Shelf-life Extension and Process Authority Consultation for a Food Technology Entrepreneur in Mediterranean Area

Project Report (February 2023): USAID Virtual Project for a Host Institution in Beirut Lebanon- May 2022 to February 2023

Dr. Aliyar Cyrus Fouladkhah, PhD, MPH, CFS, CPH
Founding Director, Public Health Microbiology Foundation[SM]
Associate Professor, Tennessee State University
Yale School of Public Health Alumnus

Photos Courtesy: Photos taken during the assignment by Aliyar Cyrus Fouladkhah and assigned staff to the workshop

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu (lifetime alumni account)
Webpage: https://publichealthmicrobiology.education/

Re: Recommendation for USAID Farmer-to-Farmer FSQ, Land O'Lakes Venture37 Assignment, Shelf-Life Extension for Hummus Tahini and Similar Products (R-L-058)
CC: Ms. Rawan Shamieh, Senior Field Coordinator, Farmer-to-Farmer FSQ, Land O'Lakes Venture37
February 20, 2023

Dear esteemed colleagues,

Although this assignment was completed remotely and during the pandemic time, we were able to meet with the entrepreneur several times via Zoom and provide important and practical recommendations. Below are list of the main topics we discussed. Am also attaching some of the presentation material I used for this assignment and also the invitation to a workshop, as a follow-up to this assignment. The workshop is scheduled to take place in person on the campus of Lebanese American University in March 2023.

Sincere regards,

Aliyar Cyrus Fouladkhah, PhD, MS, MPH, MACE, CFS, CPS
Associate Professor (Tenured), Tennessee State University
Faculty Director, Public Health Microbiology Laboratory
Yale School of Public Health Alumnus

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu (lifetime alumni account)
Webpage: https://publichealthmicrobiology.education/

Recommendation for R-L-058 Assignment:

1- Improving the packaging of the product to increase shelf-life:
   a- Sterilizing the packaging material and food contact surfaces to reduce the risk of cross-contamination with microbial pathogens and cross-contact with allergens.
   b- Considering to add antimicrobial protecting sheet to reduce topical spoilage and minimize multiplication of molds.
   c- Incorporating a Sanitation Standard Operating Procedures for reducing the chance of microbial cross-contamination and allergen cross-contact.
2- Use of chemical compounds to reduce rancidity:
   a- Could use TBHQ, BHA or BHT to reduce oxidation, natural ingredients however are preferred. Adherence to regulatory information at local level comparable to information discussed by FDA GRAS list is recommended to ensure proper utilization of these antimicrobials to ensure safety of the stakeholders.
   b- Vitamin E (tocopherol) and Vitamin C as part of the formulation to retain freshness, color characteristics, and appearance.
   c- Considering application of nisin as an antimicrobial for control of Gram-positive microorganisms.

Public Health Microbiology™
Foundation
Dr. Aliyar Cyrus Fouladkhah

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu (lifetime alumni account)
Webpage: https://publichealthmicrobiology.education/

d- Considering natural bioactive compounds with antimicrobial properties such carvacrol, thymol, and caprylic acid for ensuring the safety of the product and extending shelf-life

e- Need to check local requirements for the suggested agents and could use GRAS list of FDA website.

3- Considering the topical application of safe and permitted antimicrobials to minimize the spoilage challenges of the product.

4- Test for yeasts and molds using the FDA BAM method and testing Psychrotrophic Bacterial Counts in addition to Aerobic Plate Counts since this product is primarily a refrigerated product.

5- Incorporating environmental monitoring to ensure the safety of the consumers since this is a ready-to-eat commodity.

6- Completing a hazard analysis and preparing a food safety plan for prevention of microbial, chemical, and physical hazards.

A workshop is being organized in the entrepreneur's home country by the USAID F2F program and the Public Health Microbiology Foundation of Nashville, TN and the entrepreneur is cordially invited to attend the food safety/public health workshop at no cost. The workshop will discuss details of microbial food safety challenges associated with food commerce and procedures to conduct hazard analysis and complete a food safety plan.

