

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	TR pages 7-9: One of the major reactants used in making EDDS is EDB, which has many adverse effects. "In the petition, no information was given whether dibromoethane, one of the two major chemicals for manufacturing (S,S)EDDS, would be completely converted to the end-product of (S,S)EDDS. If the conversion is not 100%, no information was given whether the un-reacted dibromoethane would be mixed with the end-product of (S,S)EDDS or mixed with by-products." Lines.351-444 History on the hazards of EDB
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			TR page 8: "What happens to 1,2-dibromoethane when it enters the environment?" It moves into the environment from manufacturing use and leaks at waste sites. It moves into the environment from manufacturing use and leaks at waste sites. When released, it quickly moves to air and will evaporate from surface water and soil to the air. It dissolves in water and will move through soil into the groundwater. Small amounts remain attached to soil particles. It breaks down slowly in air (over 4-5 months), more quickly in surface water (2 months), and hardly at all in groundwater. It is not expected to build up in plants or animals."
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			TR page 10: Direct evidence/data are still limited.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]	X			
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Chelating agents interact with a wide range of metals and could conceivably create imbalances and/or deficiencies.

6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			TR page 10: Direct evidence/data are still limited. No TR on dibromoethane, breakdown products are not known.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TR page 10: Direct evidence/data are still limited.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TR page 10: Direct evidence/data are still limited.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			TR page 11: "Although the labeled part of (S,S)EDDS decomposed to CO ₂ gas, that did not necessarily assure that the unlabeled part also decomposed to CO ₂ gas since that part was not directly measured. Therefore, (S,S)EDDS as a whole compound might decompose rapidly, but the breakdown products might not be totally inorganic. The breakdown products of the unlabeled part of (S,S)EDDS may still need to be clarified. The potentially unbroken part is originated from 1,2-dibromoethane, a substance banned by US EPA in 1984 for most kinds of uses."
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TR page 11: "(S,S)-EDDS is considered to be of low toxicity by US EPA. US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards." However, it is unknown how much unreacted EDB might be present. MSDS page 3: Slightly irritating to skin, eyes, and respiratory system.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	TR page 4: The U.S. Environmental Protection Agency (EPA) established the exemption from the requirement of a tolerance for residues of (S,S)-EDDS when used as an inert ingredient sequestrant or chelating agent in pesticide formulations applied to growing crops only under 40 CFR Part 180.920 (EPA-HQ-OPP-2008-0250; FRL-8362-4; effective November 14, 2008). TR page 11: US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards. Petition p 8: The agency's [FDA's] final ruling was a "Finding of No Significant Impact" (FONSI) when EDDS was present at no more than 0.31% b weight of the dry fiber of food-contact paper and paperboard."
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	TR page 11: US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	TR, Petition (exempt from tolerance)

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

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			TR lines 278-292
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		TR lines 299-302. Not extracted from naturally occurring plant, animal, or mineral sources.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		The chemical process is noted above; however, lines 307-313 describes production from bacteria as an alternative.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Jay Feldman: Could be considered? Use of distilled or deionized water to eliminate interference of metals in the mixture. TR page 6. "In a laboratory experiment, EDDS was produced by bacteria at a rate of 20 grams per liter in fermentations of <i>Amycolatopsis orientalis</i> with feeding solution of glycerol (major component), glutamic acid an urea (major component), phosphates (minor) an Fe(III)citric acid (trace)."
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			TR page 11: as a chelating agent, EDTA not as an active ingredient but still as an inert.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR page 11: Several alternative cultural methods to using pesticides (or the petitioned material) were cited in the petition (page 20 – 21 of the petition): biological controls, barrier controls, repellent controls, traps, hand picking, and cultural controls.

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

Substance: EDDS

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		TR: Manufacture involves highly toxic reactants. No need established.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		TR page 11: breakdown products not all known. Unknown interactions with desirable metals in soils.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

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

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

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