September 30, 2021

Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independent Ave., SW
Room 2648-S, Mail Stop 0268
Washington, D.C. 20250-0268

Re: Meeting of the National Organic Standards Board
Docket # AMS-NOP-21-0038

Dear National Organic Standards Board Members:

The following comments are submitted to you on behalf of **The Cornucopia Institute**, whose mission is, in part, to support economic justice for family-scale farming.

Climate Change Letter—CACS

Agriculture in general can either help stabilize the climate crisis and provide critical habitat for native species *or* hasten environmental destruction and our ability to feed ourselves. Cornucopia applauds the NOSB's efforts to communicate the value of organic farming to policymakers.

It is absolutely essential that the USDA and the National Organic Program (NOP) act decisively to promote climate-supportive agriculture. Climate change isn't the future; it is here now. That fact is supported by myriad disasters—flooding in central China and Europe, 120-degree temperatures in Canada, and record drought and unprecedented wildfires across the western United States—all of which impact global food security.

Updates from the IPCC echo what we are seeing play out globally: They report that unless we globally commit to immediate, rapid, and large-scale reductions in greenhouse gas emissions, limiting warming to close to 1.5°C or even 2°C will be beyond reach.[1]

The USDA must act to adapt to the barrage of climate change impacts we're currently experiencing while the government works to mitigate future effects. Research and analysis of factors influencing loss of ecosystem services show an urgent need to depart from an intensive conventional management system.[2,3,4] The organic program is a clear answer to many of these

[1] IPCC. August 9, 2021. "Climate change widespread, rapid, and intensifying – IPCC." https://www.ipcc.ch/2021/08/09/ar6-wg1-20210809-pr/
[2] Luty L.; Musiał K.; and Zioło M. 2021. "The Role of Selected Ecosystem Services in Different Farming Systems in Poland Regarding the Differentiation of Agricultural Land Structure." Sustainability, 13: 6673. https://doi.org/10.3390/su13126673. https://www.mdpi.com/2071-1050/13/12/6673/pdf
[3] Subodh Adhikari. September 23, 2019. "Adopting Diversified Organic Farming to Increase Ecosystem Services." Organic Farmer. https://organicfarmermag.com/2019/09/adopting-diversified-organic-farming-to-increase-ecosystem-services/
[4] Kühling, Insa and Trautz, Dieter. April 1, 2013. "The Role of Organic Farming in Providing Ecosystem Services." International Journal of Environmental and Rural Development, 4-1.

difficulties.

Please consider these important changes to your letter to Secretary Vilsack regarding climate change initiatives:

- While important, the singular emphasis on carbon sequestration and soil organic carbon (SOC) is misguided. Carbon sequestration is only one of many important pieces of climate change mitigation and resilience. Further, there is a limit to how much carbon soil can hold, and in general, carbon will always be at least somewhat volatile in agriculture systems compared to native ecosystems (such as forest and native grassland ecosystems).
- *Climate resilience* should be emphasized in addition to direct mitigation of greenhouse gas (GHG) emissions and net reduction of the carbon footprint. Since our focus is necessarily food production in agriculture, resilience is necessary to ensure food security for current and future generations. Organic farms stand out in research and field trials as being both more resilient and exceeding yields of conventional systems during extreme weather events and climate uncertainty (see Rodale Institute's field trials and Berkley's Agroecology Lab, along with other citations).[5,6,7,8]
- The current language in the letter concerning the "yield gap" is misleading and inaccurate. Current and ongoing research into organic farming practices shows that yields are the same or *better* than conventional cropping systems.[9] Yield variabilities are most often identified in the first few years after converting conventional fields to organic production, before organic cropping systems are well established. Yield improves with soil stewardship. When practices, such as intensive cover cropping, no tillage or reduced tillage, and crop diversification, are "stacked," yields, climate resilience, and environmental outcomes are improved.[10] Research and farm trials show less variability in crop yields when these regenerative organic and organic agroecological principles are

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https://www.researchgate.net/publication/275713721_The_Role_of_Organic_Farming_in_Providing_Ecosystem_Services

[5] *Organic farms have better soil health and improved soil structure, both of which allow farmers to better cope with the extreme weather associated with climate change. See* Shade J and Tully K. 2020. "Organic Farming Practices for Improving Soil Health." The Organic Center. https://www.organic-center.org/sites/default/files/publication_files/2020/03/Soil-Health-Review_ShadeTully.pdf

[6] Rodale Institute Webpage. September, 2021. "Farming Systems Trial." https://rodaleinstitute.org/science/farming-systems-trial/

[7] Rodale Institute. 2014. "Regenerative organic agriculture and climate change: a down-to-earth solution to global warming." https://rodaleinstitute.org/assets/RegenOrgAgricultureAndClimateChange_20140418.pdf

[8] Katherine Bell. January, 2016. "Pay Dirt: High-nutrient Soil for High-Yeild, High-Profit Farming." Acres. http://singingfrogsfarm.com/ewExternalFiles/Pay%20Dirt!.pdf

[9] *Note there is a breadth of research on yields; Cornucopia suggests focusing on studies that were properly conducted without simply replacing conventional inputs with conventional inputs. For example, see* Organic Farming Research Foundation Webpage. August, 2021. "Soil Heath Reports." https://ofrf.org/research/reports/; Singing Frogs Farm Farming Trial (see more at http://singingfrogsfarm.com/ and Katherine Bell. January, 2016. "Pay Dirt: High-nutrient Soil for High-Yeild, High-Profit Farming." Acres. http://singingfrogsfarm.com/ewExternalFiles/Pay%20Dirt!.pdf); and Suja G,Byju G, JyothiS AN, Veena SS, Sreekumar J. April 14, 2017. "Yield, quality and soil health under organic vs conventional farming in taro." Scientia Horticulturae, 218: 334-343. https://www.sciencedirect.com/science/article/abs/pii/S0304423817300912

[10] *See* Crystal-Ornelas R, Thapa R, and Tully KL, 2021. "Soil organic carbon is affected by organic amendments, conservation tillage, and cover cropping in organic farming systems: A meta-analysis." Agriculture, Ecosystems, and Environment 312: 107356. https://www.sciencedirect.com/science/article/abs/pii/S0167880921000608

employed (see Rodale Institute's field trials and Berkley's Agroecology Lab for examples of ongoing research in this area).

- Include citations or references to current research to better illustrate the *known benefits* of organic agriculture. Cornucopia and several other organizations have recommended existing and ongoing studies showing the promise of organic practices for climate resilience, GHG emissions, and carbon sequestration.[11] For example, research from Northeastern University and The Organic Center shows that organic farming keeps more carbon in the soil and out of the atmosphere and that organically managed soils store more carbon for longer periods and have on average 44% higher levels of humic acid (a soil component that sequesters carbon over the long term).[12] We'd also suggest referencing research pertaining to organic production and the protection of ecosystem services, soil health[13], and rural community vitality.[14] All of these issues are pertinent to climate change.
- The NOSB's letter should emphasize that organic production does not allow synthetic and petroleum-based fertilizers and pesticides, which emit GHGs in their production and require a lot of energy to manufacture and transport.[15]
- Emphasize that diversified organic farming, where multiple crops and livestock are produced, increases food system sustainability and increases and stabilizes ecosystem services, both of which are essential parts of climate resilience.

Along with the above changes, it is vital that the NOSB include an important ask in their climate change letter: *Implore Secretary Vilsack to enact the NOSB's recommended regulation to*

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[11] *See* Rattan Lan. January 23, 2020. "Managing soils for negative feedback to climate change and positive impact on food and nutritional security." Japan Prize Research. *https://www.tandfonline.com/doi/full/10.1080/00380768.2020.1718548 ;* Lal R, *et al*. 2018. "The carbon sequestration potential of terrestrial ecosystems." J. Soil and Water Conservation 73(6): 145A-152A. https://abdn.pure.elsevier.com/en/publications/the-carbon-sequestration-potential-of-terrestrial-ecosystems *;* Chambers A, Lal R, and K. Paustian K. 2016. "Soil carbon sequestration potential of U.S. croplands and grasslands: implementing the 4 per Thousand Initiative." J. Soil & Water Conserv. 71(3): 68A-74A. https://www.researchgate.net/publication/302870231_Soil_carbon_sequestration_potential_of_US_croplands_and_grasslands_Implementing_the_4_per_ThoUSAnd_Initiative ; Teague WR, *et al*. 2016. "The role of ruminants in reducing agriculture's carbon footprint in North America." J. Soil& Water Conserv. 71(2): 156-164. ; Powlson DS, Whitmore AP, and Goulding KWT. 2011. "Soil carbon sequestration to mitigate climate change: a critical re-examination to identify the true and the false." Eur. J. Soil Sci. 62(1): 42–55. https://www.researchgate.net/publication/227853256_Soil_carbon_sequestration_to_mitigate_climate_change_A_critical_re-examination_to_identify_the_true_and_the_false

[12] Ghabbour EA, *et al*. 2017. " National Comparison of the Total and Sequestered Organic Matter Contents of Conventional and Organic Farm Soils." Advances in Agronomy, 146: 1-35. https://www.sciencedirect.com/science/article/abs/pii/S0065211317300676?via%3Dihub

[13] Martina Lori, *et al*. 2017. "Organic farming enhances soil microbial abundance and activity—A meta-analysis and meta-regression." PLoS One, 12(7): e0180442. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5507504/

[14] *See as example of relevant research:* Gosnell, Hannah, Kerry Grimm, and Bruce Goldstein. January, 2020. "A half century of Holistic Management: what does the evidence reveal?" Agriculture and Human Values. https://doi.org/10.1007/s10460-020-10016-w*;* Gosnell Hannah, Susan Charnley and Paige Stanley. 2020. "Climate change mitigation as a co-benefit of regenerative ranching: Insights from Australia and the United States." Interface Focus 10: 20200027. http://dx.doi.org/10.1098/rsfs.2020.0027. https://royalsocietypublishing.org/doi/10.1098/rsfs.2020.0027

[15] *See* Seufert V and Ramankutty N. March 10, 2017. "Many shades of gray—The context-dependent performance of organic agriculture." Science Advances, 3(3).DOI: 10.1126/sciadv.1602638. https://www.science.org/doi/10.1126/sciadv.1602638

eliminate incentives to convert native ecosystems to organic production regulation. If the native ecosystems recommendation is not enacted, the organic program cannot entirely live up to its climate- and eco-friendly claims. (See below for more on the legal authority for enacting the native ecosystems recommendation.)