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu

Public Health & FSMA Preventive Control for Qualified Individual (PC QI) Workshop
March 22 to 23 2022, Lead Instructor: Dr. Aliyar Cyrus Fouladkhah* *February 20, 2023*

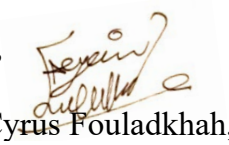
Dear participants,

It is my pleasure to welcome you to our 2023 food safety and public health certification workshop. This event is sponsored by the Public Health Microbiology Foundation in Nashville, TN and Washington and Lebanon USIAD Farmer-to-Farmer FSQ program (Land O'Lakes Venture37) and is hosted by Lebanese American University. During this multiday event, in addition to information from the public health microbiology program in Nashville, I will cover the FSPCA curriculum, currently recognized as adequate by one of the leading food safety regulatory institutions in the United States for Food Safety Modernization Act (FSMA) Preventive Control for Qualified Individuals (PC QI) training. This workshop will be held in person. Due to ongoing national and global respiratory pandemic/endemic participants are requested to adhere to public health guidelines including wearing high-quality masks and practicing social distancing to minimize the risk of respiratory disease transmission.

In-person participants are expected on March 22 to 24 2023, during the below-mentioned times. We will additionally hold optional meetings on week of March 27, 2023 for further specific and one-by-one discussions/consultation about food safety and public health practices for students and entrepreneurs. Below please find the tentative agenda for the meeting. You could also access the survey weblink and QR code that you could use for providing feedback to the instructor at the end of the workshop. I hope you find this important and timely workshop of assistance for further enhancing your education and improving the safety of your operation and meeting and exceeding the regulatory requirements for national and global commerce while ensuring the public's health.

If you have any question about the workshop, please take the liberty in contacting me at +1(970) 690-7392 or via email (aliyar.fouladkhah@aya.yale.edu).

Best wishes,



Dr. Aliyar Cyrus Fouladkhah, PhD, MS, MPH, MACE, CFS, CPS
Associate Professor, Tennessee State University
Faculty Director, Public Health Microbiology Laboratory
Founding Director, Public Health Microbiology Foundation
Yale School of Public Health Alumnus

** Funding support from the National Institute of Food and Agriculture, USAID, and Public Health Microbiology Foundation is gratefully acknowledged.*

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu

Tentative Workshop Schedule:

Wednesday, March 22, 2023 (required): 8:30 am to 5:00 pm
- Introductions from instructor and participants
- FSMA Overview*
- Food Safety Under the Landscape of Climate Change*
- Chapters 1 to 7^

Thursday, March 23, 2023 (required): 8:30 am to 5:00 pm
- Exotic and Transboundary Diseases*
- Chapters 8 to 12^

Friday, March 24, 2023 (required): 8:30 am to 5:00 pm
- Labeling and Claims and GRAS List*
- Chapters 13 to 16
- Watching 2 vidoes: Regulation Overview and FSMA Technical Assistance
- Awarding of the certificates

Monday, March 27, 2023 (Optional): 8:30 am to 5:00 pm
- One-on-one consultation with a process authority
- Individual discussions about product safety and regulatory affairs
- Discussing education opportunities in Tennessee State University

** From the public health microbiology foundation, ^from the FSPCA curriculum*

For completion of workshop evaluation survey, you could use the below weblink or Scan this QR code with your cellphone:
https://tnstateu.az1.qualtrics.com/jfe/form/SV_3D9RcylkHSbNtrg

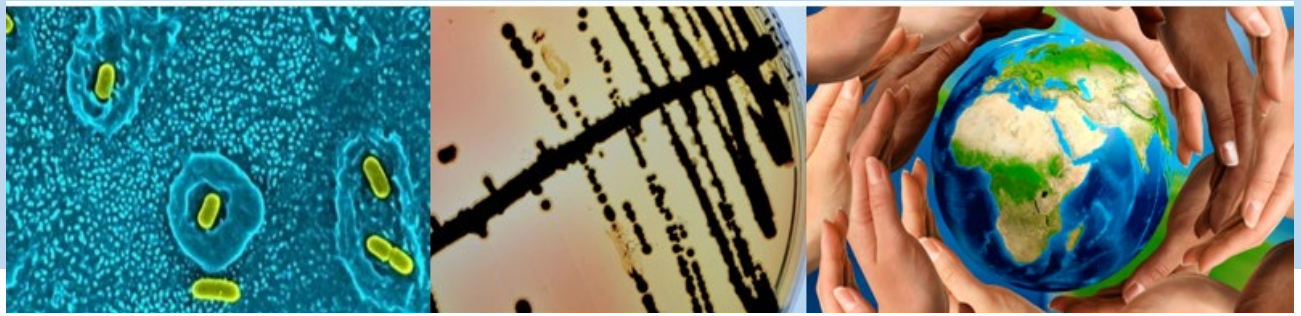
Food Labeling and Packaging Claims
FDA's Generally Recognized as Safety List

