

Novel Food Consultation Request

**Presented by
Dr. Bernhard Beitzke**
(Member of the Advisory Board)

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Procedure for Determination of Novel Food Status

Art. 4 (1), (2) Novel Food Regulation (EU) 2015/2283:

1. Food business operators *shall verify* whether or not the food which they intend to place on the market within the Union *falls within the scope of this Regulation*.
2. Where *they are unsure* whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators *shall consult the Member State* where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation.

Evaluation of Novel Food status in practice

„Unsure“ ?

- Possibility ?**
- Probability ?**
- Pre-consultation with lawyers / consultants = positive legal opinion ?**

Procedure for Determination of Novel Food Status

Evaluation of Novel Food status in practice

Legal Aspects	Scientific / Factual Aspects
Categories of food (e.g. modified molecular structure, or consisting of, isolated or produced from plants or their parts)	Characterisation of the food
New production process	Significant changes
Former authorisations	Comparable / Criterion = Specifications
Significant	Consumption before 15 May 1997 / Evidence

Self-Examination of the NF Status

Legal basis:

- 1) Novel Food Regulation (EU) 2015/2283 with its definitions, NF-categories, and exemptions, and
- 2) The Union List (Comm. Impl. Reg. (EU) 2018/1023)
- 3) The CIR's (Commission Implementing Regulations)

Not legally binding are:

- the Novel Food catalogue of the EU Commission (website); this is guidance only for FBO's
- Guideline on Human Consumption to a Significant Degree (History of Consumption – „HOC“)
- EU Botanical Lists like BELFRIT, except where these have been enacted as law (e.g. Belgium: Royal Decree)

Human Consumption to a Significant Degree (HOC) Information and Guidance Document

1. Criteria to be considered when establishing whether a food has been used for human consumption to a significant degree

1.1 Information

1.2 Documentation

1.3 Geographical aspects

1.4 Quantity of use

1.5 Intended purpose

1.6 Specific population groups/context of use

1.7 Use of other forms/parts of a food/new technologies

1.8 Availability

2. Decision tree/Questionnaire

2.1 DECISION TREE

2.2 QUESTIONNAIRE

I. Initial step

Table 1 Description of food or food ingredient:

II. Main part

Table 2 Information for the determination whether a product requires authorisation under the Novel Food Regulation

Table 3 Evidence of a history of consumption

« Human Consumption to a Significant Degree »

Information and Guidance Document

The producer, importer or any other person responsible for the placing of a product on the EU market is primarily responsible for complying with the relevant legislation. Therefore, if necessary they should provide to the competent authorities the necessary information to substantiate that the product would not fall within the scope of Regulation (EC) No 258/97.

In case of doubt, food business operators may consult the relevant competent authority for novel foods on the status of this food.

According to Article 1 (2) of Regulation (EC) No 258/97 novel foods and novel food ingredients are foods which have not been used for human consumption to a significant degree within the Community before the entry into force of the Regulation (15 May 1997). The determination whether this particular provision is fulfilled may be in certain cases difficult. This document therefore aims to assist the competent authorities and interested stakeholders to better understand it and to apply it correctly and in a uniform way.

This document does not provide an exhaustive list of relevant criteria to be considered for determination of the novel food status. Furthermore, the order of the criteria listed should not be taken as a ranking. In fact, each product has to be evaluated on a case by case basis. A specific criterion might be not applicable in one case but of significant value for another product.

Procedure for Consultation Request on Novel Food Status

Evaluation of Novel Food status in practice

Art. 4 (3), (4) NFR 2018/2283:

3. *In order to determine whether or not a food falls within the scope of this Regulation, Member States may consult the other Member States and the Commission.*
4. *The Commission shall, by means of **implementing acts**, **specify** the **procedural steps** of the **consultation process** provided for in paragraphs 2 and 3 of this Article, including **deadlines** and the means to **make the status publicly available**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).*

Consultation Procedure acc. CIR 2018/456

COMMISSION IMPLEMENTING REGULATION (EU) 2018/456

of 19 March 2018

on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

- (a) “Consultation request” means a request from a food business operator to a recipient Member State to determine the novel food status of a particular food**
- (b) „recipient Member State“ means a Member State where the food business operator intends to place on the market a particular food for the first time.**

Article 3

Submission of a consultation request

1. The food business operator shall consult the recipient Member State as provided for in Article 4(2) of Regulation (EU) 2015/2283 by submitting a consultation request to that Member State.
2. Where the food business operator intends to place the food on the market simultaneously in several Member States, the food business operator shall submit the consultation request only to one of those Member States.

