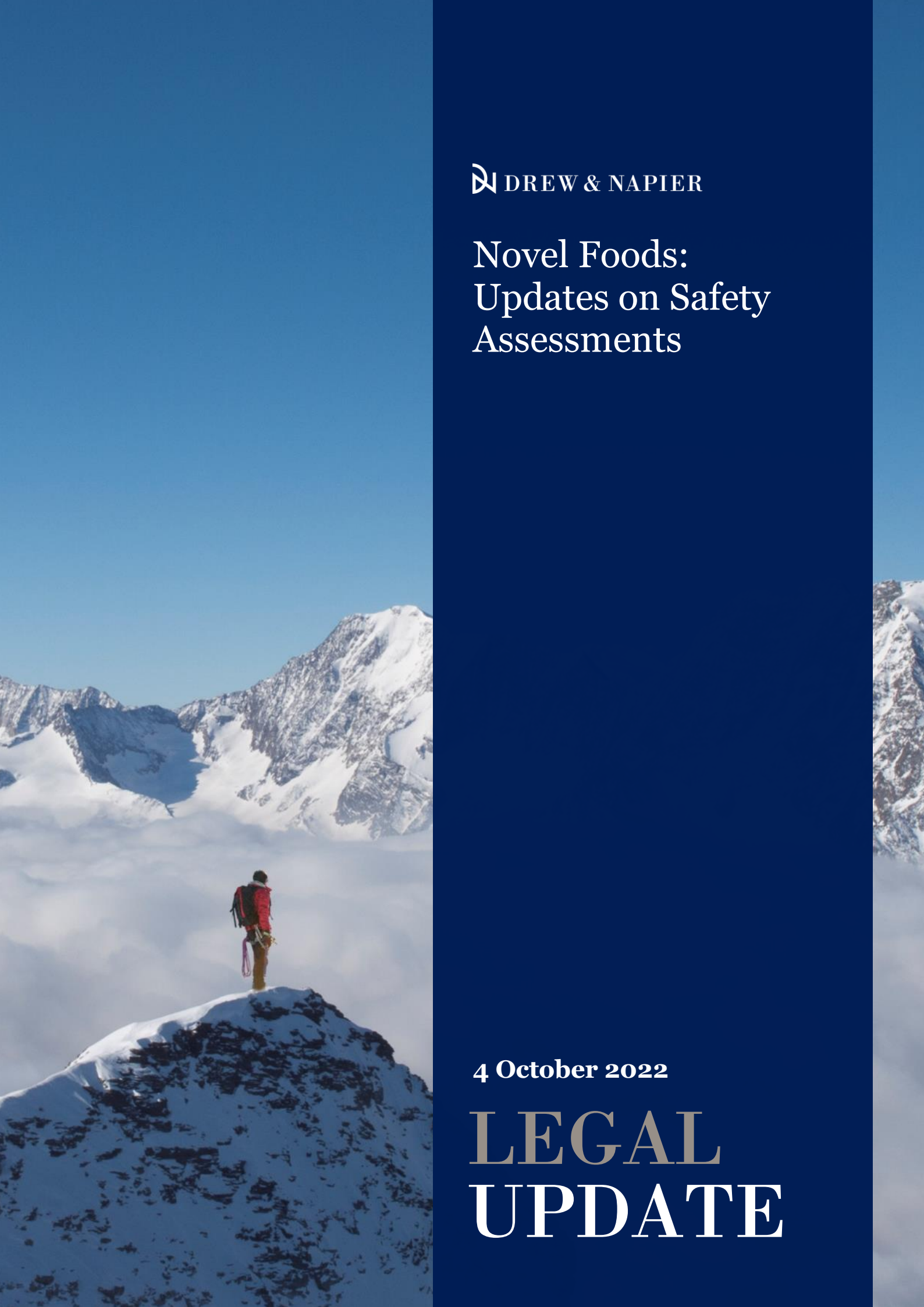




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Novel Foods: Updates on Safety Assessments

4 October 2022

LEGAL UPDATE

In this Update

The Singapore Food Agency has released its latest version dated 26 September 2022 on the “Requirements for Safety Assessment of Novel Foods and Novel Food Ingredients”.

