



TRACEGAINS WEBINAR

# Risk Assessment on Novel Ingredients

January 12, 2023



Meet  
Your Moderator

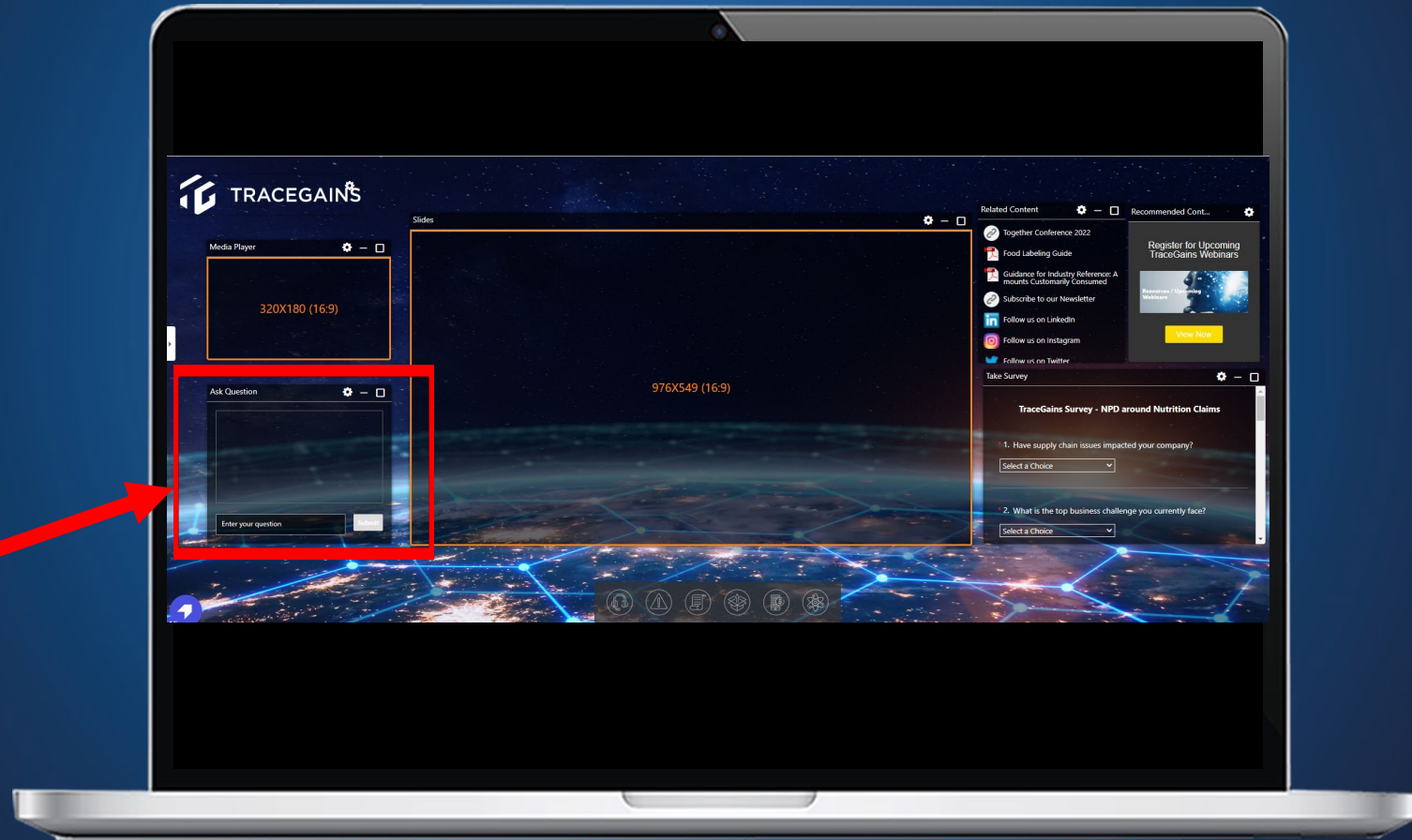


**Kristen Goodale**  
Digital Marketing Webinar &  
Podcast Specialist



# Slides And Recording Will Be Shared

# We want to hear from you! Please type your questions in the chat box.



# About TraceGains

Together we do more



**Food and Beverage** ••• **Dietary Supplements** ••• **Retail** ••• **Consumer Packaged Goods**



TRACEGAINS

Discover the Power of Networked

# What Makes TraceGains Different?

On average, companies find that 80% of their suppliers are already on TraceGains Network.