Content and presentation of a consultation request (Art. 4)

- **Shall be submitted electronically**
- **Consultation request shall consist of**
 - **Cover letter – Template cover letter in Annex I**
 - **Technical dossier – Template provided in Annex II**
 - **Supporting documentation**
 - **Explanatory note clarifying the purpose and relevance of the submitted documentation**

Confidentiality (Art. 9)

FBO may request for confidential treatment of the request with good substantiation of necessity (e.g. harm to competitive position). However, not all information will be covered by confidentiality. FBO may withdraw its consultation request within 3 weeks.

Template for Technical Dossier for Consultation Request

- 1) Description of the food
- 2) Further characterisation and/or source of the food
- 3) Conditions of use
 - 3.1) How is the food intended to be used ?
 - 3.2) Type of product(s) in which the food is intended to be used
 - 3.3) Level/concentration (or range of levels) in the product(s) in which the food is intended to be used
- 4) Production process
- 5) History of Human Consumption of the food within the Union before 15 May 1997 => to what extent ?
- 6) Consultations on availability in the Union
- 7) Additional information (e.g. demarcation vs. medicinal products)

Section 2: Extracts

8. Extracts

8.1 Any further details of the source material for the extract, if not provided in Section 1. Details shall be provided.

8.2 Specification of the extract. Details shall be provided.

8.3 If extracted from a food source, will the intake of any extract components in the food be higher than the intake of these components in the food source? Details shall be provided.

Two-stage assessment by Member State

Art. 5 – Procedures for verifying the validity of a consultation request:

- Recipient MS verifies whether the consultation request complies with the requirements of Art. 4
- If required: request to the FBO to provide additional information
- Recipient MS decides on the validity of the consultation request

➔ Without consultation of the other Member States

Two-stage assessment by Member State

Art. 6 – Procedures for evaluating a valid consultation request:

- Recipient MS concludes on the novel food status of a food within 4 months on the date on which it decided on the validity of the consultation request (may extend by another 4 months).
- If required: request to the FBO to provide additional information
- Recipient MS may (shall ?) consult the other Member States and the Commission
- (5) on concluding on the novel food status of a food, the Recipient MS shall without delay notify the food business operator, the other MS and the Commission of the decision and shall provide justification in accordance with Art. 7 of this Regulation (2018/456).

Information on the novel food status and publication (Art. 7)

(1)

- Name and description of the food concerned
- A statement indication whether the food concerned is novel, not novel or not novel only in food supplements.
- Reasons justifying that statement
- Where the food is novel, most appropriate food category under which it falls in accordance with Art. 3(2) of the NFR
- Recipient MS may (shall ?) consult the other Member States and the Commission

(2)

the Commission shall without delay make the information on the novel food status publicly available on the Commission's website.

To consult or not ?

Assessing ripeness for Consultation Request:

- Have sufficient data been gathered / generated ?
- Are the collected data representative for the food subject to consultation request ?

Getting ready for the worst case scenario:

- Are data available to promptly support a Novel Food submission ?
- Is it possible to predict the discussion with PAFF ?
(Standing Committee on Plants, Animals, Food, and Feed of the European Commission)

Consequences

- Legal remedy ?
 - Appeal possible ?
- In Germany, Principles of Administrative Law:
- Administrative decision
- 1 month for bringing an action against that decision
- Enforceability

Better chances to appeal to a national law court of the Member State than to the European Court of Justice

NF Consultation Procedure: Consequences

Consequences

There had been advice in the legislative process to consider an appeal but this was not implemented in the NFR or its Implementing Regulations

“Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of [the Novel Foods] Regulation”

This provision thus confers a new advisory role on Member State authorities. One industry association pointed out that this could lead to problems in cases where a company is convinced its product is not a Novel Food, but the Member State authority insists that it is. This association indicated that, in these instances, the company should have some form of **appeal** process available to them before being forced to submit a Novel Food application.

