SUMMARY OF TAP REVIEWERS' ANALYSES¹

Urea is being petitioned for use as an insect (fruit fly) attractant in sticky traps in order to prevent extensive damage to olive and fruit crops. Urea slowly and progressively breaks down to ammonia and carbon dioxide inside the sticky traps. Ammonia is a volatile compound that lures fruit flies into the sticky traps. The size and placement of the openings leading into the sticky traps are designed to favor the trapping of fruit flies with minimal trapping of other insects. Ammonium carbonate, a substance already approved for use as bait in insect traps, also breaks down to produce ammonia over an extended period of time. The petitioner is requesting that urea be permitted on the National List of synthetic substances allowed for use in organic crop production since its mode of action is similar to that of ammonium carbonate.

All three reviewers concluded that urea, as petitioned, is a synthetic substance. Two of the reviewers recommended, without hesitation, that urea should be included on the National List. The other reviewer had concerns about allowing urea on the National List since it has not historically been allowed for use in organic crop production and since other acceptable substances are available for insect control. However, this reviewer also recommended that urea be allowed on the National List since it will only be used as an insect attractant in sticky traps.

Synthetic or Non-synthetic?	Allow without restrictions?	Allow only with restrictions? (See reviewers' comments for restrictions)
Synthetic (3)	Yes (3)	Yes (0)
Non-synthetic (0)	No (0)	No(0)

IDENTIFICATION

Common Name: Urea CAS Registry Number: 57-13-6

¹ This Technical Advisory Panel (TAP) report was based upon the information available at the time this report was generated. This report addressed the requirements of the Organic Foods Production Act of 1990, as amended, to the best of the investigator's ability and was reviewed by experts on the petitioned substance. The substance was evaluated according to the criteria found in Section 2119 of the OFPA [7 U.S.C. 6518(m)(1-7)]. Any recommendation(s) presented to the National Organic Standards Board (NOSB) was based on the information contained within the TAP report and the evaluation of that information relative to these criteria. The TAP report does not incorporate commercial availability, socioeconomic impact, or other factors related to the petitioned substance, which NOSB and USDA may want to consider in their decision process.

Other Names: Carbamide; Carbamimidic Acid; Carbonyldiamide; Carbonyl Diamine; Isourea; Pseudourea; Ureaphil; Ureophil; Urevert; Urepearl; Urea Perhydrate; Varioform II; Nimin; Benural 70; UR; Urea-13C; Aquacare HP; Aquadrate; Alphadrate; Nutriplus; B-I-K; Urecare; Urederm; Calmurid; Carbaderm; Keratinamin; Pastaron; Prespersion, 75 Urea; Ultra Mide; Mocovina; Supercel 3000; Aqua Care; Harnstoff; Basodexan; Bubber Shet; Elaqua XX; Hyanit; Onychomal; Panafil; Superprill; NCI-C02119; component of Artra Ashy Skin Cream

CHARACTERIZATION

Composition: White, odorless crystalline powder Properties: Molecular Formula: CH₄N₂O or CO(NH₂)₂ Molecular Weight: 60.06 Melting Point: 133°C Boiling Point: Not Applicable Density: 1.34 g/cm³

Water Solubility: 1080 g/L at 20°C

PRODUCTION

Urea is mainly produced for use in fertilizer mixtures. A small amount of urea is produced for use in animal supplements. Urea is also used in the manufacture of dyes, fire-retardant paints, plastisizers, and explosive stabilizers.

The urea manufacturing process involves seven core unit operations. These operations include solution synthesis, solution concentration, solids formation, solids cooling, solids screening, solids coating and bagging, and/or bulk shipping. Urea solution production plants use only bulk shipping and solution formulation operations. Solid urea production involves a combination of all unit operations. In the urea solution synthesis process, carbon dioxide and ammonia react to form ammonium carbamate. This reaction is shown in equation one:

$$2NH_3 + CO_2 \rightarrow NH_2CO_2NH_4 \tag{1}$$

Ammonium carbamate is later dehydrated to yield a 70-77 percent aqueous urea solution. This reaction is shown in equation two:

$$NH_2CO_2NH_4 \rightarrow NH_2CONH_2 + H_2O$$
 (2)

Typical reaction conditions for equation one are temperatures ranging from 180-200 degrees Celsius and pressures ranging from 140-250 atmospheres. Vacuum concentration, crystallization, and atmospheric evaporation are the three primary methods of concentrating urea solutions, with atmospheric evaporation being the most common method [EPA, 1995].

