Nitrous Oxide TAP Report
May 2003

Executive Summary

Nitrous oxide was petitioned for use as a whipping propellant for food grade aerosols. It is made by thermal decomposition of high purity ammonium nitrate and by the separation of adipic acid off gas. N_2O released to the atmosphere can be a potent greenhouse gas. All three reviewers find nitrous oxide to be synthetic. One reviewer suggests prohibiting nitrous oxide as there are more environmentally benign substances currently on the National List which can substitute for it. One reviewer who agrees with allowing this propellant further suggests that the amount of N_2O to be used be lowered or be combined with N_2 on a 50%:50% weight ratio.

Summary of TAP Reviewer's Analyses[1]

Synthetic/ Nonsynthetic	*Allow without restrictions?*	*Allow only with restrictions? (See Reviewers' comments for restrictions)*
Synthetic (3) Nonsynthetic	Yes (2) No (1)	Yes No

Identification

Chemical names:
Nitrous Oxide- N_2O
Other Names: Laughing gas, dinitrogen monoxide, N20, factitious air, hyponitrous acid anhydride, Nitral, nitrogen oxide
CASRN: 10024-97-2
FDA labeler code: 054260

Characterization

Composition:

A nitrous oxide molecule is made up of 2 atoms of nitrogen and 1 atom of oxygen. The oxygen in nitrous oxide is chemically bound making this gas unsustainable to human life.

Properties:

Vapor Density: 1.94 kg/m^3 (0.115 lb/ft^3)
Specific Gravity(air = 1): 1.530
Solubility in Water: Soluble
Vapor Pressure (psia): 759.7
Expansion Ratio: Not applicable
Evaporation Rate (nBuAc=1): Not Applicable
Freezing Point: -90.8°C (-131.5°F)
Boiling Point (°F @ 1 atm): -88.5°C (-127.4 °F)
pH: Not applicable
Odor Threshold: Not determined

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[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(M) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.*

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Coefficient Water/Oil Distribution: 0.665 Specific Volume (ft^3/lb): 8.7

Appearance and Color: Nitrous Oxide is a colorless gas or a colorless liquid. Both the liquid and gas have a sweet odor.(Airgas-SAFECOR, 2002b) Although nonexplosive and nonflammable, it is as capable as oxygen of supporting combustion.

At 70° F it takes 760 psi of vapor pressure to hold nitrous in liquid form. The critical temperature is 97.7° F; at this temp the vapor pressure can no longer hold the nitrous in liquid form. At this point the nitrous turns gaseous and will be at 1069 psi. As temperature rises further, so will pressure, but it will remain in gaseous form. When liquid nitrous is released, it will go from 760 psi to 14.7 psi (normal atmospheric pressure). It will then begin to boil and rapidly expand; the pressure drop will cause the temperature to decrease. (2003)

How Made:

Nitrous Oxide is made by the action of zinc on dilute nitric acid, by the action of hydroxylamine hydrochloride (NH_2OH HCl) on sodium nitrite ($NaNO_2$), and, most commonly by the continuous thermal decomposition of high purity ammonium nitrate (NH_4NO_3)[2], a common ingredient used in fertilizers and explosives, and by the separation from adipic acid off gas. A low-pressure, high temperature (500° F) reaction[3] decomposes the ammonium nitrate to form steam (H_2O) and N_2O. The steam is condensed out, and "crude" N_2O is then further purified, compressed, dried, and liquefied for storage and distribution. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

Nitrous Oxide producers ship their product as a low pressure liquid to approximately 300 customers, most of whom (≈ 250) are repackers. Repackers store product in liquid tanks, utilizing pumping facilities to fill gas cylinders or to supply smaller bulk liquid requirements. Nitrous oxide is shipped in cylinders as a gas over liquid (≈ 745 psi @ 70° F) to other distributors or to end users. Annual production of nitrous oxide in the U.S. ranges between 30 million and 35 million pounds.(CGA, 2003)

Aerosol System:

There are two ways to configure this aerosol system. In the simpler design, the liquid product is poured, can is sealed, and then gaseous propellant is pumped a through the valve system. The gas is pumped in at high-pressure, so it pushes down on the liquid product with a good amount of force.

In the other way, a long plastic tube runs from the bottom up to a valve system at the top of the can. The valve is a very simple design. It has a small, depressible head piece, with a

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[2] Ammonium is manufactured by reacting gaseous ammonia with concentrated nitric acid.

