Introduction

• The new EU regulation – What you need to know.
  • Authorised novel foods
  • Process for determining novel food status
  • Applications
• Transition and adapting to the changes ahead
• Enforcement of the Regulation in the UK
THE CASE FOR CHANGE
So why do we need to change the legislation?

• Considerable scientific and technological developments have taken place since the Regulation first came into force in 1997!

• Authorisations under 258/97 were applicant specific so anyone wishing to market the same product (e.g. chia seeds) had to apply for substantial equivalence

• Under the authorisation process quite a lot of applications are risk assessed twice (At national expert level and by EFSA)

• Third countries saw the risk assessment of traditional foods as an unjustified barrier to trade and not proportionate to potential risks

• Application fees varied significantly across the EU

• It could take around 3 years to get authorisation
2015/ 2283  So what’s different?

✓ Updated and broadened definition of novel foods – to include whole insects.

✓ A simplified and centralised authorisation process – applications risk assessed by EFSA

✓ A Union list of authorised novel foods for all authorisations

✓ Generic authorisations - no longer applicant specific unless specific data protection applies
✓ Simplified notification procedure for traditional foods derived from primary production. The HoC should demonstrate it has been consumed safely by a significant number of people in a third country for over 25 years

✓ Onus on food business operators. If unsure about novel food status, they must consult Member State.

✓ Inclusion of data protection provisions that protect newly developed scientific evidence and proprietary data for 5 years
CHANGES IN DEPTH
Union list

• In December the first Union list of novel foods was established.

• This includes all the existing authorised novel foods made under 258/97, whether authorised as a substantial equivalence or a full applications, along with any conditions of use.

• Authorisations are all generic unless data protection is triggered. So there is no substantial equivalence process in the new regulation.

• To take advantage of a generic authorisation businesses would need to ensure they comply with any conditions of the authorisation.
## Chia (Case study)

<table>
<thead>
<tr>
<th>Chia seeds (Salvia hispanica)</th>
<th>Specified food category</th>
<th>Maximum levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bread products</td>
<td>5 % (whole or ground chia seeds)</td>
</tr>
<tr>
<td></td>
<td>Baked products</td>
<td>10 % whole chia seeds</td>
</tr>
<tr>
<td></td>
<td>Breakfast cereals</td>
<td>10 % whole chia seeds</td>
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<tr>
<td></td>
<td>Fruit, nut and seed mixes</td>
<td>10 % whole chia seeds</td>
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<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>
</tr>
<tr>
<td></td>
<td>Pre-packaged Chia seed as such</td>
<td>15 g/day whole chia seeds</td>
</tr>
<tr>
<td></td>
<td>Fruit spreads</td>
<td>1 % whole chia seeds</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>
</tr>
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1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Chia seeds (Salvia hispanica)’

2. Pre-packaged Chia (Salvia hispanica) seeds shall carry additional labelling to inform the consumer that the daily intake is no more than 15 g.
## Chia (Case study)

<table>
<thead>
<tr>
<th>Chia seeds <em>(Salvia hispanica)</em></th>
<th>Description/Definition:</th>
</tr>
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<tbody>
<tr>
<td>Chia (Salvia hispanica L.) 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>
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</thead>
<tbody>
<tr>
<td>Dry matter</td>
<td>90-97 %</td>
<td>Protein</td>
<td>15-26 %</td>
</tr>
<tr>
<td>Fat</td>
<td>18-39 %</td>
<td>Carbohydrate (*)</td>
<td>18-43 %</td>
</tr>
<tr>
<td>Crude Fibre (**)</td>
<td>18-43 %</td>
<td>Ash</td>
<td>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, pentosans 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.
DECIDING NOVEL FOOD STATUS
The process for determining novel food status

Is this food novel or not and how do I find out

The new Regulation places an explicit duty on food business operators to verify whether the food they intend to place on the market falls within the scope of the legislation.

• If unsure the FBO must consult and provide all necessary information to the Member State in which they first intend to market the product to enable a determination to be made.

• Member States may consult each other to make such determinations within specified timescales.