Native ecosystems store much more carbon than converted farmland ever can. These ecosystems are also refuges for pollinators, and beneficial wildlife that help maintain and contribute to the benefits afforded by sustainable farming. Native ecosystems also provide services that benefit local farming, supporting the sustainability of food production in the face of climate change.

In guidance, the NOP claims that "[t]he conservation of natural resources and biodiversity is a primary tenet of organic production…" (NOP 5020 Natural Resources and Biodiversity Conservation). This language supports *both* the notion that organic farming is an answer to climate change mitigation and resilience and the fact that regulation to protect native ecosystems is needed.

Native Ecosystems: The Legal Authority for the NOSB's Recommendation on Eliminating the Incentive to Convert Native Ecosystems

The Cornucopia Institute continues to support the National Organic Standards Board's (NOSB) proposal to add both a definition of "native ecosystems" to §205.2 and a clause to §205.200 preventing the conversion of those ecosystems into organic production [native ecosystems regulation]. Our support is not in a vacuum: the majority of consumers, organic farmers, and other non-governmental organizations support this regulation.

Cornucopia also supports the Wild Farm Alliance's (WFA) efforts and commentary on this issue. We hope both the NOSB and the NOP will look to WFA for future guidance on the implementation. However, Cornucopia has found that the NOSB's recommendation and support for regulatory change has not been enough to prompt action. The NOSB recommended the native ecosystems regulation in 2018. Since that time, there has been no apparent movement to promulgate these regulations. The NOP has expressed concerns that it will face legal action or that they "don't have the authority" to enact regulation concerning native ecosystems.

The following comment makes the argument that it is not only allowable for the NOP to enact regulation concerning native ecosystems, but that it is required by the Organic Foods Production Act of 1990 (OFPA)1, the existing organic regulations (7 CFR Part 205), and surrounding law and policy.

1. OFPA requires the establishment of standards and assurance for consumers that organic products meet a consistent standard

The stated purpose of OFPA is to establish national standards that will then be used to govern the marketing of organic products, to assure consumers that organic products meet a consistent

standard, and to facilitate commerce in organic food.[16] The rest of the law lays out how to go about doing these three tasks, with some additional guidelines.

Despite OFPA's stated purpose, in recent years the NOP has denied having authority to create regulations that fulfill these purposes.

The existing set of organic rules and regulations show that the incentive to convert native ecosystems was unintended because the incentive is incompatible with those existing standards. As discussed by the NOSB in their 2018 recommendation on native ecosystems,[17] OFPA and its surrounding law and policy include a clear bias toward protection of the natural resources present on an organic operation.

If the United States Department of Agriculture (USDA) fails to enact the native ecosystems regulation, they fail to establish uniform standards to govern marketing of organic products, and fail to assure consumers that organic products meet a consistent standard.

A. OFPA and surrounding legislative material are consistent with adding regulation to protect native ecosystems

While OFPA doesn't use the term "native ecosystem" explicitly, the law and the surrounding regulatory materials do reference environmental protection and resource conservation throughout. The recommendation to eliminate the incentive to convert native ecosystems is consistent with the rest of the statute—and allowing organic farming to cause destruction of native ecosystems is incompatible.

First, OFPA requires that three members of the NOSB have "…expertise in areas of environmental protection and resource conservation" and that the NOSB as a whole "…advise the Secretary on any other aspects of the implementation of [OFPA]."[18] The NOSB has advised the NOP by recommending that regulations be updated to get rid of the unintended incentive to destroy native ecosystems.

OFPA's Preamble to the Final Rule establishing the NOP states: "[t]he use of 'conserve' [in the definition of organic production] establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it.

Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation" [emphasis added].[19] Since destruction of native ecosystems is universally bad for biodiversity, the activity of destroying native ecosystems is anathema to the base definition of "organic production."

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[16] 7 USC § 6501
[17] National Organic Standard Board. Formal recommendation: Eliminating the Incentive to Convert Native Ecosystems to Organic Production, 2018. https://www.ams.usda.gov/sites/default/files/media/CACSNativeEcosystems.pdf
[18] 7 USC § 6518
[19] 76 FR 80563

Other areas of OFPA continue with a consistent theme of protecting the environment and conserving or improving the natural resources of an operation. For example, OFPA requires that wild crop harvesting "not be destructive to the environment."[20] Evaluation of a substance for the National List also requires a determination that the substance would not be harmful to human health or the environment.[21]

B. The existing organic regulations and guidance are consistent with protecting native ecosystems

When the NOP was established in 2001, they were tasked with "…facilitating domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards."[22]

Consistent and uniform standards require that unintended consequences, misalignment, and "holes" in rulemaking be cured as soon as possible.

Allowing native ecosystems to be destroyed to produce organic products is a mistake when read in the context of the existing organic regulations and guidance. While, like OFPA, the organic regulations do not directly use the term "native ecosystems," they directly reference qualities and resources that concern native ecosystems throughout.

The definition of "organic production" in the regulations requires that the production system "…foster cycling of resources, promote ecological balance, and conserve biodiversity."[23] Organic producers cannot destroy a native ecosystems' character and still foster cycling of resources, promotion of ecological balance, and conservation of biodiversity. Even the most careful and considerate cropping systems cannot replicate the value (in terms of biodiversity and other ecological benefits) provided by native ecosystems.

The definition of "natural resources of the operation" in the regulations is "the physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife."[24] These natural resources must either be maintained or improved by organic producers.[25] Destroying native ecosystems on-farm decreases soil[26] and water quality and historically leads to concerns like erosion and contamination that are directly addressed in

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[20] 7 USC § 6513(f)
[21] *See* 7 USC § 6517
[22] Summary of the Final Rule Establishing the National Organic Program National Organic Program. Docket Number: TMD–00–02–FR, Effective: February 20, 2001. https://www.ams.usda.gov/rules-regulations/establishing-national-organic-program
[23] 7 CFR § 205.2. Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.
[24] 7 CFR § 205.2.
[25] § 205.200
[26] "The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion." 7 CFR § 205.203(a)

the soil fertility and crop nutrient management practice standard.[27] Eradicating wetlands and woodlands, which are types of native ecosystems, also harm wildlife.

The wild-crop harvesting practice standard also speaks to maintaining the natural environment. Wild crops must be harvested such that that activity "…will not be destructive to the environment and will sustain the growth and production of the wild crop."[28] (Note that wild harvest could still occur in native ecosystems.)

Finally, the NOP's Guidance on Natural Resources and Biodiversity clarifies the importance of conservation in organic systems, stating "[t]he conservation of natural resources and biodiversity is a primary tenet of organic production."[29] It also allows organic operations to count management of native ecosystems which provide benefits to their nearby certified lands as part of their compliance with the natural resources standard.

As laid out in WFA's native ecosystem guidance, toolkit, and discussion surrounding the native ecosystem regulation, some agricultural activities can still be performed without harming the characteristics of a native ecosystem (e.g., low intensity grazing). The language of the NOSB recommendation to eliminate the incentive to convert native ecosystems to organic farmland also accounts for these allowances as well.

2. OFPA requires that consumers are assured that organic products meet a consistent standard

One of the stated purposes of OFPA is to assure consumers that organic products meet a consistent standard.[30] Consumers have a reasonable expectation of ecosystem preservation and land stewardship within the organic marketplace.

Messaging throughout the USDA's marketing of organic products and practices emphasizes the environmental benefits of organic production. Part of this marketing strategy is to frequently use the phrases "promote ecological balance" and "conserve biodiversity" on the website.[31] To then argue that removing the incentive to convert native ecosystems is somehow incompatible with OFPA goes against the established system and marketing already in place. The conversion of native ecosystems destroys ecological balance and decreases biodiversity. Any reasonable consumer would expect that destruction of native ecosystems would already be disallowed under organic production systems.

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[27] § 205.203
[28] § 205.207(b)
[29] NOP 5020 Guidance on Natural Resources and Biodiversity. https://www.ams.usda.gov/sites/default/files/media/NOP%205020%20Biodiversity%20Guidance%20Rev01%20%28Final%29.pdf
[30] 7 USC § 6501
[31] When searching the ams.usda.gov site for the phrases "conserve biodiversity" + "organic" in conjunction, there are 148 page results. When searching the ams.usda.gov site for the phrases "ecological balance" + "organic" in conjunction, there are 189 page results. These results show these phrases are used throughout the marketing of organic products and practices, and are familiar terms in the industry. Google search results, March 16, 2021.

The USDA's own Consumer Brochure from 2007 describes organic food as "…produced by farmers who emphasize the use of renewable resources and the conservation of soil and water to enhance environmental quality for future generations."[32] There is ample scientific evidence being shared with the NOP to show that the destruction of native ecosystems is unsustainable and is a serious contributor to global problems including climate change, mass extinction, pollinator loss, and food insecurity.

Climate change will worsen with the destruction of native ecosystems. Carbon is stored in woody plants, such as those found in forest and woodlands. It is stored in wetland vegetation, peats, and sediments that have built up, in some instances, over thousands of years. Carbon is also stored in soils. When a natural ecosystem is converted to cropland, 30 to 50 percent of soil carbon is lost to the atmosphere over a 50-year period.[33]

If consumers perceived that organic farming contributed to rainforest or tallgrass prairie destruction, it would likely cause deep harm to public trust in the organic label. If the NOP means to facilitate organic commerce, the program must meet the expectations established by their own marketing materials and the existing law and policy.