HISTORY OF USE

Non-Organic Growers: H. M. Rouelle first discovered urea in human urine in 1773. Friedrich Wohler first synthesized urea in 1828, making it the first organic compound that was synthesized from inorganic starting materials. Urea production began in 1870 by heating ammonium carbamate in a sealed vessel. This process led to urea's current industrial production process. Urea has been used in conventional (non-organic) agriculture as a frost protectant and fertilizer for crops as well as an animal feed supplement.

Organic Growers: Urea is not currently included as an approved synthetic substance for organic production and handling on the National List of Allowed and Prohibited Substances (National List). However, ammonium carbonate has been approved for the same use that the current petitioner requests for urea. According to § 205.601 Synthetic substances allowed for use in organic crop production of the National List:

"(e) As insecticides (including acaricides or mite control)

(1) Ammonium carbonate - for use as bait in insect traps only, no direct contact with crop or soil"

CURRENT STATUS

U.S. Regulatory Agencies:

FDA: In 1983, urea was affirmed generally recognized as safe (GRAS) as a food ingredient by the Food and Drug Administration. According to the Code of Federal Regulations (21 CFR Part 184), revised April 1, 2003:

§ 184.1923 Urea.

(a) Urea $[CO(NH_2)_2, CAS Reg. No. 57-13-6]$ is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in Sec. 170.3(o)(14) of this chapter and as a fermentation aid.

(2) The ingredient is used in yeast-raised bakery products; in alcoholic beverages as defined in Sec. 170.3(n)(2) of this chapter; and in gelatin products.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived [DHHS, 2003].

EPA: EPA first registered urea in 1995 as a frost protectant pesticide under the trade name of Enfrost. Enfrost, 43% liquid urea, is applied commercially to field crops, vegetables, and fruit trees in an effort to reduce frost damage. In 1995, EPA established a permanent exemption for urea from residue tolerance requirements when used as a frost protectant on agricultural commodities (40 CFR Part 180, §180.1117). EPA's decision resulted from various studies showing that urea has a low toxicity to animals by oral, dermal, and inhalation routes of exposure. EPA's exemption decision is only for urea when it is applied as a pesticide [Daiss, 2001].

OSHA: Urea is considered to be hazardous as defined by the OSHA Hazard Communication Standard. OSHA has established the following Permissible Exposure Limits (PELs) for urea:

1) 15 mg/m³ TWA (total) (7), and 2) 5 mg/m³ TWA (respirable),

where TWA = 8-hour Time-weighted Average.

Other U.S. Sources: The Washington State Department of Agriculture (WSDA) does not approve urea as an approved substance in organic crop production [WSDA]. All states that are accredited organic certifiers are in compliance with the NOP guidelines.²

Status Among International Certifiers:

European Union: Urea is not listed on the approved list of additives currently permitted in the European Union.

World Health Organization: WHO has listed urea as "obsolete" (discontinued) for pesticide use [Orme 2003].

Canada: According to the Canadian Environmental Protection Act (CEPA), urea is on the Domestic Substances List (DSL) and is acceptable for use under the provisions of CEPA.

² Phone interview on January 9, 2004 with Meg Moynihan, Agriculture Diversification Specialist at the Minnesota Department of Agriculture.

APPLICATION

Urea can be applied to crops in either solid or solution form. It can also be used as a foliar spray. Urea is being petitioned for use as an insect attractant in organic crop production. The urea solution, diluted with water from 20% urea down to 5% urea, is not applied directly to crops or soil. The 5% urea solution, when applied to sticky traps, works by luring fruit flies (*Bactrocera oleae* and *Ceratitis capitata*) to the sticky traps in order to prevent crop destruction.

