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.

Potassium Iodide

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Potassium iodide; hydroiodic acid, potassium salt;

Other Name:
KI; IK; iodide of potash; component of Lugol's Solution

Trade Names:
Thyro-Block
Thyroshield
ThyroSafe
IOSAT

CAS Numbers:
7681-11-0

Other Codes:
FDA UNII: 1C4QK22F9J
EINCS: 231-659-4
CHEBI: 8346

Summary of Petitioned Use

This full scope technical report provides updated information to the National Organic Standards Board (NOSB) to support the sunset review of potassium iodide, listed at 7 CFR 205.605(a)(24). This technical report focuses on uses of potassium iodide in organic processing and handling, as a nonagricultural (nonorganic) nonsynthetic ingredient.

Potassium iodide was initially reviewed by the NOSB in 1995 (NOSB, 1995). It was included on the National List of Allowed and Prohibited Substances (hereafter referred to as the "National List") with the first publication of the National Organic Program (NOP) Final Rule (65 FR 80548, December 21, 2000). However, it was originally listed at both:

- § 205.605(a), as a nonsynthetic nonagricultural ingredient, without annotation
- § 205.605(b), as a *synthetic* nonagricultural ingredient with the following annotation: *for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic''.*

The NOSB recommended the renewal of these listings in 2005 (NOSB, 2005).

After reviewing the 2011 technical report, *Potassium Iodide* (NOP, 2011), the NOSB recommended removing potassium iodide from § 205.605(b). The NOSB believed that this separate listing for synthetic potassium iodide was unnecessary, as it was implicitly included within the listing for nutrient vitamins and minerals (NOSB, 2011). The NOP removed potassium iodide from the National List at § 205.605(b), effective June 27, 2012 (77 FR 33290, June 6, 2012). The listing for nonsynthetic (natural) potassium iodide at § 205.605(a) remained.

The NOSB has subsequently recommended the renewal of potassium iodide in 2015 and 2019 (NOSB, 2015, 2019). The NOP has accepted these recommendations, and the material remains listed today.

Synthetic and nonsynthetic forms of potassium iodide exist, but only synthetic forms are commercially available (see *Source or Origin of the Substance*, below). Even though potassium iodide is only explicitly listed at § 205.605(a), both nonsynthetic and synthetic forms are allowed. This is because as previously stated, the NOSB intended for synthetic forms to be considered under the listing of nutrient vitamins and minerals at § 205.605(b)(20).

For the remainder of the report, we will refer to potassium iodide as "KI."

Characterization of Petitioned Substance

Composition of the Substance

KI is an ionic metal halide salt composed of one potassium (K^+) ion and one iodide (I^-) ion (National Center for Biotechnology Information, 2023). Numerous sources are commercially available that meet the requirements of the Food Chemicals Codex, 3rd Ed., of purity between 99.0 and 101.5 percent upon drying (see *Approved Legal Uses of the Substance* below).

When KI is exposed to oxygen and carbon dioxide in air, some of it oxidizes to form elemental iodine (I_2) and potassium carbonate, turning white crystalline KI a yellowish color (see *Equation 1*) (Kaiho, 2014a). Bright light may also convert some KI to iodine through a photochemical decomposition process. The conversion of the iodide ion to diatomic gaseous iodine is further accelerated by the presence of humidity in the air, leading to an overall loss of iodine content (Waszkowiak & Szymandera-Buszka, 2008).

$$4KI + 2CO_2 + O_2 \rightarrow 2K_2CO_3 + 2I_2$$

Equation 1

Source or Origin of the Substance

Potassium is common in the Earth's crust, while iodine is exceedingly rare by comparison (Yaroshevsky, 2006). Although variable by geologic environment, potassium makes up approximately 2-3% (by weight) of the total mass of the crust (Yaroshevsky, 2006). Iodine is even more widely variable depending on environment, but it averages approximately 300 parts per billion (ppb, or 0.00003%) in the crust (Muramatsu & Hans Wedepohl, 1998). Iodine is far more prevalent in seafloor sediments than on land, reaching 30,000 ppb in some rock types (Muramatsu & Hans Wedepohl, 1998). Seawater itself contains just 50 ppb iodine (Muramatsu & Hans Wedepohl, 1998).

Despite the small fraction of iodine in seawater, algal species are extremely efficient in absorbing it as the iodide ion (Küpper, 2015). Some kelp species on the extreme edge of the spectrum such as the *Laminaria* genus can accumulate up to 5% (but more commonly 1%) dry weight iodine (Küpper, 2015). A more typical average value for seaweed is 0.1% dry weight iodine (World Iodine Association, 2015). Iodine also accumulates in coral and sponges (Lauterbach, 2014).

Subsurface brines associated with oil and gas deposits may contain sodium or KI (Lyday, 2003). As of 2016, all commercially significant iodine production in the United States occurred in the state of Oklahoma, sourced from brines and extracted through wells (Krukowski, 2016). Producers do not extract iodides for direct manufacturing, however. Instead they employ a series of oxidation/reduction reactions to collect elemental iodine of high purity (98%) (Krukowski, 2016).

Chile is the world's leading producer of iodine, sourced as a byproduct from sodium nitrate mines in the Atacama desert (U.S. Geological Survey, 2023). Japan and the United States are the next leading producers, sourcing iodine from oil and gas fields and from iodine-rich brines in Oklahoma (mentioned previously), respectively. Azerbaijan, Turkmenistan, Indonesia, Iran, and Russia produce more modest volumes of iodine compared to the leading three producers, although actual values from the United States are unavailable due to proprietary company data. China produces iodine, but does not report official output data.

Occurrence of iodine in foods

Iodine deficiency causes several health problems including intellectual disabilities, goiter, and impaired growth and function of organs in young people and pregnant women (Haldimann et al., 2005; Todorov & Gray, 2016). With the exception of marine fish and seaweed, food generally does not provide the sufficient iodine daily requirements of 150-290 microgram ("µg", or one millionth of a gram) per day (Todorov &

Gray, 2016).[1] Many countries have made major efforts to increase iodine intake through supplementation in salt, infant formula, and cooking oils (Ershow et al., 2018; Todorov & Gray, 2016). Widespread salt iodization has nearly eliminated severe iodine deficiency but mild to moderate deficiency persists (Ershow et al., 2018).

Generally consumed unprocessed foods typically have minuscule amounts of iodine (see *Table 1*) (Haldimann et al., 2005). Processed foods such as baked goods, canned foods, and cheese contain elevated levels of iodine, but this is mostly due to the use of iodized salt in preparing or processing (Haldimann et al., 2005). Additionally, elevated iodine levels are found in some dairy and egg products due to iodine supplemented livestock feed, but generally not in muscle meat products (Haldimann et al., 2005). Iodine is excreted with milk but remains in whey when cheese curd is separated; however, many cheeses are further salted or brined with iodized salt leading to elevated iodine concentrations in cheese. Iodine does not accumulate in muscle (Haldimann et al., 2005).

