National Organic Standards Board
Crops Subcommittee
Petitioned Material Discussion Document
Potassium Sorbate as an active ingredient for plant disease and insect control/suppression
February 7, 2023

Summary of Petition:

Potassium sorbate, referred to as KS throughout the report, is being petitioned for use as an active ingredient for plant disease and insect control/suppression in field and greenhouse applications. The petition states that potassium sorbate will be an effective tool in a crop disease-resistance program with its contact mode of action, and that it is not suspected to contribute to the phytotoxicity of crops.

The petition identifies the substance as 100% food-grade KS with no ancillary substances. The proposed end-use fungicide/insecticide contains 45% KS, with the remaining 55% comprised of the inert ingredients' urea and citric acid, both of which appear on the 2004 EPA List 4A: Inerts of Minimal Concern. With KS as an active ingredient, the end-use product would be used to target crop disease and insects such as powdery mildew, downy mildew, and whiteflies on many crops, including grapes, cucurbits, roses, stone fruit, pome fruit, nuts, solanaceae vegetables, and cannabaceae plants.

Summary of Review:

KS is petitioned for addition to the National List at 7 CFR 205.601(e) for use as an insecticide and at § 205.601(i) for use as a plant disease control. KS currently is on FIFRA's (Federal Insecticide, Fungicide Rodenticide Act) list 25(b), which is for active and inert ingredients (of chemicals) that are considered a minimum risk, and therefore, do not require an EPA registration number and are exempt from EPA regulations on efficacy and toxicity. KS is generally recognized as safe (GRAS) by FDA.

KS has been petitioned unsuccessfully three additional times for inclusion on the National List. KS is not internationally approved for the petitioned use.

1. 1995, seed treatment, production aid 7 USC 6517(c)(1)(B)(1)
    a. Petitioned (sorbic acids and its salts) for use in food processing
    b. Conclusion: sorbic acid was synthetic and not compatible with organic processing or handling

2. 2002 Crops, 205.601:
    a. Petitioned for use in seed film coating as a preservative.
        i. Potassium sorbate is a weak acid antimicrobial known to cause resistance and is used in the food industry.
        ii. Conclusion: potassium sorbate was not allowed as a synthetic substance for use as a preservative, as more information was needed for justification.

3. 2002 Livestock, 205.603:
    a. Petitioned for use in organic livestock production as a mold inhibitor (preservation in aloe vera - aloe vera can be used as an alternative for antibiotics when treating livestock)
        i. Conclusion: Additional information on the ingredients in the manufacturing of potassium sorbate is questioned.

KS, used as an active ingredient, would function in a contact mode of action form. Many alternative products and cultural practices exist. The petition states that the degradation products (sorbic acid and potassium hydroxide) are more hazardous than the product itself.

In food additives, sorbic acid interacts negatively with nitrite and is known to create direct-acting mutagens and genotoxic agents. The extent of these interactions in field conditions is unknown. The TR indicates that limited information on KS, as petitioned, exists. Thus, there needs to be more available information regarding the potential interactions of KS with other crop production inputs. (TR 579-583).

In addition, the TR indicates that there was little to no information on KS as petitioned to understand its chemical interactions or its use in conventional crop pesticide application (TR 579-581), how KS interacts with soil organisms, the use of KS as a foliar spray on growing crops (TR758-759), and persistence of KS in the environment or its by-products (TR 468-470), thus in many cases the TR leverages information that was available regarding KS as a post-harvest treatment and/or as a conventional food additive (TR 74, 470-472, 857-862).

Category 1: Classification

1. For CROP use: Is the substance **Non-synthetic** or **X Synthetic**?

Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Potassium sorbate is not explicitly listed anywhere in the Organic Foods Production Act of 1990 (OFPA) nor the USDA organic regulations CFR part 205. It is implicitly on the National List as an inert ingredient of minimal concern on the National List at 205.601 (m) (i) and 206.603 (e)(1).

2. Reference to appropriate OFPA category: Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins, and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (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?

The petitioner is requesting that potassium sorbate be used as an active ingredient for plant disease and insect control/suppression under the following conditions:

1. § 205.601(e): Synthetic substances allowed for use in organic crop production – as insecticides
2. § 205.601(i): Synthetic substances allowed for use in organic crop production – as plant disease control

Note: The TR states that KS is one of the most common food preservatives; In contrast, most food preservation with KS occurs as part of food processing; it is the application during crop production and post-harvest handling of raw agricultural commodities that are considered within the scope of the current petition. Post-harvest use would have to be annotated explicitly for any KS listed at 205.601 according to the National Organic Program (NOP) Guidance 5023. (TR 99-103)

Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

Potassium sorbate, due to its antimicrobial properties, has been historically used in the food processing industry as a preservative and is used in a wide range of food products, including meats, cheeses, baked goods, fresh and fermented vegetables, dried fruit, fish, processed food, and carbonated beverages. There is little historical use of KS in organic agricultural production.

