	-8
	Alternative practices used in livestock production may include, but are not limited to, selection of species
	and types of livestock with regard to suitability for site specific conditions, resistance to diseases and
	parasites: site selection , housing, pasture and sanitation practices that minimize occurrence and spread of
	disease and parasites: stocking density: and seasonal production practices.
	When assessing alternative practices, the report should address:
	Literature, including practice description, on performance and test data:
	A comparison of the function and effectiveness of the proposed alternative practice with the
	notitioned substance and
	 Frequency or provalence of use of alternatives if known.
	• Trequency of prevalence of use of alternatives, if known.
Γ	Report Authorship
	The following individuals were involved in research data collection writing editing and/or final
	approval of this report.
	upprovid of all report.
	• Name Title Organization
	Name, Title, Organization
	Name, Title, Organization
	• manie, mile, Organization
	All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 Proventing
	Parsonal Conflicts of Interest for Contractor Employees Performing Acquisition Eurotions
	reisonal contracts of microst for contractor Employees renorming Acquisition Functions.
Г	D /
L	Keterences

Crops or Livestock

Identification of Petitioned Substance

3 Chemical Names:

4 List all chemical names

5 6 **Other Name:**

1

2

11 12

13 14

15

16 17

18

7 List other names

89 Trade Names:

10 List Trade Names

CAS Numbers:

List CAS numbers

Other Codes: List other codes

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations.

Characterization of Petitioned Substance

19 <u>Composition of the Substance:</u>

20 Describe Composition of the Substance 21

22 Source or Origin of the Substance:

- 23 Briefly describe the source or origin of the substance (to be addressed in more detail below under
- 24 Evaluation Questions 2 and 3).

2526 Properties of the Substance:

27 Describe Physical and Chemical Properties of the Substance

28

29 Specific Uses of the Substance:

- 30 Describe Specific Uses of the Substance primary focus should be given to describing the petitioned use of
- 31 the substance; secondary focus should be given to providing general information on other uses of the
- 32 petitioned substance in agricultural crop or livestock production.
- 33

34 Approved Legal Uses of the Substance:

- 35 Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA,
- 36 USDA (including APHIS or FSIS), NIEHS, etc.)
- 37

38 Action of the Substance:

- 39 Describe the Mode Action of the Substance focus should be given to describing the mode of action of the
- 40 substance, when used as petitioned.41

42 <u>Combinations of the Substance:</u>

- 43 Describe Combinations of the Substance focus should be given to describing whether the petitioned
- 44 substance is a precursor to, component of, or commonly used in combination with a substance(s) identified
- 45 on the National List.
- 46
- 47 In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients,
- 48 stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to
- 49 commercially available forms of the petitioned substance.
- 50

51	Status	
52		
53	<u>Historic Use:</u>	
54 55 56	agricultural production, please describe historic use in conventional agricultural prod	uction).
50 57	Organic Foods Production Act, USDA Final Rule:	
58 59	Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods F (OFPA) or the USDA organic regulations, 7 CFR Part 205.	roduction Act of 1990
60 61	International	
62		. 1 11
63 64 65	Describe the status of the substance among international organizations. Specifically, the address whether the petitioned substance is allowed or prohibited for use in other international such as:	ernational organic
66		
67 68	Canada –	
69 70	CAN/CGSB-32.310- Organic production systems-General principles and managemen	t standards
70 71 72	CAN/CGSB-32.311 – Organic production systems - Permitted substances lists	
73	CODEX Alimentarius Commission, Guidelines for the Production, Processing, Lab	elling and Marketing
74	of Organically Produced Foods (GL 32-1999) -	0 0
75 76 77	Note: For Codex, the reference should be cited as "guidelines," rather than as "standa	rds".
79 80 81 82	European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 88	9/2008
83 84	Japan Agricultural Standard (JAS) for Organic Production –	
85 86 87	IFOAM – Organics International	
88		
89	Evaluation Questions for Substances to be used in Organic Crop or Livesto	ck Production
90		
91 92	Classification of the substance	
93	Evaluation Ouestion #1: (A) Describe if the substance is extracted from naturally or	curring plant.
94	animal, or mineral sources. (B) Describe the most prevalent processes used to many	facture or formulate
95	the petitioned substance. Include any chemical changes that may occur during man	ufacture or
96	formulation of the substance. (C) Based on the manufacturing process description,	discuss if the
97	substance is classified as synthetic or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033	3-1]. (D) <mark>Does the</mark>
98 99	substance in its raw or formulated forms contain nanoparticles? (E) Is the substance Excluded Methods?	e created using
100		
101		
102 103		
103	Insert date report is transmitted to NOPI	Page 2 of 6

