International Conference on Novel Foods

FSE´s approach to novel foods
BELFRIT List

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International Non-Profit Organisation

Principles and legal obligations

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The new Novel Foods Regulation: The principles

1. The scope should in principle be the same as with the previous Regulation 258/97

   - The date of for determining if a food was used to a significant degree is 15 May 1997
   - The food should also fall into one of the 10 categories. These have been expanded to provide more clarity
   - Some foods are now specifically mentioned to be included (e.g. insects, foods from tissue cultures, engineered nanomaterials, etc)
   - For such foods, if lawfully marketed in the EU after 15 May 1997, a transition period applies: They can remain on the market if an application for authorisation is submitted before 1 January 2019 and the food is subsequently authorised.

The new Novel Foods Regulation: The principles

2. It is a legal obligation for the food business operator to consult a national authority in case he is unsure if his food falls within the scope of the Novel Food Regulation
   - Procedural steps and data requirements have been set in EC Implementing Regulation 2018/456

Companies should therefore include this check in the procedures for development of every new product

The Food Supplement Guidelines are intended to help companies in this process

Scope and application of the definition

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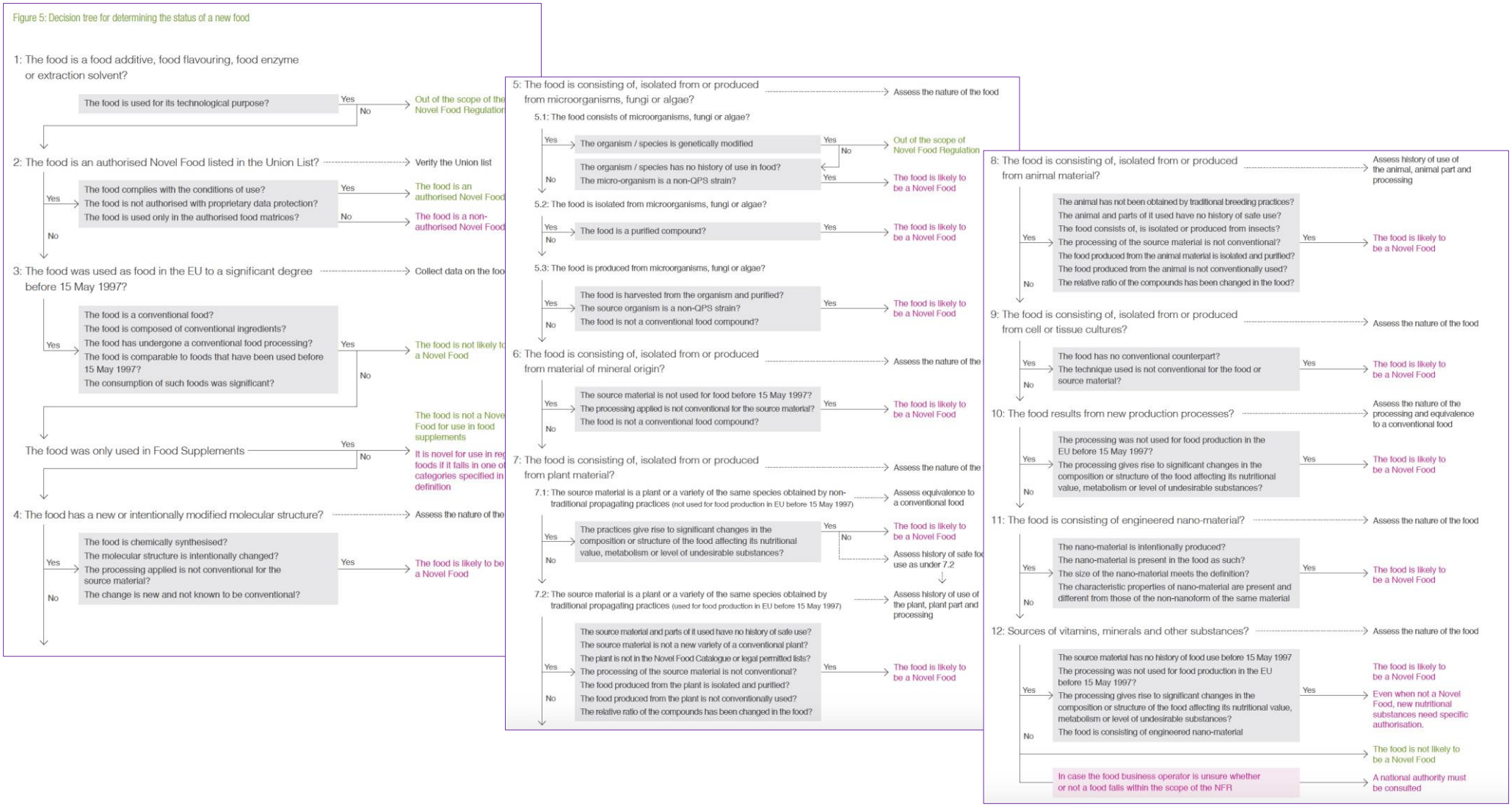
The 10 categories of novel foods

