



EFSA's Second Scientific Conference  
Shaping the Future of Food Safety, Together  
Milan, 14, 15, 16 October 2015



# NOVEL FOODS

DI Klaus Riediger

AGES- Institute for Food Safety Vienna  
Department for Foods: Food Supplements and Novel Foods

Session: Nutrition challenges ahead  
Milano, 15.10.2015

# Disclaimer



**„Meine Bemerkungen sind nicht zwangsläufig die offizielle Meinung der AGES bzw. Österreichs“**

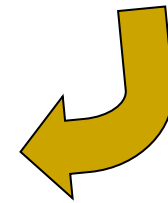
**“My remarks do not necessarily reflect the official view of AGES or Austria”**

# Overview



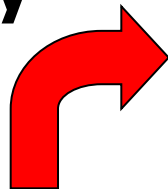
- Responsibilities and networks
  - Definition of novel foods (NF)
  - New novel food regulation?
  - Authorization of novel foods
  - Examples of novel foods
  - Contact
- 
- ANNEX: Important Homepages, Information for NF  
(will be not presented! Just for your information)

# Responsibilities in Austria



**Assessment**

**Competent authority**



**BUNDESMINISTERIUM  
FÜR GESUNDHEIT**

# Austrian Agency for Health and Food Safety



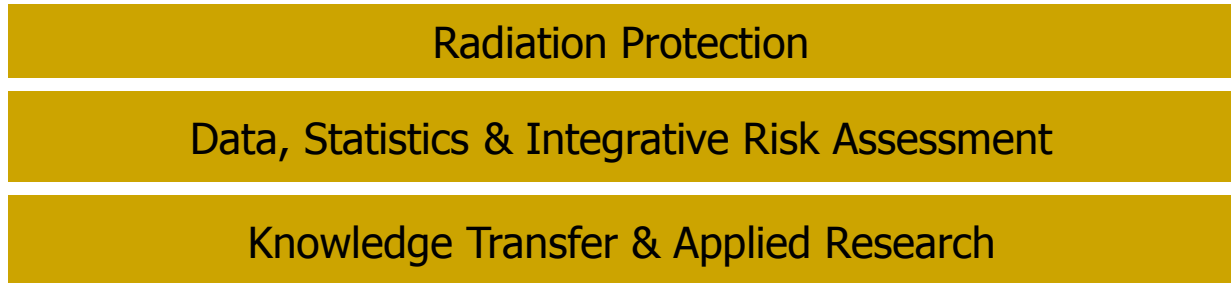
# AGES Company Structure 2012



**Business Area**



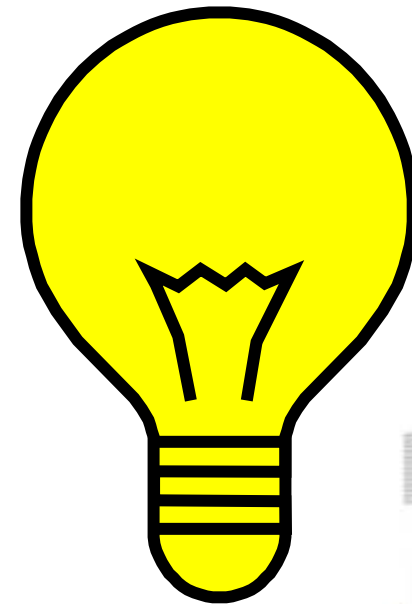
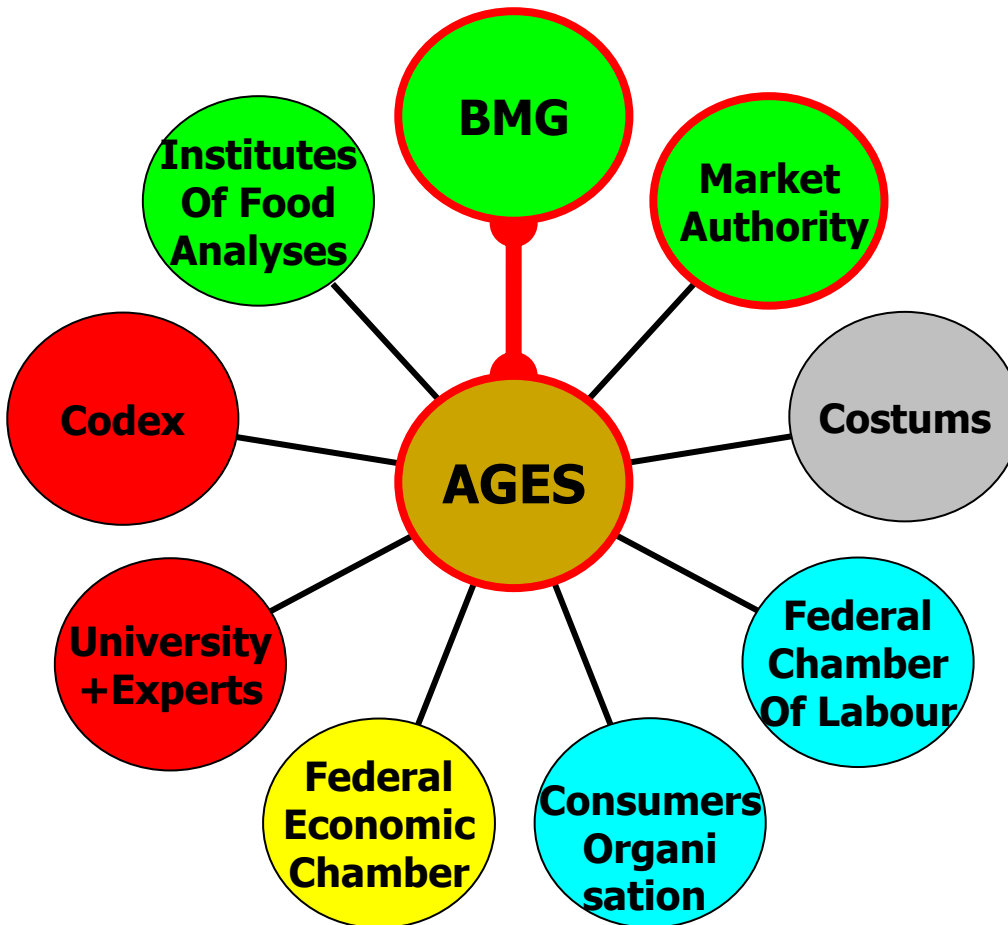
**Department**



1) Austrian Federal Office for Food Safety

2) Austrian Federal Office for Safety in Healthcare

# Novel Food Networks



## Novel Food Working Group



# Definition 1



A **novel food** is defined as a **food or food ingredient** which **does not**

**have a significant history of consumption** within the **EC**  
**before the 15th of May 1997**

and which fall into the following specific categories:  
(**Article 1, paragraph 2** without **GMO- a)** and **b)**):

**Foods and food ingredients,**



## Definition 2

- c) with a new or intentionally modified primary molecular structure (e.g. fat replacers, **Tagatose**);
- d) consisting of or isolated from micro-organisms, fungi or algae (e.g. **oil rich in DHA from a microalgae**);
- e) foods and food ingredients consisting of or isolated from plants (e.g. **Chia seed, Rapeseed Protein**) and food ingredients isolated from animals (e.g. lipid extract from antarctic Krill *Euphausia superba*), except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

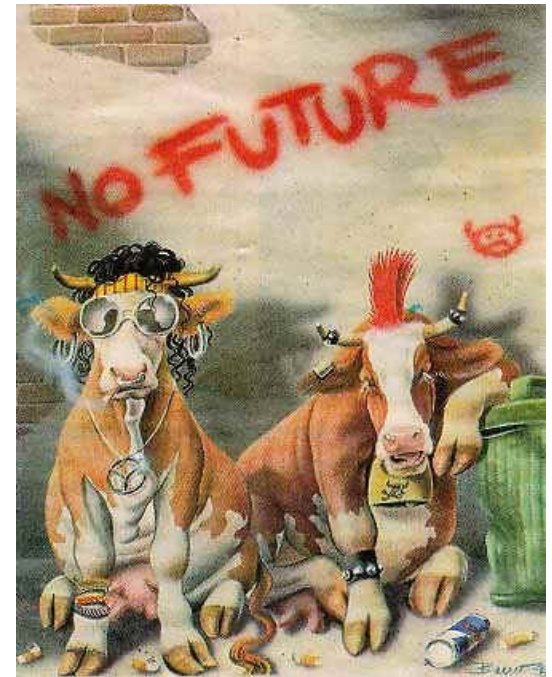
# Definition 3



- f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances (e.g. **UVC treated milk**, nanotechnology)**