104		
105		
107	Data R	equired:
108		
109	(A)	If the substance is extracted from a natural material, information should be provided on any
110		materials and methods used to extract, separate, isolate, or withdraw the substance, including any
111		solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the
112		substance is created by a naturally occurring biological process, those process(es) must be
113		described in detail.
114		
115		For the purposes of this response, naturally occurring biological processes are processes that
116		include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation,
117		various metabolic processes, and photosynthesis.
118		
119	(B)	The response must describe the processes used to manufacture or formulate the substance,
120		including a discussion of all precursors and/or feedstocks. A description of alternate
121		manufacturing methods and the extent of their commercial use which are not included in the
122		petition, if any, should be presented. The response must also describe, in detail, any chemical
123		changes effected on any naturally occurring precursor or feedstock by all manufacturing or
124		formulation processes. If any synthetic materials used in the production or extraction of a
125		substance remain in the final product, describe them.
120		For the summer of this summer of the size of the size of the second se
127		For the purposes of this response, a chemical change involves a process (i.e., chemical reaction)
128		the addition or deletion of one atom to the substance's melecular structure or other description of
129		chemical modification
130		
131		Chamical processes include but are not limited to: acid base reactions, calcification, thermal or
132		catalytic cracking esterification by drogenation mixing of substances or elements, oxidation-
134		reduction polymerization etc. obtained through process units such as compressors, cracking
135		towers heat exchangers mixers reactors numps etc
136		towers, neut exchangers, nuxers, reactors, pumps, etc.
137	(C)	Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22)
138	(0)	and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a
139		nonsynthetic. Synthetic substances have been chemically modified from the source or origin or
140		have been isolated from a natural source in a form that does not occur in nature.
141		
142	(D)	Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are
143	. ,	they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP?
144		(Policy Memo 15-2)
145		
146	(E)	Excluded Methods:
147		i. Is the substance created using excluded methods? This includes but is not limited
148		to the following list of techniques found to be "excluded methods" by the NOSB:
149		Targeted genetic modification (TagMo), Synthetic gene technologies, Genome
150		engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant
151		breeding techniques. Synthetic Biology, cloned animals and offspring, plastid
152		transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed
153		using invitro nucleic acid techniques induced mutagenesis developed through in
154		vitro nucleic acid techniques cell and protonlast fusion (NOP policy Memo 13-1)
155		ii If the substance is manufactured from agricultural raw materials are those
156		materials derived from genetically engineered gron or grons resulting from
157		evoluded methods?
1.57		

