US & EU Regulatory Perspective on BE and Novel Ingredients

SEPTEMBER 26, 2024

Presented By

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Food Tech News is Global News

Molecular Farming

AFN — FDA warns molecular farming startups of risks if food allergens are not properly managed

FoodNavigator EUROPE — Pigmentum: Meet the start-up producing dairy proteins in lettuce

green queen — PoLoPo's Molecular Farming Platform Turns Potatoes Into Egg Protein Factories

XPRIZE — Navigating New Frontiers: Keeping Up With Food Tech And Regulatory Changes In 2024 And Beyond

WIRED — The Plan to Put Pig Genes in Soy Beans for Tastier Fake Meat

Precision Fermentation

Food Business News — The future is now for precision fermentation

WSJ — Plant-Based Drinks can be Labeled as 'Milk,' FDA Says

FAST COMPANY — The eggs of the future will be from precision fermentation

Food Business News — The great milk alternative labeling debate continues

Cultivated Meat

BBC — Lab-grown meat set to be sold in UK pet food

The New York Times — What happened to lab-grown meat?

The Economist — How lab-grown meat became part of America's culture wars

FOOD manufacture — When will cultured meat be approved more widely?

The Economist — Europe decides it doesn't like lab-grown meat before it's tried it

WIRED — Lab-Grown Meat Is on Shelves Now. But There's a Catch

THE HILL — Meat lobby wants USDA to ban 'clean meat' makers from calling their products meat

The New York Times — Can Meat Made in a Lab Be Kosher or Halal? These Companies Hope So.

The New York Times — Lab-Grown Meat Approved to Sell for the First Time in the U.S.

FINANCIAL TIMES — Moves to ban lab-grown meat intensify in Republican US states

Plant-Based and Substitute Proteins

The New York Times — What, Exactly, is Meat? Plant-Based Food Producers Sue Missouri Over Labeling

Heightened Biotech Focus at White House + Federal Agencies

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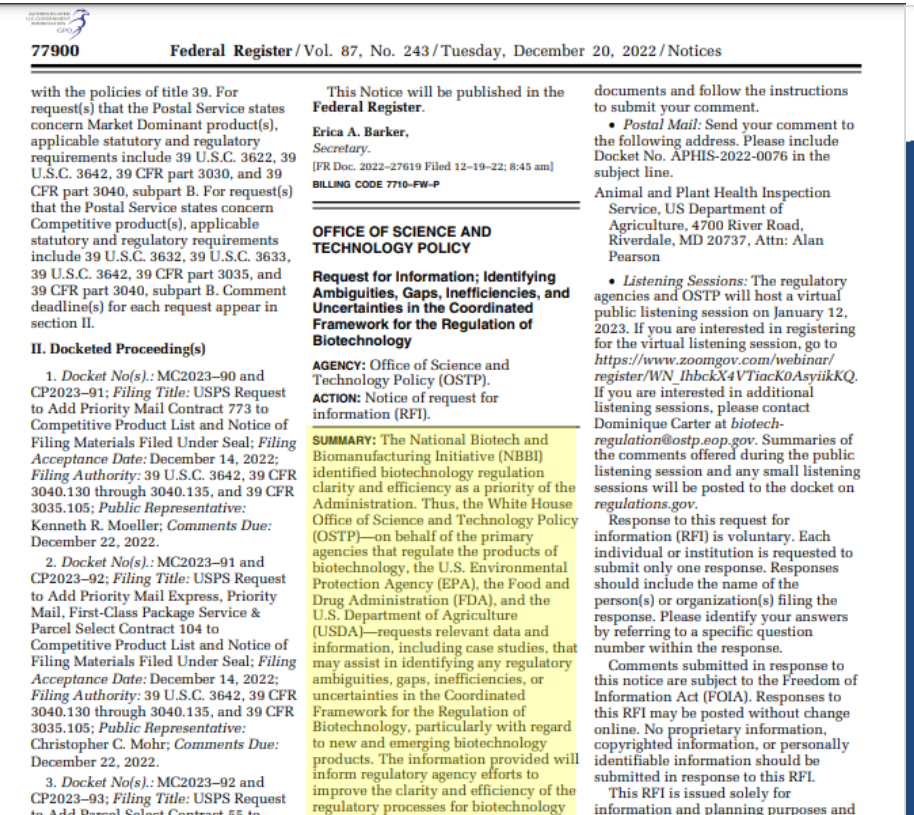
Office of Science and Technology (OSTP)

USDA

FDA



77900 **Federal Register** / Vol. 87, No. 243 / Tuesday, December 20, 2022 / Notices

with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–90 and CP2023–91; *Filing Title:* USPS Request to Add Priority Mail Contract 773 to Competitive Product List and Notice of Filing Materials Filed Under Seal; *Filing Acceptance Date:* December 14, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* December 22, 2022.