The TR notes that before receiving the 25(b) exemption, potassium sorbate was used as an active ingredient in several EPA-registered pesticides. The last of these registrations was canceled in 1989. KS is also on the 2004 EPA List 4A – Minimal risk inert ingredients. Thus, it is currently permitted as an inert ingredient in combination with permitted active ingredients in pesticide formulations used in organic crop production according to 205.601 (m) (1) (TR 206-213).

Two notable points were brought up in the TR relating to KS (and/or sorbic acid used to make KS):

1. Processed food products with sorbate and nitrite preservatives may form mutagens and genotoxic agents under certain conditions.
    a. In vitro studies on bone marrow chromosomes of mice showed that the combination of sorbic acid and nitrite creates a synergistic effect, severely affecting the spindle apparatus and chromosomal structure.
    b. Research on how these two substances would interact with humans and the field environment is unavailable.
2. Ames test and rec-assay mutagenicity found DNA-damaging activity when combined with KS, ascorbic acid, and iron salts. (TR 585-597).

2. What is the toxicity and mode of action of the substance, its breakdown products or any contaminants, and their persistence and areas of concentration in the environment?

Few studies in the literature report on using KS as a crop fungicide. Thus, information regarding its persistence or that of its by-products in the environment is limited. (TR 467-468).
The TR states that crystalline KS is relatively stable; its behavior in solutions and foods depends on factors like temperature, pH, food combination, water activity, packaging, and various metals and other additives. (TR474-477). The presence of KS in natural environments after its commercial use is considered safe. KS has a contact mode of action.
The TR notes that since KS inhibits microorganisms from colonizing a “new” substrate, KS is an effective antimicrobial. However, this bacteriostatic effect is likely to be overwhelmed in a natural community, where microorganisms can quickly degrade KS into readily metabolized compounds such as sorbitol, potassium, and sorbic acid. (TR 454-457). In general, sorbic acid and its salts have been considered compounds of low ecotoxicity.

3. Describe the probability of environmental contamination during the manufacture, use, misuse, or disposal of such substances? [§6518(m)(3)]

KS is a potassium salt of sorbic acid. Sorbic acid (synthetically manufactured using ketene and crotonaldehyde) is neutralized with potassium hydroxide (manufactured through chemical synthesis) to yield potassium sorbate, the petitioned substance. Several methods are described for isolating the KS

solid, including filtration, centrifugation spraying, or crystallization of KS and subsequent distillation. The petition states that the source of potassium sorbate is food grade and manufactured in a closed system, waste disposal certified, and chlorine-free production with multiple accreditations such as Food Safety System Certification, HACCP, and ISO 9001.

Potassium hydroxide (KOH) is considered a category-one hazardous substance under the Clean Water Act due to its impact on pH and potassium levels in wastewater. Although KOH itself may be corrosive in solid form and is listed as a hazardous substance under the Clean Water Act, it is considered a GRAS substance when produced with good manufacturing practice and currently appears on the National List at 205.605(b)(26) for use in processed products.

KS and its by-products are disposed of by landfilling in closed containers or incarceration. The TR states that KS has no potential for environmental accumulation.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

Potassium sorbate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (US FDA) at 183.3640, with the only specification being that it be used according to good manufacturing practices (GMPs). The TR states that KS and its residues are exempt from the requirement of a tolerance in food per 40 CFR 180.1233.

Since minimal data is available on potassium sorbate as petitioned, the TR provides information regarding other uses of KS (food preservation, cosmetic, personal care products, washing and cleaning products, pharmaceuticals, and other manufactured industrial products) and not necessarily for the petitioned use.

The current TR discusses the consumption of processed products that use KS as a food additive. Most of the KS is dispelled when consumed…however, 12.6% is retained (studies on rats) by internal organs, skeletal muscles, and other body parts (TR 516-519). An increased KS intake (>25mg/kg) may lead to cytotoxic and genotoxic effects by producing mutagenic compounds and inducing chromosome aberrations and DNA breakage (cancers and diabetes mellitus). Wide use of KS in food, cosmetics, cleaners, etc., could lead to higher-than-normal buildup.

On the contrary, the petition references the 2002 Technical Advisory Panel Review (TAP) that was contracted to support earlier reviews of KS. The TAP states that potassium sorbate is the potassium salt of an unsaturated fatty acid, which participates in the normal fat metabolism in the human body and will be oxidated into carbon dioxide and water finally. It will not be accumulated in the human body. The 2002 TAP states that KS is safe and has the lowest allergenic potential of all food preservatives.

The petition states that although allergic reactions to KS can be described as unusual, there was a reported incident of severe rashes by a worker in a dairy plant who had repeated occupational exposure. The petition also states that KS is a category 2B serious eye damage/eye irritation health hazard with a WARNING signal word. As petitioned to be used in the OR-159-B end-use product with KS at 45%, KS is classified by OSHA Hazard Communication Standards as not hazardous.

