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ATTORNEYS AT LAW

JUN 16 2009

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June 13, 2009

Via Hand Delivery

Robert Pooler
Standards Development and Review Branch
USDA National Organic Program
Room 4004
Ag Stop 0268
1400 Independence Ave., SW
Washington, D.C. 20250

Dear Mr. Pooler:

In response to your letter dated February 24, 2009, please find enclosed a revised copy of our petition to delist ferric phosphate. The information identified as missing in the petition, Items 4, 5, 7, 9 and 10, has now been incorporated. A copy of your February 24, 2009 letter and the November 5, 2008 cover letter accompanying our petition to delist are enclosed for your reference.

Thank you for your attention to this matter. Please give me a call if you have any questions or require additional information.

Sincerely,

Juliana Mann
Paralegal Specialist
jmann@steptoe.com

USDA

United States Department of Agriculture

Agricultural Marketing Service

STOP 0268 – Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

February 24, 2009

Ms. Julianna Mann
Steptoe & Johnson, LLP
1330 Connecticut Avenue, NW
Washington, D.C. 20036

Dear Ms. Mann,

Thank you for your petition of November 05, 2008, which requests the removal of Ferric phosphate from section 205.601 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances (National List).

We have reviewed your petition and determined that the Ferric phosphate petition cannot move forward through the petition process for the following reason:

1. Incomplete petition information provided within the Ferric phosphate petition. As submitted, there is insufficient information within your petition to conduct an adequate review to consider removing Ferric phosphate from the National List.

To assist you in the development of your petition, we recommend that you modify your current petition to address these items:

- Provide comprehensive information that adequately addresses each item in the attached document, "National Organic Program – Submission of Petitions of Substances for Inclusion on or Removal from the National List of Substances Allowed and Prohibited in Organic Production and Handling." Please address information items 4, 5, 7, 9, and 10.

Should you have any further questions, please contact me by phone at (202) 702-3252 or by e-mail at bob.pooler@usda.gov.
720

Sincerely,

Robert L. Pooler
Standards Development and Review Branch
USDA National Organic Program

cc: NOSB

Attachment

STEPTOE & JOHNSON LLP
ATTORNEYS AT LAW

WRITER'S DIRECT DIAL
202-419-5166

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November 5, 2008

JUN 16 2009

Robert Pooler
Program Manager
USDA/AMS/TM/NOP
Room 4008-So.
Ag Stop 0268
1400 Independence Ave., SW
Washington, D.C. 20250

Dear Mr. Pooler:

Under cover of this letter, we are petitioning the National Organic Program (NOP) and National Organic Standards Board (NOSB) to reevaluate and reconsider the decision to include Ferric Phosphate in section 205.601 H of the National List (71 Fed. Reg. 53299, September 11, 2006).

While ferric phosphate itself may meet the necessary criteria, for the intended use as a molluscicide, ferric phosphate must be and is formulated with ethylenediaminetetraacetate (EDTA) (or related salts), a compound which NOSB determined on November 30, 2007 to be unacceptable for inclusion on the National List. Therefore, ferric phosphate must be removed from the National List or the National List entry amended to specify no use of EDTA or related compounds.

Thank you for your attention to this matter. Please feel free to contact me or Ms. Julianna Mann (as identified on the enclosed petition) if there are any questions.

Sincerely,

Elizabeth Anne Brown

Elizabeth Anne Brown, Ph.D.
Technical & Regulatory Analyst
eabrown@steptoe.com

JUN 16 2009

PETITION TO REEVALUATE AND REMOVE SYNTHETIC SUBSTANCE FROM SECTION 205.601 H OF THE NATIONAL LIST

Petitioner: Steptoe & Johnson, LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036

Contact: Ms. Juliana Mann
Tel: 202-429-3095
jmann@steptoe.com

Substance: FERRIC PHOSPHATE (CAS Number 10045-86-0)

Petition for reevaluation and removal of a synthetic substance allowed for use in organic crop production in 7 CFR section 205.601(h), as an acceptable synthetic substance for use as a slug and snail bait in organic crop production.

JUN 16 2009

PART I DETAILED INFORMATION

1. **Substance Name**
   Ferric Phosphate (Ferric Othophosphate, Iron Phosphate, Iron Orthophosphate)
   CAS Number 10045-86-0; EINECS Number 233-149-7

2. **Original Petitioner**
   W. Neudorff GmbH KG
   Postfach 1209
   An der Mühle 3
   D-31860 Emmerthal/Germany

   Manufacturer's Name and Address
   Dr. Paul Lohmann GmbH KG
   Hauptstaβe 2
   D-31857 Emmerthal/Germany

3. **Area of Current and Intended Use**
   Pesticide (Molluscicide, specifically as a slug and snail bait)

4. **List of Crops For Which the Substance Will Be Used, Application Method and Application Rate**
   The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See pp. 2 - 3 of 25. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

   Vegetables including (but not limited to): artichokes, asparagus, beans, beets, black-eyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes, and turnips.

   Fruits including, but not limited to: apples, avocados, apricots, cherries, grapes, melons, peaches, plums, nectarines, citrus, and pears.

   Berries including, but not limited to: strawberries, blackberries, blueberries, boysenberries, loganberries, and raspberries.

   Field crops including, but not limited to: artichokes, beans, field corn, sweet corn, soybeans, sugar beets, sugar cane, asparagus, beets, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, cucumbers, lettuce, onions, peas, peppers, potatoes, radishes, strawberries, tomatoes, turnips, and wheat.

Outdoor ornamentals.

Greenhouses.

Outdoor container grown nursery plants.

Lawns and grass grown for seed production.
The end-use product that was the subject of the May 1, 2003 original petition to list, NEU1165M Slug and Snail Bait, may be applied by hand or by using standard broadcast or granular spreaders.

The application rate for commercial agriculture is 20-44 lbs/acre for vegetables (except artichokes), fruits including citrus, berries, field crops (except artichokes and wheat), and 10-44 lbs/acre for artichokes, grass grown for seed production, and wheat. For home and garden uses, the product is applied at a rate of 1 lb per 1000 square feet, or 1 level teaspoon per square yard. In greenhouses, ½ teaspoon of bait is applied in or around each 9-inch pot.

5. The Source of the Substance and Its Manufacturing Procedure

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See p. 3 - 9 of 25. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

The source of the material described in the May 1, 2003 petition to list, NEU1165M Slug and Snail Bait, is produced by a synthetic manufacturing process. The materials used in the manufacturing process are considered CBI and were deleted from the publicly available version of the May 1, 2003 petition. The information was provided by the original petitioner, W. Neudorff GmbH KG, and is available for your review in the CBI version of the petition.

6. Summary of available reviews

See information provided in PART II below.

7. Registration Information

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See p. 11 of 25. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

US EPA - NEU1165M Slug and Snail Bait was registered on August 14, 1997. The registration number is 67702-3.

FDA – Ferric phosphate is identified as a GRAS substance under 21 CFR §184.1301.

State registration – NEU1165M Slug and Snail Bait is registered in California. The registration number is 67702-3-AA.

8. Chemical Abstract Service (CAS) Number and Label

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See pp. 11 and Reference c. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

CAS number 10045-86-0.

Label – See Appendix 6.

9. Substances Physical Properties and Chemical Mode of Action

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See pp. 12 - 22. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

Information responsive to this section is attached as Appendix 7.

10. MSDS

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 . *See Appendix D. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

The MSDS is attached as Appendix 8.

PART II EXPLANATION FOR INAPPROPRIATENESS FOR INCLUSION OF FERRIC PHOSPHATE ON NATIONAL LIST

Ferric Phosphate alone is not active or effective as a molluscicide (see Appendices 1, 3). It has activity only when formulated with the chelating/stabilizing agent EDTA or its salts. Since the National Organic Standards Board has made a specific determination that EDTA or its salts are not permitted for use under the National Organic Program, the listing for ferric phosphate should be removed from the regulations.

The petitioner for the existing listing of Ferric Phosphate has clearly identified to other parties the presence and essential need for Ferric Phosphate to be associated with EDTA or related salts in order to obtain molluscicidal activity.

- Appendix 1: U.S. Patent Number 5,437,870 (Aug 1, 1995)
- Appendix 2: Technical Data Sheet for Iron (III) Phosphate as a molluscicide, showing EDTA to be present at 10% as a stabilizer in the formulation (Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling, Thirty-second session (May 10-14, 2004), Government Comments at Step 6 (CX/FL 04/5).

Independent scientific testing confirms the lack of activity when EDTA is absent. Laboratory scale testing in the OECD artificial soil test to determine the effects of molluscicidal products on earthworms (*Eisenia fetida)* clearly identifies that iron phosphate in combination with EDTA or EDDS and EDTA and EDDS alone were toxic, which implies they may be toxic to other animals.

- Appendix 3: Personal communication from C.A. Edwards et al., Soil Ecology Lab, Ohio State University
- Zheng, L., D.G. Watson, J.N.A. Tettey, C.A. Clements. 2008. The determination of iron as its EDTA complex in Helix aspera by hydrophilic interaction liquid chromatography coupled to Fourier transform electrospray ionisation mass spectrometry. Talanta 76(5): 1165-1169

Ongoing research by Dr. Edwards evaluating effects of molluscicidal products in large microcosms has identified adverse effects on *Lubricus terrestris* (decreased earthworm feeding, mortality and/or loss of weight) with iron phosphate in combination with EDTA or EDDS but not with iron phosphate alone (Personal communication from C.A. Edwards, May 28, 2008). These results confirm that the chelating agent is essential for biological activity.

Zheng et al. (2008) confirms that ferric phosphate along, without EDTA, is ineffective in controlling slugs. Feeding pellets made from ferric phosphate alone had no effect on slugs, while the addition of EDTA resulted in 100% mortality. The authors state "The snails fed on the FeEDTA pellets were fed 4-5 pellets and died 3 days after this single feeding. The snails fed on the FePO4 pellets were fed 3-4 pellets on three occasions over

3 days since they continued to eat the pellets and suffered no apparent ill effects." They further state "Snails fed with the 1% (w/w) $FePO_4$ did not suffer any ill or toxic effects and could be maintained on this diet indefinitely. Thus, it would appear that the presence of EDTA in the formulation along with iron (III) is necessary for the absorption of toxic levels of iron." Analytical results confirmed this conclusion.

EDTA is Present in Iron-Based Molluscicidal Formulations

Regardless of whether EDTA is identified as a stabilizer, chelating agent, enhancer, or other inert component of a product or is identified as a part of the complex with the iron compound, EDTA is present in molluscicidal formulations and clearly has been identified as such. As discussed above, EDTA is essential for molluscicidal activity.

- See Appendices 1 and 2
- Appendix 4: Proposed Regulatory Decision on Ferric Sodium EDTA. Health Canada, Pest Management Regulatory Agency, December 21, 2007.

EPA has acknowledged the presence of EDTA or similar chelating agents even in formulations where EDTA is not identified as a part of the active ingredient. (EPA. July 18, 2006. Metaldehyde Alternatives Assessment. EPA-HQ-OPP-2005-0231-0014, page 4). EPA also noted that these agents made the iron component more biologically available.

EDTA Has Been Determined to Be Ineligible for Inclusion on the National List

While the original petition for inclusion of ferric phosphate on the National List may have identified EDTA or similar compounds as inert components of the molluscicidal formulation, it is possible that this component was not considered in depth because it appeared on List 4 of US EPA's Lists of Inert Ingredients in Pesticide Formulations. However, in its consideration of a petition to include Sodium Ferric Hydroxy EDTA on the National List, NOSB determined it was ineligible solely on the basis of the EDTA component.

- Appendix 5: Formal Recommendation by the NOSB to the NOP, November 30, 2007

It is noted that U.S. EPA no longer categorizes inert ingredients by list designation. EPA states "All-food use inert ingredient tolerances and tolerance exemptions are considered to be safe when used according to the conditions set forth in the CFR's text and tables. As noted above, the "4A" category is still being used for the purposes of FIFRA Section 25(b), and USDA is still utilizing "List 4" for their National Organic Program." (http://www.epa.gov/opprd001/inerts/lists.html , referenced on 11/4/2008).

US EPA's current (1/7/2008) listing of nonfood inert ingredients does not identify whether any are 4A or 4B; all compounds on the list are listed simply as "permitted." No EDTA compound appears on US EPA's current list (4/10/2008) of minimal risk inert ingredients permitted in FIFRA 25(b) products. In fact, US EPA determined EDTA and salts to be List 4B in the January 28, 2004 tolerance reassessment decision for food-use inert ingredients. However, NOSB has determined EDTA and its salts to be unacceptable for use in organic products. That specific decision supersedes any listing provided by EPA.

PART III ALTERNATIVE SUBSTANCES

The petitioner is unaware of any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

PART IV CONCLUSION

Because NOSB has determined that EDTA and its salts are unacceptable for use in organic products and because EDTA is and must be present in molluscicidal products containing ferric compounds for efficacy against the target pest, ferric phosphate must be removed from the National List or the National List entry amended to specify no use of EDTA or related compounds. We further would recommend that all components of current or reformulated molluscicides containing ferric compounds be closely examined to ensure that the entire product fully meets the rigorous standards for use in organic production.

APPENDICES

APPENDIX 1

US005437870A

United States Patent [19]

Puritch et al.

[11] Patent Number: 5,437,870

[45] Date of Patent: Aug. 1, 1995

[54] **INGESTIBLE MOLLUSC POISONS**

[75] Inventors: **George S. Puritch**, Saanichton; **David S. Almond; Robert M. Matson**, both of Victoria; **Wenda M. Mason**, Saanichton, all of Canada

[73] Assignee: **W. Neudorff GmbH KG**, Emmerthal, Germany

[21] Appl. No.: **295,606**

[22] Filed: **Aug. 25, 1994**

[51] **Int. Cl.**[6] **A02N 25/34**

[52] **U.S. Cl.** **424/408**; 424/84; 424/410; 424/404

[58] **Field of Search** 424/404, 84, 410, 408; 514/492

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,765,979	8/1988	Nielsen	424/84
4,983,390	1/1991	Levy	424/404
5,290,557	3/1994	Mason et al.	424/410
5,362,749	11/1994	Henderson et al.	514/492

FOREIGN PATENT DOCUMENTS

2207866A 2/1989 United Kingdom .

OTHER PUBLICATIONS

I. F. Henderson, et al., *Ann. Appl. Biol.* (1990), 116, 273–278.

I. F. Henderson, et al., *Crop Protection*, Apr. 1990, 9 131–134.

I. F. Henderson, et al., 1989 BCP Mono. No. 41 Slugs and Snails in World Agriculture 289–294.

Hendersen, et al., *Aspects of Appl. Biol.* (1986) 13, 341–347.

Primary Examiner—Thurman K. Page
Assistant Examiner—William E. Benston, Jr.
Attorney, Agent, or Firm—Lahive & Cockfield; William C. Geary, III

[57] **ABSTRACT**

An effective, readily ingested molluscicidal bait poison includes an inert mollusc bait and two active ingredient precursors. These precursors are edible and non-toxic to terrestrial molluscs when consumed alone. However, the composition which includes the two precursors is fatally toxic to terrestrial molluscs. One precursor is a simple iron compound, while the other precursor is selected from edetic acid, its hydroxyethyl derivatives and salts of these acids. In another embodiment a single active ingredient may replace the two precursors. This active ingredient may include ferric edetate and the ferric hydroxyethyl derivative of edetic acid.

10 Claims, No Drawings

INGESTIBLE MOLLUSC POISONS

BACKGROUND OF THE INVENTION

This invention relates to ingestible compositions for the control of terrestrial molluscs.

Terrestrial pulmonate gastropods, slugs and snails (collectively, molluscs) are significant plant pests that affect commercial agriculture and horticulture and domestic gardens. These molluscs are omnivorous and consume large amounts of vegetative materials during their daily foraging. Consequently, they can seriously damage vegetable gardens and even plant crops during all phases of the growing cycle. Because of their destructive potential, control measures must be employed to ensure adequate protection of the growing plants from damage by terrestrial molluscs.

A wide variety of approaches have been used to try to combat pest molluscs. Perhaps the most common is the use of poisonous compounds called molluscicides. Molluscicides include a diversity of chemical compounds such as table salt (NaCl), calcium arsenate, copper sulfate, and metaldehyde. Molluscicides fall into two major groups, depending upon their mode of action: contact poisons and ingestible (or bait) poisons.

Contact poisons are molluscicides that, to be effective, must come into physical contact with the exterior of the mollusc, either by external application or through the action of the mollusc traversing a molluscicidal composition placed on the ground. The contact molluscicide is picked up by the proteinaceous slime coat of the mollusc and it builds up in the body of the mollusc until a lethal proportion is reached. One of the major drawbacks of contact molluscicides is that they have little effect if the molluscs do not physically contact the active chemical agent. If the molluscs are hidden or migrate into an area after a contact molluscicide is spread, the molluscs are unaffected. For these reasons, contact-acting mollusc poisons generally are considered to be unreliable.

Heavy metals, including zinc, aluminum, copper and iron, are all toxic to molluscs and are examples of compounds known to be effective molluscicides when used as contact poisons in the form of salts or chelates. See, Henderson, et al. Crop Protection (1990), 9, 131–134 and Henderson, et al., Ann. Appl. Biol. (1990), 116, 273–278.

Ingestible (or bait) mollusc poisons are those that must be ingested by a mollusc in order to be lethal. This type of mollusc poison tends to be preferred over contact poisons only because contact poisons, which rely upon passive acquisition of the active ingredient, are not considered to be reliable. One challenge associated with the development of effective bait molluscicides is to prepare a composition that is both palatable to the mollusc and effective as a lethal poison. Obviously, a sufficient quantity of the poison must be ingested to reach the lethal threshold. Often, compositions that are palatable to the mollusc are not effective as a lethal poison, while compositions that are quite potent and lethal are not readily ingested by molluscs. Many contact poisons, such as aluminum sulfate, copper sulfate and borax, are useless as ingestible poisons because they are not palatable to molluscs, and the molluscs do not ingest a lethal dose of these compounds. Ingestible poisons must be sufficiently palatable to the mollusc so that they will be consumed in lethal amounts, but the composition must also be slow acting enough to prevent the mollusc from becoming sick or cause it to cease feeding.

Typical problems associated with the development of compounds for the effective control of molluscs are discussed by Henderson, et al. in Aspects of Appl. Biol. (1986) 13, 341–347. This publication recognizes that although many compounds are known to be poisonous to molluscs, there is considerable difficulty in delivering the poison to the mollusc either as a bait or as a contact poison. The potential toxicity of a compound is irrelevant if molluscs will not consume a lethal dose of a bait poison.

One of the few compounds that act as both a contact and bait poison for terrestrial molluscs is metaldehyde. This compound is commonly used as a long lasting bait, attracting the molluscs and killing them after they ingest the poison bait. Despite its high effectiveness and its commercial popularity, metaldehyde is toxic to higher mammals and is a major contributor to domestic animal poisoning in the U.S. and Europe. More recently, U.K. Patent Application 2 207 866A has reported that specific complexes of aluminum with pentanedione compounds and iron with nitroso compounds would act as both ingested and contact poisons.

There is thus a need to develop an effective ingestible poison for molluscs that is palatable to molluscs and that does not pose a threat to the environment, crops, animals and other non-pests.

Accordingly, it is an object of the invention to provide a toxic, ingestible composition that is palatable to terrestrial molluscs. Another object is provide such a composition that poses no significant threat to the environment, crops, animals, or other non-pests. Other objects will be apparent upon review of the following description.

SUMMARY OF THE INVENTION

The invention provides an effective ingestible poison that is lethal to terrestrial molluscs. The composition is comprised of constituent compounds which do not pose any significant threat to the environment, plants, animals and other non-pests. In one embodiment the composition combines an inert carrier, such as a bait, with a simple iron compound and a second component. The simple iron compound can be an iron protein, an iron carbohydrate or an iron salt. The second component may be edetic acid, or hydroxyethyl derivative of edetic acid or a salt of these acids. Individually, neither the simple iron compound nor the second component is toxic to terrestrial molluscs. It is believed that the composition becomes toxic to molluscs only after it is ingested by the molluscs. Preferably, the molar ratio of iron in the simple iron compounds to the second component is in the range of 1:0.2 to 1:2.0. Preferably, the iron component is present in an amount such that the concentration of iron within the composition is in the range of about 200 to 10,000 ppm.

In another embodiment the composition comprises a single active ingredient in combination with an inert ingredient such as a mollusc bait. The single active ingredient may be ferric edetate or a ferric hydroxyethyl derivative of edetic acid. Preferably, the active ingredient is present in an amount such that the concentration of iron within the composition is in the range of about 200 to 10,000 ppm.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a bait poison that is effective against terrestrial molluscs. In one embodiment the composition of the invention combines an inert, edible mollusc bait with two active ingredient precursors. Individually the active ingredient precursors are not toxic to the molluscs. It is only when the entire composition, including the active ingredient precursors, is ingested by molluscs that molluscicidal activity is achieved.

One active ingredient precursor is a simple iron compound. The simple iron compound can be an iron protein, an iron carbohydrate or an iron salt. A second active ingredient precursor is selected from the group consisting of edetic acid a hydroxyethyl derivative of edetic acid, or salts of these acids.

In another embodiment the molluscicidal composition combines an inert, edible mollusc bait with an active ingredient such as ferric edetate or a ferric hydroxyethyl derivative of edetic acid.

An advantage of the molluscicidal composition of the present invention is that it exhibits good mortality against terrestrial molluscs and it is readily consumed by terrestrial molluscs. A further advantage of this composition is that the constituents of the composition are environmentally safe and pose no threat to humans, animals or other non-pests. In fact, with the exception of the iron salts of edetic acid or hydroxyethyl derivatives of edetic acid the individual components are nontoxic to molluscs when administered alone. The composition of the invention not only is lethal to molluscs, but molluscs are also poisoned to the extent that they cease feeding upon plants after consuming the composition.

Preferably, the molar ratio of iron in the simple iron compound to the second precursor ingredient is in the range of 1:0.2 to 1:2.0.

The simple iron compound can be selected from any one of a number of iron salt compounds including iron proteins, iron carbohydrates, and iron salts. The iron compound can be present in its iron (II) state (ferrous) as well as in its iron (III) state (ferric). Examples of suitable simple iron compounds are saccharated ferric oxide, ferric albuminate, ferric ammonium citrate, ferric chloride, ferric citrate, ferrous gluconate, ferrous lactate, ferric phosphate, ferrous phosphate, ferric pyrophosphate, ferric nitrate, ferrous sulfate, ferric stearate, ferrous stearate, and ferric tartrate. One characteristic of the simple iron compounds used as an active ingredient precursor in this invention is that they have little or no toxicity to the molluscs when used alone. Suitable simple iron compounds are commercially available from a variety of sources, including Dr. Paul Lohmann GmbH KG of Emmerthal, Germany.

The simple iron compound preferably is present within the composition at an amount such that the iron concentration in the composition is in the range of about 200 to 10,000 ppm. More preferably, the simple iron compound should be present in an amount such that the iron concentration in the composition is in the range of 2000 to 6000 ppm.

As noted above, the second active ingredient precursor can be edetic acid, hydroxyethyl derivative of edetic acid or salts of these acids. Preferred salts of these acids include the sodium salts, such as calcium disodium edetate, monosodium edetate, disodium edetate, trisodium edetate, tetrasodium edetate, calcium disodium hydroxyethylethylenediaminetriacetate, monosodium hydroxyethylethylenediaminetriacetate, and trisodium hydroxyethylethylenediaminetriacetate. The second active ingredient precursor preferably is present in the composition at a concentration in the range of about 2000 to 20,000 ppm More preferably this component is present at about 7,000 to 17,000 ppm.

In the embodiment of the invention in which the bait molluscicide includes a single active ingredient such as ferric edetate or the ferric hydroxyethyl derivative of edetic acid, this active ingredient preferably is present in a level such that the iron concentration is in the range of about 200 to 10,000 ppm.

The single active ingredients are available from a variety of commercial sources. One commercial source for ferric sodium edetate is Dr. Paul Lohmann GmbH KG of Emmerthal, Germany which sells ferric edetate (Lohmann ferric edetate). In addition, ferric edetate is commercially available from the Hampshire Chemical Unit of W. R. Grace & Co. of Lexington, Mass. under the mark Hamp-Ene ®. The hydroxyethyl derivative of ferric edetate is also available from the same unit of W. R. Grace under the marks Hamp-01 ® and Hampshire ®.

The inert bait component of the molluscicidal composition of the invention is one that must be readily consumed by molluscs. A variety of mollusc baits are well known and may be used in the compositions of the present invention. Such baits include agar, potato dextrose agar, gelatin, oil cake, pet food, wheat, soya, oats, corn, rice, fruits, fish by-products, sugars, coated vegetable and cereal seeds, casein, blood meal, bone meal, yeast, fats, and a variety of cereals, including wheat cereal. A preferred bait is wheat cereal which is commercially available from various sources.

The molluscicidal bait composition of the invention may also include additional formulation enhancing additives. Such additives include preservatives or antimicrobial agents, phagostimulants, water-proofing agents, and taste altering additives.

A variety of preservatives can be used effectively with this molluscicidal bait composition. Examples of preferred preservatives include Legend MK ®, available from Rohm & Haas Company of Philadelphia, Pa. and CA-24, available from Dr. Lehmann and Co. of Memmingen/Allgäu, Germany. Preservatives such as these can normally be mixed with water to form a stock solution to be added to the formulation at a concentration in the range of about 10–750 ppm.

Phagostimulants can be added to the composition to attract molluscs and to induce molluscs to feed upon the composition. A variety of phagostimulants can be used, including sugars, yeast products and caesin. Sugars, such as sucrose, are among the more preferred phagostimulants. These additives are normally incorporated within the composition in a dry form. Typically, they can be added to the composition at about 1 to 2.5% by weight of the total composition.

Waterproofing agents, which can also act as binders, can be added to the composition to improve the weatherability of the molluscicidal bait. These are typically water insoluble compounds such as waxy materials and other hydrocarbons. Examples of suitable waterproofing agents are paraffin wax, stearate salts, beeswax, and similar compounds. One preferred wax compound is PAROWAX ®, available from Conros Corp. of Scarborough, Ontario, Canada. Waterproofing agents can be incorporated into the composition, in dry form, at about 5 to 12% by weight of the total composition.

It is also desirable to include within the molluscicidal bait taste altering compounds that render the composition unpalatable to animals. Exemplary compositions include those having a bitter taste. Suitable compounds that are commercially available include BITREX, available from Mcfarlane Smith Ltd. of Edinburgh, Scotland. These compounds typically are added at very low concentrations. For example, a 0.1% BITREX solution can typically be added to the composition at about 1 to 2% by weight of the total composition.

