

SYLVIA LUKE



#### DEPARTMENT OF BUSINESS, ECONOMIC DEVELOPMENT & TOURISM

KA 'OIHANA HO'OMOHALA PĀ'OIHANA, 'IMI WAIWAI A HO'OMĀKA'IKA'I

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LT. GOVERNOR

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Statement of

James Kunane Tokioka

Director

Department of Business, Economic Development, and Tourism before the

#### SENATE COMMITTEE ON WAYS AND MEANS

Wednesday, April 2, 2025 10:01 AM State Capitol, Conference Room 211

In consideration of HB650 HD1 SD1 RELATING TO SEA SALT PRODUCTS.

Chair Dela Cruz, Vice Chair Moriwaki and members of the Committee. The Department of Business, Economic Development and Tourism (DBEDT) <u>supports the intent</u> of **HB650 HD1 SD1** which appropriates funds for DBEDT to provide education and support to local businesses regarding the federal Food and Drug Administration's (FDA) industry guidance on colored sea salt.

According to FDA, "manufacturers of sea salt that intend to add color additives that are not currently approved for food use to their products, such as charcoal or red clay, must first obtain approval for the use of these substances through the color additive petition process. Color additive petitions must be submitted to FDA's Office of Food Additive Safety, HFS-200, 5001 Campus Drive, College Park, MD 20740. The information required for color additive petitions is outlined in 21 CFR 71.1. There are guidance documents available on our [FDA] website that address the administrative, chemistry, toxicological, and environmental information that should be included in support of a color additive petition." Source: https://www.fda.gov/media/94036/download.

DBEDT notes that obtaining FDA approval of the color additives used by Hawaii sea salt companies can be a lengthy and expensive process requiring very specific

technical expertise. UH-CTAHR has a Human Nutrition, Food and Animal Sciences Department with such technical expertise on nutritional ingredients and color additives in foods. As such, UH-CTAHR would be an appropriate entity to provide education to Hawaii sea salt manufacturers regarding the requirements of FDA on color additives in sea salt. An appropriation in the amount of \$300,000. would be necessary to conduct such a project.

Thank you for the opportunity to testify.

JOSH GREEN, M.D. Governor

> SYLVIA LUKE Lt. Governor



SHARON HURD
Chairperson, Board of Agriculture

**DEAN M. MATSUKAWA**Deputy to the Chairperson

#### State of Hawai'i DEPARTMENT OF AGRICULTURE KA 'OIHANA MAHI'AI

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#### TESTIMONY OF SHARON HURD CHAIRPERSON, BOARD OF AGRICULTURE

#### BEFORE THE HOUSE COMMITTEE ON WAYS AND MEANS

APRIL 2, 2025 10:01 AM CONFERENCE ROOM 211 & VIDEOCONFERENCE

> HOUSE BILL NO. 650, HD1, SD1 RELATING TO SEA SALT PRODUCTS

Chair Dela Cruz, Vice Chair Moriwaki, and Members of the Committee:

Thank you for the opportunity to testify on House Bill 650, HD1, SD1 that appropriates moneys to the Department of Business, Economic Development, and Tourism for providing education and support to local businesses regarding the United States Food and Drug Administration's (FDA) guidance on colored sea salt.

The Hawaii Department of Agriculture (Department) supports this bill. The Seal of Quality Program, a statewide branding program administered by the Department, aims to protect the integrity and value of the marketing cachet for Hawai'i branded value-added products, includes members whose Hawaiian sea salt line of products have additives that add color. These products are popular with tourists and are sold to consumers worldwide. Providing education and support to local businesses will increase their understanding of FDA rules on food additives, including those that add color to Hawaiian sea salt.

Thank you for the opportunity to testify on this measure.





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April 2, 2025

#### HEARING BEFORE THE SENATE COMMITTEE ON WAYS AND MEANS

#### TESTIMONY ON HB 650, HD1, SD1 RELATING TO SEA SALT PRODUCTS

Conference Room 211 & Videoconference 10:01 AM

Aloha Chair Dela Cruz, Vice-Chair Moriwaki, and Members of the Committee:

I am Brian Miyamoto, Executive Director of the Hawai'i Farm Bureau (HFB). Organized since 1948, the HFB is comprised of 1,800 farm family members statewide and serves as Hawai'i's voice of agriculture to protect, advocate, and advance the social, economic, and educational interests of our diverse agricultural community.