INCOMPATIBILITIES

Urea must be stored under dry conditions because it will absorb moisture from air. Urea reacts with hypochlorites to form nitrogen trichloride. Nitrogen trichloride spontaneously explodes in air. Urea also reacts with nitric acid to form urea nitrate. Urea nitrate decomposes explosively when heated. Other chemicals to avoid include sodium nitrite, nitrosyl perchlorate, gallium perchlorate, and phosphorus pentachloride [CFL, 2003].

ORGANIC FOODS PRODUCTION ACT OF 1990 (OFPA), AS AMENDED

Section 6517 National List:

"(a) *In General.* The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this chapter in order for such products to be sold or labeled as organically produced under this chapter.

(b) Content of List. The list established under subsection (a) of this section shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c) (1) of this section or each natural substance prohibited under subsection (c) (2) of this section.

(c) Guidelines for Prohibitions or Exemptions.

(1) *Exemption for Prohibited Substances*. The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

(B) the substance

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock paraciticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;

(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; or

(iii) is used in handling and is non-synthetic but is not organically produced; and

(C) the specific exemption is developed using the procedures described in subsection (d) of this section."

Therefore, under Section 6517 National List of the OFPA of 1990, as amended, it must be determined if the use of urea as a fruit fly attractant in sticky traps is consistent with subsection (c) (1) of this section. If so, then urea should be allowed an exemption as a synthetic substance and be included on the National List.

SECTION 2119 OF THE OFPA [7 U.S.C. 6518 (m)(1-7)] CRITERIA

1. What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming systems?

Urea is incompatible with nitric acid, sodium nitrite, nitrosyl perchlorate, gallium perchlorate, hypochlorites, and phosphorus pentachloride. Urea may have a detrimental interaction with sodium nitrate, which is approved for use under § 205.602 Nonsynthetic substances prohibited for use in organic crop production:

"(h) Sodium nitrate - unless use is restricted to no more than 20% of the crop's total nitrogen requirement."

Although both sodium nitrate and sodium nitrite are classified as oxidizers, sodium nitrate is considerably more stable than sodium nitrite. Therefore, the probability of a detrimental interaction between urea and sodium nitrate is not very likely.

Detrimental interactions between urea and hypochlorites are very likely since these compounds are incompatible. Calcium and sodium hypochlorite are approved for use under § 205.601 Synthetic substances allowed for use in organic crop production:

"(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems...

(2) Chlorine materials – <u>Except</u>, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite ...

(iii) Sodium hypochlorite"

Therefore, the only potential interactions with those substances approved for use in organic crop production would be with sodium nitrate, calcium hypochlorite, and sodium hypochlorite.

2. What are the toxicity and mode of action of the substance and its break down products/contaminants and their persistence in the environment?

Urea exists in urine and animal waste. Urea, if released into the atmosphere, will exist in both vapor and particulate phases. The vapor pressure of urea is 1.2×10^{-5} mmHg at 25 degrees Celsius. The vapor phase of urea is degraded by a photochemical reaction. The half-life for this reaction is 9.6 hours. Urea has a very high mobility rate if released into soil. The breakdown process of urea begins immediately upon its application to soil. Urea is not absorbed into suspended solids and sediment if released into water.

Urea is expected to rapidly biodegrade in aquatic ecosystems, releasing carbon dioxide and ammonia. The potential for urea bioconcentration in aquatic organisms is low. A urea degradation study was performed in several river waters under varying conditions. Urea degradation was completed in 6-14 days at 20 degrees Celsius. Little to no degradation occurred within 10-14 days at lower temperatures. A maximum degradation of 3-6 percent was observed in the first seven days at temperatures below eight degrees Celsius [NIH, 2002].

3. What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?

Minimal fire and/or explosion hazard is associated with urea usage. The manufacture of urea results in minimal environmental pollution. Large amounts of urea can cause potential plant damage to seedlings and inhibit germination. Urea can also foster excessive growth of algae or microorganisms in water systems. Urea is non-toxic to aquatic organisms [CFL, 2003].