(From an Impact Assessment by the Centre for Strategy & Evaluation Services and ADAS UK Ltd on the Draft for a Novel Food Regulation, Brussels, 2014.)

However, no possibility for appeal mentioned in the NFR !

Consequences

- Legal remedy foreseen in Regulation 2018/456 ?
- ➔ NO !
- Immediate publication by Commission
- ➔ Principle of the rule of law ?
- ➔ then go to European General Law

Consequences

- Action for annulment against publication, Art. 263 (4) TFEU ?

Article 263 TFEU paragraph 4

"Any natural or legal person may, under the conditions laid down in the first and second paragraphs, institute proceedings against an act addressed to that person or which is of direct or individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures."

Consequences

- **Action for annulment against publication, Art. 263 (4) TFEU ?**

Prerequisites:

- Act or Regulatory Act => Publication = Act of the Commission (fulfilled)
[“Regulatory Acts are all acts of general application apart from legislative acts” (Def. from Law Case C 583/11 P)]
- Addressed to that person or which is of direct or individual concern;
 - **Individual concern** => publication of name and product of FBO (fulfilled)
 - **Direct** = direct consequences = does not entail implementing measures (fulfilled)
- Legality of the publication ?

Consequences

- **Action for annulment against publication, Art. 263 (4) TFEU ?**

Experiences of case law:

- **Non-privileged applicants face strict requirements for the legal admissibility**
- **Time limit of 2 months since the publication, notification or coming to knowledge of the Act
(exception: Force majeure or exceptional circumstances)**
- **Grounds for annulment:**
 - **Lack of competence**
 - **Infringement of essential procedure requirements**
 - **Infringement of the treaty or any rule of law relating to this application**
 - **Misuse of powers**

Art. 5 of NF Regulation: Implementing Power

Art. 5 of NF Regulation: Implementing Power concerning the definition on Novel Food

The Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts, whether or not a particular food falls within the definition of novel food.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(3).

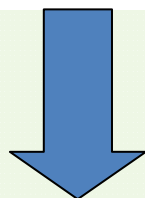
Examination Procedure for Implementing Acts

Art. 30 of Novel Food Regulation (EU) 2015/2283 Committee Procedure:

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.



REGULATION (EU) No 182/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 2011

**laying down the rules and general principles concerning mechanisms for control by Member States
of the Commission's exercise of implementing powers**

Examination Procedure for Implementing Acts

Art. 5 of (EU) No 182/2011: Committee Procedure

Article 5

Examination procedure

1. Where the examination procedure applies, the committee shall deliver its opinion by the majority laid down in Article 16(4) and (5) of the Treaty on European Union and, where applicable, Article 238(3) TFEU, for acts to be adopted on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in those Articles.

4. As from 1 November 2014, a qualified majority shall be defined as at least 55 % of the members of the Council, comprising at least fifteen of them and representing Member States comprising at least 65 % of the population of the Union.

A blocking minority must include at least four Council members, failing which the qualified majority shall be deemed attained.

The other arrangements governing the qualified majority are laid down in Article 205(2) of the Treaty on the Functioning of the European Union.

(Art. 5 NFR)

Other Options apart from Consultation Request

Traditional Food from Third Country / Countries

‘HISTORY OF SAFE FOOD USE IN A THIRD COUNTRY’

means that the safety of the food 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. *Regulation (EU) 2015/2283 - Article 3*

Commission Implementing Regulation (EU) 2017/2468:

administrative and scientific requirements as to a **notification and application for authorisation** of a traditional food from a third country which is considered novel in the EU

Traditional food from a third country

Traditional food from a third country is a food derived from primary production with a history of safe use in a third country.

