Sea moss has recently seen increasing popularity for use in "healthy" smoothie beverages, with some products formulated with sea moss appearing to be a major ingredient. Despite the unpermitted vendors selling in various local venues, there are several safety concerns associated with sea moss (*Chondrus crispus*) that require specific controls to ensure the safety of consumers. The production process requires regulatory approval, and the producer must operate from a commercial kitchen under a Retail Food Establishment permit.

## Here are the safety concerns:

- 1. The spores of *Clostridium botulinum* are present in the marine environment and may be present on the product. These bacteria, often referred to as "**C. bot**.", produce the toxin that causes botulism poisoning. In producing the sea moss gel, growth and toxin formation by C. bot. must be controlled by one of two methods:
  - Use of a scientifically backed cooking process to destroy the spores and bacteria, or
  - b. Acidification of the product to a pH of 4.6 or lower to prevent growth and toxin formation by any C. bot that may be present.

A written procedure must be submitted to the regulatory authority for approval of the production process using one of the two options above as the safety control. The "Fish and Fishery Products Hazards and Controls Guidance," March 2020 includes validated guidance on cooking processes for destruction of the spores of C. bot. If the product will be acidified, an initial product assessment for pH must be obtained from a recognized Process Authority. That report must be provided to the regulatory authority as one requirement for approval of the production process. The retail producer will be required to do their own pH testing of each process batch, and must maintain batch production records that include the pH test results for each batch.

- 2. The supplier of raw sea moss must harvest from an area free from contaminants such as heavy metals, agricultural or industrial chemicals and microorganisms associated with septic waste, which are commonly associated with runoff water from populated and industrial areas. An approved harvester/producer of the sea moss must be able to provide a letter to the retail establishment attesting that their harvesting practices meet this requirement. This letter must be made available to retail food inspectors, and a copy of the letter must be supplied to the regulatory authority as another requirement for approval of the production process.
- 3. Sea moss and seaweed are natural sources of iodine. Maximum serving sizes must consider the maximum daily allowance of dietary iodine. The concentration of iodine in the sea moss gel will depend on factors such as the local source of the raw material as well as the processing of the gel. The National Institutes of Health (NIH) have <u>published a study</u> of various seaweed products showing, anecdotally, that sea moss had the lowest concentration of iodine of all types of seaweed in the study (see Table 4 of the study). For the sample tested, an 8 gram serving of sea moss would provide 85% of the NIH recommended <u>150 micrograms daily intake</u> of iodine. NIH recommended a tolerable <u>upper limit of 650 micrograms</u> of daily iodine intake, corresponding to approximately 40 grams of sea moss. NIH further reports that <u>iodine toxicity</u> can occur with more than 1100 micrograms iodine intake per day, resulting in a variety of thyroid health problems. The best guidance is to maintain a balanced diet and moderate consumption of sea moss products.

4. Sea moss is the natural source from which the thickener/emulsifier carrageenan is refined. Use of carrageenan is regulated as a food additive under <u>21 CFR 172.620</u>. Additional information on allowed use is found at <u>21 CFR 172.623</u>. The FDA <u>Food</u> <u>Additive Status List</u> provides maximum allowed concentrations of food additives in food.

The above requested documentation should be submitted to <u>foodvariances@dhec.sc.gov</u> for review and approval.

Be aware that if the sea moss gel will be processed using the acidification option, you will need a pH meter with which to test each production batch to be sure the critical pH value is met.

The topic of health claims is one that requires specific FDA guidance to navigate the fine details of what is allowed or not allowed. No health claims can be approved by local agencies such as SC DHEC, and the use of health claims renders the associated product as a dietary supplement, and not a food. As such, the product would be regulated by FDA, not by any local regulatory agency. Here are resources to assist you:

FDA Customer Service Hotline: 1-888-463-6332

FDA Office of Nutritional Products, Labeling and Dietary Supplements 240-402-2375 CFSAN Industry Assistance Information

## Additional Resources:

FDA Warning Letter – Everything Health LLC 05-24-2021
FDA Warning Letter – Red's Kitchen Sink 03-02-2021
Consumer Advisory – Michigan Dept. of Agriculture and Rural Development
Sea Moss Fact Sheet – Ohio Department of Agriculture
Iodine Intake from Sea Moss – National Institutes of Health

Jonathan D. Wheeler PCQI, CHM
Special Processes Team Leader
Division of Food - Survey Team
S.C. Dept. of Health & Environmental Control

Office: (803) 896-0535 Fax: (803) 896-0645

Connect: www.scdhec.gov Facebook Twitter