ESHA Research

ESHA Research was established in 1981 as one of the very first nutrition software solutions. Today, ESHA’s suite of nutritional software products, services, and databases are recognized as the industry’s top choice for food and supplement formulation, recipe development, labeling, nutritional analysis, and regulatory compliance.

**ESHA Solutions**
- Genesis R&D® Food Formulation
- Genesis R&D® Supplement Formulation
- Food Processor® Nutrition & Diet Analysis
- Consulting Services

Our mission is to help remove the complexity of product development and regulatory compliance for the food, beverage, and supplement industries through software, services, and nutritional databases.
Genesis R&D Foods

Genesis R&D Foods, first released in 1991, is designed to help users manage processes, overcome industry challenges, and meet federal requirements. Industry professionals use Genesis R&D for quick and accurate nutrient evaluation, virtual product development, nutrition labeling, and regulatory compliance.

• Product Development
• Formulation Analysis
• Menu Analysis
• Reporting
• Regulatory Compliance
Using the Moisture Adjustment Feature in Genesis R&D Foods for Baked Products

Date: August 11, 2021

Cooking often results in a loss of moisture, which will affect the nutrient content of your food. Your Nutrition Facts must reflect the nutrient content of the final form of your food, so you will have to adjust for the lost moisture in order to obtain an accurate nutrition analysis. During this webinar, we will discuss when a moisture adjustment is necessary, how to determine and calculate the moisture loss or target values, how to enter those values into the Yield Adjustment feature in Genesis R&D Foods and show you how to compare a Recipe’s nutrient content before and after the adjustment.

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www.esha.com/news-events/webinars
Please Note!

✓ The webinar is being recorded
✓ All webinars available on our website
✓ Submit your questions in the GoToWebinar control panel
✓ We’ll email a copy of the recording and the slides following the webinar
What We’ll Cover Today

• FASTER Act Overview
• Sesame Defined
• Identifying Sesame
• How to Declare Sesame
• Updates to Genesis R&D
• Best Practices
• Q&A
FASTER Act of 2021

S. 578

Food Allergy Safety, Treatment, Education, and Research Act of 2021

Signed into Law April 23, 2021

Compliance Required by January 1, 2023

An Act

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.
FASTER Act Timeline

- **October 2018** – FDA issued request for information on prevalence and severity of sesame allergies in the United States to inform possible regulation changes.

- **November 2020** – FDA published draft guidance for voluntary declaration of sesame

- **April 2021** – FASTER Act becomes law
  - **April 16, 2021** – FASTER Act passed by the 117th Congress of the U.S.
  - **April 23, 2021** – FASTER Act signed into law, declares sesame the 9th major U.S. allergen

- **January 1, 2023** - Compliance date when food companies must declare Sesame on food labels.
FASTER ACT Law

• Sesame is the 9th Major Allergen under the Food Allergen Labeling and Consumer Protection Act (FALCPA)

• New framework established for review of how additional potential allergens are to be considered and reviewed

9 Major U.S. Allergens:
Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, Soy and Sesame.
FASTER Act Compliance

• **Compliance Date:** January 1, 2023

• Any food products packaged on or after this date will be required to comply with the FASTER Act.

• ~2-year compliance period allows for:
  - **Identifying** sesame within food production
  - **Establishing** allergen control programs for sesame
  - **Updating** food labels and packaging to comply
What is Sesame?

- A flowering plant in the genus Sesamum (also called benne)
- The leaves, seeds and oil are edible
- Sesame Seeds come in three colors: white, brown, and black
- Used in a variety of food products
Sesame as an Allergen

- Increased instance of allergic reaction to the Sesame plant has been reported
  - Around 4% of the U.S. population
  - Could be as many as 1.6 million Americans

- Allergic Reactions to Sesame:
  - Swelling of face, mouth, and throat
  - Asthma and difficulty breathing
  - Anaphylactic shock

- This Act is aimed to help those suffering from Sesame allergic reactions better identify the presence of the allergen in food sources
Identifying Sesame

• Sesame is not always easily identifiable in the ingredient listing
• There are multiple different names for the plant. In order to identify the presence of sesame one must:
  • Look for alternate names for sesame across all ingredients
  • If an ingredient statement says “Spices” or “Seasoning” be sure to check for the presence of sesame
  • Double check with all ingredient suppliers
Origin Names for Sesame

- Standardized Name: **Sesame**
- Botanical Synonym: **Sesamum orientale**
- **Sesamum** (Latin name)
- **Sesamon** (Greek name)
- **Sesame (Sesamum indicum) L. [Pedaliaceae]**
- Ayurvedic Name: **tila**
Alternate Names of Sesame

