Vitamin D_3

Crops

Identification of Petitioned Substance

Chemical Names:
7-dehydrocholesterol

Other Name:
Cholecalciferol
Calciferol
Calciol
9,10-Seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol

Trade Names:
Quintox

CAS Numbers:
67-97-0 (cholecalciferol)

Other Codes:
PC Code: 202901
EINECS Number: 200-673-2

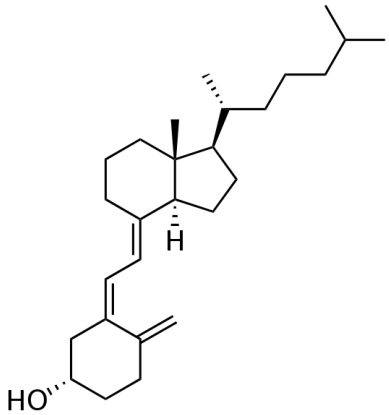
Characterization of Petitioned Substance

Composition of the Substance:

Vitamin D_3 is a biochemical nutrient that is produced naturally in the body in a multi-step process that involves chemical transformations in the skin, liver, and kidneys (Holick, 1999). The synthesis of vitamin D_3 in the body begins with the conversion of cholesterol to the vitamin D precursor 7-dehydrocholesterol. After being exposed to solar ultraviolet (UV) radiation in the skin, 7-dehydrocholesterol forms cholecalciferol. Cholecalciferol is then hydoxylated in the liver to become calcifediol. Calcifediol is then hydroxylated in the kidney and becomes calcitriol ($1\alpha25(OH)_2D_3$), a hormone that carries out the biological functions of vitamin D_3. These functions include increasing the transfer of calcium from the intestine into the bloodstream and increasing the uptake of calcium to bones (Holick, 1999).

This technical report is primarily concerned with cholecalciferol, the form of vitamin D_3 that has been used as an active ingredient in rodenticides. The molecular structure of cholecalciferol is shown in Figure 1.

Figure 1. Molecular Structure of Cholecalciferol



Properties of the Substance:

Vitamin D_3 is a crystalline solid that is not considered to be soluble in water. Vitamin D_3 may react with strong oxidizers and can produce an exothermic reaction when in contact with reducing agents (NOAA,

2010). A common product of these reactions is hydrogen gas. The physical and chemical properties of cholecalciferol are presented in Table 1.

Table 1. Chemical Properties of Cholecalciferol

Physical or Chemical Property	Value
Physical State	Solid
Appearance	White or amber, needle-like crystals
Molecular Weight	384.64
Melting Point	84-87° C
Vapor Pressure	$2.4x10^{-9}$ mm Hg at 25° C
Solubility	Insoluble in water (<0.1 g/L (20 °C)); soluble in alcohol, chloroform, acetone, ether, and fatty oils

Source: NOAA, 2010

Specific Uses of the Substance:

Vitamin D_3 is used as a food fortifier and aids in the growth and maintenance of bones. Fortification with vitamin D_3 can prevent low levels of phosphate in the blood as well as low blood calcium levels (Mayo Clinic, 2010). Commonly fortified foods include milk and cereals. The biochemical form of vitamin D_3 added to fortified foods does not require activation with sunlight.

Vitamin D_3 is used to treat conditions that cause weak bones and is effective in treating Rickets (Mayo Clinic, 2010). Multi-vitamin supplements typically contain vitamin D_3. Medications exist that contain vitamin D_3 and are prescribed to persons diagnosed as vitamin D deficient (Mayo Clinic, 2010). These medications are generally taken orally (Mayo Clinic, 2010).

Vitamin D_3 is also used as a synthetic rodenticide in gel and pellet baiting products for gophers, mice, rats, and other rodents (ATTRA, 2010b). Rodenticides containing vitamin D_3 cause an excessively elevated level of calcium in the blood of target species (ATTRA, 2010b).

Approved Legal Uses of the Substance:

Vitamin D_3 is considered by the U.S. Food and Drug Administration (FDA) as generally recognized as safe (GRAS) (21 CFR 184.1950). The regulation states that crystalline vitamin D_3 ($C_{27}H_{44}O$, CAS No. 67-97-0), also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E,)-5,7,10(19)-cholestatrien-3-ol, and can be added to food as a food ingredient (i.e., nutrient supplement). The FDA considers vitamin D_3 as the vitamin D form that is produced endogenously (i.e., biochemically in the body) in humans through sunlight activation of 7-dehydrocholesterol in the skin. Vitamin D_3 resin is the concentrated forms of irradiated ergosterol (D_2) and irradiated 7-dehydrocholesterol (D_3) that are separated from the reacting materials described in paragraphs (a) (1) and (2) of this section (21 CFR 184.1950). The resulting products are sold as food sources of vitamin D without further purification. Vitamin D_3 as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345 (21 CFR 184.1950). Vitamin D_3 resin must be of purity suitable for its intended use.

