Novel food Regulation 258/97/EU

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EU and Novel Food regulation

“Novel foods are food products and food ingredients that have not been used for human consumption to a significant degree within the European Community before 15 May 1997”
Novel Food regulation 258/97

1. Foods and food ingredients with a new or intentionally modified primary molecular structure
2. Foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae
3. Foods and food ingredients consisting of or isolated from plants and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use
4. 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
Initially, food and food ingredients containing or consisting of GM organism and those produced from but not containing GM organism were also considered as novel foods. However, since 18 April 2004 for these foods and food ingredients a separate regulation 1829/2003.
EU Novel Food regulation 258/97

The regulation was established to guarantee:
– No danger to the consumer
– Would not mislead the consumer
– Would not differ from food products or food ingredients for which new food products are a substitute to such an extent that normal consumption of those new products would be nutritionally disadvantageous for the consumer
Regulation (EC) No 882/2004

Requirements for the competent authority

- meet operational criteria, such as having a sufficient number of suitably qualified and experienced staff
- ensuring that staff are free from conflict of interest
- have contingency plans for emergencies
- have suitable facilities
- carry out internal audits and/or have external audits undertaken
- ensure that specific conditions are met if any control task is delegated
Regulation (EC) No 882/2004
Requirements for the competent authority

– ensure on-going training
– be transparent
– prepare reports
– documented procedures for carrying out controls
– ensure efficient communication between authorities
– have procedures for registration/approval
– take actions if business are infringing the law
Authorization or Notification

- Novel food have to be officially approved through the novel food authorization procedure before introduction to EU market.
- Every MS has a competent authority CA, who is authorized to review national food dossiers. For example in Finland it is the Ministry of Food and Agriculture who nominates a Novel food committee for a three years.
Authorization or Notification

• The producer must submit an application for authorization to both the CA in one of the MS and the European Commission.
• The application for authorization must contain:
  – specification of the novel food
  – the effects of the applied production processes
  – history of the organism used as source
  – anticipated intake information
  – previous human exposures to novel food
  – nutritional information
  – biological information
  – toxicological information
  – information on labeling
Authorization or Notification

- CA arranges for an assessment of the product for consumer safety
- The safety assessment is carried out on the basis of the current scientific knowledge
- CA uses the safety assessment as a basis for reaching a national decision
Authorization or Notification

- All the other EU member states are invited to assess the dossier of the applicant and the initial assessment from the CA
- This step is called “second opinion”
- If the assessment/dossier raise too many questions that consensus between the MS is unachievable, European Commission requests advice from EFSA
- The formal decision making on authorizing a novel food takes place in the Standing Committee for the Food Chain and Animal Health and if necessary in the European Council of Ministers
- Once authorized the product may be sold in EU
# List of Applications for authorization of a novel food

<table>
<thead>
<tr>
<th>No</th>
<th>Applicant</th>
<th>Description of Food or Food Ingredient</th>
<th>Initial Assessment Carried out by</th>
<th>Application Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Katholieke Universiteit Leuven Laboratory of Plant Physiology B – 3001 Heverlee</td>
<td><em>Stevia rebaudiana</em> (plant and dried leaves)</td>
<td>Hoge Gezonheidsraad RAC – Esplanadegebouw 7e verdieping Pachecolaan 19 bus 5 B – 1010 Brussel</td>
<td>7 November 1997</td>
<td>Commission Decision refusing the placing on the market of <em>Stevia rebaudiana</em> 2000/196/EC</td>
</tr>
<tr>
<td>2</td>
<td>Belovo scrl Zone industrielle, 1 B – 6600 Bastogne</td>
<td>Phospholipides from egg yolk</td>
<td>Hoge Gezonheidsraad RAC – Esplanadegebouw 7e verdieping Pachecolaan 19 bus 5 B - 1010 Brussel</td>
<td>9 February 1998</td>
<td>Commission Decision authorising phospholipides (85% and 100%) to placed on the market in the Community 2000/195/EC</td>
</tr>
<tr>
<td>115</td>
<td>MGP Ingredients Cray Business Plaza 100 Commercial Street PO Box 130 Atchinson Kansas 66002-013 USA</td>
<td>Two Phosphated distarch products</td>
<td>Food Standards Agency (UK)</td>
<td>16 November 2009</td>
<td></td>
</tr>
</tbody>
</table>

Authorization or Notification

• If new foods or food ingredients are very similar to existing products, the company may follow a simplified procedure called notification.
• The procedure evaluates substantial equivalence to existing foods or food ingredients.
• This is:
  - composition
  - nutritional value
  - metabolism
  - intended use
  - the level of undesirable substances contained
Authorization or Notification

• A history of safe use of the comparable product is an important aspect
• In practice, the producer decides whether a new product should go through an authorization or notification
• In every MS an enforcement body has the responsibility to monitor the notifications – typically a national food safety authority
• For example in Finland the body is Finnish Food Safety Authority
## List of Notifications of novel foods

<table>
<thead>
<tr>
<th>No</th>
<th>Applicant</th>
<th>Description of Food or Food Ingredient</th>
<th>Scientific Evidence</th>
<th>Notification</th>
<th>Transmission to Member States</th>
</tr>
</thead>
<tbody>
<tr>
<td>144</td>
<td>Pacifique Sud Cosmetique ZI Napollon 530 Avenue des Templiers Bat. 7 F – 13400 Aubagne</td>
<td>Dry extract from Noni juice (juice of the fruits of <em>Morinda citrifolia</em>) for use in food supplements</td>
<td>AFFSA(^3) (F) AVIS de l'Agence française de sécurité sanitaire des aliments relative à l'évaluation de l'équivalence substantielle d'un extrait sec de jus de noni avec le jus de <em>Morinda citrifolia</em> L.</td>
<td>23 November 2009</td>
<td>20 May 2010</td>
</tr>
</tbody>
</table>

