

FMC Corporation

FMC Corporation
Government Affairs
1101 Pennsylvania, NW
Suite 325
Washington, DC 20004

202.956.5200 phone
202.956.5235 fax

www.fmc.com

December 8, 2008

Cindy Smith, Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Docket No. APHIS-2008-0119
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD. 20737-1238

Re: Comments on Implementation of Revised Lacey Act Provisions

Dear Ms. Smith:

FMC Corporation is a diversified chemical manufacturer including specific products manufactured from raw materials derived from plant material. Broadly speaking, several colloidal products (i.e., natural biopolymers) we produce are made from cultivated and harvested seaweeds, or from special wood pulps.

We are submitting the following comments because we believe that the specific plant derived raw materials we import to manufacturing locations in Newark Delaware and Rockland Maine should be excluded from the Lacey Act (16 U.S.C. 3371) in section 8204 of the Food, Conservation and Energy Act of 2008 (FCEA). It is clear from the October 10 letter from the authors of this legislation to members of the Inter Agency Executive Committee, including USDA, that these provisions were intended to prevent illegal logging and illegal harvesting which leads to environmental degradation and social disruption. We submit that not only does the production of our products not lead to these negative effects, it in fact, promotes sustainable harvesting of natural resources, and is a source of good employment, particularly for marginal populations in developing countries.

The following comments seek, therefore, to describe the process by which we derive the natural biopolymers carrageenan, microcrystalline cellulose, alginates, other widely used food gums and their end uses in foods (including dietary supplements), pharmaceuticals, personal care products and industrial application, as well as how they may qualify for exclusion from the USDA's proposed rulemaking either because they should conform to the definition of a common cultivar (carrageenan and konjac flour) or "common food crop" (MCC, alginates, gums) as will be defined by the USDA.

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I. **Seaweed Derived Products:**

- a. Carrageenan is a naturally-occurring family of carbohydrates extracted from red seaweeds. The seaweed is washed to remove sand and salt before extraction with dilute alkali which solubilizes the carrageenan and separates it from the extraneous plant fiber, which is mostly cellulose, hemi-cellulose, and protein. Carrageenan is used in such commonly found household products as dairy products, meats and seafoods, dressings, sauces, creams, beverages, toothpastes, etc.

In support of the global demand for carrageenan, FMC is the largest buyer of seaweed in the world. Our seaweed sourcing operations involve developing and promoting maricultural activities in less developed countries, and include not only the identification of reputable suppliers, but the training of locals in the proper seeding, cultivation and harvesting techniques that comport with local climatic and environmental conditions. FMC has become a recognized leader in developing improved seaweed planting, cultivation and harvesting techniques, as well as providing support for local infrastructures that support this maricultural activity. Our training programs and seaweed farm stewardship activities in concert with reliable and professional local partners are recognized by local and national governments as promoting sustainable mariculture.

Recommendation: We would submit for the USDA's consideration that carrageenan is a product of farming activity, approved, encouraged and regulated by foreign governments, and therefore represents a "common cultivar." Even in those exceptional instances where FMC buys seaweed from suppliers who do not host seaweed farms, the harvesting activity is done as part of beach cleansing activities (i.e., seaweeds that have washed ashore) and therefore poses no threat to the natural environment.

- b. Alginates are a naturally-occurring family of carbohydrates extracted from brown seaweeds. The seaweed is washed to remove sand and salt before extraction with dilute alkali which solubilizes the alginate and separates it from the extraneous plant fiber, which is mostly cellulose, hemi-cellulose and protein. The alginate extract is filtered to remove the plant fiber and calcium chloride is added to the filtrate to precipitate calcium alginate. The calcium alginate is separated by centrifugation and then acid washed to remove calcium and yield water insoluble alginic acid. From here, the wet alginic acid precipitate is blended with an equivalent amount of sodium carbonate to give a sodium alginate paste which is dried and ground to a fine powder of sodium alginate. Other carbonate salts may be used, for example, potassium carbonate to yield potassium alginate. Alginates are used in such commonly found household products such as restructured foods, petfoods, bakery fillings, ice-cream, dressings, sauces, and dairy desserts. Other examples of alginate

applications include pharmaceutical excipients, as components in medical devices, and personal care items.