The molluscicidal bait of this invention typically is used in dry form and many of the constituent ingredients of the composition are included in dry form. However, it is useful to include a sufficient amount of water within the composition to form a dough so that the ingredients can be more easily formed. Water is typically added at about 15 to 60% by weight of the total composition. The water, however, typically is driven off by heating and drying the molluscicidal bait before it is used.

As noted above, the compositions of the present invention are typically used in a dry, spreadable form such as powders, granules, cubes, or pellets. The composition may be spread on or around areas infested by molluscs as well as in areas in which mollusc infestation is to be prevented.

Dry molluscicidal compositions according to the present invention can be prepared as follows.

A suitable amount of the active ingredient precursors, or the active ingredient, is blended, in dry form, with a dry mollusc bait, such as wheat flour. Thereafter, other dry ingredients (such as phagostimulants and waterproofing agents) are blended and mixed with the bait. Next, suitable amounts of liquid additives (such as preservatives, taste altering additives and water) are added to the dry mixture to form a dough. The bait can be covered, such as with plastic wrap, and heated. One preferred heating technique is by heating in a microwave oven for 30 seconds to 10 minutes. After heating, the dough can be processed in a food grinder to obtain strands of the bait material. This is then dried, at elevated or ambient temperatures, and can be made into a desired form, such as powder, pellets or granules.

An exemplary formulation of a suitable mollusc bait is as follows.

	INGREDIENT	PURPOSE	QUANTITY
DRY COMPONENTS	Wheat flour	Bait	211.1 g
	Edetic acid	a.i. Precursor	2.7 g
	Iron Compound	a.i. Precursor	5.0 g
	Paraffin Wax	Water-proofing	25.0 g
	Sucrose	Phagostimulant	6.2 g
LIQUIDS	BITREX	Taste-altering	5.0 g (0.1% sol'n)
	Legend MK ®	Preservative	33.3 g (0.015% sol'n)
	Water	—	67.1 g
		TOTAL	355.40

The barrier composition of the present invention is effective against a variety of terrestrial molluscs including Ariolimax spp.; Arion species including, Arion ater, A. hortensis, A. rufas, A. circumcriptus, A. empericorum; Deroceras spp.; Agriolimax spp.; Prophysaon spp.; Helix pomata; and Cepaea nemoralis.

The following examples serve to further illustrate the invention.

EXAMPLE 1

Molluscicidal baits were prepared according to the general procedure discussed above. The active ingredient precursors were added in sufficient amounts to yield the concentrations noted in Table 1A. The iron based active ingredient precursor used was saccharated ferric oxide (iron sugar). The following additional ingredients were also included in the mixture: 2.5% by weight sucrose and 20 ppm Legend MK ® antimicrobial agent, and 10% by weight paraffin wax. The control was prepared in a similar manner, except that it did not include the active ingredient precursors.

Tests were conducted in 25cm×50cm×5cm planting trays (two trays per treatment with 5 slugs per tray). Each tray was floored with wet potting soil and covered with a transparent, plastic lid. Each tray received five garden slugs, Arion ater. Ten grams of each of the formulations identified below in Table 1A were placed inside a petri dish and put in each planting tray along with a lettuce plant. The planting trays were placed outside in the shade during the course of the experiment. Table 1B illustrates the observed mortality (slugs killed/5) and percent of bait eaten for each formulation, at 6 days after testing (DAT).

TABLE 1A

Tested Formulations	
Treatment	Formulation
1A	2000 ppm Fe from iron sugar
1B	2400 ppm Fe from iron sugar
1C	2800 ppm Fe from iron sugar
1D	3200 ppm Fe from iron sugar
1E	3200 ppm Fe from iron sugar + 16,400 ppm edetic acid
1F	10,400 ppm edetic acid
1G	12,400 ppm edetic acid
1H	14,400 ppm edetic acid
1I	16,400 ppm edetic acid
1J	Control: Wheat flour, Paraffin wax, sucrose, 20 ppm Legend MK ®

TABLE 1B

Slug mortality (/5) and Bait Consumption (%) at 6 DAT			
Treatment		Rep 1	Rep 2
A	2000 ppm Fe	Spoiled	0/5, 50%
B	2400 ppm Fe	0/5, 100%	0/5, 70%
C	2800 ppm Fe	0/5, 80%	0/5, 60%
D	3200 ppm Fe	0/5, 70%	0/5, 40%
E	3200 ppm Fe + 16,400 ppm edetic acid	2/5, 20%	3/5, 20%
F	10,400 ppm edetic acid	0/5, 30%	0/5, 35%
G	12,400 ppm edetic acid	0/5, 30%	0/5, 30%
H	14,400 ppm edetic acid	0/5, 20%	0/5, 20%
I	16,400 ppm edetic acid	0/2, 15%*	0/5, 15%
J	Control	Spoiled	0/5, 70%

*3 slugs missing

EXAMPLE 2

The formulations identified below in Table 2A were prepared by the general procedure noted above. The active ingredient precursors were used in sufficient amounts to yield the concentrations noted in Table 2A. The iron-based active ingredient precursor used was saccharated ferric oxide. Additional ingredients used in the formulations included 10% by weight paraffin wax, 2.5% by weight sucrose and 20 ppm Legend MK ®.

Test were conducted in 36 liter plastic tubs (two tubs per treatment with ten slugs per tub). Each tub was floored with wet potting soil and covered with a lid. Each tub received ten garden slugs, Arion ater. Ten grams of each molluscicidal bait identified in Table 2A was added to two petri dishes and placed in a tub along with two lettuce plants. The tubs were left outdoors during the course of the experiment.

The tubs were examined three days after treatment and seven days after treatment to assess the slug mortality (slugs killed/10) and amount of each molluscicidal bait eaten. These data are presented in tables 2B and 2C. Bait consumption is rated according to the following standards: heavy, greater than 20% bait consumed; moderate, 10 to 20% bait consumed; and light, less than 10% bait consumed.

TABLE 2A

Test Formulations	
Formulation	Component
2A	2800 ppm Fe from iron sugar + 14,400 ppm edetic acid
2B	2800 ppm Fe from iron sugar + 10,800 ppm edetic acid
2C	2800 ppm Fe from iron sugar + 7,200 ppm edetic acid
2D	2800 ppm Fe from iron sugar + 3,600 ppm edetic acid
2E	2800 ppm Fe from iron sugar
2F	Control: Wheat flour, Parowax ®, sucrose, 20 ppm Legend MK ®
2G	2800 ppm Fe from ferric edetate (Lohmann)

TABLE 2B

Slug mortality (/10) and Bait Consumption at 3 DAT		
Treatment	Rep 1	Rep 2
2A 2800 ppm Fe from iron sugar + 14,400 ppm edetic acid	0/9, 1 heavy*	0/10, heavy
2B 2800 ppm Fe from iron sugar + 10,800 ppm edetic acid	0/10, moderate	0/10, moderate
2C 2800 ppm Fe from iron sugar + 7,200 ppm edetic acid	0/10, moderate	1/10, moderate
2D 2800 ppm Fe from iron sugar + 3,600 ppm edetic acid	0/10, heavy	0/10, heavy
2E 2800 ppm Fe from iron sugar	0/10, heavy	0/10, heavy
2F Control: Wheat flour, Parowax ®, sucrose, 20 ppm Legend MK ®	0/10, heavy	0/10, heavy
2G 2800 ppm Fe from ferric edetate (Lohmann)	0/10, moderate	0/10, moderate

*1 slug missing

TABLE 2C

Slug mortality (/10) at 7 DAT			
Treatment	Rep 1	Rep 2	Total
2A 2800 ppm Fe from iron sugar + 14,400 ppm edetic acid	6/9	5/10	11/19

TABLE 2C-continued

Slug mortality (/10) at 7 DAT			
Treatment	Rep 1	Rep 2	Total
2B 2800 ppm Fe from iron sugar + 10,800 ppm edetic acid	7/10	6/10	13/20
2C 2800 ppm Fe from iron sugar + 7,200 ppm edetic acid	7/10	5/10	12/20
2D 2800 ppm Fe from iron sugar + 3,600 ppm edetic acid	2/10	5/10	7/20
2E 2800 ppm Fe from iron sugar	0/10	0/10	0/20
2F Control: Wheat flour, Parowax ®, sucrose, 20 ppm Legend MK ®	0/10	0/10	0/20
2G 2800 ppm Fe from ferric edetate (Lohmann)	5/10	5/10	10/20

EXAMPLE 3

Compounds identified below in Table 3A were prepared according to the general procedure noted above. The active ingredient precursors were added in sufficient quantities to yield the concentration noted in Table 3A. The following additional ingredients were also added for each formulation: 10% by weight of paraffin wax, 2.5% by weight sucrose and 20 ppm Legend MK ®.

Tests were conducted in 25 cm×50cm×5cm planting trays (two trays per treatment with 5 slugs per tray). Each tray was floored by wet potting soil and covered by transparent plastic lids. Each tray received 5 garden slugs, Arion ater, and ten grams of bait which was placed inside a petri dish and placed on the soil along with a lettuce plant. The trays were placed outside in the shade during the course of the experiment.

The slug mortality (slugs killed/5) and percent of bait consumed was evaluated at 6 DAT and these data are shown in Table 3B.

TABLE 3A

Tested Formulations	
Formulation	Components
3A	2000 ppm Fe from iron-III-phosphate
3B	2800 ppm Fe from iron-III-phosphate
3C	2000 ppm Fe from iron-III-citrate
3D	2800 ppm Fe from iron-III-citrate
3E	2000 ppm Fe from iron-III-pyrophosphate
3F	2800 ppm Fe from iron-III-pyrophosphate
3G	2000 ppm Fe from iron-III-nitrate
3H	2800 ppm Fe from iron-III-nitrate
3I	2000 ppm Fe from iron-III-sugar
3J	2800 ppm Fe from iron-III-sugar
3K	Control: Wheat flour, Parowax ®, sucrose, 20 ppm Legend MK ®

TABLE 3B

Slug Mortality (/5) and Bait Consumption (%) at 6 DAT		
Formulation	Rep 1	Rep 2
3A 2000 ppm Fe from iron-III-phosphate	0/5, 30%	0/5, 20%
3B 2800 ppm Fe from iron-III-phosphate	0/4*, 15%	0/5, 30%
3C 2000 ppm Fe from iron-III-citrate	0/5, 30%	0/5, 30%
3D 2800 ppm Fe from iron-III-citrate	0/5, 20%	0/5, 20%
3E 2000 ppm Fe from iron-III-pyrophosphate	0/5, 90%	0/5, 60%
3F 2800 ppm Fe from iron-III-pyrophosphate	0/2, 15%*	0/5, 40%
3G 2000 ppm Fe from iron-III-nitrate	0/5, 60%	0/5, 60%
3H 2800 ppm Fe from iron-III-nitrate	0/5, 40%	0/5, 15%
3I 2000 ppm Fe from iron-III-sugar	0/5, 70%	0/5, 35%
3J 2800 ppm Fe from iron-III-sugar	0/5, 50%	0/5, 80%
3K Control: Wheat flour, Parowax ®,	0/5, 40%	0/5, 60%

TABLE 3B-continued

Slug Mortality (/5) and Bait Consumption (%) at 6 DAT		
Formulation	Rep 1	Rep 2
sucrose, 20 ppm Legend MK ®		

*1 slug missing
**2 slugs missing

EXAMPLE 4

The formulations identified in Table 4A were prepared according to the general procedure noted above. The active ingredient precursors were added in sufficient amounts to yield the concentration shown in Table 4A. Additional ingredients for each formulation included 10% by weight paraffin wax, 2.5% by weight sucrose, and 20 ppm Legend MK ®.

Tests were conducted in 36 liter plastic tubs (2 tubs per treatment with 10 slugs per tub). Each tub was floored by wet potting soil and covered with a plastic lid. Each tub received 10 garden slugs, Arion ater, and ten grams of bait, which was placed inside a petri dish. The petri dishes were placed on the soil along with two lettuce plants. The tubs were left outside during the course of the experiment. The tubs were examined at 1 DAT and 6 DAT to determine slug mortality (slugs killed/10) and the percent of the bait consumed. These data are illustrated below in Tables 4B and 4C.

TABLE 4A

Treatment Formulations	
Formulation	Components
4A	2800 ppm Fe from iron phosphate
4B	2800 ppm Fe from iron phosphate + 10,800 ppm edetic acid
4C	2800 ppm Fe from iron lactate
4D	2800 ppm Fe from iron lactate + 10,800 ppm edetic acid
4E	10,800 ppm edetic acid
4F	Control: Wheat flour, paraffin wax, sucrose, 20 ppm Legend MK ®

TABLE 4B

Slug mortality (/10) and Bait Consumption % at 1 DAT		
Treatment	Rep 1	Rep 2
4A 2800 ppm iron phosphate	0/10, 35%	0/10, 25%
4B 2800 ppm iron phosphate + edetic acid	0/10, 20%	0/10, 20%
4C 2800 ppm iron lactate	0/10, 20%	0/10, 30%
4D 2800 ppm iron lactate & edetic acid	0/10, 25%	0/10, 20%
4E 10,800 ppm edetic acid	0/10, 30%	0/10, 15%
4F Control	0/10, 40%	0/10, 85%

TABLE 4C

Slug mortality (/10) and Bait Consumption (%) at 6 DAT		
Treatment	Rep 1	Rep 2
4A 2800 ppm iron phosphate	0/10, 60%	0/10, 100%
4B 2800 ppm iron phosphate & edetic acid	7/10, 40%	8/10, 30%
4C 2800 ppm iron lactate	0/10, 70%	0/10, 60%
4D 2800 ppm iron lactate + edetic acid	7/10, 40%	5/10, 30%
4E 10,800 ppm edetic acid	0/10, 85%	0/10, 70%
4F Control	0/10, 100%	0/10, 100%

EXAMPLE 5

The bait compositions identified in Table 5A were prepared according to the general procedure noted above. Active ingredient precursors were added in sufficient amounts to yield the concentrations noted. Additional ingredients included 10% paraffin wax, 2.5% by weight sucrose and 20 ppm Legend MK ®.

The tests were conducted using 36 liter plastic tubs (2 tubs per treatment with 10 slugs per tub). Each tub was floored by wet potting soil and covered with a plastic lid. Each tub received 10 garden slugs, Arion ater, and ten grams of bait which was placed inside a petri dish and placed on the soil in each tub along with two lettuce plants. The tubs were left outside during the course of the experiment.

The tubs were examined at 1 DAT and 6 DAT to determine the slug mortality (slugs killed/10) and the amount of bait consumed. These data are illustrated in Tables 5B and 5C.

TABLE 5A

Test Formulations	
Formulation	Components
5A	2800 ppm Fe from iron pyrophosphate
5B	2800 ppm Fe from iron pyrophosphate + 10,800 ppm edetic acid
5C	2800 ppm Fe from iron nitrate
5D	2800 ppm Fe from iron nitrate + 10,800 ppm edetic acid
5E	10,800 ppm edetic acid
5F	Control: Wheat flour, paraffin wax, sucrose, 20 ppm Legend MK ®

TABLE 5B

Slug Mortality (/10) and Bait Consumed (%) at 1 DAT		
Treatment	Rep 1	Rep 2
5A 2800 ppm iron pyrophosphate	0/10, 50%	0/10, 40%
5B 2800 ppm iron pyrophosphate + edetic acid	0/10, 15%	0/10, 25%
5C 2800 ppm iron nitrate	0/11, 20%	0/10, 20%
5D 2800 ppm iron nitrate + edetic acid	0/10, 30%	0/10, 20%
5E 10,800 ppm edetic acid	0/10, 25%	0/10, 30%
5F Control	0/10, 40%	0/10, 60%

TABLE 5C

Slug mortality (/10) and Bait Consumption (%) at 6 DAT		
Treatment	Rep 1	Rep 2
5A 2800 ppm iron pyrophosphate	0/10, 80%	0/10, 90%
5B 2800 ppm iron pyrophosphate + edetic acid	8/10, 20%	4/10, 30%
5C 2800 ppm iron nitrate	0/10, 70%	0/10, 80%
5D 2800 ppm iron nitrate + edetic acid	1/10, 30%	3/10, 20%
5E 10,800 ppm edetic acid	0/10, 50%	0/10, 50%
5F Control	0/10, 100%	0/10, 100%

EXAMPLE 6

The bait compositions identified in Table 6A were prepared according to the general procedure noted above. Active ingredient precursors were added in sufficient amounts to yield the concentrations noted. Additional ingredients included 10% by weight paraffin wax; 2.5% by weight sucrose; and 20 ppm Legend MK ®.

Feeding tests were conducted inside 36 liter plastic containers. Two containers were used for each treatment so that there were two replicates. Each container was filled to 3 cm with potting soil that was made damp. Ten slugs, Arion ater, were placed into each tub at the start of the experiment. At the same time, 10 grams of bait was placed into a petri dish and the dish was placed on the soil in the container. Two lettuce plants or one potted marigold plant were placed on their side and positioned on the soil within the container as an alternate food source. The containers were then covered with plastic lids and the tubs were placed outside in a shaded area. The containers were evaluated at 5 DAT and 6 DAT by counting all living and dead slugs and removing the dead slugs. At the same time, the plants and the bait were examined to determine the amount of bait consumed. Table 6B, below, illustrates the slug mortality and the bait consumption for replicates 1 and 2 at 5 DAT. Table 6C illustrates the total slug mortality for the two replicates.

TABLE 6A

Test Formulations	
Formulation	Components
6A	2800 ppm Fe from iron ammonium citrate
6B	2800 ppm Fe from iron ammonium citrate plus 10,800 ppm edetic acid
6C	2800 Fe from iron chloride
6D	2800 ppm Fe as iron chloride plus 10,800 ppm edetic acid
6E	2.00% f Fe edetate (2800 ppm Fe)
6F	Control: Wheat, wax, Legend MK ®

TABLE 6B

Slug Mortality and Bait Consumption (%) at 5 DAT.		
Treatment	Rep 1	Rep 2
6A 2800 iron ammonium citrate	2/10, 90%	0/10, 70%
6B 2800 iron ammonium citrate plus edetic acid	8/10, 40%	7/10, 30%
6C 2800 iron chloride	0/10, 50%	0/8, +2, 80%
6D 2800 ppm iron chloride plus edetic acid	5/10, 30%	4/10, 30%
6E 10,800 edetic acid	0/10, 40%	0/10, 60% b
6F Control	0/10, 90%	0/10, 100%

+two slugs missing

TABLE 6C

Total Slug Mortality at 6 DAT.			
Treatment	Rep 1	Rep 2	Total
6A 2800 ppm iron ammonium citrate	2/10	0/10	2/20
6B 2800 ppm iron ammonium citrate plus edetic acid	9/10	7/10	16/20
6C 2800 ppm iron chloride	0/10	0/8	0/18
6D 2800 ppm iron chloride plus edetic acid	9/10	5/10	14/20
6E 10,800 ppm edetic acid	0/10	0/10	0/20
6F Control	0/10	0/10	0/20

EXAMPLE 7

The formulations shown in Table 7A were prepared according to the general procedure noted above. The tests were conducted using ½ liter food containers (2 containers per treatment with 3 slugs per container). Each container was floored by wet potting soil and covered with transparent, plastic lids. Each container received 3 garden slugs, Deroceras reticulatum, and a cube of bait placed directly on the soil. The containers were examined at 1 DAT and 5 DAT to determine the slug mortality and the bait consumption. Bait consumption was recorded according to a scale in which "heavy" indicates greater than 20 percent bait consumption; "moderate" indicates 10 to 20 percent consumption; and "light" indicates less than 10 percent bait consumption. The data obtained are illustrated in Tables 7B and 7C below.

TABLE 7A

Test Formulations	
Formulation Code	Components
7A	Control: wheat flour, paraffin wax, sucrose, 20 ppm Legend MK ®
7B	2232 ppm Fe from iron sugar + 16,400 ppm sodium edetate
7C	2232 ppm Fe from iron chloride + 16,400 ppm sodium edetate

TABLE 7B

Slug Mortality and Bait Consumption at 1 DAT		
Treatment	Rep 1	Rep 2
7A Control	0/3, heavy	0/3, heavy
7B 2232 ppm Fe from sugar + sodium edetate	0/3, moderate	0/3, light
7C 2232 ppm Fe from iron chloride + sodium edetate	0/3, light	0/3, light

TABLE 7C

Slug Mortality and Bait Consumption at 5 DAT		
Treatment	Rep 1	Rep 2
7A Control	0/2*, heavy	0/3, heavy
7B 2232 ppm Fe from sugar + sodium edetate	2/2* moderate	2/3, light
7C 2232 ppm Fe from iron chloride + sodium edetate	0/3, light	1/3, light

*1 slug missing

EXAMPLE 8

The baits identified in Table 8A were prepared according to the general procedure noted above. Hamp-Ene ® ferric sodium edetate was obtained from W. R. Grace and Company of Lexington, Mass. and Lohmann ferric sodium edetate was obtained from Dr. Paul Lohmann GmbH KG of Emmerthal, Germany. Tests were conducted in 36 liter tubs (2 tubs per treatment with 10 Deroceras reticulatum per tub). Each tub had a soil covering the base of the tub and the tub was covered with a plastic lid. Three lettuce plants were placed in the tubs as an alternate feeding source. Slugs were introduced to the tubs at the time the baits were added.

The tubs were examined at 4 DAT to determine slug mortality. These data are shown in Table 8B.

TABLE 8A

Test Formulations	
Formulation Code	Components
8A	2800 ppm Fe from Ferric edetate (Hamp-Ene ®) + 750 ppm CA-24
8B	2800 ppm Fe from Ferric edetate + 750 ppm CA-24
8C	Control: Wheat flour, paraffin wax, sucrose, 20 ppm Legend MK ® or Ca-24
8D	2800 ppm Fe from ferric edetate (Hamp-Ene ®)

TABLE 8B

Slug mortality at 4 DAT.		
Treatment	Rep 1	Rep 2
8A 2800 ppm Fe from Ferric edetate (Hamp-Ene ®) + 750 ppm CA-24	6/10	4/10
8B 2800 ppm Fe from Ferric edetate + 750 ppm CA-24	7/10	4/9*
8C Control: Wheat flour, paraffin wax, sucrose, 20 ppm Legend MK ® or Ca-24	0/10	0/8**
8D 2800 ppm Fe from ferric edetate	9/10	10/10

TABLE 8B-continued

Slug mortality at 4 DAT.		
Treatment	Rep 1	Rep 2
(Hamp-Ene ®)		

*1 slug missing
**2 slugs missing

One of ordinary skill in the art will appreciate that minor modifications may be made to the compositions of the present invention without departing from its intended scope.

What is claimed is:

1. A terrestrial mollusc stomach poison composition, comprising

a simple iron compound selected from the group consisting of iron proteins, iron carbohydrates, and iron salts, which, alone, have little or no toxicity to the molluscs;

a second component selected from the group consisting of edetic acid, hydroxyethyl derivative of edetic acid, or salts thereof; and

an inert carrier material edible to molluscs, wherein the molar ratio of the iron in the simple iron compound to the second component is in the range of 1:0.2 to 1:2.0.

2. The composition of claim 1 wherein the simple iron compound is present in an amount such that the iron concentration within the composition is in the range of about 200–10,000 ppm.

3. The composition of claim 1 wherein the second component is present at a concentration in the range of 2000 to 20,000 ppm

4. The composition of claim 1 wherein the simple iron compound is present in an amount such that the iron concentration within the composition is in the range of about 2000 to 6,000 ppm and the second component is present at a concentration of about 7,000 to 17,000 ppm.

5. The composition of claim 1 wherein the second component, in its salt form, is selected from the group consisting of calcium disodium edetate, monosodium edetate, disodium edetate, trisodium edetate, tetrasodium edetate, calcium disodium hydroxyethylethylenediaminetriacetate, monosodium hydroxyethylethylenediaminetriacetate and trisodium hydroxyethylethylenediaminetriacetate.

6. The composition of claim 1 wherein the simple iron compound is selected from the group consisting of saccharated ferric oxide, ferric albuminate, ferric ammonium citrate, ferric chloride, ferric citrate, ferrous gluconate, ferrous lactate, ferric phosphate, ferrous phosphate, ferric pyrophosphate, ferric nitrate, ferrous sulfate, iron stearate, and ferric tartrate.

7. The composition of claim 1 wherein the inert carrier is selected from the group consisting of wheat cereal, agar, gelatin, oil cake, pet food wheat, soya, oats, corn, rice, fruits, fish by-products, sugars, coated vegetable and cereal seeds, casein, blood meal, bone meal, yeast, and fats.

8. A terrestrial mollusc stomach poison composition, comprising:

an effective amount of an active ingredient selected from the group consisting of ferric edetate and a ferric hydroxyethyl derivative of edetic acid.

9. The composition of claim 8 wherein the active ingredient is present in an amount such that the iron concentration is in the range of about 200–10,000 ppm.

10. The composition of claim 8 wherein the inert carrier is selected from the group consisting of wheat cereal, agar, gelatin, oil cake, pet food wheat, soya, oats, corn, rice, fruits, fish by-products, sugars, coated vegetable and cereal seeds, casein, blood meal, bone meal, yeast, and fats.

* * * * *

APPENDIX 2

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

AGENDA ITEM NO. 5 **CX/FL 04/5**

E

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-SECOND SESSION
MONTREAL, CANADA, MAY 10 – 14, 2004

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS:
DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES
(ALINORM 03/22A, APPENDIX VI & CL 2003/28-FL)

GOVERNMENT COMMENTS AT STEP 6

COMMENTS FROM:

AUSTRALIA
DENMARK
EUROPEAN COMMUNITY
JAPAN
NEW ZEALAND
NORWAY
PARAGUAY
POLAND
SWITZERLAND
INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM)
INTERNATIONAL PECTIN PRODUCERS ASSOCIATION (IPPA)

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS:
DRAFT REVISED ANNEX 2 – PERMITTED SUBSTANCES (ALINORM 03/22A, APPENDIX VI & CL 2003/28-FL)

GOVERNMENT COMMENTS AT STEP 6

AUSTRALIA:

Australia supports the need for an internationally agreed set of lists as presented in Annex 2. This list will provide guidance to countries in developing their own lists, and will facilitate equivalency agreements between countries.

Australia also agrees that any new proposal that is submitted without supporting documentation for evaluation against the criteria if section 5 should not be accepted by the Ad Hoc Working Group.