# Meet

Your Speakers

## **Dr. Steven Gendel**

Principal | Gendel Food Safety LLC



## **Simon Orrell**

Senior Account Executive





# **ASSESSING RISKS FOR NOVEL FOOD INGREDIENTS**

**Steven Gendel, Ph.D.**

**Principal**

**Gendel Food Safety LLC**

**[steve@gendelfoodsafety.com](mailto:steve@gendelfoodsafety.com)**



## Introducing Myself

- **Over 30 years in food safety**
- **25 years at FDA CFSAN**
- **Independent consultant and advisor**

# The Challenge of change



“

**Intelligence is the ability to  
adapt to change.”**

—  
@HuffPostUK

**Professor Stephen Hawking, A Briefer History of Time**

# Change is happening now

## Nutritionally charged lettuce developed with CRISPR/Cas gene editing tech

By Flora Southey

04-Jan-2022 - Last updated on 04-Jan-2022 at 15:43 GMT



## Precision fermentation: Is the world ready for animal-free dairy?

By Flora Southey

14-Feb-2022 - Last updated on 14-Feb-2022 at 15:46 GMT



## Lion burger? Tiger tacos? Meet the cell cultured start-up working in exotic meats

By Katy Askew

30-Mar-2022 - Last updated on 30-Mar-2022 at 15:01 GMT



## FSA ANNOUNCES NEW DEADLINE FOR CBD NOVEL FOOD APPLICATIONS



Novel foods in practise:  
nano foods



Gender Food Safety LLC

# Novel foods are here

## FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology

### Cell-Cultured Chicken Meat Goes Live In Singapore

APRIL 9, 2022 FOOD FREEDOM

Share via ✕



FAO

<http://www.fao.org/forestry/edibleinsects/en/>

EFSA Scientific Committee, 2015. Scientific Opinion on a risk profile related to production and consumption of insects as food and feed. EFSA Journal 2015;13(10):4257, 60 pp. doi:10.2903/j.efsa.2015.4257 <http://www.efsa.europa.eu/en/efsajournal/pub/4257>

The background of the slide is a close-up, slightly blurred image of cannabis leaves. The leaves are green and have a serrated, palmate shape. They are arranged in a way that creates a sense of depth and texture. The lighting is soft, highlighting the veins on the leaves.

# Meeting the challenge of change and novelty

The background of the slide features a large, faint, light-colored image of cannabis leaves, which are slightly out of focus. The leaves are spread across the entire page, with some overlapping. The overall tone is light and natural.

# Two big questions

- **What is a novel food/ingredient?**
- **How do we evaluate safety?**

The background of the slide features a close-up, slightly blurred image of several cannabis leaves. The leaves are green and have the characteristic serrated, palmate shape. They are arranged in a way that creates a sense of depth, with some leaves in the foreground and others receding into the background. The overall tone is natural and organic.

# What is a novel food/ingredient?



# What is a novel food/ingredient?

- **Formal definitions exist in**
  - **Australia / New Zealand (218 words)**
  - **Canada (160 words)**
  - **China (41 words)**
  - **EU (456 words)**
  - **India (~ 90 words)**
  - **Israel (164 words)**
  - **Singapore (47 words)**
  - **Thailand (96 words)**

# What is a novel food/ingredient?

- **The most common concerns**
  - **No (local) history**
  - **New process**
  - **Changes in exposure**

# What about in the US?

- **Novel or not - all ingredients are under the FD&C Act**
- **Ingredients are either**
  - **Food additives**
  - **GRAS substances**

The background of the slide is a close-up photograph of cannabis leaves, which are slightly out of focus and have a light, desaturated color. The leaves are serrated and have a distinct vein pattern. A semi-transparent grey horizontal bar is positioned across the top third of the slide, containing the main title text.