Recommendation: Alginates are extracted from naturally occurring seaweeds that are harvested in oceans throughout the world. The primary seaweed species from which we derive alginates are *Laminaria hyperborea*, *Laminaria digitata*, *Laminaria japonica*, *Macrocystis pyrifera*, *Ascophyllum nodosum*, *Eklonia maxima*, and *Lessonia nigrescans*. In sum we believe alginates can be categorized as a "common food crop" under the Agency's forthcoming definition.

[Note: Apart from the fact that these products should be exempt according to the Lacey Act as amended., we would add that for both carrageenan and alginates we are concerned about the administrative burden engendered by the proposed regulation, since each seaweed shipment would be accompanied by at least one if not multiple declarations. For example, FMC imports some 18 types of red and brown seaweeds from 19 different countries and from 49 separate, approved suppliers. Alginate blends may also contain different species of seaweed and thus would be subject to multiple declarations.]

II. Wood Pulp Derived Product:

Microcrystalline cellulose ("MCC") (a.k.a. cellulose gel) is made from a high grade of pulp that is derived from managed stands of trees, which our suppliers manage to ensure a renewable, sustainable resource. During the process, the crystalline segments of alpha cellulose are acid hydrolyzed and depolymerized to remove the intermediate amorphous regions, leaving only the crystalline bundles, which are then further processed to produce two types of MCC, non-colloidal and colloidal. MCC is commonly found in most tablets and capsules where it can provide a range of attributes including immediate or sustained release and related suspension and dispersion characteristics that depend upon the specific product. MCC also functions as a stabilizer or as an anti-caking agent in foods, cosmetics and industrial applications.

Recommendation: MCC is derived from high grade of wood pulp. The pulp is derived from stands of trees on land managed by responsible suppliers with whom we have long term customer-supplier relationships and contracts. Because the source of the wood is from managed lands and not from wild harvest, it is reasonable to consider the wood as "a common food crop" and therefore excluded from the Lacey Act as amended.

III. Gums

- a. Gum Konjac Flour (a.k.a. konjac, konnyaku, konjac gum, yam flour) is a naturally-occurring glucomannan carbohydrate polysaccharide extracted obtained from the tubers of the Elephant Yam (*Amorphophallus konjac*). The tubers are thoroughly washed to remove soil, sliced and dried. Konjac flour is obtained by grinding and separating the glucomannan containing sacs from the surrounding starchy materials. The sacs are subsequently washed in dilute alcohol and reduced in particle size to produce konjac flour. The dried chips comprise up to about 50% konjac gum, the remainder being primarily starch, cellulose, protein, and inorganic salts. The dried chips are coarse ground to maintain the konjac gum in their natural sacs, and most of the starch and inorganic salts can be removed as fines by air classification. A second grind is carried out to remove some of the sac walls (mostly cellulose and protein) with additional starch and inorganic salts, yielding purified konjac gum comprising more than 70% glucomannan polysaccharide. Further purification by washing with alcohol/water yields konjac gum at over 85% glucomannan. The yield of pure glucomannan from the original tuber is up to about 30%. Konjac flour gum is used in commonly found household products such as restructured foods, noodles, gelled desserts and candies, meat analogues, and baked goods. Konjac tubers are commercially grown and harvested, and the *Amorphophallus* species are common on all continents, and in some countries is boiled and eaten.

Recommendation: As the konjac tuber is commercially cultivated and harvested, the tuber and the resulting konjac flour should be considered a "common food crop" and therefore excluded from the Lacey Act as amended.

- b. Gum Arabic (a.k.a. Acacia) is a naturally-occurring carbohydrate polysaccharide exuded by various species of Acacia, and primarily *Acacia Senegal*. The Gum Arabic is exuded in the form of large nodules about 5cm in diameter, which dry to rough spheres and are harvested. The crude dried nodules are pre-cleaned to remove bark, sand and other debris to achieve less than 0.5% foreign matter. Additional processing is carried out using either spray or roll drying, the former producing a higher quality and more functional Gum Arabic due to lower degradation of the polysaccharide and less denaturation of the protein. The final product comprises two primary fractions; about 90% of an arabinogalactan with no protein content, and about 10% of an arabinogalactan with about 10% protein. The ratio of these two fractions varies with the age of the Acacia tree up to 15 years. Gum Arabic is used in commonly found household products such as confectionary, beverages, emulsions, flavor encapsulation, bakery products, and brewing.
- c. Gum Tragacanth (a.k.a. Gum Tragacanth) is a naturally-occurring carbohydrate polysaccharide exuded by various species of *Astragalus*, and primarily *Astragalus*