# Draft revision of novel foods regulation

- common authorisation procedure - EFSA;
- updated technical guidance and tools for preparing and submitting application
- Notification process for traditional food from 3rd countries with a "history of (safe) use";
- Emerging future technologies (nanotechnology);
- **Whole Animals (Insects);**
- **Cloning**

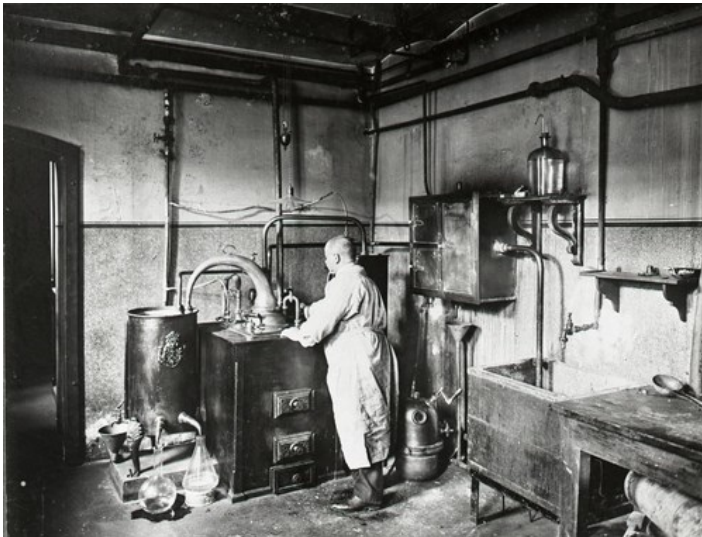


# WW I- 100 Years of „Novel Foods“ AGES

[http://www.ages.at/service/ages-akademie/programm-detail/kalender/detail/event/not\\_macht\\_erfinderisch\\_ersatzlebensmittel\\_im\\_1\\_weltkrieg/archiv/](http://www.ages.at/service/ages-akademie/programm-detail/kalender/detail/event/not_macht_erfinderisch_ersatzlebensmittel_im_1_weltkrieg/archiv/)

Ersatz(lebens)mittel = Surrogat(e)  
= „Substitute good (food)“

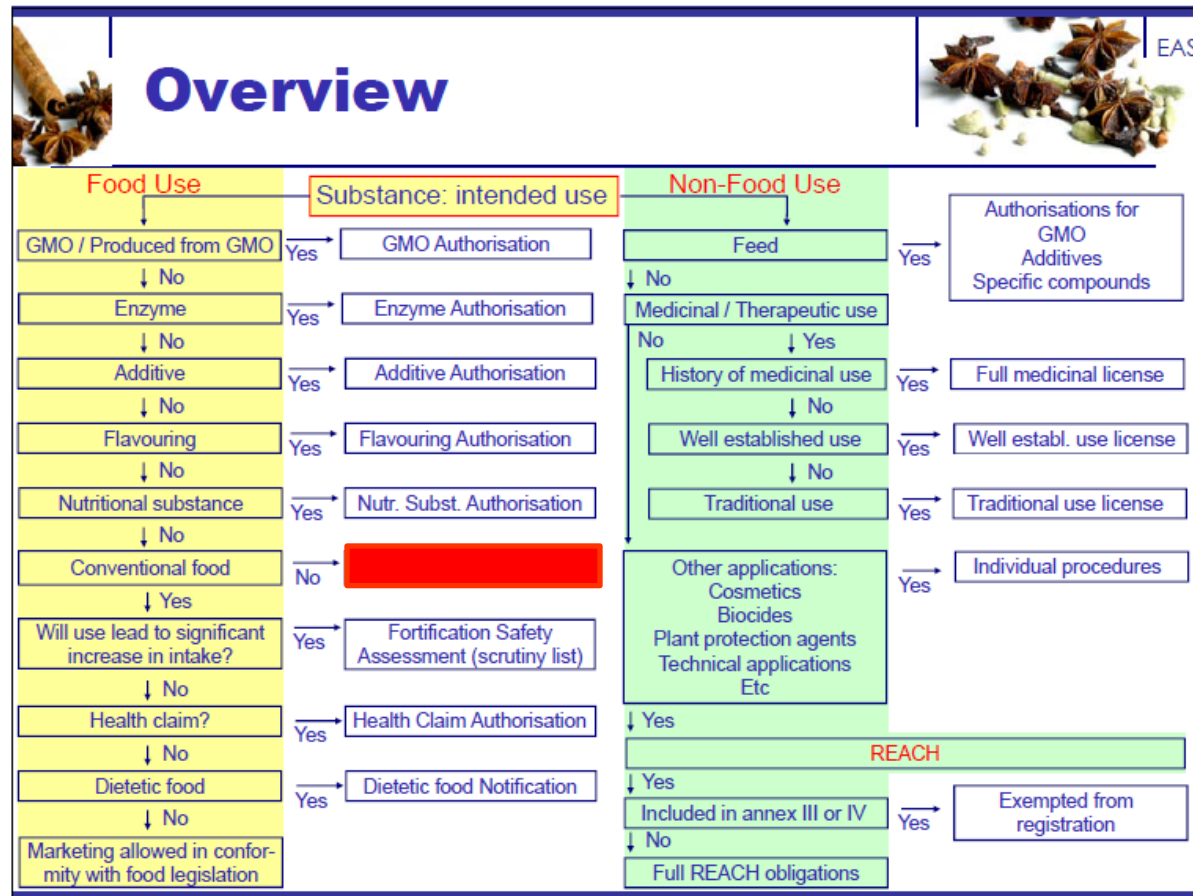
Kathreiner- barley coffee  
factory in Munich



Maize germ oil



# Overview of authorization procedures



# Safety assessment of novel foods and novel food ingredients

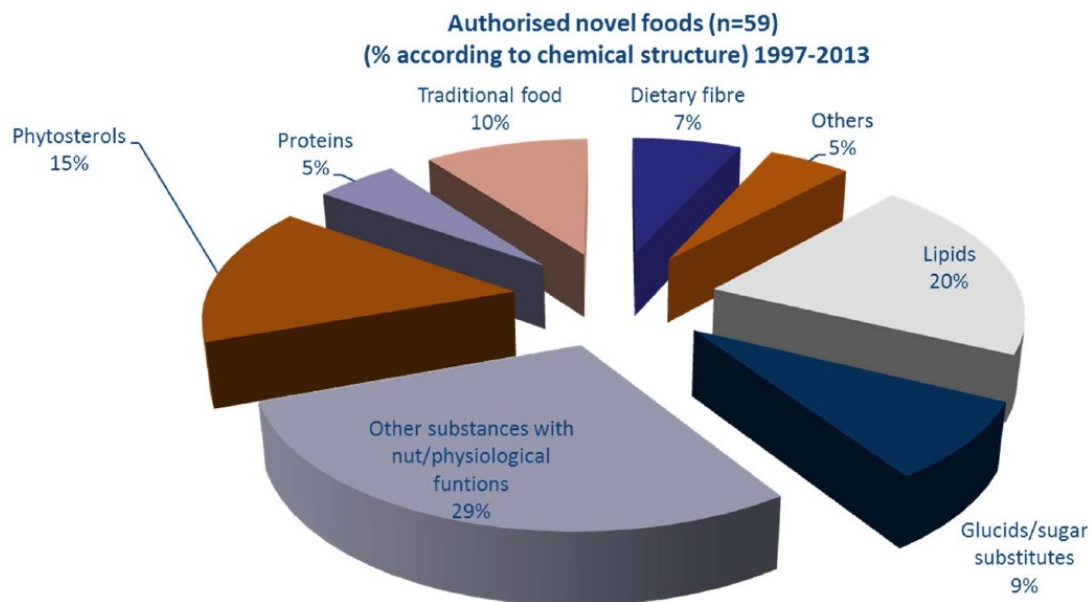


- **Foods commercialised legally in at least one Member State before the entry into force of the Regulation on Novel Foods on 15 May 1997, are on the EU market under the „principle of mutual recognition“.**
- **In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment („Community assessment“) before being placed on the EU market. Only those products considered to be safe for human consumption are authorised for marketing.**
- **Two kinds of authorisations: Notifications and Applications**