2. *Docket No(s).:* MC2023–91 and CP2023–92; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 104 to Competitive Product List and Notice of Filing Materials Filed Under Seal; *Filing Acceptance Date:* December 14, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* December 22, 2022.

3. *Docket No(s).:* MC2023–92 and CP2023–93; *Filing Title:* USPS Request

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2022–27619 Filed 12–19–22; 8:45 am]

BILLING CODE 7710–FW–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI).

SUMMARY: The National Biotech and Biomanufacturing Initiative (NBBI) identified biotechnology regulation clarity and efficiency as a priority of the Administration. Thus, the White House Office of Science and Technology Policy (OSTP)—on behalf of the primary agencies that regulate the products of biotechnology, the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—requests relevant data and information, including case studies, that may assist in identifying any regulatory ambiguities, gaps, inefficiencies, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, particularly with regard to new and emerging biotechnology products. The information provided will inform regulatory agency efforts to improve the clarity and efficiency of the regulatory processes for biotechnology

documents and follow the instructions to submit your comment.

- *Postal Mail:* Send your comment to the following address. Please include Docket No. APHIS-2022-0076 in the subject line.

Animal and Plant Health Inspection Service, US Department of Agriculture, 4700 River Road, Riverdale, MD 20737, Attn: Alan Pearson

- *Listening Sessions:* The regulatory agencies and OSTP will host a virtual public listening session on January 12, 2023. If you are interested in registering for the virtual listening session, go to *https://www.zoomgov.com/webinar/register/WN_IhbckX4VTiacK0AsyiikKQ.* If you are interested in additional listening sessions, please contact Dominique Carter at *biotech-regulation@ostp.eop.gov.* Summaries of the comments offered during the public listening session and any small listening sessions will be posted to the docket on *regulations.gov.*

Response to this request for information (RFI) is voluntary. Each individual or institution is requested to submit only one response. Responses should include the name of the person(s) or organization(s) filing the response. Please identify your answers by referring to a specific question number within the response.

Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). Responses to this RFI may be posted without change online. No proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI.

This RFI is issued solely for information and planning purposes and

USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

REVISED DRAFT

DOCUMENT ID:
BRS-GD-2023-0001

DATE:
October 13, 2023

GUIDE FOR SUBMITTING PERMIT APPLICATIONS FOR MICROORGANISMS DEVELOPED USING GENETIC ENGINEERING UNDER 7 CFR PART 340

The information contained in this document is intended solely as guidance. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations.

Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Following the guidance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

Contains Nonbinding Recommendations

Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www/regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-4658 and with the title of the guidance document.

For questions regarding this document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1200 or the Center for Veterinary Medicine (CVM) at 240-402-7002.

What is the process for commercializing an ingredient produced by biotech?

US Federal Food Regulatory Laws

- **Federal Food, Drug, and Cosmetic Act**
- Public Health Services Act

- **Federal Meat Inspection Act**
- **Poultry Products Inspection Act**
- Egg Products Inspection Act
- **Plant Protection Act**
- Animal Health Protection Act

- Federal Insecticide, Fungicide, and Rodenticide Act
- Toxic Substances Control Act

- Federal Trade Commission Act

Threshold Regulatory Questions

Is it a Food?

Is it Safe?

Intended use and function, and what claims can be made?

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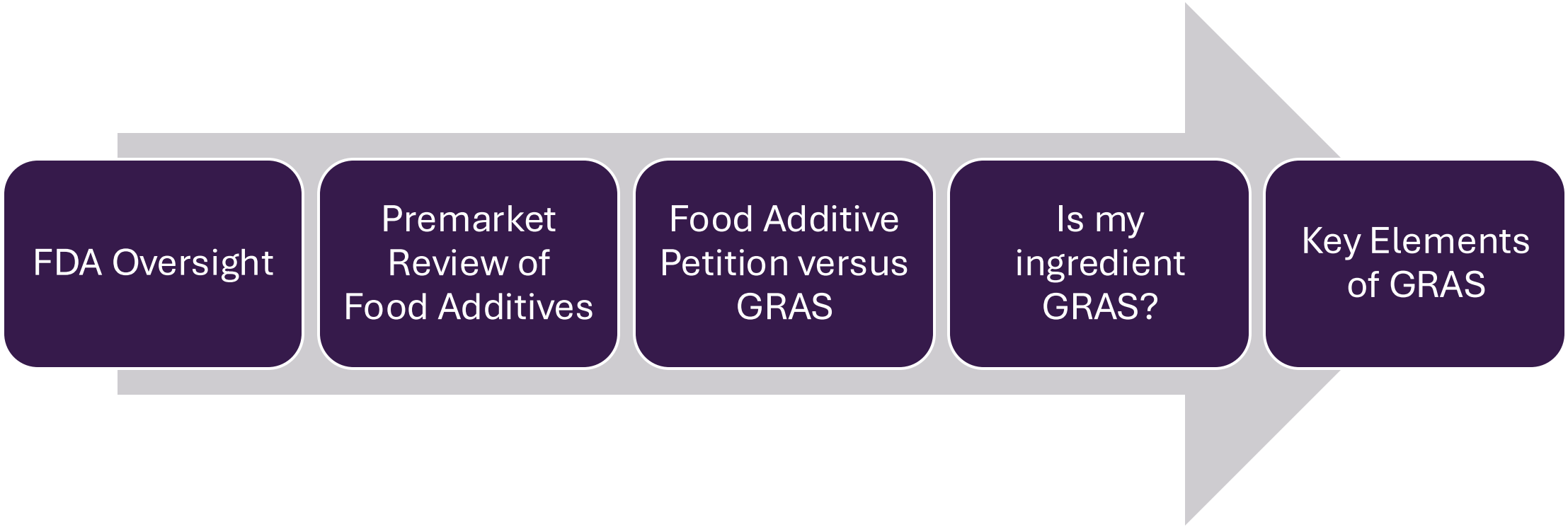
FDA Regulatory Analysis for Novel and BE Ingredients