Vitamin D also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (FDCA) or with regulations promulgated under section 412(a)(2) of the FDCA. Vitamin D also may be used in margarine. Also, in accordance with 21 CFR 184.1950 (c)(1), the vitamin D_3 may used in specific foods as the sole source of added vitamin D only within the specific limitations listed in Table 2.

In 1984, the U.S. Environmental Protection Agency (U.S. EPA) approved vitamin D_3 for use as a rodenticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and according to the current U.S. EPA pesticide registration schedule, a reregistration for vitamin D_3 is scheduled for 2017 (U.S. EPA, 2010). Currently, four vitamin D_3 rodenticide products are registered for use (PPIS, 2010). These

products all are restricted to the control of Norway rats, roof rats, and house mice in and around buildings, transport vehicles, and alleys, and all must be placed indoors or within 50 feet of a building (NPIRS, 2010).

Table 2. Levels of Vitamin D_3 Allowed in Various Food Categories Under 21 CFR 184.1950(c)(1)

Category of Food (defining regulatory citation)	Maximum Levels in Food (as served)	Functional Use
Breakfast cereals (21 CFR 170.3(n)(4))	350 (IU/100 grams)	Nutrient supplement, 170.3(o)(20)
Grain products and pastas (21 CFR 170.3(n)(23))	90 (IU/100 grams)	Do.
Milk (21 CFR 170.3(n)(30))	42 (IU/100 grams)	Do.
Milk products (21 CFR 170.3(n)(31))	89 (IU/100 grams)	Do.

Note: Not all foods containing vitamin D_3 are included in this list.

In 2008, the U.S. EPA issued final risk mitigation decisions (U.S. EPA, 2008) for ten rodenticides, including cholecalciferol (i.e., vitamin D_3). The risk mitigation decisions imposed new measures for three categories of rodenticides. For vitamin D_3, the new risk mitigation measures require that all rodenticide bait products marketed to general and residential consumers be sold only with bait stations, with loose bait (e.g., pellets and meal) as a prohibited bait form. This requirement is intended to minimize children's exposure to rodenticide products used in homes.

Vitamin D_3 is listed as an allowed synthetic substance by the U.S. Department of Agriculture (USDA), National Organic Program (NOP) for use as a rodenticide (7 CFR 205.601(g)(2)). Specifically, vitamin D_3 appears on the 'National List of Allowed and Prohibited Substances' as a synthetic substance allowed for use in organic crop production as a rodenticide. None of the four currently registered vitamin D_3 rodenticide products is included in product lists published by the Organic Materials Review Institute (OMRI, 2010).

Action of the Substance:

Small quantities of vitamin D_3 are essential for humans, but in high doses the substance is detrimental. Vitamin D_3 has a number of major functions in animal nutrition, specifically those surrounding the use of calcium. Calcium aids in the formation of new bone, egg shells in avian species, milk production, neuromuscular action, and blood clotting (Marshall, 1984). Therefore, the pool of calcium circulating in the blood is very carefully regulated. In most non-avians, changes of more than 10-15 percent can be detrimental (Marshall, 1984). A sophisticated system involving the intestines, kidneys and skeleton is primarily regulated by the hormones parathyroid hormone (PTH), calcitonin, and 1, 25-$(OH)_2D_3$ that generally keep blood calcium levels within 2-3 percent of normal (Marshall, 1984). If calcium levels fall below the normal range, the kidneys are stimulated by PTH to produce 1,25-$(OH)_2$ D_3. When low levels of calcium are needed, a shutoff mechanism is utilized and a kidney enzyme converts 25-OH-D_3 to 24,25-$(OH)_2$ D_3 (Marshall, 1984).

Following oral ingestion, vitamin D_3 accumulates in the liver. Following ingestion the induction of calcium mobilization occurs which can result in hypercalcemia and mineralization of major organs (Marshall, 1984). An increase in the calcium level results in mobilization of calcium, which circulates dissolved in the blood plasma. An elevated level of the crystals of calcium salts can cause mineralization of major organs. Mineralization results in tissue damage and can cause heart problems and possibly kidney failure. Tissue damage caused hypercalcemia and mineralization of major organs leads to death in rodents.