Given these marketing materials and language used throughout the law and policies in organic agriculture, allowing this perverse incentive to persist is equivalent to marketing fraud.

3. The USDA has the legal authority to enact native ecosystems regulations

All federal agencies are granted broad powers to enact regulations. In the U.S., "enabling legislation" refers to a law by which Congress grants an entity which depends on it (for authorization or legitimacy) the power to take certain actions. OFPA is a classic example of enabling legislation.

A. Case law stands for agency authority

The Supreme Court case *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*.[34] led to the principle of "Chevron deference" in administrative law. Chevron deference is a legal principle that compels federal courts to defer to a federal agency's interpretation of an ambiguous or unclear statute that Congress delegated to the agency to administer. In later cases, the Supreme Court narrowed the scope of Chevron deference.[35] The limitations imposed were that only the agency interpretations reached through formal proceedings, including notice-and-comment rulemaking, qualify for Chevron deference.

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[32] "Organic Food Standards and Labels: The Facts." Accessed March 16, 2021. https://www.nal.usda.gov/afsic/organic-productionorganic-food-information-access-tools

[33] National Sustainable Agriculture Coalition. 2019. "Agriculture and Climate Change: Policy Imperatives and Opportunities to Help Producers Meet the Challenge." Washington D.C.

[34] Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[35] Skidmore deference developed from the 2000 U.S. Supreme Court case Christensen v. Harris County and named for the 1944 U.S. Supreme Court decision in Skidmore v. Swift & Co. See https://ballotpedia.org/Skidmore_deference

That case law in general shows that courts are incredibly deferential to agencies when they are operating within their purview. It is well within the authority of the NOP to create regulation to protect native ecosystems from being destroyed by a producer.

B. Authority for looking back in time

Some have argued that the reach of the organic label cannot extend to activities concerning the natural resources that existed before the farm was established. However, the organic marketplace is a voluntary program. Farmers are not required to participate, meaning any requirements for entering the program are also voluntarily undertaken by the producer. Timeframes for organic certification that can extend beyond a producer's control of land are already in place. For example, if a farmer were to buy a plot of land that had been farmed conventionally but lain fallow for two years (without prohibited substances applied to it), that farmer could still "look back in time" to begin selling their produce after a subsequent year.

In fact, allowing producers to convert pristine lands directly to organic farming shows that accredited certifiers are already "looking back" at the state of the land before the farm was established. Sustainability cannot be achieved while native ecosystems are being destroyed to produce crops.

The NOSB has received substantial public comment describing loss of native ecosystems when farmers transition to organic production. The broad support in the industry and among consumers for the NOSB's recommendation should assure the NOP that organic production needs this regulation.

4. Conclusions re: Native Ecosystems Recommendation

From a legal and policy standpoint, the native ecosystem recommendation, as proposed, is consistent with the intent of OFPA,[36] the organic regulations and guidance, and the USDA's own marketing materials.

When pristine and imperiled ecosystems are destroyed, time and concerted effort are required to even give the land a chance at returning to its natural character. These lands provide valuable ecosystem services to human populations and habitat for native plant and animal species, along with many other benefits. As WFA has emphasized, "these areas, that were once delivering critical ecosystem services and providing essential habitat for wildlife, are no longer performing the same functions and [it] would take hundreds of years to reverse the damage."[37]

Without a regulatory change, the organic standards incentivize farmers to destroy wild and important native ecosystems instead of converting conventionally farmed land to organic production. Allowing native ecosystems to be destroyed by farmers is contrary to the basic tenets of organic production. As the NOP states in its guide for organic crop producers: "Sustainability can be defined as meeting the needs of the present without compromising the ability of future

[36] As amended (7 U.S.C. 6501-6524)
[37] Wild Farm Alliance website. Accessed March 18, 2021. https://www.wildfarmalliance.org/protecting_native_ecosystems

generations to meet their own needs."[38] The destruction of our environment carries similar concerns: threats of climate change, habitat destruction, and trophic collapse. It is imperative that we protect and conserve as much wild land as possible.

Biodegradable Biobased Mulch Film—Crops Subcommittee

Cornucopia urges the NOSB to reject the annotation change for biodegradable biobased mulch (BDM) films. While we appreciate the NOSB's work on this material, none of the options suggested to guide use of BDM with less than 100% biobased content address the systemic concerns with these products.

BDM technology has only been in the marketplace for a short time. We do not know with certainty how the soil microbiome, watersheds, or other biological systems will be impacted by their use. What we do know about the impacts of BDM films is concerning, particularly with respect to microplastics in the environment.

Cornucopia *does not support an annotation change* to loosen restrictions on bioplastic film. As stated in our previous comments, Cornucopia urges the NOSB and the NOP to use the *precautionary principle* with all forms of biodegradable biobased mulch films.

Excluded Methods Determinations— Materials/GMO Subcommittee Discussion Document

Cornucopia urges the NOP to codify the NOSB's past recommendations on excluded methods into regulation, beginning with the development of a guidance document for the process of evaluation (including definitions and criteria for evaluation).

Organic plant breeders and the organic seed industry need certainty to advance plant breeding efforts that meet the needs of organic operations. Delay in this area could lead to hardships by both breeders and farmers (who often have a lack of options when purchasing organic seed).

Ammonia Extract Proposal—Petitioned

The Cornucopia Institute champions the stewardship of soil in organic agriculture. We support the reasonable prohibition of ammonia extracts for use in organic crop production.

We further support the separate listing of stripped ammonia and concentrated ammonia, so that any future ammonia extracts proposed for use in organic may be readily prohibited by the National List.

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[38] Pamela Coleman, Agriculture Specialist. November 2012. "Guide For Organic Crop Producers." National Center for Appropriate Technology (NCAT). https://www.ams.usda.gov/sites/default/files/media/Guide-OrganicCropProducers.pdf

However, Cornucopia has some concerns regarding the *process* of prohibiting ammonia extracts. Non-synthetic ammonia extracts have been approved for use by OMRI since 2012, suggesting that the materials review process must be studied and updated.

High-nitrogen fertilizers and manure amendments are already in use under the organic label (some with arguably more detrimental environmental and human impact). Based on the reasoning put forth for the prohibition, this decision will logically inform the use of other fertilizers in organic cropping systems.

The NOSB must determine whether ammonia extracts cause *harm* to the soil rather than "foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring…" as OFPA requires (7 USC § 6513). Research suggests that high nitrogen fertilizers in general should be limited due to their impact on soil health.

We also support an upper limit of 20% of crop needs supplied by nitrogen products with 3:1 carbon to nitrogen ratios, as suggested by Beyond Pesticides.

Oversight Improvements to Deter Fraud: Modernization of Organic Supply Chain Traceability Discussion Document

Regarding whether land should be registered 36 months before certification, Cornucopia has serious concerns for organic farmers who are unable to purchase land. According to the National Young Farmers Coalition report, *Land Policy: Towards a More Equitable Farming Future*, one third of young farmers rent farmland.[39]

While Cornucopia is in favor of registration 36 months prior to certification in order to stabilize the market and enhance risk assessments, without some allowance for renters, this would preclude many beginning farmers from organic certification.

Carrageenan--§205.605(a) Handling Sunset

Cornucopia asks the NOSB re-classify carrageenan as a synthetic substance *before* voting to remove it from the National List.

The following comment includes research conducted and summaries of existing studies (and their researcher affiliations) to help the NOSB in their deliberations over carrageenan.

(Please also see attached questionnaire results from consumers concerning their experiences with carrageenan, including their discussions with medical professionals. NOTE: We have removed personal identifying and other contact information from the raw data provided on this public forum to respect respondent privacy. In general, we found that people off all age ranges were affected by carrageenan and many were told to avoid carrageenan by medical professionals. Cornucopia would be willing to share more details from individuals who authorized sharing their

[39] National Young Farmers Coalition. 2020. "Land Policy Towards a More Equitable Farming Future." https://www.youngfarmers.org/land/wp-content/uploads/2020/11/LandPolicyReport.pdf

information—if the NOSB or NOP has an interest—outside the public forum. Document name: CornucopiaAttachment1-ConsumerCarrageenanSurvey2021-AMS-NOP-21-0038.xlsx)

1. Carrageenan is used as a processing aid and in other applications where it does not appear on ingredient labels

Carrageenan is a common processing aid in food, particularly in dairy, dairy alternatives, and processed meat products. Carrageenan is also used as a fining agent for beer[40] and wine (meaning it is used in processing but not added to the final product). Carrageenan-based films can also be used as coatings for certain processed and unprocessed foods including meat, produce, and fruit.

The Food and Drug Administration (FDA) does not require that processing aids be displayed on the ingredient label.[41] This means, when utilized in certain applications carrageenan, *does not have to appear on the ingredient panel.*

Some allergens are required to be listed on the information panel for products.[42] There are also several food ingredients that cause non-allergic hypersensitivity reactions in sensitive individuals that require specific labeling. Again, carrageenan is not on this list.[43] In neither case is carrageenan required to be listed on product information panels. This means that if an individual is sensitive or allergic to carrageenan, they cannot avoid it in organic foods.

In addition, carrageenan exposure may not be limited to packaged and processed foods. Carrageenan has been reported to be in use as edible packaging and in protective films for fruits and other produce (again, where no labeling is required).[44] These films, which are also used in meat products, are used to prevent shrinkage, microbial contamination, and surface discoloration by delaying moisture transport (which extends shelf-life).[45] It is unclear how widely edible films are used within organic handling, requiring a closer look by a technical review.

Organic foods must conform to a higher standard than other foods, according to the Organic Foods Production Act. Cornucopia offers a carrageenan guide which lists organic products that do and do not contain carrageenan. Some of the products represented on this guide contain

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[40] *For example, see:* Mihkel Saluri, Marju Robal, and Rando Tuvikene. January, 2019. "Hybrid carrageenans as beer wort fining agents." Food Hydrocolloids, 86: 26-33. https://www.sciencedirect.com/science/article/abs/pii/S0268005X17316788

[41] 21 CFR § 101.100 - Food; exemptions from labeling.