5-23-2022

USAID F2F, Lan'o Lake Program- Lebanon (virtual)

Public Health Microbiology Foundation

Dr. Aliyar Cyrus Fouladkhah



Food Labeling and Advertising

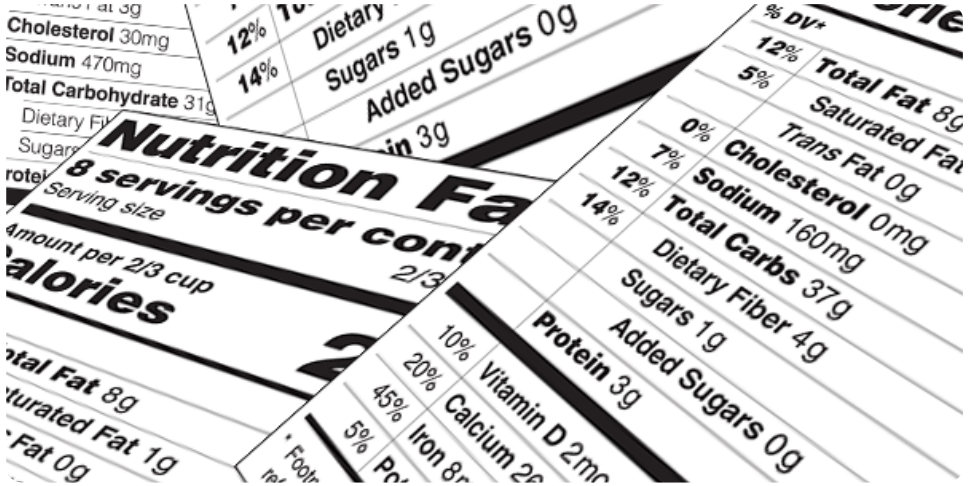
Food Labeling:

- **Valuable source of information** for consumers
- Could be **false, misleading**, or **true-but-trivial** marketing claims

e.g. Cholesterols-free potato chips; No Added sugar (added juice); Made with real fruit; N&A flavors; WONF vanilla extract

- **Challenge for consumers:**
- Distinguish the signal from noise

- **Challenge for policy makers:**
- Strengthening the signal to noise ration



Food Labeling and Advertising

Regulation for food producers:

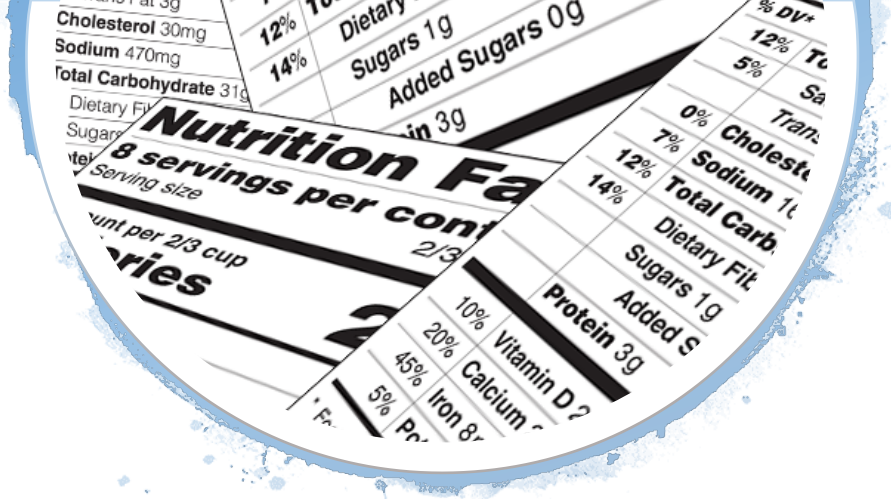
- Mandatory information
- Voluntary information: weakly regulated
- Voluntary information: strongly regulated
- Prohibited Claims