Australia still holds concerns regarding the allowance of chemical processes for extraction of carriers and binders for products to be used as fertilisers or soil conditioners (5.1, 2nd dash point)). Australia believes an explanation of how such a product would be different in nature and action to artificial fertilisers used under conventional farming systems is warranted.

Australia supports a short and restrictive list of food additives and processing aids, as this is consistent with consumer expectations of organic products.

Specific comments regarding the tables in Annex 2 follow:

Table 1:

a. suggest adding to first item of list:
   "farmyard and poultry manure/*excrements, including*
   – fresh
   – dried, or
   – composted"
   Condition of use to remain as written. Reason: by the addition of the above words the third, fourth and fifth item in the list can be removed, thus simplifying the document.

Table 2:

a. IV Other
   Condition of use of Carbon Dioxide and Nitrogen Gas:
   Add "*Only for Post Harvest Treatment of Stored Products*"

b. Rodenticides

Condition refers to livestock and not plant pests and disease. Should be placed elsewhere.

Table 3:

Australia does not support the use of nitrates/nitrites as food additives in the manufacture of organic products.
Reason: this is consistent with consumer expectations of organic products.

Table 4:

Australia believes clarification is needed regarding Vegetable oils as to whether such products include ethylised Vegetable Oils or only the pure product.

DENMARK:

Procedure for acceptance of substances
At the Codex meeting last year there was a discussion on the acceptance of substances in the tables and Denmark promised to give written comments on this subject. Some delegations expressed the opinion that a substance could be added to the tables if a matrix concerning the criteria was issued without any further discussion. Denmark is of the clear opinion that the addition of substances can only be done after an evaluation and eventual acceptance of the matrix dossier for each substance. We disagreed with several of the matrix tables present at the last meeting or missed information but there was no discussion about the matrix tables at the meeting.

If substances are added to the Codex lists only on the basis of a matrix dossier issued by one country or NGO without discussion and acceptance from the committee it will be misleading for countries who wish to develop rules giving access to the international market as the codex tables not necessarily will express how the main part of national authorities have made their legislation. Some countries will then experience problems when they want to export. The lists should be short and restrictive and only have the substances that are evaluated against the criteria and accepted by the committee. If the matrix only is evaluated by one country or NGO it should not be the basis for international trade without any discussion whatsoever. Even though the Codex lists of permitted substances are kind of indicative we should be careful when we add substances to the list as they provide advice to governments on internationally agreed inputs (see annex 2, point 4).

We encourage the Committee to refer to or send out again the old or revised matrix tables especially for the substances in brackets and to discuss them at the preparatory meeting. .

Additives and processing aids for animal products

In general, Denmark finds that many of the additives are not absolutely necessary. Especially the additives nitrite (INS 250), nitrate (INS 252) and phosphates (INS 339, 340, 450 and 452) are problematic and have a bad image amongst many consumers. In order to protect the integrity of organic production these substances should be deleted from the list.

Nitrate slowly converts into nitrite which can lead to the formation of nitrosamines in meat products. Nitrosamines are known to be carcinogenic and no safe level can be established so use should be as low as possible. Many kinds of organic meat products can be produced without nitrite and nitrate using GMP. We are aware of the fact that consequently shelf life also has to be shorter in order to secure food safety. The colour will also differ from the colour of conventional meat with nitrite. However a wish to obtain a certain colour is not an acceptable reason for allowance. Even in conventional products this is not part of the justification for nitrate and nitrite.

It is mentioned in the report from the last meeting that the use of nitrates was tied to the use of ascorbates (INS 300-303). If this is the case the use of ascorbates should be restricted accordingly.

We do not support the inclusion of Nitrous Oxide (INS 942) as a packaging gas, propellant for whipped cream. We do not find it essential that such a product should be available on the market as organic.

Sodium carbonates (INS 500) are mentioned both as additives (for pH regulation in traditional cheese prepared from sour milk (better wording than the present) and as processing aid (neutralizing substance). We find the substances should be deleted as processing aids, and we question whether sodium carbonates according to Codex Standards can be used as additives in traditional cheese prepared from sour milk.

Lactic acid is mentioned as processing aid for milk products: coagulation agent, pH regulation of salt bath for cheese. With the mentioned uses we think it is an additive and if necessary, should be placed in Table 3.

Calcium chloride is listed as processing aid for firming, coagulation agent in cheese making. By firming is probably meant firming agent, but with this function it is an additive.

EUROPEAN COMMUNITY (EC):

The European Community has the following comments on Codex Circular Letter 2003/28/FL, concerning Annex II of the Guidelines as presented in ALINORM 03/22A, Appendix VI.

❑ **<u>With regard to the substances included in Annex II:</u>**

- As to the proposed inclusion of **calcium chloride solution** in table 1, the European Community considers there is a need to clarify the relation of this substance to the existing listing of "chloride of lime".

- As to the proposed inclusion of **Chilean nitrate** in table 1, the European Community is opposed to its inclusion. It considers this substance not to be consistent with the principles of organic agriculture and not essential for its intended use. Because of its high content of mineral nitrogen directly ready for uptake by the plant, it has not been allowed in organic farming in most regions of the world.

- As to the proposed inclusion of **Sabadilla** in table 2, the European Community can not support its inclusion. It considers that there are not sufficient data on the toxicity of this substance, that it is possibly highly toxic and could therefore have a harmful impact on the health of consumers, including the users of the product.

- As to the proposed inclusion of **chitin nematicides** in table 2, the European Community considers that the substances chitin and chitin extract should be rather considered as soil improvers and could be considered for inclusion in table 1.

- As to the proposed ban on **piperonyl butoxide** as a synergist in table 2, the European Community considers that more documented information on the efficacy of its replacements, i.e. rape seed oil or sesame oil, would be useful.

- As to the inclusion of **iron (III) orthophosphate**, the European Community reiterates its proposal to include this substance as a molluscicide and proposes to remove the square brackets. To support this inclusion, the European Community has annexed a technical information sheet on this substance.

- As to the entries **sawdust, bark and wood waste** and **wood ash**, the European Community proposes to remove the square brackets around the words "from wood not chemically treated after felling".

❑ **With regard to the structure of Annex II:**

- Under heading V "Traps" of Table 2, the European Community considers that only the last indent should be maintained. Pheromones and metaldehyde should be moved to heading IV, other and the condition for use only in traps and dispensers" and "only in traps" respectively should be added. Mineral oils should be moved to heading II, "minerals".

- The European Community reiterates that the current presentation of Tables 3 and 4 could be simplified. In this regard, the two lists of food additives (including carriers) in Table 3 could be amalgamated in one sole list with several columns. These columns would provide information on the code of the food additives, the name of the latter, whether a food additive is allowed in a preparation of foodstuffs of plant and/or animal origin and specific conditions of use. The same approach should apply in the case of Table 4.

Technical fiche Iron (III) orthophosphate

Name	Description, composition requirements, conditions for use
Iron (III) orthophosphate	**Molluscicide**

1. Description

1.1 Name
Iron (III) orthophosphate (IUPAC: Ferric Phosphate)
CAS-No 10045-86-0 / EINECS-No 233-149-7

1.2 Product composition, qualitative and quantitative information on the composition of the product, the active substances and other components

Iron (III) orthophosphate (FCC grade, CAS-No 10045-86-0)	10.00 g/kg
Colourant "Patent Blue" (FCC grade, E 131)	0.10 g/kg
Stabiliser: ethylenediamine tetraacetic acid (CAS-No 60-00-4)	10.80 g/kg
Sugar (ECC Cat. II, CAS-No 57-50-1)	25.00 g/kg
Wheat flour (FCC, Type 550, CAS-No 130498-22-5)	954.10 g/kg

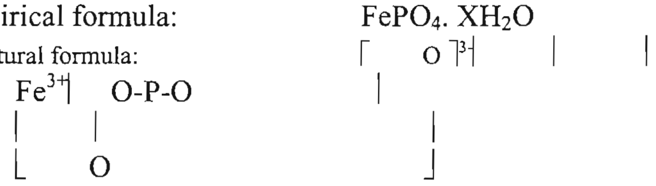
1.3 Physical state and nature of product containing the active substance
Granular bait (ready-to-use spreadable bait)

1.4 Use category (herbicide, insecticide, etc.)
Molluscicide

1.5 Method of production
1. Mix an aqueous iron sulphate solution with an aqueous disodium phosphate solution in a stainless steel boiler. Reaction temperature is 50° to 70°C.
2. Ferric phosphate precipitates out of the solution.
3. Wash the precipitate and separate off and filter with distilled water.
4. Dry the ferric phosphate with hot air.
5. Pack the resulting powder into containers; it is then ready for shipping.

1.6 Physico-chemical properties

Chemical name: Iron (III) orthophosphate
Empirical formula: $FePO_4 . XH_2O$
Structural formula:



Appearance: Powder

Explosion risk: contains no explosive substances

Acidity / alkalinity: 4.3 - 4.6 (Formulation, CIPAC MT 75)
Flammability: not flammable

Viscosity:	not applicable, solid
Density:	2.87 g/ml (20°C, DIN 5391)
Storage:	can be stored for at least 5 years
Melting point:	decomposes to iron oxide (Fe_2O_3) at 500°C
Oxidation properties:	contains no oxidative components

1.7 Technical characteristics of plant protection product

Wettability:	not applicable, not a liquid
Suspensibility:	not applicable, not a suspension concentrate
Emulsifiability:	not applicable, not an emulsion concentrate
Fluidity:	94.2% of granules flow spontaneously through a sieve in a CIPAC MT 172 test, the other 5.8% go through the sieve after it is shaken five times.

Abrasion:	5 minutes' shaking	0.02 %
	15 minutes' shaking	0.027%
	60 minutes' shaking	0.013%

Grain size distribution:	between 1 000 µm and 2 800 µm (cf. CIPAC Guideline MT 170)
Dust content:	virtually dust-free (CIPAC MT 171: category 1)

1.8 Applications

Areas of application:	outdoors and under glass
Pest:	slugs
Action:	edible bait
Dosage rate:	5 g/m²
A.i. concentration:	10g/kg iron (III) orthophosphate in the formulation
Application method:	spreading (by hand or with manure spreader)
No. of applications:	max. 5 per growing season, protection period dependent on slug population. 5 applications offer one season's protection for crop at normal population density.

2. Evaluation

2.1 Indispensable for control of harmful organism or specific disease; there are no alternatives. Examination of other options:

Biological alternatives: There are few biological control measures (mallard ducks, nematicides). These biological measures can be used on smaller farms against certain slug species in years of low infestation, but they are not a viable option in years of heavy infestation or on relatively large surfaces.

Cultivation measures: There are none for slug control. On the contrary, organic cultivation methods, involving hedges or field-edge strips, for example, form areas for slugs to withdraw to.

Chemical alternatives: Material alternatives at present are metaldehyde, a synthesised organic chemical product, which is in Annex II.B, but may only be used in traps. A traditional slug control method is caustic lime, but when used in large quantities, for instance in heavy infestations, it has undesirable side-effects.

Plant-breeding alternatives: not available

2.2 No direct contact with seed material, the crop or crop products

The product is spread between crop plants.

For practical use that means that the product can be spread using a band manure spreader between the crop plants on large surfaces. There is no contact with the plant. If infestation is heavy the product can be broadcast before sowing.

In holdings with small fields and in particular in horticulture the bait is usually spread manually in the rows between the crop plants or around the vegetable beds.

2.3 Environmental impact

Iron (III) orthophosphate in soil, water and air:

It occurs naturally in soil and its method of action is therefore known. At normal soil temperature it is highly insoluble so leaching into watercourses or evaporation into the air is more or less impossible under normal conditions. Degradation in the soil is mainly via exudates from plant roots and microbial conversion processes.

Iron as a micronutrient and phosphate as a macronutrient are essential components of plant metabolism and are therefore applied in fertilisers.

Possible toxic impact of iron (III) orthophosphate on bird and other fauna:

There is currently no precise information in the literature on what quantities of the product can effectively be taken up by birds.

It is assumed that the blue colour of the granulate will have a deterrent effect on birds, which are said to have a natural aversion to the colour blue.
Accumulation of the active ingredient in the soil seems unlikely since usually only one application is necessary. Current state of knowledge indicates that a

daily intake of the granulate by birds is also unlikely. The risk of ingesting a toxic dose is therefore correspondingly slight.

When the product NEU 1165M was actually administered to birds it was found to be non-toxic.

The granulate has also proved to be non-toxic to fish. In addition, application in the proximity of water is not intended and the active ingredient, iron (III) orthophosphate, is known to be of very low solubility in soil.

The product is also non-toxic to vertebrates and bees. The granulate form means that it is highly unlikely to be ingested by insects or worms.

In summary, it can be assumed that the product will not have a negative impact on the environment because of the following:

a) Iron (III) orthophosphate occurs naturally in the soil.
b) Iron (III) orthophosphate is present in the soil as a virtually insoluble, stable substance.
c) The product is applied at a very low dosage rate.
d) The product is not intended to be applied in or near watercourses.
e) The product is non-toxic to most animal species.
f) Iron (III) orthophosphate is an authorised food additive.
g) The product's carrier substances, flour and sugar, are also authorised food additives.
h) Iron (III) orthophosphate can in any case be present in plants' and animals' natural nutrient sources.
i) Iron (III) orthophosphate is an essential nutrient in animals' and plants' metabolism.

JAPAN:

With regard to Table 3 in Annex 2, Japanese government would like to propose the following additions and deletions. The proposed additions are indicated in *Italic* font and the proposed deletions are indicated in ~~strikethrough~~ font.

INS	Name	Specific conditions
415	*Xanthan gum*	*Milk products confectionary*
416	*Karaya gum*	*Milk products confectionary*
[340]	[Potassium phosphate]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams]
[450]	[Diphosphates]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams.]

{452}	{Polyphosphate}	{Emulsifying salt for melted and processed cheese and stabilizer for pasteurised creams.}
{303}	{Potassium ascorbate}	{In meat products, provided insufficient natural sources are available.}

Comments:

415 Xanthan gum
416 Karaya gum
Xanthan gum and Karaya gum are used for improving texture of the livestock products, these ingredients are indispensable for producing the livestock food products, such as ice cream, cheese and jellified milk (e.g. puddings). These two substances cannot be substituted by any other substances contained in the list.

These ingredients contribute to extending the self life of such products as of puddings by improving their stability against temperature changes.

They are also used for increasing viscosity to beverages such as cocoa in order to prevent sedimentation of insoluble particles.

340 Potassium phosphate
450 Diphosphates
452 Polyphosphate
Regarding the Potassium phosphate, Diphosphates and Polyphosphate, these are used for conditioning the texture of foods according to their characteristics.

Emulsifiers are required in manufacturing processed cheese (either use of one kind of emulsifiers or a mixture of some kinds of emulsifiers).

Emulsification is the most important process in manufacturing process of processed cheese and its aims are to change insoluble sodium paracaseinate of the cheese into soluble sodium paracaseinate for dispersion and to disperse and emulsify the milk fat of cheese. This makes gluey and smooth conformations which are specific characteristics to the processed cheese. These substances cannot be replaced by any other substances contained in the list.

303 Potassium ascorbate
As for meat products, meat coloring matter (Myoglobin) and fat are related each other in terms of the mutual oxidization. Consequently, peroxide are in danger of being generated.

For this reason, generally in the world, oxidization is prevented by using Sodium ascorbate effectively for the prevention of oxidization of meat coloring matter, together with Tocopherols, which is effective for the prevention of oxidization of fat.
In addition, use of this substance has an effect on the prevention of oxidization not only of meat coloring matter but of other water-soluble substances, and prevention of flavor deteriorating. As a result, it is effective for the quality stabilization of the product.

NEW ZEALAND:

The New Zealand Government would like to make the following comments:

Substances included in Annex 2

New Zealand supports the view of the Ad Hoc Working Group that proposals for the inclusion of new substances in the lists should not be considered if they are not justified against the criteria.

Structure of the table

The lists of food additives (Table 3.1) permitted should be merged into a single list for ease of use.

Table 1. Substances for use in soil fertilising and conditioning

Substance	COMMENT
Peat	The sentence "Not permitted as a soil conditioner" is not necessary. Control by the certification body is sufficient to ensure environmental protection.
common salt (Sodium Chloride)	can only be used as a soil conditioner if the salt was mined. NZ believes that that there is no valid reason to differentiate between sea salt and mined salt. In countries where sea salt is more readily available than mined salt it would be entirely appropriate to provide for its usage. We note for example that Seaweed is listed as a permitted substance to add to the soil

Table 2. Substances for plant pest and disease control

Substance	Comment
Beeswax	The use should be limited to use as a pruning agent.

Table 3.1. Food additives, including carriers

INS	Name	Comment
942	Nitrous oxide	Supported

Table 4. Processing aids

Substance	Comment
Sodium hydroxide	Its use for oil production from rapeseed is not supported as alternatives are available.

NORWAY:

Norway would like to thank the Codex Alimentarius Commission for its thorough work on the proposed revised draft amendments to Annex 2 of the Guidelines.

We have the following comments on Codex Circular Letter 2003/28/FL, concerning Annex II of the Guidelines as presented in ALINORM 03/22A, Appendix VI.

With regard to substances listed in Appendix VI, Annex II:

General comments:
The consumers commonly expect that organic food should be as natural as possible. The production of organic products should therefore be strict according to the use of additives and processing aids. We would therefore like to support former comments from Australia, Denmark and IFOAM in retaining as short and restrictive lists as possible.

Table 1: Substances for use in soil fertilising and conditioning
Comments on the structure of Table 1:
As explained in the Codex Principles of Organic Farming, Annex 1, A, Point 5, Table 1 contains substances that apply only to fertilisers and soil conditioners of conventional origin. It would be even more clear if this information was given also in the heading of the Table 1 (Substances for use in soil fertilising and conditioning – not from organic sources). In the description for the two first substances, it is said that use needs to be recognised by the certification body or authority, if the source do not come from organic farming. This last comment is not necessary and can lead to confusion about which origin the substances listed in the table have.

Comments to the substances included in table 1**:**
Under the description on the first substance "farmyard and poultry manure" it refers to factory farming. "Factory" farming refers again to industrial management systems that are heavily reliant on veterinary and feed inputs not permitted in organic farming. In our opinion the "definition" of "factory" farming should also include conditions for animal welfare or the animal natural behaviour. From that point of view, it should for example not be allowed to use farmyard manure from hens in cages or fur-bearing animals.

The substance "Compost from plant residues" has no restriction in the present proposal. Plant residues from conventional farming, could contain input residues, for example pesticides not permitted in organic farming. Therefore the substance needs to be recognised by the certification body or authority.

A condition for use of the substance "Natural phosphate rock", is that the cadmium content should not exceed 90 mg/kg P_2O_5. The substances "Seaweed and seaweed products", "Wood ash" and "Wood charcoal" could also contain cadmium. We propose the same condition with regard to cadmium content for these products as for "Natural phosphate rock".

The substance "Peat" is proposed not permitted as a soil conditioner. The occurrence of peat is different from country to country. Some countries, for example the Nordic ones, have vast resources of peat. A fundamental principle is that the peat extraction or "harvesting" always should be sustainable. We therefore suggest that the use of the substance should be recognised by the certification body or authority as proposed in the paper. Instead of having a general ban on peat used as a soil conditioner, we suggest a sentence that would reflect the principle mentioned above; e.g, "Only sustainable peat extraction".

Table 2: Substances for plant pest and disease control
***Comments to the substances in Table 2*:**
One of the principles in organic farming is respect for nature and biodiversity, and that it is an environmentally friendly production method. The consumers expect no use of pesticides in organic agriculture. To sustain high credibility in organic products, an overall goal should be to keep the list with substances for plant pest and disease control as short as possible. In the Codex guidelines for the production, processing, labelling and marketing of organically produced foods section 5, the requirements for inclusion of substances in annex 2 and criteria for the development of lists of substances is drawn up. Point 5.1 c) says that use of substances should not result in, or contribute to, harmful effects on the environment and point 5.1 d) says that substances should have the lowest negative impact on human or animal health and quality of life.

We find that some of the substances listed in Table 2 seem to have properties which are inconsistent with the criteria. In the following we will give some examples:
"Copper" is toxic for earthworms, birds and mammals and even extremely toxic for some aquatic animals. Also "Pyretriner" can give serious consequences if it is used wrong and get into water or in contact with aquatic animals. This substance is for example extremely toxic for fish and toxic for algae.

Another example is "Sulphur" which is toxic for some natural enemies of pests like parasites and beetles.

In the list of substances for plant pest and disease control, also "natural plant preparations, excluding tobacco" is listed. In our opinion, it is unsafe to accept natural plant preparations in general. The 5 first substances on the list are all natural plant preparations and they are all examples of substances that need to be recognised by the certification body. Since there are a lot of toxic plants, other "natural plant preparations" than those mentioned in the list should be recognised by the inspection body. An alternative is to make a list with plant preparations that is safe to use.

Sabadilla (*Schoenocaulon officinale)* contains *veratrine,* which is a highly toxic substance. It has traditionally been used as a parasiticide. Use of the substance could have harmful effects on health.

Some uncertainty attaches to the use of *Bacillus thuringiensis*. There should be done some research on the long-term effects on the environment after use of *Bacillus thuringiensis*.

Table 3: Ingredients of non agricultural origin referred to in section 3 of these guidelines
Comments on the structure of Tables 3.1 and 4

We consider that the division of Table 3.1 "for plant products" and "for livestock and bee products" could be simplified by making columns. These columns can include information on the code of the additives, the name of the additives, intended use and specific conditions. It should also be considered to include Table 4 into such a matrix.

Comments on the substances included in Table 3.1: Food additives, including carriers

According to Codex 5.1.d which says that suggested substances should have the lowest negative impact on human or animal health and quality of life, we do not support the inclusion of using either E 250 (sodium nitrite) or E 252 (potassium nitrate) for organic food production. These additives have an ill reputation, as they are considered to form nitrosamines, which can cause cancer. Experience gained in Norway and other places in the world have shown that organic products can be made without using E 250/E 252.

As E 300- E 303 (ascorbates) are associated and used with the nitrates, also E 300, E 301, E 302 and E 303 should not be included on the list of animals.

PARAGUAY:

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Paraguay suggests changing the terms given in English in **Table 1 Substances for use in soil fertilizing and conditioning** for Spanish terms (i.e. Sylvinite by silvinita)

It is suggested that zeolite be included only once in the list, as presently is repeated twice. See the table.

Substances	Description; compositional requirements; conditions of use
Clay (for example. Bentonite, perlite, zeolite)	----------
Zeolite	----------

Regarding the use of human excreta, the legislation of our country (Resolution N° 975/92 of the Ministry of Agriculture and Livestock) does not allow the use of human excreta. Paraguay requests a clarification about the use of this product because, if it can not be used as soil conditioner for crops destined to human consumption o edible plant parts, it would not makes sense to include it in these guidelines.

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

We request including for **bee wax**, the requisite "Need recognized by the certification body or authority", as it is done for **Propolis.**

Regarding point **IV OTHERS** in the same table, we request including, in **Herbal and biodynamic preparations**, the requisite "Need recognized by the certification body or authority", as it is done for **Natural plant preparations, excluding tobacco** (Point 1 - Plants and Animals)

TABLE 3: INGREDIENTS OF NON AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

3.1 Food additives, including carriers. For livestock and bee products.

Paraguay would like a clarification regarding why some additives are under condition to be used only in certain food products (i.e. Sulphur dioxide only in wines) Paraguay suggest that the list should be a positive list of additives allowed for these type of foods, and that the condition for their use should be that such use be allowed in the appropriate Codex Standards, and not having their use conditioned to only the foods specified in the proposed list.

POLAND:

According to the document CL 2003/28-FL, Agricultural and Food Quality Inspection acting as the Polish Codex Contact Point has pleasure to forward comments on the *Draft Amendment to the Guidelines for the Production, Processing, Labelling and Marketing* of Organically *Produced Foods: Annex 2 – Permitted Substances* (ALINORM 03/22A, Appendix VI).

We sustain our comments (sent on 9 June 2003 in response to the CL 2003/18-FL) concerning proposal to reject the following substances permitted to use in the production and processing of organic foods:

TABLE 1
SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Human excrements

We consider using human excrements unjustified and do not accept using it in soil fertilizing.

TABLE 3
INGREDIENTS OF NON-AGRICULTURAL ORIGIN

Sodium nitrite, Potassium nitrate

We do not accept using these additives (components of pickling salt for meat products) to organically produced food, as their conversion to harmful nitrosamines is evident. Our proposal is to remove these substances from the list.

Sodium phosphate, Potassium phosphate, Diphosphates, Polyphosphates
There is no technological justification for using these substances in processing of organically produced food.

SWITZERLAND:

Switzerland welcomes the opportunity to submit the following comments:

The proposals from Switzerland regarding "substances for plant pest and disease control", "food additives" and "processing aids" are listed in the tables below.
▶Where no proposals have been made, means that we agree with the Proposed Draft Amendment.

TABLE 1: SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

Substances	Description; compositional requirements; conditions of use	Swiss comment
Sawdust, bark and wood waste	Need recognized by the certification body or authority [wood not chemically treated after felling]	Remove square brackets
Wood charcoal	[Only wood charcoal from wood not chemically treated after felling]	Remove square brackets

TABLE 2: SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

Substances	Description; compositional requirements; conditions of use	Swiss comment
I. Plant and Animal		
Lecithin	Need recognized by the certification body or authority	Add in the description: Not from genetically modified organisms
IV. Other		
[Rodenticides]	[Products for pest or disease control in livestock buildings and installations]	Remove square brackets

TABLE 3: INGREDIENTS OF NON AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

3.1 Food additives, including carriers

INS	Name	Specific conditions	Swiss comment
	For plant products		
170	Calcium carbonates		Add under specific conditions: all effects without coloring
306	Tocopherols, mixed natural concentrates		Add under specific conditions: antioxidant in fat and oil
414	Arabic gum		Remove specific conditions
415	Xanthan gum		Remove specific conditions
422	Glycerol	From plant extracts	Not necessary
500	Sodium carbonates		Remove specific conditions
501	Potassium carbonates		Remove specific conditions
508	Potassium chloride		Not necessary
509	Calcium chloride		Not necessary
511	Magnesium chloride		Not necessary
	For livestock and bee products		
250	[Sodium nitrite]	[Where no alternate technology exists for certain products, may be used for: pickling salt for meat products except sausages for frying, minced meat products, products made of fish, crustaceans and mollusks]	Remove square brackets
The German Federal Research Center for Nutrition and Food in Kulmbach published in January 2004 an article concerning the relation between nitrite and cancer development: Based on their calculation the per head consumption of nitrite (derived from meat products) is around 2.5 mg per day (because of the reddening of the meat, the major part of the nitrite at the time of consumption is transformed). In the natural metabolism, the human body produces daily 50-70 mg sodium nitrite (20-28 times more!).			
[252]	[Potassium nitrate]	[Where no alternate technology exists for certain products, may be used for:	Remove square brackets

		raw pickled products and raw cured meat products.]	
[301]	[Sodium ascorbate]	[In meat products, provided insufficient natural sources are available.]	Remove square brackets
[302]	[Calcium ascorbate]	[In meat products, provided insufficient natural sources are available.]	Remove square brackets
[303]	[Potassium ascorbate]	[In meat products, provided insufficient natural sources are available.]	Not necessary, delete
327	Calcium lactate		Not necessary, delete
339	Sodium phosphate		Not necessary, chemical manufacturing of this food additive: delete this item
340	Potassium phosphate		Not necessary, chemical manufacturing of this food additive: delete this item
450	Diphosphate		Not necessary, chemical manufacturing of this food additive: delete this item
452	Polyphosphate		Not necessary, chemical manufacturing of this food additive: delete this item
942	Oxygen		Not necessary

TABLE 4: PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

As the Codex Alimentarius "Inventory of Processing Aids" (CAC/MISC3) defines ion exchange resins as processing aids, we propose to list ion exchange resins for specific uses as processing aids.