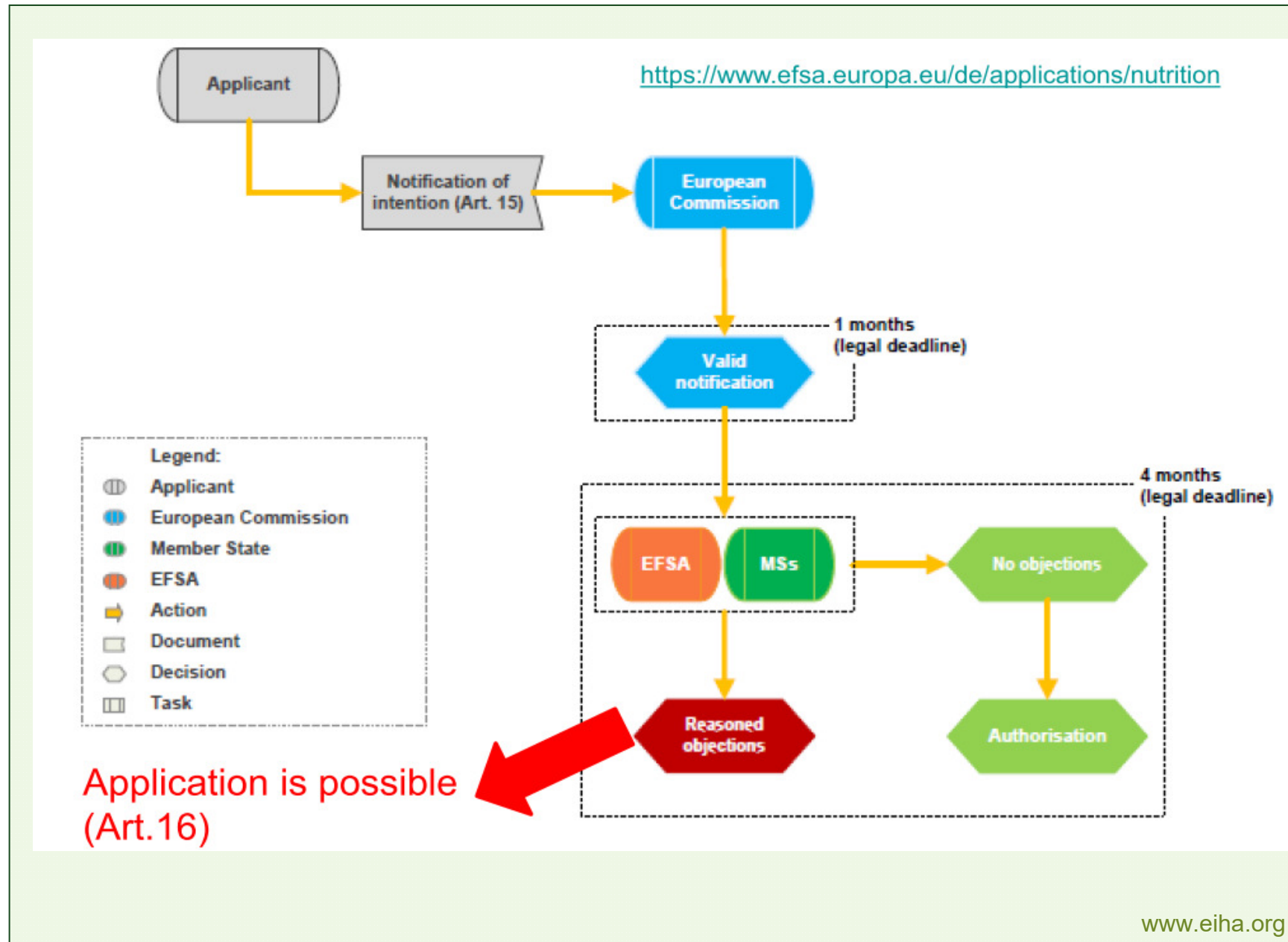
➤ Traditional food can be

- **Produced from plants/animals/micro-organisms etc.**
(juice of the fruit of *Morinda citrifolia* L)
- **From primary production** (chia seeds)
- **Processed or unprocessed** (baobab dried fruit)

