A New Approach to the Regulation of Novel Foods

A webinar presented by:
Dr Andy Bowles

Attendee Notes
A New Approach to the Regulation of Novel Foods

Dr Andy Bowles
Specialist food law solicitor

This webinar will consider

- What is a novel food?
- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement
**What is a Novel Food?**

- Any food not used for human consumption to any significant degree
  - within EU before 15th May 1997

---

**This webinar will consider**

- What is a novel food?
- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement

---

**Why are novel foods important?**

- Innovation
  - Food ingredients
  - Processes
  - Technologies

- Alternative food sources
  - Insects
This webinar will consider

- What is a novel food?
- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement

Novel foods: Prior to 1st January 2018

- Regulation (EC) 258/97 (now repealed)
  - Novel foods must be authorised
    - Prior to placing on the market
- Previous authorisation process
  - Initial approach to Food Standards Agency
  - Advisory Committee on Novel Foods and Processes (ACNFP)
    - "Substantial equivalence"
  - Consultation with other Member States / EU Commission
    - Commission Recommendation No 97/618/EC
    - Commission Decision

Problems with previous system

- Law was 20 years old
  - Didn’t reflect technological & scientific developments
- Previous authorisation very slow
  - Typical authorisation took 3 ½ years
- Inadequate
  - Provision to authorise food from 3rd countries
  - Protection of applicants’ scientific data
This webinar will consider

- What is a novel food?
- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement

### Novel foods – Main changes

- **Regulation (EU) 2015/2283**
  - Centralised authorisation
  - EFSA undertake scientific risk assessment
  - New rules for traditional food from 3rd countries
  - Protection of scientific evidence

### Regulatory framework
Main features of regulation

- Expanded categories of Novel Foods.
- Generic authorisations of Novel Foods
- Establishment of Union list of authorised Novel Foods
- Simplified, centralised authorisation procedure
- Centralised, safety evaluation
- Faster and structured notification system for traditional foods from third countries on the basis of a history of safe food use.
- Promotion of innovation by granting an individual authorisation for five years based on protected data.

Main provisions of Regulation (EU) 2015/2283
**Definition of “novel food”**

- Any food not used for human consumption to any significant degree
  - within EU before 15th May 1997
  - Irrespective of accession of Member States
- Includes food
  - With new or intentionally modified molecular structure,
  - Consisting of, isolated from or produced from
    - microorganisms, fungi or algae; material of mineral origin; plants or their parts, animals or their parts, cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
  - Resulting from a production process not used for food production with the Union before 15 May 1997;
  - Consisting of engineered nanomaterials;

**Data protection**

- On request
  - Applicant can protect newly developed evidence/data
  - Supporting application
  - 5 years
    - Subject to proprietary and exclusivity tests

**Regulatory framework**

- Regulation (EU) 2015/2283 Novel Foods
- Regulation (EU) 2017/2468 Traditional foods from third countries
- Regulation (EU) 2015/2049 Authorisation procedure
- Regulation (EU) 2017/2470 Authorised list
**Authorised list**

- Regulation (EU) 2017/2470
  - Establishes authorised list of novel foods
  - “Positive list”
    - Currently 130 pages long

**Regulation (EU) 2017/2470**

**Table 1: Example**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Identification number</th>
<th>Approval route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel foods</td>
<td>EUP5.123456</td>
<td>Approval route</td>
<td>Description of novel food</td>
</tr>
<tr>
<td>Non-novel foods</td>
<td>EUP5.123456</td>
<td>Approval route</td>
<td>Description of non-novel food</td>
</tr>
</tbody>
</table>

**Table 2: Example**

<table>
<thead>
<tr>
<th>Novel foods</th>
<th>Identification number</th>
<th>Approval route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel food 1</td>
<td>EUP5.123456</td>
<td>Approval route</td>
<td>Description of novel food 1</td>
</tr>
<tr>
<td>Novel food 2</td>
<td>EUP5.123456</td>
<td>Approval route</td>
<td>Description of novel food 2</td>
</tr>
</tbody>
</table>

**Table 3: Example**

<table>
<thead>
<tr>
<th>Novel foods</th>
<th>Identification number</th>
<th>Approval route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel food 3</td>
<td>EUP5.123456</td>
<td>Approval route</td>
<td>Description of novel food 3</td>
</tr>
</tbody>
</table>
## Additional labelling

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Additional labelling</th>
<th>Figure 2.1a (Table 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition 1</td>
<td>Definition 2</td>
<td>Definition 3</td>
</tr>
</tbody>
</table>

### Regulation 2017/2470 Table 2: Example

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Additional labelling</th>
<th>Figure 2.1b (Table 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition 4</td>
<td>Definition 5</td>
<td>Definition 6</td>
</tr>
</tbody>
</table>
Novel food determination

- Is it on positive list?
- FSA Checklist
  - Evidence food used within EU prior to 15.5.97
    - Is it a food?
    - Novel food catalogue
    - Nettox list
    - Italian food supplement lists
    - Belgian Royal Decree on Plants
  - Is food extract, isolate or concentrate of existing food?