[3] The temperature of nitrous oxide would be still below the level that would support combustion and explosion which is in excess of 650 C (1202 F).

narrow channel running through it. The channel runs from an inlet near the bottom of the head piece to a small nozzle at the top. A spring pushes the head piece up, so the channel inlet is blocked by a tight seal.

As the head piece is pushed down, the inlet slides below the seal, opening a passage from the inside of the can to the outside. The high-pressure propellant gas drives the liquid product up the plastic tube and out through the nozzle. The narrow nozzle serves to atomize the flowing liquid -- break it up into tiny drops, which form a fine spray.(Harris, 2003) However, the specific amount of N_20 contained in the aerosol system was not available in this report.

Specific Uses:
1. Whipping propellant for food grade aerosols.

Other Uses:
1. Inhalational anesthetic agent- It is a weak anesthetic and must be inhaled in fairly high concentrations mixed with air or oxygen.
2. Refrigerant
3. Leak detecting agent
4. Oxidizing agent
5. Ingredient in fuel combinations
6. Plasma etching chemical for semiconductor manufacturing.(Airgas, 1995)

Action:

An aerosol can contains one fluid that boils well below room temperature (called the propellant) and one that boils at a much higher temperature (called the product). The product is the substance actually used or consumed and the propellant is the means of getting the product out of the can. Both fluids are stored in a sealed metal can.

Nitrous oxide is used as a propellant because it is lipid soluble. In whipped cream, the gas easily dissolves in the liquid, fatty cream. And as the cream escapes from the can, the gas expands and in doing so whips the cream into foam.(shirriff@sprite.Berkeley.EDU, 2003)

Combinations:

Citric Acid Ester(CMG) - CMG is an extremely hydrophilic and anionic emulsifier. It forms a milky dispersion in water and is only partially soluble in oil and fats. Its main applications in food are as an anti-spattering agent in or as an emulsifier in whipped cream.

Status

Historic Use by Organic Producers:

The use of nitrous oxide as a whipping propellant in organic whipped cream began in 2001. Since then, only Natural by Nature manufactures this product.(Ned MacArthur, 2003)

OFPA, USDA Final Rule:

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2002]

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[CITE: **21CFR184.1545**]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.**1545** Nitrous oxide.

(a) Nitrous oxide (empirical formula N<INF>2</INF>O, CAS Reg. No. 10024-97-2) is also known as dinitrogen monoxide or laughing gas. It is a colorless gas, about 50 percent heavier than air, with a slightly sweet smell. It does not burn but will support combustion. Nitrous oxide is manufactured by the thermal decomposition of ammonium nitrate. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

(b) The Food and Drug Administration is developing food-grade specifications for nitrous oxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

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

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in Sec. 170.3(o)(25) of this chapter.

(2) The ingredient is used in dairy product analogs as defined in Sec. 170.3(n)(10) of this chapter at levels not to exceed current good manufacturing practice.

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

[48 FR 57270, Dec. 29, 1983](Food and Drug and Administration, 2002)

Regulatory: EPA/NIEHS/Other Sources
Compressed gases.

Gases such as CO_2, N_2, compressed air, or nitrous oxide may be used in a few aerosol applications, but these are often less effective because the propellant pressure gradually falls as the aerosol can is emptied (March Consulting Group, 1998). However, these gases are nonflammable and do not require the use of extra explosion-proof equipment. In addition, technological improvements have been made to offset the effects of decreased pressure through innovative valve configurations and proper selection of compatible solvents (UNEP, 1998).*(U.S.Environmental Protection Agency, 2003)*

Status Among U.S. Certifiers

Washington State Department of Agriculture (WSDA) Organic Food Program- Chapter 16-158-060 WAC, not listed in the section "Minor Ingredients and Processing Aids"- The listing only lists oxygen, nitrogen and carbon dioxide under the category of atmospheric gases(WAC, 1997)

International

Australia:

Australia New Zealand Food Authority: Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1- INS Number 942(Australia New Zealand Food Authority, 2000)

Canada:

Canadian General Standards Board (CGSB)- Permitted Substance List (PSL) for Processing, Appendix C1.2- Listed only as Nitrogen and Oxygen separately(Canadian General Standards Board, 1999)

European Union:

Food Standards Agency: Additives Permitted in Food in the European Union – E 942 Nitrous oxide*(Food Standards Agency, 2002)*

Japan:

Japan Ministry of Agriculture, Forestry and Fisheries – Not Listed(Ministry of Agriculture, 2000)

CODEX:

General Standard for Food Additive- Codex Stan 192 -Annex C- List B: Nitrous oxide INS # 942, Acceptable JECFA ADI, JECFA Review Date (1985-29)*(CODEX, 2001)*

