



Carrageenan in Organics Update

In it

June 2017



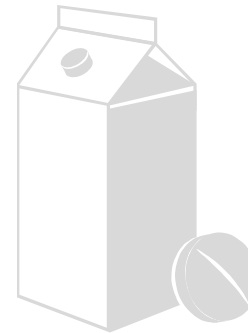
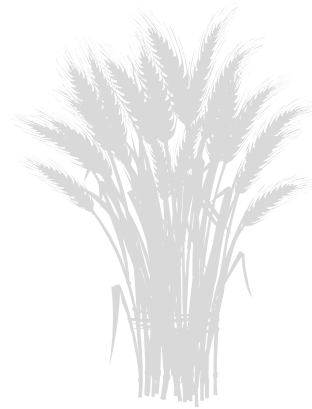
Agenda:

- **Carrageenan Regulatory Background**
- **National Organic Standards Board**
 - What is the NOSB? How does the sunset review work?
- **Outcomes of the Sunset Review**
 - Where are we in the process?
 - What's happened since the NOSB's recommendation?
- **Q&A**

We're

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Carrageenan Regulatory Background



Carrageenan

- **A refined hydrocolloid prepared by aqueous extraction from red seaweed**

Regulatory Background (food)

- **Recorded use dates back a couple of hundred years**

Example: Recorded use in Ireland to make flan

- **US**
 - 1961 – approved as food additive by FDA
- **JECFA**
 - 1969 – first JECFA review
- **Europe**
 - “Grandfathered” into Directive 95/2/EC based on use in individual European countries

Carrageenan Toxicology

- **Not acutely toxic**
- **Not carcinogenic**
- **Not a tumor promoter**
- **Not teratogenic**
- **Not embryotoxic**
- **Not genotoxic**
- **Not a reproductive toxicant**
- **Not toxic to the gastrointestinal tract**

Carrageenan Toxicology

- **Not absorbed through the gut**
- **Not metabolized to lower molecular weight material**
- **Has no adverse impact on absorption or utilization of nutrients**
- **Source does not influence toxicologic effect**
- **Type does not influence toxicologic effect**

Carrageenan Toxicology - infants

- Carrageenan has been shown to be safe to neonates from shortly after birth to the age of weaning in neonatal pigs.
- There were no toxicologically significant effects based on thorough evaluation of the gastrointestinal tract and immune system at doses up to 2250 ppm, a limit dose based on viscosity.
- Carrageenan does not cross the intestinal barrier to enter the systemic circulation in neonatal pigs.
- Safety of carrageenan in infant formula has been robustly verified in piglets and infant baboons.

Carrageenan Toxicology – infants

JECFA Review 2014

“These new studies allay the earlier concerns that carrageenan, which is unlikely to be absorbed, may have a direct effect on the immature gut. The Committee also took account of the previous toxicological database on carrageenan, which did not indicate other toxicological concerns. It also noted that at carrageenan concentrations higher than 2500 mg/kg, formula becomes highly viscous, which adversely affects palatability and growth.”

“The Committee concluded that the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern.”

Carrageenan Toxicology

- **Extensive publications on carrageenan (CGN) for decades fueled misunderstanding**
 - Many studies are non-GLP.
 - Confusion between CGN and poligeenan (PGN)
 - Characterization of test material missing
 - Often considers CGN unsafe because of injection studies.

Carrageenan Toxicology

- **FMC addressed issues and clarified misunderstandings by:**
 - conducting additional studies (*in vivo* and *in vitro*) under GLP and publishing them
 - publishing literature reviews *in vivo* (Weiner, 2014) and *in vitro* (McKim, 2014)
 - Publication of paper addressing pitfalls when undertaking research with carrageenan
 - Requesting editors/authors to publish corrections

Comparison of Carrageenan & Poligeenan

Aspect	Carrageenan	Poligeenan
Manufacturing	To preserve functionality as a food ingredient, red seaweed is processed under alkaline conditions	To degrade the complex polysaccharide into low Mw pieces, acid hydrolysis occurs at low pH (0.9 -1.3) and high temperature for extended time
Average Mw range	200,000 to 800,000 Daltons	10,000 to 20,000 Daltons
Function	Stabilizer, thickener, gelling agent, with functionality at concentrations as low as 0.01% in some systems	Dispersing agent; no gelling properties even at concentrations as high as 10.0%
Uses	Food ingredient/GRAS, pharmaceutical excipient, personal care products	Medical imaging; NO food uses
Toxicology Differences	IARC 1983: Not carcinogenic in animals: rat & hamster chronic studies found no tumors (1980)	IARC 1983: Sufficient Evidence [2B] of carcinogenicity in animals: rat chronic studies found colorectal squamous carcinomas (10% in diet)
	Not harmful to GI tract	Ulceration and irritation to GI tract.
Food additive (or GRAS): US FDA, EFSA, Codex	Yes	No
CAS No.	9000-07-1	53973-98-1