Table 1: Iodine content in commonly consumed foods, sorted by decreasing mean value, adapted from Haldimann et al. 2005[2]

Food	No. of samples	Mean (µg/g)	Median (µg/g)	Min (µg/g)	Max (µg/g)
Unprocessed and fresh foods					
Fish, marine	34	2.112	1.440	0.387	6.926
Egg	10	1.625	1.620	1.236	2.140
Egg, yolk	4	1.413	1.170	0.711	2.600
Milk	22	0.690	0.675	0.330	1.107
Fish, freshwater	17	0.375	0.205	0.011	1.571
Rice	11	0.333	0.250	0.011	0.934
Leafy greens	19	0.236	0.153	0.046	0.703
Egg, white	14	0.219	0.193	0.132	0.347
Nuts	13	0.218	0.216	0.020	0.374
Mushrooms	10	0.211	0.222	0.044	0.426
Nightshade vegetables	6	0.130	0.095	0.080	0.322
Poultry	30	0.066	0.034	0.010	0.327
Red meat	86	0.059	0.037	0.007	0.555
Fresh vegetables	36	0.047	0.033	0.009	0.203
Wheat	11	0.035	0.037	0.011	0.047
Wild game	7	0.034	0.033	0.015	0.048
Fresh fruit	62	0.018	0.015	0.002	0.075
Potatoes	3	0.016	0.018	0.004	0.026
Processed and prepared foods					
Frozen or canned vegetables	16	1.203	0.498	0.046	1.571
Yogurt	12	0.670	0.556	0.347	1.239
Cheese	27	0.473	0.396	0.146	1.323
Bread	76	0.393	0.392	0.025	1.032
Processed meat	39	0.335	0.106	0.020	1.254
Baked confectionary	13	0.245	0.148	0.032	0.893
Vegetarian meat alternative	17	0.109	0.070	0.014	0.396
Pasta	11	0.079	0.045	0.006	0.322
Breakfast cereal	10	0.042	0.022	0.009	0.174

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[1] 150-290 µg/day is the recommended dietary allowance of iodine in the United States, which is a similar range for European Union countries and many others (Todorov & Gray, 2016).

[2] Note the great variability between the minimum and maximum values detected, indicating a wide range even within the same food group. The source material is specific to foods purchased in Switzerland, so values may be even more widely variable in other countries. While some countries do include iodine in national food content databases, many do not. Efforts are underway in many countries, including the United States, to develop and continually update databases recording the iodine content of foods (Ershow et al., 2018). The current USDA research can be found at the *USDA, FDA and ODS-NIH Database for the Iodine Content of Common Foods* at https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/methods-and-application-of-food-composition-laboratory/mafcl-site-pages/iodine/

Properties of the Substance

KI forms colorless cubic crystals similar in appearance to table salt (see *Table 2*), which may turn yellow when exposed to humid air or bright light (due to photochemical decomposition of iodide to elemental iodine) (Kaiho, 2014a; Lyday, 2003; Patnaik, 2003; Waszkowiak & Szymandera-Buszka, 2008). KI is soluble in water and other polar solvents like ethanol, methanol, and acetone (Lyday, 2003).

In storage, humidity and contact with air causes table salt iodized with KI to lose iodine content. Iodide oxidizes to gaseous iodine that is released to the atmosphere (Waszkowiak & Szymandera-Buszka, 2008).

Table 2: Chemical and physical properties of KI

Property	Value[a]
Physical state or appearance	Granular or crystalline
Color	White to yellow
Odor	Odorless
Taste	Strongly bitter and saline
Molecular weight (g/mol)	166.003
Density (g/cm^3 at 25 °C)	3.12
pH	7-9 (aqueous)
Solubility (g/100 mL at 0-100 °C)	127.5-208; slightly soluble in ethanol
Boiling Point (°C)	1324
Melting Point (°C)	677
Stability	Stable in dry air; turns yellow in moist air
Reactivity	Hygroscopic; incompatible with strong reducing agents, strong acids, many metals and alloys

[a] *Sources*: (National Center for Biotechnology Information, 2023; Royal Society of Chemistry, 2023a; Whaley, 1973)

Specific Uses of the Substance

Dietary iodine supplement

KI is a common material for dietary iodine fortification worldwide. Greenwald et al. (2022) in an analysis of worldwide salt iodization regulations determined 74% of countries with mandatory salt iodization allow only KI and/or potassium iodate for this purpose. KI and potassium iodate are the only two iodine compounds recommended for salt iodization in the 2014 World Health Organization (WHO) Guidelines.

Iodized salt is a ubiquitous source of dietary iodine around the globe (Hess & Pearce, 2023). Salt iodization is widely accepted as a cost-efficient means to mitigate endemic iodine deficiency (Blankenship et al., 2018; Greenwald et al., 2022; Leung et al., 2012). The FDA recommends iodized salt be fortified at 46-76 milligram (mg) of iodide per kilogram (kg) of salt (Leung et al., 2012). Most salt iodization programs worldwide apply primarily to household salt and are not generally enforced on processed foods (Blankenship et al., 2018).

Dietary iodine fortification of processed foods is an ongoing area of research interest. A review by Blankenship et al. (2018) reported experimental evidence for a variety of processed foods prepared with KI fortified salt with no objective effect on observed sensory properties. These foods include:

- white bread
- flat bread
- potato chips
- hot dogs
- mortadella
- emulsified freshwater fish sausages
- pickled vegetables
- canned tomato juice
- canned sweet corn

Bread products are common staple foods that are prepared with iodized salt (Blankenship et al., 2018; Winger et al., 2008). Nutrition beverage powders and cereal products, including snack bars and pastas, are additional processed foods available to the consumer fortified with KI (Mehra & Srinivasan, 2009).

Other uses

KI is used in a variety of other ways beyond iodine supplement for humans. These include the following uses (Royal Society of Chemistry, 2023b):

- dietary iodine supplement in animal feeds
- antifungal medication
- treatment for iodine radiation poisoning
- reagent in analytical and diagnostic laboratory tests
- reagent in photography development solutions

Approved Legal Uses of the Substance

Since food manufacturers use KI as a nutritional food additive, the approved legal uses of the substance are regulated by the FDA (US FDA, 2023). KI is Generally Recognized as Safe (GRAS) as a nutritional additive in both human and animal food, and can also be a component of an FDA allowed sanitizing solution.

Standard of Identity, under FDA

The FDA describes the standard of identity for KI as follows (21 CFR 184.1634):

a) Potassium iodide (KI, CAS Reg. No. 7681–11–0) is the potassium salt of hydriodic acid. It occurs naturally in sea water and in salt deposits, but can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate ($KHCO_3$).
b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 246–247, which is incorporated by reference…
c) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.
d) The ingredient is used in table salt in accordance with § 184.1(b)(2) of this chapter as a source of dietary iodine at a maximum level of 0.01 percent.
e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

The FDA states that KI should meet the specifications of the third edition of the Food Chemicals Codex, which we provide below (National Research Council, 1981):

> Description:
> Hexahedral crystals, either transparent and colorless or somewhat opaque and white, or a white, granular powder. It is stable in dry air but slightly hygroscopic in moist air. One g is soluble in 0.7 ml of water at 2S", in O.S ml of boiling water, in 2 ml of glycerin, and in 22 ml of alcohol. The pH of a 1 in 20 solution is between 6 and 10.
>
> Identification:
> A 1 in 10 solution responds to the tests for *Potassium*, page 517, and for *Iodide*, page 516.
>
> Assay: Not less than 99.0% and not more than the equivalent of 10l.5% of KI after drying.
> Arsenic (as As): Not more than 3 ppm.
> Heavy Metals (as Pb): Not more than 10 ppm.
> Iodate: Not more than 4 ppm.
> Loss on Drying: Not more than I%.
> Nitrate, Nitrite, and Ammonia: Passes test.
> Thiosulfate and Barium: Passes test.

Allowed use, under FDA

The FDA states that KI "may be safely used in accordance with the following prescribed conditions" (§ 172.375):

a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:
    1) The name of the additive.
    2) A statement of the concentration of the additive in any mixture.

KI is also allowed by the FDA when used as a component of a sanitizing solution (§ 178.1010):

b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval.
    25) An aqueous solution containing elemental iodine (CAS Reg. No. 7553–56–2), potassium iodide (CAS Reg. No. 7681–11–0), and isopropanol (CAS Reg. No. 67–63–0). In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.