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FDA Oversight

- Regulates **food and feed ingredients** under Federal Food, Drug, and Cosmetic Act (FDCA).
  - Either FDA-approved food additives or generally recognized as safe (GRAS) substances.
  - Manufacturer may perform self-GRAS assessment, and also optionally file voluntary a GRAS Notice with FDA.
- Regulates **microbial, algal, and fungal cells generated by large-scale culture** and used as direct food ingredients.
- Determines **safety of new food ingredients in plant-based foods, seafood, and meat and poultry products**.
- Regulates labels and labeling, including broad authority **to ensure that labeling is not false or misleading**.

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FDA Safety Considerations

- Food ingredients must be the subject of a **food additive petition** (FAP) or a "**generally recognized as safe**" (GRAS) conclusion.
- Safety turns on **intended use**, **toxicological safety** and **dietary exposure**.
- Ingredients must be manufactured in an **FDA-registered food facility** and comply with FDA **cGMPs** and related food safety requirements (**FSMA**).
- Ingredients intended for use in meat and poultry products, must be safe and **suitable** under USDA-FSIS requirements.

Are my inputs GRAS?

Requires General Recognition of Safety.

GRAS determination must be based on publicly available data and may be corroborated by unpublished data.

GRAS determinations "may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food." (21 CFR 170.30)

Burden to prove safety primarily rests with the company.

If an ingredient is GRAS for one use, is it GRAS for all uses?

GRAS Notices

- Additional step companies may voluntarily take for transparency purposes/ supply chain diligence.
- Company informs U.S. FDA of its GRAS determination and provides all supporting information to FDA.
- Publicly available information needed to establish GRAS status.
- Does not require public rulemaking process.
- Manufacturer may meet with FDA prior to notification to review dossier and ask questions (FDA encourages).
- **Goal:** Obtain No Questions Letter from FDA.

Key Elements of a GRAS Notice

Element	Title	Description
1	Signed Statements and Certification	Include information about trade secrets, intended conditions of use, and the basis for the conclusion of GRAS status.
2	Identity, Method of Manufacture, Specifications, and Physical or Technical Effect	Include information necessary to characterize the substance well and to understand the method of manufacture.
3	Dietary Exposure	Include information about the amount of the relevant substance that consumers are likely to eat as part of a total diet, regardless of whether the conclusion of GRAS status is through scientific procedures or through experience based on common use in food.
4	Self-Limiting Levels of Use	Describe circumstances where the amount of the notified substance that can be added to food is limited because the food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical.
5	Common Use in Food Before 1958	For common use in food to be the basis for the GRAS conclusion, the pre-1958 consumption must be by a significant number of consumers.
6	Narrative	Describe the basis for the conclusion of GRAS status.
7	Supporting Data and Information	This part should specify which of these data and information are generally available and which are not.

Remilk GRN 1056 (Human Food GRAS Example)

Hiya, Gladys

Fermentation, Baby!

So Fresh, So Clean

Ta-dam!

Source: Remilk Ltd.

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Successful GRAS Notice Example

- Remilk Ltd obtained FDA No Questions Letter for GRAS Notice 863 (**February 15, 2023**).
- GRAS determination covers β-lactoglobulin (the major whey protein in cow's milk) produced via precision fermentation.
- GRAS Notice describes the construction of the production strain, the manufacturing process, provides specifications, and addresses safety of β-lactoglobulin produced via precision fermentation.

Remilk's GRN 1056 Summary of Basis for GRAS

- The fact that β-lactoglobulin is manufactured under cGMP for food (21 C.F.R. Part 117) and meets appropriate food grade specifications;
- Potential contaminants, such as heavy metals, mycotoxins, and pathogenic microbes, are either absent (not detected) or below toxicological and regulatory limits;
- Intended uses and the estimated consumption of β-lactoglobulin;
- Proper labeling of the products;
- Long history of safe use of the production organism (K. phaffi) in food production and data supporting the organism's non-pathogenic and non-toxigenic nature; and
- Long history of safe use of milk and milk protein as food.