1. Food with a new or intentionally modified molecular structure [..]
2. Food consisting of, isolated from or produced from microorganisms, fungi or algae
3. Food consisting of, isolated from or produced from material of mineral origin
4. Food consisting of, isolated from or produced from plants or their parts [...]
5. Food consisting of, isolated from or produced from animals or their parts [...]
6. Food consisting of, isolated from or produced from cell culture or tissue culture [...]
7. Food resulting from a production process not used for food production [...]
8. Food consisting of engineered nanomaterials [...]
9. Vitamins, minerals and other substances [...]
10. Food used exclusively in food supplements within the Union before 15 May 1997 [...]

Knowing under what conditions a food falls under this definition is therefore key

Flow Chart + Explanation and examples



FSE Guidelines Decision Tree

The food is a food additive, food flavouring, food enzyme or extraction solvent?

The food is used for its technological purpose?

YES → **Out of the scope of the Novel Food Regulation**

NO ↓

The food is an authorised Novel Food listed in the Union List? ⇢ Verify the Community list

YES ↓

The food complies with the conditions of use?
The food is not authorised with proprietary data protection?
The food is used only in the authorised food matrices?

YES → **The food is an authorised Novel Food**

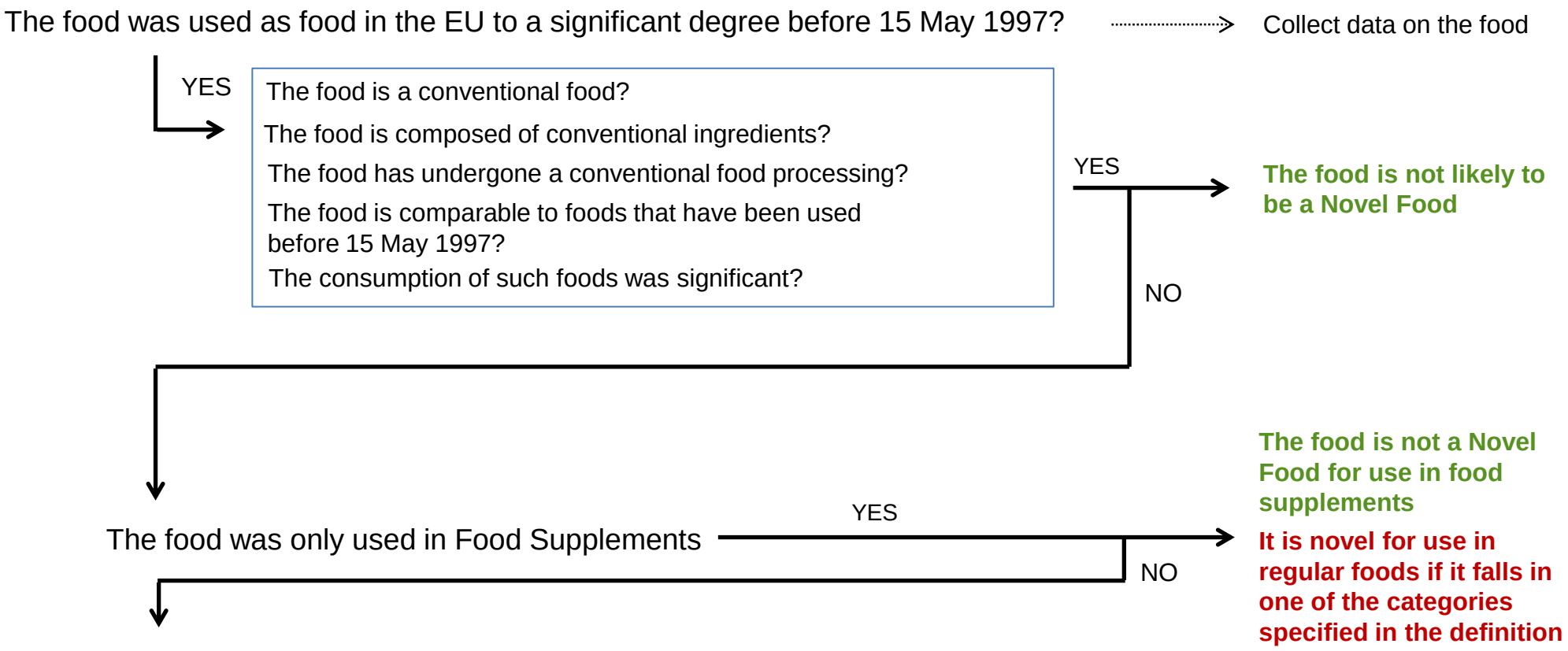
NO → **The food is a non-authorised Novel Food**