United Nations' World Health Organization and Food and Agricultural Organization:

Joint FAO/WHO Expert Committee on Food Additive: Prepared at the 55th JECFA (2000) and published in FNP 52 Add 8 (2000), superseding specifications prepared at the 29th JECFA (1985) and published in FNP 34 (1986) and in FNP 52 (1992). An ADI "Acceptable" was established at the 29th JECFA (1985). Functional Uses- Propellant, antioxidant, packaging gas, foaming agent(Joint FAO/WHO Expert Committee on Food Additive, 2003)

Section 2119 OFPA U.S.C. 6518(m) (1-7) Criteria

1. *The potential of the substance for detrimental interactions with other materials used in organic farming systems.*

The primary result of using nitrous oxide as a propellant is the release of the gas into the air. Since one of the goals of organic farming is to reduce potential environmental damage, an issue would be its contribution to the greenhouse effect. In addition, by increasing the source of available nitrogen and increasing the movement of nitrogen from one place to another, there is a potential to disrupt the ecosystem as many of the Earth's plant species are adapted to --and function best in soils and waters containing low levels of available nitrogen.(Montague, 1997)

2. *The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.*

Any adverse effect on animals would be related to oxygen deficient environments, effects on the central nervous system, and potential reproductive problems. Symptoms of exposure would be similar for those described for humans. No adverse effect is anticipated to occur to plant-life, except for frost produced in the presence of rapidly expanding gases. No evidence is currently available on its effects on aquatic life. This gas is soluble in water.

N_2O is primarily removed from the atmosphere in the stratosphere by photolysis (breakdown by sunlight). This reaction is a primary source of the oxides of nitrogen (in the stratosphere), which play a critical role in controlling the abundance and distribution of stratospheric ozone.

A secondary removal process (which accounts for about 10% of removal) is through a reaction with excited oxygen atoms. There is some evidence that soils may represent a small sink for the gas (IPCC, 1995), but, to date, there is not enough data to evaluate this.

The best estimate of the atmospheric lifetime of N_2O is 120 years. The direct radiative forcing of N_2O is estimated to be 0.14 Wm^{-2} (compared to values for CO_2 and CH_4 of 1.56 Wm^{-2} and 0.47 Wm^{-2})[4] and it has the global warming potential (GWP) relative to CO_2.

The long atmospheric lifetime of N_2O has implications for achieving stable atmospheric concentrations of the gas. If emissions were held constant at today's levels, the atmospheric concentration of N_2O would rise from 311 ppbv[5] to about 400 ppbv over several hundred years, increasing its incremental radiative forcing by a factor of four over its current level. In order for atmospheric concentrations to be stabilized near current levels, anthropogenic sources would need to be reduced by more than 50% (IPCC, 1996).(AEA Technology Environment, 1998a)

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

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[4] Irradiance (energy: *E*) =Wm-2 (watts per square meter)
[5] ppbv = parts per billion (10^9) by volume

During manufacture of Nitrous oxide, the site must have adequate ventilation. Local exhaust ventilation is preferred because it prevents Nitrous Oxide dispersing into the work place by eliminating it at its source. Automatic monitoring equipment must be installed to detect the level of oxygen or Nitrous Oxide.

For the handler, respiratory protection should be maintained. Oxygen levels should be maintained above 19.5% in the workplace. Supplied air respiratory protection should be used if oxygen levels are below 19.5% or during emergency response to a release of Nitrous Oxide.

The eyes, hands and body are protected by splash goggles, face shields or safety glasses. The face shields must be worn when using liquid Nitrous Oxide. Mechanically-resistant gloves are worn when handling cylinders and low temperature protective gloves (e.g. Kevlar) are worn when situation of splashes of liquid Nitrous Oxides occur. To protect the body from splashes from liquefied products and insulation from extreme cold, a body protection is used.

Nitrous oxide is said to dissipate rapidly in well-ventilated areas. During disposal, the substance removed from its cylinder must be disposed of in accordance with appropriate Federal, State, and local regulations and should not be disposed of locally.