What if a GRAS ingredient adds color?

- **Example Case:** Impossible's soy leghemoglobin.
  - Received No Questions Letter (NQL) on July 23, 2018.
  - Covers use of the ingredient at levels up to 0.8% soybean leghemoglobin protein to optimize flavor in ground beef analogue products intended to be cooked.
  - FDA's NQL noted the potential requirement for a Color Additive Petition, especially because ingredient described as "red/brown".
    - "Our response to GRN 000737 is not an approval for use as a color additive . . ."
- Impossible's subsequent color additive petition resulted in FDA approval of ingredient's use as a color additive.
- Center for Food Safety objected.

Notable CFS Objections and Lawsuit

CFS' Objections

- FDA should not have approved this product to be used in ground beef analogues that are not plant-based without additional safety testing and public comment.
- FDA should require labeling of this color additive as "soy leghemoglobin/ Pichia pastoris yeast protein."
- FDA should have required additional testing of the raw product.
- FDA improperly relied on Impossible Foods' GRAS Notice 737 instead of independently verifying the safety of soy leghemoglobin for use as a color additive.
- FDA should have required separate testing of P. pastoris because it is genetically engineered.

Daily Mail .com

Impossible Burgers' additive that makes plant-based food 'bleed' needs more FDA testing, claims suit that questions whether 'heme' is safe to eat

Forbes

What The FDA's Decision About Soy Leghemoglobin Means For Impossible Burger

FoodNavigator USA

Impossible Foods applauds 9th Circuit ruling over safety of its heme, slams 'anti-science, anti-GMO activist group' for 'spreading lies'

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Labeling Considerations

Anticipated for 2024 (or 2025)

FDA Draft Guidance:

Labeling of Plant-Based Alternatives to Animal-Derived Foods

USDA Proposed Rule + Guideline:

Labeling of Cultured Meat and Poultry

The National Bioengineered Food Disclosure Standard

USDA's BE Labeling Rule

July 2016
Congress passes the National Bioengineered Food Disclosure Standard

- Directs USDA to establish, by two years after enactment, a national mandatory bioengineered (BE) food disclosure standard
- Requires USDA to issue regulations, but doesn't set a date for final rules

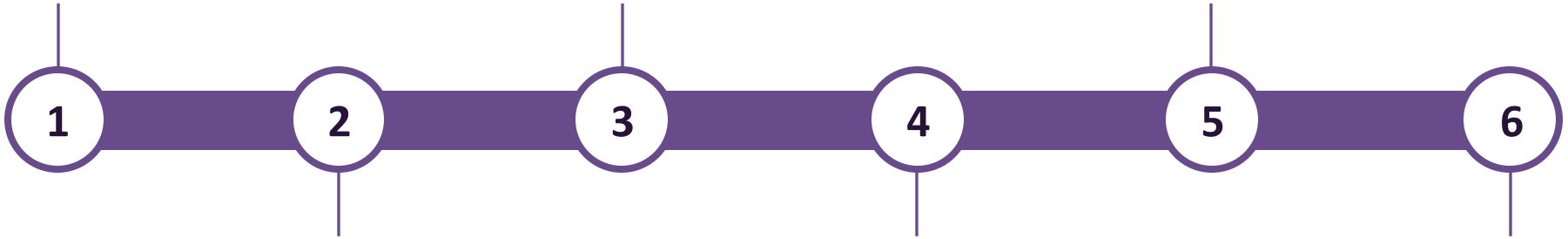
December 2018
USDA's Agricultural Marketing Service (AMS) issues a final BE disclosure rule.

December 2019
USDA-AMS proposes instructions for validating a refining process to ensure no detectable BE material.

February 2020
USDA-AMS proposes instructions on testing methods

July 2020
USDA-AMS publishes:

- Final guidance documents and FAQs on process validation and testing methods; and
- Proposed updates to list of BE Foods (would add insect-resistant sugarcane and limit squash listing to virus-resistant summer squash).



January 1, 2022
Compliance deadline.

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BE Labeling Rule: FAQs

The Standard defines bioengineered foods as those that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature.

Which foods are subject to the Standard?

- Foods subject to FDA labeling requirements.
- Foods subject to FMIA, PPIA, or EPIA labeling requirements **if** predominant ingredient would be subject to FDCA labeling requirements or predominant ingredient is broth, stock, water or similar solution and second most predominant ingredient would be subject to FDCA labeling requirements.

How must BE disclosures be made?

- On-package text.
- USDA approved symbol for BE food.
- **Electronic or digital link** (e.g., QR code).
- **Text message disclosure**.