NO ↓

Only food additives, flavourings, enzymes and extraction solvents are excluded

Authorised novel foods should respect the conditions of use as specified in the Union list

FSE Guidelines Decision Tree



Food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC

FSE Guidelines Decision Tree

The food has a new or intentionally modified molecular structure? ⇢ Assess the nature of the food

YES →
- The food is chemically synthesised?
- The molecular structure is intentionally changed?
- The processing applied is not conventional for the source material?
- The change is new and not known to be conventional?

YES → **The food is likely to be a Novel Food**

NO ↓

The food is consisting of, isolated from or produced from material of mineral origin? ⇢ Assess the nature of the food

YES →
- The source material is not used for food before 15 May 1997?
- The processing applied is not conventional for the source material?
- The food is not a conventional food compound?

YES → **The food is likely to be a Novel Food**

NO ↓

The food is consisting of, isolated from or produced from cell or tissue cultures? ⇢ Assess the nature of the food

YES →
- The food has no conventional counterpart?
- The technique used is not conventional for the food or source material?

YES → **The food is likely to be a Novel Food**

NO ↓

FSE Guidelines Decision Tree

The food is consisting of, isolated from or produced from microorganisms, fungi or algae? ⇢ Assess the nature of the food

The food consists of microorganisms, fungi or algae?

YES → The organism / species is genetically modified

YES → **Out of the scope of Novel Food Regulation**

NO

NO → The organism / species has no history of use in food?
The micro-organism is a non-QPS strain?

YES → **The food is likely to be a Novel Food**

The food is isolated from microorganisms, fungi or algae?

YES → The food is a purified compound?

YES → **The food is likely to be a Novel Food**

NO

The food is produced from microorganisms, fungi or algae?

YES → The food is harvested from the organism and purified?
The source organism is a non QPS strain?
The food is not a conventional food compound?

YES → **The food is likely to be a Novel Food**

NO

FSE Guidelines Decision Tree

The food is consisting of, isolated from or produced from plant material? → Assess the nature of the food

The source material is a plant or a variety of the same species obtained by non-traditional propagating practices (not used for food production in EU before 15 May 1997)

YES

The practices give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances?

→ Assess equivalence to a conventional food

YES → **The food is likely to be a Novel Food**

NO → Assess history of safe food use as under 7,.2

NO

The source material is a plant or a variety of the same species obtained by traditional propagating practices (used for food production in EU before 15 May 1997) → Assess history of use of the plant, plant part and processing

YES

The source material and parts of it used have no history of safe use?
The source material is not a new variety of a conventional plant?
The plant is not in the Novel Food Catalogue or legal permitted lists?
The processing of the source material is not conventional?
The food produced from the plant is isolated and purified?
The food produced from the plant is not conventionally used?
The relative ratio of the compounds has been changed in the food?

