

Life After Meat: The Bioeconomy's Alternative Protein Sources – Part 3

As the production of meat comes under increasing scrutiny for its environmental impacts, efforts to develop alternative proteins have been increasing. In our previous two articles in this series, we've taken a look at some of the alternative proteins that are either available or in development, and a look at who's doing what, particularly in the UK. A reoccurring theme highlighted in the series so far is the regulatory requirements that exist within the sector. Novel foods in particular require specific authorization both in the EU and elsewhere. This article will therefore take a further look at alternative proteins and the regulatory barriers that may present themselves when taking a new product to market.

General Food Law

In 2002, the EU Regulation 'General Food Law' came into effect. Its objectives included the establishment of common definitions and laying down overarching guiding principles and objectives for food law to ensure a high level of health protection, applied to all stages of food production. In England, the subsequent Food Safety and Hygiene Regulations and the General Food Regulations provides for the enforcement of certain aspects of the General Food Law. Post-Brexit, when placing a regulated product on the market, the Food Standards Agency (FSA) will carry out the risk assessment, which is to be carried out in accordance with the requirements of retained EU law and the guidance previously developed by the European Food Safety Authority (EFSA).

Novel Foods

Novel Food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force. The most updated regulation on novel foods is 2015/2283.

'Novel Food' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

The underlying principles underpinning Novel Food in the European Union are that Novel Foods must be:

- Safe for consumers
- Properly labelled, so as not to mislead consumers
- If novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer.

New products follow a process of authorization from the relevant authority before being placed on the market. In the UK, the FSA considers a number of criteria before a novel nutritional substance or food ingredient is considered 'Generally Recognized as Safe' (GRAS), and can be used in the manufacture of consumed substances. In addition, food business operators are required to pass a specific authorization process.



Cultured Meat

Cultured meat is a relatively new technology, still in its early stages of development. It also doesn't align with the definition of meat or a meat product, so can't be regulated in the same way. The EU defines meat as 'the edible parts of animals', while meat products are defined as 'processed products resulting from the processing of meat or the further processing of such processed products'

In the EU, cultured meat would be regulated by the Novel Food Regulation because food consisting of, isolated from, or produced from a cell culture or tissue culture from animals, plants, microorganisms, fungi or algae is considered one of the novel food categories listed in the regulation. The EU requires a verification process for cultured meat food producers to verify the safety of their product before it is introduced to the market. Additionally, like all novel food products, cultured meat is subject to a pre-market authorization, including a safety assessment conducted by the EFSA.

Some countries outside of the EU have produced regulatory guidance on cultured meat in its assessment of novel foods. Singapore Food Agency has laid out detailed definitions and guidance for approval of cultured meat. In fact Singapore approved the sale of cultured meat for the first time in December 2020. Israel has a pre-market authorization process outlined in its novel food regulation framework, with the safety assessment modelled on the EU. The joint competent regulatory authority in Australia and New Zealand, Food Standards Australia and New Zealand (FSANZ) has stated that its regulation the Food Standards Code is equipped to deal with foods produced by new technologies such as cultured meat. The FDA in the US has not yet outlined detailed requirements for tissue collection and cell culture, but has said products from cultured animal cells will involve thorough pre-market assessment.

Fermented Products

The use of microbes in food processing is an old technology, having been used for many years. With regards to the regulation surrounding the use of microbes, any that are used in food production are regarded as ingredients and as such must fulfil the requirements of the General Food Law.

As for potential novelty, the Novel Foods regulation does encompass foods consisting of microorganisms, fungi or algae. However, since the introduction of the Novel Food regulation in 1997, there haven't been any microorganisms used or consumed as a live culture that have been subject to novel food evaluation and authorization.

Quorn is the main brand of mycoprotein-containing foods in the UK. Any food rich in protein and processed from an edible fungus is considered to be mycoprotein. Quorn is sold widely in Europe and elsewhere in the world and Quorn is not considered a novel food. Important to note, the Quorn process, and indeed other fermented food products that use microbes for their production in the EU, don't use genetically modified organisms. The microorganisms used can be optimized for production using other biotechnological routes. Gene modification of microbes would be classed as novel, however, in that case it is subject to different regulation.

A Note on GMOs

Genetically modified organisms (GMOs) are often the first thought when it comes to regulation surrounding food. They are organisms that have a specific element of DNA added to their genetic makeup, with the aim of giving them some new or different characteristic. Crops can be GMOs, modified to have favourable qualities such as pest resistance. Food can be produced from GMOs, for example, microbes can be modified for optimum fermentation processes. The Novel Food



Regulation doesn't apply to GMOs for food and feed, it applies to those novel foods whose novelty is not attributable to genetic modification.

GMOs are well regulated in the EU, and indeed elsewhere. According to EU regulation 1829/2003 authorization and supervision requirements apply to: GMOs for food use; food containing GMOs; and food produced from or containing ingredients produced from GMOs. According to regulation 1830/2003, traceability and labelling requirements apply to: products containing GMOs; food produced from GMOs; and feed produced from GMOs. These requirements are extensive and the European Food Safety Authority provides a case-by-case review of each GM food, although there are exceptions to the requirements such as cheese made from GM enzymes, and milk from cows that were fed GM crops.

Consumer perception, particularly in the EU, means that the labelling requirement has a similar effect to a ban on GMO containing foods. Food companies often avoid the use of GM ingredients in their products due to the negative effect it would have on their reputation. Consumer acceptance of GM foods is the main barrier, not necessarily any regulatory hurdles. Feed doesn't face the same barriers, as GM soy for example is a commonly imported material to the EU used as protein for animal feed.

All food we eat has to undergo some level of approval according to Food Safety Laws. Some of the new and not-so-new protein sources we see as a result of biotechnological processes have to have varying levels of approval for consumption. Primarily, the novel foods regulation has the most consequence on some of these protein sources, and it will be interesting to see how some of these regulations develop in the coming years.

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Biocentre, York Science Park, Innovation Way, Heslington, York, YO10 5NY

www.nnfcc.co.uk



