United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

# Ethylene

## Handling/Processing

### Identification of Petitioned Substance

**Chemical Names:**
acetene; $C_2H_4$; elayl; ethene

**Other Name:**
bicarburreted hydrogen; olefiant gas

**Trade Names:**
Banana Gas; Color Ripe; Ethylene; Fruit Ripening Ethylene; Natur-Ripe

**CAS Numbers:**
74-85-1

**Other Codes:**
UN II: 91GW059KN7
EPA: PC code 41901
EC number: 200-815-3

### Summary of Petitioned Use

The United States Department of Agriculture (USDA) National Organic Program (NOP) included ethylene on National List of Allowed and Prohibited Substances (hereafter referred to as the National List) at 7 CFR 205.601(k) as originally published December 2000, for use to regulate flowering in pineapple (65 FR 80547). It was also listed for post-harvest handling to ripen tropical fruit at §205.605(b). In November of 2003, the NOP changed the annotation for the post-harvest allowance to also allow for degreening of citrus (68 FR 61987). This Handling technical report focuses on the post-harvest handling uses of ethylene for tropical fruit ripening and citrus degreening, while the Crops technical report principally addresses the use of ethylene to regulate pineapple flowering.

### Characterization of Petitioned Substance

**Composition of the Substance:**

$C_2H_4$

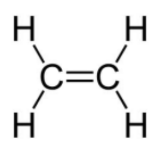

**Figure 1: Structure of ethylene** (CanHealth, 2016)

Ethylene is the simplest of the alkenes. Alkenes are defined as hydrocarbons with a carbon-carbon double bond (Bruice, 2001). Hydrogen atoms surround the two-carbon chain. The structure is analogous to ethane ($C_2H_6$), but with a double bond rather than a single bond and fewer hydrogen atoms (see Figure 1).

Ethylene is a colorless, flammable gas that is lighter than air and has a sweet odor and taste (NCBI, 2022a). When ignited, it can quickly burn back to the source of the leak. It can be shipped as a gas in canisters, or as a refrigerated, pressurized liquid (cryogenic liquid) which must be shipped below 50°F (10°C). Fruit producers and handlers sometimes make ethylene on site, converting ethanol with a catalytic generator (see *Evaluation Question* #2). Vapors arising from the boiling liquid are lighter than air (NCBI, 2022a). It is non-toxic, but it is an asphyxiant (NCBI, 2022a). Under prolonged exposure to fire or intense heat, containers of ethylene may rupture violently and rocket (NCBI, 2022a).

Synthetic ethylene gas used in crop production is chemically identical to the natural form produced by plants (Abeles, 1992; Bartholomew, 2014).

**Source or Origin of the Substance:**
Most ethylene gas manufactured globally is made as a pyrolysis product of petroleum hydrocarbon feedstocks, such as natural gas liquids or crude oil (NCBI, 2022a; Zimmerman & Waltz, 2011). Ethylene gas can also be produced in small quantities in on-site fruit ripening facilities by catalytic generators from ethanol (Zimmerman & Waltz, 2011; NW Hort. Council, 2008).

**Properties of the Substance:**
Ethylene is a colorless gas with a sweet odor and taste, and is lighter than air.

**Table 1: Chemical and Physical Properties of Ethylene**

| Property | Value[a] |
|---|---|
| Physical State and Appearance | Colorless gas with a sweet odor. Pressurized liquid when shipped below 50°F. |
| Odor | Sweet odor |
| Taste | Sweet taste |
| Color | Colorless |
| Molecular Weight | 28.05 g/mol |
| Solubility | Slightly soluble in water, 131 mg/L at 25 °C. Very soluble in ethanol, ether; soluble in acetone, benzene. |
| Boiling Point | -103.7 °C |
| Melting Point | -169.0 °C |
| Vapor Pressure | 0.978 (lighter than air) |
| Stability | Stable under recommended storage conditions. |

[a] *Source: (National Institutes of Health: https://pubchem.ncbi.nlm.nih.gov/compound/6325)*

**Specific Uses of the Substance:**

Ethylene is used in organic post-harvest handling for ripening of tropical fruit and degreening of citrus. Ethylene products are labeled in the U.S. for ripening avocados, bananas, kiwis, melons, mangos, papayas, pears, persimmon, pineapple, stone fruits, tomatoes, and other fruiting vegetables (Airgas, 2011; Livingston, 2005). Ethylene products are also labeled for sprout suppression in stored potatoes (Airgas, 2011) and to accelerate flue curing of tobacco (Livingston, 2008).