YES → **The food is likely to be a Novel Food**

NO

FSE Guidelines Decision Tree

The food is consisting of, isolated from or produced from animal material?

Assess history of use of the animal, animal part and processing

YES

NO

The animal has not been obtained by traditional breeding practices?

The animal and parts of it used have no history of safe use?

The food consists of, is isolated or produced from insects?

The processing of the source material is not conventional?

The food produced from the animal material is isolated and purified?

The food produced from the animal is not conventionally used?

The relative ratio of the compounds has been changed in the food?

YES → **The food is likely to be a Novel Food**

The food results from new production processes?

Assess the nature of the processing and equivalence to a conventional food

YES

NO

The processing was not used for food production in the EU before 15 May 1997?

The processing gives rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances?

YES → **The food is likely to be a Novel Food**

FSE Guidelines Decision Tree

The food is consisting of engineered nano-material? → Assess the nature of the food

YES

NO

- The nano-material is intentionally produced?
- The nano-material is present in the food as such?
- The size of the nano-material meets the definition?
- The characteristic properties of nano-material are present and different from those of the non-nanoform of the same material

YES → **The food is likely to be a Novel Food**

Sources of vitamin, minerals and other substances? → Assess the nature of the food

YES

NO

- The source material has no history of food use before 15 May 1997
- The processing was not used for food production in the EU before 15 May 1997?
- The processing give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances?
- The food is consisting of engineered nano-material

YES → **The food is likely to be a Novel Food**

Even when not a Novel Food. New nutritional substances need specific authorisation.

The food is not likely to be a Novel Food

IN CASE THE FOOD BUSINESS OPERATOR IS UNSURE WHETHER OR NOT A FOOD FALLS WITHIN THE SCOPE OF THE NOVEL FOOD REGULATION

A national authority must be consulted

Traditional Foods from a Third Country

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Traditional foods from a third country - Conditions

- The food should not fall under categories (i), (iii), (vii), (viii), (ix) and (x) of the definition
- The food should have been consumed in at least one third country.
- The food should have been consumed for at least 25 years.

  As part of the customary diet of a significant number of people in the third country. Safety of the food must have been confirmed with compositional data and from experience of continued use.

  Requirements: Commission Implementing Regulation 2017/2468 and EFSA guidelines on data requirements.

- The history of safe food use should not include non-food uses.

  Should cover uses of products that in the EU would be considered as acceptable under food law. Use of products for the prevention, treatment or cure of diseases are not acceptable.

- The food should be derived from primary production.

  Regulation 178/2002: “Production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting, fishing and harvesting of wild products”.

  => only edible parts derived directly from plants or animals can qualify for this procedure.

Traditional foods from a third country - Conditions

- **The food should be derived from primary production.**

  It is likely to mean that traditional food processing techniques can be applied.

  - E.g. Processing to remove inedible parts or compounds that may be of safety concern.
  - E.g. A plant or commodity may be used in the raw state, or traditionally processed to increase durability by e.g. heating, salting, acidifying or applying other traditional food processing techniques
  - A plant or commodity may be traditionally consumed in a certain physical state, such as powdered or used in a matrix, e.g. vinegar, alcohol, etc.

  A product would however no longer be considered as derived from primary production:

  - Food ingredients that are isolated or produced from the raw material's edible parts.
  - Extracts or preparations that do not retain the essential characteristic properties of the source material (e.g. the nutritive value, the flavour, the colour, the characteristic other substances contained, etc.). Also, the ratio between the constituents should not be significantly different from that present in the source material. In other words, the primary material should still be recognisable. The products from selective extractions and/or purification processes would in general no longer be considered as products derived from primary production.
  - Products incorporated in a food or mixed with other ingredients. E.g. fruit puree vs fruit jam would not.

  If the product is not consumed as such but only used as ingredient in specific foods or combined with other foods. In such case, it would be possible to apply the notification procedure to the ingredient as such.

  - A plant or commodity may be traditionally consumed as a specific preparation or extract.

In case of uncertainty, it is best to consult a Member State authority.