Nitrous oxide's use as a propellant, for example in whipped cream dispensers, and most cases of abuse today involve those who have access to commercial products which produce whipped cream. Its effects were described as good, delightful, intoxicating and relaxing, and it was considered the 'genteel way' of getting drunk.*(Re-Solv, 2002)* Potential problems with nitrous oxide can result from careless use. The biggest risk involves inhaling the gas straight from pressurized tanks or mask attachments. A 1984 study by researchers at the Medical College of Virginia found that nitrous-filled tanks pose potentially serious risks to unwitting users, including:

- Brain injury and suffocation from lack of oxygen.
- Very cold temperatures of the gas can freeze the lips and throat.
- High levels of pressure may rupture blood vessels in the lungs and force air into the chest cavity, causing the lungs to collapse.
- Careless use of nitrous oxide can also cause nausea, vomiting, and disorientation. The chemical produces a temporary loss of motor control.(Fantes, 1999)

People who profit from nitrous oxide abuse typically steal the cylinders from distributors or legitimate users. Sometimes these profiteers try to legitimize this abuse by illegally obtaining a legitimate nitrous oxide use permit, or obtain the cylinders by misrepresenting themselves as legitimate users.(CGA, 2003)

Nitrous oxide (N2O) added to the atmosphere is a potent greenhouse gas, allowing sunlight in but refusing to allow heat to escape, thus tending to warm the planet. When it reaches the stratosphere (6 to 30 miles up in the sky) nitrous oxide

contributes to the destruction of the Earth's ozone shield. Reducing the ozone shield in turn increases the ultraviolet radiation striking the surface of the Earth which, in turn, damages some of the creatures that form the bottom of the oceans' food chains. Its contribution to the calculated greenhouse effect is roughly 7.5 percent.

4. *The effects of the substance on human health.*

Cardiovascular:

The circulatory effect of Nitrous oxide is based on its tendency to affect the sympathetic nervous system. Because of the stimulation of catecholamines from the sympathetic nervous system, arterial blood pressure, cardiac output and heart rate remain essential unchanged or even slightly elevated in spite of depressed cardiac contractility secondary to nitrous oxide. Higher levels of catecholamines (epinephrine) may increase the risk of cardiac arrhythmias.

Respiratory:

Nitrous oxide increases respiratory rate causing tachypnea but decreases tidal volume as a result of central nervous system stimulation. The ventilatory response to hypoxia (hypoxic drive) can be markedly depressed even by small amounts of nitrous oxide.

Cerebral:

By increasing cerebral blood flow, nitrous oxide produces a mild elevation of intracranial pressure and increases oxygen consumption in the brain.

Renal:

Renal blood flow can decrease secondary to constriction of the blood vessels leading the decreased filtration in the kidneys and lower urine output.

Other Potential Health Effects:

Contact with liquid or rapidly expanding gases (which are released under high pressure) may cause frostbite. Symptoms of frostbite include change in skin color to white or grayish yellow. The pain after contact with liquid can quickly subside.

Risks from Exposure:

Acute

The most significant hazard associated with this gas is inhalation of oxygen-deficient atmospheres and effects on the central nervous system. Symptoms of oxygen deficiency or central nervous system depression include respiratory difficulty, ringing in ears, headaches, dizziness, indigestion and nausea. At high concentration, unconsciousness or death may occur.

Chronic

Nitrous oxide inhibits enzymes that are vitamin B12-dependent by irreversibly oxidizing the cobalt atom in the vitamin's structure. These enzymes include methionine synthetase, which is necessary for myelin formation and thymidylate synthetase, which is necessary for DNA synthesis. The result of these effects can produce injury to the nervous system and symptoms of such overexposure manifests itself include numbness, tingling of the hands and legs, loss of feeling in the fingers, and muscular weakness (peripheral neuropathies). Exposure to the gas may be associated with an increase in spontaneous abortions in humans. Single, prolonged exposures have resulted in bone marrow damage leading to megaloblastic anemia and pernicious anemia.

Teratogenicity:

Nitrous oxide may cause teratogenic effects in humans. Exposure to the gas has caused embryo and fetal toxicity effects in laboratory animals. Such effects include reduced fetal weight, delayed ossification and an increased incidence of visceral and skeletal variations.(Airgas-SAFECOR, 2002a; Morgan & Mikhail, 1999)

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

Nitrous oxide naturally occurs from microbial action in soil. It is one of the end products of denitrification with inert nitrogen gas. It is also produced by fuel burning. Scientists say its production is increased by the use of nitrogen based fertilizer in agriculture, as well as by the use of catalytic converters in automobiles.(www.gdrc.org, 2003) It has also been theorized that the soil can act as a natural sink for nitrous oxide. (IPCC, 1995)

6. *The alternatives to using the substance in terms of practices or other available materials.*

Two main techniques have been identified for controlling emissions of N_2O from the production process:

In *catalytic destruction,* a catalyst bed (of metal oxides such as CaP and MgO) is used to decompose the N_2O into N_2 and O_2. The reaction is strongly exothermic and the heat produced must be removed; if there is a suitable demand on the production site, then it may be recovered and used to produce steam. Potential problems with the process include the need to recharge poisoned catalyst twice a year, and the complex design needed to generate useful steam from the process. A more expensive catalytic destruction technique involves the use of catalysts to decompose the N_2O to NO, which can then be oxidized and converted to nitric acid.