Combinations of the Substance:

It is unlikely that vitamin D_3, when used according to its label (Bell Laboratories, Inc., 2010) as a rodenticide, will be mixed with any other substances used in organic crop or livestock production. No additional information has been identified that describes the use of vitamin D_3 in combination with other substances.

Status

Historic Use:

As early as the 1600s, vitamin D_3 deficiency was reported and described as what is now identified as Rickets (University of California, Riverside, 1999). In the early 1900s, it became understood that a lack of vitamin D_3 served as the causative factor in many diseases associated with calcium deficiency (University of California, Riverside, 1999).

Vitamin D_3 has historically been added to food as a fortifier to improve calcium levels in the human body. It is commonly added to milk and other similar food products.

Vitamin D_3 (i.e., cholecalciferol) has been used as a rodenticide since the 1970s. It is used in the creation of pellets and other baits targeted at mice, rats, moles, and gophers (ATTRA, 2010b).

OFPA, USDA Final Rule:

Under authority of the Organic Food Production Act (OFPA), vitamin D_3 is listed as a synthetic rodenticide on the National List of Allowed and Prohibited Substances (7 CFR 205.601(g)(2)) .

International

The Canada Food Inspection Agency, Food and Drug Regulations states that "Vitamin D_3 (Cholecalciferol) may be used outdoors and inside greenhouses for rodent control when methods described in par. 5.6.1 of CAN/CGSB-32.310, *Organic Production Systems – General Principle and Management Standards*, have failed. Not allowed inside on-farm food processing and food storage facility." (Last modified in 2009)

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: What category in OFPA does this substance fall under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

(A) Vitamin D_3 is considered a vitamin.

(B) Vitamin D_3 is identified as an inert ingredient, on the U.S. Environmental Protection Agency's "List 4B", in pesticide formulations (U.S. EPA, 2004).

Evaluation Question #2: 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)).

The commercial manufacture of vitamin D_3 utilizes cholesterol obtained by organic solvent extraction of animal skins (pig, sheep, or cow) and extensive purification (Norman, 2000). Typically, cholesterol is extracted from the lanolin of sheep wool and converted to 7-dehyrdocholesterol after a process of chemical synthesis that involves eighteen steps (Norman, 2000). The crystalline 7-dehyrdocholesterol is then dissolved in an organic solvent and irradiated with UV light. This process causes a photochemical transformation of 7-dehyrdocholesterol into cholecalciferol that is similar to the natural process that occurs

in the skin of humans. It is then purified and crystallized further before being formulated for use (Norman, 2000). Details of the manufacturing process are subject to several patents (Norman, 2000) and are not publicly available.

Evaluation Question #3: Is the substance synthetic? 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).

Although vitamin D_3 is a product of a natural biochemical process, a synthetic process is used to manufacture cholecalciferol for use as a rodenticide and food fortifier. This synthetic process, described under Evaluation Question #2, includes UV conversion of 7-dehyrdocholesterol to cholecalciferol), as well synthetic chemical transformations.

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

It is possible for vitamin D_3 to be released to the environment as a result of production and also because of its use in various medications. The substance will remain in the atmosphere in the particulate-phase based on its vapor pressure ($2.4x10^{-9}$ mm Hg at 25° C). Vitamin D_3 is removed from the atmosphere by wet or dry deposition (HSDB, 2006). Photolysis by sunlight is expected to occur because vitamin D_3 can absorb light at wavelengths greater than 290 nm (HSDB, 2006).

In the soil, vitamin D_3 is expected to remain immobile based on its estimated K_{oc} of 1.5×10^6 (HSDB, 2006). Based on its vapor pressure, volatilization from dry soil is not expected; however, volatilization from moist soil surfaces may occur based upon an estimated Henry's Law constant of 2.3×10^{-4} atm-cu m/mole (HSDB, 2006).

In water, volatilization of cholecalciferol is expected and its half-life is estimated as 85 years from a model pond when considering adsorption to sediment and suspended solids in the water column (HSDB, 2006). Bioconcentration in aquatic organisms is low based on an estimated bioconcentration factor (BCF) of 3. Vitamin D_3 lacks the functional groups that hydrolyze under environmental conditions; hydrolysis is not expected (HSDB, 2006).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

In minute quantities, vitamin D_3 is not considered toxic. However, elevated levels can be lethal and cause hypercalcemia and mineralization of organs.