The Hawai'i Farm Bureau supports HB 650, HD1, SD1, which appropriates funds to the Department of Business, Economic Development, and Tourism to provide education and support to local businesses regarding the United States Food and Drug Administration's guidance on colored sea salt.

Authentic Hawaiian red alaea and black sea salt have become increasingly popular. The two colorants used in Hawaiian sea salt, activated charcoal, and Hawaiian red alaea clay, were recently added to the FDA's approved colorants list, requiring a Color Additive Petition (CAP) application filed by sea salt producers and suppliers.

Obtaining FDA approval for the color additives used by Hawai'i sea salt companies is a lengthy and costly endeavor. Detailed research, studies, and analysis by science and industry experts must be conducted and submitted to the FDA for review. In 2019, DBEDT estimated that the cost of engaging in this process would be a minimum of \$100,000. Today, the estimated cost is \$300,000. Most of Hawai'i's salt producers are small businesses and can't afford the high cost of the CAP process.

Thank you for the opportunity to comment on this measure.



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#### **Executive Officers**

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TO: Committe on Ways and Means

FROM: HAWAII FOOD INDUSTRY ASSOCIATION

Lauren Zirbel, Executive Director

DATE: April 2, 2025

TIME: 10:01am

RE: HB650 HD1 SD1 Relating to Sea Salt Products

Position: Support

The Hawaii Food Industry Association is comprised of two hundred member companies representing retailers, suppliers, producers, manufacturers and distributors of food and beverage related products in the State of Hawaii.

HFIA is in support of this measure to appropriate funds to the department of agriculture to provide education and support to local businesses regarding the federal Food and Drug Administration's industry guidance on colored sea salt.

Colored sea salt is an important industry in our state and it needs the support of the legislature to survive and thrive.

Making colored sea salt is culturally and historically significant in Hawaii. It's also an industry that supports jobs and contributes to our economy. Unfortunately, due to an oversight during an FDA rule change in 2015 the traditional ingredients that give Hawaiian salts their color, alea and black lava, were not included in the list of approved additives.

Hawaiian sea salt companies have already dedicated years and spent thousands of dollars to get this situation rectified, and now they need the help of their legislators to preserve this industry. We often talk about diversifying and strengthening Hawaii's economy, and the potential growth in manufacturing in our state. This is an ideal opportunity for the state to support that diversification and growth. We urge you to vote yes on this measure and we thank you for the opportunity to testify



#### Testimony to the Senate Committee on Ways and Means Senator Donovan M. Dela Cruz, Chair Senator Sharon Y. Moriwaki, Vice Chair

Wednesday, April 2, 2025, at 10:01AM Conference Room 211 & Videoconference

#### RE: HB650 HD1 SD1 Relating to Sea Salt Products

Aloha e Chair Dela Cruz, Vice Chair Moriwaki, and Members of the Committee:

My name is Sherry Menor, President and CEO of the Chamber of Commerce Hawaii ("The Chamber"). The Chamber supports House Bill 650 House Draft 1 Senate Draft 1 (HB650 HD1 SD1), which appropriates funds to the Department of Business, Economic Development, and Tourism for providing education and support to local businesses regarding the United States Food and Drug Administration's guidance on colored sea salt.

HB650 HD1 SD1 aligns with our 2030 Blueprint for Hawaii: An Economic Action Plan, specifically under the policy pillar for Business Services. This bill promotes policies that drive economic growth, enhance workforce opportunities, and improve the quality of life for Hawaii's residents.

Hawaii's sea salt industry is experiencing a surge in popularity, playing a key role in promoting the state's unique products and local businesses. The legislature finds that sea salt products enhanced with natural ingredients like Hawaiian charcoal and volcanic clay are in high demand, and it is critical to incorporate the FDA's guidance on color additives to ensure these products meet federal standards. To maintain the viability of this sector, the measure mandates that manufacturers who wish to use unapproved color additives must first secure approval through the FDA's color additive petition process, while also providing education and support to local businesses.

The measure appropriates funds for fiscal years 2025-2026 and 2026-2027, to be used by the Department of Business, Economic Development, and Tourism for educating and supporting local sea salt manufacturers in navigating the FDA requirements. By helping these businesses comply with federal standards and capitalize on rising consumer demand, the measure promotes industry sustainability and economic growth. The Chamber supports this legislation because it safeguards a vital local industry, drives economic progress, and enhances Hawaii's reputation for innovative, high-quality products.