We propose to add to the list **"For plant products"**

Ion exchange resins	**Allowed in the saccharification of starch**

We propose to add to the list "**for livestock and bee products**"

Ion exchange resins	**Allowed in the whey powder production**

Reasons for introducing ion exchange resins

In the area of organic products, processes and treatments should be limited to those which are strictly necessary. Where there are alternatives, only the simplest, most straightforward, least aggressive and least artificial process should be chosen.

1) The necessity of the ion exchange process to meet market quality demands.

The quality of glucose syrup is determined by neutral taste, absence of color and salts, good clarity and color stability during storage.

Starch and whey powder products are for example used in baby- and weaning food production. For these products, the legal requirements are very high. To be in compliance with legal maximum levels of mineral content, the use of ion exchange process is necessary.

On the other hand, for example the clarification of an organic fruit juice by ion exchange should not be allowed. The quality of a fruit juice is determined by all natural flavors, colors, taste components, vitamins, etc. which must be retained. Together with other parameters, the quality of an organic fruit juice is determined by the natural and not artificial presence of all these substances.

2) Ion exchange process widely used in the organic production

The ion exchange process for the above-mentioned production has obtained the organic label in some EU countries. Some products using the resin refining process are also certified organic under the USDA National Organic Program.

INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM):

1. Introduction

IFOAM submits the following comments regarding the substances for Annex 2 of the Codex Guidelines for Organic Food. For some of the products, which might not be acceptable for all member states and Observer Organisations e, IFOAM has added short dossiers or fact sheets, which could help in the evaluation and decision making process. IFOAM has also prepared comprehensive dossiers on sodium (Chilean) nitrate in Soil Fertilizing and Conditioning, and on the use of the Phosphates in dairy processing. These documents are available from IFOAM upon request.

2. Substances Review

IFOAM has reviewed the substances in Annex 2 as they are presented by the "Report of the thirty-first session of the codex committee on food labelling Ottawa 28 April – 2 May 2003" (ALINORM 03/22A) with regard to the existing IFOAM Basic Standards 2002. The IFOAM Comments are put in a separate column. For several substances in brackets IFOAM made an evaluation against the Codex Criteria and for some substances added fact sheets. See Chapter 3 and Annex.

Table 1 Substances for use in Soil Fertilizing and Conditioning

Substance	Proposed by	Description; Compositional Requirements; Conditions of Use	IFOAM Comments
Human excrement	Chile	Need recognized by certification body or authority. The source is separated from household and industrial wastes that pose a risk of chemical contamination. It is treated sufficiently to eliminate risks from pests, parasites, pathogenic micro organisms, and is not applied to crops intended for human consumption or to the edible parts of plants.	*Agree with the more detailed description*
Sawdust, bark, and wood waste	European Union	Need recognized by certification body or authority [wood not chemically treated after felling]	*Agree with text in brackets*
Wood ash	European Union	Need recognized by certification body or authority [from wood not chemically treated after felling]	*Agree with text in brackets*
Wood charcoal	European Union	[Only charcoal from wood not chemically treated after felling].	*Agree with text in brackets*

Table 2 Substances for Plant Pest and Disease Control

IFOAM Comment to the title: better to speak of substances <u>and methods</u> for plant pest and disease control

Substance	Proposed by	Description; Compositional Requirements; Conditions of Use	
Chitin nematicides	IFOAM[1]	natural origin	*Agree, see IFOAM criteria comment 2003*
Sabadilla	IFOAM	—	*Agree, See IFOAM criteria comment 2003*
Beeswax	Switzerland	—	*Agree*
[Iron phosphates]	IFOAM	[molluscicide]	*See IFOAM criteria comment 2003, take away brackets.*
[Rodenticides]	Switzerland	[Products for pest or disease control in livestock buildings or installations]	*IFOAM does not agree to put generally rodenticidial material on Annex 2 without being more specific with regard to the kind of substance (specific dossier and evaluation against criteria needed)*
Mineral oils (in traps)	Switzerland	Need recognized by certification body or authority.	*Agree, but it should better be put under IV. Others.* *IFOAM proposes only to allow paraffin based oils*

Mechanical control devices such as e.g. crop protection nets, spiral barriers, glue-coated plastic traps, sticky bands	Switzerland	—	*Agree, but leave it under IV. others*

Table 3 Ingredients of Non Agricultural Origin Referred to in Section 3 (Processing)

For Plant Products

INS#	Substance	Specific Conditions	IFOAM
333	Calcium citrate	Acidity regulator, stabilizer, dispersing agent, antioxidant.	Agree
334	Tartaric acid	---	Agree
[422]	[Glycerol]	[from plant extracts]	*IFOAM has not listed this substance, no support*
551	Silicon dioxide	Anti-caking agent for herbs and spices	*Agree*

For livestock and bee products

INS#	Substance	Specific Conditions	*IFOAM Comment*
153	Wood ash	Specified traditional cheeses as recognized by the certification body or authority.	*Agree*
170	Calcium carbonate	Milk products, not as a colouring agent.	*Agree*
[250]	[Sodium nitrate]	[Where no alternate technology exists for certain products, may be used for: pickling salt for meat products except sausages for frying, products made of fish, crustaceans, and molluscs.]	*No not listed in IFOAM Basic Standards, in discussion See fact sheet*
[252]	[Potassium nitrate]	[Where no alternate technology exists for certain products, may be used for: raw picked products and raw cured meat products.]	*No, not listed in IFOAM Basic Standards. in discussion See fact sheet*
270	Lactic acid	Sausage casings / milk products.	*Agree*
290	Carbon dioxide	---	*Agree*
300	Ascorbic Acid	In meat [and dairy] products, provided insufficient natural sources are available.	*Agree*
[301]	[Sodium ascorbate]	[In meat products, provided insufficient natural sources are available.]	*No, not listed in IFOAM Basic Standards, relates with the use of nitrates/nitrites Only Sodium Ascorbate is needed for the proposed usage. And this usage makes only sense if nitrite or nitrate will be allowed! The use of Sodium Ascorbate reduces the rests of nitrite in the products to those substances which were added. IFOAM doesn't accept Nitrite and Nitrate until now and has therefore not listed ascorbates.*
[302]	[Calcium ascorbate]	[In meat products, provided insufficient natural sources are available.]	*No, not listed in IFOAM Basic Standards, relates with the use of nitrates/nitrites, see above*
[303]	[Potassium ascorbate]	[In meat products, provided insufficient natural sources are available.]	*No, not listed in IFOAM Basic Standards, relates with the use of nitrates/nitrites, See above*
306	Tocopherols, mixed natural concentrates	As an antioxidant in mixed products to prevent fat oxidation.	*Agree*
322	Lecithin	Obtained without the use of bleaches or organic solvents. Mil products / milk based infant food / fat products / mayonnaise.	*Agree*
327	Calcium lactate	Stabilizer for thickening pasteurized milk and cream products.	*Agree*
330	Citric acid	As coagulation agent for specific cheese products and for cooked eggs.	*Agree*
331	Sodium citrate	Sausages / pasteurization of egg whites / milk products, emulsified sausage, and melted cheese. Stabilizer for thickening pasteurized milk and cream products, and emulsifying salt for processed cheeses.	*Agree*
332	Potassium citrate	---	*Agree*
333	Calcium citrate	Stabilizer for thickening pasteurized milk and cream.	*Agree*

[339]	[Sodium phosphate]	[Stabilizer for thickening pasteurized milk and cream products]	*IFOAM opposes the listing of phosphates. See IFOAM fact sheet and evaluation against criteria table*
[340]	[Potassium phosphate]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurized creams]	*IFOAM opposes the listing of phosphates. See IFOAM fact sheet and evaluation against criteria table*
400	Alginic acid	As a thickener for milk based and mixed products.	*Agree*
401	Sodium alginate	As a thickener for milk based and mixed products.	*Agree*
402	Potassium alginate	As a thickener for milk based and mixed products.	*Agree*
406	Agar	---	*Agree*
407	Carrageenan	Milk products	*Agree*
410	Locust bean gum	Milk products / meat products	*Agree*
412	Guar gum	Milk products / canned meat / egg products	*Agree*
413	Tragacanth gum	---	*Agree*
414	Arabic gum	Milk products / fat / confectionery / glazing agent	*Agree*
440	Pectin (unmodified)	Milk products	*Agree*
[450]	[Diphosphates]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurized creams]	*IFOAM opposes the listing of phosphates See fact sheet and evaluation against criteria*
[452]	[Polyphosphates]	[Emulsifying salt for melted and processed cheese and stabilizer for pasteurized creams]	*IFOAM opposes the listing of phosphates See fact sheet and evaluation against criteria*
500	Sodium carbonates	Milk products for pH regulation in traditional cheese varieties prepared out of sour milk.	*Agree*
509	Calcium chloride	Milk products / meat products	*Agree*
938	Argon	---	*Agree*
941	Nitrogen	---	*Agree*
[942]	[Nitrous Oxide]	[Packaging gas, propellant for whipped cream]	*IFOAM has not listed this substance. The proposed application and product is not seen as necessary for organic milk products and as organic milk product.*
948	Oxygen	---	*Agree*

Table 4 Processing Aids Which May Be Used for the Preparation of Products of Agricultural Origin

For plant products

Substance	Specific Conditions	
Sodium hydroxide	PH adjustment in sugar production. [Oil production for rape seed (*Brassica spp.*)]	*Agree*

For livestock and bee products

Substance	Specific Conditions	
Calcium carbonate	---	*Agree*
Calcium chloride	Firming, coagulation agent in cheese making.	*Agree*
Kaolin	Extraction of propolis	*Agree*
Lactic acid	Milk products: coagulation agent, pH regulation of salt bath for cheese.	*Agree*

Sodium carbonates	Milk products; neutralizing substance	*Agree*
Water	---	

3. IFOAM Evaluation of some controversial substances against the criteria in the Codex Guidelines for organically produced food (ALINORM 03/22A)

IFOAM applied the following scoring:

SCORING	++ very positive	+ positive	0 not to evaluate	~both positive and negative	- negative	-- very negative

A. Substances, which should not be included in Table 1 for fertilization and soil conditioning purposes:

IFOAM Evaluation of CHILEAN SODIUM NITRATE (proposed by Chile)

Criteria for the non-inclusion or amendment of a substance in Annex 2, Table 1.

Criteria for review	**IFOAM Evaluation of Chilean Sodium Nitrate against criteria** include: detailed description of use and consequences if use of a substance is not permitted	Score
Section 5.1 *General Principles* Consistent with the principles of organic production	The principles state that the 'fertility and biological activity of the soil should be maintained or increased, where appropriate, by cultivation of legumes, green manures or deep-rooting plants in an appropriate multi-annual rotation programme; incorporation in the soil of organic material . . .' Specific substances may be applied 'only to the extent that adequate nutrition of the crop or soil conditioning are not possible by [these] methods.' (Codex Alimentarius GL 32-1999, rev 2001, Chapter Annex I Principles of organic production point 5). Sodium (Chilean) nitrate application is directly counter to these principles because it contains no organic matter, and because it is possible to obtain adequate nutrition of crops from organic material without the application of sodium nitrate. Organic material that contains nitrogen enhances soil fertility for a longer period of time, and stimulates biological activity more than sodium nitrate. While certain specific mineral fertilizers may be used to supply nutrients that are otherwise depleted, soil micro organisms dissolve these nutrients first. In organic agriculture one of the basic principles is to fertilize/nourish primary the soil and not directly the plant. In contrast, sodium nitrate is immediately soluble without being digested by soil organisms. Some papers indicate that sodium nitrate has no effect, either beneficial or adverse, on soil organism populations. However, studies show that soluble nitrogen fertilizers simplify soil ecology and reduce biodiversity of soil organisms. In particular research has shown that applications of soluble nitrogen fertilizers in general and sodium nitrate in particular depress the activity of nitrogen fixing organisms. The allowed mineral fertilizers are different rocks, natural rock phosphate, calcium and magnesium carbonate, gypsum and others. The nutrients are generally not in an easy soluble form. In case of Chilean nitrate the substance is a water soluble extract of *caliches; the rock used,* and is not comparable with the hardly soluble rock phosphates and the other mineral fertilizers (see below).	--
Substance is necessary / essential for its intended use	In organic farming systems, nitrogen is obtained from crop rotations that include nitrogen-fixing leguminous crops, free-living nitrogen fixing organisms, and the application of compost and manure. Plant and animal by-products can be used to provide supplemental nitrogen. Organic agriculture relies on "slow release" fertilizers by using less soluble mineral fertilizers, but also with the use of organic nitrogen fertilizers. Therefore, given the abundance and ready availability of such sources, Sodium nitrate is unnecessary and cannot be considered essential for its intended use.	--

Manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	Most sodium nitrate fertilizer is mined in Chile. The environmental impact is similar to that of other mined minerals. Given the geographically limited reserves and isolated supply, the transportation of nitrogen long distances has a potential to cause greater adverse environmental impacts than most other mined minerals. In most areas in the world there are local resources available for the production of organic commercial fertilizers, however these might be more expensive or more complicated than manufacturing sodium nitrate.	-
lowest negative impact on human or animal health and quality of life	Research has shown that crops fertilized by sodium nitrate will have significantly higher levels of free nitrate than crops fertilized with compost or manure. This effect is most pronounced in winter when fertilizing with pure soluble sodium nitrate is the only nitrogenous soil amendment. Sodium nitrate potentially increases the nitrate content in leafy vegetables such as salads. Although this risk must also be taken into consideration when using organic fertilizers, the unique use of Sodium (Chilean) nitrate in the spring which would be likely the case in practice, raises this risk. Nitrate will be reduced in the human body to nitrite, which has been linked to methemoglobinemia, a potentially fatal condition whereby nitrites interfere with oxygen uptake. Pregnant women and small children are at a particularly high risk from methemoglobinemia. Nitrites can also be further reduced to nitrosamines which compounds are strong carcinogens.	-
approved alternatives not available	Organic growers throughout the world have successfully developed systems that use compost, green manure, and plant and animal by-products to supply the nitrogen needed to grow all commercial crops throughout the year over a wide range of climates and soils.	--
Section 5.1(a) Used for fertilization and soil conditioning Essential for obtaining or maintaining fertility of the soil or fulfil specific nutrition requirement of crops, soil conditioning and rotation purposes witch cannot be satisfied by the practices included Annex 1, or other products included in Table 2 of Annex 2.	An organic fertilizing system is based on cultivation of legumes in a crop cycle with cash crops and green manure in combination with farmyard manure and compost where available. Such a system contains a balance of nitrogen and carbon sources, both of which nourish soil organisms that are essential for the cycling of nutrients. Carbon stabilizes the soil biomass and provides energy to soil organisms. Nitrogen is stored in the form of proteins that are slowly released by the biological decomposition of organic matter. By contrast, sodium (Chilean) nitrate contains no carbon and supplies soluble nitrates in a simple form similar to synthetic fertilizers such as potassium nitrate or calcium nitrate. A nitrate fertilizer that lacks carbon creates a carbon: nitrogen imbalance that increases the metabolic rate of soil microbial biomass that in turn accelerates the mineralization of soil organic matter. The crop response and increase in soil fertility is short-lived. With organic commercial fertilizers it is also possible to get a higher mineralization in cold soils for vegetable growing in the early season. These commercial fertilizers are for example based on horn or feather meal, malt sprouts, fish meal, or bean meal among others. With these fertilizers it is possible to grow even heavy feeding crops such as cauliflower with products found on annex 2 in the early spring. Although such fertilizers are usually more expensive per unit of nitrogen and often more difficult to handle, they are nonetheless available alternatives that better maintain the long-run fertility and condition of the soil and are more suitable for crop rotations than sodium (Chilean) nitrate. More research is clearly needed to improve the efficiency of organic sources of nitrogen, but this does not support the case that sodium nitrate is essential.	--

Ingredient is of plant, animal, microbial or mineral origin; may undergo the following processes: Physical (Mechanical, thermal), enzymatic or microbial (composting, fermentation); only when the above processes have been exhausted, chemical processes may be considered and only for the extraction of carriers and binders.	The Chilean source fulfils the criterion of being a source of mineral origin without further chemical processing. However, sodium nitrate may also be synthesized by a number of processes (Collings, 1950). Most of the sodium nitrate mined in the Atacama desert is processed into potassium nitrate, with iodine a significant co-product (USGS). A certain amount of chemical processing may take place to separate the iodine and remove toxic impurities such as perchlorates. At present, most of the beneficiation involves raising the potassium level and does not appear to be used to maintain the fertilizer guarantee levels in the sodium nitrate. However, products identified as 'nitrate of soda-potash', 'Chile salpeter', or 'niter' would not meet this criterion and should not be considered 'Chilean nitrate' even though they originate from Chile and contain nitrate. Although only small amounts of sodium nitrate are known to exist at present, it is conceivable that another commercial deposit could be opened somewhere else in the world. "Chilean nitrate" implies that one nation should be given license to control an international monopoly over the production of a given input. For the purpose of clarity, the dossier should refer to 'natural sodium nitrate' and not 'Chilean nitrate'.	+
Their use does not have a harmful impact on the balance of the soil ecosystem or on the soil physical characteristics, or water and air quality	Sodium nitrate accelerates the mineralization and depletion of soil organic matter, in contrast to organic nitrogen fertilizers that maintain and improve soil organic matter. Nitrate is highly mobile in soil. Nitrate that is not immediately assimilated by plants can be leached in the ground water. The salt index of Chilean nitrate is 100, which is higher than almost every other fertilizer (Rader et al., 1943). For most crops and in many areas, the addition of sodium which can pose a problem in some areas. In irrigated regions or in greenhouses it is necessary to leach the sodium periodically "out of the system" to prevent the salinity of the soil. A higher consumption of water and a load of salt to the environment is the negative impact/consequence. Although some organic fertilizers can also leach nitrates and salts, the impact is reduced by the smaller percentage and lower solubility of sodium and nitrate contained in such products. Risks of sodium and nitrate contamination are more easily managed by the use of Good Management Practices, such as application at appropriate soil temperatures and moisture. Because sodium nitrate is highly soluble and has a high salt index, such management practices are less effective at mitigating such harmful effects. The caliche used to produce Chilean nitrate contains perchlorate as a contaminant. Perchlorate is mobile in the soil as nitrate. Perchlorate was discovered in a number of US water supplies, prompting the US EPA to add it to its Contaminant Candidate List. The ecological impact of perchlorate is not well known. Perchlorate has been discovered in crops, including organically produced lettuce. The contamination of perchlorate in potable water is difficult to treat.	-

Use may be restricted to specific conditions, specific regions or specific commodities	In the relatively few cases where sodium nitrate has been permitted, it has been restricted to use only as a supplement to an organic soil building program, or to a specific crop such as spirulina. Sodium nitrate can enable a farm that is going through transition to avoid a crop failure when the soil biological activity has not been established to provide nitrogen from organic sources. However, such farms have developed a long-term dependence because the addition of sodium nitrate depresses the organisms needed to effectively cycle nitrogen. In such situations, some authorities have attempted to limit the amount of nitrogen provided by sodium nitrate. Monitoring a numerical limit on nitrogen contributions has proven to be a recordkeeping burden on the farmer, a verification problem for inspectors, and an administrative burden on the certifier. Experience with growing spirulina under standards where Sodium nitrate is prohibited has demonstrated that Sodium nitrate is not necessary for this particular crop.	0

Historical development of the regulatory situation of Chilean Sodium Nitrate in Organic Agriculture

The use of sodium (Chilean) nitrate from natural deposits has been one of the most contentious and divisive issues throughout the organic agriculture's history. The first IFOAM Basic Standards published in 1980 permitted the restricted use of Chilean Nitrate, reflected by the fact that the fertiliser was still allowed in some countries. IFOAM has published several papers on the subject, recognizing the value of its use, particularly with regard to nitrogen uptake in cold weather at the beginning of the growing season (IFOAM 1984). However even at that time the use of sodium nitrate has been criticised as unnecessary and seen as a controversial practice. In 1984 the use of sodium (Chilean) nitrate was restricted to the use during conversion. Based on an extensive literature review (IFOAM Technical Committee, 1989) and broad discussions with the IFOAM member organizations, the General Assembly in 1989 decided to prohibit sodium (Chilean) nitrate in the IFOAM Basic Standards. The reasons for exclusion correspond with those listed in the table above.

The Codex Working group considered sodium (Chilean) nitrate in 1997 and 1998 when the criteria for fertilisers were discussed. When the first Codex Alimentarius guideline was published, the Codex Alimentarius Commission decided to not include sodium (Chilean) nitrate in the Annex.

For the same reasons as IFOAM, the European Union, the Japan Organic Standards as well as most of the international certifiers (including major US certifiers) do not allow the use of Chilean Sodium Nitrate in their standards. In the NOP Chilean Nitrate is still allowed, however with restrictions. In a recent review (2002) of sodium (Chilean) nitrate by the USDA National Organic Standards Board Technical Advisory Panel (NOSB TAP), two reviewers were in favour of removing Chilean Nitrate while one favoured a phase out to permit farmers to develop viable alternatives. The Organic Trade Association's American Organic Standards, a voluntary private standard of the organic industry in the United States prohibited the use of sodium nitrate effective January 1, 2003 (OTA, 2003).

Because of the salt index and sodium content, sodium nitrate is considered by many agronomists and soil scientists to be an inferior source of nitrogen to ammonium nitrate, calcium nitrate, or potassium nitrate. Unlike these other forms of nitrate, sodium nitrate does not provide any additional fertility benefit besides nitrogen, instead carrying with it sodium, generally recognized to be detrimental in most soils. Sodium nitrate is an anomaly that undermines the case that organic food is better for soil and water quality than other food. Consumers who pay a premium for organic food in part because it has lower free nitrate levels than food grown with synthetic fertilisers are cheated when "organic" vegetables grown in the cold season with sodium (Chilean) nitrate are no different *ceteris paribus* from those grown with a conventional fertiliser like ammonium nitrate, calcium nitrate, or potassium nitrate. While sodium nitrate lowers production costs in certain situations, the principles of organic farming are undermined by its use.

Key references:

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IFOAM (1989): Chilean Nitrate of Soda – an evaluation for its use, respectively its non-use in organic agriculture. The recommendations of IFOAM Technical Committee. IFOAM, Tholey-Theley. 14 p.

IFOAM (2002): *IFOAM Basic Standards*. In: Norms for Organic Production and Processing. IFOAM. Tholey-Theley. 144p. Kross, B.C., Ayebo, A.D., Fuortes, L.J., 1992. Methemoglobinemia – Nitrate Toxicity in Rural America. Am. Fam. Physician, 46 (1): 183-188.

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University of California Extension, Sustainable Agriculture Research and Education Program (SAREP). 2002. Chilean Nitrate for general use as an adjuvant in crop production. Compiled for the USDA National Organic Program as a Technical Advisory Panel Review.

A detailed IFOAM dossier about Chilean Sodium Nitrate will be available in April 2004 for the Codex Alimentarius CCFL Meeting in May 2004.

B. Substances, which should be included in Table 2 for plant pest and disease control:

a. Chitin nematicides (Natural Origin) *Already submitted 2003 by IFOAM*

Criteria for the inclusion or amendment of a substance in Annex 2, Table 2.

Criteria for review		IFOAM evaluation of Chitin nematicides against Codex criteria	**Substance to be included** (evaluation)
Section 5.1 General Principles	consistent with the principles of organic production	Natural origin: derived from crab shells, oyster shells or other aquatic animals. Non-toxic.	++
	substance is necessary/essential for its intended use	Nematodes can cause extensive damage.	+
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	Made from crab shells, oyster shells. Some manufacturing processes use sulphuric acid, potassium hydroxide, and urea.	+
	lowest negative impact on human or animal health and quality of life	Beneficial for many soil organisms. No negative impact on human health, livestock, or wildlife.	+

	approved alternatives not available	Compost, diatomaceous earth, beneficial organisms, neem cake. It is more effective and a viable substitute for methyl bromide and other chemical nematicides.	++
Section 5.1(b) Used for Plant Disease or Pest and Weed Control	essential for the control of a harmful organism or particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available	Used to control plant nematodes where biological, physical or plant breeding alternatives and the above alternatives are not effective.	+
	[use should take into account potential harmful impact on the environment, ecology and health of consumers, livestock and bees]	Beneficial to the environment in that it provides a way to recycle wastes from the seafood industry. Consumers are not exposed to any residues. Not harmful to livestock or bees.	+
	undergo physical, enzymatic or microbial process	Some products are treated with strong acids and bases—in particular hydrochloric acid and potassium hydroxide. One theory of the mode of action is that this stimulates the growth of micro organisms that produce chitinase.	+
	products used in traps and dispensers which are chemically synthesized if other products are not available provided use does not result in residue in the edible part	Not applicable	0
	use restricted to specific conditions, regions or commodities	Mechanically processed without the addition of synthetic chemical treatments.	+

b. IFOAM Evaluation of Sabadilla *Already submitted 2003 by IFOAM*

Criteria for the inclusion or amendment of a substance in Annex 2, Table 2.