An alternative process is *combustion* of the off-gases in the presence of methane. The N_2O acts as an oxygen source and is reduced to nitrogen, giving non-negligible quantities of NO and some residual N_2O. The combustion process can be used to raise steam, if a demand exists on site.

Although Nitrous Oxide is the currently preferred whipping propellant, other expanding agents may also be used, such as CO2. A Japanese patent application JP 0 407 14 62, which is an aerosol for dispensing vegetable-based whipping cream, nitrogen is used as a propellant and carbon dioxide as an expanding agent; in this aerosol, the nitrogen: carbon dioxide volumetric ratio is 50-90:50-10.

Another consideration is by diluting the concentration of nitrous oxide with nitrogen. The gas mixture preferably comprises 30-80% by weight nitrous oxide and 70-20% by weight nitrogen, preferably 40-60% by weight nitrous oxide and 60-40% by weight nitrogen, and most preferably approximately 50% by weight nitrous oxide and

50% by weight nitrogen. In this context, the term "approximately" is understood to mean a deviation of at most 5% by weight.*(CAMPINA MELKUNIE B.V., 2001)*

Future options:

Potential further options identified by Oonk (1995) are the biofiltration of off-gases using denitrifying bacteria and photo-catalytic conversion. The applicability of the options to nitric acid production offgases and the reduction potential and costs of these options are not yet known.(AEA Technology Environment, 1998b)

7. *Its compatibility with a system of sustainable agriculture.*

Environmentalists and ecologists share the consensus that there should be an 80 percent reduction in the total greenhouse gases below the 1990 level and that that would be needed by 2025. For industrial gases, which contribute to 12 percent of the problem, they recommend complete elimination.

Specifically, nitrous oxide contributes roughly 7.5 percent of the calculated greenhouse effect caused by human activity. The concentration in the atmosphere is increasing at a rate of 0.2 per cent a year and it is recommended that phasing out fossil fuels and better soil management can help in reducing the levels.(Mazza & Dauncey, 2001; 2002)

Criteria From the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if:

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.

Nitrous Oxide occurs naturally due to the action of soil bacteria. Only synthetic material is commercially available.

Nitrous oxide is used as a propellant because it is lipid-soluble gas. The nitrous oxide under pressure dissolves in the fat of a dairy product. When the pressure is released, the nitrous oxide is released from the fat and returns to the gaseous state.

Carbon dioxide also is lipid-soluble. Carbon dioxide, either alone or in combination with nitrogen gas, apparently also works in these applications, by a similar mechanism.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6510 of the OFPA.

Nitrous oxide is a potent greenhouse gas with an atmospheric half-life of 120 years.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.

Nitrous Oxide dissipates into the atmosphere. It is 'inert" and does not affect the nutritional value of the food.

The most significant hazard associated with this gas is inhalation of oxygen-deficient atmospheres (hypoxia) and effects on the central nervous system. Symptoms of oxygen

deficiency or central nervous system depression include respiratory difficulty, ringing in ears, headaches, dizziness, indigestion and nausea. At high concentration, unconsciousness or death may occur. Nitrous Oxide is abused as a "recreational drug."

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

Nitrous Oxide is used as a propellant to recreate the texture of whipped cream, which can not be retained during processing.

5. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

Nitrous Oxide is an ingredient permitted under 21CFR 184.1545 as a propellant, aerating agent, and gas for use in dairy product analogs at levels not to exceed current good manufacturing practice.

6. Its use is compatible with the principles of organic handling.

Nitrous Oxide of commerce is a synthetic substance manufactured by the thermal decomposition of ammonium nitrate, a synthetic substance. Ammonium nitrate is a conventional fertilizer. Ammonium nitrate can be used as an explosive.

Nitrous Oxide does not alter the food, only its texture.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

Although Nitrous Oxide is the currently preferred whipping propellant, other expanding agents may also be used, such as carbon dioxide (CO_2). Japanese Patent Application JP 0 407 14 62 discloses an aerosol for dispensing vegetable-based whipping cream, wherein nitrogen is used as a propellant and carbon dioxide is uses as an expanding agent. In this aerosol, the nitrogen: carbon dioxide volumetric ratio range is 50-90:50-10.