➤ Traditional food cannot be

- **New molecules; from mineral origin; from a new process; from engineered nanomaterial; already authorised vitamins; minerals for which a new process has been applied or contains engineered nanomaterials; food used only in food supplements**

Traditional Foods Notification Art. 15 NF Reg



8. Traditional food consultation process

- **EFSA, Member states and EC can collaborate during the consultation and evaluation process** through the system (4 month once the dossier is considered valid)
- They can also **submit comments and any safety objection(s)** through the consultation tab
- The **applicant cannot see this consultation tab**
- **Applicant** will be notified by EC if the dossier is rejected for duly reasoned safety objections
- If there is no objection during the period the **application goes to risk management**

Other Options for Authorities

Procedure under Art. 8 of Regulation 1925/2008

Putting substances or ingredients under:

- **Prohibition**
- **Restriction**
- **Scrutiny**

food in European Union, while Article 8 of Regulation 1925/2006 is applied where a substance other than a vitamin or mineral, or an ingredient containing a substance other than a vitamin or mineral, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

Other Options for Authorities

On its own initiative or basing on information of a Member State the Commission may include a substance or ingredient in Annex III of 1925/2006, into one of the following categories:

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

▼ M6

Ephedra herb and its preparations originating from *Ephedra* species

▼ B

Part B — Restricted substances

Part C — Substances under Community scrutiny

▼ M6

Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

Which Choice should be made by the FBO ?

There are the following options:

1. **Be sure that the hemp extract in question is traditional food, document well the evidence for that, and continue selling** as in the last three years.
Risk: EU takes a decision on its own initiative (Art. 5 NFR) against you.
2. **Go for consultation on national level (Art. 4 NFR)**
Risk: you get the decision that it is novel (very early or at the latest after 4 or – with extension - 8 months).
3. **go for simplified authorization (3rd country).**
It must have been the **customary diet** of a significant number of people in at least one third country !
4. **Go for full authorization as Novel Food**
Risk: you lose licence to sell your product after application, or you try to get the “Interim Ruling” applied because of slight changes in wording of NF definition in the new NFR compared to old NFR, or because of the new obligation for consultation (request).

Interim Ruling on Food Novel only since 2018

Old and new NF definition regarding plants

Article 1(2)(e) Reg 258/97:

“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**”



Meisterernst

Rechtsanwälte

Article 3(2)(a)(iv) Reg 2015/2283:

“**food consisting of, isolated from or produced from plants** or their parts, except when the food has a **history of safe food use** within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species **obtained by:**

- **traditional propagating practices** which have been used for food production within the Union before 15 May 1997; or
- **non-traditional propagating practices** which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances”

Christian Ballke, LL.M.

09.07.2018

Interim Ruling on Food Novel only since 2018

Art. 35 (2) of (EU) No 2015/2283 and

Foods **not falling within the scope of Regulation (EC) No 258/97**, which are lawfully placed on the market by 1 January 2018 and **which fall within the scope of this Regulation** may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following **an application for authorisation of a novel food** submitted by the date specified in the implementing rules but no later than 2 January 2020.

Art. 8 (5) CIR 2017/2469

The **deadline for the submission of the applications** referred to in Article 35(2) of Regulation (EU) 2015/2283 **shall be 1 January 2019**.

Burden of Proof in Novel Food court cases:

“Secondary burden of proof” on to the FBO for demonstrating that his product is not Novel Food:

See court case decisions Germany:

BGH, Urteil vom vom 16.04.2015, Az. I ZR 27/14 (on Kudzu root as FS);

*BGH, Urteil vom vom 22.11.2007, Az. I ZR 77/05
(on Luo Han Guo Fruit Extract).*