# **How do we evaluate safety?**

# What FDA says

- **Guidance for**
  - **Food Additives and GRAS substances**
  - **Food from New Plant Varieties**
  - **Food Made with Cultured Animal Cells**
  - **Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives**

# What is a significant change?

- “The identity of, manufacturing process for, or the conditions of use of the food substance do not comply with a regulation”
- “The identity of, manufacturing process for, or the conditions of use of the food substance are significantly different from those of the substance affirmed or identified as GRAS”

# What is a significant change?

- **Identity - Includes quantitative composition, impurities, contaminants**
- **Manufacturing - Includes precision fermentation, genetic modifications, etc.**
- **Use - Includes repurposing existing ingredients (especially if that changes exposure)**

# GRAS and history

- **GRAS status can be obtained “through experience based on common use in food prior to January 1, 1958”**
- **“Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance.”**



# GRAS and history

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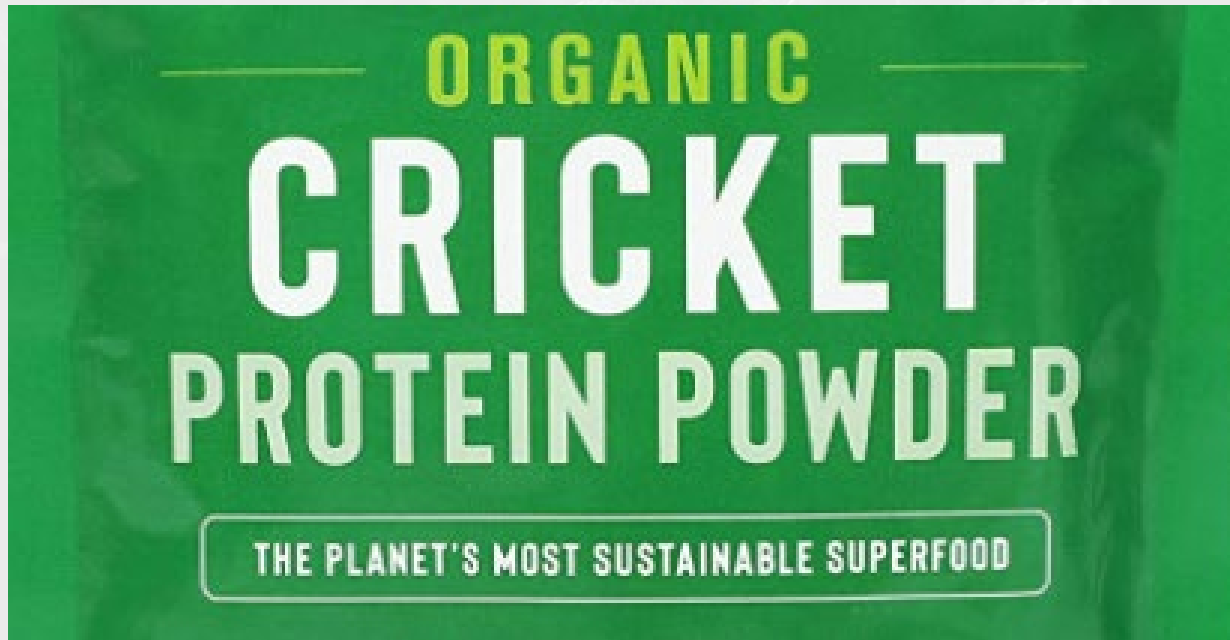
# GRAS and history

- GRAS status can be obtained “through experience based on common use of the substance”
- Common use of the substance is significantly different from those of the substance affirmed or identified as GRAS”
- Corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance.