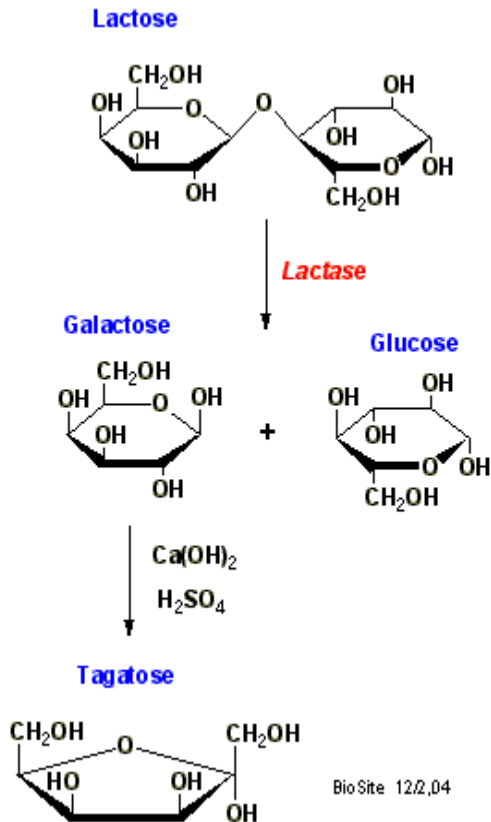


# Novel Food- Industry view (→Henk Aalten, DSM)

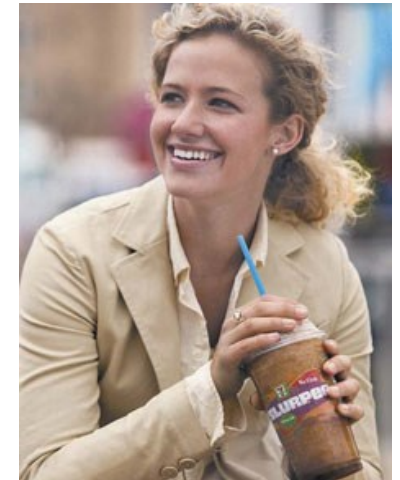
## Which type of novel ingredients have made it?



# D- Tagatose (authorized NF) (FSA)

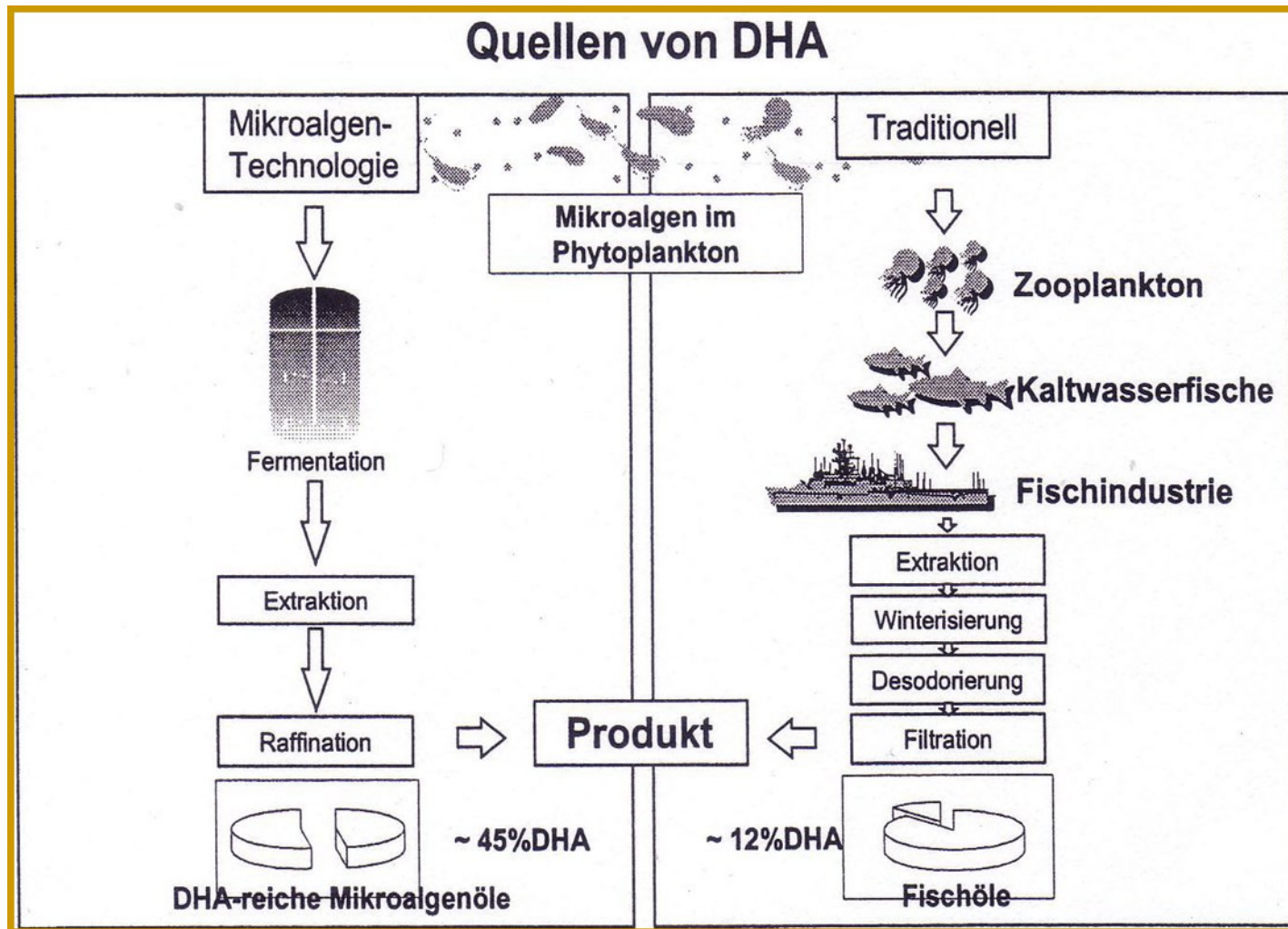


- is lowering the blood sugar increasing effect compared to Saccharose (< GI)
- Calories: Tagatose = 1,5 kcal/g (Saccharose = 4,0 kcal/g)
- praebiotic
- Sweetness: Tagatose = 0,9 (Saccharose = 1,0)
- Tagatose induces no Karies





# DHA-rich algal oil (authorized)



From Praxishandbuch Functional Food- BEHRS Verlag

# Chiaseeds + Chiaoil (*Salvia hispanica*) (authorized NF)

Chia is an annual herbaceous plant. The seed is rich in omega-3 fatty acids.