Recurring “questions” that:

- **Have been resolved by JECFA;**
- **Were not/are not an issue with FDA;**
- **Will be addressed by the European Food Safety Authority under re-evaluation – BUT –**
- **Remain as topics for social media, the press, activist groups and “researchers”/”investigators “who fail to understand the chemistry and toxicology of carrageenan:**
 - Degradation in the GI tract
 - Formation of colorectal tumors
 - Ulcerogenic effects
 - Immune effects
 - Effect on the immature gut

- **Several Studies Have Reported CGN Caused Adverse Effects in Humans**
 - **Joanne Tobacman Laboratory Associate Professor, Dept of Medicine**
 - **University of Illinois Chicago**
 - **In vitro studies (NCM460, HT29) and mouse drinking water studies**

 - **Following Statements (Tobacman Hypotheses) CGN is absorbed and enters systemic circulation**
 - **CGN taken orally is broken down by hydrolysis**
 - **CGN is absorbed in the GIT induces innate immune responses**
 - **CGN binds to TLR4 and induces inflammation**
 - **CGN induces oxidative stress**
 - **CGN travels to liver contributes to onset of type II diabetes**

We're

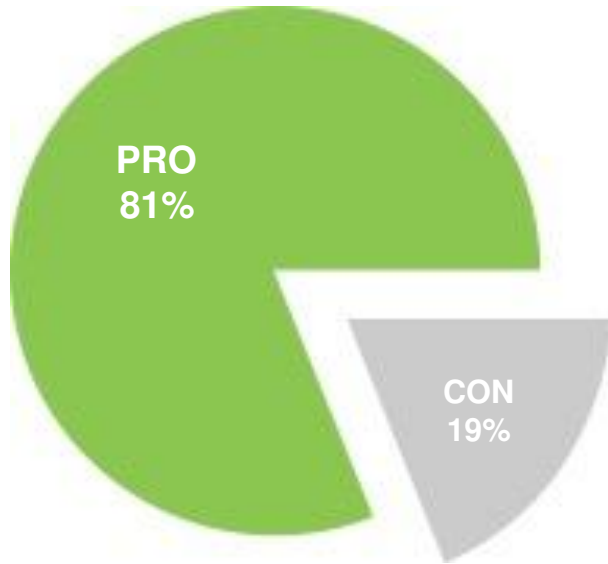
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**National Organic Standards
Board & Sunset Review**

National Organic Standards Board

- Every five years, all ingredients on the National List approved for use in **organic foods** undergo a sunset review.
 - Carrageenan underwent sunset review this year.
- NOSB evaluates the safety, sustainability, and essentiality of each ingredient.
- NOSB submits its recommendation to the USDA, which makes a final decision.
- Conventional, non-organic products are not affected by NOSB recommendations.

STRONG COALITION OF SUPPORT FOR CARRAGEENAN



Of the 1,094 public comments submitted to the NOSB about carrageenan, more than 800 comments were in favor of keeping it in organic foods.

Food stability is important for infants and people with medical needs. No alternatives work as well as carrageenan.

“”**Manojit Basu**
Grocery Manufacturers Association

My work supports the findings... carrageenan has no adverse effects...when administered in diet.

“”**Dr. Jim McKim**
IONTOX
Testimony to the NOSB, November 18, 2016

The NOSB should not set a precedent that makes it difficult for organic...to compete with non-organic foods.

“”**Susan Finn, RDN**
United 4 Food Science
Testimony to the NOSB, November 17, 2016

...if the NOSB allows anecdotal evidence to drive the decision to delist carrageenan, it would be a sad day for science.

“”**Dennis Seisun**
IMR International

Delisting carrageenan...may lead to a profound catastrophe. Seaweed farming is one of the fastest ways to alleviate poverty and support job creation in coastal communities.

“”**Reza Pahlevi**
Embassy of Indonesia
Testimony to the NOSB, November 18, 2016

How do we get the best product to the consumer? We have found that nothing works as well as carrageenan.