When too much vitamin D_3 is ingested, the small intestine is stimulated to absorb more phosphorus and calcium. Bone is also mobilized and begins releasing phosphorus and calcium into the blood stream (Marshall, 1984). The kidneys begin reabsorbing calcium, which adds to the elevated concentrations of calcium in the blood. When the blood calcium level is too high, hormone activity can no longer regulate and counteract this process and the system fails. System failure results in calcification and blockage of the circulatory system (Marshall, 1984). This is the fatal action when rodents consume large quantities of vitamin D_3-based rodenticides. Rodents require a smaller dose than humans to produce lethal effects because of their size. When calcium levels are elevated, hormones are released by the thyroid to counteract the process. Hormones react rapidly in mammalian species to ensure that blood and other fluids are fully saturated with normal levels of calcium so that bones and other reactions requiring calcium can occur (Marshall, 1984). When a lethal dose is ingested, normal hormone regulation of calcium is inhibited (Marshall, 1984).

Vitamin D_3 is not expected to mobilize in soil and its bioconcentration in aquatic life is expected to be very low (HSDB, 2006). Information on its concentration in the environment is not available.

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

The manufacture of vitamin D_3 may result in environmental release (HSDB, 2006). Upon release to the atmosphere, the vapor pressure of vitamin D_3 ($2.4x10^{-9}$ mm Hg at 25° C) indicates that the substance will be in the particulate phase (HSDB, 2006). Vitamin D_3 will be removed from the atmosphere by wet or dry deposition (HSDB, 2006). Because vitamin D_3 is capable of absorbing light at wavelengths greater than 290 nm, it may undergo direct photolysis by sunlight (HSDB, 2006).

If vitamin D_3 is not used properly in bait stations or in indoor environments (where soil is not present), it is possible for the substance to be released to the soil. However, the estimated K_{oc} of vitamin D_3 is considered to be $1.5x10^6$ and mobility in soil is unlikely (THSDB, 2006). It is unlikely that vitamin D_3 would volatilize from dry soil based on its vapor pressure ($2.4x10^{-9}$ mm Hg at 25° C) (HSDB, 2006).

In water, vitamin D_3 is considered insoluble and, based on the K_{oc}, may adsorb to sediment and other suspended solids (HSDB, 2006). Volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column (HSDB, 2006). The BCF has been estimated to be 3 and bioconcentration in aquatic organisms is unlikely (HSDB, 2006). Vitamin D_3 lacks functional groups that hydrolyze under environmental conditions, making hydrolysis an unlikely occurrence (HSDB, 2006). Because of the insolubility of vitamin D_3, the substance is unlikely to cause groundwater contamination or contamination to other water sources (Kegley et al., 2010).

Ingestion of large amounts of vitamin D_3 rodenticides can cause hypercalcemia in children and domestic pets. Evidence has shown that vitamin D_3-containing rodenticides have caused death in household pets (Morrow, 2001). Toxicity has been observed more among cats than dogs, and adverse effects correspond to 6 g (79 pellets or about ½ tbsp) of a typical 0.075 percent cholecalciferol rat bait ingested by a 20-lb (9-kg) dog (Morrow, 2001). Signs of acute toxicosis develop within 12 to 36 hours after ingestion and include vomiting and diarrhea (sometimes bloody), anorexia, depression, and possibly polyuria and polydipsia (Morrow, 2001). With high doses, acute renal failure can occur within 24 to 48 hours and can result in death (Morrow, 2001). Animals that survive may lose renal or musculoskeletal function and may develop cardiac arrhythmias (Morrow, 2001). Clinical signs and subsequent treatment may last for weeks because of the lipid storage and slow elimination of the cholecalciferol metabolites (Morrow, 2001).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

The manufacturer states (Bell Laboratories Inc., 2010) that it is unlikely that vitamin D_3 rodenticide products, when used as directed, will be mixed with any other substances used in organic crop or livestock production . Vitamin D_3 is manufactured into pellets and blocks used to bait mice and rats. The U.S. EPA (2008) requires that vitamin D_3 containing rodenticides be used in a bait station when non-target wildlife and children could be in contact with the rodenticide.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil) crops, and livestock (7 U.S.C. § 6518 (m) (5)).

No studies have been found that investigate the effects of vitamin D_3 on soil-dwelling organisms. Vitamin D_3 is unlikely to be mobile in the soil based on its K_{oc} and solubility.