ANNEX II

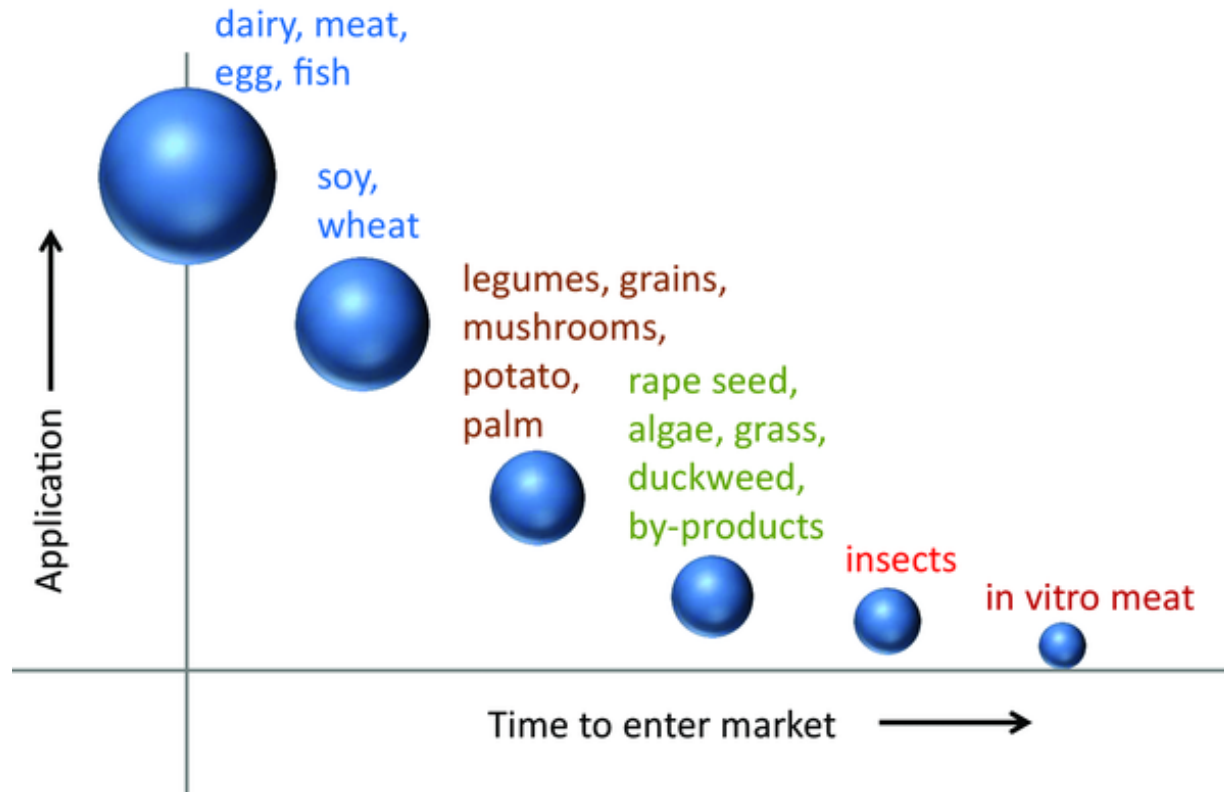
USES OF CHIA (*SALVIA HISPANICA*) SEED

Baked products	not more than 10 %
Breakfast cereals	not more than 10 %
Fruit, nut and seed mixes	not more than 10 %
Pre-packaged Chia seed as such	not more than 15 g per day



<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:021:0034:0035:EN:PDF>

# Novel Protein Sources



**Comprehensive Reviews in Food Science and Food Safety**

Volume 12, Issue 6, pages 662-678, 15 OCT 2013 DOI: 10.1111/1541-4337.12032

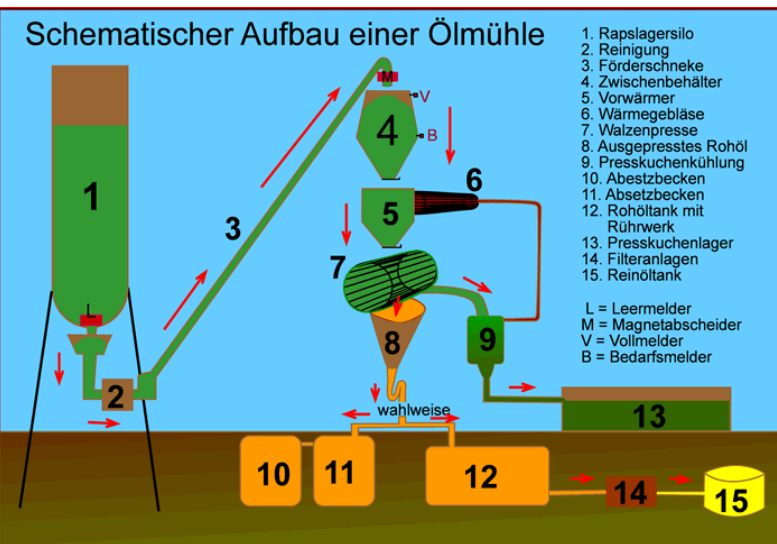
<http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12032/full#crf312032-fig-0001>



# Rapeseed protein (= Canola protein) (instead of Soja protein)



The labelling of any foodstuff containing rapeseed protein shall bear an easily visible and legible statement that the product containing 'rapeseed protein' as a food ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof.



Where relevant, this statement shall appear in close proximity to the list of ingredients.



# Insects 1

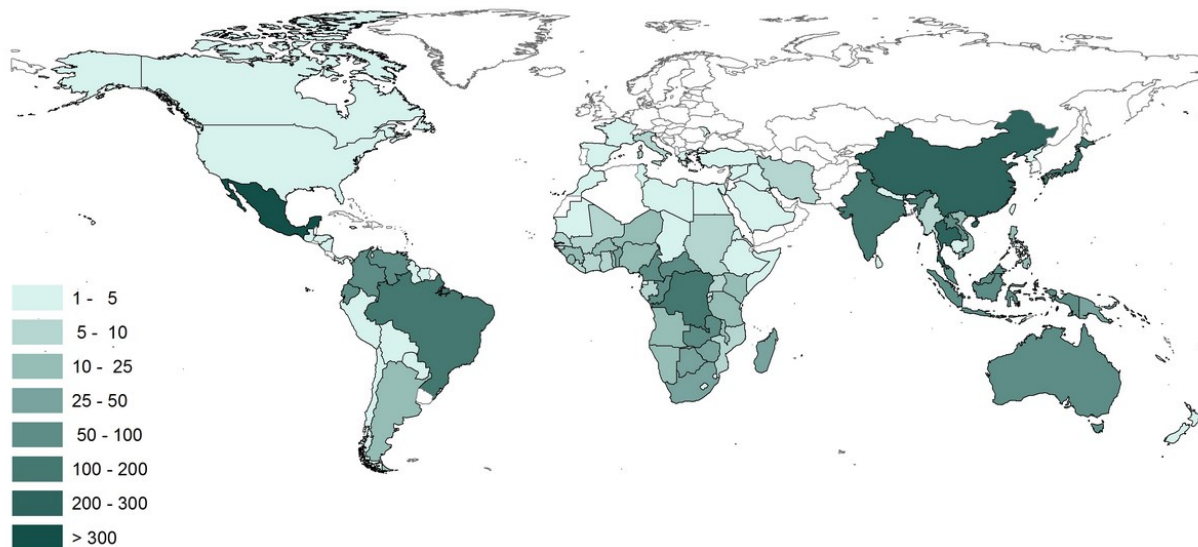


EFSA Scientific Committee, 2015. Scientific Opinion on a risk profile related to production and consumption of insects as food and feed. EFSA Journal 2015;13(10):4257, 60 pp. doi:10.2903/j.efsa.2015.4257 <http://www.efsa.europa.eu/en/efsajournal/pub/4257>

# Insects 2

<http://www.wageningenur.nl/en/Expertise-Services/Chair-groups/Plant-Sciences/Laboratory-of-Entomology/Edible-insects/Worldwide-species-list.htm>

Recorded edible insect species, by country



Source: Centre of Geo information by Ron van Lammeren, Wageningen University, based on data compiled by Yde Jongema, 2015