Botanicals

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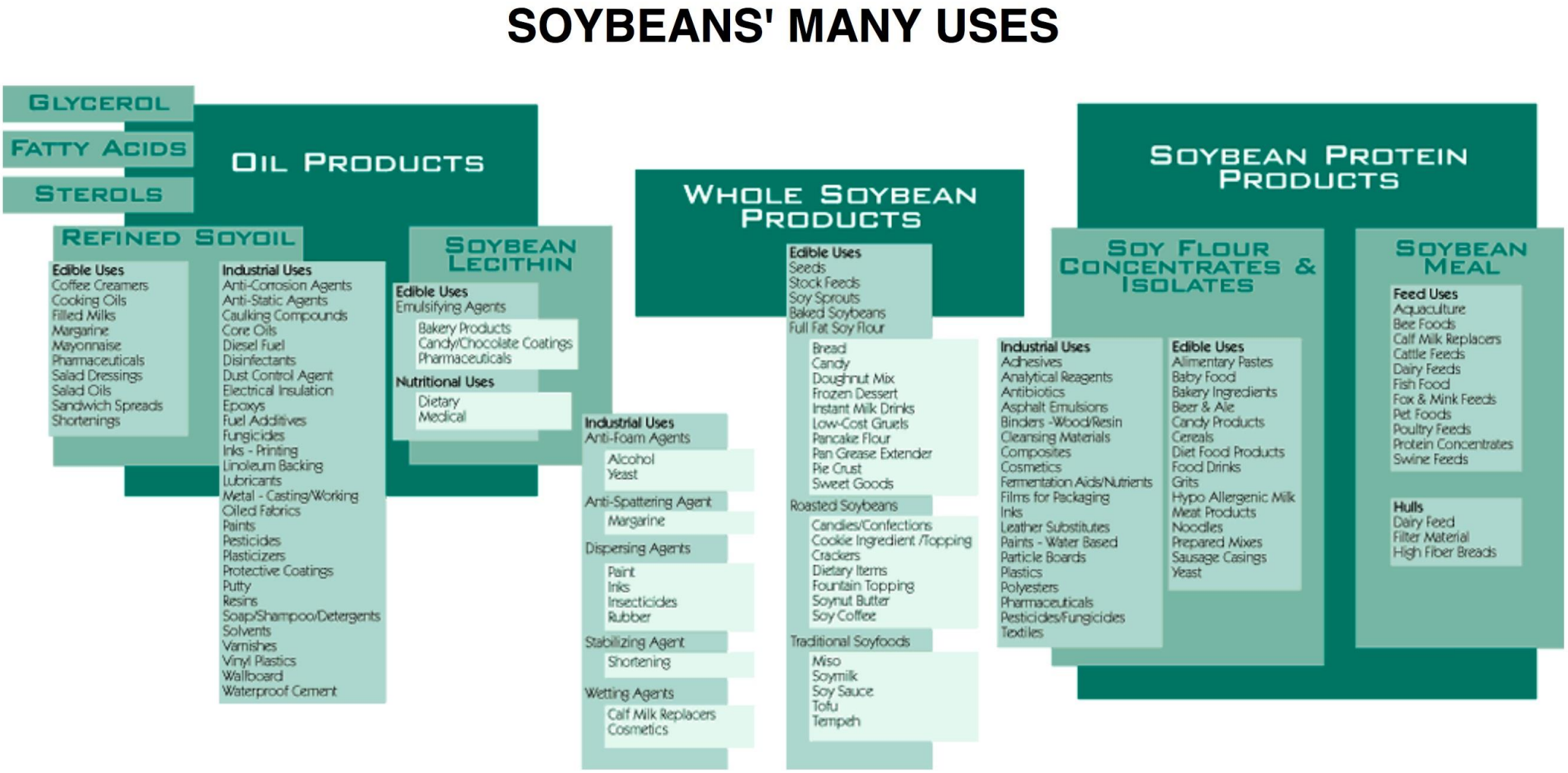
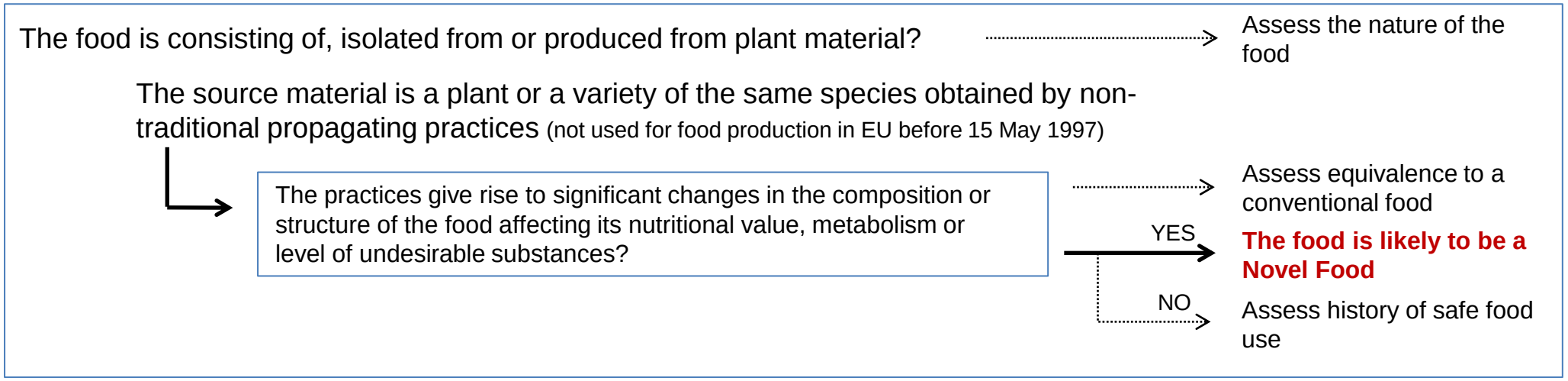
Botanicals and botanical preparations