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TAP Reviewer Discussion

Reviewer 1: *[Ph.D. biochemistry, research and consulting in the food industry; southeast]*

Comments on Database
The database (Characterization and Status) is reasonably complete and fairly accurate.

1. *NOSB Processing Criteria Evaluation (check all that apply and supply any additional info)*

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
I agree with the criteria evaluation.

Carbon dioxide may be a suitable alternative to nitrous oxide. If so, organic carbon dioxide may be a commercially feasible organic alternative to nitrous oxide. Carbon dioxide can be produced naturally, by fermentation.
Manufacturing a non-synthetic source of nitrous oxide is not realistic.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.
I agree with the criteria evaluation. Use of nitrous oxide, a greenhouse gas with a long environmental half-life, entails its entry into the atmosphere and so cannot be accomplished without an adverse effect on the environment.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.
I agree with the criteria evaluation.

Low concentrations of gaseous nitrous oxide (rather than its indirect effects via oxygen displacement or the freezing effect of the pure liquid during volatilization) have relatively low toxicity, which is what one would expect considering the medical and dental use of "laughing gas."

Nutritional value is unaffected by "whipping by effervescence." In whipping by effervescence, a liquid food product such as cream is introduced to a pressurized container and a gas (such as nitrous oxide alone or mixed with carbon dioxide or carbon dioxide alone) is dissolved or dispersed in the cream under pressure. The solubility of a gas in the cream is generally directly proportional to the pressure encountered. Upon release of the pressurized cream to the atmosphere through a suitable nozzle, the gas passes out of solution but the fat masses tend to remain as foam.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

I agree with the criteria evaluation.

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

I agree with the criteria evaluation. The heavy metal specifications of the Food Chemicals Codex monograph should be provided in the document.

6. *Its use is compatible with the principles of organic handling.*

I agree with the criteria evaluation. Additional supporting information is provided in the Review under OFPA Criteria 2 and 7. The environmental impact of nitrous oxide, a greenhouse gas with a half-life of >100 years, make its use incompatible with the principles of organic handling. Carbon dioxide, a potential alternative, also is a greenhouse gas, but is utilized by green plants in photosynthesis.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*

I agree with the criteria evaluation.
No data are provided that compare carbon dioxide or carbon dioxide mixtures with nitrous oxide in the "whipped cream" application or that show that nitrous oxide is indispensable for this application.
Patents have issued on mixtures of gases already allowed in §205.605 [(b)(8) carbon dioxide, (a)(12) nitrogen] for this application so nitrous oxide does not appear to be uniquely required in this application.

2. Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

Nitrous oxide is a synthetic substance with an adverse effect on the environment. This is incompatible with organic systems. More environmentally benign substances currently on the National List can substitute for nitrous oxide in the petitioned application (propellant for whipped cream). Thus, nitrous oxide should be prohibited in organic food handling systems. [Use of nitrous oxide in veterinary medicine is not the subject of this petition or this TAP Review].

3. Recommendation Advised to the NOSB:

a. The substance is **Synthetic**. The substance is **Non-Agricultural**.

b. in a product labeled 95% organic

The substance should be **Prohibited (do not add to National List).**

c. in a product labeled "made with organic (specified ingredients)"

The substances should be **Prohibited (do not add to National List).**

Reviewer 2: *[Ph.D .nutrition, extension specialist of food processing and safety, east]*

Comments on Database

I find the database to be reasonably complete and accurate.

Overview and Chemical /Processing Properties

Propellants are used in foods that are packaged in pressurized containers to allow spraying or forming of the products. Foamed food products (whipped cream and dairy and vegetable fat-based toppings) generally utilize water-soluble propellants such as nitrous oxide or carbon dioxide; the propellant expands upon use of the product and aids in foam formation. Although an asphyxiant at high concentrations, nitrous oxide is considered GRAS under GMP in the US. However, it is important to note that nitrous oxide is prohibited in Canada and prohibited in cheese products in Denmark, Netherlands, Spain, UK, and Germany.