GRAS status, under FDA

KI is also included in the FDA's list of Nutrients and/or Dietary Supplements that are considered to be Generally Recognized as Safe (GRAS) (§582.5634):

a) Product. Potassium iodide.
b) Tolerance. 0.01 percent.
c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing or feeding practice.

KI is also considered to be GRAS when added to animal feed as a nutritional supplement (§ 582.80).

For FDA recommendations (not legal/regulatory requirements) on the concentration of KI in salt, see *Specific Uses of the Substance*.

Action of the Substance:

Physiology

Potassium is critical in the acid-base balance of fluids, the pressure gradient across cell membranes, and the balance of electrical charge gradients (Pavlech et al., 2021). However, the amount of potassium provided by KI supplementation is so minuscule to be effectively insignificant compared to other sources of dietary potassium. The purpose of KI supplementation is for adequate iodine intake.

Iodide is transported through the circulatory system to the thyroid, where it is oxidized by hydrogen peroxide with the enzyme thyroid peroxidase acting as a catalyst (Rokita, 2014; Smyth, 2003). Hydrogen peroxide is a potent agent of oxidative damage to the thyroid (Smyth, 2003). Since hydrogen peroxide is consumed in the reaction, iodide acts as an antioxidant (Smyth, 2003).

The thyroid gland utilizes the resulting iodine in the synthesis of thyroxine and triiodothyronine, essential hormones for growth, bone formation, brain development, and overall metabolism (Cooper, 2007; Hartwig, 2017). Inorganic forms of iodine, including KI, are almost completely absorbed by the gastrointestinal tract when ingested (Hartwig, 2017; Zimmermann, 2014). The majority of bodily iodine is stored in the thyroid, although smaller concentrations may be stored in the salivary glands, mammary glands, and stomach lining (Hartwig, 2017).

Antiseptic

Iodide (I^-) has no antimicrobial potential because it is not an oxidizing material, so KI is not used directly for disinfection (Gottardi, 2014). However, free elemental iodine (I_2) and hypoiodous acid (HOI) have bactericidal effects due to their oxidizing activity, much like free chlorine (Cl_2) and hypochlorous acid (HOCl) (Gottardi, 2014).

Elemental iodine is poorly soluble, but its solubility is increased in aqueous solution of KI (Gottardi, 2014). When elemental iodine is dissolved in KI, some of it reacts to form dissolved triiodide ion (I_3^-). This reaction is exploited for the production of common topical iodine solutions in human or livestock health care applications. While the triiodide ion has little value as a bactericidal agent itself, it creates extra oxidation capacity in the complicated equilibrium of iodine-bearing ions in solution. The triiodide ion is also the cause for the dark yellow staining observed when iodine solution is applied topically (Gottardi, 2014).

Combinations of the Substance

The Food Chemicals Codex characterizes KI as not less than 99.0% and not more than the equivalent of 10l.5% of KI after drying (National Research Council, 1981). Arsenic (<3 ppm), heavy metals including lead (<10 ppm), and iodate (<4 ppm) may compose the remaining fraction. KI is a deliquescent material and will absorb moisture from the air (Royal Society of Chemistry, 2023b). Consequently, long term exposure of KI to humid conditions may result in KI with an iodate fraction.

To prevent oxidation of the iodine, sodium thiosulfate and dextrose are stabilizers sometimes added with KI to iodized salt. (Greenwald et al., 2022; Tyler, 1985). Salt producers may also add sodium carbonate or sodium bicarbonate to increase alkalinity of the iodized salt product (Greenwald et al., 2022). These materials can also act as iodide stabilizers (Tyler, 1985). Less common stabilizer materials include calcium hydroxide, disodium phosphate, and basic phosphates.

Status

Historic Use

The ancient Chinese and Greeks both used iodine-rich seaweed for its goiter-preventing effects (Küpper, 2015). Bernard Courtois, a French chemist and manufacturer of gunpowder, identified elemental iodine in 1811.

In the 1830s, Jean Baptiste Boussingault, another French chemist, suggested that iodine be added to salt for the purpose of dietary iodine supplementation (Leung et al., 2012). Yet another French chemist, Adolphe Chatin, published a hypothesis associating iodine deficiency with endemic goiter in 1852.

Research on iodine supplementation to address endemic iodine deficiencies received renewed interest in the United States and Europe in the 1910s. This is in part due to the success of experiments by the Marine Lab at the Cleveland Clinic that demonstrated the reduction of goiter in school age children receiving iodine therapy (Markel, 1987). In 1922, the Swiss Goiter Commission recommended KI for the purpose of dietary iodine supplementation, taken in salt or as tablets. Iodized salt was available to consumers in the United States as early as 1924 (Leung et al., 2012). Beginning in the 1940s iodized salt was used in commercial bakeries in the Netherlands (Blankenship et al., 2018).

Animal science researchers in the 1920s demonstrated the advantages of supplementing dairy cows with dietary iodine for reproductive performance (Phillips, 1997). Consequently, iodized salt was introduced to livestock diets starting in the 1920s (Mitchell, 1924; Phillips, 1997). Iodine enriched cattle feed mix became available starting in the 1930s (Phillips, 1997).

Scientists at Los Alamos Scientific Laboratory (now Los Alamos National Laboratory) in New Mexico in 1961 demonstrated they could reduce radioactive iodine uptake by the thyroid in rats given KI by injection (Lengemann & Thompson, 1964). In an effort to minimize the accumulation of radioactive isotopes of iodine, the government of Poland distributed KI to the populace in response to the Chernobyl nuclear accident in 1986 (Leung et al., 2017).

In 1994, the WHO and UNICEF recommended salt iodization as a method to eliminate iodine deficiency disorders worldwide, and released guidelines to achieve this in collaboration with what is now the Iodine Global Network (Greenwald et al., 2022). The 2014 update to the WHO Guidelines specifically recommends KI as an effective material for salt iodization (Greenwald et al., 2022).

Organic Foods Production Act, USDA Final Rule:

OFPA does not include any reference to KI (Organic Foods Production Act of 1990, 1990).

For processing and handling purposes, USDA organic regulations include nonsynthetic KI on the National List without annotation [7 CFR 205.605(a)(24)]. It was included in the first iteration of the Final Rule, published on December 21, 2000 (65 FR 80548). Synthetic forms of KI are allowed in organic production when used as nutrient minerals, in accordance with 21 CFR 104.20, *Nutritional Quality Guidelines for Foods* [7 CFR 205.605(b)(20)].

As described in *Summary of Petitioned Use* (above), KI was originally listed at both:

- § 205.605(a), as a nonsynthetic nonagricultural ingredient, without annotation
- § 205.605(b), as a *synthetic* nonagricultural ingredient with the following annotation: *for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic''.*

In 2011, the NOSB recommended removing KI from § 205.605(b). The NOSB believed that listing of synthetic KI was unnecessary, as it was included within the listing for nutrient vitamins and minerals (NOSB, 2011). The NOP removed KI from the National List at § 205.605(b), effective June 27, 2012 (77 FR 33290). The listing for nonsynthetic KI at § 205.605(a) remained.

International

KI is only allowed explicitly under the Canadian Organic Standards (see Table 3, below). It does not appear to be permitted under the Japanese Agricultural standard for Organic Processed Foods. Other standards include provisions that may allow for the use of minerals like KI, if legally required.