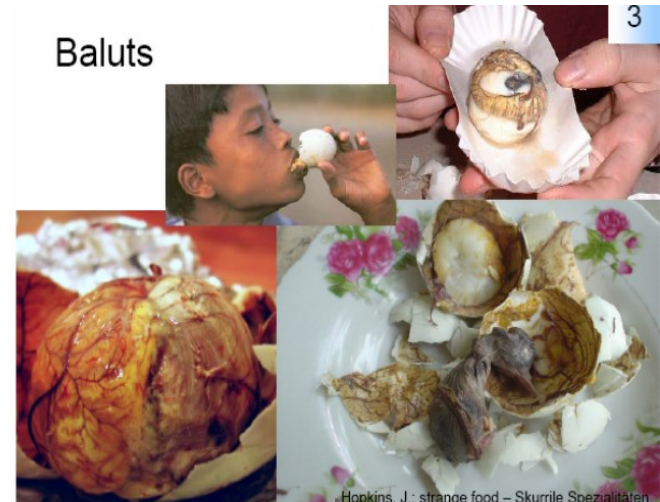
version: 150518



# Exotic animals

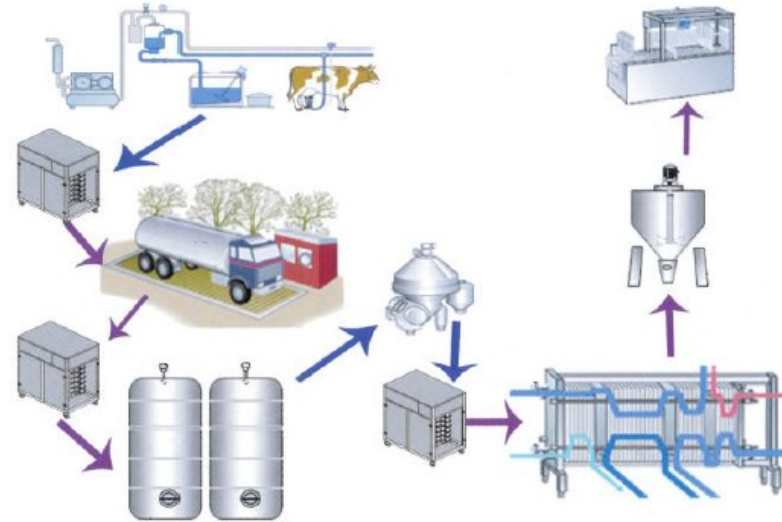
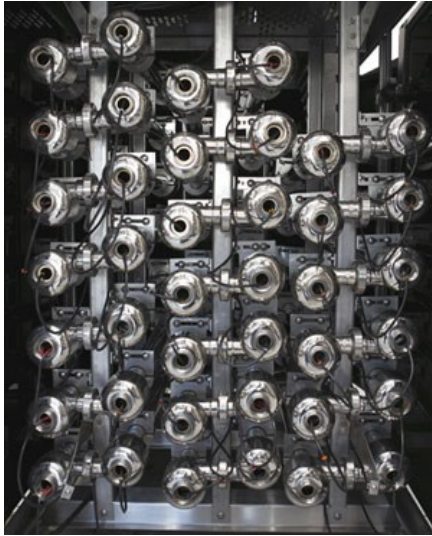


Baluts



Hopkins, J.: strange food – Skurrile Spezialitäten

# UVC treated milk (not authorized until now in EC)



Layout of UV photopurification in a dairy plant (source: SurePure)

SurePure™ Technology: Pasteurization and treatment with UV-C Pulsed Light (200 – 310 nm).

As a result, the bacteria count is reduced, thus prolonging the shelf life of the milk from 12 to 21 days.

As a side effect the vitamin D3 content in the product is increased from the UVC-treatment. The higher the fat content of the milk, the higher the vitamin D3 content.



# Contact



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**E-Mail: [klaus.riediger@ages.at](mailto:klaus.riediger@ages.at)**

**<http://www.ages.at/startseite/>**

**<https://www.verbrauchergesundheit.gv.at/Lebensmittel/neuartige/Im/neuartige/Im.html>**

# ANNEX



The screenshot shows the 'Novel food' page on the European Commission website. At the top, there are navigation links for 'Cookies', 'Legal notice', 'Contact', 'Search', and 'English (en)'. The main header features the European Commission logo and the word 'FOOD'. Below this is a breadcrumb trail: 'European Commission > Food Safety > Food > Novel food'. A navigation bar includes 'HEALTH', 'FOOD' (highlighted), 'ANIMALS', and 'PLANTS'. On the left, a sidebar lists 'NOVEL FOOD' with sub-items: 'Legislation', 'Authorisations', and 'Novel food catalogue'. Below this is an 'ALL TOPICS' button. The main content area is titled 'Novel food' and contains the following text:

## Novel food

### What is Novel Food?

Novel Food is defined as food that has not been consumed to a significant degree by humans in the EU prior to 1997, when the first Regulation on novel food came into force.

'Novel Food' can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.

Examples of Novel Food include agriculture products from third countries (chia seeds), newly produced nutrients (synthetic zeaxanthin) or extracts from existing food (rapeseed protein).

Novel Food **must be**:

- **Safe** for consumers
- Properly **labelled** to not mislead consumers

On the right side, there is a 'QUICK LINKS' section with the following items:

- Rapid Alert for Food and Feed (RASFF)
- Food and Veterinary Office (FVO)
- European Food Safety Authority (EFSA)
- Better Training for Safer Food (BTFSF)
- Standing Committee - PAFF
- E-News
- Events
- Videos

At the bottom of the page, a footer indicates 'Last update: 26.08.2015' and provides links for 'Legal notice', 'Contact', and 'Top'.

## Panel on dietetic products, nutrition and allergies [NDA]

- **assessment of nutrition and health claims,**
- **setting of dietary reference values,**
- **guidance on how to establish food-based dietary guidelines,**
- **setting of tolerable upper intake levels for vitamins and minerals,**
- **advice on food allergens,**
- **advice on novel foods,**
- **assessment of ingredients to be used in infant formulas.**

# UK 1

<http://www.food.gov.uk/science/novel>



The screenshot shows the Food Standards Agency website page for Novel Foods. The page has a green header with the FSA logo and navigation tabs for Home, News & updates, Business & industry, Enforcement & regulation, Science & policy, and About us. The main content area is titled "Novel foods" and provides information on novel food assessments, food from cloned animals, and nanotechnology. A left sidebar contains a "Science and policy" menu with sub-items like "Our approach to science", "Applying for research funding", "Management and policy", "Research reports", "Acrylamide", "Additives or E numbers", "Allergy and intolerance", "Bisphenol-A (BPA)", "Food poisoning", "Irradiated food", "Novel foods", "Cloned animals", "GM foods", "Nanotechnology", "Novel food assessments", "Novel foods FAQs", "Regulation of novel food", "Unauthorised novel foods", "Radioactivity in food", and "Scientific committees". The main text includes sections for "Advisory Committee on Novel Foods and Processes (ACNFP)", "Cloned animals", "Novel foods frequently asked questions", "Unauthorised novel foods", "Nanotechnology", and "GM foods". A "See also" box on the right lists "Novel foods" and "GM foods". A "Feedback" button is visible on the right edge of the page.



Accessibility | A A A

- ▶ Advisory Committee on Novel Foods and Processes (ACNFP)
- ▶ ACNFP membership
- ▶ ACNFP meetings
- ▶ ACNFP annual reports
- ▶ Papers, guidelines and correspondence
- ▶ More about the ACNFP
- ▶ Novel food assessments

ACNFP Secretariat  
Food Standards Agency  
2nd floor Aviation House  
125 Kingsway  
London WC2B 6NH

Tel: +44 (0)20 7276 8596  
Fax: +44 (0)20 7276 8513

[acnfp@foodstandards.gsi.gov.uk](mailto:acnfp@foodstandards.gsi.gov.uk)



## Advisory Committee on Novel Foods and Processes (ACNFP)



The Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory, independent body of scientific experts that advises the Food Standards Agency on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation).

The Committee carries out safety assessments of any novel food or process submitted for approval under the EC novel food regulation. Until April 2004 the scope of this regulation included all foods produced using genetically modified organisms. However, GM foods are now subject to approval under a separate regulation. Approval of GM foods now involves centralised risk assessments, which are the responsibility of the European Food Safety Authority (EFSA).

Nevertheless, the Committee still has a role in advising the Food Standards Agency on GM foods - for example by contributing to EFSA's risk assessments or by advising the Agency on other GM issues.

The ACNFP is supported in its work by a secretariat provided by the Food Standards Agency. The secretariat has scientific expertise that enables them to provide Members with comprehensive background information and briefing papers that inform the decision-making processes of the Committee. As well as formal meetings, the Committee organises workshops on specific topics related to its remit.

The reports of the ACNFP's evaluations and the minutes of the Committee's meetings are published on this site. The ACNFP also publishes an annual report which explains the work the Committee has undertaken during the reporting year and provides a full list of the Committee's Members and any interests that they might have.

### News

#### Views sought on chia seeds

A company has asked the FSA's expert advisers on novel foods to consider an application for chia seeds to be approved for use in the European Union (EU) under the simplified approval procedure. Views are wanted on the independent expert committee's draft opinion.

