Novel Foods: Designing a winning analytical strategy for successful EFSA applications

White Paper

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Abstract

Submitting a compliant novel food application is challenging. It demands an integrated approach, where a strategic understanding of current regulatory guideline informs the process and strong scientific capabilities deliver the correct data. Here we explain why and what needs to be considered.

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Introduction

With political instability, climate change related events and economic shocks continuing to disrupt the global food supply chain, the need to embrace novel food technologies has never been greater. For populations without access to good nutrition, they offer significant potential for more effective food fortification. An additional opportunity is to create better choices for those with specific dietary restrictions such as allergies and intolerances, as well as more sustainable food production systems.

Precision fermentation, for example, typically uses genetically engineered microorganisms to cultivate specific proteins, enzymes and other compounds. By creating the ideal growth medium in a fermentation vessel, innovators have been able to produce a range of novel ingredients including food colourings, sweeteners and flavouring agents, as well as dairy proteins such as casein and beta-lactoglobulin.

Cellular agriculture, on the other hand, involves growing cells extracted from animals or plants in a laboratory-controlled environment. Best known for producing 'lab grown' meat from animal cells, this technology has the potential to transform the meat industry by reducing reliance on traditional farming methods.

Of course, novel food applications are not just the result of innovative technologies. New ingredients developed via traditional methods or those commonly consumed in other regions may also be subject to safety legislation before launch. In every case, understanding what is required to meet the latest regulatory requirements in each target market is vital. Relevant and robust data that demonstrates the product is safe for consumption, properly labelled and doesn't mislead consumers must be provided. Without the right scientific evidence presented in the correct format, applications are likely to fail – leading to longer lead times, increased costs and no guarantee of a positive outcome.

However, regulatory submission is a highly complex and time-consuming process, made even more complicated by the fact that regulatory frameworks and associated safety assessments vary between regions. The European Food Standards Authority (EFSA) and US Food and Drug Administration (FDA), for example, may be ahead of the UK Food Standards Agency (FSA) which is yet to fully define its guidance – but each differs in scope. Not only that, many regulators are struggling to keep pace with the speed of novel food technologies, which means certain standard safety assessments may not be applicable and new methods need to be developed to demonstrate materials are safe.

That's why it is essential that companies work with an experienced partner that has both the regulatory knowledge and analytical expertise to successfully guide them through the process.

Novel or not novel?

At RSSL, we provide comprehensive support that starts with addressing the fundamental question of whether the material qualifies as novel or not in the market(s) of interest. And if so, the exact safety and regulatory data that needs to be provided to support the stated conclusion, as well as subsequent novel food submission.

This process generally involves gathering all available scientific information and data related to the material in question, including historic use in the market, composition, production process, potential allergenicity, toxicity and nutritional content. This is achieved by:

- Analysing historic use data to assess if the material has been significantly consumed by humans within the specified timelines.
- Analysing the collected data to identify any areas where information may be lacking or insufficient to fully assess the safety and suitability of the material for human consumption.
- Using the available data to carry out a comprehensive risk assessment to evaluate potential risks associated with the material, such as allergenicity, toxicity and any other health concerns.
- Establishing a strategy for a subsequent novel food submission. This is likely to include planning additional scientific studies, toxicological assessments, allergenicity tests and other relevant research to fill in missing information.
- Providing clients with an estimated time and cost for the novel food submission process in the market(s) of interest.

Characterisation studies

Characterisation studies are focused on substantiating the identity of the novel material, this allows a specification to be developed which highlights any important health or functionality associated with a novel material. Typically – and certainly for an EFSA novel food submission – five batches need to be characterised and it is essential that they are all representative of the final production process. Far better to get it right from the beginning of the data generation process, rather than having to secure additional novel food approvals further down the line.

We use different analytical techniques – such as liquid and gas chromatography, mass-spectrometry and nuclear magnetic resonance (NMR) – to understand the composition, structure and other key properties of the novel material. This data provides crucial insights into the safety, quality and potential applications of a material in food. Purity and microbial assessments are also needed to ensure the material meets required standards and doesn't contain any harmful substances, toxins or other unwanted contaminants, such as heavy metals.

Depending on the nature of the novel material, further characterisation tests may be needed to address key safety concerns. For example:

- Materials derived from microorganisms must demonstrate the successful elimination of any remaining DNA from the novel material.
- Materials produced from genetically modified microorganisms should be evaluated in the context of GM status and product labelling.
- New proteins must undergo amino acid sequencing and in-silico allergenicity assessments to establish whether they are similar to any known allergens and, if so, require further in-vitro and in-vivo tests.

Method development and validation

Generating robust data that stands up to regulatory scrutiny and avoids being challenged – or even repeated – during the review process is essential. That means first selecting the most appropriate techniques and establishing protocols for sample preparation, measurement and analysis. And then verifying that each method can effectively identify and quantify the compound of interest, particularly the identifying chemical marker.

Not surprisingly, developing and validating methods to accurately analyse novel materials is not straightforward. An isolated novel ingredient, for example, may behave differently in the specified food matrix so it's important to anticipate these interactions as part of the method development process. Ultimately, however, the absence of a clear frame of reference for many of these innovative materials means that our ability to pivot and find new ways of measuring specific product attributes is a crucial capability.