# What does this mean for ingredient developers?

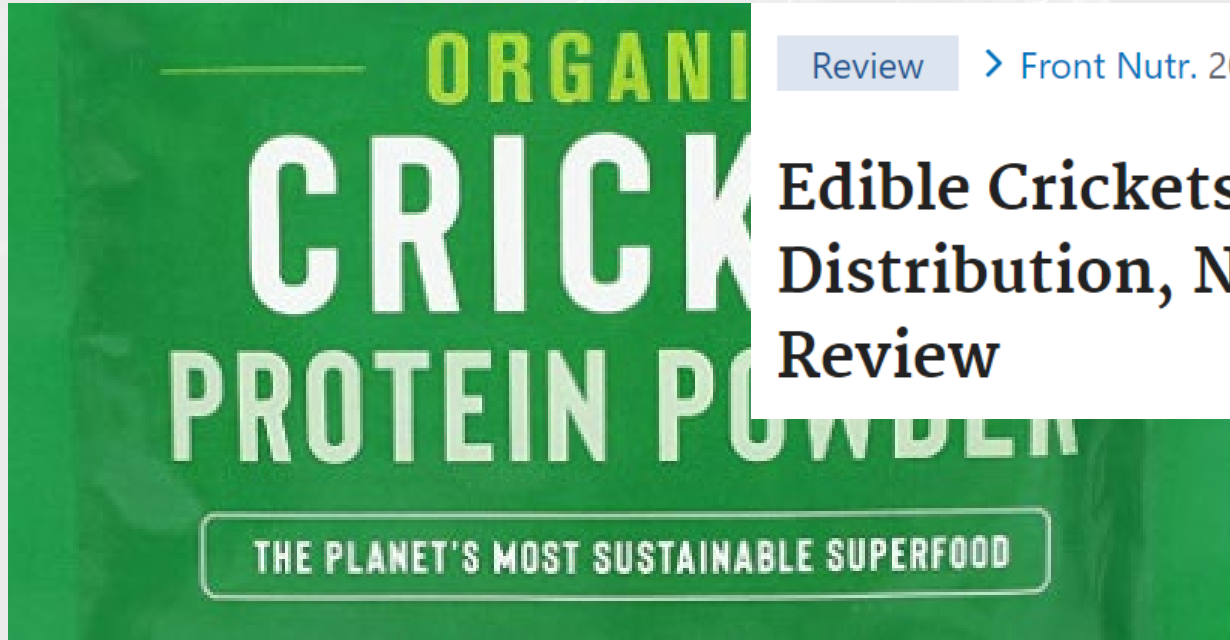
- **You are making food and food ingredients**
  - **You MUST understand the ag and food industries**
  - **Do a safety assessment**
  - **Have someone else evaluate it**

# A quick example



- **Has product safety been documented/reviewed?**
- **What are the specifications for composition and potential contaminants?**
- **Is it made in a food GMP facility, under HACCP or Preventive Controls?**

# A quick example



Review

> [Front Nutr. 2021 Jan 12;7:537915. doi: 10.3389/fnut.2020.537915. eCollection 2020.](#)