[Feedback](#)

# BELGIUM

<http://www.health.belgium.be/eportal/foodsafety/foodstuffs/novelfoods/index.htm?fodnlang=en#.VhfqN0Y73pJ>



federal public service  
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT



My health

Food safety

Health care

Animals and Plants

Environment

Home / Food safety / Foodstuffs / Novel foods

Search

in "Food safety"  Expanded search

Back to

Food safety

Meat from slaughtered animals

Fish

Dairy produce

Additives

Flavourings

Food supplements

Novel foods

Water

Codex alimentarius

Foods for particular nutritional uses

      follow  this page

## Novel Food

The term "Novel Food" refers to novel foods and novel food ingredients which had not been used for human consumption to a significant degree before 15 May 1997 and which fall under one of the following categories:

- foods and food ingredients with a new or intentionally modified primary molecular structure;
- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals (except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use);
- foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.
- Examples of Novel Foods are fruit juices like noni juice, milk or voohurt

### Related documents

▸ Law (3)

### More about:

food voedselingredienten nieuwe  
ingredients novel voedingsmiddelen

# GERMANY



(1) [http://www.bmel.de/DE/Ernaehrung/SichereLebensmittel/SpezielleLebensmittelUndZusaetze/NovelFood/novelFood\\_node.html](http://www.bmel.de/DE/Ernaehrung/SichereLebensmittel/SpezielleLebensmittelUndZusaetze/NovelFood/novelFood_node.html)



Bundesministerium  
für Ernährung  
und Landwirtschaft

(2) [http://www.bvl.bund.de/DE/01\\_Lebensmittel/03\\_Verbraucher/06\\_NovelFood/ImNovelFood\\_node.html](http://www.bvl.bund.de/DE/01_Lebensmittel/03_Verbraucher/06_NovelFood/ImNovelFood_node.html)



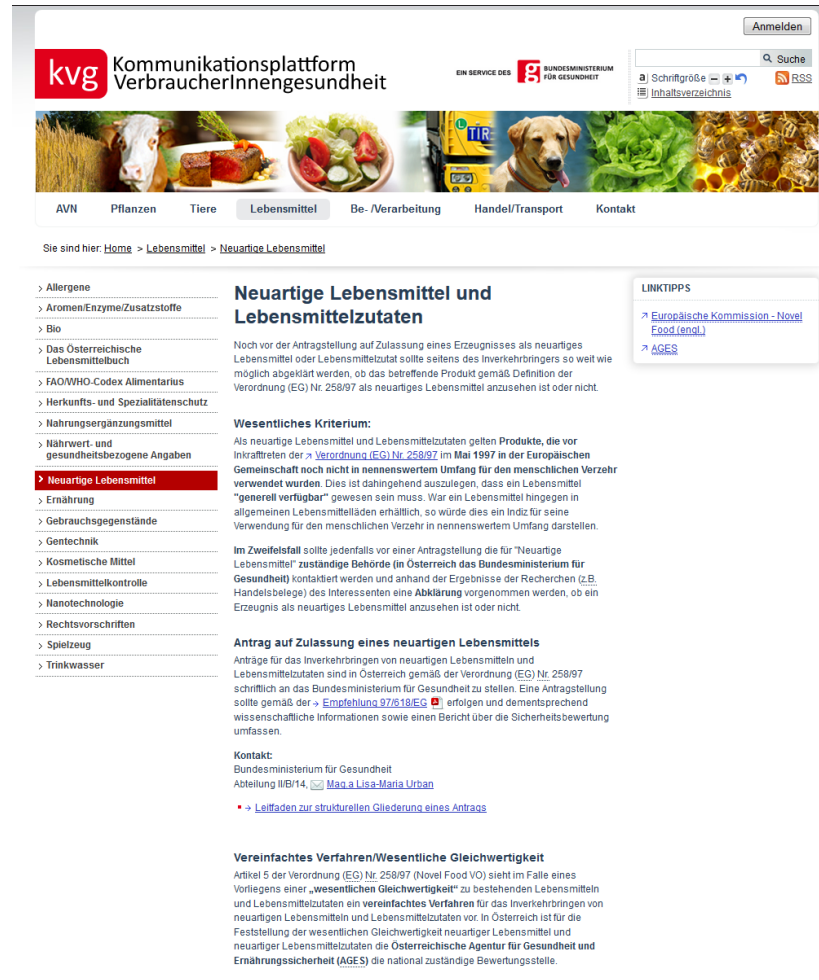
Bundesamt für  
Verbraucherschutz und  
Lebensmittelsicherheit

(3) [http://www.bfr.bund.de/de/novel\\_foods-215.html](http://www.bfr.bund.de/de/novel_foods-215.html)



Risiken erkennen – Gesundheit schützen





**kvg** Kommunikationsplattform VerbraucherInnen-gesundheit

EIN SERVICE DES BUNDESMINISTERIUM FÜR GESUNDHEIT

Suche

Schriftgröße

Inhaltsverzeichnis

AVN Pflanzen Tiere **Lebensmittel** Be-/Verarbeitung Handel/Transport Kontakt

Sie sind hier: [Home](#) > [Lebensmittel](#) > [Neuartige Lebensmittel](#)

**Neuartige Lebensmittel und Lebensmittelzutaten**

Noch vor der Antragstellung auf Zulassung eines Erzeugnisses als neuartiges Lebensmittel oder Lebensmittelzutat sollte seitens des Inverkehrbringers so weit wie möglich abgeklärt werden, ob das betreffende Produkt gemäß Definition der Verordnung (EG) Nr. 258/97 als neuartiges Lebensmittel anzusehen ist oder nicht.

**Wesentliches Kriterium:**

Als neuartige Lebensmittel und Lebensmittelzutaten gelten Produkte, die vor Inkrafttreten der [Verordnung \(EG\) Nr. 258/97](#) im Mai 1997 in der Europäischen Gemeinschaft noch nicht in nennenswertem Umfang für den menschlichen Verzehr verwendet wurden. Dies ist dahingehend auszulegen, dass ein Lebensmittel "generell verfügbar" gewesen sein muss. War ein Lebensmittel hingegen in allgemeinen Lebensmittelformen erhältlich, so würde dies ein Indiz für seine Verwendung für den menschlichen Verzehr in nennenswertem Umfang darstellen.

Im Zweifelsfall sollte jedenfalls vor einer Antragstellung die für "Neuartige Lebensmittel" zuständige Behörde (in Österreich das Bundesministerium für Gesundheit) kontaktiert werden und anhand der Ergebnisse der Recherchen (z.B. Handelsbelege) des Interessenten eine Abklärung vorgenommen werden, ob ein Erzeugnis als neuartiges Lebensmittel anzusehen ist oder nicht.

**Antrag auf Zulassung eines neuartigen Lebensmittels**

Anträge für das Inverkehrbringen von neuartigen Lebensmitteln und Lebensmittelzutaten sind in Österreich gemäß der Verordnung (EG) Nr. 258/97 schriftlich an das Bundesministerium für Gesundheit zu stellen. Eine Antragsstellung sollte gemäß der [Empfehlung 97/618/EG](#) erfolgen und dementsprechend wissenschaftliche Informationen sowie einen Bericht über die Sicherheitsbewertung umfassen.

**Kontakt:**  
Bundesministerium für Gesundheit  
Abteilung II/B/14, [Fax](#) [Mail](#) [Lisa-Maria Urban](#)

• [Leitfaden zur strukturellen Gliederung eines Antrags](#)

**Vereinfachtes Verfahren/Wesentliche Gleichwertigkeit**

Artikel 5 der Verordnung (EG) Nr. 258/97 (Novel Food VO) sieht im Falle eines Vorliegens einer „wesentlichen Gleichwertigkeit“ zu bestehenden Lebensmitteln und Lebensmittelzutaten ein vereinfachtes Verfahren für das Inverkehrbringen von neuartigen Lebensmitteln und Lebensmittelzutaten vor. In Österreich ist für die Feststellung der wesentlichen Gleichwertigkeit neuartiger Lebensmittel und neuartiger Lebensmittelzutaten die Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES) die national zuständige Bewertungsstelle.