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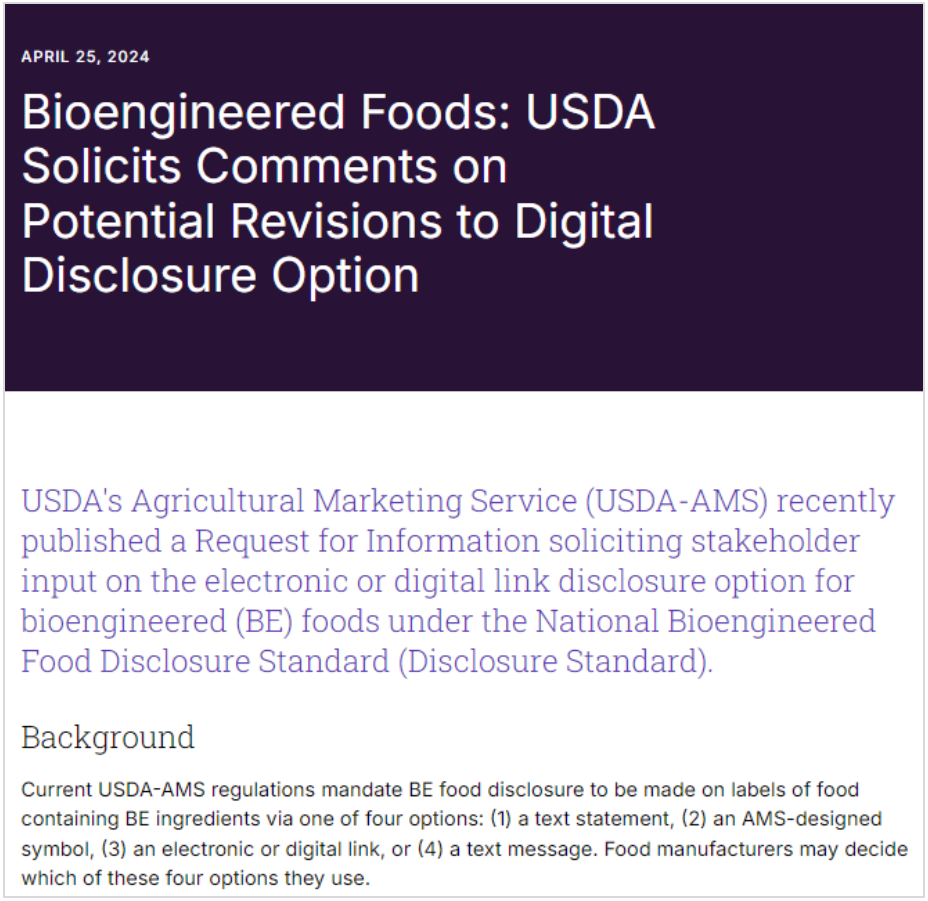
Additional Request for Information for BE Disclosures

- In September 2022, a federal district court:
  - Invalidated the text message disclosure option;
  - Ordered USDA-AMS to **reconsider the text message and electronic or digital link disclosure options**; and
  - Remanded the regulations, without vacating the current regulations.

- On April 10, 2024, USDA published a Request for Information to solicit stakeholder input on the electronic or digital link disclosure option for bioengineered (BE) foods.

- Stakeholder comments were due on June 10, 2024.



APRIL 25, 2024

Bioengineered Foods: USDA Solicits Comments on Potential Revisions to Digital Disclosure Option

USDA's Agricultural Marketing Service (USDA-AMS) recently published a Request for Information soliciting stakeholder input on the electronic or digital link disclosure option for bioengineered (BE) foods under the National Bioengineered Food Disclosure Standard (Disclosure Standard).

Background

Current USDA-AMS regulations mandate BE food disclosure to be made on labels of food containing BE ingredients via one of four options: (1) a text statement, (2) an AMS-designed symbol, (3) an electronic or digital link, or (4) a text message. Food manufacturers may decide which of these four options they use.

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USDA BE List

- The List of Bioengineered Foods appears at 7 CFR § 66.6
- Foods included on the List are presumed BE.
- AMS must consider updates to the List annually.
- On November 29, 2023, USDA-AMS published a final rule making the following changes to the List:
  - Adding "sugarcane (Bt insect-resistant varieties)"
  - Modifying existing entry for squash to read "squash (summer, coat protein-mediated virus-resistant varieties)."

EU perspective on BE and novel ingredients

- Regulatory framework in EU
- What is a BE/GM Food
- Case studies
- Regulatory challenges
- Future outlook

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EU Regulatory Framework

Risk Management & Approval

Food additive/NF application

EC mandate

EFSA opinion

GM Food application

MS request

EFSA opinion

Risk Assessment

EU novel ingredient framework

Food, **ingredient** or **manufacturing process** not consumed/used in the EU before **15th May 1997 "Novel" – Regulation (EU) 2015/2283**

Traditional food consumed outside the EU

- ✓ Whole foods, minimally processed

Novel food (10 categories):

- ✓ (ii) food **consisting** of, **isolated** from or **produced** from **microorganisms**, **fungi** or **algae**
- ✓ (iv) food consisting of, isolated from or produced from **plants** and their parts
- ✓ (vi) food consisting of, isolated from or produced from **cell culture** or **tissue culture** derived from **animals, plants, microorganisms, fungi** or **algae**

NOT novel foods:
Food additives (incl. colours)
Food enzymes
Flavourings
Extraction solvents
GM Food

EU Novel Food Authorisation Process

Regulation (EU) 2015/2283

Timeline from submission to authorisation 1.5 years

EU QMV, 55% EU MS representing 65% of EU population!