[42] Specifically, the Food Allergen Labeling and Consumer Protection Act of 2004 requires that eight foods as major food allergens be specifically labeled with the name of the allergen source: milk, eggs, fish shellfish, tree nuts, peanuts, wheat, and soy. Sesame will be added to this list of "major allergens" in January, 2023.

[43] Food and Drug Administration website. "Food Allergies." *See* https://www.fda.gov/food/food-labeling-nutrition/food-allergies

[44] Elham Tavassoli-Kafrani, Hajar Shekarchizadeh, Mahdieh Masoudpour-Behabadi. 2016. "Development of edible films and coatings from alginates and carrageenans." Carbohydrate Polymers, 137: 360-374. https://www.sciencedirect.com/science/article/abs/pii/S0144861715010541 ; *See also The Cornucopia Institute's summary of the research for more papers on the uses of edible films.*

[45] Demeng Zhang, Mengxue Zhang, and Xiaoxiao Gu. January, 2018. "8 - Seaweed-Derived Hydrocolloids as Food Coating and Encapsulation Agents."Bioactive Seaweeds for Food Applications, Academic Press, Pages 153-175. https://www.sciencedirect.com/science/article/pii/B978012813312500008X

carrageenan that does not appear on the ingredient panel (this information was collected by contacting the brands in question).

2. Carrageenan is a synthetic substance

Organic standards are designed to allow natural substances in organic foods while prohibiting synthetic substances. Carrageenan is currently considered an allowed Nonagricultural (nonorganic) substance and is listed under § 205.605.

The term "synthetic" is defined as:

> ... a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. - 7 USC § 6502(22)

In traditional use, carrageenan is extracted by boiling the red seaweeds from which it is derived in water and milk. This process is not used in food manufacturing, as it is much more labor intensive and expensive than the process currently favored by industry. [46]

Raw carrageenan must be further refined and extracted to produce usable forms of the polysaccharide for industrial food production. The final product is a tasteless white powder.

Carrageenan is processed into fully refined or semi-refined products. Fully refined carrageenan products are processed using an alcohol-precipitation method or a gel-press method. Semi-refined carrageenan for human consumption, called "processed Eucheuma seaweed" (PES), is extracted with potassium hydroxide (lye).

Nearly all food-grade carrageenan is processed and extracted using alkali solutions that help to remove carrageenan from the seaweed into an aqueous solution. The alkaline treatments used in the manufacture of refined carrageenan cause chemical changes to occur in the algal extracts.[47] As stated by the FAO, "Alkali is used because it causes a chemical change that leads to increased gel strength in the final product…"[48] None of the most common food grade carrageenan is "created by naturally occurring biological processes."

Note that these methods of extraction are further summarized in the Technical Evaluation Report (TR) from 2011.[49] The TR acknowledges that some methods of extraction may be synthetic.

3. The History of the NOSB Review of Carrageenan

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[46] The Food and Agriculture Organization (FAO). "Carrageenan." http://www.fao.org/3/y4765e/y4765e0a.htm
[47] *See* The Food and Agriculture Organization (FAO). "Carrageenan." http://www.fao.org/3/y4765e/y4765e0a.htm
[48] The Food and Agriculture Organization (FAO). "Carrageenan." http://www.fao.org/3/y4765e/y4765e0a.htm
[49] Agricultural Marketing Services, United States Department of Agriculture. 2011. "Technical Evaluation Report: Carrageenan." https://www.ams.usda.gov/sites/default/files/media/Carrageenan%20TR%202011.pdf

The Organic Foods Production Act of 1990 (OFPA) requires that prohibited materials may be added to the National List for a five-year period only if the use of such substances *would not be harmful* to human health or the environment, and only if it is considered essential because no alternatives exist.

Carrageenan was first added to the National List in the 1990s, as the organic standards were being developed and the organic label was in its infancy. The NOSB relied on technical reviews by scientists to determine the safety of any materials petitioned for use in organics. At that time, the scientific review of carrageenan was conducted by Ralston Purina/Beech Nut executive, Dr. Richard Theuer, and two other agribusiness-related food scientists. They did not emphasize its known impacts on human health or the environment, noting that carrageenan had been widely used in conventional food for decades.

The research showing harmful biological effects in human cells and in animals exposed to carrageenan has mounted since carrageenan was first listed. Dr. Joanne K. Tobacman of the University of Illinois, Chicago, made oral comments at the spring 2012 NOSB meeting, detailing the findings of her own work showing negative health effects of carrageenan.

Following their 2012 meetings, the NOSB recommended that carrageenan be listed again as an allowed substance in foods labeled organic in the US. However, the NOSB recommended that carrageenan be excluded from use in organic infant formula at that time, citing safety concerns.[50] The NOSB also recommended to indicate specific allowed forms of carrageenan by Chemical Abstract Service (CAS). The NOP rejected this recommendation.

In 2016, during carrageenan's next sunset review, the NOSB recommended removing carrageenan from the National List entirely, citing their reasoning that alternatives exist in the marketplace.[51] The NOSB also noted that public comments reported anecdotal evidence of health problems with carrageenan ingestion and that: "[t]his was not seen as a primary reason to remove carrageenan since it is listed on the labels as a food ingredient." It seems clear that the NOSB at that time did not fully understand that carrageenan *can be used as a processing aid and not appear on ingredient panels*.

Presenting for the Subcommittee, Zea Sonnabend did ask that companies "…please put full labels on those products" and later acknowledged that "…as a processing aid, [carrageenan] does not have to be on the label." [November 2016 NOSB Meeting Transcript, page 363 & 367].

The USDA did not follow the NOSB's recommendation for the 2018 sunset, stating their reasoning as: "[we] found sufficient evidence in public comments to the NOSB that carrageenan continues to be necessary for handling agricultural products because of the unavailability of

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[50] Natural Products Association. April 14, 2016. "Department of Agriculture, Agriculture Marketing Services; Notice of Public Meeting for the National Organic Science Board." https://www.npanational.org/regulatory/food-and-drug-administration-fda/department-agriculture-agriculture-marketing-services-notice-ofpublic-meeting-national-organic-science-board/

[51] Agricultural Marketing Services, United States Department of Agriculture. November, 2016 "Sunset 2018 Review Summary, NOSB Final Review. Handling Substances §205.605(a), §205.605(b), §205.606." https://www.ams.usda.gov/sites/default/files/media/HS2018SunsetReviews.pdf

wholly natural substitutes."[52] [Emphasis added.] The USDA's own language suggests the agency believed carrageenan did not qualify as a natural substance.

Discussion surrounding carrageenan prior to their 2016 recommendation also made it clear that the NOSB would likely have recommended that carrageenan's classification be changed to "synthetic" had they not asked instead for the substance's removal from the National List at that time (that discussion can be found in the 2016 meeting transcripts). Specifically, in Zea Sonnabend's presentation concerning carrageenan, she noted that whether carrageenan is synthetic or not "…will be looked at, if it remains on the list, when the guidance is out" [November 2016 NOSB Meeting Transcript, page 360]. The question of whether carrageenan should be re-classified as a synthetic substance was not addressed by the USDA since it was not part of the NOSB's formal recommendation. *This makes it appear that the 2016 Board members intended for carrageenan's next review to determine whether carrageenan is actually synthetic.*

4. Researcher Bias and The Carrageenan Controversy

Authorship bias is common when the researcher is funded by the industry producing the studied product. Outcomes can be influenced by study design choices.

When examining the research surrounding food-grade carrageenan, it is therefore essential that the Handling Subcommittee (HS), the National Organic Standards Board (NOSB), and the National Organic Program (NOP) consider the *source* of that research or review.

For example, some of the commentary that was cited in the Handling Subcommittee's summary came directly from sources within the carrageenan industry (*Bixler*). Also, the majority of review articles and research that insists carrageenan is safe for human consumption was performed by the carrageenan industry or industry consultants. Specifically, Dr. Myra L. Weiner, the owner and president of TOXpertise, LLC (an industry consultant) is repeatedly cited. Many reviews by TOXpertise, LLC were funded by FMC Corporation, which has "over 60 years of experience in the development and production of carrageenan products..."[1]

Note that the limited scope TR on carrageenan references review articles funded by FMC Corporation, a manufacturer of carrageenan.

In contrast, research showing that consumption of carrageenan is a potential health risk is largely conducted by academic institutions and funded through those academic institutions or sources such as the National Institute of Health.

The Subcommittee discussion concerning carrageenan does not appear to take into account the evolving research or the increasing awareness and concern of consumers in the marketplace.

Carrageenan is routinely consumed in the typical Western diet. An average individual is predicted to consume as much as 2 to 4 grams/day; an industry-sponsored study suggested an

[52] Federal Registrar. April 4, 2018. "National Organic Program: USDA Organic Regulations." https://www.federalregister.gov/documents/2018/04/04/2018-06867/national-organic-program-usda-organic-regulations

average daily intake of 1.08 to 7.2 g/day in a 132lb person.[2] Carrageenan intake has likely *increased* in Western diets since carrageenan was last reviewed by the NOSB, and many routes of exposure to carrageenan have never been considered by the NOSB (including the use of protective film coatings in organic fruits and produce).

5. Summary of Carrageenan Research

The following is a summary of the research, research funding, and affiliations of researchers and commenters. While not comprehensive, these studies were those found to be most applicable to the question of human health implications (because carrageenan is used to induce inflammation in countless animal experiments, this curated research sample focuses only on research into carrageenan itself). The more recent research (since 2017) extends to actual clinical trials and research into carrageenan's effect on actual human populations, not cell-line or animal experiments.

1970s

Pittman K, Golberg L, and Coulston F. (1976) "Carrageenan: The effect of molecular weight and polymer type on its uptake, excretion and degradation in animals." Food and Cosmetics Toxicology 14 (2):85-93.