For bananas, treatment with ethylene gas allows traders to minimize loss in transportation and to release product in a timely manner at the desired ripening stage (Maduwanthi & Marapana, 2019). Producers of dried mango and papaya products use ethylene gas in order to obtain uniform ripening and thereby provide a predictable supply for drying. Ethylene treatment also prevents loss from extra handling and multiple sorting operations, as mangos and papayas naturally ripen at uneven rates (Santero, 1999).

For post-harvest ripening of tropical fruit, producers or handlers introduce ethylene into sealed ripening rooms that are controlled for temperature, humidity, ventilation and air circulation (Kays & Beaudry, 1987). Different products require different rates of ethylene and time periods for holding. For instance, bananas are gassed at concentrations of 100 ppm for 24 hours, then held in the ripening room for 6-7 days before being shipped to retailers. Ethylene gas can be introduced using pressurized bottles of gas (steel cylinders) in a "one shot" method, or by a flow-through system where the gas is slowly metered into a vented room where fresh air is constantly being introduced. The flow-through method prevents a build-up of carbon dioxide and maintains the ethylene concentration longer (Kays & Beaudry, 1987).

Handlers also use catalytic generators on site for ripening rooms that produce ethylene by a dehydration process using a solid bed catalyst. These generators produce a relatively pure source of ethylene, which is diluted with air as it goes into the ripening room. The primary advantage of catalytic generators is safety (less chance of fire or explosion). Improper use of bottled gas cylinders has resulted in serious accidents (Kays & Beaudry, 1987).

Handlers degreen citrus in a similar manner as for ripening of tropical fruit, by placing in a controlled ripening room (Airgas, 2011). However, ethylene levels used are much lower at 1-10 ppm (Airgas, 2011). Handlers use degreening methods for early varieties of citrus that are physiologically ripe, to accelerate peel color change in order to extend the market season. It is also used in warm, tropical climates like Florida and India where natural color development is weaker (Mayuoni, et al., 2011).

The USDA NOP and the National Organic Standards Board (NOSB) have not provided a definition of the term "tropical fruit." The NOSB voted in October 1999 to approve the use of ethylene for ripening of "tropical fruit" and for degreening of citrus. The NOSB recommendation did not specify which types of tropical fruit, although the early Technical Advisory Panel review mentioned bananas, mangos, and papayas (NOP 1999b). The UN Food and Agriculture Organization (FAO) considers that the "major" tropical fruits are pineapple, avocado, papaya, and the commodity group that includes mango, mangosteen, and guava (FAO, 2011). There are many other species of fruit that are grown in tropical regions. The website for a manufacturer of catalytic generators describes uses for organic producers, including: "bananas, mangoes, avocados, and perhaps more, contact your certification agency" (Catalytic Generators, 2022).

**Approved Legal Uses of the Substance:**

*Environmental Protection Agency (EPA)*
Ethylene is considered a plant growth regulator (pesticide) and has an exemption from the requirement of a tolerance for residues at 40 CFR 180.1016:

> §180.1016. Ethylene is exempted from the requirement of a tolerance for residues when:
> a. For all food commodities, it is used as a plant regulator on plants, seeds, or cuttings and on all food commodities after harvest and when applied in accordance with good agricultural practices.

In the United States, pesticide manufacturers must register their products with the EPA as well as the appropriate state pesticide control agencies (EPA, 2022; NPIC, 2022).

*USDA Animal Plant Health and Inspection Service (APHIS)*
USDA APHIS has an active program to control witchweed, a parasitic plant that can significantly damage corn, rice, sorghum, and sugarcane. In 2021, APHIS worked with cooperating farmers to treat 999 acres out of an estimated 1,600 acres infested. Methods used included tillage, herbicides, hand pulling, and the use of ethylene gas injection to cause premature seed sprouting (USDA APHIS, 2022; EPA, 1995).

*United States Food and Drug Administration (FDA)*
FDA includes "treating to manipulate ripening" under the definition of "manufacturing /processing" at 21 CFR 117.5 and 21 CFR 112.3. These food safety regulations consider that "treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the 'farm' definition." This means that use of on-farm ripening rooms would not cause a farm to be considered a manufacturing facility, subject to additional regulation under FDA food safety rules.

**Action of the Substance:**

Ethylene is a plant growth regulator that is produced naturally by plants and has effects on many aspects of plant growth, development, and survival, including (Chang, 2016):
- seed germination
- shoot growth
- root development

- flowering, sex determination
- fruit ripening
- abscission of leaves and fruits
- senescence of flowers and leaves

Ethylene also has a role in plant adaptation to a variety of stresses, such as drought, flooding, pathogen attack and high salinity (Chang, 2016).