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Average Novel Food Timelines[1]

Average timeline from submission to authorisation ca. **2.5 years**

Fastest = 1 year, 6 months
Longest = 5 years
Average 3 x clock-stops

[1]Unpublished analysis performed by Atova – based on 35 approved novel food dossiers for which all data points were available. Analysis did not include modification of use dossiers

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EU GMO Framework

GM Foods:
Food additives (incl. colours)
Food enzymes
Flavourings
Novel Foods

Bioengineered food = genetically modified food

Genetically modified organisms (GMOs) are strictly regulated in the EU

Directive 2001/18/EC defines a GMO as:

an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

GM food must be authorised in accordance with Regulation (EU) 1829/2003

Contained use of genetically modified microorganisms (GMMs) defined in Directive 2009/41/EC

Which techniques result in a GMO?

Techniques resulting in a GMO (Annex 1A Part 1)
Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation
Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection, and micro-encapsulation
Cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally

Which techniques do not result in a GMO?

Techniques not resulting in a GMO (Annex 1A Part 2 & Annex 1B)
In vitro fertilisation* Natural processes such as: conjugation, transduction, transformation* Polyploidy induction*
Mutagenesis**
Cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods

*Not considered to result in GMO, on the condition that they do not involve the use of recombinant nucleic acid molecules

**EU Court of Justice concluded in 2018 that organisms obtained by mutagenesis are GMOs, with the exemption of techniques that have conventionally been used and have a long history of safe use.

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Precision fermentation & GMMs as processing aids

- Food produced '**from**' a GMM (Regulation (EU) 1829/2003 on GMO) vs food produced '**with**' a GMM (Regulation (EU) 2015/2283 on NF)
- Determining criterion: No viable cells
- Traces of rDNA is not a regulatory requirement. Arbitrary threshold of 10 ng/ml or g LOD! Ongoing discussions at EC & MS

	GMM Category 1	GMM Category 2	GMM Category 3	GMM Category 4
Definition	Chemically defined, purified substances. GMM removed	Complex products in which both GMMs and newly introduced genes are no longer present	Products derived from GMMs, where GMMs capable of capable of multiplication or of transferring genes are not present, but in which newly introduced genes are still present	Products consisting of or containing GMMs capable of multiplication or of transferring genes
Example	Amino acids, vitamins	Purified proteins	Biomasses/proteins with host DNA present	Live starter cultures for fermented foods
In scope of GM regulation	No	No	????	Yes
Different product categories defined as per EFSA guidance 2011 on the risk assessment of GMM and their products				

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Regulatory Approval Procedure – Regulation (EU) 1829/2003

QMV = 55% of EU Member States representing 65% of EU Population!

GM Food authorisations renewed after 10 years!

GM Food should take 9-12 month to be approved……

Reality.....

No QMV (for or against) ever reached for a GM food!

All GM food authorisations even at appeal stage have received a “no opinion”

Member states can give different reasons for a negative vote or abstention

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Draft Implementing Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 was presented to the Committee.

One Member State provided comments on the PMEM plan in the context of a recent spillage in a crushing facility concerning an authorized oilseed rape, and raised the question of whether the PMEM for oilseed rape should be updated. This was supported by three Member States. The Commission presented the follow-up to the spillage incident mentioned, and informed Member States that the relevant documents were available to the Committee. It was agreed to discuss the PMEM plan related to all GM oilseed rape authorisations at the next Committee meeting.

Vote taken: no opinion.

Reasons for negative vote or abstention:

- No agreed national position
- Negative public opinion
- Precautionary principle
- Scientific reasons
- Political reasons

Consequently, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

Reality.....

Product	EFSA			EC			Total time
	Dossier received	Dossier validated	Opinion published	MS Expert Committee	Appeal Committee	Authorisation	
GM oilseed rape 73496	29 MAY 2012	04 DEC 2012	17 JUN 2021	17 DEC 2021	10 FEB 2022	31 MAR 2022	9 years and 10 months
	Number of clock-stops: 11			Vote: No opinion	Vote: No opinion	–	
GM soybean GMB151	09 OCT 2018	04 MAR 2019	19 APR 2021	20 JAN 2022	03 MAR 2022	31 MAR 2022	3 years and 5 months
	Number of clock-stops: 7			Vote: No opinion	Vote: No opinion	–	

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Case Study: Impossible Foods Soy Leghaemoglobin

- Intended use as a colour
- Category 3 GMM
- No viable cells, but host strain DNA present (ca. 300 mg/L)
- GM Food + Food Additive application!

