National Organic Standards Board Crops Subcommittee Petitioned Material Proposal Pear Ester

Summary of Petition and Background Information

In September 2023, the National Organic Program (NOP) received a petition from Trece Incorporated requesting the addition of Pear Ester (i.e., Ethyl-2E,4Z-Decadienoate), a semiochemical material, to the National List as a synthetic allowed for use in crop production [7CFR§205.601(j)]. Semiochemicals are bioactive molecules released by an organism to signal or provoke a behavioral or physiological response (Klassen et al., 2023). Signaling may be between members of the same species or between two or more distinct species. Pheromones, kairomones, and allomones are sub-categories of semiochemicals. Pear ester was previously allowed for use in organic crop production under the synthetic pheromone classification until its correct reclassification as a kairomone. Even though pheromones and kairomones are both semiochemicals, they differ in a couple of significant characteristics. Pheromones are volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior (EPA, 2011).

Pear ester is synthesized by a condensation reaction between two chemicals that are by-products of petroleum processing. The prevalent process for manufacturing pear ester is the condensation reaction between the eight-carbon allyl alcohol, oct-1-yn-3-ol (CAS No. 818-72-4), and triethylorthoacetate (CAS No 78-39-7). The condensation product is heated with propanoic acid as a catalyst, and the subsequent Johnson-Claisen rearrangement gives ethyl 2E, 4Z-decadienoate. It is a convenient one-step synthesis with good yields (Trécé, Inc., 2023; Tsubi et al., 1993).

Pear ester appears on the FDA list of Substances Added to Food (*formerly EAFUS*) for use as a flavoring agent or adjuvant food additive (US FDA, 2024). The EPA has registered pear ester formulations for pest management. This behavior-altering chemical (i.e., semiochemical) is particularly useful in the management of the codling moth, *Cydia pomonella* – an economically significant pest that principally affects apple, pear, and walnut crops (Trécé, Inc., 2023).

The proper classification of pear ester as a kairomone, instead of a pheromone rendered its continued use under the pheromone category, untenable in organic crop production (Trécé, Inc., 2023). The petition is aimed at providing organic crop producers with pest management tools that were available to them prior to the reclassification of pear ester as a kairomone instead of a pheromone.

The 2024 technical report on pear ester has detailed information on significant improvements in pest management outcomes from the incorporation of pear ester relative to results obtained with the use of pheromones alone. The report covers various uses of pear ester in codling moth management. This includes their use,

- (a) As lures in traps to monitor populations of codling moth in orchards. These traps help to determine the "biofix point" which is date on which codling moths first appear in monitoring paths. Pear ester monitoring traps provides information for determining action thresholds and the timing of treatments.
- (b) In mating disruption efforts. Research findings show mating disruption dispensers loaded with both codling moth sex pheromone and pear ester can be more than dispensers with pheromone alone.

Available data show that pear ester exerts significant economic impacts on pear and apple growers. The positive economic impact of pear ester is exerted through its documented direct impact on mass trapping, mating disruption and proper timing of treatments (including pesticide applications). These interventions result in significant reductions in fruit damage. The improved effectiveness of traps and monitoring tools when pear ester is combined with pheromones is well documented.

Subcommittee Review Fall 2024

Subcommittee discussions were based on a discussion document that was informed by the 2024 technical report (TR) on pear ester. Discussions covered pertinent elements of the petition (to add pear ester to the National List). Discussions also included the previous misclassification of kairomones as pheromones and the distinction between these behavior-altering chemicals. The essentiality of pear ester in apple and pear production was emphasized. There was a suggestion to explore the possibility of broadening the proposal to cover kairomones as a group instead of pear ester alone. All eight attendees voted to accept the discussion document on pear ester.

Fall 2024 Meeting Public Comments

Comments received at the Fall 2024 meeting were in favor of adding pear ester to the National List. A commenting organization stated that synthetic pear ester-based mating disruption products are Generally Recognized as Safe (GRAS) and are more effective in insect pest management in organic orchards relative to their alternatives. It was also pointed out that the chemical structure of synthetic pear ester is identical to the natural kairomone.

One commenter advised the Board to direct significant attention to determining whether the word "pheromones" was used in OFPA §6517.c.1.B.i to refer to only pheromones or if it could be interpreted to include other semiochemicals such as kairomones. The commenting organization was of the view that this determination will provide a basis (or otherwise) for continuation of the evaluation of pear ester, in addition to helping to clearly articulate the Board's intent for handling future petitions involving semiochemicals. A historical context of negotiations that resulted in the inclusion of pheromones in OFPA was provided. The Crops Subcommittee (CS) was advised to determine the correct interpretation of pheromones in OFPA §6517.c.1.B.i. to ascertain whether it covered only materials that satisfy the technical definition of pheromones or include other semiochemicals. It was argued that the absence of internet-based resources and poor access to technical expertise during the negotiations pertaining to the inclusion of pheromones in OFPA may have led to the wrong interpretation of the intent of OFPA drafters. The commenting organization was of the view that if the drafters of OFPA had access to the information available in the 2024 technical report on pear ester, OFPA §6517.c.1.B.i. would have highly likely contained the term "semiochemicals" instead of "pheromones."