“”**Carl Freund**
Unistraw
Testimony to the NOSB, November 17, 2016

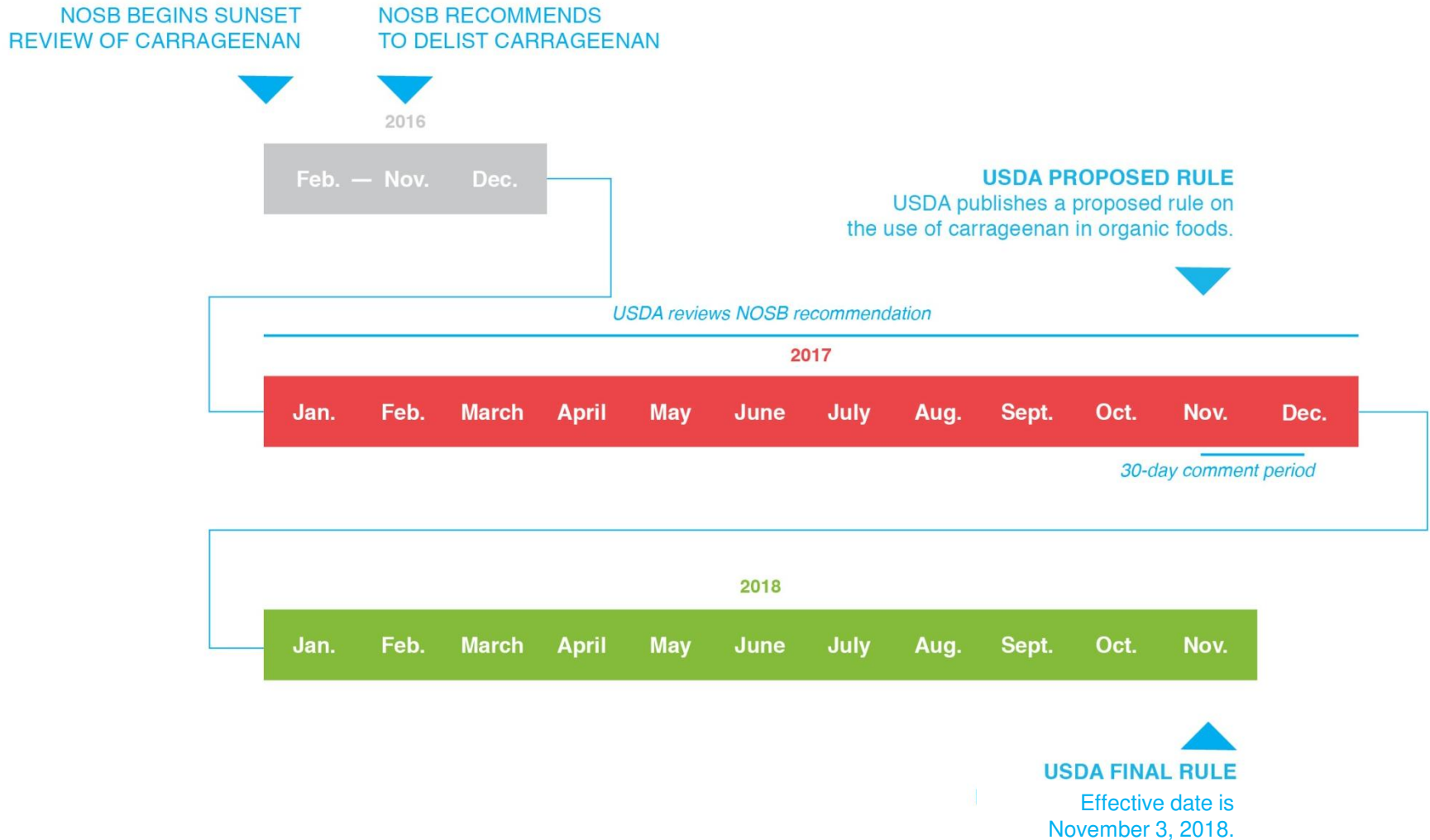
The weight of evidence presented to the board established the safety, essentiality, and sustainability of carrageenan.

However, the NOSB recommended that carrageenan be taken off the list of approved ingredients.

This recommendation is not a final decision.

- **The USDA will make a final decision in 2018.**
- **After carrageenan's last sunset review, the USDA overturned the NOSB's recommendation to restrict usage of carrageenan in organic foods.**
- **We are confident they will overturn this recommendation, as well.**

SUNSET REVIEW TIMELINE



Carrageenan is safe and sustainable.

- **The NOSB agreed safety and sustainability are not issues:**

“We find that the body of scientific evidence does not support claims of widespread negative human health impacts from consumption of carrageenan in processed foods.”