In this latest version, there are some notable refinements to SFA’s safety assessment criteria. As the world of novel foods continues to develop, the laws around such innovations will correspondingly evolve. It is important for businesses participating in this area of science to keep abreast of the regulations to be complied with.

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INTRODUCTION

The “Requirements for Safety Assessment of Novel Foods and Novel Food Ingredients” (“**Safety Requirements**”) define “novel foods” as “foods and food ingredients that do not have a history of safe use”; that is, not having a history of consumption by a “significant human population” for at least 20 years without adverse effects on health. It bears to note that “compounds that are chemically identical to naturally occurring substances but produced through advances in technology” are also considered novel foods. Where in doubt as to whether a food or ingredient is novel, consultation with the Singapore Food Agency (“**SFA**”) is recommended.

The overarching rule is that novel foods are prohibited from being produced, manufactured, imported, distributed, or sold in Singapore without pre-market regulatory approval from SFA. A self-assessment checklist is available from SFA for businesses to ascertain if they are ready for pre-market regulatory approval. The safety assessment of novel foods submitted to SFA for review must provide the information required under the Safety Requirements. It is the responsibility of the applicant to provide “all available proprietary, confidential, or published scientific data” relating to the novel food, including any safety concerns.

It is stated in the Safety Requirements that since novel foods is an area that is “rapidly evolving”, it should be expected that SFA “will periodically update and revise this document to facilitate safety assessments by the industry”. The latest version of the Safety Requirements is dated 26 September 2022 and contains several refinements to the safety assessment criteria.

KEYPOINT

This update highlights the key refinements which reflect a deeper understanding by SFA of the cell-culture process and the regulations needed to promote safe commercialization.

KEY REFINEMENTS: CELL CULTURE

Biological substances used in media for cell culture

The Safety Requirements now prescribe new safety procedures for biological substances used as culture media during the production of cultured meat and seafood. SFA defines “cultured meat” and how the process works in section 4.6 of the Safety Requirements:

Cultured meat refers to meat developed from animal cell culture. The process to produce cultured meat involves growing the selected cell lines

(or stem cells) in a bioreactor. The cells are grown in a suitable growth media and may subsequently be assembled on a “scaffold” to produce products resembling meat muscle.

A new safety assessment approach to assessing biological media in the culture process is prescribed in section 5 of the Safety Requirements. Information required to satisfy section 5 is in general divided into three parts: about the biological substance, about the use of the biological substance in culture media, and about consumption of the biological substance into the human body. The approach follows a flowchart methodology, requiring applicants to provide adequate analysis every step of the way.

The biological substance must first be assessed for history of safe use and health-based guidance value, if any. Toxicological data should then be considered. If the substance is produced using recombinant DNA technology, details that must be provided include *inter alia* those relating to the genetic modification process, primary sequencing, toxicity, allergenicity, virulence-related genes, antibiotic resistance, and chemical purity. Where the substance is detectable in the final novel food product, the applicant shall describe the purpose of adding the substance to culture media, the characterization and specification data, levels of substance presence, any history of safe use, allergenicity, viral or prion contamination, and other safety concerns.

Safety assessment is also required to determine the synthesis and mode of action of the substance in the human body, how the substance may respond to food processing, whether the substance is absorbed and if so, whether this is at safe levels, the connection between consumption of the substance and other dietary factors, and mechanisms responsible for that connection.

Although not immediately obvious from the language of the Safety Requirements, the new safety assessment criteria for biological media culture would presumably apply equally to biological substances used in producing “scaffolds” or microcarriers in the culture process.

Genome instability and genetic drift

To protect against food safety hazards that may result from genome instability or genetic drift, the Safety Requirements now stipulate strategies for identifying and analysing potentially undesirable substances in end-product cells.