Source: American Soybean Association

1. Importance of the propagation method



- Traditional techniques
- No GMO -> excluded from Novel Food Legislation
- Techniques excluded from GMO

If obtained by non-traditional propagating practices, provide:

- Verifiable evidence that shows that the practices have not given rise to significant changes in the composition or structure of the food that affects its nutritional value, metabolism or level of undesirable substances. It is not defined what is “significant’.

Substantial Equivalence can help to demonstrate no significant changes

1. Importance of the propagation method

The food is consisting of, isolated from or produced from plant material? ⇢ Assess the nature of the food

The source material is a plant or a variety of the same species obtained by traditional propagating practices (used for food production in EU before 15 May 1997) ⇢ Assess history of use of the plant, plant part and processing

YES →

The source material and parts of it used have no history of safe use?
The source material is not a new variety of a conventional plant?
The plant is not in the Novel Food Catalogue or legal permitted lists?
The processing of the source material is not conventional?
The food produced from the plant is isolated and purified?
The food produced from the plant is not conventionally used?
The relative ratio of the compounds has been changed in the food?

YES → **The food is likely to be a Novel Food**

NO ↓

If obtained by traditional propagating practices, consider:

- Source material
- Nature of the food
- History of safe use
- Manufacturing process

2. Importance of the source material

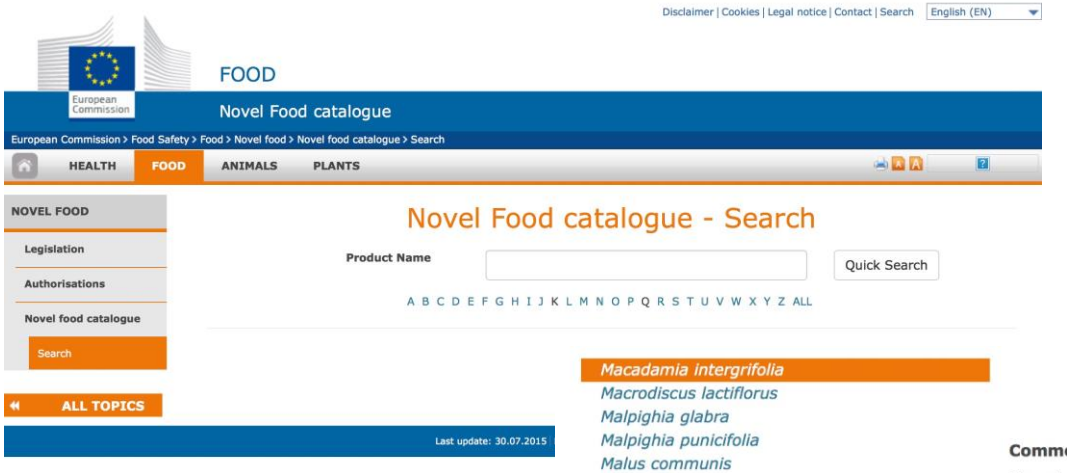
Importance of correct characterisation (Identity and Nature)