Table 3: Allowance of KI in processing and handling applications under a selection of international organic standards

Standard	Applicable regulations	Allowed?	Source and use restrictions (if applicable)
Canada Organic Standards (CAN/CGSB 32.311-2020)	PSL Table 6.4, *Ingredients not classified as food additives.*	Yes, when legally required.	Shall be used when legally required or permitted.
European Union Organic Standards (EU No. 2021/1165 & EU 2018/848)	Not listed in EU No. 2021/1165 Annex V, *Authorised products and substances for use in the production of processed organic food and of yeast used as food or feed.* However, minerals are listed at *Part IV: Processed food production rules*, 2.2.2 (f).	Yes, when legally required.	Minerals (trace elements included) are allowed if their use in food for normal consumption is 'directly legally required' (paraphrased). If KI is legally required in a food, it could be allowed under this provision.
Japanese Agricultural Standard for Organic Processed Foods	Not listed.	No	-
Codex Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)	Table 3: *Ingredients of non-agricultural origin referred to in Section 3 of these guidelines.* 3.5: *Minerals (including trace elements), vitamins, essential fatty and amino acids, and other nitrogen compounds.*	Yes, when legally required.	Only approved in so far as their use is legally required in the food products in which they are incorporated.
IFOAM-Organics International	7.2.4 Minerals (including trace elements), vitamins and similar isolated ingredients.	Yes, when legally required.	Shall not be used unless their use is legally required or where severe dietary or nutritional deficiency can be demonstrated in the market to which the particular batch of product is destined.

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)].

Approximately 55% of iodine is sourced from *caliche* deposits in the Chilean Atacama desert (Krukowski, 2014). The remaining 45% is sourced from brines associated with oil and gas wells in the United States, Japan, Russia, Turkmenistan, Azerbaijan, Indonesia, and Uzbekistan (Krukowski, 2014). We found no evidence that any commercially significant KI products are directly extracted from any natural source without prior isolation of iodine and further chemical reaction.

KI is produced using various methods and reagents, in individual reactions or in multi-step reactions (Kaiho, 2014a). Diatomic iodine (I_2) reacts with potassium hydroxide (KOH) to form KI, potassium iodate, and water (see Equation 2) (de Dios Azorín Abraham et al., 2023; Kaiho, 2014a; Lyday, 2003). The resulting potassium iodate can then be reduced using activated carbon to yield KI and carbon dioxide (see Equation 3) (Kaiho, 2014a).

$$6KOH + 3I_2 \rightarrow 5KI + KIO_3 + 3H_2O$$

potassium hydroxide + iodine → KI + potassium iodate + water

Equation 2

$$2KIO_3 + 3C \rightarrow 2KI + 3CO_2$$

potassium iodate + carbon → KI + carbon dioxide

Equation 3

Alternatively, iron powder and diatomic iodine are reacted to form iron (II) iodide (see Equation 4 and Equation 5) (Kaiho, 2014a). The iron (II) iodide is then reacted with potassium carbonate to form KI, carbon dioxide, and iron oxide (see Equation 6) (Kaiho, 2014a).

$$Fe + I_2 \rightarrow FeI_2$$

iron + iodine → iron (II) iodide

Equation 4

$$3FeI_2 + I_2 \rightarrow Fe_3I_8$$

iron (II) iodide + iodine → iron iodide

Equation 5

$$Fe_3I_8 + 4K_2CO_3 \rightarrow 8KI + 4CO_2 + Fe_3O_8$$

iron iodide + potassium carbonate → KI + carbon dioxide + iron oxide

Equation 6

Chilean caliche deposits

Iodine is produced as a byproduct of sodium and potassium nitrate mining in northern Chile, occurring in the associated calcium iodate minerals lauterite ($Ca(IO_3)_2$) and dietzite ($Ca_2(IO_3)2(CrO_4)$) (Lauterbach, 2014).

Caliche is a nitrate-bearing sedimentary rock. Caliche deposits are commonly composed of sodium nitrate, sodium chloride, sodium sulfate, potassium chloride, and quartz (SiO_2), along with other minor salts (including those that contain iodine) and silicates (Ghorbani et al., 2016; Wisniak, 2001). Caliche occurs in several arid environments around the world, but the Chilean deposits are unique in that they contain iodates, perchlorates, and chromates, substances not found in salt deposits elsewhere (Lauterbach, 2014; Wisniak, 2001). The occurrence of these exotic constituents is not well understood, but it is thought that the source of iodine is aerial deposition from the sea (Lauterbach, 2014).

The water soluble fraction of caliche may be as high as 40% (Ghorbani et al., 2016). Iodates from the calcium iodate minerals, along with nitrate salts, are dissolved into brine by piling caliche ore in heaps 10 meters high and leaching with water (Ghorbani et al., 2016).

The collected leachate contains dissolved iodate as well as a smaller fraction of dissolved or crystallized elemental iodine (Lauterbach, 2014). Several chemical reactions may be utilized individually or in series. The brine is treated with sulfur dioxide gas (derived from burning sulfur) in absorption towers, reducing iodate to iodide (see Equation 7, Equation 8, and Equation 9) (Lauterbach, 2014).

$$2IO_3^- + 5SO_2 + 4H_2O \rightarrow I_2 + 5SO_4^- + 8H^+$$

iodate ion + sulfur dioxide + water → iodine + sulfate ion + hydrogen ion

Equation 7

$$I_2 + SO_2 + 2H_2O \rightarrow 2I^- + SO_4^- + 4H^+$$

iodine + sulfur dioxide + water → iodide ion + sulfate ion + hydrogen ion

Equation 8

$$2IO_3^- + 6SO_2 + 6H_2O \rightarrow 2I^- + 6SO_4^- + 12H^+$$
iodate ion + sulfur dioxide + water → iodide ion + hydrogen ion

Equation 9

Alternatively, sodium iodate may be reduced with sodium bisulfite to iodide which is subsequently treated with remaining mother liquor containing dissolved iodate, producing free iodine (see *Equation 10* and *Equation 11*) (Lyday, 2003). The elemental iodine may either be blown out with air and collected, or extracted with kerosene before both dissolved solution streams are combined (Lauterbach, 2014). The final product may be sold as concentrated iodide solution or be further treated by mixing with remaining iodate solution (see *Equation 12*), resulting in elemental iodine crystals in residual brine (Lauterbach, 2014). The slurry enters a heat exchanger where the crystallized iodine melts prior to collection and drying as prills or flakes (Lauterbach, 2014; Lyday, 2003).

$$2NaIO_3 + 6NaHSO_3 \rightarrow 2NaI + 3Na_2SO_4 + 3H_2SO_4$$
sodium iodate + sodium bisulfite → sodium iodide + sodium sulfate + sulfuric acid

Equation 10

$$5NaI + NaIO_3 + H_2SO_4 \rightarrow 3Na_2SO_4 + 3H_2O + 3I_2$$
sodium iodide + sodium iodate + sulfuric acid → sodium sulfate + water + iodine

Equation 11

$$5I^- + IO_3^- + 6H^+ \rightarrow 3I_2 + 3H_2O$$
iodide ion + iodate ion + hydrogen ion → iodine + water