One of the comments was for the Board to make a distinction between pear ester that is released from traps and those that are microencapsulated in polyamide materials that are then sprayed. The commenting organization considers the use of pear ester in traps to be consistent with OFPA, unlike its use in microencapsulated formulations. The commenter stated that polyamide particulates are microplastics and must be evaluated as such. According to the commenting organization, the Board needs to consider the following pieces of information in its deliberations on pear ester: (a) the essentiality of microplastics in microencapsulated potential health risks to individuals exposed to polyamide microplastics. The Board was asked to consider the delivery mechanism in its deliberations on pear ester. An annotation to restrict the use of pear ester to traps was recommended.

Another commenting organization acknowledged the efficacy of semiochemicals in insect pest management but stressed the importance of guardrails that permit the use of synthetic materials that are identical to natural kairomones. In the perpetual quest for more effective pesticides, this guardrail would prevent the development of products that exert unintended/unexpected adverse impacts on non-target organisms in the farm ecosystem because they differ significantly from natural kairomones. The comment endorsed the use of pear ester in trapping and monitoring insect pests but opposed the broad application of microencapsulated formulations which release microplastics in the organic environment.

Fall 2024 NOSB Board Meeting Review:

There was widespread support for adding pear ester to the list. Board members sought information from public commenters on whether there were other kairomones (i.e., apart from pear ester) that were in use in insect pest management. This was to inform the NOSB's decision on whether to pursue the addition of pear ester alone or kairomones as a group to the National List. The Board did not receive any information that justified the addition of kairomones as a group.

Subcommittee Review Spring 2025

Category 1:Classification/categorization

There is a need for clarification and/or pursuit of supporting documentation on the intent or correct interpretation of the word "pheromone" in OFPA §6517.c.1.B.i. A section of the organic community is requesting information on the interpretation that informed the removal of pear ester from the National List. The current position/trajectory of the Crops Subcommittee (CS) is to proceed with a proposal to add pear ester to the National List until a determination that the drafters of OFPA intended to refer to semiochemicals instead of "pheromones" in particular. This approach is informed by the fact that even though kairomones and pheromones are both semiochemicals, they are technically different. The removal of pear ester from the National List represents a previous (correct or incorrect) determination that OFPA drafters did not intend to refer to semiochemicals in general. CS will proceed with the proposal while it pursues documentation and/or clarification of the intent of OFPA drafters on the use of pheromones and other semiochemicals.

Another item that will feature prominently in discussions on pear ester is its categorization based on the various delivery systems used in deploying them. This will inform the possible introduction of an annotation to distinguish between systems that may be consistent and inconsistent with OFPA.

Category 2: Adverse Impacts of Pear Ester

Human Health Impacts

Pear ester is a Generally Recognized as Safe (GRAS) food additive. In 2013, the EPA exempted it from the need to establish food tolerance for residues in or on food crops at 40 CFR 180.1323. The EPA concluded that "there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposures to ethyl-2E-4Z-decadienoate (pear ester)" (78 FR 53051, August 28, 2013). Pear ester has low acute toxicity to mammals, and the oral LD₅₀ for rats is 4,027 mg/kg. This number means pear ester is nearly non-toxic. Additionally, pear ester is an FDA-approved food additive, and average human consumption in the U.S. is about 3 μ g per day (US EPA, 2013). According to the EPA, pear ester also has low chronic toxicity, and is not a likely developmental toxicant or mutagen. It is not on the EPA list of carcinogens, or on the IARC carcinogen list. The EPA reported in 2013 that pear ester had not been evaluated for endocrine disruption.

Even though the 2024 technical report on pear esters found no publications indicating harm to humans from pear ester or polyamide particulates, the product's safety data sheet states that it may cause allergy or asthma symptoms or breathing difficulties if inhaled. Contact with skin or eyes may cause irritation. It must be noted that the food tolerance exemption provided by the EPA does not include an evaluation for occupational exposure. The maximum label amount is about 400 µg pear ester/day, which is well below the acute toxicity of 4027 mg/kg. Pear ester vapors are not likely a health problem for orchard workers.