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Case Study: Impossible Foods Soy Leghaemoglobin

GMO

Food and Feed - Regulation (EC) No 1829/2003

EFSA-Q-2019-00651 | Status: Ongoing Risk Assessment

Clockstop expected until: 31/12/2024 | Last updated: 08/07/2024

Subject

Request for placing on the market of Soy Leghemoglobin produced from genetically modified Pichia pastoris (EFSA-GMO-NL-2019-162)

Output

No Output has been formed yet for this question.

Supporting documents

All files

Document Type	Download file
EPA Charter	PDF (123.8KB)

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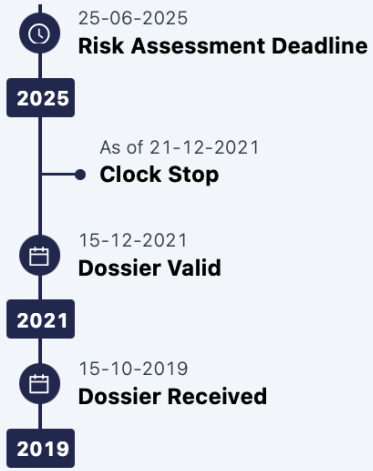
Timeline



Filed via the Dutch competent authority on 7th October 2019

Dossier received by EFSA on 15th October 2019

Validated by EFSA on 15th December 2021!

Clock-stopped 7 days later and remains so to this day!

Risk assessment deadline June 2025 – 5.6 years....

Then Risk Management!

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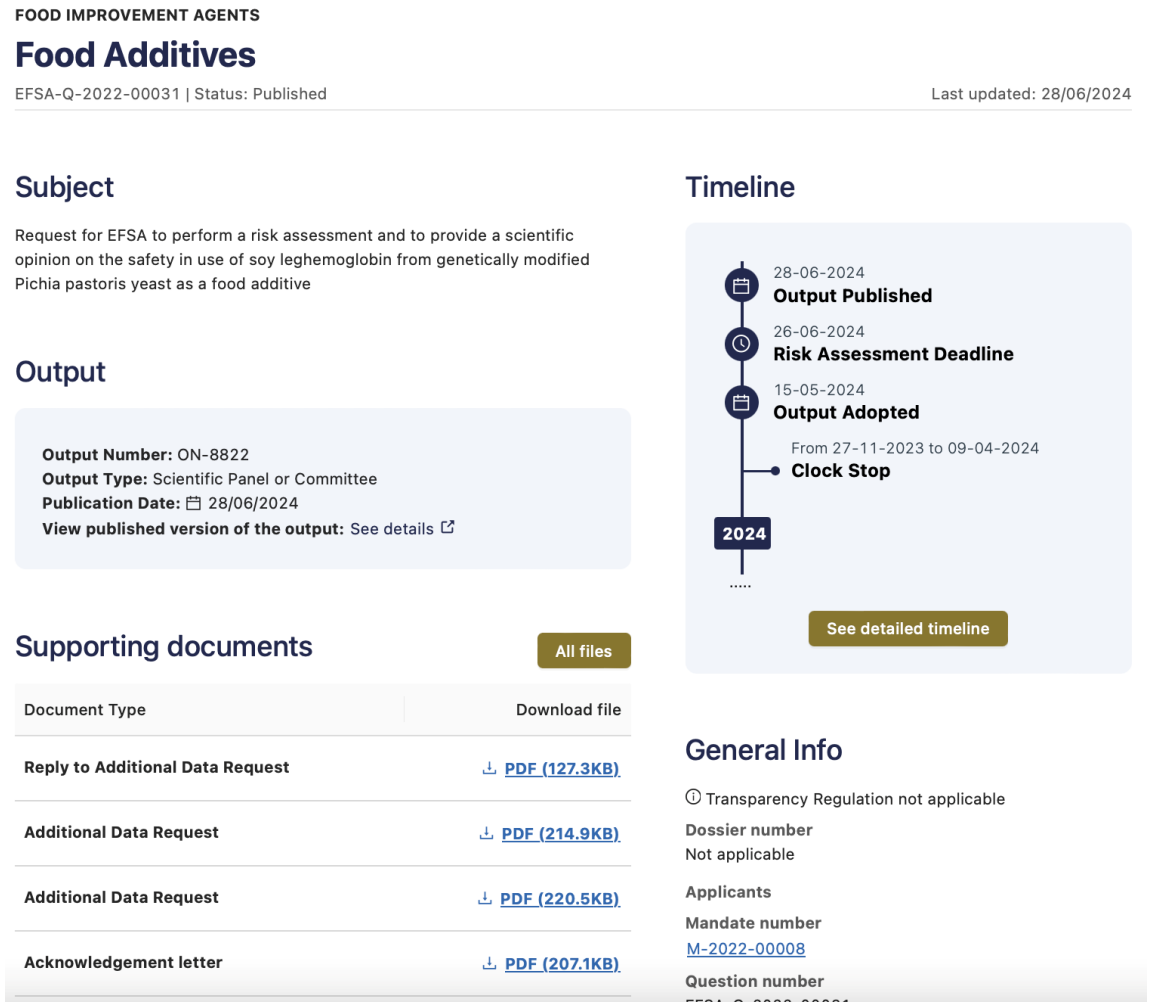
Case Study: Impossible Foods Soy Leghaemoglobin