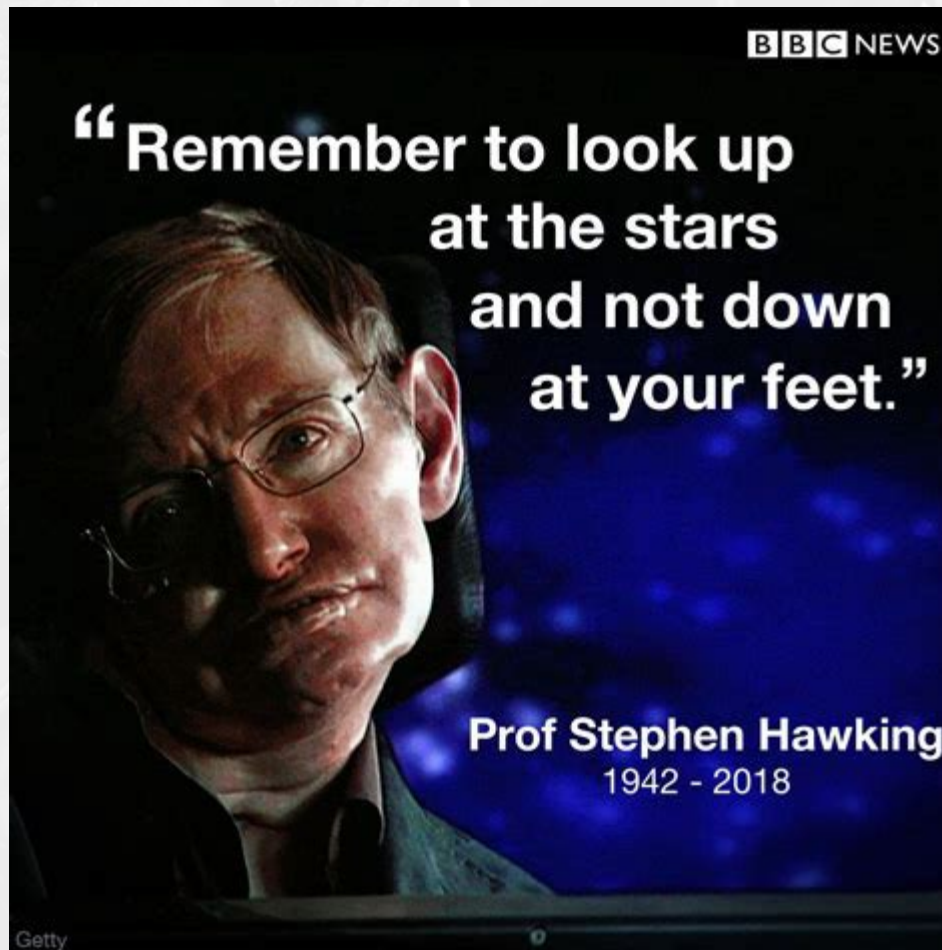
**Edible Crickets (Orthoptera) Around the World: Distribution, Nutritional Value, and Other Benefits—A Review**

The background of the slide features a large, faint, light-colored cannabis leaf with serrated edges, centered behind the text. A solid orange vertical bar is positioned on the left side of the slide, partially overlapping the top header area.

## **Lessons you can use**

- **This is a unique time for the food industry**
- **No one is an expert on everything - get help to fill your gaps**
- **Embrace change but don't be reckless**

# A final thought



**For support and help  
steve@gendelfoodsafety.com**





**Simon Orrell**  
Senior Account  
Executive



Ingredient Specifications

Suppliers & Locations

CoMan Information

Claims & Labeling  
Information

Packaging Information

Horizon Scanning

Emerging Risks

Global Restricted  
Substances

Citations

New & Novel Applications

Associated Recipes &  
Formulas

Associated Finished Good  
Specs

Sourcing Options

Lot Compliance Metrics

Supplier Scorecards

Global Regulation

Market Entry Guides

Regulatory Information  
Management

Food Fraud Information

Import/Export Data



# Marketplace search

Find items, suppliers, packaging, and more



Search

Browse by category



## Items

Food ingredients, dairy, flavor, organic, vitamins, non-GMO, spices



## Packaging

Food contact, non-food contact, bottles, labels, corrugated, glass



## Suppliers

Raw ingredients, co-manufacturer/co-packer, broker distributor, importer

Looking for a company to partner with to help manufacture your product?

Find Co-manufacturers using Marketplace search

Search co-manufacturers



A: Allergen

COO: Country of Origin

IQ: Item Questionnaire

N: Nutrition

Product Specification

SDS: Safety Data Sheet

SR: Suitability Requirements

Guar gum | X Search

Recent searches: Guar gum

Items (912) Packaging Suppliers

Search within... Countries Categories Attributes Apply Filters More...