Consumers can get information:

- **Search** properties: comparing products in market
- **Experience** properties: relying on personal experience
- **Credence properties**: consumers cannot confirm product quality

e.g.: **organic** production; **country of origin**; **nutrition and health claims**; **humane treatment** of workers or animals (fair trade)

Food Labeling and Advertising



- The food industry is one of the United States' **largest manufacturing sector**
- **10 percent of all shipments** in the United States are associated food industry
- More than a **third of the world's top 50 food and beverage processing firms** are headquartered in the United States (CASE, 2021)
- **Efficiency and public health?**

FDA's Four Flavor Categories

- **Natural Flavors**
- **Natural With Other Natural Flavors (WONF)**
- **Artificial Flavors**
- **Natural and Artificial (N&A) Flavors**

Claims About Nutrition and Health

- Four Types of Claims are Possible for Food Products:
- (1) Nutrient Content Claim
- (2) Health Claim
- (3) Qualified Health Claims
- (4) Structure/Function Claims

- **All must be in close harmony with Dietary Guidelines for Americans**
- Must be evaluated by regulatory agencies

Claims About Nutrition and Health

(1) Nutrient Content Claim:

Describes level of nutrient or food component

e.g. "Low sodium," "Low fat," "High in oat bran."

Must follow **specific requirements** of NLEA

The Nutrition Labeling and Education Act of 1990 (NLEA)

Sodium as an example:

< 5 mg per reference amount*: "**Sodium Free**"

Reduced by at least 25% from reference amount "**Reduced Sodium**"

Reduced by at least 50% from reference amount "**Light in Sodium**"

140 mg or less per reference amount "**Low Sodium**"

Reference amount should be obtained from: ***Reference Amount Customarily Consumed (RACC)***

Claims about Nutrition and Health

(1) Nutrient Content Claim:

- **True-but-misleading claims** must be prohibited *e.g.* "*low-fat broccoli*"
- **Half-truth** and misleading claims must be prohibited

e.g. if the product: **Both high in saturated fat and high in fiber, the claim:**

Claim could not just mention "High in fiber"

Reason: Against the Dietary guideline: Food high in Saturated fat could not be promoted

Claims about Nutrition and Health

(2) Health Claim (aka *Real* or *Authorized* Health Claim)

- Connects a food product to **disease** **or health condition**

e.g. " may reduce the risk of heart diseases"

Another example: Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, **may reduce the risk of osteoporosis later in life.**

- This **requires approval from Food and Drug Administration**
- Only approved if there is "**significant scientific agreement**"
- **Has to be derived from** a **statement from Dietary Guideline** or highly respected authorities/institutions (**IOM**)
- Usually, a **lengthy process and rare in food industry** ***[Oat and Cholesterol]***
- ***[Cost for clinical trials >$40K per patient, >$19m for a new drug or health claim]***

U.S. FOOD & DRUG ADMINISTRATION

Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard

Approved Health Claims

Calcium, Vitamin D, and Osteoporosis

- 21 CFR 101.72 Health claims: calcium and osteoporosis
- Final Rule: Food Labeling; Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis September 2008

Dietary Lipids (Fat) and Cancer

- 21 CFR 101.73 Health claims: dietary lipids and cancer

Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

- 21 CFR 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease
- Interim Final Rule: Food Labeling; Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease December 2016

Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries

- 21 CFR 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries
- Final Rule: Food Labeling; Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries May 2008
- Final Rule: Food Labeling; Health Claims; D-tagatose and Dental Caries July 2003
- Final Rule: Food Labeling; Health Claims; Dietary Sugar Alcohols and Dental Caries December 1997
- Final Rule: Food Labeling; Health Claims; Sugar Alcohols and Dental Caries August 1996

Fiber-containing Grain Products, Fruits and Vegetables and Cancer

- 21 CFR 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer

Claims about Nutrition and Health

(3) Qualified Health Claim

- Is a claim that **lack significant scientific agreement**
- **FDA allows such claim when some health benefit studies are available.**
- **Label should indicate:**
- **“** *FDA has determined that this evidence is limited and not conclusive”*
- They should also indicate “*This statement is not approved by FDA.”*

- “Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, **may reduce the risk of diabetes mellitus type 2**.”