> **Summary of findings:** Food-grade carrageenan was given to guinea pigs, monkeys, and rats through drinking water or in the diet. Fecal and liver samples were examined by gel electrophoresis and carrageenans present in the feces were reduced to 100kDa or less. Carrageenans were also found in the liver, demonstrating that high molecular weight carrageenans are degraded after passing through the digestive tract and can be absorbed.
>
> **Author affiliations:** Institute of Comparative and Human Toxicology, Center of Experimental Pathology and Toxicology, Albany Medical College (Albany, New York).

Engster M and Abraham R. (1976) "Cecal response to different molecular weights and types of carrageenan in the guinea pig." Toxicology and Applied Pharmacology 38:265–282.

> **Summary of findings:** In this short-term study, researchers administered different types of carrageenan in the diet and drinking water of guinea pigs for two weeks. They found ulceration of the intestines in guinea pigs given undegraded iota-carrageenan in the drinking water. No changes were observed in the other groups, and it is unclear what effects would have been seen if the experiment had been continued for longer than two weeks.
>
> **Funding:** National Institute of Environmental Health Sciences, National Institutes of Health.
>
> **Author affiliation**: Albany Medical College (Albany, New York).

Watanabe K, Reddy BS, Wong CQ, Weisburger JH (1978) "Effect of dietary undegraded carrageenan on colon carcinogenesis in F344 rats treated with azoxymethane or methylnitrosourea." Cancer Research 38:4427–4430.

> **Summary of findings:** This study found higher rates of tumors in rats fed undegraded carrageenan in the diet.
>
> **Funding:** National Cancer Institute (National Institutes of Health).
>
> **Author affiliations:** Naylor Dana Institute for Disease Prevention, American Health Foundation.

1980s

Watt J and Marcus R (1980) "Potential hazards of carrageenan." The Lancet 315(8168): 602-603.

> **Letter to The Lancet:** Leading carrageenan researchers R. Marcus and James Watt publish two letters in The Lancet, titled "Danger of Carrageenan in Foods" and "Potential Hazards of Carrageenan," pointing out health concerns with the consumption of carrageenan. Highly respected, The Lancet is one of the world's leading medical journals.

Watt J and Marcus R (1981) "Harmful effects of carrageenan fed to animals." Cancer Detection and Prevention 4(1-4): 129-34.

> **Review article:** The authors reviewed the scientific literature and found "an increased number of reports … describing harmful effects of degraded and undegraded carrageenan supplied to several animal species in their diet or drinking fluid."
>
> "Harmful effects [of food-grade carrageenan] are almost certainly associated with its degradation during passage through the gastrointestinal tract. There is need for extreme caution in the use of carrageenan or carrageenan-like products as food additives in our diet."

Watt J and Marcus R. (1981) "Danger of carrageenan in foods and slimming recipes." The Lancet 317(8215): 338.

> **Letter to The Lancet:** Scientists repeat their concern with the use of carrageenan in food in a letter to *The Lancet*.

Thomson AW & Fowler EF. (1981) "Carrageenan: a review of its effects on the immune system." Agents and Actions, 11:265–273. https://link.springer.com/article/10.1007/BF01967625

> **Summary of findings:** Carrageenans (kappa, lambda and iota) can markedly suppress immune responses both in vivo and in vitro. The mechanism responsible for carrageenan-induced immune suppression is believed to be its selective cytopathic effect on

macrophages. This property of carrageenan has led to its adoption as a tool for analyzing the role of these cells in the induction and expression of immune reactivity.

Author affiliations: Department of Pathology, University of Aberdeen (Aberdeen, Scotland, UK) and the Department of Histopathology, St Bartholomew's Hospital (London, UK).

Arakawe S, Okumua M, Yamada S, Ito M, Tejima S. (1986) "Enhancing effect of carrageenan on the induction of rat colonic tumors by 1,2-dimethylhydrazine and its relation to ß-glucuronidase activities in feces and other tissues." Journal of Nutritional Science and Vitaminology 32:481–485.

Summary of findings: This study found higher rates of tumors in rats fed undegraded carrageenan in the diet.

Author affiliations: Nagoya City University (Nagoya, Japan).

Nicklin S and Miller K (1984) "Effect of orally administered food-grade carrageenans on antibody-mediated and cell-mediated immunity in the inbred rat." Food and Chemical Toxicology 22:615–621.

Summary of findings: Researchers using undegraded carrageenan administered in the drinking water of rats showed that carrageenan penetrates the intestinal barrier.

Author affiliations: The British Industrial Biological Research Association, a privately-owned consulting firm.

Calvert RJ and Reicks M (1988) "Alterations in colonic thymidine kinase enzyme activity induced by consumption of various dietary fibers." Proceedings of the Society for Experimental Biology and Medicine 189:45–51.

Summary of findings: Researchers examined the reported effects of various dietary fibers on chemically induced colon carcinogenesis in rats. This study found a four-fold increase in thymidine kinase activity (a measure for malignant disease) in colonic mucosa following exposure to food-grade carrageenan. No differences were found following exposure to guar gum (a food additive often used as an alternative to carrageenan).

Funding: Food and Drug Administration.

Author affiliations: Food and Drug Administration.

1990s

Weiner M. (1991) "Toxicological properties of carrageenan." Agents and Actions 32(1-2): 46-51.

Summary of findings: *C*arrageenan is safe based on the author's review of various animal feeding studies.

Author affiliation: FMC Corporation (a chemical corporation and leading carrageenan manufacturer).

Wilcox DK, Higgins J, Bertram TA. (1992) "Colonic epithelial cell proliferation in a rat model of nongenotoxin-induced colonic neoplasia." Laboratory Investigation 67:405–411.

Summary of findings: This study shows an association between loss of epithelial cells (the cell membranes in the intestine) and the consumption of both undegraded and degraded carrageenan.

Funding: Proctor & Gamble Company.

Author affiliations: Proctor & Gamble Company.

Capron I, Yvon M, Muller G. (1996) "In-vitro gastric stability of carrageenan." Food Hydrocolloids, 10(2):293–244.

Summary of findings: This study analyzed the rate of degradation in an artificial stomach which simulated realistic conditions for human digestion, wherein the pH gradually decreases from 5 to 1.5 over 3 hours prior to gastric emptying. The findings showed that, under the most unfavorable conditions of gastric digestion (slow emptying rate and rapid acidification), about 10" of the carrageenan had a molecular weight of less than 100 kDa.

Funding: Proctor & Gamble Company.

Author affiliations: Proctor & Gamble Company.

Corpet DE, Taché S, and Préclaire M. (1997) "Carrageenan given as a jelly does not initiate, but promotes the growth of aberrant crypt foci in the rat colon." Cancer Letters 114:53–55.

Summary of findings: Consumption of food-grade carrageenan promotes the growth of aberrant crypt foci in the rat colon. Aberrant crypt foci are abnormal glands in the colon that are precursors to polyps and are one of the earliest changes seen in the colon that may lead to cancer.

Author affiliations: French National Institute of Agronomic Research (Toulouse, France).

Tobacman JK. (1997) "Filament disassembly and loss of mammary myoepithelial cells after exposure to lambda-carrageenan." Cancer Research 57:2823-2826.

Summary of findings: Mammary myoepithelial cells exposed to lambda-carrageenan at rates as low as 0.00014% exhibited disruption of the internal cellular architecture and cell death. Destruction of these cells in tissue culture by a low concentration of a widely used food additive suggests a dietary mechanism for mammary carcinogenesis not considered previously.

Author affiliations: Department of Internal Medicine, College of Medicine, The University of Iowa (Iowa City, Iowa).

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). (2018) "Re-evaluation of carrageenan (E 407) and processed Eucheuma seaweed (E 407a) as food additives." EFSA J., 16(4): e05238. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7009739/

Summary of findings: Authors concluded that taking into account the lack of adequate data to address uncertainties in health data, the existing group acceptable daily intake for carrageenan and processed Eucheuma seaweed of 75 mg/kg bw per day should be considered temporary.

Author affiliations: European Food Safety Authority (EFSA).

2000s

Suzuki J, Na HK, Upham BL, Chang CC and Trosko JE. (2000) "Lambda-carrageenan-induced inhibition of gap-junctional intercellular communication in rat liver epithelial cells." Nutrition and Cancer 36(1): 122-8.

Summary of findings: This study aimed to better understand the role of food-grade carrageenan in carcinogenesis. The experiments in this study were designed to test the hypothesis that carrageenan might function as a tumor-promoting chemical by inhibiting GJIC (Gap-junctional intercellular communication is believed to help healthy cells fight cancer). The data revealed inhibition of GJIC by carrageenan similar to that by the well-documented tumor promoter phorbol ester.

Author affiliations: Michigan State University (East Lansing, Michigan).

Tobacman JK (2001) "Review of Harmful Gastrointestinal Effects of Carrageenan in Animal Experiments." Environmental Health Perspectives 109(10): 983-994.

Review summary: This study examined existing research done to date (2001). The author concluded: "Because of the acknowledged carcinogenic properties of degraded carrageenan in animal models, and the cancer-promoting effects of undegraded carrageenan in experimental models, the widespread use of carrageenan in the Western diet should be reconsidered."

Author affiliation: University of Iowa, College of Medicine, The University of Iowa (Iowa City, Iowa).

Hagiwara A, Miyashita K, Nakanishi T, Sano M, Tamano S, Asai I, Nakamura M, Imaida K, Ito N and Shirai T. (2001) "Lack of Tumor Promoting Effects of Carrageenan on 1,2-Dimethylhydrazine-induced Colorectal Carcinogenesis in Male F344 Rats." Journal of Toxicologic Pathology 14; 37.

> **Summary of findings:** This study found no statistically significant increases in malignant tumors in rats given food-grade carrageenan in the diet. The study was terminated as higher rates of tumors in the carrageenan group were detected. The rats were killed after 90 days (a rat's natural lifespan is 2 years). When the study was terminated, tumor rates were higher, but not yet high enough to be statistically significant.
>
> **Author affiliations:** Nagoya City University, Daiyukai Institute for Medical Science and San-Ei Gen FFI, Inc. One of the authors has a work history with SanEi Gen FFI, Inc., a Japanese carrageenan manufacturer.