- Ajonjoli, anjonolies
- Alegria
- Benne, benne seed, benniseed
- Bijan
- Bukenyimu
- Bununya
- Busosyi
- Bwengo
- Chamkkae

- Chih mah
- Chitowe
- Ellu
- Geching
- Gingelly, gingelly oil
- Gomasio, Gomashio (sesame salt)
- Halvah (Halavah)
- Kura Goma (Japanese black sesame seeds)

- Seeds
- Sesam
- Sesame flour
- Sesamol, sesamolina
- Sesamum indicum
- Simsim
- Tahini, Tahina (sesame paste)
- Teel
- Til Oil
Common Foods that May Contain Sesame

- **Baked goods**
  - Bagels
  - Bread
  - Breadsticks
  - Hamburger buns
  - Rolls
  - Breadcrumbs

- **Cereals**
  - Granola
  - Muesli

- **Seasoning**
  - Spices
  - Herbs
  - Seasoning Mixes

- **Vegetable oil**
  - (may contain sesame oil)

- **Snack foods**
  - Pretzels
  - Candy
  - Halvah
  - Japanese snack mixes
  - Rice cakes

- **Crackers**
  - Melba toast
  - Sesame snap bars

- **Chips**
  - Bagel chips
  - Pita chips
  - Tortilla chips

- **Sauces**
  - Dressings
  - Gravies
  - Marinades
  - Tahini
Common Foods that May Contain Sesame (Cont.)

- **Asian Cuisine**
  - Flavored Rice
  - Noodles
  - Sushi
  - Goma-dofu
  - Stir Fry

- **Middle Eastern Cuisine**
  - Baba Ghanoush
  - Falafel
  - Hummus
  - Halvah
  - Baklavah

- **Other Examples:**
  - Risotto
  - Shish Kababs
  - Tempeh
  - Processed Meats
  - Vegetarian Meat Alternatives
  - Pasteli
  - Foods Fortified with Vitamin E (tocopherols)
The FDA released a guidance document in November 2020 for voluntary declaration of Sesame as an allergen.

This guidance document is the current best practices for food companies to use to comply and begin tracking sesame now.

The FALCPA regulations have not yet been updated to include the sesame changes outlined in the FASTER Act.

Draft Guidance for Industry: Voluntary Disclosure of Sesame as an Allergen | FDA
Declaring Sesame

To comply with FALCPA requirements, food packages must display allergens using their common name and list them in two ways:

1. In the ingredient statement.
   
   *Examples:*
   
   - spice (sesame), spices (including sesame)
   - flavor (sesame), flavors (including sesame)
   - Tahini (sesame)

2. In a separate “Contains” statement.
   
   *Example: Contains Sesame.*
Genesis R&D: Declaring Sesame

- **Sesame Seed** is currently included as an allergen in Genesis R&D
- You can use Sesame Seed to start *tracking* the allergen or:
  - Voluntarily declare Sesame now (recommended by FDA)
    - Create a custom allergen for “Sesame” within the **Contains** statement
    - Identify all ingredients that contain the allergen and begin marking the allergen
- Genesis R&D will be updated to report Sesame with the U.S. allergens
- Once Genesis R&D is updated, we can assist you in merging your custom allergen data with the existing Sesame allergen
Options for Declaring Sesame

1. Begin Tracking Sesame Now and *Declare Later*
   - Utilize Sesame Seed allergen in Genesis R&D
   - Update ingredient statements later

2. Begin Tracking Sesame Now and *Voluntarily Declare Now*
   - Create a custom allergen in Genesis R&D & merge later
   - Update ingredient statements now
Best Practices to Implement Now

• Review all ingredients & recipes now
• Request updated spec sheets from all ingredient suppliers
  • Read your spec sheets carefully
  • Ask suppliers to identify all sources of sesame (including spices and flavorings)
• Test final products for presence of sesame at a certified laboratory
• Establish allergen control programs if sesame is present in the facility
• Full compliance is required for all food packaged on January 1, 2023
Genesis R&D Training

Genesis R&D Foods Professional + FDA Regulations
This 2-day training session covers the fundamentals of the Genesis R&D Food program with a primary focus on FDA regulations: creating ingredients and composite ingredients, building recipes/formulas, nutrition analysis, moisture loss, reporting, labeling, best practices, and much more. In addition, this session covers a comprehensive FDA regulatory review.

Genesis R&D Foods Advanced Training
The 1-day Advanced session builds upon the skills learned in the Professional training and offers deeper learning on topics including PDCAAS, International Food Labeling, Advanced Label Settings, and more.

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