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Novel foods beyond January 2018 - New vs Old: a regulator's ...perspective....

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Introduction

- The new regulations – What you need to know.
- Transition and adapting to the changes ahead
- Enforcement of the regulations in the UK
- Preparing dossiers top tips from the risk assessors

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 are applicant specific so anyone wishing to market the same product (e.g. chia seeds) must apply for substantial equivalence
- Under the current process quite a lot of applications are risk assessed twice (At national expert level and by EFSA)
- Third countries see the risk assessment of traditional foods as an unjustified barrier to trade and not proportionate to potential risks
- Application fees vary significantly across the EU
- It can take around 3 years to get authorisation

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2015/ 2283 So what's different?

- ✓Updated and broadened definition of novel foods – to include whole insects.
- ✓A simplified and centralised authorisation process – applications will be risk assessed by EFSA
- ✓A Union list of authorised novel foods will be established
- ✓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

Changes in depth

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.

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Changes in depth - 2

Novel food applications

- One dossier: one risk assessment.
- Builds on experience of the past.
- 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.

Changes in depth - 3

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.
- Focus is on notification which contains information for Member states and EFSA to consider
- Where safety objections are raised a response to the safety objections raised can be considered by EFSA.

Transition measures

- The basic 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.
- Existing dossiers become dossiers under 2015/2283 EU.

UK enforcement measures

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

In addition to the current hierarchy of enforcement the tools available for enforcers will include:

- Compliance notices;
- Fixed monetary penalties;
- Stop Notices and
- Back stop offences where needed.

WHAT ACNFP LOOKS FOR WHEN CONSIDERING A DOSSIER

Novel foods must NOT

- Present a danger to the consumer
- Mislead the consumer
- Replace current nutrients in normal diets in ways that would be nutritionally disadvantageous for consumers.

(Article 3 of EU Regulation 258/97 and article 7 of 2015/2283 EU)

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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.

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Top tips

- Is it clear the food that it being assessed?
- Are the potential risks from the food identified?
- How will this food be used by consumers?
- Is the data presented scientifically robust?
- Is the information presented in accessible way?

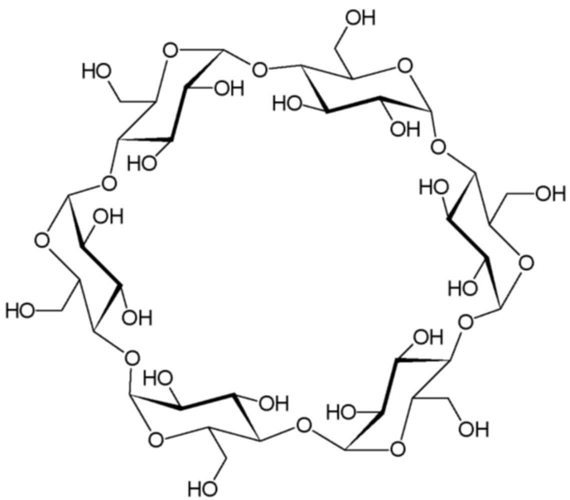
What is it are we assessing? - Specification

If it is plant or animal…what is the biological classification?

What chemical(s) are involved?

Production processes?

- Flowchart of the process
- Show us how production works on a commercial scale and that any associated food safety risks are managed.



Help us with the context…

What is normal expected use?

Does it add choice / replace existing foods?

Who is the product aimed at?

- Everyone/adults/children/people with health issues…?

Are there the risks if it not used as intended?

- And how will risks be minimised?

Scientifically robust data

Present analysis to **show this particular product or process is safe**

Are confidence intervals and measurement uncertainty clear?

Five batches?

Laboratory analysis – by an accredited laboratory

Make it easy to read…

Can all the relevant information be found easily?

If information is in the annex is this referenced in the main text?

Has the information been presented in an accessible way. - Summary tables, charts etc.

In summary

- Implementing measures currently under development will provide detail on how the new processes will work in practice.
- This is an evolution of the previous regime and we should learn from the past.
- The key for dossiers is to make the evidence scientifically robust and the key information accessible.

Thank you for your time and attention