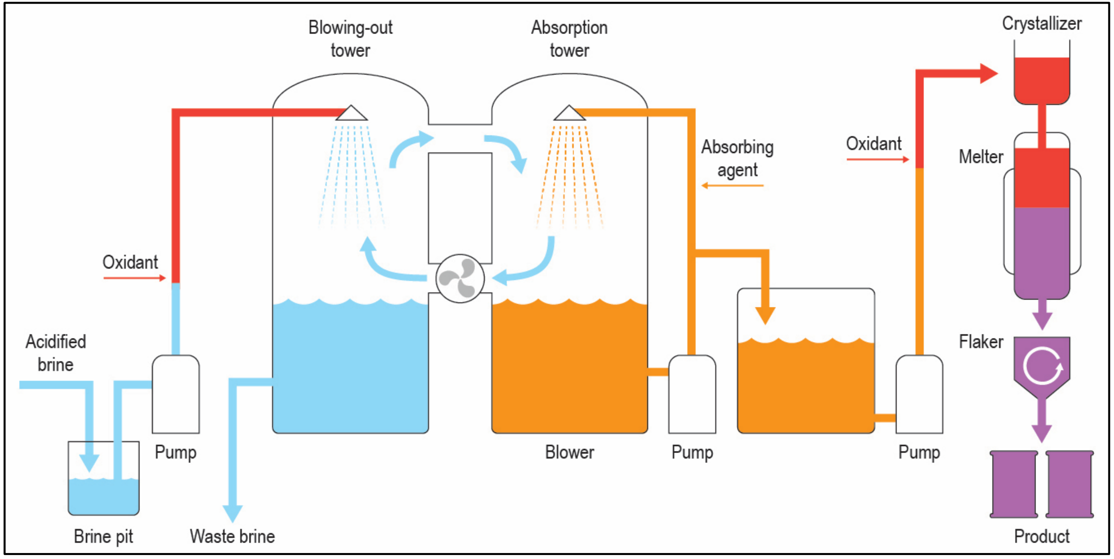
Equation 12

Brines associated with natural gas deposits

The ultimate source of the iodine in submarine sediments associated with natural gas fields is not well understood, but it may be associated with uptake and concentration by microalgae (Kaneko & Kaiho, 2014). Most iodine derived from natural gas associated brines is manufactured in Japan using a “blow-out” method (alternatively known as air-stripping) or ion-exchange (Kaneko & Kaiho, 2014; Krukowski, 2014).

For the “blow-out” method, brine is first pumped from gas wells into pits to allow settling of sand (Kaneko & Kaiho, 2014). The brine is then acidified using hydrochloric or sulfuric acid, then oxidized with chlorine or sodium hypochlorite. These steps liberate iodine. The brine containing free iodine is pumped through a *blow-out tower* as air is blown from below, releasing gaseous iodine. The iodine gas enters another tower containing circulating sodium hydrogen sulfite, which absorbs iodine by reduction into iodide. The iodide solution is then oxidized again with chlorine, forming iodine crystals in sludge. The sludge enters a melting tank where it is heated with steam, melting the iodine crystals. The melt sinks to the bottom of the tank for removal where it meets water-cooled drums of iodine resistant alloy. Iodine recrystallizes on the surface of the drums and is scraped for packaging (see *Figure 1*).

Figure 1: Blow-out method for iodine production (adapted from Kaneko and Kaiho, 2014)



The ion-exchange method is similar to the blow-out method, but the absorption material is different (Kaneko & Kaiho, 2014). In this method, the brine is oxidized with chlorine or sodium hypochlorite. The oxidized brine is filtered through a bed of anion exchange resin, converting iodine into adsorbed polyiodide. The resin, carrying polyiodide, is treated with a sulfite solution to remove the iodide and oxidized with chlorine back to iodine. The crystallization steps are the same.

Oilfield brines

Brines associated with petroleum exploration wells in Oklahoma, United States, contain approximately 300 ppm dissolved iodide (Krukowski, 2014). These exploratory well brines are used directly for iodine production. Waste brines containing 100-1000 ppm iodine from petroleum production wells are also processed to recover iodine as a secondary by-product (Krukowski, 2014).

Pumps carry brine to the surface, where natural gas is either flared off or separated from the brine using gas separators (Krukowski, 2014). Skimming and settling removes oils, clays, and other impurities. Injection of chlorine oxidizes the brine, converting dissolved iodide into iodine. Iodine is blown-out with air as in the natural gas method described above, and the depleted brine is reinjected underground to maintain fluid pressure and prevent land subsidence. The stripped iodine gas enters an absorption column where sulfur dioxide gas and water reduce iodine, resulting in hydroiodic acid (HI), iodide, and sulfuric acid. Chlorine again oxidizes the acid solution, producing crystalline iodine.

The resulting mixture of iodine crystals, sulfuric acid, hydrochloric acid, and water is filtered and vacuum dried (Krukowski, 2014). The iodine filter cake is melted. Continued contact with sulfuric acid removes impurities in the melt and controls humidity. The melt is crystallized into flakes or prills.

Other methods

Several methods for obtaining iodine from seaweed or brines were used in the past but are no longer commercially important (Kaiho, 2014c; Lyday, 2003). Seaweed was a major source of iodine prior to 1959, but only minuscule amounts are produced as a by-product of sodium alginate production currently, in China (Kaiho, 2014c; World Iodine Association, 2015).

Methods utilized in the past include the following (Kaiho, 2014c; Wisniak, 2001):

- Seaweed is collected and dried on dunes, then burned in pits or trenches. The resulting ash is soaked with water, dissolving iodide. Other salts are crystallized out by evaporation and the remaining liquid is acidified with sulfuric acid and oxidized with manganese dioxide, after which iodine may be distilled from the solution.
- Naturally occurring brines are treated with sulfur dioxide and the solution is filtered through containers holding bundles of copper wire. Insoluble copper iodide precipitates, which can be shaken from the surface of the bundles. The suspension of copper iodide crystals and water is then oxidized to produce iodine.
- Silver nitrate is added to brines to precipitate silver iodide, which is filtered from solution. Scrap iron is added, forming silver metal and dissolved ferrous iodide. The solution is treated with chlorine, freeing gaseous iodine.
- Brine is acidified with sulfuric acid and oxidized with sodium nitrite, liberating dissolved free iodine. Activated charcoal is added which adsorbs iodine. The iodine is then recovered by the addition of sodium hydroxide or sodium carbonate. The eluted solution is then acidified again with sulfuric acid and oxidized with sodium nitrite once again, resulting in an iodine precipitate.
- Brine is acidified with sulfuric acid and oxidized with sodium nitrite, liberating dissolved free iodine. Starch is added, forming a starch-iodine complex, which is separated by centrifugation. The iodine can be removed from the complex with water and the resulting solution is acidified and oxidized, forming iodine which is separated by centrifugation.

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.

Synthetic/nonsynthetic classification

During research for this report, we did not encounter any reference to direct KI extraction from natural sources for commercial production. All of the modern and historical manufacturing process information consulted involves multiple transformation and purification steps involving oxidation/reduction reactions, chemical adsorption, and acid/base extraction; in many cases, all three. Synthetic KI previously appeared at § 205.605(b) as an allowed synthetic material, permitted "*for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic,""* but it was removed in 2011 because the NOSB considered KI to be included in the allowance of synthetic nutrient vitamins and minerals (NOP, 2011). KI remains listed at § 205.605(a) despite no apparent commercially available nonsynthetic versions.

A detailed analysis of the classification of the substance, based on *NOP 5033-1 Guidance Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016a), follows.

1. *Is the substance manufactured, produced, or extracted from a natural source?*

If KI is the starting substance, the answer is no, resulting in an immediate synthetic classification. In terms of the constituents making up KI, we can follow the decision tree further. Iodate minerals in Chilean caliche deposits are naturally occurring substances. Brines associated with oil or gas deposits are similarly naturally occurring substances. Iodine in seaweed is naturally absorbed from seawater by algae. The iodine content of KI is unequivocally derived from a natural source. The potassium content of KI may come from natural sources or synthetic sources. While in some cases, iodine is an extracted material, KI itself is not.

An analysis of answers to question 2 and 3 in the decision tree are provided for consideration.

2. *Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?*

In the case of Chilean caliche deposits, iodate minerals have undoubtedly been chemically changed through isolation of elemental iodine and further reaction with potassium compounds. In the case of dissolved iodide in oil and gas associated brines, the iodine is also isolated before production of KI using potassium compounds.

3. *Is the chemical change created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter?*

No. The isolation of iodine through oxidation/reduction, chemical adsorption, or acid/base extraction is not a naturally occurring biological process. Neither is the further reaction with potassium hydroxide or potassium carbonate. All of the references consulted for this report indicate that KI is a synthetic substance.

Agricultural/nonagricultural classification

Evaluation of KI against Guidance NOP 5033-2 *Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling* (NOP, 2016b) is discussed below.