Criteria for review		**IFOAM evaluation of Sabadilla against Codex criteria** include: detailed description of use and consequences if use of a substance is not permitted	**Sub-stance to be included** (evaluation)
Section 5.1 General Principles	consistent with the principles of organic production	Safely used in many sustainable systems for hundreds of years as a natural form of pest control.	+
	substance is necessary/essential for its intended use	Necessary and essential in some regions for the management of insect pests of the orders Anoplura (lice), Hemiptera (true bugs), Orthoptera (grasshoppers), Thysanoptera (thrips). Often the least toxic available natural control for certain target pests.	+

Criteria for review		IFOAM evaluation of Sabadilla against Codex criteria include: detailed description of use and consequences if use of a substance is not permitted	Sub-stance to be included (evaluation)
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	From the dried ripe seeds of *Schoenocaulon officinale*, a relative of the lily, native to northern South America. Mixed with sulphur, lime, or diatomaceous earth and applied as a dust, or sprayed in a kerosene solution. Use according to instructions is not harmful to the environment. A natural product, it is fully and quickly biodegradable.	+
	lowest negative impact on human or animal health and quality of life	Highly selective, even within the same family of insects. Effectively toxic to only a small number of pest insects. Non-toxic to most beneficial organisms. Accidental exposure causes irritation,	+
	approved alternatives not available	Non-toxic alternatives exist but are not always effective. Less toxic than other approved alternatives such as rotenone. Some other alternatives may not be locally available because of resistance. Also, because the mode of action is different, it is useful to manage insect resistance to *Bacillus thuringiensis,* pyrethrum, and other approved treatments.	~
Section 5.1(b) Used for Plant Disease or Pest and Weed Control	essential for the control of a harmful organism or particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available	Locally essential for the treatment of insects in the orders Anoplura, Hemiptera, and Thysanoptera when biological, physical or plant breeding alternatives and other management practices fail.	++
	[use should take into account potential harmful impact on the environment, ecology and health of consumers, livestock and bees]	Consists of about 0.3% alkaloids, of which crystalline veratrine (cevadine) and veratraidine are the chief members. Historically used as a medicinal herb in South and Central America. LD50 (ip, mouse): 7.5 mg/kg. Exposure to consumers is not much of an issue. Poisoning of applicators is rare, but has been known to happen. No record of toxicity to bees.	~
	undergo physical, enzymatic or microbial process	Physically processed by crushing. Some products may then be combined with petroleum solvents.	~
	products used in traps and dispensers which are chemically synthesized if other products are not available provided use does not result in residue in the edible part	May be used in various traps as an alternative to carbamates and organophosphates. These uses will not result in residue in the edible part.	+

Criteria for review		IFOAM evaluation of Sabadilla against Codex criteria include: detailed description of use and consequences if use of a substance is not permitted	Sub-stance to be included (evaluation)
	use restricted to specific conditions, regions or commodities	Because it is narrow-spectrum, locally produced, and limited to certain regions, sabadilla use is self-limiting.	+

C. IFOAM Evaluation of Iron phosphates as molluscicide

Already submitted 2003 by IFOAM

Criteria for the inclusion or amendment of a substance in Annex 2, Table 2.

Criteria for review		IFOAM evaluation of Iron phosphate against Codex criteria include: detailed description of use and consequences if use of a substance is not permitted	Substance to be Included (evaluation)
Section 5.1 General Principles	consistent with the principles of organic production	Iron phosphate occurs in nature, is non-toxic, and degrades into essential nutrients.	++
	substance is necessary/essential for its intended use	Slugs and snails are a widespread problem. While there are some non-chemical alternatives, many organic farmers need a least-toxic molluscicide to reduce populations.	+
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	Occurs in nature; synthetic form is nature identical. Adequately pure sources do not pose a problem with heavy metals.	+
	lowest negative impact on human or animal health and quality of life	Iron phosphate appears to be the least toxic chemical control for molluscs.	++
	approved alternatives not available	There are some cultural and biological alternatives, but the efficacy varies according to climate, target pest, and cropping system.	+
Section 5.1(b) Used for Plant Disease or Pest and Weed Control	essential for the control of a harmful organism or particular disease for which other biological, physical or plant breeding alternatives and/or effective management practices are not available	Molluscs are vectors of human parasites in certain parts of the world. In many places they are very destructive to food crops. While a number of cultural and biological practices can help reduce mollusc damage, certain organic practices such as growing green manures and mulching may make the problem worse.	+
	[use should take into account potential harmful impact on the environment, ecology and health of consumers, livestock and bees]	Iron is an essential nutrient. Generally non-toxic; safe for livestock and wildlife. Iron phosphate is approved as a nutritional supplement for food. While long-term build-up may be toxic in low pH soils already high in iron, plants and animals have a high tolerance for iron. Bees are not exposed.	+

Criteria for review		IFOAM evaluation of Iron phosphate against Codex criteria include: detailed description of use and consequences if use of a substance is not permitted	Substance to be Included (evaluation)
	undergo physical, enzymatic or microbial process	Most commercial sources are produced by the reaction of steel manufacturing by-product with phosphoric acid. Usually combined with chelating agents, such as ethylene diamine tetraacetic acid (EDTA).	-
	products used in traps and dispensers which are chemically synthesized if other products are not available provided use does not result in residue in the edible part	Baits are applied to soil and are not intentionally applied directly to the edible parts of plant.	++
	use restricted to specific conditions, regions or commodities	Not for use as a phosphate fertilizer unless from a mined source.	+

C. Substances, which should not be included in Table 3 as ingredients of non-agricultural origin (3.1 Food additives):

IFOAM fact sheet and evaluation of Sodium Nitrite / already submitted January 2003

Substance (E – number)
Sodium Nitrite E 250
Usage
Colour maintaining agent, Preservative,
Origin
A product out of Nitrates
Proposed usage
For the production and processing of meat products and different sausages

CRITERIA		IFOAM evaluation of Nitrites against Codex criteria include: detailed description of use and consequences if use of a substance is not permitted	SCORING	PROPOSED BY
Section 5.1 General Principles	consistent with the principles of organic production	Yes. The substance is in very small amounts present in nature.	-	IFOAM
	substance is necessary/essential for its intended use	Yes, see 5.1c.	0	
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	No special negative effects are known. The environmental problems of the nitrogen industry (e.g. energy use) are related to these products to.	+	
	lowest negative impact on human or animal health and quality of life	The substance has mutagenic effects on different micro-organisms. JECEFA 0,2 mg/kg/d SCF 0,06 mg/kg/d (not valid for children).	--	

	approved alternatives not available	no. The most products can be produced without nitrite.	-	
Section 5.1 (c) Used as additives or processing aids in the production/preservation of food	[substance used only where not possible to preserve (additive) or produce (processing aid) in the absence of other available technology that satisfies these Guidelines]	The substance is used for the production of meat products and sausages. The most important effect is that the "red colour" of the fresh meat will be protected and nitrites will produce the typical flavour. The secondary effects are the anti microbiological effect, which is an additional food safety aspect during processing of such foods.	+	
	undergo mechanical/physical, biological/enzymatic or microbial processes	No.	0	
	undergo chemical synthesis if alternative substances/technologies not available	Produced out of nitrogen oxides/ salts of nitric acid. It's a simple chemical reaction. Nitrite is product out of Nitrates.	+	
	use maintains authenticity of the product	On one hand the Substance keeps the original meat colour. In the most countries the consumer expectation toward the outfit of these products is related to the effects caused by nitrates. That's the very delicate problem with nitrates and nitrites.	+	
	[does not detract from the overall quality]	No information is available which demonstrate a negative impact on overall quality of product.	-	

IFOAM fact sheet and evaluation of Sodium and Potassium nitrate ("Salts of nitric acid") / January 2003

Substance (E – number)
Sodium- Potassium nitrate E 251 250/ Salts of nitric acid
Usage
Preservative, Colour stabilizer (Sausages/Cheese), Antioxidants
Origin
Produced out of nitrogen oxides/ salts of nitric acid

CRITERIA		**IFOAM evaluation of Nitrates against Codex criteria** include: detailed description of use and consequences if use of a substance is not permitted	**SCO-RING**	**PRO-POSED BY**
Section 5.1 General Principles	consistent with the principles of organic production	Yes. The substance is often present in nature.	+	IFOAM
	substance is necessary/essential for its intended use	Yes, see 5.1c.	0	
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	No special negative effects are known. The environmental problems of the nitrogen industry (e.g. energy use) are related to these products to.		
	lowest negative impact on human or animal health and quality of life	ADI 5 mg/kg/d (JEFCA). The biggest problem related to nitrate is Nitrite which will be produced out of Nitrate during the food processing.	-	

	approved alternatives not available	no.	--	
Section 5.1 (c) Used as additives or processing aids in the production/preservation of food	[substance used only where not possible to preserve (additive) or produce (processing aid) in the absence of other available technology that satisfies these Guidelines]	The substance is used for the production of meat products and sausages. The most important effect is that the "red colour" of the fresh meat will be protected and nitrates will produce the typical flavour. The secondary effects are is the antioxitative activity, which prevents the fat and the anti microbiological effect, which is an additional food safety aspect during processing of such foods.	0	
	undergo mechanical/physical, biological/enzymatic or microbial processes	No.	0	
	undergo chemical synthesis if alternative substances/technologies not available	Produced out of nitrogen oxides/ salts of nitric acid. It's a simple chemical reaction. Alternatives are available.	-	
	use maintains authenticity of the product	On one hand the substance keeps the original meat colour. In the most countries the consumer expectation toward the outfit of these products is related to the effects caused by nitrates. That's the very delicate problem with nitrates and nitrites.	+	
	[does not detract from the overall quality]	No information is available which demonstrate a negative impact on overall quality of product.	0	

Documentation "nitrites, Nitrates and sulphites as food additives – health aspects and the EU regulation" Danish minister of agriculture 2001.

Arguments in favour and against nitrates/nitrites

Arguments in favour

- The usage of nitrites is primarily to gain a typical colour and taste for different sausages.
- Because the consumer is very much adapted to this taste and colouring, if a company wants to reach a lot of consumers it will not have the possibility to inform them about the use of nitrites, they are important for the success in selling organic products. The grey coloured sausages, produced without nitrites, can be judged as rotten or poor quality sausages.
- Nitrite also works as a preservative and significantly reduces the fat oxidation and enables a longer keeping time for a lot of products.
- For some products (e.g. raw sausages or raw meat products) the substance has functionality in helping to avoid the growth of dangerous micro-organisms (salmonella and clostridium botulinum). There are possibilities to process safe products without nitrites but it needs a special technological know-how which is not present everywhere, especially not in small-scale on farm processing units.

Arguments against

- For many years, consumer organizations have been strongly opposed to Nitrites because the substance is a well know toxin. And they cannot understand that this substance would be actively added to foods (especially to organic foods)!
- A number of companies (smaller and middle sized) have developed certain techniques to produce organic meat and sausage products without Nitrites. They strongly fight for their know-how and they push the argument that Nitrites and organic processing should not be combined where possible.
- In respect to the growing awareness of the consumers toward food safety, Nitrites with clear limitations should be used.

Description of the discussion process

- The discussion about Nitrites has been going on since the beginning of organic meat processing. It is a very difficult issue, which has lead to sometimes a very emotional discussion. The IFOAM General Assembly has rejected in the year 2000 to list Nitrates in the IFOAM Basic Standards.
- In practice, organic meat and sausages produced both with and without Nitrites are present on the market place.
- Several certifiers have allowed Nitrites because of the arguments that. 1. It's a help to prevent, especially amongst the very small processors, problems that could be caused by inappropriate technologies. 2. That it is needed to reach the consumers because they would not accept meat products without Nitrites.
- Ultimately it is a political decision that has to be taken. Some certifiers have also proposed to set a time limit for the allowance during 3-4 years, after which a re-evaluation of the situation will be done.

Documentation "nitrites, Nitrates and sulphites as food additives – health aspects and the EU regulation"
Danish minister of agriculture 2001.

IFOAM fact sheet and evaluation of Phosphates / February 2004

Substance (E – number)
Sodium phosphate Potassium Phosphate Diphosphates Polyphosphates
Usage
Phosphates can be used for several purposes, as: acids, acidity regulators, emulsifying salts, stabilisers, emulsifiers, firming agent, and humectants. The substance was proposed for the Codex Guidelines for organically produced food for two type of applications: *A. as a stabiliser for pasteurised milk and cream* *B. as an emulsifying salt for melted and processed cheese* These two different proposed applications will be evaluated and discussed separately in the criteria's where relevant.
Origin
Today only mineral sources are used for the production of phosphates used in foods.

CRITERIA		**IFOAM evaluation of phosphates against Codex criteria** include: detailed description of use and consequences if use of a substance is not permitted	**SCO-RING**	**PRO-POSED BY**
Section 5.1 General Principles	consistent with the principles of organic production	Yes. The substance (phosphate) is often present in nature.	+	IFOAM
	substance is necessary/essential for its intended use	*A. as stabiliser for pasteurised milk/cream:* No *B. as emulsifying salt for processed cheese:* Yes	- +	
	manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment	No special negative effects are known...	0	
	lowest negative impact on human or animal health and quality of life	For all phosphates the reference is the intake of phosphorous. The ADI level is very high because phosphorous is an essential nutrient for humans. An ADI level was fixed because excessive phosphate intake is known to negatively influence the rate that calcium and iron is replenished. The ADI level of 70 mg means a daily intake of around 20 mg of phosphate (P_2O_5). It was shown in a study in the year 2000 that for children especially the ADI for phosphates is being exceeded. While it has long been a point of contention that high intake of phosphates contributes to the "hyper kinetic syndrome" in children this hypothesis has never yet been scientifically proven or disproven. However, given the reasonable By the fact that there is a tendency, that children have a too high daily intake of phosphates, the questions about an impact on the "hyper kinetic syndrome" and the information that phosphates replace calcium and iron in human admonish is a reason why many consumer organisations are critical with regard to phosphates as a food additive.	-	

	approved alternatives not available	A. Alternatives are available (*as stabiliser for pasteurised milk/cream)*! Substance is not needed! B. Alternatives are available *(as emulsifying salt in cheese processing)*!	-- -	
Section 5.1 (c) Used as additives or processing aids in the production/preservation of food	[substance used only where not possible to preserve (additive) or produce (processing aid) in the absence of other available technology that satisfies these Guidelines]	*A. Use as stabiliser in pasteurised milk/cream:* Organic fluid milk has been marketed in both pasteurised and UHT forms for many years without additives. Goat milk may have a problem with casein flocculation. Three solutions are known to solve this problem: 1. Management of the goat's stage of lactation 2. Improving heat treatment technology 3. Adding phosphate Heat-treated organic goat's milk produced without phosphates is available on the market. A number of different types of organic cream without added phosphate are currently on the market. Coffee cream that is UHT treated and has a long shelf life presents a special problem that has been solved without the use of phosphates as additives. Gayer (1987) showed that the flocculation of casein is results from the homogenisation of the cream. Technology based on a procedure that applies a series of successive heating and homogenisation steps B. Use as emulsifying salt for processed cheese: *Cheese that is heat-treated and melted loses texture because the fat and protein are separated unless an emulsifying agent is added. Phosphates are the most widely used emulsifying agents for conventional cheeses. Trisodium citrate is the most common emulsifying agent for processing organic heat-treated and melted cheeses. Sodium citrates are currently approved by a number of standards, and the IFOAM Basic Standards allows them with no restrictions.* Use of citrates results in a slightly different texture from cheeses that use phosphates.	-- -	
	undergo mechanical/physical, biological/enzymatic or microbial processes	No.	--	
	undergo chemical synthesis if alternative substances/technologies not available	Although some of the phosphates used are found in nature in small amounts, the commercial product is synthetic.	-	
	use maintains authenticity of the product	Relatively little negative impact on authenticity (see below)	-	

	[does not detract from the overall quality]	*A. Use as stabiliser in pasteurised milk/cream:* Phosphates may detract from the overall quality of such products because pasteurised milk and cream can be kept stable through careful handling and inventory management without the use of phosphates. Phosphates may be added to processed products that are not handled with the same degree of care.	-	
		B. Use as emulsifying salt for processed cheese: Traditional cheeses have a typical structure and quality associated with techniques linked to certain specific qualitative characteristics. Processed cheese is melted by the application of heat, creating a product qualitatively different from traditional cheese. Thus, the quality of processed cheese is fundamentally different.	0	

Source: Beck, A. (2004): Dossier on the use of phosphates in organic food processing. Büro für Lebensmittel und Qualität. IFOAM Technical dossier. 8 pages. Can be sent on request.

INTERNATIONAL PECTIN PRODUCERS ASSOCIATION (IPPA):

International Pectin Producers Association has noted that in the list of Food Additives to be permitted in livestock and bee products that the entry for INS 440 is quoted as Pectin (unmodified).

The term "unmodified" applied to pectins is liable to cause some ambiguity. Pectins are extracted from nature with various mean molecular weights and degrees of esterification. These parameters may also be modified either incidentally or deliberately during processing, such that it is not always clear whether and to what extent the pectin (either high or low in ester content) could be regarded as "unmodified".

We believe that this type of modification is not what is intended in the use of the term "unmodified", but that the intent is to disallow the use of pectins where a different type of functional group has been introduced - in other words, amidated pectins. If this is the case, we would suggest that the entry is modified to read
"440 Pectin (non-amidated)".

APPENDIX 3

ARTIFICIAL SOIL TEST DRAFT
RELATIVE TOXICITY OF METALDEHYDE AND IRON PHOSPHATE MOLLUSCICIDES TO EARTHWORMS

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Abstract

Molluscs, including slugs and snails, are important pests of a wide range of crops in North America and Europe. They are managed by bran baits or pellet formulations with molluscicides which poison the molluscs when consumed. The baits and pellets are also consumed by earthworms, so their toxicity and effects of feeding and behavior of earthworms is critical particularly for organic and sustainable farmers. The two most commonly-used molluscicides are metaldehyde and iron-based compounds, such as iron phosphate, usually with the addition of chelating agents such as EDTA and EDDS.

OECD Artificial Soil Test. These data were obtained by exposing earthworms (*Eisenia fetida*) directly to the chemicals, using the OECD artificial soil test (which was designed by Edwards, 1983, 1984) for assessing the effects of chemicals on earthworms. The artificial soil consisted of:

- 10% sphagnum peat (Ph 5.5-60) finely ground and dried
- 20% kaolinite clay (containing > 30% kaolinite)
- 70% industrial quartz sand (dominant fine sand with more than 50% of particle size of 0.05-2.0 mm
- 1% pulverized calcium carbonate ($CaCO_3$)— to bring the pH to 6.0 ± 0.5.

The dry components were blended in the correct proportions and mixed thoroughly, in a large-scale laboratory mixer. Moisture content was determined by drying a small sample at 105°C and re-weighing, then adding deionised water to bring the moisture content of to about 35%. The complete mixture was moist but no water appeared when the artificial soil was compressed. One litre glass jars each received 750 g of artificial soil treated with test chemicals (or a control). Ten *Eisenia fetida* (each approximately 1mg) were added to each jar, with four replicates of each treatment. $L.D._{50}$ values were less than 10,000mg.kg.$^{-1}$ for metaldehyde and iron phosphate. 156.5 mg.kg.$^{-1}$ for EDTA, 145.6mg.kg.$^{-1}$ for EDDS, 72.2 mg.kg.$^{-1}$ for iron phosphate with EDTA, and 83.0 mg.kg.$^{-1}$ for iron phosphate with EDDS. Clearly metaldehyde and iron phosphate alone were not toxic to earthworms, but iron phosphate in combination with EDTA or EDDS and EDTA and EDDS alone were toxic, which implies they may be toxic to other animals.

APPENDIX 4

PRD2007-13

Proposed Registration Decision

Ferric Sodium EDTA

(publié aussi en français)

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OVERVIEW

Proposed Registration Decision for Ferric Sodium EDTA

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, is proposing full registration for the sale and use of Safer's Ferric Sodium EDTA Technical, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer, containing the technical grade active ingredient ferric sodium EDTA to control slugs and snails in greenhouses and outdoors.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Safer's Ferric Sodium EDTA Technical, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and the risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" is defined by subsection 2(1) of the *Pest Control Products Act* as "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

When a similar chemical compound, disodium EDTA, was given to pregnant animals at a very high dose, effects on the developing fetus were observed at doses that were not toxic to the mother. This indicates that the fetus was more sensitive to disodium EDTA than the adult animal. These effects are believed to be the result of binding of the essential mineral zinc to EDTA in the pregnant animals and not directly due to the EDTA. To reduce the potential for exposure of sensitive populations to ferric sodium EDTA, the statement "Avoid hand-to-mouth contact" is required on the product labels.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The acute toxicity of ferric sodium EDTA is low and there is no indication of genotoxicity, short-term or chronic toxicity, carcinogenicity, neurotoxicity, or reproductive toxicity in animal studies.

The overall low toxicity and proposed use of ferric sodium EDTA is such that risks due to exposure of fruits and vegetables in the diet of the general population, including infants and children, are not of concern.

Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are proposed to be applied to soil surface and not directly to water. Therefore, no risk from exposure to ferric sodium EDTA through drinking water is anticipated. As such, a quantitative assessment of residues in drinking water is not necessary.

The proposed use of ferric sodium EDTA is not expected to result in residues that are of toxicological concern. Therefore, the establishment of a Maximum Residue Limit (MRL) is not required for ferric sodium EDTA under section 4(*d*) of the *Food and Drugs Act* (adulteration of food) as defined under Division B.15.002 of the Food and Drugs Regulations. The Agency is not aware of any country requiring a tolerance for ferric sodium EDTA, nor have any CODEX MRLs been established for any crop. In the U.S., the Environmental Protection Agency has proposed EDTA chemicals be exempt from the requirement of a tolerance in or on raw agricultural commodities.

Occupational Risks From Handling Safer's Slug & Snail Bait and Safer's Slug & Snail Killer

Occupational risks are not of concern when Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are used according to label directions, which include protective measures.

Farmers and pesticide applicators loading or applying Safer's Slug & Snail Bait as well as field workers re-entering freshly treated fields may have direct skin contact with ferric sodium EDTA. Applying Safer's Slug & Snail Killer for domestic purposes can also result in direct skin contact with ferric sodium EDTA. Therefore, the label specifies that hands should be washed with soap and water after handling Safer's Slug & Snail Bait and

Safer's Slug & Snail Killer. Based on this label statement and the expectation that occupational exposure will be brief, these products are not likely to be a concern to farmers, applicators, workers or domestic users.

For bystanders, exposure is expected to be negligible. Therefore, health risks to bystanders are not of concern.

The wheat in Safer's Slug & Snail Killer and Safer's Slug & Snail Bait may be of concern to individuals with wheat sensitivities. Therefore, the pre-cautionary label statement "Warning, contains the allergen wheat" is required.

Environmental Considerations

What Happens When Ferric Sodium EDTA is Introduced Into the Environment?

Ferric sodium EDTA is nonpersistent in aerobic soils, although it is relatively stable in anaerobic soils. Ferric sodium EDTA is soluble in water, where it is rapidly degraded by natural light. No major breakdown products are formed in soil and water. Ferric sodium EDTA or EDTA associated with another metal may leach to groundwater under acidic and sandy soil conditions ($pH < 5$). Based on its low volatility, ferric sodium EDTA is not expected to enter the atmosphere.

Ferric sodium EDTA is ubiquitous in the environment as a result of its widespread use in detergents, pharmaceuticals, food additives, analytical chemistry, textile, metal treatment and agricultural industries. For the proposed use pattern, negligible ferric sodium EDTA will enter the environment as compared to other industrial, agricultural and domestic uses.

Ferric sodium EDTA is expected to pose negligible risk to terrestrial and aquatic organisms under conditions of use.

Value Considerations

What is the Value of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer?

Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are lower risk alternatives to conventional molluscicides used to control slugs and snails in a variety of vegetable, fruit, grass and ornamental crops in greenhouses and outdoors.

Safer's Ferric Sodium EDTA Technical is to be used in two end-use products: a new commercial class molluscicide, Safer's Slug & Snail Bait and a domestic class molluscicide, Safer's Slug & Snail Killer. Both products are to be applied around various vegetable, fruit, grass and ornamental crops, both in greenhouses and outdoors, to control slugs and snails. The efficacy data demonstrates that slugs and snails can be adequately controlled using Safer's Slug & Snail Bait and Safer's Slug & Snail Killer at the application rate of 11 to 22 kg product/ha.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

  Because there is a concern that users coming into direct contact with ferric sodium EDTA on the hands and then transferring it to the eyes, anyone loading, applying or cleaning up after applying Safer's Slug & Snail Bait and Safer's Slug & Snail Killer must wash hands with soap and water after handling.

  To reduce the potential for exposure of sensitive populations from ingestion of ferric sodium EDTA during hand-to-mouth contact, the product label advises against this type of contact.

Next Steps

Before making a final registration decision on ferric sodium EDTA, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision document, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision, and the Agency's response to these comments.

Other Information

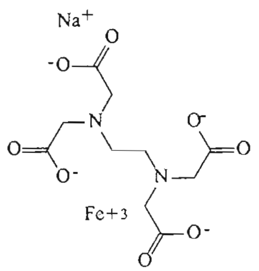
When the PMRA makes its registration decision, it will publish a Registration Decision document on ferric sodium EDTA (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Ferric Sodium EDTA

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Ferric Sodium EDTA
Function	Molluscicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Iron(III) sodium ethylenediamine tetraacetic acid
2. Chemical Abstracts Service (CAS)	[[N,N'-1,2-ethanediylbis[N-(carboxymethyl)glycinato]](4-)-N,N',O,O',ON,ON']-ferrate(1-), sodium
CAS number	15708-41-5
Molecular formula	$C_{10}H_{12}FeN_2NaO_8$
Molecular weight	367.05
Structural formula	
Purity of the active ingredient	100% nominal (limits: 99–100%)

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Safer's Ferric Sodium EDTA Technical

Property	Result
Colour and physical state	Dark yellow-green powdery solid
Odour	No detectable odour

Property	Result
Melting range	No melting point observed up to 400°C
Boiling point or range	TGAI is not a liquid at room temperature
Density	1.05 g/cm^3 at 20°C
Vapour pressure at 20°C	No vapour pressure could be measured at or above ranges listed in OPPTS 830.7950 as the product has a melting point of less than 400°C.
Henry's law constant at 20°C	
Ultraviolet (UV)—visible spectrum	λ_{max} < 300 nm at pH 4, 6, 8 and 10
Solubility in water at 20°C	90 g/L
Solubility in organic solvents at 20°C (% w/w))	**Solvent** / **Solubility** n-heptane < 0.1 xylene < 0.1 2,2-dichloroethane < 0.1 methanol < 0.1 isopropanol < 0.1 acetone < 0.1 ethyl acetate < 0.1
n-Octanol–water partition coefficient (K_{ow})	The product has a solubility in n-octane of less than 0.1% w/w. Therefore, the partition coefficient for octanol/water over a pH range of 4 to 9 is less than 0.005
Dissociation constant (pK_a)	pK_1 = 1.99 pK_2 = 2.67 pK_3 = 6.16 pK_4 = 10.29
Stability (temperature, metal)	No significant changes greater than 5% from the mean control samples were observed when the test material was placed in direct contact with copper sulphate, zinc sulphate, copper shot and zinc at ambient and elevated temperatures for 0 to 14 days.