4. What are the effects of the substance on human health?

Urea may cause adverse reactions including headache, nausea, vomiting, disorientation, transient confusion, and electrolyte depletion. Urea may also cause tissue irritation. Urea is a known human skin irritant. The toxic dose of

urea in cattle is 0.45 g/kg. The toxic dose of urea in ruminants is 0.3-0.5 g/kg for those species not accustomed to urea [NIH, 2002].

The 1983 National Occupational Exposure Survey (NOES) estimated that 783,504 workers are exposed to urea in the United States. Females account for 326,824 of the exposed workers. This estimate excludes farm workers. Urea exposure may occur through inhalation or dermal contact in the workplace. High-risk occupational exposure results from those workers who handle urea fertilizers. General population urea exposure results from food and water ingestion and dermal contact with urea-containing compounds [EOHS, 1983].

5. What are the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock?

Urea has a high mobility in soil based on a K_{oc} value of eight. Urea rapidly hydrolyzes in soil to ammonium ions, which produce carbon dioxide and ammonia. The reaction time for this process is 2-4 days. Urea hydrolyzes faster in soils with higher pH values. The hydrolysis can potentially be completed within 24 hours. This rate is dependent on soil type, urea formation, and moisture content. An increase in the pellet size of urea fertilizers may decrease urea decomposition rates from days to weeks. Studies indicate that the majority of soil-applied urea is lost in the gaseous form [NIH, 2002].

The volatility of urea in soil mainly depends on the pH and the temperature of the soil. Tables 1 and 2 show the dependence of urea (nitrogen fertilizer) decomposition on soil temperature and pH [Overdahl, 1991].

	Temperature (F)								
Days	45 degrees	60 degrees	75 degrees	90 degrees					
	(% of added Nitrogen volatilized)								
0	0	0	0	0					
2	0	0	1	2					
4	2	2	4	5					
6	5	6	7	10					
8	5	7	12	19					
10	6	10	14	20					

Table 1. Percent of surface-added urea volatilized as ammonia at different temperatures and days on the surface.

Data abstracted from curves in SSSP 24, pages 87-90, 1960. Urea was added on a silt loam soil at 100 lbs N.

	Soil pH								
Days	5.0	5.5	6.0	6.5	7.0	7.5			
	(% of	added Nitr	ogen volat	ilized)					
0	0	0	0	0	0	0			
2	0	0	0	0	1	5			
4	1	2	5	10	18	20			
6	4	5	7	11	23	30			
8	8	9	12	18	30	33			
10	8	10	13	22	40	44			

Table 2. Percent of surface-added urea volatilized as ammonia at varioussoil pH levels and days on the surface.

Data abstracted from curves in SSSP 24, pages 87-90, 1960. Urea was added on a silt loam soil at 100 lbs N.

6. What are the alternatives to using the substance, including other practices or other available materials?

Under the USDA Final Rule (§ 205.601), the use of sticky traps/barriers have been approved for use as insecticides, and pheromones have been approved for use as insect attractants in organic crop production. This section also lists ammonium carbonate, boric acid, elemental sulfur, lime sulfur, horticulture oils, and insecticidal soaps as approved insecticides for the organic grower.

7. Is the substance compatible with a system of sustainable agriculture?

Sustainable agriculture is defined as the integration of environmental health, economic profitability, and social/economic equity.³ Urea profitability is continually suffering as a result of the spike in high natural gas prices. High natural gas prices have caused some urea production plants to close down in North America and Western Europe. "Western Europe's share of the urea market has fallen from 20% in 1980 to 11% in 1996." China's decision to halt imports causes unpredictability in the world urea market. China accounts for 25% of the world urea demand and for 40% of the world urea trade. China's decisions regarding urea production and importation continually affect the U.S. market and urea prices worldwide [McElligott, 2000].