Exposure to Polyamide Particulates

Sprays of about 30 g/ha decadienoic acid (DA) ethyl ester (i.e. pear ester), commercially known as DA MEC[™], are applied to tree canopies with an air blast sprayer (Cidetrak, 2020). Even though exceedingly tiny amounts of DA MEC[™] are used, the sprays contain a large number of small polyamide particles. Each tree canopy receives about five hundred million microencapsulated pear ester particles. There might be a respiratory hazard from inhaling plastic microparticles when the spray is applied by air blast sprayer to individual trees. However, effects of exposure to the polyamide spherical capsules in the spray have not been evaluated by the EPA. Given the 4-hr re-entry restriction, the greatest acute risk is probably during spray applications with an air blast sprayer. But the DA MEC[™] label does not require respiratory protection for workers (Cidetrak, 2020). It is important to note that maximum 8-hr worst case chronic exposure would be about 0.0357 mg/m³ or 36 µg/m³. This exposure is below the U.S. 24-hr particulate standard of 150 µg/m³ for PM 10 (89 FR 16202, May 6, 2024).

Given the fact that sprayable microencapsulated pheromone particles can be washed out of tree canopies by wind, rain, and overhead irrigation sprays, pear esters are assumed/expected to meet the same fate.

Environmental and Ecological Health Impacts

The EPA did not require testing for bird, fish, and aquatic invertebrate toxicity because pear ester is expected to quickly disperse and degrade in the environment. However, the pear ester safety data sheet from Boudakian Research (Boudakian Research, 2023) states that pear ester is "very toxic to aquatic life with long lasting effects." The substance is, however, exempt from testing for toxicity to bird, fish, and aquatic invertebrates. According to the safety data sheet, pear ester is a marine toxicant and hazard (Boudakian Research, 2023). Environmental damage may be mitigated by the low application rate of 12 g DA MEC[™]/acre or 30 g/ha. That is about 0.27 mg DA MEC[™]/ft². That is a small amount, but each ml of the usual diluted field spray contains about 260,000 particles (Light & Beck, 2010). Once applied, microcapsules probably stay on the leaves until dislodged by wind and rain, which is the case for microencapsulated sprayable pheromones (A. L. Knight et al., 2004). When particles are dislodged by rain, they likely become part of runoff from an orchard (Trécé, Inc., 2023). Once the microencapsulated particles reach water, fish or other aquatic creatures might ingest them. No density information is given (Light & Beck, 2010), but it is likely the polyamide particles are less dense than water. The pear ester contained in the microparticles is an aquatic hazard (Boudakian Research, 2023). The 2024 technical report found no information on the environmental effects of pear ester polyamide microcapsules. There is no published information on the effects of these particles on earthworms. Birds can be exposed by feeding on earthworms that ingest polyamide microcapsules. However, again, the amounts of pear ester involved are exceedingly small. Because of its volatility, pear ester dissipates quickly in the environment. Manufacturers encapsulate volatile components of spray formulations to limit volatilization and produce products that have a lasting effect (US EPA, 2013).

The EPA did not require the product manufacturer to submit environmental toxicity tests of microencapsulated pear ester (US EPA, 2013).

Category 3: Alternatives/Compatibility

Performance of Alternatives

It is important to note that codling moth management performance of natural alternatives to synthetic pear ester tend to be enhanced when combined with the synthetic product. Products such as granulosis virus, Spinosad, BT products and the use of degree day methods are employed against the codling moth. The performance of these alternatives is, however, enhanced by pear ester in monitoring traps to determine the biofix point and, thus, the correct and most effective timing of pesticide applications.

Subcommittee Next Steps:

The NOSB has deemed the 2024 TR sufficient and has used the document as a basis for the Fall 2024 discussion document and the ongoing proposal for the Spring 2025 meeting. Comments received so far on pear ester have been positive.

The CS will seek additional information on the reasons behind the EPA not requiring testing for fish and aquatic invertebrate toxicity given the fact that the safety data sheet for pear ester states that it is a marine toxicant and hazard (Boudakian Research, 2023).

Questions for Stakeholders:

The CS has the following specific questions for stakeholders and welcomes any additional perspectives, solutions, and information related to pear ester.

- 1. Additional/new research-based information on the environmental and human health impacts of pear ester used in microencapsulated formulations and in traps.
- 2. Information on other kairomones that may be in use in the management of moths and other major insect pests.

Subcommittee Vote:

Motion to classify pear ester as synthetic. Motion by: Franklin Quarcoo Seconded by: Brian Caldwell Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Motion to add pear ester to the National List at §205.601(j). Motion by: Franklin Seconded by: Logan Yes: 6 No: 0 Abstain: 1 Recuse: 0 Absent: 0