Applicants are required to conduct a “systematic scientific literature review” to identify all known harmful substances associated with the relevant animal species that is cultured. A list must be established for subsequent targeted analysis. SFA allows applicants the flexibility of choosing the strategy for target analysis. Applicants can either perform an “*in-silico* genome screen” against databases such as WHO/IUIS Allergen Nomenclature database, The Allergome database, and The Protein family (Pfam) database, to

extract a list of potential toxins and allergens, or they can conduct a “qualitative comparison of the end-product cells against the starter cells” using known methodologies such as transcriptomics, proteomics or metabolomics, to discover a list of differentially expressed substances that might pose safety concerns.

The Safety Requirements also mandate that information should be provided to demonstrate “good cell culture practices (GCCP)”. GCCP as stated in the Safety Requirements may be a reference to the Guidance on Good Cell Culture Practice published by the European Centre for the Validation of Alternative Methods (“**ECVAM**”). However, this is not made explicitly clear by SFA. It is also not clear how the concepts in ECVAM’s GCCP, while relevant to setting minimum standards of quality control for *in vitro* procedures, are expected to be applied under the Safety Requirements.

New checklists

To facilitate better understanding of the safety criteria for biological media and the consequences of genetic drift, SFA has designed new self-assessment checklists for those who wish to apply for pre-market regulatory approval in relation to novel foods derived from precision and biomass fermentation, as well as for cultured meat and seafood.

KEY REFINEMENTS: PRE-APPROVAL TASTING

Administrative exemption

Significantly, businesses who wish to conduct tasting of novel foods as part of research and development, before completion of the safety assessment process, now need to seek an administrative exemption from SFA. This exemption is in turn made subject to stringent conditions.

Conditions for exemption

Tasting of any novel food that has not been granted pre-market regulatory approval must not be made available to the general public. Each tasting session may only have a maximum of thirty participants, all of whom must have been selected and identified to SFA prior to the tasting event.

Food safety must be ensured despite that the novel food has not yet been approved by SFA for entry into the market. A “minimum threshold of food safety” needs to be demonstrated such that the one-time consumption of such food will not be harmful. The novel food business seeking an administrative exemption must provide information on the purpose of the tasting session and a declaration of compliance with SFA’s conditions for exemption, such as certificates of analyses, acute risk assessments, and description of measures to minimise microbial and chemical contamination.

If there is an Institutional Review Board, its requirements should also be complied with.

Businesses conducted novel food tasting must ensure traceability. Tasting must also be conducted in a non-food service facility designed for sensory evaluation research and development, for example, test kitchens instead of restaurants. In addition, medical contingencies to handle unforeseen allergic reactions must be provided and SFA must be informed of any such adverse event.

Participants who wish to attend a novel food tasting session must be asked to acknowledge in writing prescribed terms for participating in the relevant novel food tasting session and a template of the form containing these prescribed terms ("**Participation Form**") must be submitted to SFA.

Prescribed terms

The Participation Form must be drafted to include certain mandatory terms:

- (a) that participation in the tasting session is voluntary;
- (b) that the participant is aware that the novel food in question has not received SFA approval and hence is also aware of the potential risks;
- (c) that the participant may withdraw at any time without penalty or reason; and
- (d) that the participant agrees to waive all liabilities that SFA may incur due to the consumption of the unapproved novel food.

To ensure that the Participation Form is properly drafted to protect both the interests of the participant and the business conducting novel food tasting, it is recommended that legal advice is obtained.

CONCLUDING NOTE

The Safety Requirements make explicit reference to the Sale of Food Act and the Wholesome Meat and Fish Act, indicating that pre-market regulatory approval of novel foods is only the first step. Commercialization of novel foods must also be carried out in compliance with all other food laws, such as food labelling and handling regulations. Businesses engaged in the area of novel foods are advised to ensure a clear understanding of these laws in addition to keeping up with the fast- moving changes in the Safety Requirements.

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