The manufacture of urea results in minimal environmental pollution, although large amounts of urea can cause damage to plant seedlings and inhibit seed germination. Urea can also foster excessive growth of algae and microorganisms in water systems. However, urea is non-toxic to aquatic organisms [CFL, 2003].

³ University of California Sustainable Agriculture Research and Education Program. "What is Sustainable Agriculture?" 1997; http://www.sarep.ucdavis.edu/concept.htm.

Since urea poses minimal environmental risks, increased price stability in the urea market would aid its compatibility with a system of sustainable agriculture.

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REVIEWER 1

Ph.D., Professor of Food Science and Technology, West Coast, USA

A. <u>Comments on Database</u>

The report is somewhat disjointed in presentation, however all evaluation criteria are addressed in sufficient detail. Insufficient information is provided as to the details of how urea will be integrated into pest attractant systems.

B. OFPA Criterion Evaluation

1. What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming?

The petitioner provides a list of known chemical interactions between urea and other inorganic compounds. Most relevant are interactions with nitrites and hypochlorites which could be present in organic systems. Proper labeling would alert users to this. However the specific proposed application of urea in insect traps precludes any likelihood of such chemical interactions.

2. What are the toxicity and mode of action of the substance and its breakdown products/contaminants and their persistence in the environment?

Urea does not persist in the environment due to its rapid degradation by soil microorganisms and oxidation by photochemically produced hydroxyl radicals in the atmosphere. It is a favored nitrogen source by plants and microorganisms by virtue of its easy uptake and catabolism. The breakdown products are innocuous and quickly recycled by various organisms.

3. What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?

Degradation of urea can lead to the presence of ammonia which is toxic to aquatic animals if sufficient accumulations in water run-off. However this concern is only relevant when urea is used as a fertilizer incorporated into soil. The petitioned application does not include fertilizer use of urea.

4. What are the effects of the substance on human health?

Direct contact with urea has been reported to cause a host of low grade irritation reactions including coughing, skin redness and itching, and eye redness and itching. There are no data to indicate mutagenic or carcinogenic potential. Safety precautions include gloves, goggles and dust masks if handling powered forms. Urea has contact and health ratings of 2 (moderate). Urea is commonly used as a

nutritional supplement for beef cattle in amounts up to 0.15 kg/per head/day without any adverse health effects.

5. What are the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock?

For the specific petitioned application of urea, there is little if any concern of the compound entering the water/soil environments. Assuming urea is used as a pest attractant, it is immobilized in the trap matrix; there will be little environmental impact. However, the petitioner needs to provide more information regarding exact applications in order to make a more accurate assessment.

6. What are the alternatives to using the substance, including other practices or available materials?

Other alternatives may be considered, such as insecticidal soaps.

7. Is the substance compatible with a system of sustainable agriculture?

The petitioner's arguments are poorly presented especially in regard to urea and world markets. No relevant points are made in regard to sustainable agriculture. Nonetheless, based on available information, I believe urea when used as a pest attractant will have little if any negative impact on sustainable systems. Conversely, it is hard to recognize if urea would have any promoting or beneficial contribution to sustainable production practices.

C. <u>Conclusion</u>--Summarize Why This Material Should Be Allowed or Prohibited for Use in Organic Systems

This reviewer is of the general opinion that the petition has provided relevant information which taken together with other sources of information provides a convincing argument that urea meets all criteria for acceptance into the National List. The most important parameters which led to this recommendation are:

- 1) FDA GRAS Status
- 2) Minimal human health effects
- 3) Minimal environmental effects
- 4) No direct contact with agricultural products

D. <u>Recommendation Advised to the NOSB</u>

Urea is a <u>synthetic</u> compound that is commercially produced by the reaction of ammonia and carbon dioxide to ammonium carbamate which is subsequently dehydrated to urea. The intended use of urea does not permit for contact of the

petitioned substance during the processing or post harvest handling of any agricultural product. This coupled with minimal health or environmental impacts form the justification for my recommendation that urea be included on the National List.