5. Discuss any effects the substance may have 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. [§6518(m)(5)].

Few studies are found in the literature that report on the use of KS as a crop fungicide, thus, information regarding its persistence or that of its by-products in the environment resulting from this use is limited. No studies on KS used to control the target organism identified on the petitioned product's label were found to expound on its potential effects on soil microbial communities. (TR 467-470).

For crops: The TR mentions KS being tested for phytotoxicity in cotton in the 1970s. The treatments caused a reduction in the primary root elongation at three different concentrations and showed that the KS severely affected the dry weight of cotton seedling shoots and roots. (TR 606-608). The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions, as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity (TR 618-620).

For Livestock: The TR mentions that when KS was petitioned for use in livestock in 2002, one reviewer in the TAP stated that one should determine directly at what level KS, as an anti-bacterial, will interfere with ruminant metabolism. The TR noted that future research that identifies the concentrations of KS affecting the ruminant microbiome is needed (TR 633-637).

6. Are there any adverse impacts on biodiversity? (§205.200)
KS antimicrobial properties and characteristics could alter the microbiome in the soil, The petition states that it is reasonable to expect that it would inhibit the growth of soil microorganisms, and additionally, that a significant number of organisms regarded as beneficial are suppressed.

The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions (TR618-620), as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity.

In general - sorbic acid and KS are considered compounds of low ecotoxicity. However, the TR states that high concentrations of KS can impair photosynthetic functions in algae, negatively affect the microbiome of fishes, inhibit mycelial growth in fungi, and affect the soil pH (TR 615, 617, 669).

Category 3: Alternatives/Compatibility

1. **Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

The petition states that KS is necessary as an organic input pesticide active ingredient because it has a contact mode of action where organic crop farmers in the US can use the petitioned product in a disease resistance management program rotating with fungicides with different modes of action. The petition includes testing data showing efficacy on powdery mildew, downy mildew, and white fly, and observed no phytotoxicity even at double the use rate on the crops tested. Other trials of the effectiveness of KS, as petitioned, were not found.

The petition discusses efficacy, indicating that KS is comparable to conventional pesticides and carries a higher efficacy rate than other allowed organic or natural actives. The petition included research regarding in vitro efficacy of eight food additives as possible alternatives to synthetic fungicides for controlling soil-borne pathogens. Also included in the petition is a breakdown of a comparison study of the efficacy of potassium salts against soil-borne and air-borne fungi reviewing KS and potassium

bicarbonate (active ingredient listed on 7 CFR 205.601i(9)). According to the petition, in tests done at Michigan State, KS significantly outperformed potassium bicarbonate and sulfur in controlling downy mildew, an important, difficult-to-control grape disease. Few other published pesticide trials have been done with this material. However, the petition also notes that there are currently non-synthetic and natural substances that could be used in place of potassium sorbate.

A literature review for KS uncovered limited information on use as a foliar spray for growing crops. (TR 758-759). The TR indicates that over 750 biological controls were approved for use as crop pests, weeds, and disease controls under NOP standards on the OMRI Products List (OMRI 2022) (TR 764-765). The petition states that searching in the OMRI database under the "Crop Pest, Weed, and Disease Control" keyword "fungicide" yields 464 fungicide products that are OMRI approved. The TR indicated that there were over 500 pesticides formulated with plant-derived active ingredients on the OMRI Products List (OMRI, 2022). Fixed coppers and copper sulfate, potassium silicate, lime sulfur, hydrogen peroxide, horticultural oils, potassium bicarbonate, and polyoxin D zinc salt are all alternative products.

In terms of cultural practices, applying a systems-based approach and deploying preventive practices and ecological processes to promote beneficial microbial diversity in the soil and biodiversity to attract beneficial insects, as well as cover cropping, crop rotations, and cropping schedules, are examples of management practices that can also assist in insect and disease mitigation.

1. **In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

KS is already used in organic production as it is an allowed substance for use in organic crop production at 205.601 (m) - As synthetic inert ingredients as classified by the EPA.

As petitioned, KS is not approved to be used internationally. However, it is permitted under the European Economic Community Council Regulations as a preservative in organic livestock feed. KS has been petitioned two other times, in crops as a seed treatment and in livestock as a mold inhibitor, and was not added to the national list due to reasons discussed in the summary of the review section. In addition, KS is not made from renewable resources, the materials used to produce KS are not recyclable, do not complement the use of natural and biological controls, and many alternative substances and practices exist currently.

As the TR states in several places, more research is needed to understand the impacts of allowing KS to be used as an active ingredient for insect and plant disease control, therefore, an abundance of caution needs to be considered.

Questions for stakeholders:

1. Is there a need for potassium sorbate (KS) for use as an insecticide or plant disease control?
2. Is there any additional known research available to understand KS's potential and efficacy if used as an insecticide or plant disease control?

Subcommittee Vote:
Motion to accept the discussion document on potassium sorbate
Motion by: Amy Bruch
Seconded by: Jerry D'Amore
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 3