AGES > Themen > Service > EN / DE AAA AGES

AGES / Themen / Lebensmittel / Neuartige Lebensmittel

## Themen

- Krankheitserreger
- Schaderegger
- Landwirtschaft >
- Tierernährung >
- Umwelt >
- Rückstände & Kontaminanten >
- GVO >
- Strahlenschutz >
- Lebensmittel** >

- Allergene
- Flüssige Lebensmittel >
- Gewürze
- Haltbarkeit
- Zusatzstoffe und Aromen
- Lebensmittelkennzeichnung
- Lebensmittelkontrolle
- Lebensmittelsicherheit

## Neuartige Lebensmittel

Services Verwandte Inhalte

Zuletzt geändert: 12.12.2014

In der Regel können Lebensmittel ohne vorherige Genehmigung auf den europäischen Markt gebracht werden. Eine Ausnahme stellen neuartige Lebensmittel und Lebensmittelzutaten dar. Diese Produkte müssen einer einheitlichen Sicherheitsbewertung unterworfen werden, bevor sie in der EU in Verkehr gebracht werden können. Neuartige Lebensmittel dürfen keine Gefahr für den Verbraucher darstellen und keine Irreführung bewirken. Weiters dürfen sie sich von herkömmlichen Lebensmitteln und Lebensmittelzutaten, die sie ersetzen sollen, nicht so unterscheiden, dass ihr normaler Verzehr Ernährungsmängel für den Verbraucher zur Folge hätte.

Neuartige Lebensmittel ("Novel Foods") sind Lebensmittel und Lebensmittelzutaten, die vor dem 15. Mai 1997 in der Europäischen Union noch nicht in nennenswertem Umfang für den menschlichen Verzehr verwendet wurden. Novel Foods sind Lebensmittel und Lebensmittelzutaten, die folgenden vier Kategorien zuzuordnen sind:

- Lebensmittel mit neuer oder gezielt modifizierter primärer Molekularstruktur (z. B. synthetische, kalorienfreie Fettersatzstoffe)
- Lebensmittel, die aus Mikroorganismen, Pilzen oder Algen bestehen oder aus diesen isoliert worden sind wie beispielsweise Algenöl
- Lebensmittel, die in Europa unbekannte und exotische Pflanzen und Pflanzenteile enthalten (z. B. Noni-Saft) oder Lebensmittelzutaten, die aus Tieren isoliert wurden.
- Lebensmittel, die mit einem neuen, nicht üblichen Verfahren hergestellt wurden, das eine Veränderung der Zusammensetzung oder Struktur bewirkt (z. B. hochdruckpasteurisierte Fruchtzubereitungen).

Lebensmittelzusatzstoffe, Lebensmittelaromen, gentechnisch veränderte Lebensmittel und Extraktionslösungsmittel zur Herstellung von Lebensmitteln sind keine neuartigen Lebensmittel, da für sie eigene gesetzliche Regelungen bestehen.

### Beispiele für neuartige Lebensmittel und Lebensmittelzutaten

Neuartige Lebensmittel, die in der EU genehmigt sind, sind beispielsweise cholesterinsenkende Phytosterole in Streichfetten, Noni-Saft und Trehalose als süßende Lebensmittelzutat. Die Anträge zum Süßkraut Stevia rebaudiana, zu Nangainüssen und zu jodangereicherten Eiern wurden abgelehnt.

### Links

[Informationen der Europäischen Kommission zu Novel Foods](#)

# Other EU MS



- [https://www.fsai.ie/legislation/food\\_legislation/novel\\_foods/application\\_procedure.html](https://www.fsai.ie/legislation/food_legislation/novel_foods/application_procedure.html)
- <http://www.evira.fi/portal/en/food/manufacture+and+sales/novel+foods/>
- <http://english.cbg-meb.nl/human/novel-foods/contents/european-authorisation-and-assessments/european-authorisation>
- <https://www.anses.fr/en/content/novel-foods-and-food-ingredients>
- [http://aesan.msssi.gob.es/AESAN/web/cadena\\_alimentaria/subseccion/nuevos\\_alimentos\\_nuevos\\_ingredientes.shtml](http://aesan.msssi.gob.es/AESAN/web/cadena_alimentaria/subseccion/nuevos_alimentos_nuevos_ingredientes.shtml)
- [http://ec.europa.eu/food/safety/docs/novel-food\\_ms-authority-list\\_en.pdf](http://ec.europa.eu/food/safety/docs/novel-food_ms-authority-list_en.pdf)
- <http://www.eufic.org/article/de/expid/review-novel-foods/>

# Other countries



- <http://www.blv.admin.ch/themen/04678/04817/04818/04822/index.html?lang=de>
- <http://www.fda.gov/Food/DietarySupplements/ucm109764.htm>
- <http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx>
- <http://www.foodstandards.gov.au/industry/novel/documents/Guidance%20Tool%20-%20for%20website%202.pdf>
- <http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/novel-foods-aliments-nouveaux-eng.php>
- <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>
- <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html>

# Novel foods checklist

<http://multimedia.food.gov.uk/multimedia/pdfs/novel-foods-checklist.pdf>



This Food Standards Agency (FSA) checklist provides advice about online lists that you can check, as well as how to ask for information to be sent to you, which may help you to find out the novel status of a particular food.

## « Human Consumption to a Significant Degree » Information and Guidance Document

[http://ec.europa.eu/food/food/biotechnology/novelfood/documents/substantial\\_equivalenc\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/novelfood/documents/substantial_equivalenc_en.pdf)

# Risk assessment and risk management of novel plant foods- Concepts and principles 1



<http://norden.diva-portal.org/smash/get/diva2:702553/FULLTEXT01.pdf>

**"Worldwide 30 food plants deliver 95% of human daily intake of plant food calories and around 300 other plant species are delivering the last 5%. These some 300 food plants are likely to be considered traditional in Europe, while the nearly 7000 other plant species traditionally used in the human food supply in other parts of the world may be considered novel in Europe. Novel food regulation is already in force in the European Community, Australia/New Zealand and in Canada where the novel plant foods need to go through a premarket assessment procedure.**

# Risk assessment and risk management of novel plant foods- Concepts and principles 2



<http://norden.diva-portal.org/smash/get/diva2:702553/FULLTEXT01.pdf>

**This paper propose criteria and definitions to be used in determining novelty of a plant food and also propose a safety assessment approach for novel plant food with no or limited documented history of safe consumption.**

**A 2-step management procedure is recommended for a smooth introduction of fruits and vegetables; first to establish the novelty and second to define and commit resources for the safety assessment. The procedure builds upon the use of a worldwide network of global, regional, local and ethnobotanical positive lists for food plants to guide the decision on novelty at the first step and to enable the safety assessment at the second step."**

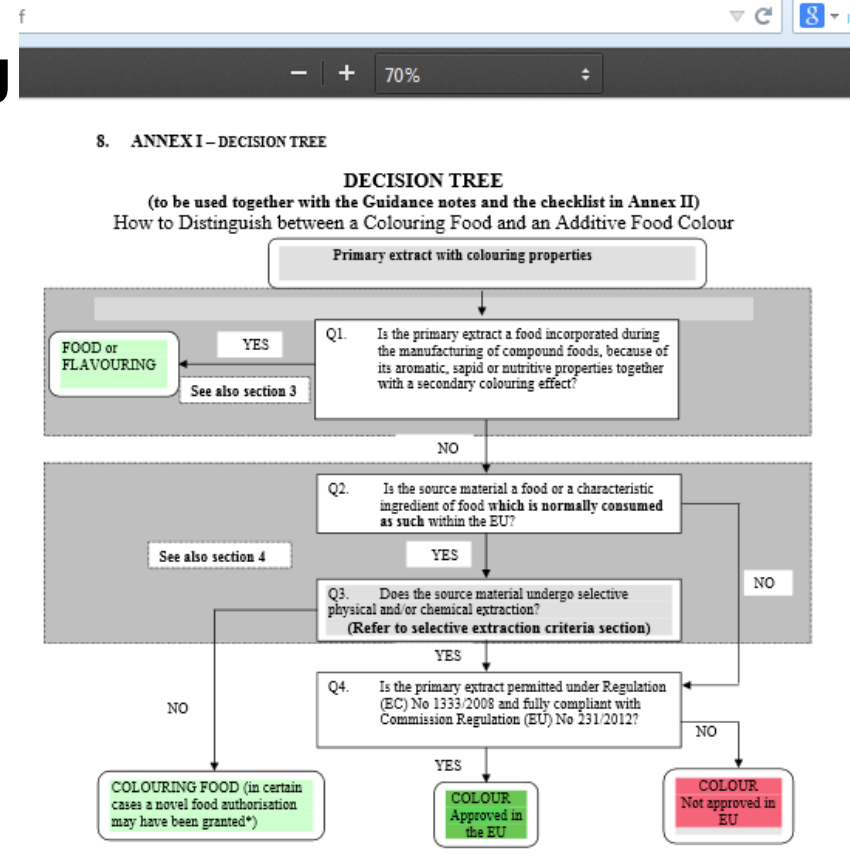
# Guidance notes on the classification of food extracts with colouring properties