REVIEWER 2

USDA Accredited Certifier, Midwest, USA

A. <u>Comments on Database</u>

The information from the TAP report does not provide much information on urea used for the purpose named in the petition. Most of the information is about urea used as a fertilizer.

B. <u>OFPA Criterion Evaluation</u>

1. What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming?

Urea is incompatible with nitric acid, sodium nitrite, nitrosyl perchlorate, gallium perchlorate, hypochlorites, and phosphorus pentachloride. Urea may have a detrimental interaction with sodium nitrate, which is approved for use under CFR 205, Section: 205.602(h).

2. What are the toxicity and mode of action of the substance and its breakdown products/contaminants and their persistence in the environment?

The information provided in the TAP does not indicate that there is. Since this petition is for its use as bait, it is not likely large enough amounts would be used to make this a concern.

3. What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?

From the TAP, "Urea must be stored under dry conditions because it will absorb moisture from air. Urea reacts with hypochlorites to form nitrogen trichloride. Nitrogen trichloride spontaneously explodes in air. Urea also reacts with nitric acid to form urea nitrate. Urea nitrate decomposes explosively when heated. Other chemicals to avoid include sodium nitrite, nitrosyl perchlorate, gallium perchlorate, and phosphorus pentachloride [CFL, 2003]." Sodium nitrate is allowed in organic farming with restrictions.

4. What are the effects of the substance on human health?

Urea can be harmful to human health in its manufacture. From the TAP, "Urea may cause adverse reactions including headache, nausea, vomiting, disorientation, transient confusion, and electrolyte depletion. Urea may also cause tissue irritation. Urea is a known human skin irritant. The toxic dose of urea in cattle is

0.45 g/kg. The toxic dose of urea in ruminants is 0.3-0.5 g/kg for those species not accustomed to urea [NIH, 2002]."

Also from the TAP, "The 1983 National Occupational Exposure Survey (NOES) estimated that 783,504 workers are exposed to urea in the United States. Females account for 326,824 of the exposed workers. This estimate excludes farm workers. Urea exposure may occur through inhalation or dermal contact in the workplace. High-risk occupational exposure results from those workers who handle urea fertilizers. General population urea exposure results from food and water ingestion and dermal contact with urea-containing compounds [EOHS, 1983]."

5. What are the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock?

The small amounts used in insect traps should not be a problem in this area.

6. What are the alternatives to using the substance, including other practices or available materials?

Alternatives exist. There are many natural materials that can attract fruit flies. According to the TAP, "Urea is not currently included as an approved synthetic substance for organic production and handling on the National List of Allowed and Prohibited Substances (National List). However, ammonium carbonate has been approved for the same use that the current petitioner requests for urea. According to § 205.601 Synthetic substances allowed for use in organic crop production of the National List:

(e) As insecticides (including acaricides or mite control)

(1) Ammonium carbonate - for use as bait in insect traps only, no direct contact with crop or soil"

Ammonium carbonate is already approved for the same use that the petitioner requests for urea.

7. Is the substance compatible with a system of sustainable agriculture?

Insect traps are consistent with a system of organic and sustainable agriculture. However, urea, historically, has not been allowed in organic farming. As fruit flies are attracted to many natural substances, it would seem that many alternatives to urea would exist. There are many certifiers who have never allowed the use of urea, as well as farms whose certification has been denied for using it as a fertilizer. According to the TAP, "The Washington State Department of Agriculture (WSDA) does not approve urea as an approved substance in organic crop production [WSDA]. All states that are accredited organic certifiers are in compliance with the NOP guidelines" which do not allow urea. Also according to the TAP, "Urea is not listed on the approved list of additives currently permitted in the European Union."

C. <u>Conclusion</u>—Summarize Why This Material Should Be Allowed or Prohibited for Use in Organic Systems

The process by which urea is made indicates it to be synthetic. According to the TAP, "The urea manufacturing process involves seven core unit operations. These operations include solution synthesis, solution concentration, solids formation, solids cooling, solids screening, solids coating and bagging, and/or bulk shipping. Urea solution production plants use only bulk shipping and solution formulation operations. Solid urea production involves a combination of all unit operations. In the urea solution synthesis process, carbon dioxide and ammonia react to form ammonium carbamate."

