FERA COLLABORATIVE INSIGHTS

A LOOK AT THE CURRENT REGULATORY CONTEXT OF NOVEL FOODS.

A response to Defra's **Implications of Emerging Novel Protein Sources for Food Authenticity and Labelling** report.

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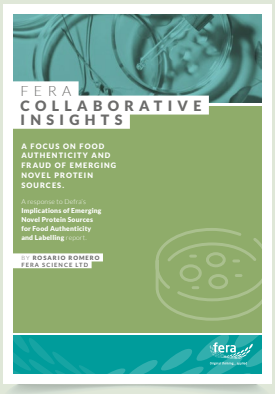
Original thinking... applied

THE REPORT'S CORE FINDINGS

Defra has recently published a report, commissioned to Fera Science Ltd, focussing on potential emerging risks regarding authenticity and labelling of alternative protein food products. Discussed in this report are aspects such as how these products may fit under the current regulatory labelling framework, how current testing capability can support product authentication and detection of emerging fraud risks and future research needs in this sector.

Following this publication, and to continue the debate into the current challenges and future opportunities within the industry, Fera is producing a series of articles culminating in a webinar, bringing together key industry stakeholders, researchers, and representatives from regulatory bodies.

Authored by Rosario Romero, Science Lead from Fera Science with input from several subject matter experts in this field, Defra's report has the potential to shape our understanding of and inform future authenticity method development needs to ensure testing capability for alternative proteins and future research needs are considered.



CLICK HERE TO READ THE FULL REPORT

In this brief article the co-authors delve into the key findings and the broader implications.

THE REPORT'S CORE FINDINGS

The report, titled **Implications of emerging novel protein sources for food authenticity and labelling** provides an expert review of the information available in relation to potential food labelling and authenticity risks associated with alternative proteins (AP).

Its findings can be distilled into several key themes:

KEY FINDING 1

Currently, not much consideration has been given to potential food fraud in the alternative protein sector, as most of the effort has been focused on developing products and associated technologies.

KEY FINDING 2

The use of new production and processing techniques as well as novel sources of protein may present challenges for current analytical methods for food authentication.

KEY FINDING 3

In addition to analytical methods, the wider food supply chain control systems must evolve to accommodate increasing complexities.

KEY FINDING 4

Labelling of AP faces two important challenges concerning the use of descriptors and imagery traditionally used for animal-derived foods and the question of transparency regarding methods of production.

A Synergy of Findings & Expertise:

In this article Rosario and Hannah Lester, Atova Regulatory Consulting, will present an overview of the current market and regulatory landscape across UKand Internationally.

INTRODUCTION

from **Dr Rosario Romero**

Rosario Romero
Science Lead, Novel Foods

The world's population is projected to reach 9.7 billion in 2050 and ensuring that everyone has access to safe and nutritious food whilst protecting natural resources represents a serious challenge.

Alternative sources of proteins are thought to have potential in helping to tackle this problem.

The interest in alternative proteins has been increasing as a result in recent years and this trend is expected to continue.

Perceived benefits for animal welfare, health and sustainability are key drivers of this behaviour.

Technological advances are enabling an acceleration of innovations, and a plethora of alternative proteins products are being developed. There are still challenges and research gaps, but innovations are progressing rapidly across different categories - plants, algae, microalgae, insects, fermentation, cellular agriculture - and new products are becoming available to consumers.

Alternative proteins include a wide variety of sources. Many of these are classed as Novel Foods (NF) and require Novel Food authorisation before they can be marketed.

In the European Union, foods that have not been used for human consumption to a significant degree in EU countries before 15 May 1997, fall under the Novel Food definition unless they involve genetic modifications, in which case they are regulated as genetically modified organisms (GMOs).

Novel Foods also include products that are the result of modified or new production technologies. Regulatory frameworks differ across countries. The UK, as part of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union, transitioned the novel food regulatory framework from EC/EFSA to the Food Standards Agency (FSA).