End-use Product — Safer's Slug & Snail Bait and Safer's Slug & Snail Killer

Property	Safer's Slug & Snail Bait	Safer's Slug & Snail Killer
Colour	Rust	Rust
Odour	Flour-like odour of mild intensity	Flour-like odour of mild intensity
Physical state	Solid	Solid
Formulation type	Pellets	Pellets
Guarantee	6.0% nominal (limits: 5.70%–6.30%)	6.0% nominal (limits: 5.70%–6.30%)

Property	Safer's Slug & Snail Bait	Safer's Slug & Snail Killer
Container material and description	Nylon-lined paper bags, 1kg	Nylon-lined paper bags, 1kg
Density	0.76 g/mL	0.76 g/mL
pH of 1% dispersion in water	6.63 at 20°C	6.63 at 20°C
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.	The product does not contain any oxidizing or reducing agents.
Storage stability	Not provided	Not provided
Explodability	The product is not potentially explosive.	The product is not potentially explosive.

1.3 Directions for Use

The commercial class end-use product, Safer's Slug & Snail Bait, controls slugs and snails in various vegetable, fruit, grass and ornamental crops in greenhouses and outdoors. For most uses, Safer's Slug & Snail Bait is to be applied at an application rate of 11 to 22 kg product/ha, with application of the higher rate when pest pressure is elevated. For greenhouse vegetables and ornamentals, the product is to be applied at a rate of 2 g product/m^2 or 1g product/10 pots measuring 23 cm in diameter. For outdoor container-grown nursery plants, the application rate is 2 g product/m^2 or 3 g product/10 pots measuring 46 cm in diameter. For outdoor ornamentals and turf, the application rate is 2 g product/m^2. The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem.

The domestic class product, Safer's Slug & Snail Killer, controls slugs and snails in vegetables, orchard fruits, berries, ornamentals (shrubs, flowers, trees) and lawns. The end-use product can be used both outdoors and in greenhouses at an application rate of 2 g product/m^2. The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem.

1.4 Mode of Action

While the mode of action is not completely understood, it is known that iron salts are toxic to slugs and snails as a contact and stomach poison.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Technical Grade of Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Safer's Ferric Sodium EDTA Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulations Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA has conducted a detailed review of the submitted data and publicly available toxicological information for ferric sodium EDTA. The database is considered adequate, consisting of the full array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies and waivers for specific elements of information currently required for health hazard assessment purposes. The submitted toxicology studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is such that the database is considered adequate to qualitatively assess the toxicological hazards of this pest control product.

Ferric sodium EDTA is of low acute toxicity by the oral, dermal and inhalation routes in Sprague Dawley rats. It was slightly irritating to the skin and corrosive to the eyes in one of three New Zealand albino rabbits. Results of skin sensitization testing in Dunkin-Hartley albino guinea pigs using the Buehler method were negative.

The available acute toxicity data and irritation information for the technical grade active ingredient (TGAI) were used to estimate the acute toxicity and irritation of both Safer's Slug & Snail Bait and Safer's Slug & Snail Killer end-use products. It is anticipated that the acute toxicity will be low for both end-use products, regardless of the route of exposure. The end-use products are anticipated to be minimally irritating to the skin and neither are likely to be skin sensitizers. It is not possible to determine the eye irritation or potential for corrosion of either end-use product, based on the absence of product testing, but results for the TGAI showed it to be corrosive to eyes. There is the potential for an allergic reaction in sensitive individuals exposed to Safer's Slug & Snail Bait and Safer's Slug & Snail Killer because the formulations contain the allergen wheat.

Swine exposed to radiolabelled ferric sodium EDTA (5 mg introduced into the esophagus) resulted in 95% recovery in the feces and 0.3% in the urine. Absorption of a single, nonlethal, oral dose of ferric sodium EDTA introduced into the esophagus was anticipated to be poor, with nearly complete excretion in the feces. Metabolism of ferric sodium EDTA is anticipated to be negligible, based on a review of published scientific information.

The requirement for a short-term study was waived on the strength of the chronic toxicity information for similar compounds below.

Published literature demonstrating the chronic toxicity potential of ferric sodium EDTA was not available for evaluation. However, information on the chronic effects of similar compounds was considered in lieu of actual data. Fischer 344 rats and B6C3F1 mice fed trisodium EDTA in their diets for 103 weeks did not show any treatment-related signs of toxicity at any of the dose levels tested or any treatment-related tumours.

Likewise, in a chronic toxicity study performed on mongrel dogs, calcium sodium EDTA fed to the animals for one year did not result in any treatment-related effects at any of the dose levels tested.

Publicly available information suggests that normal individuals are capable of controlling iron absorption and that chronic toxicity (i.e. hemochromotosis) is generally limited to individuals with inherited metabolic disorders affecting maintenance of iron balance in the body.

Administration of a large quantity of disodium EDTA (954 mg/kg bw/day) in the diet of pregnant CD rats (day 7 through 14 of gestation) resulted in maternal effects marked by weight loss, decreased food consumption and diarrhea in all test animals. Gross fetal malformations included cleft palate, micrognathia, microphthalmia, menigocoele, phocomelia, clubfoot and electrodactyly, umbilical hernia, and short curly tail. Internal malformations were identified as great vessel anomalies, interventricular septal defects, small or missing lung lobes, missing thymus, small kidneys with associated hydronephrosis and hydroureter, and small undifferentiated gonads lateral to the kidneys. Skeletal malformations included extreme dysplasia, including shortened, missing or wavy ribs, misaligned and fused centra, as well as anomalies associated with external defects. Gross external brain malformations were also noted. There was also a significant increase in the mean percentage of fetal resorptions per litter and mean percentage of malformed fetuses per litter. The average fetal weight was also significantly reduced. Since only one dose of disodium EDTA was assessed, it was not possible to identify an appropriate no observed adverse effect level (NOAEL).

When disodium EDTA (3% by weight) was added to the diet of pregnant Sprague Dawley rats from days 6 to 14 of gestation or from day 6 to term, the majority of fetuses were grossly malformed. When the diet of exposed rats was supplemented with zinc (1000 ppm), no fetal malformations were noted, suggesting that the malformations were not directly caused by EDTA but were the result of secondary effects due to sequestering of zinc required for normal fetal development.

In short, the published sources of information suggest that oral administration of EDTA to rodents will result in significant teratogenic effects. With the available information, it cannot be definitively ascertained whether this is a direct result of the presence of EDTA or of EDTA binding with an essential component such as zinc, required for normal fetal development. There was evidence of genotoxic potential of ferric sodium EDTA in mouse lymphoma cells in the presence and absence of metabolic activation. It should be noted, however, that it is anticipated that the Fe and EDTA will dissociate in solution and that Fe uptake by a transferrin-independent transport system requires reduction of Fe^{3+} to Fe^{2+} at the cell surface. The ferrous ion is then subject to a Fenton reaction.

$$Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + \cdot OH + OH^-$$

The hydroxyl free radical is expected to attack the DNA, resulting in the observed genotoxicity. The genotoxic reaction is therefore likely to be an indirect result of iron and not of the ferric sodium EDTA.

There was no evidence of genotoxicity/mutagenicity when trisodium EDTA was tested in mouse lymphoma cells, *Salmonella typhimurium* strains (TA98, TA100, TA1535, TA1537, and TA1538) with and without metabolic activation, or *Escherichia coli* WP uvrA. This suggests that the EDTA moiety is not mutagenic/genotoxic and that ferric sodium EDTA is not likely to be mutagenic/genotoxic.

An evaluation of available literature suggests that ferric sodium EDTA is not expected to be neurotoxic.

3.2 Determination of Acceptable Daily Intake

As indicated in Section 3.4.5, the promulgation of an MRL for ferric sodium EDTA is not required. Thus, a value for an acceptable daily intake was not necessary.

3.3 Determination of Acute Reference Dose

A NOAEL could not be determined from the administration of a single dose of ferric sodium EDTA, regardless of the route of exposure. Therefore, an acute reference dose could not be set.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to either Safer's Slug & Snail Bait or Safer's Slug & Snail Killer is expected to be short-term and predominantly by the dermal route when pellets are handled during application. Inhalation of loose particles is also possible but is likely to only be a minor route of exposure. A developmental study demonstrated that administration of disodium EDTA in the diet (954 mg of EDTA/kg bw/day) to pregnant CD rats (day 7 through 14 of gestation) resulted in gross, internal and skeletal malformations in the fetuses. There was also a significant increase in the mean percentage of resorption per litter and mean percentage of malformed fetuses per litter. A NOAEL could not be identified as only one concentration of disodium EDTA was tested. Although a margin of exposure could not be estimated with available information, it is not expected that exposure to the end-use products in pellet form, as per label instructions, will result in any significant potential for adverse effects. An accidental ingestion of the end-use products by a pregnant animal (human or companion pet) may result in the adverse effects noted above. The publicly available information supports the position that ferric sodium EDTA is unlikely to have any chronic or nervous system toxicity or to be classified as a carcinogen or genotoxicant.

In lieu of insufficient information regarding the potential for developmental toxicity necessary to calculate an MOE, mitigation will be proposed such that the statements **"Avoid contact with skin, eyes, and clothing"** and **"Avoid hand-to-mouth contact"** be included in the **PRECAUTIONS** section of the draft label.

Note that the developmental toxicity noted in the test animal study was not a primary effect of ferric sodium EDTA but the result of zinc sequestering by EDTA in the animal, that is, the developmental toxicity appears to be a secondary effect.

3.4.2 Dermal Absorption

Since the available published literature suggests a negligible dermal absorption of the administered dose and since adequate hygiene statements have been placed on the product label, a dermal absorption study was not considered necessary to complete the health hazard assessment of ferric sodium EDTA.

3.4.3 Mixer, Loader and Applicator Exposure and Risk Assessment

Significant exposure to the loader and applicator is not anticipated based on the physical properties of the pellets and the mitigating statements on the product label. As such, an operator exposure assessment was not performed.

3.4.4 Bystander Exposure and Risk Assessment

Significant exposure to bystanders is not anticipated due to the physical properties of the pellets and due to the mitigating statements on the product label. As such, a bystander exposure assessment was not performed.

3.4.5 Food Residue Exposure Assessment

Section 3.1 details the overall toxicity of ferric sodium EDTA and demonstrates that the active ingredient is of low acute toxicity. Aside from being categorized as mildly irritating to the skin and corrosive to eyes, ferric sodium EDTA is not genotoxic, carcinogenic or considered to have any significant effect with respect to short-term chronic toxicity and reproductive toxicity. Based on short- and long-term clinical observations and on the structure and associated functional groups of ferric sodium EDTA, it is not expected that the active ingredient will be neurotoxic. It should also be noted that although developmental toxicity was associated with ingestion of an EDTA complex in rodents, the amount necessary to elicit this effect was excessive and above exposure levels expected from the proposed use of the end-use products.

The proposed application of both Safer's Slug & Snail Bait and Safer's Slug & Snail Killer is to the soil surface and not directly to water. It is therefore anticipated that there will be no risk from exposure to ferric sodium EDTA in drinking water. As such, a quantitative assessment of residues in drinking water is not necessary.

The pelleted end-use product is applied on top of the soil and is not likely to come in contact with foods such as fruits and vegetables. The risk due to exposure from the diet is therefore considered negligible.

Ferric sodium EDTA falls under the category of a mineral nutrient as per the definition in Part D, Division 2 of the Food and Drug Regulations and may also be exempt from the status of agricultural chemical as per the definitions provided in Part B, Division 1 of the Food and Drug Regulations. Ferric sodium EDTA has also been listed as a micronutrient component of fertilizers and may also be exempt from the adulteration provisions of food, as per Division 15, Part B.15.002(2)(a) of the Food and Drug Regulations.

When used as proposed, ferric sodium EDTA would not result in residues that are of toxicological concern. As such, promulgation of maximum residue limits for ferric sodium EDTA is not necessary. The Agency is not aware of any country requiring a tolerance for ferric sodium EDTA, nor have any CODEX MRLs been established for any crop. In the U.S., the Environmental Protection Agency has proposed exempting EDTA chemicals from the requirement of a tolerance in or on agricultural commodities.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Ferric sodium EDTA is soluble in water and will not bioaccumulate. Based on the vapour pressure (2×10^{-12} mm Hg) and Henry's law constant (7.7×10^{-16} atm $\times$ m^3/mol) of EDTA, its organic component, ferric sodium EDTA is expected to be relatively nonvolatile from water and moist surfaces under field conditions. Ferric sodium EDTA is mobile under some environmental conditions. However, it is expected to be readily biotransformed under environmental conditions in aerobic soil, reducing its potential to leach to groundwater. In acidic soil, ferric sodium EDTA is resistant to biotransformation and is relatively stable to transformation in anaerobic soil. Ferric sodium EDTA is rapidly phototransformed by natural light in water and is degraded by a mixed population of aerobic aquatic microorganisms.

Data on the fate and behaviour of ferric sodium EDTA are summarized in Table 2 of Appendix I.

4.2 Effects on Nontarget Species

Risk characterization integrates environmental exposure and ecotoxicology data to estimate the potential for adverse effects on nontarget species. A deterministic quotient method is used where appropriate. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity endpoint. A screening-level risk assessment is initially performed using the expected environmental concentrations (EECs) for a conservative scenario and the most sensitive toxicity endpoint. Negligible risk is predicted if the RQ is less than the level of concern (LOC) of one. In these cases, no further assessment is done. For those groups of organisms for which the RQ is greater than one, a refined assessment is undertaken. A refined assessment takes into consideration more realistic exposure scenarios and may consider additional toxicity endpoints.

4.2.1 Effects on Terrestrial Organisms

An original avian acute oral toxicity study was submitted based on the potential for birds to consume ferric sodium EDTA through feeding on end-use products Safer's Slug & Snail Bait and Safer's Slug & Snail Killer, which are applied in pellet form. Waiver requests for most of the data requirements were submitted and were based on the claim that ferric sodium EDTA would only target the copper-based blood system (with hemocyanin as an oxygen carrier), found in crustaceans and molluscs. Data on invertebrates were submitted in support of this claim. Waiver requests and data were deemed acceptable. Data for terrestrial organisms is summarized in Table 3 of Appendix I.

4.2.1.1 Birds

The risk to birds was assessed using the acute oral toxicity of ferric sodium EDTA to the Northern bobwhite (*Colinus Virginianus*) assuming exposure through direct consumption of pellet bait. The screening level risk assessment indicated that there was a potential risk (RQ > LOC) to birds that directly consume Safer's Slug & Snail Bait and Safer's Slug & Snail Killer (Table 4 and Table 5 of Appendix I). However, wild birds might have limited access to the pellets since the pellets will be scattered only in areas of infestation in damp, shady places around plants where birds are expected to spend limited time. According to the label, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are applied to soil while the ground is moist, in early morning, late evening or after rainfall. Additionally, the large diameter of the pellets (1.6 mm to 6.4 mm, averaging 4.8 mm) indicates that they are unlikely to be consumed by small birds. Larger birds, such as gulls, crows, and pheasants, could consume the pellets but must consume a significant number of pellets (over 200) to reach a potentially toxic dose; consumption of this number of pellets is unlikely. Therefore, considering the proposed use pattern in damp shady areas, the size of the pellets, and the large number of pellets that would need to be consumed to reach a potentially toxic dose, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are expected to pose a minimal risk to wild birds.

4.2.1.2 Invertebrates

The proposed use of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer is expected to target pill bugs, crustaceans and molluscs, but will not pose a risk to beneficial insects such as *N. gravis* and *D. bellulus* (Table 3 of Appendix I). Other invertebrates using haemocyanin as an oxygen carrier—including stoneflies, the Entognatha, and most hemimetabolan taxa, some of which are beneficial arthropods (Hagner-Holler et al. 2004)—are expected to be targeted by ferric sodium EDTA. However, the limited use pattern of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer is not expected to impact populations of those beneficial insects.

4.2.2 Effects on Aquatic Organisms

No data were submitted by the registrant addressing potential toxic effects of ferric sodium EDTA on aquatic organisms (invertebrates, fish, plants). While ferric sodium EDTA is expected to be toxic to aquatic organisms with haemocyanin blood systems, such as daphnia, crabs, crayfish, lobsters and shrimp, it is expected to pose negligible risk under conditions of field use, as there is negligible potential for exposure.

5.0 Value

5.1 Effectiveness Against Pests

Four small-scale outdoor field trials were submitted that examined the efficacy of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer to control slugs and snails in the presence of alternative food sources (strawberries, petunias, lettuce). The efficacy trials tested application rates between 6 and 45 kg product per hectare on garden snails (*Helix aspersa*) and two slug species (*Arion fasciatus* and *Agriolimax reticulates*). The efficacy data demonstrated that adequate control of slugs and snails is obtained using Safer's Slug & Snail Bait and Safer's Slug & Snail Killer at the application rate of 11 to 22 kg product/ha. Higher application rates should be used at higher pest pressures. In trials where plant damage was assessed, there were lower levels of plant damage in petunias and higher yields of lettuce compared to the untreated control.

5.1.1 Acceptable Efficacy Claims

Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are to be used to control slugs and snails in various vegetable, fruit, grass and ornamental crops in greenhouses and outdoors. Both end-use products are to be scattered at an application rate of 11 to 22 kg/ha or equivalent to protect plants from slugs and snails. The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem. For further details, refer to Table 5.1.1.1, Acceptable uses and application rates for Safer's Slug & Snail Bait and Safer's Slug & Snail Killer.

Table 5.1.1.1 Acceptable uses and application rates for Safer's Slug & Snail Bait and Safer's Slug & Snail Killer

Product	Pest	Use Sites	Application Rate	Remarks
Safer's Slug & Snail Bait (Commercial)	Slugs and Snails	vegetables, orchard fruits, berries, field crops, vineyards, wheat, grass grown for seed production	11-22 kg/ha*	*Use the higher application rate at higher pest pressures. The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem.
		greenhouse vegetables and greenhouse ornamentals	2 g/m^2 or 1 g/10 pots measuring 23 cm in diameter	
		outdoor container-grown nursery stock	2 g/m^2 or 3 g/10 pots measuring 46 cm in diameter	
		turf, golf courses, sod farms	2 g/m^2	
Safer's Slug & Snail Killer (Domestic)	Slugs and Snails	vegetables, orchard fruits, berries, ornamentals (shrubs, flowers, trees) and lawns, in greenhouses and outdoors	2 g/m^2	The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem.

5.2 Phytotoxicity to Host Plants

It is unlikely that the application of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer will result in phytotoxicity to host plants. No phytotoxic effects were observed in the efficacy trials and ferric sodium EDTA is used as a micronutrient in some fertilizers. A phytotoxicity warning statement was added to the labels of the end-use products because of the extensive diversity of crops being treated.

5.3 Impact on Succeeding Crops

It is unlikely that the application of Safer's Slug & Snail Bait and Safer's Slug & Snail Killer will impact succeeding crops.

5.4 Economics

No information was provided.

5.5 Sustainability

5.5.1 Survey of Alternatives

Several active ingredients are registered to control slugs and snails, including silicon dioxide present as diatomaceous earth, metaldehyde and ferric phosphate. Non-chemical practices used to control slugs and snails include hand removal of the pest, traps, habitat modification (e.g. removal of vegetable refuse, leaves, weeds, bricks, boards and other places slugs and snails may live) and barriers (e.g. copper wires, eggshells). Refer to Table 6 for further information on alternatives.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

The two end-use products, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer, are considered to be lower risk alternatives to conventional molluscicides. These products could be used in conjunction with current slug and snail control practices, such as removal of habitat, barriers, traps and hand removal of the pest.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance to ferric sodium EDTA is unlikely.

5.5.4 Contribution to Risk Reduction and Sustainability

Safer's Slug & Snail Bait and Safer's Slug & Snail Killer provides an alternative to conventional molluscicides used to protect a variety of vegetable, fruit, grass and ornamental crops from slugs and snails in greenhouses or outdoors.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, ferric sodium EDTA was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of ferric sodium EDTA were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in end-use products Safer's Slug & Snail Bait and Safer's Slug & Snail Killer. The PMRA has reached the following conclusions:

1. Ferric sodium EDTA is not expected to be persistent and is not bioaccumulative. The octanol-water partition coefficient (log K_{ow}) is less than 0.005, which is below the TSMP Track 1 cut-off criterion of greater than or equal to 5.0.

2. Ferric sodium EDTA does not form any major transformation products that meet the TSMP Track 1 criteria.

3. Ferric sodium EDTA (technical grade) does not contain any by-products or microcontaminants that meet the TSMP Track 1 criteria. Impurities of toxicological concern are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

4. Ferric sodium EDTA does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

5. Safer's Slug & Snail Bait and Safer's Slug & Snail Killer do not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

Therefore, the use of ferric sodium EDTA is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

The available information for ferric sodium EDTA is adequate to qualitatively define the majority of toxic effects that may result from human exposure to ferric sodium EDTA. Eye corrosion was observed in a single laboratory animal exposed to ferric sodium EDTA. As well, fetal malformations occurred in cases where an excessive amount of disodium EDTA, a compound chemically similar to ferric sodium EDTA, was ingested by pregnant animals. No other toxicologically significant effects were observed in any other available studies for ferric sodium EDTA.

Loaders, applicators, workers and bystanders entering treated areas are not expected to be exposed to levels of ferric sodium EDTA that will result in an unacceptable risk when Safer's Slug & Snail Bait and Safer's Slug & Snail Killer are used according to label directions.

The precautionary statements on the product labels are adequate to protect workers and bystanders, and no additional personal protective equipment is required.

Because ferric sodium EDTA is of low toxicity, does not represent a risk due to exposure from the diet or drinking water, may be considered a mineral nutrient, may be exempt from the status of agricultural chemical, has been listed as a micronutrient component of fertilizers, and may be exempt from the adulteration provisions of food in the Food and Drug Regulations, promulgation of an MRL is unnecessary.

The Agency is not aware of any country requiring a tolerance for ferric sodium EDTA nor have any CODEX MRLs been established for any crop. In the U.S., the Environmental Protection Agency has proposed that EDTA chemicals be exempt from the requirement of a tolerance in or on raw agricultural commodities.

Supervision of children around areas containing Safer's Slug & Snail Bait and Safer's Slug & Snail Killer is suggested, especially in cases where an individual is allergic to wheat. Accidental ingestion may result in an allergic reaction.

7.2 Environmental Risk

Based on the use pattern for ferric sodium EDTA as pelleted bait around ornamentals, vegetables, fruit crops, shrubs and crops in greenhouses, or on lawns and gardens, ferric sodium EDTA presents a negligible risk to nontarget terrestrial and aquatic organisms.

7.3 Value

The data submitted to register Safer's Slug & Snail Bait and Safer's Slug & Snail Killer demonstrates that the end-use products will control slugs and snails in the presence of an alternative food source. The product may be reapplied as the bait is consumed or at 14-day intervals if slugs and snails continue to be a problem. These products are lower risk alternatives to conventional molluscicides.

7.4 Unsupported Uses

All uses proposed by the applicant were supported from an efficacy perspective.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient ferric sodium EDTA and the end-use products, Safer's Slug & Snail Bait and Safer's Slug & Snail Killer, to control slugs and snails in greenhouses and outdoors. An evaluation of current scientific data from the applicant and scientific reports has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARD	acute reference dose
atm	atmosphere
bw	body weight
CAS	chemical abstracts service
cm	centimetre(s)
d	day
DF	dry flowable
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in the test population)
DT_{75}	dissipation time 75% (the dose required to observe a 75% decline in the test population)
dw	dry weight
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EEC	Expected environmental concentration
ER_{25}	effective rate for 25% of the population
Fe	iron
FeNaEDTA	ferric sodium EDTA
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
$K_{d\text{-}ads}$	soil-water adsorption coefficient
K_F	Freundlich adsorption coefficient
km	kilometre(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation

LR_{50}	lethal rate 50%
m	metre(s)
mg	milligram(s)
mL	millilitre(s)
mm	millimetre(s)
MAS	maximum average score
MIS	maximum irritation score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
RQ	risk quotient
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
µg	microgram(s)
µL	microlitre(s)
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
w/w	weight per weight

Appendix I Tables and Figures

Table 1 Toxicity Profile of Technical Ferric Sodium EDTA

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
METABOLISM			
Absorption of $FeNa^{55}[2\text{-}^{14}C]EDTA$ in swine (5 mg introduced into the esophagus) demonstrated a rapid transfer of ^{55}Fe to the plasma pool (peak at 1 hour) and subsequent incorporation of 4.6% of the orally administered dose into the circulating hemoglobin. 0.3% of the administered ^{55}Fe was excreted in the urine and 95% remains unabsorbed and excreted via the feces (3% in a soluble form, e.g. FeEDTA, and 92% in an insoluble form). Very little ^{14}C[EDTA] could be detected in the plasma at any time. Approximately 5% of the administered dose of ^{14}C[EDTA] was absorbed by mucosal cells of the pylorus and upper jejunum portion of the digestive tract (5–20 hours) and quantitatively excreted in the urine. The literature points out that Fe dissociates from EDTA prior to being absorbed and that the Fe is absorbed by the normal pathway for Fe uptake. Intravenous injection of FeNaEDTA into rats resulted in 70–90% of the iron being excreted in the urine within 24 hours, with a small portion to be used in hemoglobin synthesis from the iron pool in the body. The available information suggests that neither Fe or EDTA undergo biotransformation to any significant degree, but are excreted unchanged after oral administration of FeNaEDTA. The data also suggests that EDTA metal complexes are rapidly excreted and not likely to accumulate.			
ACUTE STUDIES - TECHNICAL			
Oral	Sprague Dawley Rats Dose: 3900, 5000 and 6300 mg/kg bw	LD_{50} (♂♀) > 5000 mg/kg bw	**Low toxicity** Significant effects greater than or equal to 5000 mg/kg include ano-genital staining, hypoactivity, hunched posture, soft feces and diarrhea as well as lung, liver, and intestinal discolouration for both male and female test animals in the mid- and high-dose groups.
Dermal	Sprague Dawley Rats Dose: 5000 mg/kg bw	LD_{50} (♂♀) > 5000 mg/kg bw	**Low toxicity**
Inhalation	Sprague Dawley Rats Dose: 2.05 mg/L	LC_{50} (♂♀) > 2.0 mg/L	**Low toxicity**
Skin Irritation	New Zealand Albino Rabbits (1♂ and 2♀) Dose: 0.56 g dry paste of ferric sodium EDTA (90% w/w with distilled water)	MAS = 0/8 (24, 48 and 72 hrs) MIS = 1.0/8 (24 hrs)	**Slightly irritating** Based on MIS of 1.0/8 at 24 hours.