The following scheme summarizes the requirements for description of the identity of the botanical:

Scientific (Latin) name:	*full systematic species name incl. botanical family, genus, species, variety, subspecies, author's name, and chemotype if applicable*
Synonyms:	*botanical name(s) that may be used interchangeably with the preferred scientific name*
Common names:	*vernacular name(s)*
Part used:	*e.g. root, leaf, seed …*
Geographical origin:	*continent, country, region*
Growth and harvesting conditions:	*wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth.*

Novel Foods focuses on non-conventional plants and plant parts

Novel Food Catalogue



Novel Food catalogue - Search

Product Name Quick Search

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ALL

- *Macadamia intergrifolia*
- *Macrodiscus lactiflorus*
- *Malpighia glabra*
- *Malpighia punicifolia*
- *Malus communis*
- *Malus sylvestris*
- *Mangifera indica*
- *Manihot esculenta*
- *Manihot utilissima*
- *Manilkara achras*
- *Manilkara zapota*
- *Manilkara zapotilla*
- *Medicago sativa*
- *Mespilus germanica*
- Methyl Sulphonyl-Methane
- *Momordica charantia*
- *Momordica grosvenorii*
- *Monarda didyma*
- *Monascus albidus*
- *Monascus anka*
- *Monascus araneosus*
- *Monascus major*
- *Monascus purpureus*
- *Monascus rubiginosus*
- *Monascus vini*
- *Moringa oleifera*
- *Morus alba*
- *Morus nigra*
- *Musa acuminata*
- *Musa nana*
- *Myrciaria divaricata*
- *Myrciaria dubia*
- *Myrciaria floribunda*
- *Myrciaria protracta*
- *Myrothamnus flabellifolia*

Macadamia intergrifolia

Common Names

Macadamia (DE) (ES), Australian nut (EN), makadamia całolistna (PL), orzech australijski PL), makadamia pähkinä (FI), tervelehine makadaamia (ET), nuez australiana (ES), makadám dió (HU), μακαντάμια (EL), Makadāmija, Austrālijas riekstkoks (LV), makadamski oreh (SL)

Common Names

Macadamias belong to the Proteaceae Family. The first Macadamia plantation was planted in Queensland (Australia) in 1870. By the 1890´s nuts was being grown on the volcanic slopes of Hawaii. From there it was introduced to the world as the "Hawaiian Nut". Some of these trees (to about 15 metres with a bushy habit) are still producing nuts over 100 years later.

Only the use of nuts and oil of Macadamia intergrifolia is known in the EU.

Status

What does it mean?

National lists

e.g. Belgian Royal Decree of 29 August 1997 on the manufacturing and marketing of foods consisting of or containing plants and plant preparations

Botanische naam / Nom botanique	Familie / Famille	Synoniem / Synonyme	Naam	Nom	Toegelaten plantendeel of specifieke bereiding	Parties de plante autorisée ou préparation particulière	Voorwaarden	Conditions
Abelmoschus esculentus (L.) Moench	Malvaceae		oker, okra	okra, gombo, cabo, calou	vrucht	fruit		
Abelmoschus moschatus Medik.	Malvaceae		ambrettezaad, muskuszaad	ambrette	zaad	graine		
Abies alba Mill.	Pinaceae		gewone zilverspar, grote spar, zilverspar	sapin pectiné, sapin blanc, sapin argenté	schors, tak, naald, knop, zaad, hars	écorce, rameau, aiguille, bourgeon, graine, résine		
Abies balsamea (L.) Mill.	Pinaceae		balsemspar, canadabalsem	sapin baumier	schors, naald, hars, twijg	écorce, aiguille, résine, brindille		
Abies nordmanniana subsp. equi-trojani (Asch. & Sint. ex Boiss.) Coode & Cullen	Pinaceae	Abies pectinata Dc. Var. Equi-Trojani Asch. & Sint. Ex Boiss	nordmann-spar, kaukasische spar, krimspar	sapin de nordmann, sapin du caucase, sapin de crimée	schors, naald	écorce, aiguille		
Abies sibirica Ledeb.	Pinaceae		siberische zilverden	sapin de sibérie	schors, tak, naald, hars	écorce, rameau, aiguille, résine		
Abroma augusta L. f	Malvaceae				wortelschors	écorce de racine	De etikettering moet de volgende waarschuwingen bevatten : Niet gebruiken bij de zwangerschap of borstvoeding.	L'étiquetage doit comporter les avertissements suivants : Ne pas utiliser en cas de grossesse ou d'allaitement.