Novel Food Catalogue


Novel Food Catalogue Symbols

- ✓ Product on market as a food/ingredient and consumed to a significant degree before 15th May 1997
- FS Product used only as or in food supplements before 15th May 1997
- ✗ Not used as a food before 15th May 1997 – will need authorisation before use
- ? Further information required on this product
### Regulatory framework

- **Novel Foods**  
  - Regulation (EU) 2015/2283
- **Traditional foods from third countries**  
  - Regulation (EU) 2017/2468
- **Authorisation procedure**  
  - Regulation (EU) 2017/2469
- **Authorised list**  
  - Regulation (EU) 2015/2470

---

### Conditions for authorisation

- **To be authorised, novel foods must not**
  - Present a risk to public health
  - Be nutritionally disadvantageous
    - when used as a replacement for existing food.
  - Mislead the consumer

---

### Authorisation Procedure

1. **Scientific evidence demonstrating that novel food does not pose safety risk**
2. **Risk management**
3. **Assess safety of novel food and conditions of use within 7 months of EFSA opinion**
4. **Commission Regulation updating the Union List**
5. **EFSA**
   - Provides an opinion within 9 months
6. **Applicant**
   - Normally seeks opinion from EFSA
Regulatory framework

- Regulation (EU) 2015/2283
  - Novel Foods

- Regulation (EU) 2017/2468
  - Traditional foods from third countries

- Regulation (EU) 2015/2469
  - Authorisation procedure

- Regulation (EU) 2015/2470
  - Authorised list

EFSA

Traditional Foods from 3rd Countries

- Novel food
  - derived from primary production
  - with a history of safe food use in a 3rd Country
    - Continued use of at least 25 years
    - in customary diet of significant number of people.

- Authorisation procedure
  - ‘Reasoned safety objections’
    - from EFSA or Member state within 4 months
    - If no objection
      - Food added to register

Some examples:

- Insects
  - Whole insects and
    - products made from whole insects (eg flours)
  - Previously exempt from novel food assessment
    - Included from 1st January 2018
  - Businesses wishing to market insects
    - Must submit evidence of consumption prior to 15.5.97
      - To FSA
Regulatory framework

- Regulation (EU) 2015/2283: Novel Foods
- Regulation (EU) 2017/2468: Traditional foods from third countries
- Regulation (EU) 2017/2469: Authorisation procedure
- Regulation (EU) 2017/2470: Authorised list
- EFSA

This webinar will consider

- What is a novel food?
- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement

Enforcement

- Regulation (EU) 2015/2283
  - Article 29 “Penalties”
- England – Novel Foods (England) Regulations 2018
  - Detention/seizure
  - Fixed monetary penalties
  - Compliance notices and stop notices
- Wales: Novel Food (Wales) Regulations 2017
  - Detention/seizure/Improvement Notices
- Scotland: Novel Food (Scotland) Regulations 2017
  - Detention/seizure
- Northern Ireland: Novel Food Regulations (NI) 2017
  - Detention/seizure/Improvement Notices
Novel Foods (England) Regulations 2018

**Enforcement options**

- Detention/seizure
  - Section 9 Food Safety Act
- Compliance Notice
- Stop Notice
- Fixed penalty notice

**Compliance notices**

- Requirement to
  - take such steps as the food authority may specify.
  - within such period as it may specify.
  - to secure that an offence under these Regulations does not continue or recur.
- Before serving
  - must be satisfied beyond reasonable doubt that person has committed offence.
- May not be imposed on a person on more than one occasion in relation to the same act or omission.
- Compliance notice must include information as to—
  - Grounds for imposing the notice;
  - What compliance is required and the period within which it must be completed;
  - Rights of appeal; and
  - Consequences of failing to comply with the notice.
- Person may not at any time be convicted of the offence in respect of the act or omission giving rise to the compliance notice except where that person fails to comply with the compliance notice.