According to manufacturer instructions, rodenticide baits (i.e., pellets or blocks) are self contained in baiting stations and do not interact with the agro-ecosystem (Bell Laboratories Inc., 2010). Baiting stations are generally specific to the target organism and prevent any mixing within the agro environment. Moreover, all currently registered vitamin D_3 rodenticide products are intended for use in or around buildings or transportation vehicles (NPIRS, 2010).

Labeling instructions require that vitamin D_3 rodenticide products not be used in areas where non-target organisms, including livestock, would have contact (Bell Laboratories Inc., 2010). It is also recommended that the products be used where livestock are not present and also within contained baiting stations or traps. It is possible that non-target organisms may be poisoned by ingesting vitamin D_3 rodenticides. Accidental poisonings and lethal effects on domestic pets have been documented in the past (Morrow, 2001). Based on observed effects in domestic pets, it can be inferred that similar effects may be observed in non-target wildlife or livestock. However, risk mitigation requirements imposed by U.S. EPA since 2008 were conceived to reduce accidental poisonings (see the "Approved Legal Uses of the Substance" section above).

Evaluation Question #9: Discuss and summarize findings on whether the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Based on chemical properties, mobility of vitamin D_3 in soil is unlikely and volatilization from dry soil surfaces is not expected (HSDB, 2006). Data on the biodegradation of vitamin D_3 in soil are not available.

In the ambient atmosphere, vitamin D_3 is expected to remain as a particulate due to its vapor pressure and may be removed from the air by wet and dry deposition (HSDB, 2006). Photolysis (i.e., photochemical degradation) from direct sunlight is likely to occur because vitamin D_3 can absorb light at wavelengths greater than 290 nm (HSDB 2006).

Very limited information is available on the environmental toxicology of vitamin D_3. Vitamin D_3 is virtually insoluble in water and is likely to adsorb to sediment and suspended solids (HSDB, 2006). The substance is not predicted to cause adverse effects to aquatic wildlife (U.S. EPA, 1984). It is unlikely that vitamin D_3 would bioaccumulate in aquatic life (HSDB, 2006).

Toxicity studies in birds have indicated that vitamin D_3 is of low toxicity (U.S. EPA, 1984).

There have been reports of acute poisoning in domestic pets and effects appear to be similar to those of humans. Clinical signs of poisoning include depression, lethargy, anorexia, vomiting, and polydipsia and severe clinical signs include calcification of the kidneys and stomach (Mason and Littin, 2003). Internally, poisoned dogs show calcification of vascular walls, gastrointestinal hemorrhage, and myocardial necrosis (Mason and Littin, 2003). Poisoned horses exhibited leg stiffness, anorexia, weakness, recumbency and, internally, extensive mineralization of cardiovascular and other soft tissues (Mason and Littin, 2003).

The U.S. EPA's final risk mitigation decision for ten rodenticides (U.S. EPA, 2008), including cholecalciferol, were intended to protect children, pets, and wildlife from accidental poisonings. These decisions include specifications for packaging (e.g., tamper-resistance) and use practices of registered rodenticides.

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)).

Rodenticide containing vitamin D_3 can be toxic to humans when ingested in excess. Rat studies indicate that signs of toxicity can occur with ingestion of 0.5 mg/kg (20,000 IU/kg) (Cannell, 2003). The oral LD_{50} is reported as 88 mg/kg in dogs (3,520,000 IU/kg) (Cannell, 2003). This would be equivalent to a 110 pound adult taking 176,000,000 IU or 440,000 of the 400 unit vitamin D_3 capsules (Cannell, 2003). Therefore, the risk of toxicity in humans due to exposure to vitamin D_3 rodenticides is low.

In instances of chronic, low dose human poisonings, victims typically exhibit clinical symptoms of vomiting, weight loss, depression, headaches, nausea, pain and intense discomfort in areas of the body, and irritability (Mason and Littin, 2003). It was reported that a woman who ingested vitamin D_3 every day for two months developed renal and mental impairment and another individual exhibited signs of

permanent renal damage (Mason and Littin, 2003). In fatal cases, heart and lung tissue, renal tubes, and arteries have exhibited signs of calcification (Mason and Littin, 2003).