Technical Evaluation Report	[Name of Material]	Crops or Livestock
iii.	If the substance is manufactured from other biolog those produced by fermentation or enzymatic action materials derived from genetically engineered org resulting from excluded methods?	gical raw materials – such as on – are those biological anisms, or crops organisms
Evaluation Question #2 does it contain an activ sulfur compounds; toxi treated seed, vitamins a including netting, tree cleansers; or (ii) is used the Administrator of th	For substances classified as synthetic: Is the sub synthetic ingredient in the following categories: ns derived from bacteria; pheromones, soaps, hor nd minerals; livestock parasiticides and medicine vraps and seals, insect traps, sticky barriers, row in production and contains synthetic inert ingred e Environmental Protection Agency as inerts of to	ostance used in production, and : [§6517(c)(1)(B)(i)]; copper and ticultural oils, fish emulsions, es and production aids covers, and equipment dients that are not classified by oxicological concern?
Evaluation Question #3 and other substances u	<u>:</u> Describe any known chemical interactions betw ed in organic crop or livestock production or han	veen the petitioned substance adling. (7 U.S.C. § 6518(m)(1)).
Data Required : The rest known chemical interact organic production or h the petitioned substance	ponse to this request for development of technical ions between the petitioned substance and other s andling as applicable. Describe any common comb . Describe any substances resulting from these inte	information must describe any ubstances allowed for use in inations of materials used with eractions.
Evaluation Question #4 and mode of action of i of concentration in the	: Discuss (A) the toxicity and mode of action of the breakdown products or any contaminants; and environment (7 U.S.C. §6518(m)(2)).	he substance; (B) the toxicity (C) their persistence and areas
Data Required:		
 (A) Describe wheth action can cause (B) Describe wheth been reported to environmental substance over (C) Describe wheth or cumulative ver 	er the petitioned substance has been reported to ha adverse health and/or environmental effects. er the petitioned substance contaminants, or any of have toxic effects and are capable of causing adve ffects either present in the substance or arising from ime. er and how the petitioned substance and/or the bro- hen used in organic crop or livestock production a	we toxic effects and if its mode of f its breakdown products have erse health and/or m the degradation of the eakdown products are persisten as petitioned.
Evaluation Question #8	: Discuss the probability of environmental conta of the substance (7 U.S.C. §6518(m)(3)).	mination during manufacture,
Data Required : The rest during the manufacture International universitie response when availabl EPA, FDA, and/or NIE	ponse must describe the occurrence and severity o use, misuse, or disposal of the petitioned substance s, agencies, independent groups, or other news rep . This data may also be available through review o IS review.	f environmental contamination ce. Data or reports from U.S. or ports should be included in this of assessments performed per
Evaluation Question #6 the agroecosystem. Incl organisms (such as aqu §6518(m)(5))	: Discuss the effects of the substance on biologic ude the physiological effects of the substance on atic) that could be affected by the substance when	cal and chemical interactions in soil, crops, livestock or other n used as petitioned. (7 U.S.C.
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211 212 213 214	Data Required : The response must describe the substances (the petitioned substance an byproducts in combination with naturally occurring substances over time) that are capa agro-ecosystem.	d/or its ble of affecting the
214 215 216 217 218 219 220 221 222 222 223	The response should describe whether and how the petitioned substance affects the sur- function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria and protozoa by changing soil temperature, water availability, pH levels, nutrient availa concentration, solubility or other parameter. For crops, the response should also describ how the substance affects plant physiology by creating changes in plant pH, nutrient or or other parameters when used as petitioned. For livestock production, the response sh whether and how the substance affects animal physiology by creating changes in behave metabolism or other parameters.	vival and/ or a, nematodes, algae, ability, salt be whether and water utilization, ould also describe ior, fertility,
224 225 226 227 228	In addition, the response should describe the potential or actual impacts of the substance endangered species, population, viability or reproduction of non-target organisms and t measurable reductions in genetic, species or eco-system biodiversity, if possible.	es upon he potential for
229 230 231 232	Evaluation Question #7: Discuss and summarize findings on whether the use of the substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S. (i)).	petitioned C. § 6517 (c) (2) (A)
232 233 234 235 236 237 238	Data Required: Considering the information described in questions #1-6 and any other information, discuss if the petitioned substance and/ or its breakdown products can cau on the environment. Describe the biological, chemical and physical factors that may be a of the substance and/ or its breakdown products.	relevant ise harmful effects iffected by the use
238 239 240 241 242 242	Harm to Human Health <u>Evaluation Question #8:</u> Describe and summarize any reported effects upon human h the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and (m) (4)).	ealth from use of 1 7 U.S.C. § 6518
243 244 245 246 247 248	Data Required : Drawing upon responses to above questions #1-7 and any other relevant describe the reported health effects that may be attributed to the petitioned substance are breakdown products.	nt information, nd/or its
249 250 251	Necessity and Alternatives	
252 253 254	<u>Evaluation Question #9:</u> Describe all natural (non-synthetic) substances or products v in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allow that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).	vhich may be used ved substances
255 256 257 258 259 260 261 262 263 264 265	 Data Required: The response must describe the availability of non-synthetic or natural sincluding organic agricultural products, which could be substituted for petitioned substexamination should address: a comparison of the effect, form, function, quality, and quantity of the substitute natural product with the petitioned substance; literature, including product or practice description, on performance and test data name and address of the manufacturer(s), if applicable; and For livestock (and pet food) feed substances, information on technical barriers to organic agricultural products that may serve as alternatives. 	substance(s), ance. The e non-synthetic or ata; o production of
	[Insert date report is transmitted to NOP]	Page 5 of 6

266 267 268	<u>Evaluation Question #10:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).		
269 270 271 272	Data Required : The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.		
273 274 275 276 277 278 279 280 281	 When assessing alternative practices, the report should address: Literature, including specific practice description, on performance and test data; A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and, Frequency or prevalence of use of alternatives, if known. 		
282	Report Authorship		
283 284 285 286 287 288 289	 The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report: Name, Title, Organization Name, Title, Organization Name, Title, Organization 		
290 291 292 293	All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11–Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.		
294	References		