Stability assessments

Our comprehensive assessments are designed to demonstrate the stability of novel food ingredients throughout their intended shelf life, both as a raw material life and in the food applications defined in the novel food submission. The resulting data is crucial, both for the regulatory safety evaluation and future commercialisation of the product.

In practical terms, this involves developing real-time and accelerated stability studies to assess how the material performs under different conditions, such as low pH, high temperature and oxidation. This provides valuable insights into the physical, chemical and microbiological changes that may occur in the novel food over time, as well as its compatibility with different food matrices.

In addition – and where appropriate – our team will also conduct trials with model food matrices that are representative of its final use in commercial food products. When coupled with sensory factors, such as taste, texture and colour, this builds a representative picture of how the material's quality, functionality and organoleptic features may degrade over time.

Health and nutrition profiling

A detailed evaluation of the novel material's impact on human health must include data related to its absorption, distribution, metabolism and excretion, and often involves in-vitro and in-vivo studies. These assessments are crucial for evaluating the safety and potential risks associated with consumption.

So too is nutritional profiling. In the case of lab grown meat, for example, RSSL analyses the product for the presence of essential nutrients, such as proteins, fats, carbohydrates, vitamins and minerals. This data is not only used to demonstrate the product's nutritional value, it can also be used as evidence that consumption at recommended levels won't take overall nutritional intake of the general population above regulated levels. As a general rule, these values should align with no more than the 95th percentile intake of consumers in each target market.

Nano-particle assessment

To comply with EFSA regulations, the potential presence of nanomaterials in a novel food and their associated risk for future consumers need to be evaluated. This involves, for example, examining the material's ability to dissolve in water or simulated gastro-intestinal fluids. If the material is highly soluble, no further assessment is required as the initial nanostructure is lost, but those that are not will require further evaluation.

Our experts use electron microscopy, dynamic light scattering and other specialised methods to assess particle size, shape, surface characteristics and potential aggregation of poorly soluble food materials. Should a substantial fraction of nanoparticles be detected in the novel food, the scientific dossier will have to account for potential additional risks and thoroughly evaluate the potential implications in terms of safety, toxicity and physiological interactions.

By conducting comprehensive nano-particle assessments, we provide essential data to support regulatory submissions and ensure the safe and responsible use of nanomaterials in novel food products.

Summary

Faced with a challenging regulatory environment, it can be easy to lose sight of its ultimate purpose which is to ensure novel foods are safe for human consumption. To make this judgement, regulatory authorities need to be presented with relevant, accurate and complete scientific evidence.

That's why we tailor our approach to ensure both the analytical methods and data are correct for each product. This level of sophistication is only possible due to the depth of scientific expertise and regulatory knowledge within the RSSL team.

About the author

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Dr. Daniele Leonarduzzi, an Oxford graduate in chemistry, has been part of the RSSL team for six years.

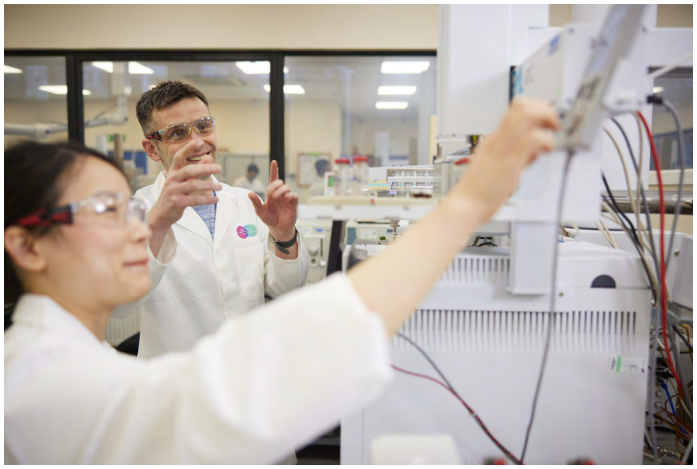
In his capacity, he utilizes his expertise to advise clients on novel food applications, ensuring that their scientific documentation aligns with the necessary standards.

With a solid academic background and practical experience in the characterisation of food materials, he brings a wealth of knowledge to the table.

How RSSL can help

Our specialist team interprets complex dossier requirements and carries out the right analysis to give your regulatory submission the best chance of success. We provide an integrated service designed to guide you through the regulatory process, which means we don't just identify what analytical data is required but have the experience and technical capabilities to deliver it too. An approach that ensures your submission is fully compliant.

To find out more about our novel foods and regulatory support service please contact us on **+44 (0)118 918 4076**, email **foodsales@rssl.com**, or visit **www.rssl.com**



About Reading Scientific Services Ltd (RSSL)

RSSL is a cutting-edge food research company, pushing the boundaries of science and innovation to help make our world safer, healthier and more sustainable. Our clients trust us to deliver innovative solutions to real-world problems through rigorous analytical testing, state-of-the-art research and development and customised consultancy. In everything we do, we are focused on transforming lives through science, innovation and collaboration.

Find out more about RSSL's novel foods and regulatory support service **here**.

Contact us to find out how we can support your novel food application requirements.

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