- **The NOSB based its recommendation to delist carrageenan on its belief that carrageenan is not essential.**

Carrageenan is essential.

- In a double-blind, independent survey of food-industry professionals, carrageenan ranked significantly higher in ingredient preference.
- *The board made an unprecedented recommendation to remove an ingredient without an organic alternative while allowing other stabilizers to remain that are no safer and do not perform as well.*

Customer Update



FMC Corporation
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June 5, 2017

Dear Customer:

As you may know, last fall the National Organic Standards Board recommended that carrageenan be removed from the National List of additives allowed in organic foods. This was not a final decision. The NOSB's recommendation is being reviewed by the USDA, which is responsible for making the final decision. The USDA will publish a proposed rule at the end of this year and a final decision in November 2018. At this time, carrageenan remains approved for use in organic products.

FMC continues to dedicate significant effort toward supporting the ongoing use of carrageenan as an ingredient in organic products. FMC remains optimistic that the USDA will keep carrageenan on the National List of additives approved for use in U.S. organic foods, as it did in 2012 when the USDA overturned the NOSB's recommendation to restrict carrageenan's use to a limited set of products.

In a notable win for carrageenan, Congress recently provided guidance and a reminder to the USDA to follow the letter and spirit of the law in their decision-making process for the Organics program. In the federal appropriations bill passed in early May, Congress included language in the legislation specifically reminding the USDA to use sound science and to follow the law in making its final decision:

"As USDA reviews the NOSB's recommendations, the agreement directs USDA to fully consider all currently available scientific information and stakeholder comments during the rulemaking process...The Department is reminded that the spirit of the organic program is to allow for the use of natural processes and materials to the greatest extent practicable."

On behalf of our customers, FMC will continue to work closely with our coalition of allies and strategic partners in Washington, DC, to support a positive decision by the USDA in 2018. We will continue to share information with you regarding the decision and path forward as it becomes available.

Thank you for your ongoing business, and please don't hesitate to contact us if you have questions or concerns.

Sincerely,

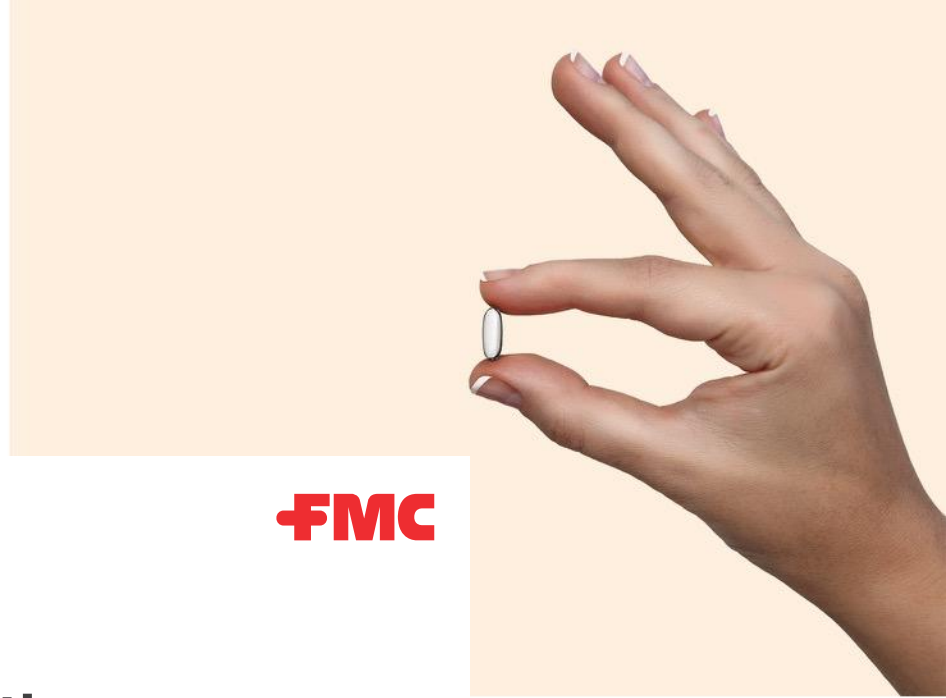
A handwritten signature in black ink, appearing to read 'Eric W. Norris'.

Eric W. Norris
President
FMC Health and Nutrition

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FMC is confident carrageenan will continue to be allowed in organic foods, as it has been for as long as there has been an organics program in the United States.



FMC

Questions



In it