Eye Irritation	New Zealand Albino Rabbits (1♂ and 2♀) Dose: 0.1 g	MAS = 9/110 (24, 48 and 72 hrs) MIS = 12/110 (24 hrs) Irreversible corneal opacity in the male rabbit at 21 days.	**Extremely corrosive or irritating** **Irreversible within 21 days** Based on corneal opacity in the male at 21 days.
Skin Sensitization (Buehler Method)	Albino Hartley Guinea Pigs (8♂ & 12♀) Induction dose: 0.4 g of Sodium Ferric EDTA (80 % w/w with distilled water) Challenge dose: 0.4 g of Sodium Ferric EDTA (75 % w/w with distilled water)	Negative results	**Negative skin sensitizer**
ACUTE STUDIES - FORMULATION [Safer's Slug & Snail Bait] N.B. The acute information for the TGAI was used as surrogate information for this EP.			
ACUTE STUDIES - FORMULATION [Safer's Slug & Snail Killer] N.B. The acute information for the TGAI was used as surrogate information for this EP.			
SHORT-TERM TOXICITY			
61-day dietary	0, 35, 70 and 140 mg/kg FeNaEDTA in the diet 0, 2.8, 5.7 and 11 mg Fe/kg BW/day Sprague Dawley Crl:CD BR rats (40 ♂ per dose group; 20 sacrificed at day 31 and 20 at termination)	Could not identify an NOAEL or LOAEL from the available information.	↑ non-haem iron in liver, spleen, and kidneys after 31 and 61 days (concentration not disclosed). Accumulation of iron in the spleen was confined to the red pulp (concentration not disclosed).
90-day dietary	0, 1, 5, and 10% Na_2H_2EDTA in the diet Holtzman rats (10 ♂ per dose group)	NOAEL 1% Na_2H_2EDTA LOAEL 5% Na_2H_2EDTA	1.0%: 47–118 mg/kg bw/day; 5.0%: 337–627 mg/kg bw/day; 10.0%: 596–1429 mg/kg bw/day. ↓ bw gain in the 5 and 10% groups. Diarrhea throughout study in the 5 and 10% groups. Priapism (10/10) in the 10% group and (2/10) in the 5% group. Mortality (2/10) in the 5% group and 6/10 in the 10% group.

CHRONIC TOXICITY AND ONCOGENICITY			
1-year dietary	0, 58, 130 and 338 mg/kg bw/day Ca_2Na_2EDTA Mongrel dogs (4 per dose)	NOAEL 338 mg/kg bw/day Ca_2Na_2EDTA	No significant treatment-related effects.
103-week dietary	0, 3750 and 7500 ppm Na_3EDTA in diet B6C3F1 mice and Fischer 344 rats (50 ♂ and 50 ♀ for mid- and high-dose groups, 20 ♂ and 20 ♀ for the control group)	NOAEL (♂♀) 7500 ppm Na_3EDTA	No treatment-related effects.
REPRODUCTION AND DEVELOPMENTAL TOXICITY			
Single generation	F_0: 0, 0.5, 1 and 5% Na_2EDTA in diet for 12 weeks. Rats (number per dose not disclosed)	NOAEL 1% Na_2EDTA LOAEL 5% Na_2EDTA	Animals mated once they were 100 days old and 10 days after weaning. Diarrhea and ↓ food consumption at 5%. Test animals produced normal first and second litters, except at 5%, where dams failed to produce litters.

GENOTOXICITY		
STUDY	**SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES**	**RESULTS**
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538; *E. Coli* WP2uvrA Up to 1000 µg/plate without activation Up to 1000 µg/plate with activation	Negative for Na_3EDTA.
Gene mutations in mammalian cells in vitro	L5178Y TK +/- mouse lymphoma cells 0–5000 µg/ml without activation 0–5000 µg/ml with activation	Negative for Na_3EDTA.
Gene mutations in mammalian cells in vitro	L5178Y TK +/- mouse lymphoma cells 0–325 µg Fe/mL without activation 0–6.5 µg Fe/mL with activation	Positive for NaFeEDTA. Likely due to hydroxyl free radical produced from Fenton reaction of the available iron, not the direct result of NaFeEDTA.

Compound-Induced Mortality: Mortality was observed as a compound-induced effect in the 90-day short-term study at 5.0 (337–627 mg/kg bw/day) and 10.0% (596–1429 mg/kg bw/day) Na_2H_2EDTA in the diet.

Recommended ARD: As a result of a lack of an acute NOAEL, the ARD was not calculated.

Recommended ADI: Since an MRL will not be promulgated, the ADI was not calculated.
MOE for other critical endpoint(s): Although an MOE was not calculated, consideration must be provided for reproduction/developmental toxicity as a critical endpoint.

Tox Endpoints for Occupational Risk Assessment:

Reproduction and developmental toxicity
In lieu of insufficient information regarding the potential for developmental toxicity necessary to calculate an MOE, mitigation will be proposed such that the statements "**Avoid contact with skin, eyes, and clothing**" and "**Avoid hand-to-mouth contact**" be included in the **PRECAUTIONS** section of the draft label.

Note that the developmental toxicity noted in the test animal study was not a primary effect of the ferric sodium EDTA but the result of zinc sequestering by EDTA in the animal, i.e. developmental toxicity appears to be a secondary effect.

Table 2 Fate and Behaviour in the Environment

Property	Test Substance	Value		Comments	Reference (PMRA #)
Biotransformation in terrestrial system (after 30 days)					
Biotransformation in aerobic soil Study carried out in aerated soil suspensions from 5 types of soils of different pHs.	FeEDTA Reaction between Fe and Na ^{14}C-labelled EDTA	pH 5.7 and 6.1 pH 6.75 pH 7.3 and 7.85	75–90% remaining 15–20% remaining <5% remaining	persistent slightly persistent nonpersistent	1122092 Norvell and Lindsay (1969)
Biotransformation in anaerobic soil Study carried out in anaerobic soils from 3 types of agricultural soils of different pHs.	FeEDTA Reaction between $FeCl_3$ salt and [^{14}C]EDTA	pH 6.0 pH 6.4 pH 7.4	not transformed	stable (no CO_2 was produced)	1122092 Tiedje (1975)
Mobility					
Adsorption/desorption in soil Study carried out on Rehovot sand (sand, 88%; silt, 5%; clay, 7%) [pH 7.1–7.2] in batches equilibrium studies and column studies. Only results from column studies were valid.	FeEDTA	$K_{d\text{-ads}}$ values of K_d were estimated from breakthrough curves of column experiments. No K_{oc} was calculated.	0.57	highly mobile	1122092 Lahav and Hochberg (1975)
Transformation in aquatic system					
Phototransformation in water Study was carried out in aqueous buffer solutions at different pHs. Photolysis was by artificial lamp (5500-W Xenon).	FeEDTA radiolabelled FeEDTA	pH 4.5 and pH 6.9 pH 8.5	No parent remaining after 24 hr No parent remaining after 32 hr	Photolysis is expected to be an important route of transformation.	1122094 Lockhart and Blakeley (1975)
Study was carried out in both distilled and lake water, each at pH 3.1 and 6.5. Photolysis was by UV radiation emitted by two black light lamps.	FeEDTA	pH 3.1 pH 6.5	$t_{½}$ = 14–31 min $t_{½}$ = 45–56.8 min		1434305 Metsärinne et al. (2001)
Biotransformation in aerobic water systems Study was carried out on serum media inoculated with biological extracts from water samples collected from an EDTA-contaminated lagoon.	FeNaEDTA	Transformation products were not quantified.	89% of parent compound disappeared after 5 days	Aerobic aquatic microbial degradation is expected to be an important route of transformation	1122092 Belly et al. (1975)

FeNaEDTA: ferric sodium EDTA
FeEDTA: ferric EDTA

Table 3 Toxicity to Nontarget Species - Terrestrial Organisms

Organism	Exposure	Test substance	Endpoint Value	Degree of toxicity	Reference (PMRA #)
Beneficial arthropods	Carabid beetle, *Notonomus gravis*; 48-h dietary	Multiguard® (total of 0.38 mg a.i. consumed/ larvae	no mortality	harmless (< 25% mortality)	1122100
	Ladybird larvae, *Harmonia conformis*; 48-h dietary	Multiguard® (total of 0.913 mg a.i. consumed/ larvae	no mortality	harmless (< 25% mortality)	
	Melyrid beetle, *Dicranolaius bellulus*; 48-h dietary	Multiguard® (total of 1.152 mg a.i. consumed/ larvae	no mortality	harmless (< 25% mortality)	
Other terrestrial arthropods	Woodlouse (*Porcello laevis*) 48-h dietary	Multiguard® (total of 0.271 mg a.i consumed /larvae)	mortality	harmful (70% mortality)	
Northern bobwhite	acute oral	FeNaEDTA	LD_{50} >2038 mg a.i/kg bw NOEL: 1253 mg a.i/kg bw Sublethal and behavioural effects Hyporeactivity, low body carriage, difficulty walking, lack of balance. Discoloured liver, kidney and heart, dehydrated organs, yellowish fluid in gastrointestinal tract.	practically nontoxic	1122103

Table 4 Screening Level Risk Assessment on Nontarget Species - Terrestrial Birds

Organism	Toxicity Endpoint value	EDE	RQ	Risk
Large bird (1000 g)	NOEL = 1253 mg a.i/kg bw (1.253 g a.i./kg bw)	3.5 g a.i./kg bw/day	3	RQ > LOC
Northern bobwhite (178 g)		6.37 g a.i./kg bw/day	5	RQ > LOC
Small bird (20 g)		15.3 g a.i./kg bw/day	12	RQ > LOC

Table 5 Screening Level Risk Assessment on Nontarget Species - Terrestrial Birds (values expressed in terms of number of pellets)

Organism	Toxicity Endpoint value in # pellets to reach toxicity endpoint (= Toxicity in mg a.i./kg bw × kg bw × pellet/6 mg a.i.)	Exposure in # pellets consumed/day (100% diet composed of pellets)	RQ (Exposure/ Toxicity)	% diet to reach RQ of 1	Risk
Large bird (1000 g)	NOEL = 209 pellets (1253 mg a.i./kg bw × 1 kg bw × pellet/6 mg a.i.)	581 pellets/day (58.1 g dw/d × pellet/0.10 g)	3	33%	RQ > LOC
	LD_{50} > 340 pellets (>2038 mg a.i./kg bw × 1 kg bw × pellet/6 mg a.i.)		>1.7	>58%	
Northern bobwhite (178 g)	NOEL = 37 pellets (1253 mg a.i./kg bw × 0.178 kg bw × pellet/6 mg a.i.)	189 pellets/day (18.9 g dw/d × pellet/0.10 g)	5	20%	RQ > LOC
	LD_{50} > 60 pellets (>2038 mg a.i/kg bw × 0.178 kg bw × pellet/6 mg a.i.)		>3	>32%	
Small bird (20 g)	NOEL = 4 pellets (1253 mg a.i/kg bw × 0.020 kg bw × pellet/6 mg a.i.)	51 pellets/day (5.1 g dw/d × pellet/0.10 g)	12	8%	
	LD_{50} > 7 pellets (>2038 mg a.i/kg bw × 0.020 kg bw × pellet/6 mg a.i.)		>7	>14%	RQ > LOC

Table 6 Alternative Molluscicides for the Control of Slugs and Snails

Active Ingredient	Class Designation	Pest	Locations of Use (Refer to product labels for specific use directions)
Carbaryl	Domestic/Commercial	slugs	
Ferric phosphate	Domestic/Commercial	slugs and snails	greenhouse or outdoor use; ornamentals (flowers, shrubs, trees), vegetables, fruit trees, berries, field crops, lawns, grass grown for seed production, nursery plants
Metaldehyde	Domestic	slugs and snails	greenhouse or outdoor use; ornamentals, pathways, rockeries, hedges, ivy and other ground covers, lawns, seedlings, fruit (melons, blackberries, apples, avocados, cherries, citron, grapes, peaches, plums, strawberries), vegetables (asparagus, beans, cabbage, carrots, celery, cucumbers, lettuce, onions, peas, peppers, potatoes, radishes, spinach, squash, tomatoes, turnips)
Methomyl	Commercial/Restricted	slugs	Brussels sprouts, strawberries
Methyl bromide	Restricted	slugs and snails	fumigant for raw agricultural commodities (post-harvest), processed foods, certain structures, pre-plant soil applications, mulch, wood and wood products
Silicon dioxide (in the form of diatomaceous earth)	Domestic	slugs	indoor or outdoor use; where pest is found, including along foundations, gardens, shrubs, flowerbeds

End-use products

PMRA 1113967 — 2005, DACO 3.1.1 to 3.1.4, N/A, MRID: N/A, DACO: 3.1

PMRA 1113968 — 2003, Product Chemistry of Slug & Snail Control, N/A, MRID: 45848101, DACO: 3.2

PMRA 1113969 — 2003, Product Chemistry of Slug & Snail Control q, N/A, MRID: 45848101, DACO: 3.3.1

PMRA 1113970 — 2001, PCC1030: Chemistry and Physical Properties, PLT-197, MRID: 45848102, DACO: 3.5

PMRA 1113971 — 2003, Product Chemistry of Slug & Snail Control, N/A, MRID: 45848101, DACO: 3.4

PMRA 1352454 — 2006, Slug & Snail Bait - Preliminary Analysis, 2720-128, MRID: N/A, DACO: 3.7

2.0 Impact on Human and Animal Health

PMRA 1437509 — EPA (2005) *Ferric sodium EDTA; notice of filing a pesticide petition to establish a tolerance for a certain pesticide chemical in or on food.* FR Doc 05-11165.

PMRA 1122054 — Heimbach, J. *et al.* (2000) *Safety assessment of iron EDTA [sodium iron (Fe3+) ethylenediaminetetraacetic acid]: summary of toxicological fortification and exposure data.* Food and Chemical Toxicology, **38**:99-111.

PMRA 1437510 — World Health Organization (2005) *796. Sodium iron EDTA.* WHO Food Additive Series: 32

PMRA 1447533 — Candela, E. *et al.* (1984) *Iron absorption by humans and swine from Fe(III)-EDTA. Further studies.* Journal of Nutrition, **114**:2204-2211.

PMRA 1122048 — Merkel, D.J. (2001) *Acute oral toxicity study in rats - defined* LD_{50}. Product Safety Labs. Laboratory Study Number 11267, December 6, 2001.

PMRA 1122049 — Merkel, D.J. (2001) *Acute dermal toxicity study in rats - limit test.* Product Safety Labs. Laboratory Study Number 11268, December 6, 2001.

PMRA 1122050	Merkel, D.J. (2001) *Acute inhalation toxicity study in rats - limit test*. Product Safety Labs. Laboratory Study Number 11269, December 6, 2001.
PMRA 1122051	Merkel, D.J. (2001) *Primary eye irritation study in rabbits*. Product Safety Labs. Laboratory Study Number 11270, December 6, 2001.
PMRA 1122052	Merkel, D.J. (2001) *Primary skin irritation study in rabbits*. Product Safety Labs. Laboratory Study Number 11271, December 6, 2001.
PMRA 1122053	Merkel, D.J. (2001) *Dermal sensitization study in guinea pigs (Buehler method)*. Product Safety Labs. Laboratory Study Number 11272, December 6, 2001.
PMRA 1122054	Wynn, J.E. *et al.* (1970) *The toxicity and pharmacodynamics of EGTA: oral administration to rats and comparisons with EDTA*. Toxicology and Applied Pharmacology, **16**:807-817.
PMRA 1122054	National Cancer Institute (1977) *Bioassay of trisodium ethylenediaminetetraacetate trihydrate (EDTA) for possible carcinogenicity*. NCI Carcinogenesis Tech. Report. Ser., 11.
PMRA 1122054	Oser, B.L. *et al.* (1963) *Safety evaluation studies of calcium EDTA*. Toxicology and Applied Pharmacology, **5**:142-162.
PMRA 1444631	Yang, S.S. (1964) *Toxicology of EDTA*. Food and Cosmetics Toxicology, **2**:763-767.
PMRA 1122054	Kimmel, C.A. (1977) *Effect of route of administration on the toxicity and teratogenicity of EDTA in the rat*. Toxicology and Applied Pharmacology, **40**:299-306.
PMRA 1122054	Swenerton, H. and Hurley, L.S. (1971) *Teratogenic effects of a chelating agent and their prevention of zinc*. Science, **173**:62-64.
PMRA 1122054	Dunkel, V.C. *et al.* (1999) *Genotoxicity of iron compounds in Salmonella typhimurium and L5178Y mouse lymphoma cells*. Environmental and Molecular Mutagenesis, **33**:28-41.
PMRA 1122054	McGregor, D.B. *et al.* (1988) *Responses to the L5178Y tk+/tk- mouse lymphoma forward mutation assay: III 72 coded chemicals*. Environmental and Molecular Mutagenesis, **12**:85-154.

4.0 Impact on the Environment

PMRA 1122079	Summaries, DACO: 8.1, 2005. 4 pp.
PMRA 1122080	Active Substance Analytical Methods, University of Melbourne, Volume 14, DACO: 8.2, 2002. 6 pp.
PMRA 1122081	Summary, DACO: 8.2.3.1, 2005. 2 pp.
PMRA 1122082	Hydrolysis, DACO: 8.2.3.2, 2005. 1 pp.
PMRA 1122083	Phototransformation Soil, DACO: 8.2.3.3.1, 2005. 1 pp.
PMRA 1122084	Phototransformation Water, DACO: 8.2.3.3.2, 2005. 1 pp.
PMRA 1122085	Aerobic Soil Biotransformation, DACO: 8.2.3.4.2, 2005. 1 pp.
PMRA 1122086	Anaerobic Soil Biotransformation, DACO: 8.2.3.4.4, 2005. 1 pp.
PMRA 1122087	Aerobic Water Sediment Biotransformation, DACO: 8.2.3.5.4, 2005. 1 pp.
PMRA 1122088	Anaerobic Aquatic Sediment Biotransformation, DACO: 8.2.3.5.6, 2005. 1 pp.
PMRA 1122089	Adsorption Desorption, DACO: 8.2.4.2, 2005. 1 pp.
PMRA 1122090	Summary, DACO: 8.2.4.1, 2005. 2 pp.
PMRA 1122091	Summary, DACO: 8.4.1, 2005. 1 pp.
PMRA 1122092	Active Substance Fate & Behavior in the Environment, University of Melbourne, 2002, DACO: 8.6 Volume 9A, 181 pp.

Within this reference, the following studies are included:

Belly R.T., Lauff J.J., and Goodhue C.T. 1975. Degradation of ethylenediaminetetraacetic acid by microbial populations from an aerated lagoon. Appl. Microbio. 29:787-794.

Dynand, S. And Sinha, M.K. 1979. Kinetics of FeEDTA reactions in calcareous soils. Soil Sci, 127:202-210.

Hill-Cottingham D.G., and Lloyd-Jones C.P. 1961. Absorption and breakdown of Fe ethylenediaminetetraacetic acid by tomato plants. Nature 189:312.

PMRA 1122100 Waiver Request of Requirements for Futher Testing, Platte Chemical Co., DACO: 9.3, 2001. 74 pp.

PMRA 1122103 Avian Single-Dose Oral LD50 Test with EDTA in Northern Bobwhite, Genesis Laboratories, Inc. Report # 01023, DACO: 9.6.2.1, 2002. 71 pp.

PMRA 1122105 Active Substance Ecotoxicity, University of Melbourne, DACO: 9.9, 2000.Volume 18.

5.0 Value

PMRA 1113994 Slug Control Trial. Cornell University. Study report date: 16-June-2004 to 01-July 2004. pp. 5. DACO 10.2.3.3.

PMRA 1113995 Slug Bait Lettuce Field Trial. Washington State University. Study report date: November-2005. pp. 2. DACO 10.2.3.3.

PMRA 1113996/1113999 Efficacy of Differential Rates of PCC-1030 Compared to Current Industry Standard Materials in Control of Snails. Bio Research, 180-01 Study report date: 18-May-2001. pp. 22. DACO 10.2.3.3.

PMRA 1292449 Effect of Experimental Compounds PCC-1030, 1225, 1226 and 1227 Compared to Industry Standards in the Control of Snails. Bio Research, 313-01 Study report date: December-2001. pp. 24. DACO 10.2.3.3.

PMRA 1113993 Volume 13 Active Substance Additional Information. University of Melbourne. Study report date: October-2002. pp. 11. DACO 10.6.

PMRA 1114000 Part 10 Value Summary. pp. 7. DACO 10.1.

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Impact on Human and Animal Health

PMRA 1437508 World Health Organization (2000) *970. Sodium iron ethylenediamine tetraacetic acid (EDTA)*. WHO Food Additive Series: 44

2.0 Impact on the Environment

PMRA 1434305	Metsärinne S., Tuhkanen T., Aksela R. 2001. Photodegradation of ethylenediaminetetraacetic acid (EDTA) and ethylenediamine disuccinic acid (EDDS) within natural UV radiation range. Chemosphere 45:949-955
PMRA 1434309	Hagner-Holler S., Schoen A., Erker W., Merden J.H., Rupprecht R., Decker H., and Burmester T. 2004. A respiratory hemocyanin from an insect. Proceedings of the National Academy of Sciences of the United States of America (PNAS). 101:871-874.

APPENDIX 5

FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: November 30, 2007

Subject: Sodium Ferric Hydroxy EDTA

Chair: Andrea M. Caroe

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X
Guidance Statement: ____
Other: ____

Statement of the Recommendation (including Recount of Vote):

Add Sodium Ferric Hydroxy EDTA as snail and slug bait to the National List §205.601(h).

NOSB Vote: Motion: Gerald Davis Second: Jeff Moyer

Board vote: Yes - 0 No- 15 Abstain- 0 Absent - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Is not consistent with environmental and compatibility with organic farming OFPA criteria primarily due to the behavior of EDTA in the environment and the toxic chemicals used to manufacture.

Response by the NOP:

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Novermber 2007 | **Substance: Sodium Ferric Hydroxy ETDA**

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: adding sodium Ferric Hydroxy EDTA as snail and slug bait to the National List § 205.601(h)

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

		Yes	No	N/A
1.	Impact on Humans and Environment	☐	X	☐
2.	Essential & Availability Criteria	☐	X	☐
3.	Compatibility & Consistency	☐	X	☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	☐	☐	X

B. Substance Fails Criteria Category: 1,2, and 3 Comments: Ferric phosphate is already listed for this use, harm to humans and the environment, not consistent with organic farming and handling.

C. Proposed Annotation (if any): ______

Basis for annotation: To meet criteria above: ______ Other regulatory criteria: ______ Citation: ______

D. Recommended Committee Action & Vote (State Actual Motion): Motion is to add Sodium Ferric Hydroxy EDTA to the National List on 205.601(h) as a slug and snail bait.

9/12/07 *Motion by: Jeff Seconded: Tina Yes: 0 No: 6 Absent: 0 Abstain 0*

11/29/07 1st: Rigo; 2nd Tina: yes 5 No 0 Absent: 1

Crops	X	Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling		Synthetic	X	Rejected[3]	X
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance voted to be added as "allowed" on National List to § 205.______with Annotation (if any) ______

2) Substance to be added as "prohibited" on National List to § 205.______with Annotation (if any) ______

Describe why a prohibited substance:______

3) Substance was rejected by vote for amending National List to § 205. 601(h). Describe why material was rejected: Sodium Ferric Hydroxy EDTA failed categories 1, 2, and 3.

4) Substance was recommended to be deferred because ______ If follow-up needed, who will follow up ______

E. Approved by Committee Chair to transmit to NOSB:

Gerald Davis — **Committee Chair**

9/12/07 — **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance –** Sodium Ferric Hydroxy EDTA

Question	Yes	No	N/A 1	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Petition pg. 13—petitioner says no, but with ingredients like hydrogen cyanide, formaldehyde and sulfuric acid it seems intuitive that there would be adverse effects from the manufacture.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Not enough information. Pg 9 of the petition only addresses iron and not SFH EDTA. The EDTA clearly has the potential to be harmful to the environment (EU Commission risk assessment on EDTA)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				Not enough Info. Ferric sodium EDTA is a list 4B, but this is not the petitioned compound
5. Is there potential for detrimental chemical interaction with other materials used?[§6518 m.1]		X		Pg 9 of the petition iron and only how the petitioned substance should react in an organic system.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Page 15 of the petition had conclusions based on iron and ferric sodium EDTA. EDTA can result in the detrimental movement of metals in soils and river sediments (EU Commission Risk Assessment on EDTA)
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				Insufficient information provided in the petition. Once again, the information in the petition are based on iron, EDTA, and ferric sodium EDTA, none of which are the petitioned compound.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Also, add in the reference used in #10: Page 14 of petition, but eye irritant page 15, and possible chronic iron overload. EDTA is a very strong metal chelating agent, especially for calcium. It is poorly absorbed in mammalian GI tract and concerns have been raised that excessive usage in food could deplete the body of Ca and other minerals. It is a FDA GRAS direct food additive, but the maximum amounts in different foods are regulated. It is also added to some food systems as a Na2Ca salt rather than the Na form to prevent Ca depletion (O. R. Fennema 1985, Food Chemistry, 2'ed edition, pp. 641 - 642).
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			EDTA is not degraded rapidly in the environment and is the most abundant anthropogenic chemical in some European surface waters http://en.wikipedia.org/wiki/EDTA#_note-1 accessed 1 August 07). Its strong chelating power can enhance the movement of metals such as Zn, Cd, Ni, Cr, Cu and Fe in soil and river sediments. EDTA is very soluble in water and is not sequestered in municipal sewage treatment plants (Frank and Rau 1990, in petition). The biodegradation rate strongly depends on the metal complexed to the EDTA. Ca and Mg complexes are easier to degrade than Cu and Fe for example (see EU Commission risk assessment on EDTA p 12 in petition). Photo degradation appears easier. However, the high solubility in water can limit the time exposed to sunlight. Since EDTA is inert under some environmental conditions and rapidly degrades under other conditions (very alkaline water - such as in waste water treatment from paper pulp mills (EU Commission risk assessment on EDTA), some environmental accumulations must occur.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Page 14 of petition, but eye irritant page 15, and possible chronic iron overload. EDTA is a very strong metal chelating agent, especially for calcium. It is poorly absorbed in mammalian GI tract and concerns have been raised that excessive usage in food could deplete the body of Ca and other minerals. It is a FDA GRAS direct food additive, but the maximum amounts in different foods are regulated. It is also added to some food systems as a Na2Ca salt rather than the Na form to prevent Ca depletion (O. R. Fennema 1985, Food Chemistry, 2'ed edition, pp. 641 - 642).