Uno Y, Omoto T, Goto Y, Asai I, Nakamura M and Maitani T. (2001) "Molecular weight distribution of carrageenans studies by a combined gel permeation/inductively coupled plasma (GPC/ICP) method." Food Additives and Contaminants 18: 763-772.

> **Summary of findings:** The study measured the molecular weight of 29 samples of food-grade carrageenan and concluded that no sample had a significant level of degraded carrageenan. The detection limit was 5%. However, the lowest average molecular weight detected over the three days was 718 kDa, indicating that some degradation of the carrageenan did occur
>
> **Author affiliations:** San-Ei Gen FFI, Inc, a Japanese food additive manufacturer. In addition to carrageenan, San-Ei Gen FFI manufactures flavors, colors, preservatives and the artificial sweetener sucralose.

Cohen SM and Ito N. (2002) "A critical review of the toxicological effects of carrageenan and processed euchema seaweed on the gastrointestinal tract." Critical Reviews in Toxicology 32(5): 413-44.

> **Summary of findings:** The authors of this review criticized research studies pointing to gastrointestinal harm from consuming carrageenan. The authors conclude that "there is no credible evidence supporting a carcinogenic effect or a tumor-promoting effect on the colon in rodents."
>
> **Author affiliations:** Department of Pathology/Microbiology, University of Nebraska Medical Center (Omaha, Nebraska) and Nagoya City University Medical School (Japan). The authors have ties to the carrageenan industry.

Weiner M, Nuber D, Blakemore WR, Harriman JF and Cohen SM. (2007) "A 90-day dietary study on kappa-carrageenan with emphasis on the gastrointestinal tract." Food and Chemical Toxicology 45(1): 98-106.

> **Summary of findings:** The study found no clinical signs in rats fed high doses of food-grade carrageenan with up to 12% degraded carrageenan, other than soft stool. The authors reported that the gastrointestinal tract "appeared normal," even in the rats given high doses of carrageenan in the diet.
>
> **Funding:** FMC Corporation (a leading carrageenan manufacturer).
>
> **Author affiliations:** FMC Corporation. In addition to manufacturing carrageenan, FMC Corporation produces pesticides and industrial chemicals.

Borthakur A, Bhattacharyya S, Dudeja PK and Tobacman JK (2007) Carrageenan induces interleukin-8 production through distinct Bcl10 pathway in normal human colonic epithelial cells. American Journal of Physiology, Gastrointestinal and Liver Physiology 292(3): G829-38.

> **Summary of findings:** Exposure of human colonic epithelial cells in tissue culture to small quantities of undegraded (food-grade) carrageenan produced inflammation by a second pathway of reactive oxygen species, as well as by the innate immune pathway.
>
> **Funding:** Department of Veterans Affairs; National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.
>
> **Author affiliations:** University of Illinois and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Bhattacharyya S, Borthakus A, Dudeja PK and Tobacman JK (2007) Carrageenan reduces bone morphogenetic protein-4 (BMP4) and activates the Wnt/beta-catenin pathway in normal human colonocytes. Digestive Diseases and Sciences 52(10): 2766-74.

> **Summary of findings:** This study identified mechanisms by which food-grade carrageenan influences the development of human intestinal polyps. Untreated intestinal polyps can develop into colon cancer.
>
> **Funding:** National Institutes of Health.
>
> **Author affiliations:** University of Illinois at Chicago (Chicago, Illinois).

Tobacman JK, Bhattacharyya S, Borthakur A, Dudeja PK. (2008) "The carrageenan diet: not recommended." Science 321(5892):1040-1041.

NOTE: This research was cited in the Handling Subcommittee summary review.

Summary of findings: Concluded that efforts at cultivation of carrageenan-producing seaweed have demonstrated how a "natural product" can produce harmful effects to the marine environment; similarly, harmful effects to humans may be attributable to carrageenan exposure.

Author affiliations: Department of Medicine, University of Illinois (Chicago, Illinois).

Bhattacharyya S, Dudeja PK and Tobacman JK (2008) "Carrageenan-induced NFkappaB activation depends on distinct pathways mediated by reactive oxygen species and Hsp27 or by Bcl10." Biochimica and Biophysica Acta 1780(7-8): 973-82.

Summary of findings: Exposure to human colonic epithelial cells in tissue culture to small quantities of food-grade carrageenan produced inflammatory responses.

Funding: National Institutes of Health

Author affiliations: University of Illinois (Chicago, Illinois).

Bhattacharyya S, Borthakur A, Dudeja PK and Tobacman JK (2008) "Carrageenan induces cell cycle arrest in human intestinal epithelial cells in vitro." Journal of Nutrition 138(3): 469-75.

Summary of findings: Exposure of human colonic epithelial cells in tissue culture to small quantities of undegraded (food-grade) carrageenan produced an increase in cell death with cell cycle arrest, effects that can contribute to ulcerations.

Funding: National Institutes of Health

Author affiliations: University of Illinois at Chicago and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Bhattacharyya S, Gill R, Chen ML, Zhang F, Linhardt RJ, Dudeja PK and Tobacman JK (2008) "Toll-like receptor 4 mediates induction of the Bcl10-NFkappaB-interleukin-8 inflammatory pathway by carrageenanin human intestinal epithelial cells." Journal of Biological Chemistry 283(16): 10550-8.

Summary of findings: Exposure of human colonic epithelial cells in tissue culture to small quantities of food-grade carrageenan was associated with changes in molecular signaling pathways that resemble the changes found in human colonic polyps. Untreated polyps can develop into colon cancer.

Funding: National Institutes of Health; Veterans Administration.

Author affiliations: University of Illinois (Chicago, Illinois); Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois); and, Rensselaer Polytechnic Institute (Troy, New York).

Bhattacharyya S, Borthakur A, Tyagi S, Gill R, Chen ML, Dudeja PK, Tobacman JK (2010) "B-cell CLL/lymphoma 10 (BCL10) is required for NF-kappaB production by both canonical and noncanonical pathways and for NF-kappaB-inducing kinase (NIK) phosphorylation." Journal of Biological Chemistry. 1;285(1):522-30.

Summary of findings: Carrageenan stimulates innate immune-mediated pathways of inflammation.

Funding: National Institutes of Health; Veterans Administration

Author affiliations: University of Illinois (Chicago, Illinois).

Bhattacharyya S, Liu H, Zhang F, Jam M, Dudeja PK, Michel G, Linhardt RJ, and Tobacman JK (2010) "Carrageenan-induced innate immune response is modified by enzymes that hydrolyze distinct galactosidic bonds." Journal of Nutritional Biochemistry 21(10): 906-13.

Summary of findings: This study examines the immune response by which food-grade carrageenan causes inflammation.

Funding: Veterans Administration

Author affiliations: University of Illinois (Chicago, Illinois); Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois); Rensselaer Polytechnic Institute (Troy, New York); University Pierre and Marie Currie/Sorbonne University (Paris, France).

Bhattacharyya S, Dudeja PK and Tobacman JK (2010) Tumor necrosis factor alpha-induced inflammation is increased but apoptosis is inhibited by common food additive carrageenan. Journal of Biological Chemistry 285(50): 39511-22.

Summary of findings: This study examines the particular mechanisms by which food-grade carrageenan cause inflammation.

Funding: Veterans Administration

Author affiliations: University of Illinois (Chicago, Illinois) and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Borthakur A, Bhattacharyya S, Anbazhagan AN, Kumar A, Dudeja PK and Tobacman JK (2012) "Prolongation of carrageenan-induced inflammation in human colonic epithelial cells by activation of an NFκB-BCL10 loop." Biochimica and Biophysica Acta 1822(8): 1300-7.

Summary of findings: Inflammation of the colon caused by exposure to low levels of food-grade carrageenan persists beyond the initial period of exposure.

Funding: National Institutes of Health

Author affiliations: University of Illinois (Chicago, Illinois).

Yang B, Bhattacharyya S, Linhardt R and Tobacman JK (2012) "Exposure to common food additive carrageenan leads to reduced sulfatase activity and increase in sulfated glycosaminoglycans in human epithelial cells." Biochimie 94(6): 1309-16. https://pubmed.ncbi.nlm.nih.gov/22410212/

Summary of findings: Exposure to small amounts of food-grade carrageenan reduces the activity of sulfatase enzymes, which are critical for many vital cellular processes.

Funding: National Institute of General Medical Sciences, National Institutes of Health.

Author affiliations: University of Illinois (Chicago, Illinois); Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois); Rensselaer Polytechnic Institute (Troy, New York).

Bhattacharyya S, O-Sullivan I, Katyal S, Unterman T and Tobacman JK (2012) "Exposure to the common food additive carrageenan leads to glucose intolerance, insulin resistance and inhibition of insulin signaling in HepG2 cells and C57BL/6J mice." Diabetologia 55(1): 194-203. https://pubmed.ncbi.nlm.nih.gov/22011715/

Summary of findings: Carrageenan in the diet may contribute to diabetes. Carrageenan impairs glucose tolerance, increases insulin resistance, and inhibits insulin signaling in vivo in mouse liver and human HepG2 cells. These effects may result from carrageenan-induced inflammation.

Funding: National Institutes of Health and American Diabetes Association.

Author affiliations: University of Illinois (Chicago, Illinois).

Bhattacharyya S, Feferman L, and Tobacman JK (2014) "Increased Expression of Colonic Wnt9A through Sp1-mediated Transcriptional Effects involving Arylsulfatase B, Chondroitin 4-Sulfate, and Galectin-3." The Journal of Biological Chemistry 289(25): 17564-17575.

Summary of findings: Mechanism by which Wnt expression was increased by carrageenan exposure was unknown. This study showed that Sp1 activated Wnt9A transcription through changes in arylsulfatase B, chondroitin 4-sulfation, and galectin-3.