Ethylene is biosynthesized by a series of reactions which transform methionine into ethylene:

L-methionine
↓
S-adenosylmethionine (SAM)
↓
1-aminocyclopropane-1-carboxylic acid (ACC)
↓
ethylene

The biosynthesis process is regulated at each step by enzymes and other factors that control the amount of ethylene produced (Chang, 2016; Schaller, 2002). Ethylene can promote or inhibit growth and senescence processes in plants, depending on its concentration, timing of internal production or external application, and the plant species (Iqbal, 2017).[1] The specific mechanism of action of ethylene in plants continues to be under active investigation. Plants increase the production of ethylene-related enzymes in response to environmental cues and stresses such as wounding, drought, low temperature, or flooding (Chang, 2016).

In general, ethylene gas is produced in fruit when physiological maturity is reached. Bananas, papayas, mangoes and other fruits such as apple, avocado, fig, guava, kiwi, passion fruit, pear, peach, persimmon, plum, sapodilla and tomato are considered "climacteric" fruits (Maduwanthi & Marapana, 2019). This means that as ripening proceeds, there is a strong peak in respiration rate of the fruit, accompanied by high levels of internal ethylene production.[2] Non-climacteric fruits include citrus, pineapple, pomegranate, melons, strawberry, and grape, among others. In non-climacteric fruits, the respiration rate is almost constant, or shows a steady decline until senescence occurs, with little or no increase in internal ethylene production. Climacteric fruits are capable of ripening after harvest, and generally show a response to exogenous ethylene. The gas triggers the chemical changes (starch conversion to sugar, cell wall softening) which take place at ripening. This causes them to ripen more rapidly and to produce more ethylene naturally (Maduwanthi & Marapana, 2019).

When used for degreening of citrus, ethylene does not stimulate ripening of the fruit. Instead, ethylene affects the ripening-related processes that lead to the destruction of chlorophyll and accumulation of orange/yellow carotenoids in the peel tissue (Mayuoni et al., 2011).

**Combinations of the Substance:**

Ethylene is a colorless gas used in compressed gas form (bottled), or generated on–site in gas form.

There are currently five active registrants of agricultural grades of ethylene gas in the U.S., with seven labeled products. They are labeled with ethylene concentrations ranging from 98.5% to 99.9% (NPIRS, 2022). One product (Banana Gas 32, Praxair) is labeled as containing 6.3% ethylene and 93.7% carbon dioxide. Ethylene used in post-harvest ripening is sometimes combined with nitrogen gas to limit flammability (NWHort, 2008).

[1] Senescence is a process of deterioration due to age; biological aging.
[2] The respiration rate is the rate at which the cell breaks down stored carbohydrates in the presence of oxygen, to produce carbon dioxide, water, and stored energy (ATP).

## Status

**Historic Use:**

The NOP added ethylene to the National List as published December 2000 for use to regulate flowering in pineapple (FR 65 80547). It was also included for post-harvest handling to ripen tropical fruit. In November of 2003, the NOP made a change to the annotation for the post-harvest allowance to also allow for degreening of citrus (68 FR 61987). Prior to the USDA organic regulations, private certifiers and state programs in the U.S. generally allowed ethylene for use to ripen bananas, and some permitted ripening of mangos (NOP, 1999b).

The NOSB voted in October 1999 to recommend approval of the use of ethylene for ripening of "tropical fruit" and for degreening citrus. The NOSB recommendation did not define tropical fruit, although the Technical Advisory Panel review mentioned bananas, mangos, and papayas (NOP, 1999b). They also voted at that meeting to reject the use of calcium carbide for ripening, and the use of ethylene to improve bean sprout production.[3] A petition to modify the handling annotation to permit ethylene gas use for ripening pears was received by NOP in 2008, however the NOSB voted to reject this use in November 2008.

Early uses of natural ethylene included the gashing (wounding) of figs in the Middle East to promote fruit growth and ripening, and the use of weights to encourage bean sprout thickening (Abeles, 1992). Both cases resulted in stress-induced ethylene production by the plants (Abeles, 1992). Farmers have long used smoke (e.g., from wood or combusted kerosene) or off-gassing from ripe fruit to hasten fruit ripening, even before ethylene was recognized as the active agent (Collins, 1960; Kays & Beaudry, 1987).

**Organic Foods Production Act, USDA National Organic Program regulation**

*Organic Foods Production Act of 1990:*
Ethylene is not specifically mentioned in the Organic Foods Production Act. It is not specifically mentioned as an allowed class of materials at 7 U.S.C. 6517(c)(1)(B), however it could be considered a "production aid," which is a permitted class.

*USDA NOP regulation:*
Ethylene is approved for organic crop use:

> 7 CFR 205.601(k) as plant growth regulators. (1) Ethylene gas - for regulation of pineapple flowering.