FOOD IMPROVEMENT AGENTS

Food Additives

EFSA-Q-2022-00031 | Status: Published

Last updated: 28/06/2024

Subject

Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in use of soy leghemoglobin from genetically modified Pichia pastoris yeast as a food additive

Output

Output Number: ON-8822
Output Type: Scientific Panel or Committee
Publication Date: 28/06/2024
View published version of the output: See details

Supporting documents

All files

Document Type	Download file
Reply to Additional Data Request	PDF (127.3KB)
Additional Data Request	PDF (214.9KB)
Additional Data Request	PDF (220.5KB)
Acknowledgement letter	PDF (207.1KB)

Timeline

28-06-2024
Output Published

26-06-2024
Risk Assessment Deadline

15-05-2024
Output Adopted

From 27-11-2023 to 09-04-2024
Clock Stop

2024

See detailed timeline

General Info

Transparency Regulation not applicable

Dossier number
Not applicable

Applicants

Mandate number
M-2022-00008

Question number

Food additive application received by EFSA in January 2022

Validated June 2022

Clock-stopped for 5 months

Opinion published 28th June 2024

EFSA issues a positive opinion – no safety concerns.

2 Years, 5 months to the opinion

FA assessment provisional, pending ongoing evaluation of the GM Food

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Case Study: Impossible Foods Soy Leghaemoglobin

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

15 December 2020
[145-20]

Approval report – Application A1186

Soy leghemoglobin in meat analogue products

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Impossible Foods Inc. for the voluntary addition of soy leghemoglobin, produced by microbial fermentation, in meat analogue products.

On 6 August 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 15 submissions.

FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Ca. 17 months!

Government of Canada / Gouvernement du Canada

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MENU

Canada.ca › Health › Food and nutrition - Canada.ca › About novel and genetically-modified (GM) foods

› Completed safety assessments of novel foods including genetically modified (GM) foods

Soy leghemoglobin (LegH) preparation as an ingredient in a simulated meat product and other ground beef analogues

Novel Food Information

On this page

- Backgound
  1. Introduction
  2. Development of the Production Organism
  3. Manufacturing of the LegH Preparation
  4. Product Information
  5. Dietary Exposure
  6. Nutrition
  7. Microbiology
  8. Chemistry

Ca. 24 months

Approved in multiple countries including Singapore, Hong Kong.....

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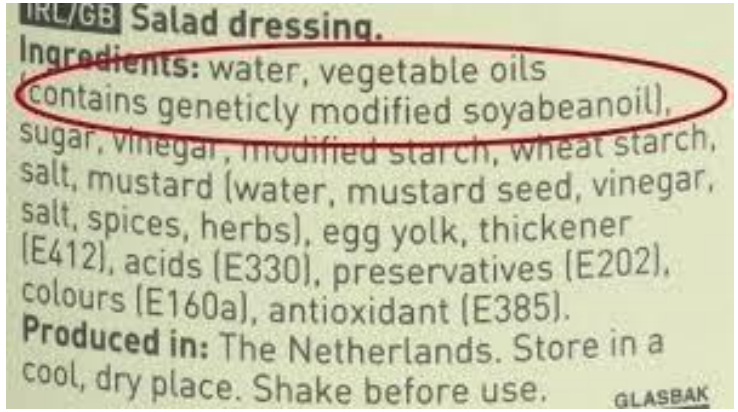
GM Labelling?

GMO Labelling EU



Defined in Regulation (EC) 1830/2003

Ensures traceability at all stages of production

Mandatory labelling "*product contains GMOs*"

A product may contain traces of GMOs (below 0.9 %), if this is technically unavoidable

Products made "with" GMM not labelled as GMO

Individual Member States responsible for testing and enforcement

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What are the main regulatory concerns about GM Food?.....

Regulatory/Safety Concerns

- Public perception & consumer acceptance
- New allergens
- Nutritional adequacy
- Toxicity
- Traceability & testing

Future Outlook & Key Takeaways

- GM food strictly regulated
- Highly political!
- Most concerns not related to safety
- Consumer acceptance?
- Some countries more open to GM food

- NF/FA safer route
- GM food route long & unpredictable
- Need clarification on Cat 3 GMMs & rDNA
- Impossible Foods!
- Regulatory uncertainty

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Thank you!

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