Evaluation Question #11: 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 National List allows for the use of sulfur dioxide for underground rodent control only (smoke bombs). The U.S. EPA has not registered sulfur dioxide for use as a rodenticide. However, U.S. EPA has registered rodent control smoke bombs with the active ingredients sulfur, potassium nitrate (saltpeter), and charcoal carbon. Currently registered sulfur-based smoke bomb products include:

- The Giant Destroyer: Atlas Chemical Corp., P.O. Box 141, Cedar Rapids, IA, 52406
- Revenge Rodent Smoke Bomb: Roxide International, P.O. Box 249, New Rochelle, NY, 10802

Ignition of the smoke bomb generates sulfur dioxide and other gasses and consumes oxygen. The sulfur dioxide generated by these products is synthetic. Although some marketing information[1] indicates that rodent control smoke bombs cause death by asphyxiation (e.g., depriving the rodents of oxygen), the product labels do not indicate this mode of action and note that the product produces toxic fumes.

Sulfur-based smoke bombs may only be used in underground burrows and not for above ground baiting. The use of additional pest control measures would be required in order to control rodents dwelling above ground.

Castor bean oil has been made into a pellet that can be used in smaller gardens to kill rodents. Disadvantages of this method include a high amount of labor required to upkeep the application of the pellets in the tunnels. These pellets can be dangerous because they can poison household pets. Castor oil can also be sprayed.

Currently manufactured products containing castor oil:

- Dr. T Whole Control Mole Repellent: Dr. T's Nature Products, P.O. Box 682, Pelham, GA 31779
- MoleMax Mole and Vole Repellent: Bonide Products Inc., 6301 Sutliff Rd., Oriskany, NY 13424

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

One suggestion for reducing populations of tunnel dwelling rodents is to place rotten eggs in the tunnels or to use animal scents, such as urine, to deter pests (ATTRA, 2010a). Hair has also been suggested as a deterrent of rodents (ATTRA, 2010a). It is also important to remove weeds and other potential food sources as well as encourage good sanitation and cleanliness practices (ATTRA, 2010a).

Planting repellant plants have been utilized as a non-synthetic method for controlling gopher populations. These plants include castor bean, daffodils, squill, and euphorbia (ATTRA, 2010a). Gophers should be removed from the area prior to planting, which can be difficult to achieve. If all animals are not removed, the gophers will be trapped inside.

A majority of organic farmers rely on trapping for some level of rodent control. In order to maintain efficacy, trapping should be done on a daily basis and especially during critical times in the life cycle of the rodent and the cropping season (ATTRA, 2010b). The removal of food sources and shelter can deter rodents from farms.

[1] For example: http://www.get-revenge.us/molecontrol.html; http://www.wholesale-garden-supplies.com/product.php?productid=22734&cat=0&page=1;

There are many types of traps and barriers that are commonly used for rodent control. The use of live traps is common for capturing ground squirrels. These traps include a model called a 'repeating trap' that can catch a whole colony from one baiting. One advantage of using traps is that the level of precision is higher because the exact tunnels can be followed. A second advantage is cost as traps are less expensive. Disadvantages of traps include the necessity of handling the animals that are caught, whether alive or dead. Ground squirrels have been found to carry bubonic plague and rabies and cases have been reported after humans reported contact. Traps also require regular monitoring and additional skill to set them. Examples of barriers include fencing and "gopher cages" or wire baskets placed in a hole at planting time to keep gophers out of the root zone. Because of their burrowing nature, gophers and ground squirrels can defeat most fences and the caging idea is confined to use on small acreages with valuable perennial plants (ATTRA, 2010b).

Flooding out tunnels using large amounts of water has been used in some instances (ATTRA, 2010a). This practice is not effective, however, on sloped ground or when rodents other than gophers have been the source of infestation. This practice also uses a large amount of water and can create soil erosion. It may also be unfeasible to transport water to the location.

An increased population of predators is an effective control option. The corn snake (*Elaphe guttata)* and the rat snake (*Elaphe obsoleta*) are two snakes on the United States mainland that feed on rodents, such as mice, rats, and squirrels (ATTRA, 2010b). Note that both species also feed on small birds, so a key disadvantage to this method is that chicks and eggs might be at risk as well as rodents. Domestic cats can provide long-term control, but are known to prey on birds (ATTRA, 2010b). Over 95 percent of the diet of barn owls usually consists of small mammals, including rodents. Each barn owl may consume about one or two rodents per night. Per year, a nesting pair and their young can eat more than 1,000 rodents. Barn owls will commonly use nest boxes. This alternative would certainly not be as feasible as the use of vitamin D_3 pellets and bait blocks, but could have effective results.

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