Ethylene is also approved for organic handling use:

> 7 CFR 205.605(b) Ethylene - allowed for postharvest ripening of tropical fruit and degreening of citrus.

**International**

*Canada, Canadian General Standards Board – CAN/CGSB-32.311-2020 Organic Production Systems Permitted Substances Lists*
Ethylene is allowed for organic use under the Canadian Organic Production Systems, General Principles and Management Standards (CAN/CGSB-32.310-2020). Clause 1.5 states that plant growth regulators are prohibited except if listed in the Permitted Substances Lists (PSL), CAN/CGSB-32.311.

The PSL states at Table 8.3 - Post-harvest substances:

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[3] Calcium carbide reacts with water to form acetylene, which degrades to yield ethylene. It is still used in some countries to induce flowering in pineapple by directly applying the granules into the center whorl of leaves. It also is used in some countries in sachets in fruit boxes to ripen bananas or mangos. It is not legal in the U.S. or Sri Lanka due to food safety concerns (Maduwanthi & Marapana, 2019).

> "Ethylene: For post-harvest ripening of tropical fruit and degreening of citrus and to control sprouting of potatoes post-harvest in holding bins."

*CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)*
Codex guidelines do not mention the use of ethylene, and it is not included in Annex 2 as a permitted substance (Codex, 2007).

*European Economic Community (EEC) Council Regulation – EC No. 834/2007, 889/2008, 2018/848 and 2021/1165*
Ethylene is permitted as listed in Annex 2, Pesticides — plant protection products.

> "Ethylene: Degreening bananas, kiwis and kakis; Degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions" (EEC, 2008).

The most current EU organic standards, 2018/848, which became enforceable in January 2022, permit ethylene under 2021/1165 Annex I, "Active substances contained in plant protection products authorised for use in organic production as referred to in point (a) of Article 24(1) of Regulation (EU) 2018/848:"

> "Only on bananas and potatoes; however, it may also be used on citrus as part of a strategy for the prevention of fruit fly damage."

*Japan Agricultural Standard (JAS) for Organic Production*
The JAS standards (JAS, 2017) list ethylene in Appended Table 5, as:

> "Ethylene, Limited to those used for ripening bananas, kiwifruits and avocados after harvest."

*IFOAM – Organics International*
Ethylene is listed as approved in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handling aids:

> "Ethylene: De-greening of citrus and ripening." (IFOAM, 2018)

## Evaluation Questions for Substances to be used in Organic Handling

**Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**

*Thermal cracking*
Ethylene is the petrochemical produced in the largest quantities worldwide (IARC, 1994). In 2014, world ethylene production was 134 million (metric) tonnes (Lazonby, 2017). As of 1994, over 95% of worldwide annual production is based on thermal "cracking" of petroleum hydrocarbons with steam (IARC, 1994). These fractions are obtained from drilling (or hydrofracturing) of oil or natural gas. Thermal cracking (sometimes referred to as pyrolysis) is a chemical process by which long chain hydrocarbons with higher molecular masses are converted to short chain hydrocarbons of lower molecular mass.

Various feedstocks, including ethane, propane, butanes, naphthas and gas oils are used to produce ethylene, depending on availability, price, and products desired (Lazonby, 2017). Naphthas are the principal raw material used in western Europe and Japan, accounting for over 80% of the ethylene produced. Ethane is the primary feedstock in the U.S., followed by propane, naphthas, gas oils, and butane (Zimmerman & Waltz, 2011).

In thermal cracking the feedstock gases (ethane, propane or butane) or the liquids (naphtha or gas-oil) are preheated and vaporized, and are mixed with steam and heated to 1050-1150 K (777-877 °C) in a tubular reactor. The high temperature and pressure cause the long chain hydrocarbon to be converted to low relative molecular mass alkenes plus by-products (Lazonby, 2014).

World use of ethylene (134 million tonnes, 2014) (Lazonby, 2017)

- 60% - polyethylene
- 16% - ethylene oxide
- 11% dichloro-1,2-ethane (precursor to PVC, polyvinyl chloride)
- 5% - ethylbenzene (precursor to polystyrene)

A "relatively small" amount of industrially produced ethylene gas is used for agriculture and controlled ripening (IARC, 1994). No estimate was found of the actual amount used in agriculture or post-harvest ripening per year.