- Could lead to **legal complication** for companies if not stated correctly.

Claims about Nutrition and Health

(4) Structure and Function Claim

- **Connects food to structure or function of human body**
- Most common in the food industry
- Allows food industry to **"hint" at health benefits**
- Does not requires FDA approval
- But companies would **need to have strong scientific evidence *[DGA or IOM]***

"***Prevents Osteoporosis***" is a **health claim** requires lengthily **FDA approval**

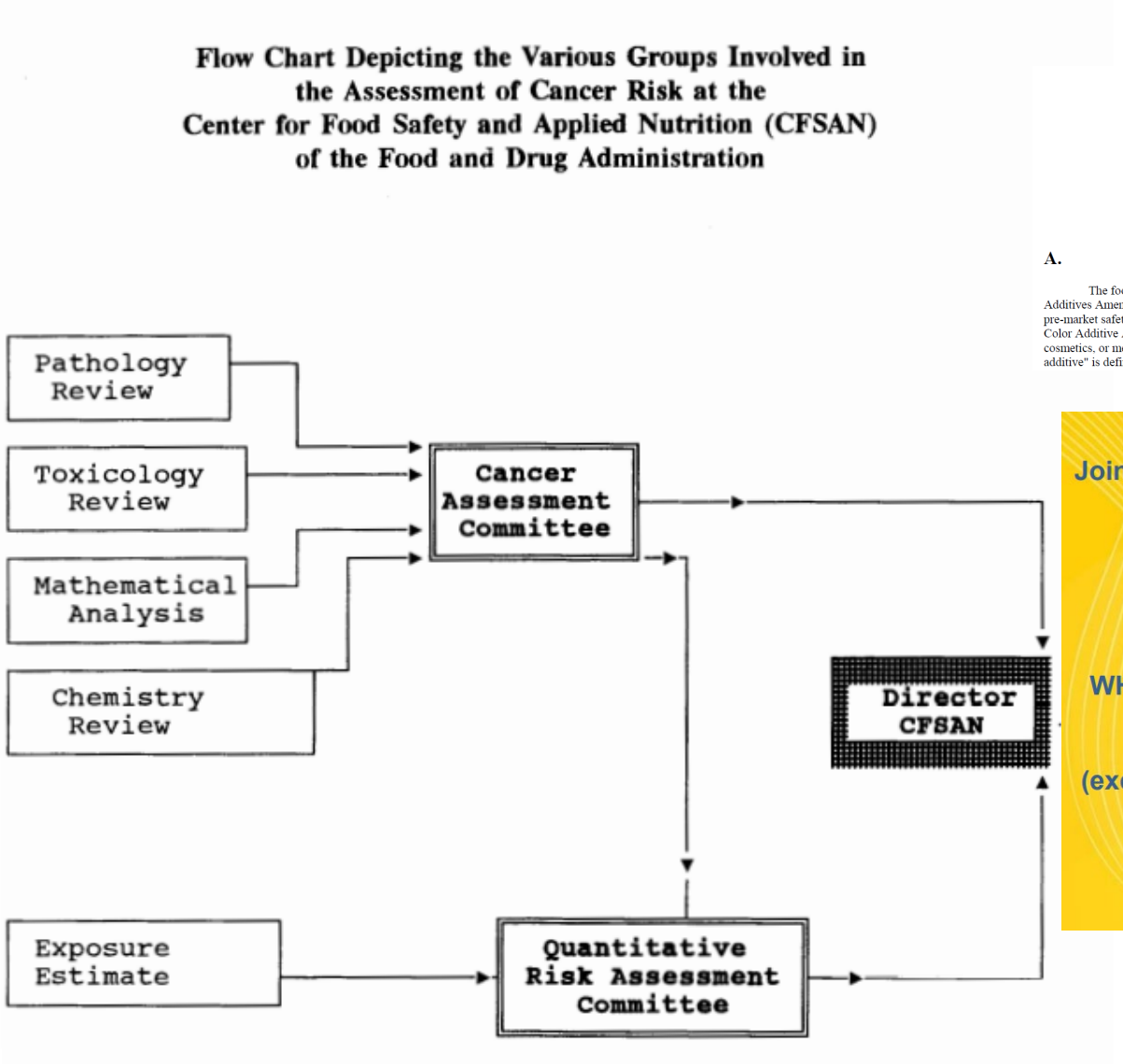
"***Builds strong bones***" is a **structure/function claim** that does **not require FDA approval**