Guar Gum

Documents: A COO IQ N PS SDS SR COA

12 documents

Colony Gums

1 location

Send Request

Organic Guar Gum

Documents: A COA COO IQ N PS SDS SR

30 documents

Colony Gums

1 location

Send Request

GUAR GUM (5500 CPS)

Documents: A COA COO IQ N PS SR SDS

24 documents

Colony Gums

1 location

Send Request

**Allergens**

**Country of Origin**

# Requests sent

Documents Information Samples Quotes

Search requests sent... Applications Status Apply Filters

Requested date	Subject	Sent by	Sent to	Documents requested	Applications	Item	Status
12/13/2022	N&A Chocolate Vanilla Flavor	Justin Busch	Jogue Inc. Northville Labs	6 types		N&A Chocolate Vanilla Flavor	Expired

## Suppliers

Search suppliers... Q

Supplier	Average response time	Last contact	Requests	Status	
<input type="checkbox"/> Jogue Inc. Northville Labs	N/A	N/A	0 requests	Prospect	Send Request
<input type="checkbox"/> Kerr by Ingredion	N/A	N/A	0 requests	Prospect	Send Request
<input type="checkbox"/> Prairie State Group dba ProAmpac	N/A	N/A	0 requests	Prospect	Send Request
<input type="checkbox"/> TG Test Supplier Group	N/A	N/A	0 requests	Prospect	Send Request
<input type="checkbox"/> TGCon - Brandon (Supplier Group)	N/A	N/A	0 requests	Prospect	Send Request

20 per page >

20 per page >

1

5 results in 1 page

### Location Documents

1 document type selected



Locations



Search location docs



Apply Filters

	Location	Type	Effective	Expiration
↓	CLP Chemical - Apical (PT Sari Dumai Sejati) - MITSUBISHI	GRAS/NDI/ODI Statement	12/22/2021	12/22/2024

20 per page >

1

1 result in 1 page

# Flavors

Is this item a flavor or does it contain flavor components?

-- Select --

Does the item contain only FEMA, GRAS or FDA GRAS flavor components?

-- Select --

Does this item contain any FEMA Priority Chemicals? A full list of chemicals can be found at the following link: [Click Here](#)

-- Select --

## Location Documents

1 document type selected

Locations

Search location docs

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20 per page >

1

1 result in

December 22, 2021

### Subject: GRAS/NDI/ODI Statement

We herewith confirm that Apical Palm Refined Glycerin USP Kosher Grade 99.7% complies with the specifications of the Food Chemical Codex (FCC) and United States Pharmacopoeia (USP). This product is also considered Generally Recognized As Safe (GRAS), whether it is a New Dietary Ingredient (NDI), or an Old Dietary Ingredient (ODI) "grandfathered" per DSHEA, the Dietary Supplement Health and Education Act of 1934, also known as Pre-DSHEA ingredients.

*Neil W Camp*

Neil W Camp  
Glycerin Manager  
CLP Chemicals, Inc.



# TraceGains Network

The global ecosystem built on networked ingredient data

**50K+**

Supplier Locations

**425K+**

Items & Ingredients

**130+**

Supplier Countries

**3M+**

Supplier, Item &  
Ingredient Documents

**615k**

Completed Standard  
Online Forms



# TraceGains Product Suite

R&D / NPD TEAMS

QUALITY and REGULATORY COMPLIANCE TEAMS

Marketplace

Supplier Management

Networked Finished Goods

Formula Management

Networked Intelligence

Spec Management – Raw Materials / Spec Management – Finished Goods

Audit Management

Supplier Compliance

Quality Management

Customer Management

Explore Concept

Validate Product

Build/Manage Product

CONCEPT

**TRACEGAINS C TO C SUITE**

CONSUMPTION

# Win a Gift Card...

Take our survey and be entered to win a \$50 gift card!



## Live Q&A

Type your questions into the chat box!



# Thank You

Together we do more