*Catalytic cracking*

Catalytic cracking uses a catalyst, typically a zeolite, which adsorbs the long-chain hydrocarbon feedstocks and removes hydrogen atoms. [4] This causes the long chains to split into shorter chain molecules with double bonds, which are useful to the petrochemical industry. The feedstock is gas oil, which is vaporized, passed through a fine zeolite powder, and heated to 700-800 K (427 - 527 °C) in a reactor. The products behave like a fluid and continuously flow out of the furnace with the cracking products. The temperature, residence time, and the catalyst determine the product proportions (Lazonby, 2014).

*Dehydration of ethanol*

Dehydration of ethanol is another commercial route to ethylene (IARC, 1994; Zimmerman & Waltz, 2011; Fan 2013). In the catalytic dehydration of ethanol to form ethylene, an acid catalyst first protonates the hydroxyl group, which leaves as a water molecule. The conjugate base of the catalyst then deprotonates the methyl group, and the hydrocarbon rearranges into ethylene (Fan, 2013). This method is not used commonly to produce large volumes of ethylene as it is endothermic with a high optimal reaction temperature (180-500 °C), which makes the ethylene expensive to produce. Dehydration of bioethanol is occurring in Brazil and India and holds promise for producing ethylene from non-fossil fuel sources (bioethanol from sugar cane or cellulose). At present the output is relatively limited, and used for further production of polyethylene (Fan, 2013; Lazonby, 2017; Schill, 2010).

*Catalytic generators*

Small catalytic generators are used in sealed ripening rooms to dehydrate ethanol into ethylene, and can deliver controlled levels of ethylene gas to ripen fruit, e.g., 100-150 ppm for bananas. (NWHort 2008, Catalytic Generators 2022). This process uses dehydration of ethanol by passing it over a bed of solid catalyst held at high temperatures. The catalysts are typically activated alumina and phosphoric acid or zinc oxide with alumina (Kays & Beaudry, 1987).

**Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.**

As described in *Evaluation Question #1*, the principal source of commercial ethylene is from thermal or catalytic cracking of hydrocarbon feedstocks such as natural gas or crude oil. During this process chemical bonds within the hydrocarbon molecules are broken, and a different chemical substance is produced.

Catalytic cracking uses a catalyst, typically a zeolite, which absorbs the long-chain hydrocarbon feedstocks by removing hydrogen atoms, and causes the long chains to split into shorter chain molecules with double bonds (Lazonby, 2014). Small catalytic generators dehydrate ethanol by a similar process (Kays & Beaudry, 1987).

[4] Zeolites are hydrated aluminum silicate compounds that may occur naturally as minerals but may also be produced synthetically.

All of these methods involve reactions which produce a chemically changed substance (ethylene) from either petroleum feedstocks, or from dehydration of ethanol mediated by catalysts. Thus all these forms should be considered synthetic (NOP, 2016a) and from nonagricultural sources (NOP, 2016b).

**Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)).**
A traditional method in Sri Lanka for ripening bananas involves laying them in a pit covered with banana leaves or a sheet cover. Smoke generated from burning dried leaves is directed into the pit. Smoking induces faster ripening, but compared to other methods it led to less marketability due to blackening and over-softening (Maduwanthi & Marapana, 2019).

Ripening fruit produces ethylene, and Sherman (1985) suggested that operators of ripening rooms could carefully monitor ethylene production in the rooms and control ripening that way. However, he conceded that this method is generally only useful for home ripening of fruit. Researchers in Nepal (Pokhrel, 2015; and Ruwali et al., 2022) have explored the use of apples and suggested using avocados, pears, or tomatoes as ripening agents. See Evaluation Question #12 for more details.

**Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.**
Ethylene is not listed as GRAS, or regulated by FDA. It is considered a pesticide by EPA and exempt from any residue tolerance restriction at 40 CFR 180.1016.

FDA does include "treating to manipulate ripening" under the definition of "manufacturing /processing" in 21 CFR 117.5: *Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food*. These food safety regulations consider that "treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the 'farm' definition." This mean that use of on-farm ripening rooms would not cause a farm to be considered a manufacturing facility, as related to FDA food safety rules.

**Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR 205.600(b)(4)).**
Ethylene is used post-harvest to accelerate ripening. This use is not as a preservative, since it actually shortens the storage life of the produce, as for example in bananas (Ahmad et al., 2001). Ethylene-absorbing sachets are sometimes included in products to remove ethylene and prolong storage life.

**Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR 205.600(b)(4)).**
Ethylene gas is applied to a raw agricultural product that is not otherwise processed. It is used to accelerate the ripening process, which improves the color, flavor and texture of produce as would eventually occur naturally during unaided ripening (Abeles, 1992; Kays & Beaudry, 1987). Ethylene used in degreening citrus improves the color of raw unprocessed citrus (Mayuoni et al., 2011).

**Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).**
After ethylene was identified in the 1920s as the chemical that hastened ripening in many fruits, researchers were concerned over the possibility that its use might cause undesirable effects in nutritional and other quality factors. Kays & Beaudry (1987) reviewed a number of studies conducted on fruit quality and found, in general, that fruits that had been induced to ripen using ethylene were of comparable quality to those at a similar stage of maturity that had ripened naturally. For treatment of ethylene to be effective at accelerating ripening, the crop treated must be physiologically mature, i.e., capable of continuing normal ripening when detached from the plant (Abeles, 1992; Sherman, 1987).

In a review of methods for inducing banana ripening, the authors found that the use of ethylene or acetylene did not significantly affect the final levels of sugar, starch or the soluble solids content in ripe pulp (Maduwanthi & Marapana, 2019). Authors of another study on sensory evaluations of bananas in relation to flavor, sweetness, astringency and acceptability found significant superiority of bananas ripened at higher temperatures (20°C) and with ethylene treatment over those ripened at lower temperature (14°C) and without ethylene treatment (Ahmad et al., 2001). This study demonstrated that stage of ripeness was the most important factor in banana quality, rather than the ethylene and temperature treatment (Ahmad et al., 2001).

One study did indicate that naturally ripened bananas contained more aroma compounds, both qualitatively and quantitatively, than those with ripening induced by ethylene (Sonmezdag et al., 2014). The authors of the study observed no major differences in total soluble solids, pH, ash, starch, or concentration of glucose and fructose after ethylene treatment as compared to naturally ripened samples. Sucrose content did decrease significantly and firmness was slightly higher for treated bananas. Based on sensory analysis, non-treated bananas were preferred because of their better fruity aroma and general impression attributes (Sonmezdag et al., 2014). An earlier study found that exogenously applied ethylene caused banana skin to ripen more quickly than the flesh. The authors suggested that at the same peel color rating, a naturally ripened banana would be riper than an ethylene-treated banana (Scriven et al., 1989).

Several studies examining the postharvest application of ethephon[5] on mangos indicated it increased total aroma volatiles, including monoterpenes, sesquiterpenes, aldehydes, esters, and tetradecane in 'Kensington Pride' mangos (Lalel et al., 2003; Singh, 2011).

A study on the quality of citrus fruit when treated with ethylene for degreening demonstrated that there was no effect on flavor perception, vitamin C content, total phenols and flavonoids, or antioxidant activity of citrus juice. The authors concluded that ethylene is probably not involved in the internal ripening process in citrus, a non-climacteric fruit, and does not affect fruit quality (Mayuoni et al., 2011).

**Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).**
Ethylene is not considered a food ingredient, and is not regulated by FDA (see *Approved Legal Uses of the Substance*, above). It is exempt from residue tolerances established by EPA when used as a postharvest plant growth regulator on food crops.

The purity of ethylene is normally greater than 99.9 % by weight; quality is adjusted to meet specific requirements (IARC, 1994). Sulfur, oxygen and acetylene can be impurities but are carefully controlled. A survey of ten US manufacturers in 1993 yielded the following specification ranges (mg/kg) for maximal levels of key contaminants in ethylene (IARC, 1994):

- methane + ethane, 50–2000
- propylene, 7–200
- acetylene, 1.4–10
- hydrogen, 0.1–10
- carbon monoxide, 0.15–10
- carbon dioxide, 2.2–50
- oxygen, 0.6–10
- sulfur, 1–10
- water, 0.6–20

Ethylene gas sold as banana gas includes carbon dioxide as a second ingredient (NPIRS, 2022).

[5] Ethephon is an ethylene releasing compound with the chemical name (2-chloroethyl)phosphonic acid; also known by the trade name "*Ethrel*."

**<u>Evaluation Question #9:</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)).**

*Contamination from manufacturing*

The cracking of naphtha or of ethane to manufacture ethylene is highly energy-intensive (Ghanta et al., 2014; Zimmerman & Waltz, 2011). The energy expended during the extraction and ocean-based transportation of fossil fuel sources (crude oil and natural gas) contributes significantly to adverse environmental impacts such as greenhouse gas emissions, acidification, and eco-toxicity (air and water). A life-cycle assessment comparing environmental impacts for thermal and steam cracking of hydrocarbons to dehydration of bioethanol from corn or biomass found similar requirements for energy and overall impact on the environment. The fuel burning to produce energy at power plants was deemed by far the biggest contributor to the various adverse environmental impacts for all methods (Ghanta et al., 2014).