1. *Is the substance a mineral or bacterial culture, as included in the definition of nonagricultural substances at section 205.2 of the USDA organic regulations?*

Yes. KI is a binary ionic compound derived from mineral sources, chemically similar to table salt from an elementary perspective. It is not a product of agriculture, so it meets the definition of "nonagricultural substance" at § 205.2 of the USDA organic regulations. The substance is nonagricultural.

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)].

As stated in *Evaluation Question #2*, although nonsynthetic KI is allowed in organic handling, most if not all commercially available KI is synthetic.

Iodine occurs in several commonly consumed food products, typically in insufficient dietary amounts (see *Source or Origin of the Substance* and *Table 1* above). However, much of the iodine in commonly consumed foods results from the use of iodized salt in manufacturing or the use of iodine supplementation in livestock feed (Haldimann et al., 2005).

Seaweed is essentially the only food that can provide adequate dietary iodine without direct (e.g., iodized salt) or secondary (e.g., through supplementation of animal feeds) fortification. Since marine algae may have widely variable iodine content depending on type and geographical origin (0.6-6,250 µg/g), care must be taken to avoid excessive intake in those individuals who consume large volumes of seaweed products (Krela-Kaźmierczak et al., 2021).

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.

KI is GRAS as a nutritional additive in food, and as a GRAS substance, is also a component of FDA allowed sanitizing solutions (see *Approved Legal Uses of the Substance*, above):

- As a source of essential mineral iodine (21 CFR 172.375).
- As a nutrient and/or dietary supplement (§ 582.5634).
- As a component of a sanitizing solution (§ 178.1010).

For FDA recommendations (not legal/regulatory requirements) on the concentration of KI in salt, see *Specific Uses of the Substance*.

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)].

KI has no technical function as a preservative.

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)].
KI is primarily used to increase the nutritive value of food commodities as required by law. KI is not used to recreate or improve flavors, colors, or textures.

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)].
KI fortification of salt and food commodities is a cost-effective way of guaranteeing daily iodine intake that can mitigate endemic iodine deficiency globally (Blankenship et al., 2018; Greenwald et al., 2022; Leung et al., 2012).

In mammals, the thyroid gland utilizes iodine in the synthesis of thyroxine and triiodothyronine, essential hormones for growth, bone formation, brain development, and overall metabolism (Cooper, 2007; Hartwig, 2017). As described within *Source or Origin of the Substance*, *Specific Uses of the Substance* and *Evaluation Question #6*, lack of the proper intake of iodide can cause several diseases, some of a severe nature.

The prevention of iodine deficiency generally outweighs the risks from iodine excess (Farebrother et al., 2019). However, iodine excess may induce physiological changes in susceptible groups, particularly those previously exposed to iodine deficiency, pregnant women, or infants (Farebrother et al., 2019). In some people, excessive iodine may precipitate hyperthyroidism, hypothyroidism, goiter, and/or thyroid autoimmunity (Farebrother et al., 2019).

The amount of potassium provided by KI supplementation is insignificant.

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)].
The FDA establishes "action levels" for poisonous or deleterious substances that are unavoidable in human food and animal feed (U.S. FDA, 2000). These include aflatoxin, cadmium, lead, polychlorinated biphenyls (PCBs), and many other substances. The FDA uses different action level tolerances for these substances, depending on the commodity. Commodities are largely food items; however, the FDA also includes tolerances for ceramic and metal items, such as eating vessels and utensils. KI is not included on the list of commodities with action levels (U.S. FDA, 2000).

According to the current (2023) version of the Food Chemicals Codex, the inorganic impurities that KI can contain are (United States Pharmacopeial Convention, 2008):

- Iodate, no more than 4 mg/kg per 1.1 g of potassium iodide
- Lead, no more than 4 mg/kg per 10 g of potassium iodide
- Nitrate, nitrite and ammonia, at concentrations that should not turn blue the test paper during colorimetric test
- Thiosulfate and Barium, at concentrations that should not cause turbidity in the sample after sulfuric acid test

Other trace impurities in KI may include: chloride, bromide, phosphate, iron, calcium, magnesium, sodium, cadmium, arsenic, mercury, cobalt, vanadium, nickel (Deep Water Chemicals, 2019) and sulfates (National Center for Biotechnology Information, 2023).

Evaluation Question #9: 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)].

Use

At the concentrations used in food commodities, KI is unlikely to have a negative impact when disposed into the environment where it dissociates into potassium and iodide species. Our response does not discuss the fate and effect of potassium ions in the environment. This information can be found in detail in *Evaluation Question #4* of the *2023 Potassium Chloride* (Crops) technical report (USDA, 2023).

Iodide ions are oxidized by sunlight, which forms elemental iodine (Dudin et al., 2015). This material is volatile and ends up in the air (Dudin et al., 2015). Once in the air, iodine can combine with water or other particles, where it can then enter the ground (when absorbed by soil and vegetation) and surface water (when it rains) (ATSDR, 2004).

Iodine remains in soil for a long time, because it combines with organic material (Cox & Arai, 2014). In the soil, iodine concentrations range from <0.1 to 150 mg kg^{-1}. Soils that are closer to the ocean have a higher concentrations of iodide. The average concentration in the lithosphere is 0.3 mg kg^{-1} (Cox & Arai, 2014).

Iodide is used by all mammals in the thyroid gland (Cox & Arai, 2014). Although it can be extremely toxic to rainbow trout and daphnia, it is generally not toxic to aquatic organisms (Cox & Arai, 2014). The acute toxicity of iodide in mammals and other terrestrial organisms is also generally quite low (See *Table 4*).

Table 4. Iodine toxicity in some organisms

Organism	Dose	Unit	Reference
Daphnia	0.17 mg/L	LC50	(Cox & Arai, 2014)
Microarthropods	25 mg/kg	EC25	(Cox & Arai, 2014)
Earthworms	1000 mg/kg	No Observed Effect Concentration (NOEC)	(Cox & Arai, 2014)
Rainbow trout	0.53 mg/L	LC50	(Cox & Arai, 2014)
Rats	14,000 mg/kg	LD50	(Ilin & Nersesyan, 2013)
Mice	22,000 mg/kg	LD50	(Ilin & Nersesyan, 2013)
Humans	28 mg/kg	LDL0	(Ilin & Nersesyan, 2013)

Environmental impact of Iodine production in Chile

About two thirds of the total iodine production in the world originates from Chile (Kaiho, 2014b), where production involves the mining and leaching of nitrate ores as described in *Evaluation Question #1*.

The biggest environmental impact of iodine production in Chile is water depletion, which directly affects the biodiversity of some regions. Iodine recovery from caliche mining requires a substantial amount of water and this process is performed in the driest of the world's deserts (Lauterbach, 2014; Pfeiffer et al., 2021; Quade et al., 2008), where significant precipitation (1mm or more) occurs only a few times per century (Lauterbach, 2014; Pfeiffer et al., 2021). The groundwater deposits in the Atacama Desert are a non-renewable resource because they were last recharged between 17,000 to 10,000 years ago when rain was more abundant in the region (Santoro et al., 2018). For context, Chile's iodine production was some 22,000 metric tons in 2022 (Statista, 2024), and about 130 m^3 of water is needed per metric ton of iodine produced (Roche et al., 2023).

Lithium extraction can require about eight times more water than iodide extraction (i.e. 100–800 m^3 of water per ton of lithium carbonate) (Vera et al., 2023) and there are many other water-intensive mining operations in this area. In addition, water is taken to supply agricultural operations and urban areas. Therefore, iodine extraction is not the single cause of the severe groundwater depletion that has happened in Chile for the last 50 years (Chávez et al., 2016).