**Stop notices**

- A “stop notice” is a notice prohibiting a person from carrying on an activity specified in the notice until the person has taken the steps specified in the notice.
- A stop notice must include information as to—
  - Grounds for serving the stop notice;
  - Steps the person must take to comply with the stop notice;
  - Rights of appeal; and
  - Consequences of non-compliance.
- Grounds of appeal are—
  - Decision was based on an error of fact;
  - Decision was wrong in law;
  - Decision was unreasonable;
  - Step specified in the notice is unreasonable;
  - Person has not committed the offence and would not have committed it had the stop notice not been served;
  - Person, by reason of any defence, has been liable to be convicted of the offence had the stop notice not been served.
- Where, after service of a stop notice, the food authority is satisfied that the person has taken the steps specified in the notice,
  - the food authority must issue a certificate to that effect (a “completion certificate”).
Novel Foods (England) Regulations 2018
Fixed penalty notices

- Authorised officer may serve a fixed monetary penalty notice
  - In relation to an offence under the regulations
  - £200
- Before doing so:
  - must be satisfied
  - beyond reasonable doubt
  - that the person has committed the offence.

Novel Foods (England) Regulations 2018
Fixed penalty notices

- Fixed monetary penalty notices must include:
  - Amount of the fixed monetary penalty;
  - Grounds for imposing the penalty;
  - Details of how payment may be made;
  - Period of 56 days within which payment must be made;
  - Details of early payment discounts and late payment penalties;
  - Rights of appeal; and
  - Consequences of non-payment.

Novel Foods (England) Regulations 2018
Fixed penalty notices

- Discount for early payment
  - 50% of the penalty within 28 days beginning with the day on which the notice was received.
    - If penalty not paid within 56 days the amount payable is increased by 50%.

- Appeals
  - Grounds of appeal are—
    - Decision was based on an error of fact;
    - Decision was wrong in law;
    - Decision was unreasonable.
Novel Foods (England) Regulations 2018

Fixed penalty notices

- If fixed monetary penalty is imposed on any person,
  - that person may not at any time be convicted of the offence in respect of the act or omission giving rise to the penalty

Summary

What is a novel food?

- Why are novel foods important?
- Previous rules for novel foods
- The new regulatory framework
- Enforcement

Questions?

www.abcfoodlaw.co.uk
@abcfoodlaw
01603 274486
Main provisions of Regulation (EU) 2015/2283

Chapter I
Subject matter
- Article 2
  Scope
- Article 3
  Definitions
- Article 4
  Determining novel food status

Chapter II
placing on the market
- Article 6
  List of authorised novel foods

Chapter III
Authorisation procedures
- Section 1
  General rules
- Section II
  Rules for 3rd Country traditional foods

Chapter IV
Additional procedural rules

Chapter V
Data protection

abc Food Law
Consultancy, training and legal services
Regulation (EU) 2017/2470

ANNEX

UNION LIST OF NOVEL FOODS

Content of the list

1. The Union list shall consist of Tables 1 and 2.

2. Table 1 includes the authorised novel foods and contains the following information:

   Column 1: Authorised novel food

   Column 2: Conditions under which the novel food may be used. This column is further subdivided into two:
               Specified food category and Maximum levels

   Column 3: Additional specific labelling requirements

   Column 4: Other requirements

3. Table 2 includes the specifications on novel foods and contains the following information:

   Column 1: Authorised novel food

   Column 2: Specifications
### Regulation 2017/2470 Table 1: Example

<table>
<thead>
<tr>
<th>Chia oil from <em>Salvia hispanica</em></th>
<th>Specified food category</th>
<th>Maximum levels</th>
<th>The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia oil (<em>Salvia hispanica</em>')</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fats and oils</td>
<td>10 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pure chia oil</td>
<td>2 g/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Food Supplements as defined in Directive 2002/46/EC</td>
<td>2 g/day</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chia seeds (<em>Salvia hispanica</em>)</th>
<th>Specified food category</th>
<th>Maximum levels</th>
<th>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia seeds (<em>Salvia hispanica</em>')</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bread products</td>
<td>5 % (whole or ground chia seeds)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Baked products</td>
<td>10 % whole chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Breakfast cereals</td>
<td>10 % whole chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fruit, nut and seed mixes</td>
<td>10 % whole chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fruit juice and fruit/vegetable blend beverages</td>
<td>15 g/day for addition of whole, mashed or ground chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-packaged Chia seed as such</td>
<td>15 g/day whole chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fruit spreads</td>
<td>1 % whole chia seeds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yoghurt</td>
<td>1.3 g whole chia seeds per 100 g of yoghurt or 4.3 g whole chia seeds per 330 g of yoghurt (portion)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses</td>
<td>5 % whole chia seeds</td>
<td></td>
</tr>
</tbody>
</table>
## Additional labelling

<table>
<thead>
<tr>
<th>Fermented soybean extract</th>
<th>Specified food category</th>
<th>Maximum levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder form) intended for the adult population, excluding pregnant and lactating women</td>
<td>100 mg/day</td>
</tr>
</tbody>
</table>

1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Fermented soybean extract’.