In conclusion, a decline in arylsulfatase B leads to transcriptional effects mediated by Sp1 and galectin-3. The significance is that extracellular events can regulate transcription through changes in arylsulfatase B and chondroitin 4-sulfation.

Author affiliations: University of Illinois (Chicago, Illinois) and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Bhattacharyya S, Feferman L, Borthakur S and Tobacman JK (2014) "Common Food Additive Carrageenan Stimulates Wnt/β-Catenin Signaling in Colonic Epithelium by Inhibition of Nucleoredoxin Reduction." Nutrition and Cancer 66(1): 117-127.

Summary of findings: Exposure to carrageenan may be a risk factor in development of colorectal cancer. The findings indicate that environmental exposure stimulates both Wnt signaling and suggest that carrageenan exposure in vivo may contribute to development of colonic neoplasia (uncontrolled growth of cells). Average daily intake of carrageenan in the U.S. in the 1970s was calculated to be 108 mg by the National Academy of Sciences, but recently the average daily carrageenan intake was reported to be ~250 mg/day. Increased attention to the effects of carrageenan on vital cell processes, including the Wnt/β-catenin pathway, may lead to significant clinical benefit, as well as increased understanding of relationships between environmental exposures and human disease.

Funding: Veterans Affairs Merit Award.

Author affiliations: University of Illinois (Chicago, Illinois) and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Bhattacharyya S, Feferman L, and Tobacman JK (2014) "Regulation of Chondroitin-4-Sulfotransferase (CHST11) Expression by Opposing Effects of Arylsulfatase Bon BMP4 and Wnt9A." Biochim Biophys Acta 1849(3): 342-352.

Summary of findings: Exposure to the common food additive carrageenan, which reduces ARSB activity, reduced expression of bone morphogenetic protein (BMP)-4 in colonic epithelium and increased Wnt9A expression and Wnt/β-catenin signaling.

Funding: University of Illinois (Chicago, Illinois).

Author affiliations: Department of Medicine, University of Illinois (Chicago, Illinois).

Jung TW, Lee SY, Hong HC, Choi HY, Yoo JH, Baik SH, and Choi KM (2014) "AMPK activator-mediated inhibition of endoplasmic reticulum stress ameliorates carrageenan-induced insulin resistance through the suppression of selenoprotein P in HepG2 hepatocytes." Molecular and Cellular Endocrinology 382(1):66-73.

Summary of findings: Carrageenan causes inflammation through toll-like receptor 4, which plays an important role in insulin resistance and type 2 diabetes mellitus. Carrageenan induces endoplasmic reticulum (ER) stress in a time- and dose-dependent manner. ER stress plays a crucial role in selenoprotein P regulation. Salsalate relieves ER stress and is a new therapeutic strategy to treat insulin resistance.

Author affiliations: Division of Endocrinology and Metabolism, Department of Internal Medicine, Korea University Guro Hospital

Bhatacharyya S, Feferman L, Unterman T, and Tobacman JK (2015) "Exposure to common food additive carrageenan alone leads to fasting hyperglycemia and in combination with high fat diet exacerbates glucose intolerance and hyperlipidemia without effect on weight." Journal of Diabetes Research Volume 2015, Article ID 513429.

> **Summary of findings:** Mice exposed to 10mg/L food grade lambda and kappa carrageenan in drinking water and fed an 8% fat diet for 1 year showed glucose intolerance after 6 days and earlier onset of fasting hyperglycemia, higher glucose levels, and exacerbated dyslipidemia compared with the control. This suggests that carrageenan exposure may exacerbate harmful effects of a high fat diet and contribute to development of diabetes.
>
> **Author affiliations:** Department of Medicine, University of Illinois (Chicago, Illinois).

Bhattacharyya S, Feferman L, and Tobacman JK (2015) "Carrageenan inhibits insulin signaling through GRB10-mediated Decrease in Tyr(p)- ISR1 and through Inflammation-induced Increase in Ser(P)307-IRS1." Journal of Biological Chemistry 290(17): 10764-10774.
https://pubmed.ncbi.nlm.nih.gov/25883986/

> **Summary of findings:** Inflammation induced by exposure to the common food additive carrageenan leads to insulin resistance by increase in Ser(P) (307)-insulin receptor substrate 1 (IRS1) and subsequent decline in the insulin-stimulated increase in Ser(P)(473)-AKT. Studies were performed in human HepG2 cells and in C57BL/6J mice. and indicate that carrageenan inhibited insulin signaling by two mechanisms. These mechanisms provide internal feedback, mediated by Ser(P)(473)-AKT, Ser(P)(401)-GATA2, and nuclear GATA2, which modulates insulin responsiveness.
>
> **Author affiliations:** University of Illinois (Chicago, Illinois) and Jesse Brown Veterans Affairs Medical Center (Chicago, Illinois).

Tobacman JK (2015) "The Common Food Additive Carrageenan and the alpha-gal epitope." Journal of Allergy and Clinical Immunology 136(6): 1708-9.
https://pubmed.ncbi.nlm.nih.gov/26518095/

> **Summary of findings:** Antibodies to the oligosaccharide epitope galactose-a-1,3-galactose (alpha-gal) are of considerable interest because they are so prevalent, include all isotypes, and are specific to humans and Old World apes. Alpha-gal–mediated responses, including immediate and delayed anaphylaxis, appear to be increasing. In the recent review ''The alpha-gal story: lessons learned from connecting the dots,'' sources of exposure to the alpha-gal epitope were presented, with particular attention to cetuximab, mammalian meat products, and tick bites. This communication is intended to bring attention to including carrageenan, a very commonly used food additive, to the list of sources of exposure to the alpha-gal epitope.
>
> **Author affiliations:** Department of Medicine, University of Illinois (Chicago, Illinois).

Coleman MT. (2015) "Dairy-free" dietary substitute, abdominal pain, and weight loss." Clinical Medical Reviews and Case Reports 2:8. https://clinmedjournals.org/articles/cmrcr/clinical-medical-reviews-and-case-reports-cmrcr-2-079.pdf

> **Summary of findings:** Elimination of carrageenan containing almond milk from the diet of a patient that had substituted it for cow's milk several months prior resulted in stabilization of weight and resolution of abdominal pain. Certain food substitutions for dairy products may expose patients to additives like carrageenan, for which there is evidence of its contribution to gastrointestinal disturbances. Considering an etiology for gastrointestinal symptoms brought on by dietary additives in the diagnostic differential gives the practitioner avenues to pursue prior to ordering expensive testing and treatments.
>
> **Author affiliations:** Louisiana State University School of Medicine (New Orleans, Louisiana).

Weiner, M. (2016) "Parameters and pitfalls to consider in the conduct of food additive research, Carrageenan as a case study." Food and Chemical Toxicology, 87: 31-44. https://pubmed.ncbi.nlm.nih.gov/26615870/

> **Summary of findings:** FMC Corporation announced that this analysis found significant weaknesses in food additive research, using carrageenan as a primary example.
>
> **Funding:** FMC Corporation, an agricultural sciences company and stakeholder in the carrageenan industry.
>
> **Author affiliations:** Dr. Myra L. Weiner, is the owner and president of TOXpertise, LLC, a firm that consults for the carrageenan industry.

Weiner M, McKim J, and Blakemore W. "Addendum to Weiner, M.L. (2016) "Parameters and Pitfalls to Consider in the Conduct of Food Additive Research, Carrageenan as a Case Study." Food Chemical Toxicology 87, 31-44. https://pubmed.ncbi.nlm.nih.gov/28651808/

> **Summary:** This paper is an addendum to a 2016 paper outlining pitfalls and parameters to consider in the conduct of food additive research with carrageenan.
>
> **Author affiliations:** TOXpertise, LLC; IONTOX, LLC; and Celtic Colloids, Inc. As previously noted, all of these are associated with the carrageenan industry.

McKim Jr JM, Heidi Baas, Rice G, Willoughby Sr J, Weiner M, Blakemore W. (2016) "Effects of carrageenan on cell permeability, cytotoxicity, and cytokine gene expression in human intestinal and hepatic cell lines." Food and Chemical Toxicology, 96: 1-10. https://www.sciencedirect.com/science/article/pii/S0278691516302265

Summary of findings: Three common forms of the food additive carrageenan were tested in vitro cell lines, looking for permeability, cytotoxicity, and induction of cytokines. Carrageenan was negative in all endpoints evaluated.

Author affiliations: All the authors hail from businesses and consultants associated with carrageenan manufactures. The specific affiliations include: IONTOX, LLC; Cyprotex; TOXpertise, LLC; Celtic Colloids, Inc. Dr. Myra L. Weiner, is the owner and president of TOXpertise, LLC, a firm that consults for the carrageenan industry.

Tavassoli-Kafrani E, Shekarchizadeh H, Masoudpour-Behabadi M. (2016) "Development of edible films and coatings from alginates and carrageenans." Carbohydrate Polymers, 137: 360-374. https://www.sciencedirect.com/science/article/abs/pii/S0144861715010541

Summary of review: This review highlights production and characteristics of carrageenan and alginate as sources of film-forming materials. Water-soluble hydrocolloids like polysaccharides usually impart better mechanical properties to edible films and coatings than do hydrophobic substances. They also are excellent barriers to oxygen and carbon dioxide making them useful in extending shelf lives.

Author affiliations: Department of Food Science and Technology, College of Agriculture, Isfahan University of Technology (Isfahan, Iran).

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Sumit Bhattacharyya, et al. (2017) "A Randomized Trial of the Effects of the No-carrageenan Diet on Ulcerative Colitis Disease Activity." 181 – 192. DOI: 10.3233/NHA-170023. https://content.iospress.com/articles/nutrition-and-healthy-aging/nha170023

Summary of findings: A randomized, double-blind, placebo-controlled, multicenter, clinical trial published in 2017 showed that people with colitis should avoid carrageenan. Patients who received carrageenan-containing capsules relapsed, and none of the patients who received placebo-containing capsules relapsed in their colitis disease. Laboratory tests showed increases in inflammatory biomarkers in those trial participants who received carrageenan.