Zimmerman & Waltz (2011) note that the manufacture of ethylene does produce “significant” amounts of carbon dioxide, and notes that this may be a factor in development of alternative technologies for production of ethylene. Zhao et al. (2018) looked at the production life cycle for ethylene and state that the chemical industry, which is highly energy-dependent, is responsible for 16% of direct global $CO_2$ emissions. Ethylene, as one of the most important chemicals in use, consumes 30% of the total energy of the chemical industry. This study found that China reduced $CO_2$ emissions by 29.4% per ton of ethylene produced from 2000-2016 due to improvements in technology, and evaluated various methods for future increased reductions (Zhao et al., 2018).

Petroleum refineries are a major source of hazardous and toxic air pollutants such as benzene, toluene, ethylbenzene, and xylene (EPA, 2003). They are also a major source of other air pollutants: particulate matter, nitrogen oxides, carbon monoxide, hydrogen sulfide, and sulfur dioxide. Refineries also release natural gas (methane) and other light volatile fuels and oils. Some of the chemicals released are known or suspected cancer-causing agents, responsible for developmental and reproductive problems. Refineries are also potential major contributors to ground water and surface water contamination. Some refineries use deep-injection wells to dispose of wastewater generated inside the plants, and some of these wastes end up in aquifers and groundwater (EPA, 2003).

*Contamination through use*

When synthetic ethylene gas is used in postharvest handling, it is applied in closed rooms or containers which are then vented to the atmosphere. Since ethylene is a gas at environmental temperatures, this is the primary route of exposure to the environment. Health Canada considered environmental modelling studies and found that ethylene released to the air will remain in the air, and that only negligible amounts will partition to soil, water and sediment (HealthCan, 2016).

According to the U.S. EPA Toxic Release Inventory (EPA, 2021), in 2021 the total release of ethylene as airborne emissions in the U.S. was 18.2 million pounds. Of that, 17.2 million pounds was emitted by the chemical manufacturing industry, and 0.7 million pounds was from the petroleum industry. It is not known how much ethylene is released in the atmosphere due to ripening and degreening uses. It is no doubt much smaller than the amount estimated to be applied to pineapple crops in the field. The Food and Agriculture Organization of the United Nations estimates that in 2021, there were 1,046,712 hectares of pineapples grown worldwide (FAO, 2022). If every hectare in the world was treated with 800 grams of ethylene (unlikely, as the harvest takes 12-18 months from flower induction), that would result in application of 837,369 kg (1,846,082 pounds) totally.

*Ecotoxicity*

The Health Canada screening review (HealthCan, 2016) found no effects data on invertebrates or birds, which are most likely to be exposed to ethylene. Ethylene is not expected to be released to water and thus no water exposure is expected. Health Canada did not find adequate empirical toxicity studies on aquatic species. Health Canada’s review of mammalian studies also found that the concentrations of ethylene tested to determine adverse levels in rats are considerably higher than concentrations expected in the Canadian environment.

Health Canada noted that terrestrial plants are highly sensitive to ethylene in air, and considered that was the primary risk for environmental concerns. They performed a risk quotient analysis based on industrial monitoring dates for four years, and found on average one occurrence per year that had potential to be harmful to plants. The agency concluded that there is little risk of harm to the environment or to organisms since the substance is not present in quantities or concentrations that could cause long term harmful effects on the environment or biodiversity (HealthCan, 2016).

**<u>Evaluation Question #10:</u> 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)).**

The main safety concern in relation to ethylene use has been due to the explosive nature of the gas in the air. This is of primary concern in design and operation of ethylene treatment facilities. The EPA, local fire marshal rules, and insurance companies all have very specific labelling and registration requirements for the ethylene itself and the process used to apply it, down to the electrical wiring and piping used in ripening rooms (Sherman, 1985). The gas is explosive in air at concentrations from 3.1% to 32% (31,000 to 320,000 ppm). The minimum explosive concentration (3.1%) exceeds the suggested ethylene concentrations for tomato ripening and citrus degreening respectively by 200 and 6,200 times (Sherman, 1985). The "banana gas" (cylinders with 6% ethylene content) and catalytic generator sources of ethylene are considered the safest because they are more easily monitored, but explosive accidents have happened in the past, and operators should be well trained and prepared (Sherman, 1985).

Ethylene is highly flammable and explosive. Overexposure causes headache, drowsiness, and muscular weakness (NOAA, n.d.). High concentrations of ethylene (>1000 ppm) can cause dizziness or light-headedness. For several decades in the 1900s, ethylene was used as a general anesthetic (Chang, 2016; EPA, 1992).

Ethylene is classified as a simple asphyxiant and acts primarily to limit oxygen (OSHA, 2018). The U.S. Department of Labor Occupational Safety and Health Administration (OSHA) limits exposure levels in OSHA Construction and Maritime standards. The limiting factor is the available oxygen which shall be at least 19.5% in construction and at least 18% for maritime standards (OSHA, 2018).