I suspect that the small amounts used in the traps do not have nearly the potential for environmental or human health problems as the amounts used for fertilizers.

D. <u>Recommendation Advised to the NOSB</u>

Under OFPA, a synthetic material may be allowed if the substance is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock paraciticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. Urea is appropriately petitioned for in this case, specifically for its use as bait in insect traps for fruit flies.

REVIEWER 3

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A. <u>Comments on Database</u>

The use of UREA as a fruit fly trap is a natural solution to the problem, because urea (although in this case from a synthetic source) is a natural component of urine and other waste in insects, mammals and reptiles. Thus its presence in crop areas is already expected and is not a problem. Urea is already accepted as an ingredient used in food with no limitation other than current general manufacturing practice; therefore, should not be a problem when not put in contact with food or crops. In fact, the use of urea solutions as bait to trap fruit flies would not expected to pose any ingestion hazard, both because it is safe and it will not be in contact with foodstuffs. Moreover, urea is not volatile under the application it is planned for; thus, it will stay right where it is put--in the fruit fly trap solution which can be disposed of simply into the sewer system (this handles much larger quantities of urea on a daily basis).

B. OFPA Criterion Evaluation

1. What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming?

There is no potential of the substance to have detrimental interactions with other materials used in organic farming such as sodium nitrate; there should be no confusion between sodium nitrate which has no detrimental interactions and is used in organic farming, and sodium nitrite that is not used in organic farming and thus is not a consideration. Oxidants, such as calcium or sodium hypochlorite do not create any toxic substances with urea; however calcium or sodium hypochlorite should not be used since these are toxic in large amounts.

2. What are the toxicity and mode of action of the substance and its breakdown products/contaminants and their persistence in the environment?

There is not expected to be toxicity of breakdown substances because urea is biodegraded in any living situation without any harmful effects. Urea is biodegraded rapidly with release of carbon dioxide and ammonia, neither of which pose any problems. Furthermore, degradation is slow if not bioenhanced, as evidenced by the fact that at 20 degrees Celsius urea degrades in river waters in 6-14 days. 3. What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?

There is no problem of environmental contamination during manufacture since minimal fire or explosion hazard is associated with urea manufacture, and there is minimal environmental pollution.

4. What are the effects of the substance on human health?

There are no severe adverse effects on human health, of course, urea is efficiently removed and degraded by biological systems. Any general population exposure has come from food and water ingestion or dermal contact, which is not likely to occur when used in the small aqueous amounts employed for bait-trap solutions.

5. What are the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock?

There are not anticipated to be adverse effects on the agroecosystem. First, the volatility of urea is low, therefore it will not affect the air. Second, urea should already be found in the soil and groundwater from natural organisms that secrete urea on a daily basis. Because the bait-traps are stationary, urea is not anticipated to escape the traps. However, if any did find its way into soil or ground water, it would be much smaller than amounts already there from natural organisms.

6. What are the alternatives to using the substance, including other practices or available materials?

Alternatives to urea do exist for organic farming.

7. Is the substance compatible with a system of sustainable agriculture?

Sustainable agriculture integrates environmental health, economic profitability, and social and economic equity. Urea is non-toxic to organisms, aquatic or otherwise, and represents minimal (if any) environmental risk. The economics of urea production appear to fluctuate like any commodity. However, the synthesis using ammonia and carbon dioxide is as inexpensive as possible for any synthetic chemistry.

C. <u>Conclusion</u>—Summarize Why This Material Should Be Allowed or Prohibited for Use in Organic Systems

Urea is the most suitable compound of any available for use as bait for aqueous fruit-fly traps, which are isolated from any environmental contact and will not be

ingested. Moreover, urea does not present any threat for contamination because it is already present in the environment from natural sources.

D. <u>Recommendation Advised to the NOSB</u>

The petitioned material (urea) is synthetic and should be allowed for use in organic systems.