FDA GRAS LIST

- Any substance that is **intentionally added to food** is a **food additive**
- **All additives** are: subject to **premarket review and approval by FDA**, **unless those with GRAS status**
- Food Industry is **extremely dynamic** with many ingredients (**natural and artificial**)
- **Practically impossible** for companies to test all ingredients for safety
- There is a similar list (**Animal Food GRAS) for feed industry**
- **When an ingredient is not listed in GRAS list:**
- Manufacturer may obtain GRAS status by **applying to the FDA**
- This is much **less conservative than pharmaceutical industry**. [LD50 in animals/100]
- Takes over **10 years** to receive approval for new drugs [typically >$19 B]

Pre-market safety evaluation process

- **1958:** Congress enacted the **Food Additives Amendment** to the **Federal Food, Drug, and Cosmetic Act**
- **1960:** Color Additive Amendments to the **Federal Food, Drug, and Cosmetic Act**



Chapter II

Agency Review of Toxicology Information in Petitions for Direct Food Additives and Color Additives Used in Food

A. Introduction

The food additive petition review process came into existence in 1958 when Congress enacted the Food Additives Amendment [1] to the Federal Food, Drug, and Cosmetic Act (the Act). [2] This Amendment provides a pre-market safety evaluation process for new substances added to food, "food additives." A similar statute, the Color Additive Amendments of 1960, [3,4] created analogous requirements for color additives used in foods, drugs, cosmetics, or medical devices. "Color additive" used in food is defined in section 201(t) of the Act; "food additive" is defined in section 201(s) of the Act.

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Guidance document for WHO monographers and reviewers evaluating food additives

(excluding enzyme preparations and flavouring agents)

FDA GRAS LIST

- GRAS (Generally Recognized as Safe) list of FDA:
- **Help producers avoid unnecessary testing**
- Provide a list of all **approved ingredients** and **approval concentrations *[e.g. nisin 900 IU/gram]***
- **Created in 1958** as amendment to Food and Drug Cosmetic Act
- Ingredients already in use **before 1958** received GRAS status **without testing (Old Additives)**
- **This created some problem:**
- Example: 1985 cinnamyl anthranilate (artificial cinnamon flavor) linked to liver cancer.
- **Was part of GRAS list from 1958 to 1985**, banned in 1985.

Generally Recognized as Safe (GRAS)

Share Tweet LinkedIn Email Print

"GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

- Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. General recognition of safety through scientific procedures is based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

FDA GRAS LIST

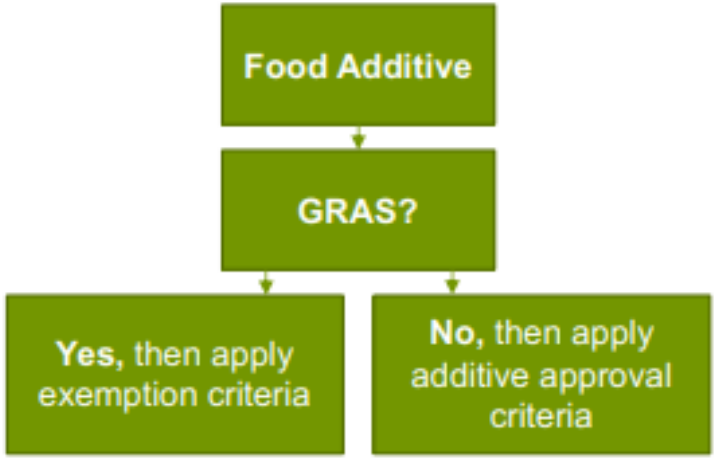
- A large online data inventory: **GRAS Notice Inventory**
- **Some decision controversial:**
- **Lysozyme**: an natural enzyme in human breastmilk
- In 2006, Artificially produced Lysozyme did not receive GRAS status for **infant formula**
- Other examples:
- **Caffeine** did not receive GRAS status for **caffeinated alcoholic beverages**
- ***Trans* fats** were part of GRAS list until 2015
- **Sodium chloride** is still on GRAS list, **IOM recommends removal**