The biggest iodine manufacturer in the world is Sociedad Química Minera (SQM) and it recovers iodine as a parallel product from the caliche mining happening in several regions on the northern Atacama Desert

(Lauterbach, 2014). To supply SQM's operation at Nueva Victoria, they extract water from several wells in the Pampa de Tamarugal area and from wells in the Salar de Llamara that are directly connected to lagoons called "puquios." These two sites are biodiversity protected sites and have been directly affected by the water extraction (Bonelli & Dorador, 2021; Chávez et al., 2016; Larraín & Poo, 2010).

At the Pampa del Tamarugal aquifer, Tamarugo trees (*Prosopis tamarugo*) form an ecosystem where about 30 other plant and animal species reside, some of them endangered and/or endemic (Chávez et al., 2016). Chavez et al. (2016) predicts that if the extraction of ground water continues at its current rate, about 50% of the existing Tamarugo trees will be in great danger by 2050.

The puquios system in the Salar the Llamara, is a complex high salinity water system consisting of four main lakes and several small pools were highly diverse microbial ecosystem coexist (Suosaari et al., 2022). The diversity and structure of these microbial communities are directly related to the salt concentrations diluted in the water of each pool and each pool has a different salinity (Suosaari et al., 2022). Caliche mining operations extract water from this pool system (Bonelli & Dorador, 2021; Larraín & Poo, 2010). When the water level drops below an agreed level, mining companies inject fresh water back into the pools (Bonelli & Dorador, 2021). This practice can harm these microbial ecosystems due to the osmotic shock caused by the salinity differences between the extracted and the injected water (Bonelli & Dorador, 2021).

The largest of the puquios, or lagoons in the previously described system has an area of about 4650 m^2 and a depth less than 1 meter (Suosaari et al., 2022). Therefore, the total volume of surface water that such space could collect is about 1,228,400 of US gallons. The water needed to leach half of Chile's annual iodine production (i.e. 11,000 metric tons) is about 300 times more water than the total volume that the largest puquio could hold.

Environmental impact of iodine production in Japan (Brines associated with natural gas deposits)

Japan is the second leading producer of iodine and the Minami-Kanto Gas Field near Tokyo is responsible for 90% of Japan's iodine production (Kaneko & Kaiho, 2014). Iodine is recovered from this region as explained on *Evaluation Question #1*. From our research we found that the main environmental impact associated with brine extraction of iodine is land subsidence, or the gradual settling of the earth's surface, caused when brine is pumped from the subsurface reservoir (Kawano et al., 2020; Muramoto et al., 2020). Japan's iodine production has remained at constant levels because the amount of water extracted for this purpose has to be maintained at constant levels to prevent land subsidence from occurring (Kaneko & Kaiho, 2014).

Environmental impact of iodine production in the United States, Oklahoma (Oilfield Brines)

As described in *Evaluation Question #1*, this iodine production method is linked to oil production. Some consider this process as a beneficial use of water (United States Geological Survey, 2014) because the waste stream product from the oil well extraction is used to source a valuable commodity. Some potential environmental concerns that relate to iodine production from oil field brine streams include spills, leaks, and other environmental releases, which can cause ground and water pollution (United States Geological Survey, 2014). If the wells are not properly managed, migration of the liquids can affect the quality of shallow water (United States Geological Survey, 2014). Deep injection of these streams can also cause earthquakes (Clark et al., 2005; Ellsworth, 2013; Folger & Tiemann, 2015; United States Geological Survey, 2014).

Other environmental considerations

In the production of iodine, special considerations must be taken into account when handling, managing, and disposing of input chemicals required for manufacturing. When produced from caliche, these chemicals are (Roche et al., 2023):

- kerosene
- ammonium nitrate
- sulfur
- sulfuric acid
- hydrogen peroxide
- quick lime
- sodium hydroxide

When produced from brines, these chemicals are (Krukowski, 2016):

- chlorine
- sulfur dioxide
- ammonia
- sulfuric acid

In addition, the production of iodine from caliche can leach mineral and non-mineral wastes from the caliche ore. Mineral wastes include spent leached material, overburden (the rock and/or soil layer that is removed to expose the ore), and non-target mineral salts. These materials are deposited in stockpiles and the industrial areas covered by these stockpiles are more than 1,328 hectares (3281.6 acres) with the material accumulation cakes reaching 50 meters high (SQM, 2022). The waste was quantified by SQM (2022) at, 4,997,000 tons/year of discarded salts and 110,150 tons/year of gypsum (from both, nitrate and iodide production).

The non-mineral hazardous waste produced by iodide extraction operations comes from process discards, used lubricant oil maintenance generated by changing equipment and machinery, batteries, paint residue, ink cartridges, fluorescent tubes, contaminated cleaning materials, among others (SQM, 2022).

The production of iodine from brine wells in United States generates three main types of waste, which possess some hazardous characteristics and should be disposed of in specific disposal wells (*Table 5*).

Table 5. Iodine from brine production wastes (Modified from NSCEP, 1988)

Process	**Waste**	**Hazardous waste characteristics**	**Disposal**
Hydrogen Sulfide Removal	Sulfur compounds	Potential Reactivity Potential Corrosivity	Hazardous waste disposal facility (Class V disposal wells)
Air Stripping of Iodine from Brine	Waste Brine	Potential Reactivity Potential Corrosivity	Reinjection into Class IV disposal wells
Iodine Precipitation	Liquid Waste	Potential Reactivity Potential Corrosivity	Management practice for the waste bleed liquor was not identified
Filtration	Filtrate Waste	Potential Reactivity Potential Corrosivity	May be recycled, waste acid and sludge are also produced in this step

Evaluation Question #10: 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)].

At the doses present in food commodities (*Table 1*), KI is unlikely to have a detrimental effect upon human health. However, at higher concentrations like the ones used in the medical field, and if certain pathological circumstances coexist, KI may have a detrimental effect in certain individuals as described below.

Beneficial uses or effects of iodine include (Osborne, 2023):

- It is used as a treatment for thyrotoxicosis
- It protects the thyroid during radioactive iodine therapy
- It is used as an expectorant (Costa et al., 2013)
- It may be beneficial as immune modulator in several inflammatory dermatoses
- It may be beneficial as a protective agent in fungal infections

Caution should be taken when consuming KI if (Osborne, 2023):

- Drugs that cause hyperkalaemia are also being consumed
- There is a record of one or more of the following conditions: previous thyroid disease and/or positive thyroid autoantibodies (multinodular goitre, Grave's disease, autoimmune thyroiditis). These increase the risk of hypothyroidism as there is dysfunctional thyroid autoregulation
- There is a record of one or more of the following conditions: Addison's disease, cardiac disease, myotonia congenita or renal impairment
- The person presents acne, since it may be aggravated by excess iodine intake

Adverse effects of excessive doses of KI (Osborne, 2023):

- **Gastrointestinal adverse effects**: Common and usually mild to moderate. They include nausea, vomiting, diarrhea and epigastric pain. They are often dose related and can be limited by slow and small dose increments. Rarely, small bowel ulceration.
- **Thyroid dysfunction**: Occurs due to loss of normal thyroid gland autoregulation. Hypothyroidism is more likely the longer KI is taken and when there is pre-existing thyroid disease; it arises due to inhibition of thyroid hormone production by an excessive iodine supply (Wolff–Chaikoff effect). This is usually reversible. Thyrotoxicosis may also occur when taking KI if there are pre-existing functional thyroid foci, e.g., multinodular goitre (Jod–Basedow effect).
- **Metabolic**: hyperkalemia and metabolic acidosis may cause confusion, arrhythmias, weakness, paraesthesia
- **Iodism/KI poisoning**: Usually occurs at high doses or after prolonged use and may cause oral ulceration and soreness, lacrimation, drooling, runny nose, and blurred vision. The side-effects usually resolve within a few days of discontinuing KI.
- **Hypersensitivity**: Swelling, skin irritation and rashes, tightening of the muscles around the airways and lungs, excess fluid in the lungs, headache, fever, joints pain and blood vessels inflammation can occur.
- **Dermatological (iododerma)**: Pustular, cystic, and acneiform reactions can result. Ulcerating nodules and plaques appear more common where there is co-existing systemic disease. Blistering cutaneous disorders may be exacerbated.
- **Ocular toxicity in humans:** Has occurred only after exposure to doses of 600 to 1,200 mg per individual (Ilin & Nersesyan, 2013).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary [7 U.S.C. 6518(m)(6)].