*Updated 15-06-2010*
Authorization or Notification

• Most foods are clearly traditional food and some are clearly novel food
• Some discussion exist regarding the terminology used in the Regulation
Novel Food Catalogue

The information about food and food ingredients that has been collected since the "Novel Food Regulation" 258/97/EC entered into force is in three parts

1. Full authorizations
2. Notifications
3. Novel Food catalogue

http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm
The Novel Food Catalogue is the result of the continuing discussions in the Novel Food Working Group, a group comprised of Novel Food experts from the Member States together with officials from the European Commission. Novel Food Catalogue does not represent as an exhaustive list. It contains a list of products of plant and animal origin as well as other substances which have been discussed in relation to their status only within the meaning of the Novel Food Regulation.
Novel Food Catalogue

• The Novel Food Catalogue may provide exclusively orientation whether or not a product would require authorization under the Novel Food Regulation. But in some Member States the placing on the market of this product as a food or food ingredient may be restricted by specific legislation.
Novel Food Catalogue

• The Novel Food Catalogue is a "living database", therefore its contents will be amended as a result of new information provided to and by the Member States or as the outcome of surveys carried out by Member States and notified to the Commission.

• The information provided by Novel Food Catalogue should be used without prejudice to decisions that might be taken by Member States or the Commission on the basis of new or more completed information.
Novel food catalogue

Camelina sativa L.

Common Names
Camilina oil, Gold of pleasure oil (EN), Cameline cultivatee, vlasdodder (NL), ruistankio, kitupellava, camellina-kasvi (FI), Leindotter (DE), pőldtuder (ET), Inička setá (CZ), Sésamo bastardo (ES), vetési gomborka (HU), Idras, idri, judras (LV), navadni riček (SL), Lnicznik siewny (PL), Oljedádra (SE), Camelina (PT)

Description
Plant belonging to the Brassicaceae Family. It is native to Eastern Europe and Southwest Asia, where wild weedy forms survive other weedy types have evolved and are found in cereal and flax crops. The developed crop form was widely grown across Europe until the 1950s.

Only the oil of Camelina sativa is known to be used in the EU as a food or food ingredient.

status
**Novel food catalogue**

*Hylocereus undatus* (Haw.) Britton & Rose

**Common Names**
Pitahaya, Hylocereus falowaty, (PL), lohikäärmehedelmä, pitaya (FI), Drachenfrucht (DE), maasik-metskaktus (ET), pitahaya (CZ) (ES), opuncie (CZ), Cactus trepador (ES), Pitahaja kaktusz (HU), Pitahajja (LV), pitahaya kaktus (SE), Pitaya vermelha (PT)

**Description**
Hylocereus is a climbing cacti native to the tropical forest regions of Mexico and Central and South America. The fruit of these plants is also known as ‘pitahaya’ which is however a common name applying to a broad variety of warm-climate cacti fruits. These fruits have a white spongy pulp with small black seeds and thick skin red or pink.

Only the use of the fruits of *Hylocereus undatus* as food or food ingredient is known in the EU.

**status**

✅
This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EC) No. 258/97. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.
Four symbols in the Novel Food Catalogue

According to information available to Member States competent authorities this product was used only as or in food supplements before 15 May 1997. Any other food uses of this product have to be authorized pursuant to the Novel Food Regulation.
There was a request whether this product requires authorization under the Novel Food Regulation. According to the information available to Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.
Four symbols in the Novel Food Catalogue

There was a request whether this product requires authorization under the Novel Food Regulation. Further information is required.
Discussions

• The term “significant degree” related to consumption before 15 May 1997 in EU

For example it is clear that human consumption of camel milk is common in many Asian and African countries. However, it is difficult to determine whether camel milk has been consumed to a significant degree in EU before May 1997. (Camel milk differs in composition from cow milk)
Discussions

• The term “significant changes” related to change in production process

For example Mycryo was introduced as a powdered form of cocoa butter. Mycryo is produced by a cryogenization process. Though cocoa butter has already been used for a long time, its use in gryogenized form with its specific characteristics is new.
Discussions

• *Animal feed* related to changed *composition* of foods

For example the Columbus egg has a fatty acid composition that differs from eggs traditionally consumed because of the differences in feed.
Discussions

- **New varieties** of organisms

For example, many different potato varieties exist and the composition of these varieties differ, i.e., glycoalkaloids. Glycoalkaloids are potentially toxic to humans; it is desirable that glycoalkaloid levels are evaluated before new potato varieties are released for consumption.
Discussions

• Safety not assessed for new target groups

For example a probiotic drink that aims at a new, specific target group; children from age of 1 year onwards. Consumption of probiotics is generally considered to be safe for adults, the effects in children might be different.
Discussions

• Growth stage of crops

Verjuice is an acidic juice, originally from France, made by pressing unripe grapes and it is used in salads as a sour substitute for vinegar and lemon.
The case “Betel nut” in Finland

- Areca nuts are chewed with betel leaf for their effects as stimulant causing a heightened alertness
- Areca nut has a novel food status in some European countries, however Finland has banned its use

Why?
- As mentioned earlier there may be national laws which are “stronger” than the EU directive
- In Finland The law of medicines and its 6§ determines that FIMEA is the body which make a decision if a product is a medicine or not