FDA GRAS LIST

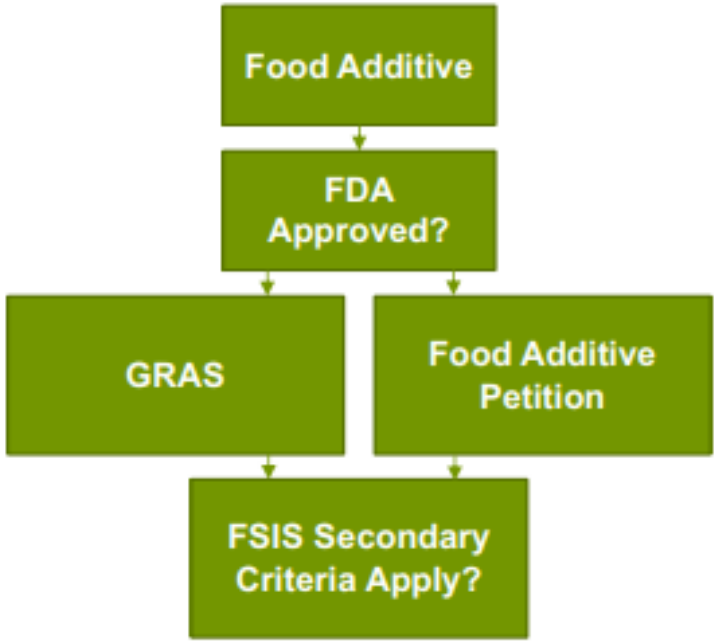
- **Major problems with GRAS list:**
- **Old additives** were not all reviewed
- Studies are not from **human clinical trials** (in vivo or animal studies) *[LD50 in animals divided by 100]*
- Do not consider the **additives synergism** *[Benzoic acid, sulfate, phosphoric acid, citric acid]*
- **Does not address color additives** (covered by FD&C act)
- **Does not address pesticides**
- **Does not address GMO**

- **Other agencies have additional requirements:**
- **USDA FSIS: additives for meat products**
- **Animal Food GRAS List**

FDA GRAS LIST



Food Additive Decision Tree for FDA Products



Food Additive Decision Tree for FSIS Products

Differentiating between **Food Additives** and **processing aids:**

Antimicrobials in meat industry
Enzymes (lactase) in dairy industry

Source: Institute of Food Technologists

Dr. Aliyar Cyrus Fouladkhah,

Faculty Director, Public Health Microbiology Laboratory, Tennessee State University

afouladk@tnstate.edu|
Phone: (970) 690-7392

Photos Courtesy: Adobe Stock, royalty purchased (standard license) by public health microbiology laboratory

LAND O'LAKES VENTURE37 FARMER-TO-FARMER PROGRAM

Remote Volunteering – Daily Timesheet

Please fill in the necessary information below at the end of each day spent on the assignment. Include any specifics that help track the progress of the assignment and notes of any edits that are made to previous/current sections over the duration of the assignment.

Day #	Hours spent on assignment	Assessment conducted/host assisted	Additional notes
May 11, 2022	1 hour	Introductory meeting with Awni	
May 14, 2022	3 hours	Review of previous conducted test in preparation for the meeting	
May 15, 2022	2 hours	Checking the sent material from the team regarding Triple A process	
May 20, 2022	3 hours	Preparation of outreach material for extending shelf life of the product- Discussion of GRAS list additives and shelf-0life microbial testing	
May 22, 2022	4 hours	Preparation for presentation to claims and regulatory compliance of additives	Slides are provided
May 23, 2022	30 mins	Presentation and Technical Assistance via Zoom	
October 12, 2022	2 Hours	Review of previous conducted test in preparation for the meeting	
October 13, 2022	30 mins	Revising the test results send from the team	
October 28, 2022	3 hours	Review of previous conducted test in preparation for the meeting	
October 31, 2022	1 hour	Meeting two with Triple A and the team	
December 16, 2022	3 hours	Review of previous conducted test in preparation for the meeting	
December 16, 2022	30 mins	Follow up with the team	
February 20, 2023	8 hours	Report, preparation of material for upcoming assignment and workshop to be conducted in March 2023	
Total Hours	31.5 hours		