gummifer. The Gum Tragacanth is mostly collected by tapping into tap roots or lower stems rather than direct exudation. The crude dried gum is pre-cleaned to remove bark, sand and other debris to achieve less than 0.5% foreign matter. Additional processing is not normally carried out. The final product comprises two primary fractions; about 60-70% of a water-swellable arabinogalactan, and about 30-40% of a water soluble arabinogalactan. Gum Tragacanth is used in commonly found household products such as confectionary, icings, dressings, sauces, oil and flavor emulsions, frozen desserts and bakery fillings.

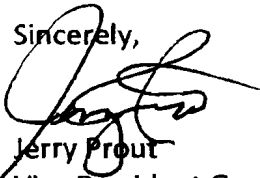
- d. Gum Karaya (a.k.a. Sterculia gum) is a naturally-occurring carbohydrate polysaccharide exuded by various species of *Sterculia*, and primarily *Sterculia urens*. The Gum Karaya is mostly collected by tapping into tap roots or lower stems rather than direct exudation. The crude dried gum is pre-cleaned to remove bark, sand and other debris to achieve less than 0.5% foreign matter. Additional processing is not normally carried out. The final product comprises mostly a polygalactan with partially charged side groups including glucuronic acid, normally present as a mixed calcium/magnesium salt. Gum Karaya is used in commonly found household products such as dressings, sauces, dairy products, frozen desserts, bakery products, and meat products.
 - e. Locust Bean Gum ("LBG") (a.k.a. Carob Bean Gum) is a naturally-occurring carbohydrate polysaccharide (galactomannan) extracted from the locust bean plant (an evergreen tree), *Ceratonia siliqua*. The tree bears sugar-rich pods about 10-20 cm long, each containing 15-20 seeds or carob beans. The beans are removed from the pods, and these seeds have a dark-brown coating over the white galactomannan endosperm. The beans are thermally baked and the outer coating broken by coarse milling, and this brittle coating breaks away from the flexible endosperm. This thermal/milling process also removes the germ that lies between the two endosperm halves. The endosperm halves are then fine-ground to produce LBG. The yield of LBG is less than 30% of the original seed weight. LBG is used in commonly found household products such as ice cream, fermented milk products, drinks and shakes, desserts, mayonnaises, dressings and ketchups, soups and sauces, deep frozen foods, noodles, batters, and meat products.
 - f. Guar Gum is a naturally-occurring carbohydrate polysaccharide (galactomannan) extracted from the annual bushy plant, *Cyamopsis tetragonolobus*. The plant bears sugar-rich pods about the same size as garden peas, each containing about 6-10 beans about 4mm diameter. The beans are processed in a similar way as described for LBG. The yield of guar gum is about 20-30% of the original seed weight. Guar gum is used in commonly found household products such as ice cream, fermented milk products, drinks and shakes, desserts, mayonnaises, dressings and ketchups, soups and sauces, deep frozen foods, noodles, batters, and meat products.
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Recommendation: As these gums are naturally occurring, exudates which are each harvested without damaging the tree, and in fact, provide a viable alternative to tree harvesting, and are used in food and related food products, we believe products made from exudates should be considered a "common food crop" and therefore excluded from the Lacey Act as amended. Guar and Locust Bean gums are in fact seed gums that are harvested in the same manner as perennial fruit trees, leaving the trees completely intact.

FMC Corporation's business practices reflect our commitment to sustainable harvesting of plants and plant products. As described above in detail, we believe the amendments do not apply to our products, which are either common cultivars or common food crops. We believe that our products meet these criteria and therefore should not be subject to the regulations pursuant to the Lacey Act Amendments of Section 8204 of the Food, Conservation and Energy Act of 2008.

We respectfully submit these comments for your consideration and please do not hesitate to address any questions to me at 202-956-5209 or jerry.prout@fmc.com.

Sincerely,



Jerry Prout

Vice President Government Affairs