BELFRIT list

Harmonisation of the positive lists of plants by Belgium, France and Italy

- For purposes of mutual recognition
- Presented to the other Member States on 26 November 2013

Systematic approach

- One botanical expert per country
- Compilation of the national lists (BE (645), FR (548), IT (1182)
- Literature review per plants (covering plant parts, chemical composition, preparations used, traditional knowledge, adverse effects described, …), based on reference books, monographs, database search, information from EFSA, EMA, WHO, and other organisations.
- Novel foods check

Outcome: List of 1026 Plants + plant parts (uniform terminology)

- Already incorporated in BE legislation (Royal Decree of 24 January 2017)
- Notified by IT (TRIS notification 28 June 2017)
- On FR authority's website (28 April 2014)

3. Importance of the nature of the food

Food consisting of plants

- Source material and plant part

Isolated from (non-conventional sources)

- Highly purified compounds: history of safe use is critical
- E.g. phytosterols, specific proteins and peptides, fats and oils, …

Produced from (non-conventional sources)

- Not every new extract is novel: history of safe use is critical: traditional use
- Extent of selectiveness and level of concentration
- Importance of the manufacturing process

4. Importance of the history of safe use

Not defined

History of safe food use in a third country" is defined as meaning "that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14.

The notion of "safe food use" of the food must be different from determination if the food was used to a significant degree before 15 May 1997. This is valid for the source material.

4. Importance of the history of safe use

At the level of the plant species, new varieties would not be novel.

A food produced from a plant should also in principle not be novel if:

There is history of safe use of the plant or plant variety and the plant part

E.g. novel food catalogue, national lists of plants,. BELFRIT, …

There is history of safe use of the processing

E.g. traditional manufacturing process

The Food is currently lawfully marketed

E. .g. duly notified as food supplement

The source material is not novel and the food is not substantially modified

New selective extracts are not automatically novel

Typical characteristics of the source material must be retained (e.g. relative ratio)

4. Importance of the history of safe use

Applies to the food or preparation as such.

E.g. lutein: safe history of use

Not novel if derived from conventional food source

Novel if derived from non-conventional food source

Bio-fortification of plants would normally result in the food falling under the NFR when the composition of the food is such that it falls significantly outside the normal range of conventional counterparts of the foods derived from the plant.

5. Importance of the manufacturing process

Production process not used for food production within the EU before 15 May 1997

- E.g. extraction solvent, purification methods, etc not yet used
- For the specific product?

Such a food would only fall under the scope if the processing applied gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.

The concept of substantial equivalence can play a role in assessing the extent to which a new food is significantly different from a reference food in terms of:

- Composition
- Structure
- Nutritional status
- Metabolism
- Level of undesirable substances

Quality and Safety

Food Supplements Europe Quality Guides

- Good Manufacturing Practices Guide
- Good Manufacturing Practices Questionnaire
- Botanical Preparations Quality Guide
- Botanical Preparations Quality Questionnaire

Conclusions

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Conclusions

The new Novel Foods Regulation triggers a legal obligation to verify the status of every new food

- Knowledge of the definitions is required
- The Food Supplements Europe guidelines can be a useful tool

It is recommended to include the novel food status in specifications and market procedures

- Ensure non-novel food status certificate from suppliers
- Always consider own processing applied also

Not all new botanical preparations will be considered novel foods

- History of the source material (cfr. Belfrit)
- History of the manufacturing process
- Nature of the food

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Thank You

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