The Chamber of Commerce Hawaii is the state's leading business advocacy organization, dedicated to improving Hawaii's economy and securing Hawaii's future for growth and opportunity. Our mission is to foster a vibrant economic climate. As such, we support initiatives and policies that align with the 2030 Blueprint for Hawaii that create opportunities to strengthen overall competitiveness, improve the quantity and skills of available workforce, diversify the economy, and build greater local wealth.

We respectfully ask to pass House Bill 650 House Draft 1 Senate Draft 1. Thank you for the opportunity to testify

#### <u>Testimony</u> <u>for the Legislative Bill of the State of Hawaii</u>

HB 650 H.D. 1, S.D. 1

**Year 2025** 

3-30-2025

#### **Hawaiian Black & Red Sea Salts**

Submission of Color Additive Petition (CAP) to FDA

Save the Age old and Culturally Significant
Businesses of the State of Hawaii and

increase export and tax revenue for Hawaii

#### History

- In October of 2015, the FDA issued a "Guidance" making the Hawaiian Black & Red Sea Salts as adulterated products. The two ingredients in the Black and Red Hawaiian Sea Salts are high quality Activated Charcoal and Hawaiian Red Alaea Clay.
- According to the new guidelines from FDA these are not on the list of approved colorants, hence the products containing them could be taken out of the market. According to FDA, activated charcoal and Hawaiian Red Alaea clay needs to be added to the list of approved colorants for the Hawaiian Black & Red sea salts to considered "Unadulterated" products.
- This process with FDA, Color Additive Petition (CAP), requires extensive FDA required lab tests, data analysis, toxicology exposure studies, which are cost prohibitive to small businesses.
- A group of manufactures and distributors of Hawaiian sea salt products approached the State of Hawaii for financial support for the FDA approval process

## History - continued

- The fear of FDA banning the Hawaiian Black & Red sea salts, resulting possible FDA enforcements caused:
  - Major retailers (Costco, Amazon, Whole Foods) refused to carry these products and asked us to come back when we have FDA approval. These companies carry plentiful non-Hawaiian salts on their shelves, including foreign made salts.
  - Major Distributors in the USA and in other countries refused to distribute these products, causing significant reduction of revenue for Hawaii based sea salt businesses.
  - Significant reduction of existing employment in Hawaii for this sector and absolutely no expansion plans for the sea salt production operations.
  - Proportionate reduction of tax base and export revenues for the State of Hawaii.

### History - continued

- The Hawaiian sea salt business is an important, age-old, culturally relevant Hawaiian tradition.
- In 2019, the legislative body of the State of Hawaii introduced two bills (Senate & House) to fund the FDA approval project.
- The Bills did not pass due to lack of money in the 2019 state budget. They were reintroduced in 2020 and 2021 but did not pass due to COVID-19.
- The state introduced the same bills in 2022, which were passed, and \$300,000 was allocated to the project.
- With the money available and the University of Hawaii's willingness do the administration, the state hired a team of qualified and experienced FDA consultants by the end of 2023.
- In 2024, with the help of this team of FDA consultants, working with the University of Hawaii and a group of Hawaiian Sea Salt businesses, we made tremendous progress towards the goal.
- We met every month as a group, and each did their part to move the project forward, under the guidance of these experienced FDA consultants and with the help of the University of Hawaii.



## What we have achieved in 2024

Under the expert guidance of the FDA consultants:

- We collected samples of Red Alaea from three Hawaii locations.
- We did extensive chemical analysis of the Red Alaea using FDA-approved independent third-party labs.
- Nothing harmful to humans was found in Red Alaea.
- FDA consultants contacted a reputable Activated Charcoal manufacturer.
- The manufacturer agreed to cooperate by sharing all the favorable testing and exposure studies they had already done.
- Based on these, FDA consultants did an initial assessment of the maximum use of these two ingredients and the possible exposure to humans based on food habits and the use of Hawaiian Black and red sea salts in daily food consumption.
- The University of Hawaii and the Department of Agriculture monitor meticulously how each dollar is spent to avoid waste and increase the efficiency of the whole project.