Exposure to 37.5% ethylene for 15 min may result in marked memory disturbances (NCBI, 2022b).Humans exposed to as much as 50% ethylene in air, where the oxygen availability is decreased to 10%, experienced a loss of consciousness. In fatal human intoxication, ethylene affects the respiratory center of the brain and kills by suffocation. In workers chronically exposed, ethylene has been associated with a decrease in maximum arterial pressure, slower pulse, decreased visual-motor response, hearing and smelling loss, and problems with bodily temperature control (NCBI, 2022b).

Occupational exposure to ethylene may occur through inhalation and dermal contact at workplaces where ethylene is produced or used. Monitoring data indicate that the general population may be exposed to ethylene via inhalation of ambient air and smoking cigarettes (NCBI, 2022a; NCBI, 2022).

According to the National Institutes of Health Hazardous Substance Database, there is inadequate evidence in humans for the carcinogenicity of ethylene, and it is “not classifiable as a human carcinogen” (NCBI, 2022b).

Based on *in vivo* and *in vitro* studies, ethylene does not induce gene mutations (HealthCan, 2016). Using rats as a model organism, these studies show that ethylene is not carcinogenic when inhaled over a two year period. In addition, epidemiology studies do not show evidence of cancer in exposed workers, although these studies are limited. For other non-cancer health effects, the “lowest-observed-adverse-effect concentration” (LOAEC) for inhalation exposure in rats is 11,500 mg/m$^3$ (10,000 ppm) based on slight nasal effects observed in rats in a 13-week inhalation study (HealthCan, 2016).

Health Canada compared the upper bounds of estimates of exposure from ethylene in indoor and outdoor locations[6] to the critical effects levels observed in the literature and concluded that ethylene does not enter the environment in enough quantity or concentration to be of concern for human health (HealthCan, 2016).

**<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).**

An alternative to using ethylene for post-harvest ripening is to let the fruit ripen naturally. This can be done for local markets where fruit is picked closer to full ripeness and time to market is short.

Researchers have found that low-moderate temperatures (6-15 °C) as the fruit is maturing on the tree promotes peel degreening (Manero et al., 2012). Mitalo et al. (2020) investigated the relationship between temperature in storage and ethylene application to peel degreening in lemons. They compared lemons treated with ethylene to those kept at storage temperatures ranging from 5 –25°C for up to 42 days. Complete degreening was achieved at 15 °C after 28-42 days in storage. In contrast, the ethylene assisted degreening achieved a full yellow color 8 days after treatment (Mitalo et al., 2020).

Post-handling recommendations from the University of Florida (Ritenour, 2015) and the University of California (Arpaia, 2015) do not recommend using cold temperatures as a means of degreening. They do discuss limitations of ethylene application, including faster senescence, and problems with decay.

We did not find any other cultural practices for promoting ripening or degreening in the literature reviewed for this report.

**<u>Evaluation Question #12:</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 substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)).**

Smoke from burning plant material would be considered a nonsynthetic substance according to the NOP *Decision Tree for Materials Classification* (NOP, 2016a), as the smoke is produced from combustion of a biological material.

However, the traditional Sri Lankan pit method described in *Evaluation Question #3* resulted in blackening and over softening of bananas, leading to decreased marketability (Maduwanthi & Marapana, 2019). Smoke was historically used to degreen citrus in the U.S., though usually it came from kerosene stoves (a synthetic source) and caused problems with fire hazards, heat and decay (Chace, 1934; Abeles, 1992).

A report from Nepal (Pokhrel, 2013) noted that use of calcium carbide is prohibited there, and ethylene canisters are unavailable. The author suggests the use of fully ripened fruit to produce ethylene in storage with unripened fruit at a rate of 1:100 in a closed room. Ruwali et al. (2022) found effective results for banana ripening when a mature apple is placed in a perforated polyethylene bag with a sample size of a dozen green bananas. Pokhrel (2013) noted drawbacks of using fruit as a ripening agent: it can cause over-ripening and decay. Both authors frame their recommendations as being applicable to local vendors and markets. These techniques are likely not practical for large volume export crops.

**<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).**

Fully ripe organic fruit can be used to ripen climacteric tropical fruit, as noted above. No reference to the use of ripe fruit for degreening of citrus was identified in the literature reviewed for this report.

## Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Emily Brown Rosen, Organic Research Associates

[6] Testing was done in both urban and rural locations, though not specifically in crop or post-harvest treatment locations.

- Tina Jensen Augustine, Senior Technical Coordinator, OMRI
- Peter O. Bungum, Senior Technical Coordinator, OMRI
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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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