This petition documented clearly various ways of making nitrous oxide. Commercially nitrous oxide (laughing gas) is most commonly made by the thermal decomposition of ammonium nitrate (NH_4NO_3). The chief impurity of the product is N_2, although, NO_2, N, O_2, and CO_2 may also be present, however, usually not in any quantity to approach toxicity. The resulting mixture is passed through water for purification. In addition, it might be helpful to point out that nitrous oxide is a greenhouse gas that is produced both naturally and anthropogenically. Due to its long atmospheric lifetime (approximately 120 years) and radiative forcing effects—about 310 times more powerful than carbon dioxide on a per molecule basis (U.S. EPA, 1998)—nitrous oxide is considered a major greenhouse gas. In the United States, anthropogenic emissions of N_2O are primarily generated by agricultural soil management, mobile and stationary sources of fossil fuel combustion, adipic acid production, and nitric acid production. Also, N_2O is produced naturally from a wide variety of biological sources in soil and water.

Use of nitrous oxide as a whipping propellant in organic whipped cream began in 2001. The configuration of the food-grade aerosol system was described in detail in the petition. However, it is critical to specify the amount of nitrous oxide contained per aerosol system in order to evaluate the safety of the aerosol system accordingly.

Conclusion: The commercially produced N_2O in this petition should be considered SYNTHETIC.

Environmental Considerations

N_2O is removed from the atmosphere mainly by photolysis (i.e., breakdown by sunlight) in the stratosphere, which accounts for its long lifetime. The imbalance between sources and sinks corresponds to about 3.9 Teragrams (Tg) (N_2O). The best global emissions estimate is 3 to 8

Tg(N)/year, with natural sources accounting for twice as much of the emissions as anthropogenic sources.

Atmospheric concentrations have increased from about 270 parts per billion by volume (ppbv) in pre-industrial times to 314 ppbv as of 1998. Atmospheric concentrations of N_2O continue to increase at a rate of 0.25%/yr (1980 to 1998). The average growth rate over the period 1990 to 1999 was 0.8 ppbv/yr. There has been significant multi-year variance in the observed growth of N_2O concentrations, with suggested causes including: a decrease in the use of nitrogen-based fertilizers, lower biogenic emissions, and larger stratospheric losses due to volcanic-induced circulation changes. However, the multi-year trends of this greenhouse gas remain largely unexplained (IPCC, 2001).

Conclusion: This petition provided to some extent the severity of environmental impacts by nitrous oxide. However, the justifications under OFPA Criteria #1 'The potential of the substance for detrimental interactions with other materials used in organic farming systems' should be further justified with estimated discharge of nitrous oxide from propellant consumption.

Nutritional / Human Health Effects

*** Summary of toxicology**

1. Effects on Animals: Nitrous oxide has central nervous system, teratogenic, bone marrow, and liver effects in animals (ACGIH, 1991). Rats exposed to an 80 percent concentration for 2 or more days showed signs of bone marrow toxicity (ACGIH, 1991). However, rats exposed to a 1 percent concentration of nitrous oxide for periods ranging from 7 days to 6 months showed no bone marrow effects (ACGIH, 1991). Exposure to nitrous oxide also causes neurotoxic (spinal cord lesions, demyelination, peripheral neuropathy) and hepatotoxic (focal inflammatory lesions) effects in experimental animals (ACGIH, 1991). In one study, pregnant rats were exposed to 50 percent nitrous oxide for 24 hours/day starting on day 8 of gestation and continuing for 1, 2, 4, or 6 days; dose-related embryolethal and teratogenic effects occurred among the offspring. The most common effects were embryonic death, resorption, and abnormalities of the ribs and vertebrae (Rom, 1992). Nitrous oxide was negative in three carcinogenicity assays in mice and rats exposed to concentrations as high as 400,000 ppm for 4 hours/day, 5 days/week for 78 weeks. The results of mutagenicity assays involving nitrous oxide were negative (ACGIH, 1991).

2. Effects on Humans: Nitrous oxide is an asphyxiant at high concentrations. At lower concentrations, exposure causes central nervous system, cardiovascular, hepatic, hematopoietic, and reproductive effects in humans (Hathaway et al., 1991). At a concentration of 50 to 67 percent (500,000 to 670,000 ppm) nitrous oxide is used to induce anesthesia in humans (Rom, 1992). Patients exposed to a 50:50 mixture of nitrous oxide:oxygen for prolonged periods to induce continuous sedation developed bone marrow depression and granulocytopenia (Hathaway et al., 1991; ACGIH, 1991). Although most patients recover, several deaths from aplastic anemia have been reported (Hathaway et al., 1991). Neurotoxic effects occur after acute exposure to concentrations of 80,000 to 200,000 ppm and above;

effects include slowed reaction times and performance decrements (Hathaway et al., 1991). Long-term occupational exposure (dentists, dental assistants) has been associated with numbness, difficulty in concentrating, paresthesias, and impairment of equilibrium (Hathaway et al., 1991; ACGIH 1991). Epidemiological studies, primarily of operating room personnel, have shown increased risks of spontaneous abortion, premature delivery, and involuntary infertility among these occupationally exposed populations (Hathaway et al., 1991).