• Detailed Rules are set down in Commission Implementing Regulation adopted on 20 February to be published shortly.
Process for assessing the novel food status

1. Development and submission of a dossier.
2. Validation of the request
3. Assessment of the information
   - 4 months with option to extend by 4 months where justified
4. Option to consult other member states
5. Conclusion on status made publicly available
Deciding on novel food status: Advantages

• Stepwise approach to the information requested that reflects the types of questions on novel food status received.
• Encourages businesses to share information on History of consumption to the benefit of everyone.
• Improves EU wide information on products that have a history of consumption so there is greater regulatory certainty for products.
Foods new to the scope - Transition measures

- The Regulation states that foods that were not subject to 258/97 that were lawfully placed on the market prior to January 2018 may continue to be marketed until a decision is made on the food or by 2020 at the latest.
- This is contingent on an application being submitted for the food by the deadline in the implementing act on the scientific requirements for full dossiers and traditional foods – 1 January 2019.
Transition measures 2 - Insects

- Views on whether insects have been legally sold on Member states markets, and therefore whether they can benefit from the transitional arrangements, differ across the EU. The UK considered whole insects outside the scope of the novel food regulation and therefore legally on the market.

- So, in the UK the species of whole insect that were marketed in the EU before the end of 2017 can be continue to be sold until 2020 subject to an application for these foods being submitted by the 1 January 2019.

- In UK we do not have a list of insects that have been sold in the UK and wider EU member states.
APPLICATIONS
Transition measures - Applications

- Dossiers accepted under 258/97 that were ongoing and had not achieved a decision by the end of 2017 become dossiers under 2015/2283 EU.
- The Commission is now responsible for managing these through the new process.
- Assessment by EFSA is likely except in the cases where the 60 day Member State consultation was completed and no reasoned safety objections had been raised.
Novel food applications

• One dossier: one risk assessment.
• Builds on experience of the past.
• Submission via an e-portal
• Retains key areas of specification, production process, use and intakes, nutrition, microbiology, toxicology and allergy
• Clearer requirements outlined in EFSA guidance and supported by an Implementing Act.
Novel food full application process

Submission
• Application submitted to the Commission via e-portal. Validation of the application before it is formally accepted

Assessment
• Assessment by EFSA – Opinion in 9 months if no further information is needed

Authorisation
• Commission have 7 months from a positive opinion to draft an implementing decision to update the Union List of novel foods which consists of a specification and conditions of use.
Features of the new assessment

• Requirement to outline the strategy for the scientific evaluation.
• Literature review.
• Consideration of consumption by non target groups.
• Stability – information on the conditions the ingredient will experience.
• Making use of other specific guidance - Engineered nano materials.
• Allergenicity.
Traditional foods from 3rd Countries

- Designed for foods that have been consumed for over 25 years elsewhere in the world but not in the EU as a shorter process to gain access to the market.
- Notification application required which contains information for Member states and EFSA to consider
- Where safety objections are raised, an application can be submitted and evaluated by EFSA.
Traditional foods application process

**Submission**
- Notification application submitted to the Commission via e-portal. Validation of the notification within 1 month before it is formally accepted.

**Assessment**
- Option for EFSA, Commission and all 28 Member States to assess the information and raise reasoned safety objections within 4 month period.

**Notification Authorisation**
- No objections - The food is authorised by updating the Union List without delay.

**Objections raised**
- Objections – Applicant can submit a traditional foods application through the e-portal which addresses the safety concerns raised.
- This would be subject to a risk assessment by EFSA. There is 6 months for this process where further information is not needed.

**Application Authorisation**
- Commission have 3 months from a positive opinion to draft an implementing decision to update the Union List of novel foods which consists of a specification and conditions of use.
IMPLEMENTATION
Enforcement measures

• The Novel Foods (England) Regulations 2018 (SI 2018/154) (Separate, equivalent legislation in other UK countries)

• Aim – to put in place a proportionate and risk based approach to enforcement that provides enforcers with a set of tools to encourage compliance.

• Within the current hierarchy of enforcement, specific tools the Regulations provide for enforcement authorities in England are:

  • Compliance notices;
  • Fixed monetary penalties;
  • Stop Notices and
  • Back stop offences where needed.
EU Exit

• The Government has confirmed that the UK will be leaving the EU in March 2019.

• At this point, the European Union (Withdrawal) Act and subordinate legislation will come into effect and;

• The provisions of the EU Novel Foods Regulation will become UK law and the national enforcement provisions will continue to apply.

• We will not know what the future UK system for regulated products will look like until our future relationship with the EU is agreed.
In summary

• The Regulation represents an evolution of the previous EU novel foods regime with improvements made in the light of experience.
• It will take time for operators and regulators get used to the new systems in the Regulation but Commission implementing measures provide more detail.
• The aim is consistent approach to novel foods, making it easier for businesses to trade in the EU.
• We – as the FSA – feel that the Regulation provides a firm foundation for managing novel foods for the future beyond EU Exit.
Thank you for your time and attention

Questions?