[http://ec.europa.eu/food/food/FAEF/additives/docs/guidance\\_en.pdf](http://ec.europa.eu/food/food/FAEF/additives/docs/guidance_en.pdf)

**Give guidance for differentiating Properties (Colouring Foods) from additive food colours.**

**The concept could also be used for the evaluation of the novel food status of special extracts with calculation of the enrichment factor of interest.**

- **“Vitamin D mushrooms”**
- **“Greentea extract” (EGCG)**





# EFSA Scientific Colloquium WHAT'S NEW ON NOVEL FOODS



<http://www.efsa.europa.eu/de/search/doc/colloquianovelfood.pdf>



## WHAT'S NEW ON NOVEL FOODS

**DG1: History of (safe) use and traditional foods from non-EU –countries**

**DG2: Data requirements and approach for anticipated intake**

**DG3: Key issues in absorption, distribution, metabolism, and excretion (ADME ) studies, toxicology and allergenicity**

**DG4: Data requirements to demonstrate safety of foods derived by nanotechnology**

19-20 November 2009, Amsterdam, The Netherlands



# The United Nations Conference on Trade and Development (UNCTAD)

[http://www.biotrade.org/ResourcesPublications/UNCTAD\\_DITC\\_BCC\\_2009\\_5.pdf](http://www.biotrade.org/ResourcesPublications/UNCTAD_DITC_BCC_2009_5.pdf)



ISSUE PAPER

CONCERNING THE PROPOSED AMENDMENTS TO THE EUROPEAN  
NOVEL FOODS REGULATION (EC) 258/97  
WITH PARTICULAR REFERENCE TO  
TRADITIONAL FOODS FROM DEVELOPING COUNTRIES



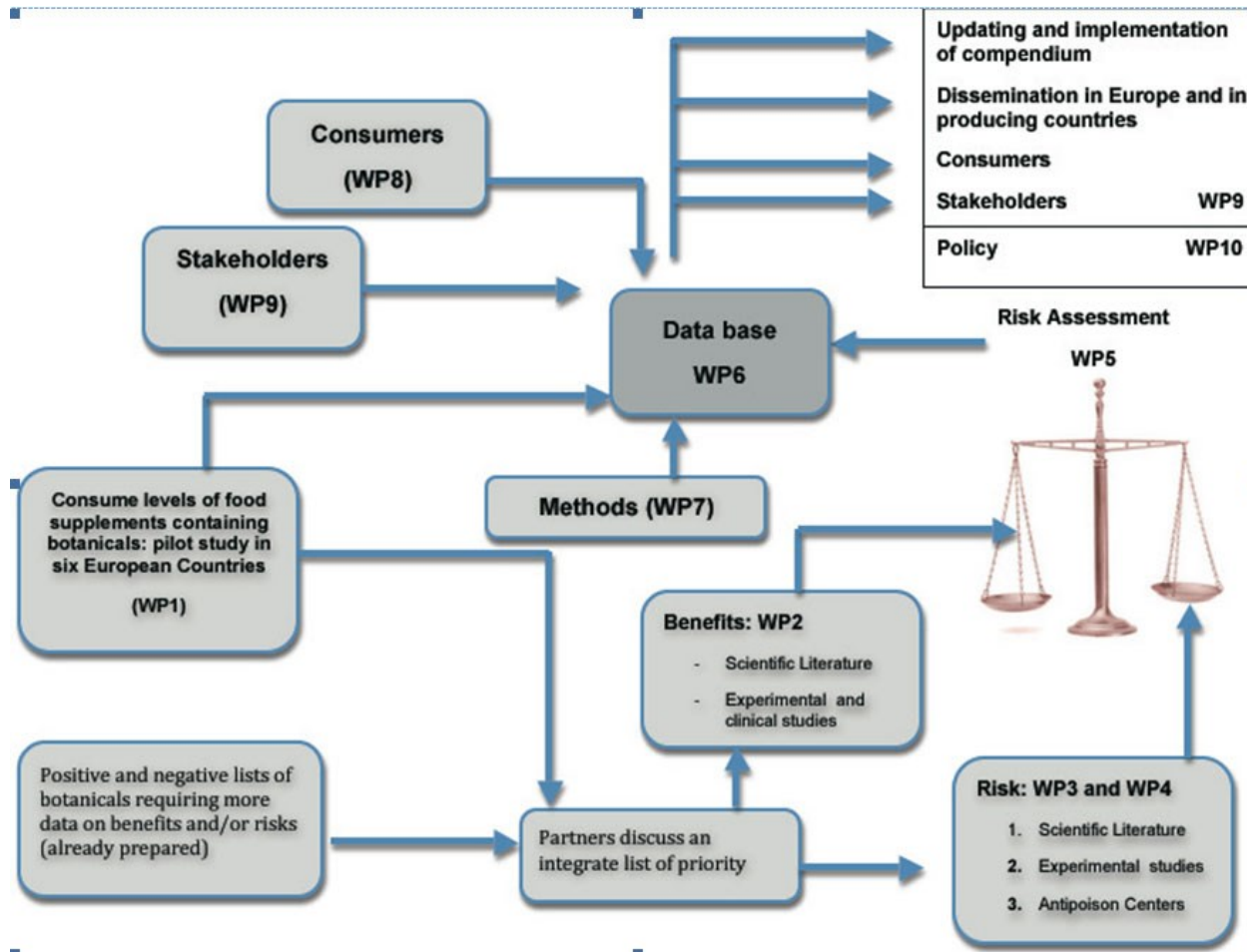
November 2009

# Plant Libra: Project + Links

<http://www.plantlibra.eu/web/?q=node/63>



## PLANT food supplements: Levels of Intake, Benefit and Risk Assessment



# EFSA Botanicals (Plants, Fungi, Algae)

<http://www.efsa.europa.eu/en/topics/topic/botanicals.htm>



- **European Food Safety Authority; Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663. [60 pp.].**  
<http://www.efsa.europa.eu/en/efsajournal/doc/2663.pdf>
- **EFSA Scientific Committee; Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, on request of EFSA. EFSA Journal 2009; 7(9):1249. [19 pp.].**  
<http://www.efsa.europa.eu/en/search/doc/1249.pdf>
- **Scientific Opinion on a Qualified Presumption of Safety (QPS) approach for the safety assessment of botanicals and botanical preparations**  
<http://www.efsa.europa.eu/de/efsajournal/pub/3593.htm>

# BOTANICALS- National initiatives like **BELFRIT**



- **BELGIUM, FRANCE, ITALY**

[http://www.bvl.bund.de/SharedDocs/Downloads/01\\_Lebensmittel/stoffliste/07\\_Geelen\\_Vortrag\\_SL.pdf?blob=publicationFile&v=3](http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/stoffliste/07_Geelen_Vortrag_SL.pdf?blob=publicationFile&v=3)

- **GERMANY**

[http://www.bvl.bund.de/DE/01\\_Lebensmittel/03\\_Verbraucher/08\\_Stoffliste/Im\\_stoffliste\\_node.html](http://www.bvl.bund.de/DE/01_Lebensmittel/03_Verbraucher/08_Stoffliste/Im_stoffliste_node.html)

[http://www.bvl.bund.de/SharedDocs/Downloads/01\\_Lebensmittel/stoffliste/stoffliste\\_pflanzen\\_pflanzenteile\\_EN.pdf?blob=publicationFile&v=5](http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/stoffliste/stoffliste_pflanzen_pflanzenteile_EN.pdf?blob=publicationFile&v=5)

- **AUSTRIA (Tea and tea like products)**

<http://www.lebensmittelbuch.at/tee-und-teeaehnliche-erzeugnisse/>

- ...