Low iodine content in some plant-based foods leaves people with certain specialized diets (e.g. vegans) susceptible to iodine deficiency without iodized supplements or iodized salt (Fuge & Johnson, 2015). Fortification of crops with iodine is an alternative practice that could hypothetically make use of KI unnecessary. We found no data suggesting that iodine fortification of crops for the purpose of human dietary iodine fortification have been implemented on the commercial scale, but this is an area of current research interest (Gonzali et al., 2017; Weng et al., 2014).

Scientists demonstrated in a few studies that the use of seaweed fertilizer produces crops with enhanced iodine content (Duborská et al., 2022; Fuge & Johnson, 2015). Field trials demonstrated levels of pre-harvest iodine fortification in leafy greens as a promising direction for future research interest, and to a lesser extent potatoes and tomatoes (Gonzali et al., 2017). Iodine fortified celery produced with seaweed fertilizer demonstrated less iodine loss from cooking than iodized salt (Weng et al., 2014).

Evaluation Question #12: 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)].

The annotation at 7 CFR 205.605(b)(20) for nutrient vitamins and minerals references 21 CFR 104.20. This National List entry consequently provides an allowance for dietary iodine supplementation in USDA organic production. KI (21 CFR 172.365) and kelp (21 CFR 172.365) are the only sources of iodine currently allowed by the FDA for human dietary iodine supplementation.

KI

There are no apparent commercially available nonsynthetic versions (see *Evaluation Question #2*).

Seaweed

Non-organically produced Pacific kombu and Wakame (*Undaria pinnatifida*) appear at 7 CFR 205.606(q) and § 205.606(t), respectively. Additionally, organic seaweed products are available and allowed (see *Evaluation Question #13*). Achieving sufficient dietary iodine fortification with seaweed is possible. A number of countries even regulate the maximum levels of iodine permitted in seaweed foodstuffs to curb excess iodine consumption (Guo et al., 2023). Scientists observed excessive dietary iodine consumption in countries where seaweed is part of traditional diet (Duborská et al., 2022). Health concerns arising from this excess iodine consumption via seaweed include goiter, hypothyroidism, and Hashimoto's thyroiditis.

Doh et al. (2018) demonstrated in a laboratory setting that water extracted Pacific kombu spray dried to create a novel iodized salt had similar iodine retention and storage stability to commercial iodized salts. Seaweed is susceptible to loss of iodine from further processing, including soaking and boiling (Guo et al., 2023). However, current data available is extremely limited and warrants further research to discern the variability of iodine retention between different seaweed species.

Wild crop seaweed has a widely variable nutritional profile (Salido et al., 2024). Nutritional composition of cultured seaweeds is generally less variable. A variety of factors influence seaweed nutritional composition including species, growing conditions, harvesting methods, and processing procedures (Guo et al., 2023). Most seaweeds are a rich dietary source of iodine (Fuge & Johnson, 2015). Brown algae (*Phyaeophyta*) generally has the highest levels of iodine, followed next by red algae (*Rhodophyta*), and green algae (*Chlorophyta*) the least. Seaweed accumulates not just iodine from the marine environment, but also other metals (Guo et al., 2023). Arsenic, cadmium, lead, and mercury in seaweeds amass at variable levels. Ficheux et al. (2023) observed that seaweeds were very low contributors to total dietary exposure to these heavy metals based on consumption data from two French studies. Seaweed consumption levels are on the rise in many parts of Europe, inspired by the globalization of food. These consumption levels are not as high as traditional diets found in Asia that center seaweed in the diet, sometimes to the extent of excessive dietary iodine. Scientists advise that all dietary sources of iodine should be monitored comprehensively to avoid health risks associated with excess iodine, but iodine deficiency is typically the greater health risk (Farebrother et al., 2019).

Seaweed is available domestically and globally (García-Poza et al., 2022) and 96% of seaweed production worldwide comes from aquaculture sources (Salido et al., 2024). We found no data evaluating the direct comparison of KI and seaweed products as relates to their production methods. Evidence continues to build suggesting that sustainability of wild crop seaweed is not as sustainable as seaweed aquaculture (García-Poza et al., 2022). Harvesting methods and the subsequent impact on marine ecosystems associated with wild crop are some of the variables understood to contribute to this. Harvesting wild crop seaweed to minimize ecosystem disruption is critical (Salido et al., 2024). Cultivation of seaweed risks the introduction of invasive species if locally endemic species are not propagated. Regulations to protect marine ecosystems against these risks are currently limited. In 2020, the NOSB recognized this challenge and made a formal recommendation to add a harvest parameters annotation for marine microalgae used as crop fertility inputs (NOSB, 2020).

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

No forms of KI are agricultural (see *Evaluation Question #2*). However, KI is a common material for dietary iodine fortification worldwide (Greenwald et al., 2022). Both dairy products and seaweed are rich sources of dietary iodine (Fuge & Johnson, 2015).

Dairy products

Milk products can be a major contributor of dietary iodine (Farebrother et al., 2019). The UK eliminated endemic iodine deficiency by the 1960s and scientists suggest that increased dairy consumption and changes in farming practices (*e.g.,* iodophor disinfectants) are factors that contributed to this, since the UK did not require the iodization of salt (Bath & Rayman, 2020; Fuge & Johnson, 2015). Dairy products as a dietary source of iodine is not limited to cow milk products. Scientists in the UK found a higher concentration of iodine in goat milk than cow milk (Bath & Rayman, 2020). Furthermore, other animal milks can be substantial sources of dietary iodine, including goat and camel (Farebrother et al., 2019).

Iodine content in milk can vary depending on the diet of the animal (Bath & Rayman, 2020; Walther et al., 2022). Scientists observed in multiple studies that organic milk contained lower iodine levels than conventional milk (Bath & Rayman, 2020; Fuge & Johnson, 2015). The lower iodine levels in organic milk and the contributing factors are currently under review by industry stakeholders in the UK (Bath & Rayman, 2020). Heat pasteurization of milk also results in drop in iodine content (Bath & Rayman, 2020; Fuge & Johnson, 2015).

Organic milk is available both domestically and globally (Mercaris & Organic Trade Association, 2021). Dairy products may not offer realistic alternatives for consumer populations abstaining from dairy products for cultural, medical, or ethical reasons (Fuge & Johnson, 2015). Iodine intake is cumulative (Farebrother et al., 2019). Scientists advise that all dietary sources of iodine should be monitored comprehensively to avoid health risks associated with excess iodine, but iodine deficiency is typically the greater health risk.

We found no data evaluating the direct comparison of KI and organic dairy products as relates to their production methods.

Seaweed

Seaweed is an agricultural product that throughout history and to present day provides dietary iodine to the human diet (Doh et al., 2018). A variety of organic seaweed products are currently available from operations domestically and globally (USDA, 2024). We found no data evaluating the direct comparison of KI and organic certified seaweed as relates to their production methods. Risks to human health and environmental effects with seaweed derived products are generally associated with a comparison of wild crop to aquaculture sourced seaweed (see *Evaluation Question #12*).

Report Authorship

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

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