Novel Food authorisations for England, Scotland and Wales are now coordinated and assessed by the FSA and Food Standard's Scotland. However, products intended for sale in Northern Ireland must still be submitted through the EC/EFSA regulatory pathway as per the Northern Ireland Protocol.

The FSA has maintained the same application criteria and evaluation standards as the EC/EFSA, which are currently the most comprehensive, lengthy and strict in the international sphere, and this is considered by many in the AP industry to be a barrier to the development and commercialisation of these products, and hence, a barrier to the potential that AP represent in terms of food security and environmental impact of food production.

However, ensuring the safety of any novel foods is paramount, and the FSA, as other food authorities around the world, are faced with the task of balancing the fast pace of technological advances and the AP industry demands for rapid approval processes with potential long-term population health interests.

OVERVIEW & OPINION

from **Dr Hannah Lester**

Hannah Lester
Atova Regulatory Consulting

Since leaving the EU, the UK is in a unique position to create a new and exciting regulatory environment that will foster and support novel food innovation.

The FSA has recently performed a review of their novel food framework and is committed to building something that is more in pace with innovation and allows applicants to get products to market in a shorter timeframe without compromising on safety.

This is very welcome news for the alternative protein industry!

We are still waiting to hear exactly what this updated framework will look like, but from what we understand, the changes will be implemented by 2026.

We have already seen the FSA in collaboration with Food Standards Scotland (FSS) launch a new regulated product application portal which is designed to be more user-friendly and help applicants submit a complete application.

Applicants will be able to see the progress of their application and will also receive regular updates via the platform.

There have been some interesting developments recently in terms of novel food submissions for alternative proteins.

In August, Aleph Farms became the first cultivated meat company to submit a novel food dossier for the approval of their cultivated beef product in the UK and Switzerland.

Whilst there have been no novel food dossiers submitted to the EC and EFSA yet for cultivated meat and seafood, back in May, EFSA held a scientific colloquium on cell-cultured foods and said that they were ready and waiting for cultivated meat dossiers!

Regarding the ongoing novel food applications relating to alternative proteins, in the UK the FSA is currently reviewing eight novel food dossiers:

1 x insect protein,
1 x mycelium derived protein,
1 x single cell protein,
2 x microbial biomass products
3 x plant proteins

and all but one are in the risk assessment phase.

In the EU, EFSA is reviewing their novel food guidance with the aim of updating and clarifying certain sections especially relating to precision fermentation derived ingredients and cell-cultured products.

The updated guidance will be published for public consultation before being adopted so interested stakeholders will have the opportunity to provide feedback. The anticipated timeline for the publication of the new guidance is in 2024.

In the USA, we have not seen any further outputs from the Food and Drug Administration (FDA) in terms of new cultivated meat and seafood dossiers and the FDA is still pending to publish guidelines for applicants specifically for human food derived from cell culture.

Continued...

OVERVIEW & OPIONION

from **Dr Hannah Lester**

The FDA recently updated the Generally Recognised as Safe (GRAS) notice inventory, and it includes a new GRAS notice from ImaginDairy for their beta-lactoglobulin derived from precision fermentation.

The FDA is pending to review this GRAS notice. This means that there are now seven proteins derived from precision fermentation that have been submitted to the FDA, five of which have received a no questions letter from the FDA meaning that they agree with the conclusion of the applicant that the product is safe.

There continues to be a lot of regulatory activity around alternative proteins. It will be interesting to see how quickly the FSA will review the Aleph Farms dossier, which is still in the validation phase.

It will also be important to see how quickly EFSA will review the two beta-lactoglobulin dossiers, both of which are under the validation phase meaning the actual risk assessment has not yet started!

Moreover, we are all waiting for the first cultivated meat dossier to be submitted in the EU and this will serve as a very important precedent that everyone will be watching closely!

Click to access the full report and delve deeper into its findings.