Author affiliations: Department of Medicine, University of Illinois (Chicago, Illinois); Jesse Brown VA Medical Center (Chicago, Illinois); Department of Medicine, University of Chicago, (Chicago, Illinois); Division of Epidemiology and Biostatistics, University of Illinois at Chicago, (Chicago, Illinois) and Faculty of Health Sciences, Simon Fraser University (Burnaby, BC, Canada); Department of Kinesiology and Nutrition, University of Illinois at Chicago, (Chicago, Illinois).

John Vincent Martino, Johan Van Limbergen1, and Leah E. Cahill. (2017) "The Role of Carrageenan and Carboxymethylcellulose in the Development of Intestinal Inflammation."

Front. Pediatr., 1(5):96. doi:10.3389/fped.2017.00096.
https://pubmed.ncbi.nlm.nih.gov/28507982/

> **Summary of findings:** Research found that carrageenan may trigger or magnify an inflammatory response in the human intestine. The researchers determined that more study was needed because it seemed consumption of carrageenan was a risk factor, but did not seem to be the sole cause involved in the development of IBD or in disease recurrence after treatment. The researchers also highlighted the prevalence of carrageenan in pediatric diets as a cause for concern.
>
> **Author affiliations:** Pediatric Gastroenterology, Hepatology and Nutrition, IWK Health Centre, (Halifax, NS, Canada); Medicine, Dalhousie University (Halifax, NS, Canada); and Department of Nutrition at the Harvard T.H. Chan School of Public Health (Boston, Massachusetts).

Bixler, HJ. (2017) "The carrageenan controversy." Journal of Applied Phycology, 29:2201–2207. https://link.springer.com/article/10.1007/s10811-017-1132-4

NOTE: This paper was cited in the subcommittee summary review.

> **Summary of article:** (NOTE this is not a research paper) The article describes how the negative attitude toward carrageenan evolved, stating it came from research from a group at the University of Illinois who claim that carrageenan upregulates inflammatory genes of the intestinal epithelium. There is no evidence that this in vitro model applies in vivo and a growing body of research is showing it does not. Nevertheless, it was picked up by various bloggers feeding on contradictory issues and quickly went viral. This paper describes the evolution of the "carrageenan controversy" and provides information for food producers and consumers on new more robust studies confirming that it is safe to consume foods containing carrageenan. This article also presents actions being taken by carrageenan producers and users, to reduce the noise in the public domain from the controversy.
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> **Author affiliations:** Ingredients Solutions, Inc, a carrageenan supplier. The company calls themselves "The World's Largest Independent Supplier of Carrageenan" and is a world leader in the development, design and marketing of Specialty Hydrocolloids.

Shlomit D, et al. (2019) "Revisiting the carrageenan controversy: do we really understand the digestive fate and safety of carrageenan in our foods?" Food Funct., 10, 1763. DOI: 10.1039/C9FO00018F.
https://pubs.rsc.org/en/content/articlelanding/fo/2018/c7fo01721a#!divAbstract

> **Summary of findings:** A review of carrageenan safety research in 2019 came to three conclusions. First, they concluded that there isn't enough information about current consumption rates. Second, the link between carrageenan's properties, its impact on digestion, and the colon microbiome and inflammation are yet to be fully resolved. Third, there is not enough research on carrageenan's effect on predisposed populations, such as

elderly people or IBD patients. The review of the existing concluded carrageenan has not been definitively determined as "safe" and more research needs to be done.

Author affiliations: Laboratory of Chemistry of Foods and Bioactives, Department of Biotechnology and Food Engineering, Technion, Israel Institute of Technology (Haifa, Israel).

Myra L. Weiner and James M. McKim, Jr. (2019) "Comment on 'Revisiting the carrageenan controversy: do we really understand the digestive fate and safety of carrageenan in our foods?' by S. David, C. S. Levi, L. Fahoum, Y. Ungar, E. G. Meyron-Holtz, A. Shpigelman and U. Lesmes, Food Funct., 2018, 9, 1344–1352.
https://pubs.rsc.org/en/content/articlelanding/2019/fo/c8fo01282b

Summary: This piece is a *comment* rather than research or review. The comment is critical of the above paper.

Author Affiliations: TOXpertise, LLC and IONTOX, LLC. Both TOXpertise and IONTOX provide professional consulting services in the field of toxicology, and both businesses are known to be hired as consultants for the carrageenan industry. Note the previous "reviews" in this listing, including the same author (Weiner, M), that were critical of carrageenan research done through non-industry sources.

Ye Mi Y, et al. (2020) "Native κ-carrageenan induced-colitis is related to host intestinal microecology." International Journal of Biological Macromolecules, 147: 284-294. DOI: 10.1016/j.ijbiomac.2020.01.072.
https://www.sciencedirect.com/science/article/abs/pii/S0141813019390828

Summary of findings: Research into inflammation and carrageenan in 2020 found that inflammatory properties of carrageenan are related to carrageenan's modification of the intestinal microbiome. In addition, researchers found that carrageenan can exacerbate chronic inflammation (which could explain why people with existing chronic conditions improve with a carrageenan-free diet).

Author affiliations: Human Health Research Laboratory, College of Food Science and Engineering, Ocean University of China (Qingdao, China); Institute of Ocean and Earth Sciences, University of Malaya (Kuala Lumpur, Malaysia).

Bhat, Mugdha & Sharma, Ashwani & n rao, Nagashree & Biotechnology, B. (2020). "Carrageenan-based edible biodegradable food packaging: A review." Journal of Food Science and Nutrition. 5. 69-75. https://www.researchgate.net/publication/344016334_Carrageenan-based_edible_biodegradable_food_packaging_A_review

Summary of review: This review summarizes food packaging and edible food film uses for carrageenan. Edible coatings consist of a layer of the carrageenan polysaccharide that

is sprayed, dipped, or spread over the surface of certain fruits and produce to extend shelf life.

Author affiliations: Rashtreeya Vidyalaya College of Engineering (Bengaluru, Karnataka, India).

de Lima Barizão C, et al. (2020) "Biodegradable films based on commercial κ-carrageenan and cassava starch to achieve low production costs." International Journal of Biological Macromolecules, 165 (Part A): 582-590. ISSN 0141-8130.
https://www.sciencedirect.com/science/article/abs/pii/S0141813020345098

Summary of findings: Biodegradable films were produced by casting commercials kappa-carrageenan (κ-car) and cassava starch at different κ-carrageenan/cassava starch weight ratios. Physical, thermal, and mechanical properties were evaluated.

Author affiliations: Laboratory of Materials, Macromolecules, and Composites (LaMMAC), Federal University of Technology – Paraná (UTFPR), (Apucarana, Brazil); Analitycal Applied in Lipids, Sterols, and Antioxidants (APLE-A), State University of Maringá (UEM), Colombo avenue, (Maringá, Brazil); Group of Polymeric Materials and Composites (GMPC), Department of Chemistry, State University of Maringá (UEM), (Maringá, Brazil).

Zhou J, et al. (2021) "Long-term kappa-carrageenan consumption leads to moderate metabolic disorder by blocking insulin binding." Pharmacological Research, 165: 105417.
https://www.sciencedirect.com/science/article/abs/pii/S1043661820317254

Summary of findings: The purpose of this study was to investigate the impact of κ-carrageenan (CGN) on glucose intolerance and insulin resistance from the perspective that κ-CGN may interfere with insulin receptor function and affect insulin sensitivity and signaling, thereby leading to body weight loss. The study concluded that κ-CGN reduced weight gain without affecting food intake, but impaired glucose metabolism in mice by interfering with insulin binding to receptors, causing non-diabetic weight gain reduction due to metabolic disorder.

Author affiliations: State Key Laboratory for Managing Biotic and Chemical Threats to the Quality and Safety of Agro-Products, Ningbo University, (Ningbo, Zhejiang, China); Department of Laboratory Medicine, Ningbo Medical Center Lihuili Hospital, (Ningbo, Zhejiang, China); Department of Laboratory Medicine, Taipei Medical University Ningbo Medical Center, (Ningbo, Zhejiang, China).

Fang Liu, et al. (2021) "Food-grade carrageenans and their implications in health and disease." Comprehensive Reviews in Food Science and Food Safety 20(1).
https://onlinelibrary.wiley.com/doi/full/10.1111/1541-4337.12790

Summary of findings: This research reviewed the molecular mechanisms by which carrageenans exert their biological effects and examined the interactions between carrageenans and the gut microbiome in the pathogenesis of gastrointestinal disorders. This review argues for personalized guidance on carrageenan intake based on individuals' health status. Future research efforts that aim to close the knowledge gap on the effect of low-dose and chronic carrageenan intake as well as interactions among food additives should be conducive to the improved safety profile of carrageenans in processed food products.

Author affiliations: College of Food Science and Engineering, Ocean University of China (Qingdao, China); Affiliated Hospital of Qingdao Binhai University, Qingdao, China; Laboratory of Marine Drugs and Biological Products, Pilot National Laboratory for Marine Science and Technology (Qingdao, China); USDA-ARS Animal Genomics and Improvement Laboratory (Beltsville, Maryland).

Ali AJ, Abdulla HI, Al-Nimer MS. (2021) "The Pharmacological Effects of Kappa Carrageenan on Different Human Cell Lines and Genomic DNA: An in vitro study." Iraqi J Pharm Sci, Vol 30:1. https://bijps.uobaghdad.edu.iq/index.php/bijps/article/view/1229

Summary of findings: Kappa-carrageenan inhibited the cancer cell growth and fibroblast cell lines growth (in vitro) experimental model. The carrageenan solution completely and significantly damaged the DNA molecule bin the research. This study shows that the k-carrageenan pharmaceutical preparations exert biological activities as anticancer in vitro studies. The authors reference how carrageenan's properties lead it to be commonly used in the oral healthcare products and cosmetics.

Author affiliations: International Association for Dental Research (Alexandria, Virginia); Hawler Mediacl University (Erbil, Iraq).