2. The labelling of food supplements containing fermented soybean extract shall bear a statement that persons taking medication should only consume the product under medical supervision.

<table>
<thead>
<tr>
<th>Spermidine-rich wheat germ extract (Triticum aestivum)</th>
<th>Specified food category</th>
<th>Maximum levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Food Supplements as defined in Directive 2002/46/EC intended for the adult population</td>
<td>Equivalent of max. 6 mg/day spermidine</td>
</tr>
</tbody>
</table>

The designation of the novel food on the labelling of the food supplements containing it shall be ‘spermidine-rich wheat germ extract’.
### Additional labelling

<table>
<thead>
<tr>
<th>UV-treated milk</th>
<th>Specified food category</th>
<th>Maximum levels of vitamin D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasteurised whole milk as defined in Regulation (EU) No 1308/2013 to be consumed as such</td>
<td>5-32 μg/kg for general population excluding infants</td>
<td></td>
</tr>
<tr>
<td>Pasteurised semi-skimmed milk as defined in Regulation (EU) No 1308/2013 to be consumed as such</td>
<td>1-15 μg/kg for general population excluding infants</td>
<td></td>
</tr>
</tbody>
</table>

1. The designation on the label of the novel food shall be 'UV-treated'.
2. Where UV-treated milk contains an amount of vitamin D that is considered significant in accordance with Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council, the designation for the labelling shall be accompanied by 'contains vitamin D produced by UV-treatment' or 'milk containing vitamin D resulting from UV-treatment'.

Food Law
Consultancy, training and legal services
### Regulation 2017/2470 Table 2: Example

<table>
<thead>
<tr>
<th>Authorised Novel Food</th>
<th>Description/Definition:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chia oil from <em>Salvia hispanica</em></td>
<td>Chia oil is produced from Chia (<em>Salvia hispanica L.</em>) seeds (99.9% pure) by cold-pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities. It can also be produced by extraction with supercritical CO₂.</td>
</tr>
<tr>
<td></td>
<td><strong>Production process:</strong></td>
</tr>
<tr>
<td></td>
<td>Produced by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities.</td>
</tr>
<tr>
<td></td>
<td>Acidity expressed as oleic acid: ≤ 2.0%</td>
</tr>
<tr>
<td></td>
<td>Peroxide value: ≤ 10 meq/kg</td>
</tr>
<tr>
<td></td>
<td>Insoluble impurities: ≤ 0.03%</td>
</tr>
<tr>
<td></td>
<td>Alpha linolenic acid: ≥ 60%</td>
</tr>
<tr>
<td></td>
<td>Linoleic acid: 15-20%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorised Novel Food</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chia seeds (<em>Salvia hispanica</em>)</td>
<td>Chia (<em>Salvia hispanica L.</em>) is a summer annual herbaceous plant belonging to the Labiatae family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed.</td>
</tr>
<tr>
<td></td>
<td><strong>Dry matter:</strong> 90-97%</td>
</tr>
<tr>
<td></td>
<td><strong>Protein:</strong> 15-26%</td>
</tr>
<tr>
<td></td>
<td><strong>Fat:</strong> 18-39%</td>
</tr>
<tr>
<td></td>
<td><strong>Carbohydrate (μ):</strong> 18-43%</td>
</tr>
<tr>
<td></td>
<td><strong>Crude Fibre (</strong>):** 18-43%</td>
</tr>
<tr>
<td></td>
<td><strong>Ash:</strong> 3-7%</td>
</tr>
</tbody>
</table>

(*) Carbohydrates include the fibre value (EU: carbohydrates are available = sugar + starch)  
(**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pectins and lignin  
**Production process:**  
Production process of fruit juices and fruit juice blends beverages, containing Chia seeds, includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.
Authorisation Procedure

1. Applicant
   - Scientific evidence demonstrating that novel food does not pose safety risk

2. Commission
   - Normally seeks opinion from EFSA
   - Risk management

3. EFSA
   - Provides an opinion within 9 months
   - Assess safety of novel food and conditions of use within 7 months of EFSA opinion

4. Commission
   - Regulation updating Union List

Food Law
Consultancy, training and legal services