11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

[1] If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? **Substance** – Sodium Ferric Hydroxy EDTA

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Page 22, Page 8, page 13 of the petition and summarized below. It is commercially produced in either a single or two step process. The single step process is most widely used commercially. The synthesis starting with ethylenediamine (2-a aldehyde and sodium cyanide to form a Na EDTA salt and ammonia and a Na salt of NTA (nitrilotriacetic acid) by reaction between the ammonia and the starting materials. Acidification precipitates the EDTA, leaving the NTA in solution. Hydrochloric or sulfuric acids are used. The NTA is considered a waste product, although the NTA can also be used as a chelator in detergents. Excess ammonia is either volatilized or recovered (see Ullmann's Encylopedia of industrial chemistry vol. A10 for details). The two step process uses the same starting materials and forms a Na salt of EDTA, and ammonia (no NTA) Formaldehyde and sodium cyanide are hazardous chemicals
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		Page 13 of the petition-tetra sodium salt is a synthetic reacted with ferric sulfate to give ferric sodium EDTA.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Page 13 of the petition summarized above.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Page 20 of the petition-diatomaceous earth, barriers, physical controls.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			Ferric Phosphate
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Petition page 20 copper tape, diatomaceous earth, barriers, physical and cultural controls.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance –Sodium Ferric Hydroxy EDTA

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		It's a synthetic material that does not present a compelling need for it as well as the toxic substances necessary for its manufacture.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		EDTA is inert under some circumstances and can build up in soil. It is the most abundant anthropomorphic chemical in some European surface waters. It can enhance the movement of metals in soil and river sediments.(EU commission risk assessment on EDTA)
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance – Sodium Ferric Hydroxy EDTA

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

APPENDIX 6

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 *. See pp. 11 and Reference c. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

NEU 1165M
SLUG AND SNAIL BAIT

Active Ingredient:	By weight
Iron phosphate	1.0%
Inert Ingredients:	99.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT 20 LBS

EPA registration #67702- **EPA establishment #67702-WG-1**

STATEMENT OF PRACTICAL TREATMENT
If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals: Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards: For terrestrial uses. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The slugs and snails controlled by this product include (but are not limited to): *Deroceras reticulatum* (Field slug), *Deroceras laeve* (Smooth slug), *Arion subfuscus* (Dusky slug), *Arion circumscriptus* (Gray garden slug), *Arion hortensis* (Black field slug), *Arion rufus* (Large red slug), *Arion ater* (Large black slug), *Limax flavus* (Spotted garden slug), *Limax tenellus* (Slender slug), *Ariolimax columbianus* (Banana slug), *Helix* spp., spp., *Helicella* spp., and *Cepaea* spp.

trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders.

Non-Commercial Berries

The bait can be used to protect non-commercial berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Domestic or Non-Commercial Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz., or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Non-Commercial Greenhouses

Where snails are a problem in non-commercial greenhouses, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot.

Domestic Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with a granular spreader where the slugs or snails are observed.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

CONTAINER DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

[The following claims and product information may be presented on the product's label or labeling:
-NOTE: This package is sold by weight. Contents may have settled during shipment.
-US Patent number 5,437,870.
-This container is made from XX% recycled materials.]

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

This product is a unique blend of an iron phosphate active ingredient, originating from soil, with slug and snail bait additives. It is used as an ingredient in fertilizers. The bait which is not ingested by snails and slugs will degrade and become part of the soil in your garden.

The bait is extremely (highly) attractive to slugs and snails and lures them from their hiding places and plants. Ingestion, even in small amounts, will cause them to cease feeding. This physiological effect of the bait gives immediate protection to the plants even though the slugs and snails may remain in the area. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within three to six days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the dramatic decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to home lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers or fruit trees or bushes to be protected.

Registrant: W. Neudorff GmbH KG, Postfach 1209, an der Mühle 3,
D-31860 Emmerthal, Germany

APPENDIX 7

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 *. See pp. 12 - 22. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

PART III-SUPPLEMENTARY INFORMATION

9.1 DETAILED FINDINGS

a) Detrimental Chemical Interactions with Other Materials

Ferric phosphate is a stable substance that is virtually insoluble in water. It is very unlikely that it would react with any other products used in organic farming. It may break down to iron and phosphate ions at an acidic pH. Both of these ions will react with substances in the soil to form compounds that commonly occur in the soil, e.g. iron oxides, various mineral phosphates. These compounds are not detrimental to the environment. Therefore no detrimental chemical interactions would occur with other materials used in organic farming.

b) Toxicity and Persistence in the Environment

Ferric phosphate does not pose a hazard to the environment. This conclusion is based on: a) the natural occurrence of ferric phosphate in the soil, b) the insolubility and stability of ferric phosphate, c) the low rate of application, d) the use pattern of the end-use product, NEU1165M, that does not include marine or any other aquatic uses, e) the lack of toxicity to animals, of NEU1165M, f) the use of ferric phosphate as a nutrient and dietary supplement in foods, g) ferric phosphate (or degradates) may already be present in the food/nutrient sources of plants, wild birds and other animals, and h) the inherent function (as essential nutrients) of the components of ferric phosphate in the metabolic pathways of animals and plants.

Ferric phosphate occurs naturally in the soil and as a consequence its activity in the soil is known. Because of the different mineral constituents of different soils no standard values of the content of iron and phosphate in the soil can be stated. Ferric phosphate occurs as the minerals Strengite, Metastrengite, Vivianite, and Dufrenite. "Iron salts are normally present in the environment. Iron is the fourth most abundant element and the second most abundant metal in the earth's crystal rocks. Iron occurs in a wide variety of minerals, and is present in foods naturally and through added ingredients."[a] "In summary, the fate and transport of Fe(II) and Fe(III) salts in the environment is dominated by three major processes: (1) the pH-redox potential dependent oxidation of Fe(II) to Fe(III); (2) the formation of insoluble oxides and hydroxides that are also well known components of soils; and (3) the distinct surface chemistry of the oxides and hydroxides of iron that control the adsorption of anions, cations and organic material or the adsorption of iron species onto the surfaces of mineral and organic components of soils, contributing to the aggregation of soil particles into larger units."[a]

The insolubility of ferric phosphate ensures that breakdown is a slow process. Although the solubility of ferric phosphate increases with water temperature, 0.67 g/100 cc of 100°C water, at normal soil temperatures it is practically insoluble. The product is not intended for use in an aquatic environment but it should be noted that ferric phosphate's insolubility in water combined with its ready adsorption to the soil render it immobile. As a consequence it is unlikely that the ferric phosphate would migrate from the area of application into aquatic systems. In addition, ferric phosphate is a highly stable compound that does not break down in sunlight, and is a non-volatile solid that would not be mobile in the air.

There are natural mechanisms whereby soil microorganisms and plant rootlets, aided by carbon dioxide and other root exudates, will transform the insoluble ferric phosphate into forms that are usable by plants. Both the iron and the phosphate components are then used to meet the nutritional requirements of the plant. Iron is a plant micronutrient and phosphorus is a macronutrient, both of which are essential to plant growth and development. Iron is required for chloroplast development and is a component of cytochromes. Phosphorous is required for formation of "high-energy" phosphate compounds (ATP and ADP) and is a component of nucleic acids and of several essential coenzymes (Curtis, 1979). The transformation of ferric phosphate is a very slow process which becomes slower with time because by "processes of aging, phosphate availability is reduced."[b] Soils high in organic matter are more effective in releasing the iron and phosphorous so that plants can utilize them. (Brady, 1974.) As a matter of fact, due to the lack of availability of iron and phosphorous in soils, both often need to be added to soils as fertilizers.

The amount of iron and phosphorus added to the soil through the use of the end use product, NEU1165M, is negligible compared to the amounts the soil already contains. Soils contain a range of iron from 5,000 to 50,000 ppm (0.5 to 5%) and a range of phosphorus from 0.01 to 0.20%. (Brady, 1974) The content of these nutrients in soils is not solely dependent on soil type. Tested soil values of P average 83.7 mg/l and of Fe average 262 mg/l, on soils in Belgium that are predominantly silty loams. For this same soil type in Argentina the average P value is 24 mg/l and the average Fe value is 207 mg/l. For tested, predominantly clay, soils of Lebanon the average value for P is 42.5 mg/l and for Fe is 140 mg/l. For this same soil type in Egypt the average value for P is 18.7 mg/l and for Fe is 195 mg/l. (Sillanpää, 1982) The application of NEU1165M to the soil as a slug bait would add 0.014 g iron and 0.036 g phosphate or 0.008 g phosphorus per square meter. Using weight values of an 18 cm depth of different soils from Klingman, 1975, this equates to approximately:

Soil Type	Wt. Soil (g)		Wt.	% Iron		ppb	
	to 18cm		Iron (g)				
Sand	291600		0,014	0,0000048011		4,801	
Loam	233280	277020	0,014	0,0000060014	0,0000050538	6,001	5,054
Clay or Silt	189540	233280	0,014	0,0000073863	0,0000060014	7,386	6,001
Muck	116640		0,014	0,0000120027		12,003	
Peat	58320		0,014	0,0000240055		24,005	
Soil Type	**Wt. Soil (g)**		**Wt.**	**% Phosphor.**		**ppb**	
	to 18cm		**Phos. (g)**				
Sand	291600		0,012	0,0000040286		4,029	
Loam	233280	277020	0,012	0,0000050357	0,0000042406	5,036	4,241
Clay or Silt	189540	233280	0,012	0,0000061978	0,0000050357	6,198	5,036
Muck	116640		0,012	0,0000100715		10,071	
Peat	58320		0,012	0,0000201429		20,143	

NEU1165M adds between 6,000 and 300,000 times less iron and between 800 and 80,000 times less phosphorus to the soil than already exists in it.

The amounts of iron and phosphate that are applied to the soil in fertilizers are also far greater than the amounts added with the use of NEU1165M. To see the effects of fertilizer application approximately 0.65 g iron/m^2 and 2.0 g phosphate/m^2 are required. These amounts are 13 times greater for the iron and 100 times greater for the phosphate when compared to the amounts added with the slug bait.

It should also be noted that ferric phosphate is an iron salt. In their Reregistration Eligibility Document (RED) on Iron Salts, page 12, the US EPA exempts iron salts from environmental chemistry and fate requirements. Their conclusion is based on the use of iron salts as herbicides or fertilizers. The use of iron salts as herbicides or fertilizers "is not expected to contribute significantly to the chemistry and fate of the compounds existing naturally in the environment."[a] It should be noted that iron from iron sulfate fertilizers (which are used in agriculture) is applied at the rate of 0.67 g/m^2 whereas the iron from the end-use product, NEU1165M, is applied at the rate of 0.014 g/m^2. In addition iron sulfate is more soluble than ferric phosphate.

The end-use product, NEU1165M, is registered as a domestic molluscicide in the United States. The conclusion drawn in the US EPA's decision memorandum was that "no unreasonable adverse ecological or environmental fate effects were identified."[c]

Ferric phosphate is included in the Food Chem Codex where it is recognized as a food additive: nutrient and dietary supplement. "Further, the iron salts are generally recognized as safe (GRAS) by the [US] Food and Drug Administration for use as flavoring agent and nutrient supplement in foods (please see 40 CFR 180.2(a))."[a] Iron phosphate is listed specifically at 21 CFR §182.5301 and §184.1301. As a matter of fact both the iron and the phosphate ions occur in foods naturally because they are an inherent part of plant and animal metabolism, as discussed below. The flour and sugar inert ingredients in NEU1165M together comprise 97.95% of the product and both are common foods.

In plants and animals iron is important for a) oxygen transport, b) electron transfer, c) DNA synthesis and d) many other cellular functions. Phosphorous is a component of ATP and ADP, which are the cell's primary energy sources, nucleic acids and several essential coenzymes. Both the ferric and phosphate ions of ferric phosphate are, therefore, essential in plant and animal metabolism.

c) Environmental Contamination Resulting From Use and Manufacture

The environment would not be contaminated as a result of the use of ferric phosphate in the slug bait end-use product (See Section 9.1.b).

Care is taken in the manufacture of ferric phosphate and the only by-products of the manufacturing process are Na_2SO_4 (sodium sulfate), and H_2O. The Na_2SO_4 is precipitated with lime and is used as a secondary raw material. The wastewater, which in this case contains only water, is purified and prepared in a separate process so that it can be released into a wastewater clarification plant.

Sodium sulfate "occurs in nature as the minerals *mirabilite, thenardite.*" (Merck Index, 1996) Sulfur is essential to the growth of plants. In fact it is a macronutrient required in large quantities by plants. However excesses of sodium salts in the soil are detrimental to plant growth. (Brady, 1974)

d) Effects on Human Health

Ferric phosphate is of low risk to human health. It is found naturally in the environment and is used as an additive in foods.

Both iron and phosphorous are minerals that are essential to the metabolism of plants and animals. Iron is involved in oxygen transport, electron transfer, DNA synthesis and many other cellular functions. Phosphorous is a component of ATP and ADP (which are the cell's primary energy sources), nucleic acids and several essential coenzymes. As

As iron salts, including ferric phosphate, have been used as food additives over many generations without exhibiting adverse effects, it can also be concluded that chronic toxicity via ingestion, would not occur.

The soluble iron salts $FeCl_3$ and $Fe_2(SO_4)_3$, are highly toxic after parenteral injection in animals. For example, the intraperitoneal LD50 of anhydrous $FeCl_3$ for the mouse is 68 mg/kg. In mice the intraperitoneal LD50 of the hexahydrate $FeCl_3$-$6H_2O$, was reported as 260 mg/kg. For this reason it may be concluded that iron phosphate also has an acute percutaneous toxicity but it is expected that ferric phosphate would have less toxicity than the other compounds because of its very low solubility.

The acute dermal toxicity and dermal irritation of ferric phosphate should be low. It is unlikely that it would be absorbed through the skin because of its particularly low water and lipid solubility.

From eye irritation studies with soluble iron compounds like iron sulfate, it is known that iron compounds may be corrosive. The corrosive effects are due to the formation of an acidic pH if the compounds are dissolved in a liquid. For this reason it may be concluded that ferric phosphate would have a moderate eye irritation. Because of its very low solubility ferric phosphate would be less corrosive than the other iron compounds.

For inhalation exposure, no chronic data was found relating to iron phosphate specifically. Predicting the chronic inhalation toxicity of this compound from that observed for the other forms of iron is problematic. However, prudence would require the inference that this insoluble form of iron also may cause siderosis if high levels are inhaled over prolonged periods. This syndrome is considered benign since, in the lungs, no progressive fibrosis occurs and, as a rule, pulmonary function is not significantly impaired. A single study was located that assessed ferric phosphate's ability to cause fibrosis of the lung after intratracheal instillation in rats up to one year after injection (Stacy, 1959). While materials such as alumina and various forms of silica caused fibrosis, ferric phosphate did not. The more severe lung diseases might also occur with heavy exposure but only if iron phosphate were contaminated with silicates or radon similar to mining/refining exposures. Excess cancers connected with iron exposure, have been attributed mostly to co-exposure to contaminants such as crystalline silica and radon (Beliles, 1992). Otherwise, only siderosis might reasonably be predicted.

Chronic iron overload is usually predisposed by pathological conditions. "In certain pathological conditions iron overload may result from an increased absorption of dietary iron, by parenteral administration of iron or both. The magnitude, rate and distribution of iron accumulation will influence the onset and severity of complications and differ for the various pathological conditions, a number of which have an inherited genetic basis. .... Extensive tissue damage often occurs in iron loaded tissues." (British Nutrition Foundation, 1995) Some of the pathological conditions leading to chronic iron overload are: genetic haemochromatosis, neonatal haemochromatosis, secondary haemochromatosis, thalassaemia, excess absorption of orally ingested iron (rare), alcohol misuse. Chronic iron overload does not involve the ingestion of massive doses of iron but rather moderate overdoses over a prolonged period of time. At low to moderate oral doses, the water solubility of the various iron salts determines their bioavailability (i.e., propensity to be absorbed from the gastrointestinal tract into the body) this, in turn, governs toxicity. Ferric phosphate has a low bioavailability. Also this type of iron overload is usually predisposed by pathological conditions and normal, healthy people would not be at risk. Consequently, it is unlikely that ferric phosphate would be a causal factor in chronic iron overload.

The United States Environmental Protection Agency has issued a re-registration eligibility document in which they evaluated the health risk of ferric phosphate. The US EPA concluded that ferric phosphate could be approved with a "reasonable certainty of no harm". In short BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary cumulative exposure issues as they may affect infants and children and the general population." (US EPA, 1997)

In conclusion, ferric phosphate is a tightly bound mineral that is practically insoluble, highly stable and not readily available to be metabolized by animals. It is poorly bioavailable upon ingestion, and, thus, is of low toxicological risk by this route of exposure for single, second dose or repeated dose exposure. Its insolubility prevents it from exhibiting toxic effects via dermal exposure. Ferric phosphate is also of low risk from the inhalation route of exposure. In particular, as the end-use product will be a non-volatile, solid granule, inhalation exposure will most likely not occur. It can be concluded that ferric phosphate does not represent a toxicological risk. Adverse health effects would be unlikely to occur from exposure to ferric phosphate.

e) Effects on Soil Organisms, Crops and Livestock

Ferric phosphate is not expected to cause adverse effects on soil organisms, crops and livestock. This conclusion is based on: a) the natural occurrence of ferric phosphate in the soil, b) the known effect of ferric phosphate on living organisms, c) the lack of toxicity of the end-use product NEU 1165 M, d) the use of ferric phosphate as a nutrient and dietary supplement in foods, e) ferric phosphate may already be present in the food sources of the living organisms in the environment, f) the inherent function of ferric phosphate in the metabolic pathways of living organisms, both iron and phosphorous are essential nutrients for plants and animals, g) the practical insolubility of ferric phosphate and fact that it adsorbs to the soil, and is thus rendered immobile and h) the use pattern of the product does not include aquatic uses.

"Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9." (US EPA, 1993) Because ferric phosphate occurs naturally much is known about its effect on living organisms. Ferric phosphate is an iron salt. "No adverse effects to avian, mammalian or aquatic populations are anticipated from the use of iron salts. Iron is one of the most abundant elements and will be immobilized at the environmentally important pH range of 5-9. There is very little likelihood for runoff to aquatic systems since the parent compounds convert very rapidly to less soluble forms in the environment. Furthermore these oxidized iron compounds bind tightly to soil under turf." (US EPA, 1993)

In approving the US EPA registration of the end-use product the EPA concluded: "A number of ecological effects toxicology data requirements are waived based on the known lack of toxicity of iron phosphate to birds, fish and non-target insects, its low solubility in water, conversion to less soluble form in the environment (soil), and its use pattern (soil application). Based on these factors, the data requirements for the toxicity studies in Mallard duck, rainbow trout, freshwater invertebrates, and nontarget insect/honeybees are waived." (US EPA, 1997)

Ferric phosphate is included in the Food Chem Codex where it is recognized as a food additive: nutrient and dietary supplement. The Food and Agriculture Organization of the United Nations has set the ADI (Acceptable Daily Intake) for humans, of iron phosphate at 70. This "includes the free acid, PMTDI (Provisional Maximum Tolerable Daily Intake) of 0.8 mg/kg of body weight for iron from all sources except for iron oxides used as colouring agents and supplemental iron" (Food and Agriculture Organization of the United Nations. 1991). In addition, "the average human diet contains 10-15 mg of iron a day." (US EPA, 1997)

It should be noted that "grains and fruits are low in iron usually ranging from 1 to 20 mg Fe/kg. The daily recommended iron requirement for humans is 10 mg for children, adult males and non-menstruating females. A daily amount of 15 to 18 mg of iron is recommended for rapidly growing children and menstruating females." (US EPA, 1997) "Further, the iron salts are generally recognized as safe (GRAS) by the Food and Drug Administration for use as flavoring agent and nutrient water temperature, 0.67 g/100 cc of 100°C water, at normal soil temperatures it is practically insoluble. The product is not intended for use in an aquatic environment but it should be noted that ferric phosphate's insolubility in water combined with its ready adsorption to the soil render it immobile. As a consequence it is unlikely that the ferric phosphate would migrate from the area of application into aquatic systems. Even if the bait existed in aquatic systems, the insolubility of ferric phosphate would minimize its risk to aquatic life. When tested on aquatic organisms, ferric phosphate elicited no toxic responses. The results of these tests are summarized below.

STUDY	**RESULTS**
Acute Toxicity - Rainbow Trout	EC_{50} > 100 mg/L with a probability of 99.9 %, NOEC > 100 mg/L
Acute Toxicity - *Daphnia magna*	EC_{50} > 100 mg/L with a probability of 99.9 %, NOEC > 100 mg/L
Toxic Effects - Single Cell Green Alga	EC_{50} > 100 mg/L with a probability of 95 %, NOEC > 100 mg/L

9.2 REFERENCES (See attached copies of references "a" to "o")

a) US EPA. 1993. The Reregistration Eligibility Document (RED) on Iron Salts, US EPA 738-2-93-001.

b) Brady, Nyle C. 1974. The Nature and Properties of Soils. 8th Edition. Macmillan Publishing Co., Inc., New York.

c) US EPA Publication. Decision Memorandum and Reregistration Eligibility Document on Iron Phosphate. US EPA. 1997.

d) Curtis, Helena. 1979. Biology, 3rd Edition, Worth Publishers, Inc. New York, NY. pp. 69-70, 164-165, 541, 696-697.

e) Sillanpää, Mikko. 1982. Micronutrients and the nutrient status of soils - a global study., Food and Agriculture Organization of the United Nations, Rome

f) Klingman, Glenn C. 1975. Weed Science: Principles and Practices, John Wiley & Sons, New York

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10.1 MATERIAL SAFETY DATA SHEET

The material safety data sheet for ferric phosphate is found in Appendix D.

APPENDIX 8

The following information was extracted from the public docket copy of the original petition to list ferric phosphate (original submitted May 1, 2003 by W. Neudorff GmbH KG), available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057488 *. See Appendix D. It is provided here for reference only, at the specific request of Robert Pooler of the Standards Development and Review Branch. Steptoe & Johnson LLP, the submitter of this petition to delist this compound and associated products, can neither confirm nor verify the correctness of the information.*

SAFETY DATA SHEET
91/155/EEC

Dr. Paul Lohmann
Chemische Fabrik seit 1886 GmbH KG

Print date: 17.08.1998

Version of: 09.01.1998

Trade name Ferric Phosphate

1. Name of company

Manufacturer/supplier
Dr. Paul Lohmann GmbH KG
Hauptstr. 2
D-31860 Emmerthal

Tel.: (49) 5155 - 630
Fax: (49) 5155 - 63118
Telex: 92858 lohma d

Contact department: QC/Kn

2. Composition/information on ingredients

CAS-No.	Name of substance	Hazard symbol	R-phrases
10045-86-0	Ferric Phosphate		

Chemical characterisation (preparation)	EINECS-No.	Code-No.
$FePO_4 \cdot xH_2O$	233-149-7	331

3. Hazard risks

Specific information on human and environmental hazards
Not classified as hazardous. When used in accordance with good manufacturing practices it should present no significant hazard to users.

4. First aid measures

General informations
Change clothings if contaminated with the product.

Inhalation
Remove to fresh air.

Skin contact
Wash with soap and plenty of water.

Eye contact
Flush with copious quantities of water and obtain medical attention.

Ingestion
Refer for medical treatment.

Advice for physicians
none

5. Fire-fighting measures

Suitable extinguishing media
Product itself is non-combustible; use any means suitable for extinguishing

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Trade name	Ferric Phosphate

5. Fire-fighting measures (continued)

6. Accidental spillage measures

Personal precautions

See under section 8.

Clean up and disposal measures

Spills should be mechanically collected in a suitable container for proper disposal or recovery. Wash area with sufficient water.
Avoid raising dust.

7. Handling and storage

Advice on safe handling

Usual safety precautions should be observed to ensure safe handling.
Adequate exhaust system in areas where workers are exposed to dusting.

Further information on storage conditions

To be kept in well-closed containers in a cool and dry place.

8. Exposure controls/personal protection

Requirements for technical facilities

Provision of adequate exhaust system in working areas.

General protective and hygienic measures

Wash thoroughly after handling.

Respiratory protection

Dust mask

Hand protection

Protective gloves

Eye protection

Goggles

Body protection

Rubber or plastic apron.

9. Physical and chemical properties

Form	Powder	
Colour	Yellowish to buff	
Odour	Practically odourless	
Flash point		n.d. °C
Ignition temperature		n.d. °C
Upper explosion limit		n.d. Vol %
Lower explosion limit		n.d. Vol %

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Trade name Ferric Phosphate

9. Physical and chemical properties (continued)

Further information

Practically insoluble in water.
The product is non-combustible.
n.d. = no data available

10. Stability and reactivity

no relevant data known

11. Toxicological information

Acute toxicity
For classification relevant values

no relevant data known

Subacute / chronic toxicity
Longterm tests

no information available

Human experience

no information available

12. Ecological information

Information on elimination (persistancy and biodegradability)

Environmental effects

Water hazard class: 1 (see section 15)

Ecotoxical effects
Aquatic toxicity

no relevant data available

Effect on water treatment process

no relevant data available

Further information

no relevant data available

13. Disposal considerations

Product disposal

As permitted under appropriate Federal, State, and Local Regulations.

Contaminated packaging

As permitted under appropriate Federal, State, and Local Regulations.

Recommended cleansing agent

no information available

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Trade name	Ferric Phosphate

13. Disposal considerations (continued)

14. Transport information

ADR/RID-GGVE/E class	Figure	Hazard-No.	Substance-No.
ADNR class	Figure	Categorie	
IMDG/GGVSee class	UN-No.	EMS-No.	MFAG-No.
ICAO/IATA class	UN-No.		

Further information

Not classified for conveyance.

15. Regulatory information

Labelling according to EEC Directives

National regulations

Water hazard class (Germany)

- 1 - weakly hazardous to water
Own classification

16. Other information

no information available

The data provided herein are based upon information believed to be reliable. This information is not to be considered as a warranty or quality specification and we do not assume any responsibility, including injury or damage, resulting from its use as such or in combination with other materials.