*** Signs and symptoms of exposure**

1. Acute exposure: The signs and symptoms of acute exposure to nitrous oxide include dizziness, difficult breathing, headache, nausea, fatigue, and irritability. Acute exposure to nitrous oxide concentrations of 400,000 to 800,000 ppm may cause loss of consciousness (Sittig, 1991).

2. Chronic exposure: The signs or symptoms of chronic overexposure to nitrous oxide may include tingling, numbness, difficulty in concentrating, interference with gait, and reproductive effects.

Reviewer 2 Conclusions: This petition provided good information about the toxicity and mode of action of nitrous oxide. The authors mentioned the work done by Oonk (1995) yet failed to provide the citation source in the bibliography. In the opinion of this reviewer, several important references should be considered as listed at the end of this review.

Summary

With additional NOSB criteria not being addressed or answered, it is in the opinion of this reviewer that nitrous oxide is synthetic and be allowed without annotation.

References

ACGIH (1991). Documentation of the threshold limit values and biological exposure indices. 6th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.

Hathaway GJ, Proctor NH, Hughes JP, and Fischman ML (1991). Proctor and Hughes' chemical hazards of the workplace. 3rd ed. New York, NY: Van Nostrand Reinhold.

IPCC (2001). Technical Summary: A Report Accepted by Working Group I of the IPCC but not approved in detail. A product resulting from The Third Assessment Report of Working Group I of the Intergovernmental Panel on Climate Change, January 2001.

Rom WN (1992). Environmental and occupational medicine. 2nd ed. Boston, MA: Little, Brown and Company.

Sittig M (1991). Handbook of toxic and hazardous chemicals. 3rd ed. Park Ridge, NJ: Noyes Publications.

Reveiwer 3: *[Ph.D . chemistry, Professor Department of Chemistry ,southeast]*

Comments on Database

I find the database (Characterization and Status) to be reasonably complete and accurate.

Summary

The use of nitrous oxide as a propellant will not affect the consumption of any food item with which it is mixed, because it is released from the foodstuff when it leaves its holding container. Thus the primary issue of using nitrous oxide as a propellant is the release of the gas into the air and atmosphere. Since one of the goals of organic farming is to reduce potential environmental damage, an issue would be its contribution to the greenhouse effect. The data presented shows that nitrous oxide contributes 7.5% of the greenhouse gases from industrial practices. Therefore, lowering the amount of N_2O by using it in combination with N_2 seems like the best idea. It was suggested that 50%:50% weight ration of N_2O:N_2 would be suitable for propellant needs, therefore this is recommended.

4. Assessment as to the completeness and accuracy of database and evaluation.

1 *The natural availability*
Although found in mammals, this is not suitable for industrial production.

2 Methods described are safe and suitable for nitrous oxide production.

3 *The nutritional quality and adverse effects on human health*
Because the nitrous oxide is not ingested by humans, there is no issue with nutritional quality nor adverse effects on human health due to ingestion from expected use of propellant activated foods.

4 *The technical effect in the food*
The primary purpose of nitrous oxide in the food is for texture, and does not serve any purpose for food preservation, nor is it ingested.

5: *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock., GRAS.*
This product is generally regarded as safe in foodstuffs, because it is not ingested.

6 *Its compatibility with a system of sustainable agriculture*
Because nitrous oxide does not serve a role in the dietary considerations, and is only temporarily used for texture, it does not need to be judged as a foodstuff (e.g. whipped cream). However, if organic handling includes contribution of nitrous oxide to the atmosphere, then

reduction in use is warranted. As recommended above, combination of nitrous oxide with harmless nitrogen will reduce nitrous oxide use.

7 *The alternatives to using the substance in terms of practices or other available materials.* Nitrous oxide is used because it is a lipid soluble gas. An alternative is carbon dioxide, as presented in Japanese patent application JP 0 407 14 62, which can be used as an aerosol for dispensing vegetable-based whipping cream, where nitrogen is used as a propellant and carbon dioxide as an expanding agent. However, the use of carbon dioxide is not recommended because it is the primary component of "green-house gases", and therefore does not solve the problem.

Reviewer 3: Recommendation Advised to the NOSB:

The substance is synthetic and it is the recommendations of this reviewer that nitrous oxide be allowed without restrictions.

[End of TAP reviewer comments]