# Summary of the CAP process (2024)

- FDA categorizes Concern Levels (CL) into three classifications.
- CL1, CL2, CL3.CL1 is the least problematic and requires minimal scrutiny, while CL3 is the most troublesome, requiring extensive chemical and toxicology studies and data research, which would be the most expensive.
- Based on their extensive past experiences, the FDA consultants believe the case of Red Alaea and Activated Charcoal used in Hawaiian sea salt products falls into the "CL1" category, which requires the minimum scrutiny and is hence the least expensive.
- They believe we are in the 20-yard line, closer to the goal post. However, at the 20-yard line, the resistance also becomes harder before the intended touchdown.
- However, we are so close to the finish line. With a little more push, the goal is achievable.

# Recent developments with one of the large distributors

(3-10-2025)

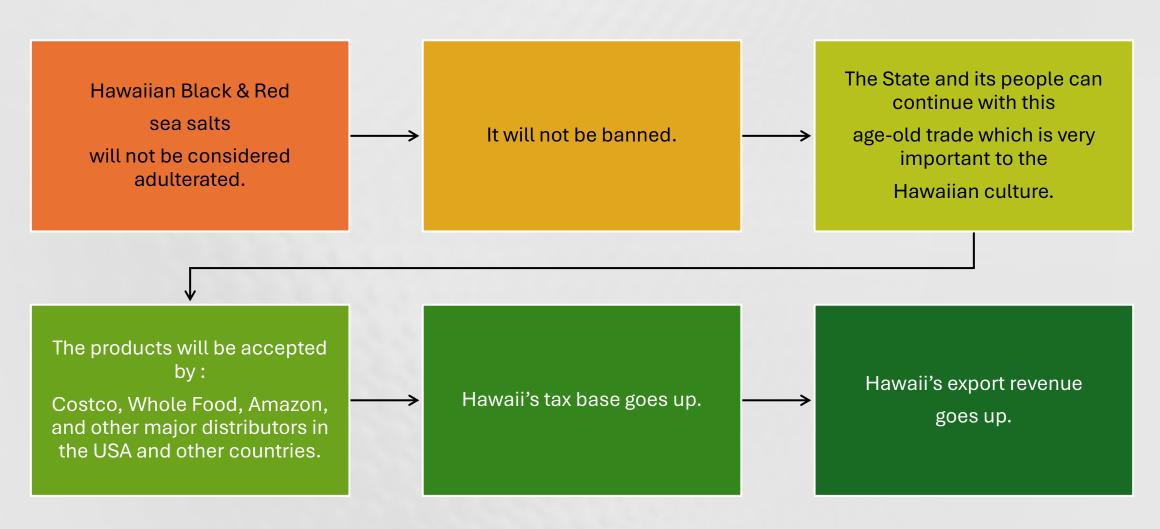
- One of the loyal and long-time distributor called us.
- According to them, they need some concrete evidence of FDA approval or confirmation that we are fast tracking our FDA approval process.
- (We have been giving them updates during the last 9 years, but now they need more than just talk.)
- Their large customers are demanding it, for the fear of any FDA enforcements.
- On March 10, 2025, we arranged a meeting with the FDA consultants and the distributor.
- FDA Consultants gave them an update, which, hearing from a third-party expert, made them little more comfortable.
- According to this large distributors, their customers like the "Colored Hawaiian Sea Salts" and have a great demand for it, and they want it.
- They had no complaints from any of their customers with the products, except the fear of any possibility of FDA banning the products and/or any FDA enforcements due to lack of efforts from the producers to have the approval process completed.
- However, unless we show them a steady progress of the FDA approval process, they may have to cancel all the further orders, which could force us to close all the salt producing operations in Hawaii.

#### Budget Update (with reasonable contingency built in)

	Summary of Cost Estimates (updated in January 2025)	
Phase 1	Chemical Analysis and the initial assessment of Concern Level (Already Spent)	\$90,000
Phase 2	Detailed study of exposure level and Concern Level for FDA	\$187,000
Phase 3	Final filing with FDA for approval	\$120,000
Contingen	cies (for unexpected further requests from FDA for additional data research and tests)	\$103,000
Administra	tive Fees for UH (to be spent in the state of Hawaii)	\$100,000
	TOTAL	\$600,000

Note: \$300,000 is already approved and funded in 2022. we are requesting an additional \$300,000, including some contingencies anticipated.

#### Advantages / Benefits of an FDA approval



The following is our contact information if you need clarification on any points or need more explanation.

#### **CONTACT INFORMATION:**

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