Market Access for Novel Foods in Europe

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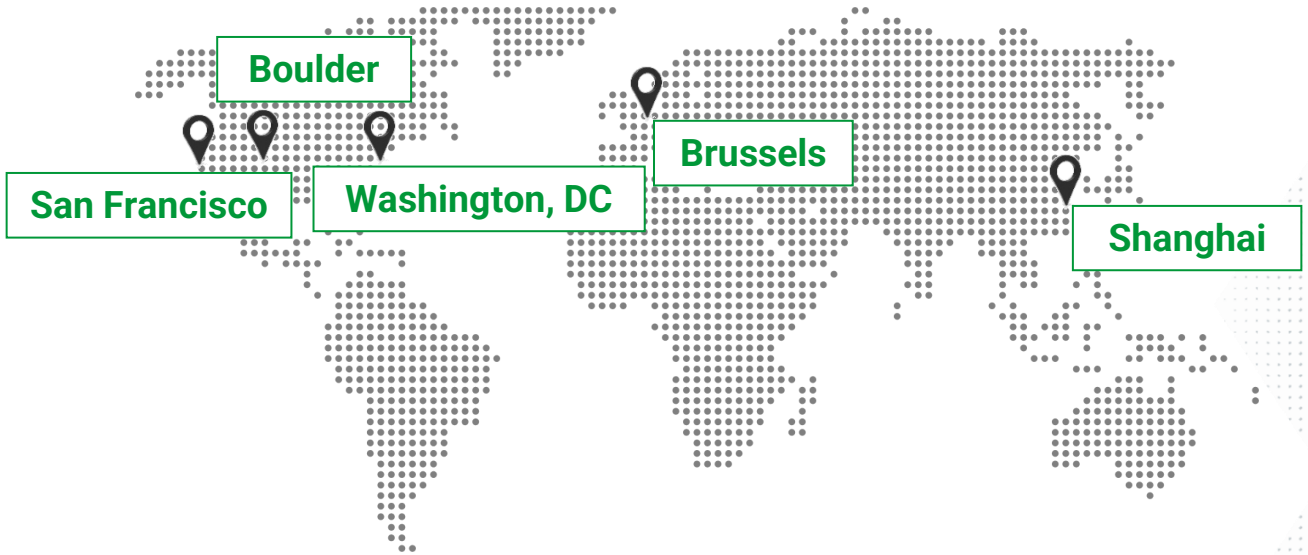
KELLER & HECKMANN'S EUROPEAN FOOD AND FEED REGULATORY PRACTICE

Leading the Practice Team: Craig Simpson

- UK qualified lawyer with over 20 years' experience in private practice and public sector advising on food and feed regulatory compliance
- Prior to Keller & Heckman, Senior Legal Officer in Food and Veterinary Unit of EFTA Surveillance Authority ("guardian of EEA Agreement")
  - ◊ infringement proceedings against EFTA States (Norway and Iceland) for non-compliance with EU food and veterinary obligations under EEA Agreement
  - ◊ advising on regulatory compliance issues in the same areas
  - ◊ understanding of how the application of EU law differs in the EFTA States compared to EU Member States
- 13 years as Of Counsel in EU life sciences practice of another international law firm (food and feed, chemicals, medical devices, biocidal products, and product safety)
- Former Member of the EFSA Management Board

A Global Law Firm with a Scientific Advantage



- Offices in US, Europe and China
- The only law firm with a specific and longstanding reputation in European food law (30 years in Brussels)
- Lawyers work alongside in-house scientists creating efficiencies from clients

The Practice – How de we assist clients?

- Counselling multinational corporations and European trade associations including:
  - regulatory status of food and feed and ingredients including pre-market authorisation procedures (novel food, food improvement agents and GM food) and relevant restrictions or prohibitions
  - product positioning and compliance with food information requirements including claims
  - interpretation of current and future EU regulatory requirements as applicable to specific client circumstances
  - advocacy strategies, including position papers
  - representing clients before national enforcement authorities in cases of product non-compliance in order to minimise sanctions, reputational damage and business interruption
  - challenging unjustified trade barriers preventing the placing on the market of food and feed products
  - advising and providing training to trade associations on regulatory and compliance

Representative Matters

- Advising third country EU Mission on challenging threatened EU safeguard measures against its imports containing prohibited food additive
- Counselling producer of plant-based dairy and meat substitutes on European food information requirements including claims
- Advising supplier of food additive with skin sensitiser properties on hazard classification and related obligations in the EU and China
- Drafting complaint to European Commission concerning EU Member State ban on sales of energy drinks to minors
- Counselling multinational beverage companies on compliance with EU Spirit Drinks Regulations
- Successfully defending food distributor against allegation of breach of EU food hygiene requirement at storage warehouse
- Advising US food supplements producer on EU pre-market authorisation, food information and ingredient requirements
- Assessing and drafting potential arguments to challenge categorisation of microbiological food cultures as food additives
- Advising Rhiza fungal mycoprotein producer concerning application for novel food authorisation in the European Union
- Representing animal feed multinational before enforcement authorities re unauthorised placing on market of feed additive

MARKET ACCESS FOR NOVEL FOODS IN EUROPE

Overview

- Which regulatory framework? Novel food or another?
- Procedures for authorisation of novel foods in the European Union
- Market access issues for alternative proteins in the European Union
- Compare and contrast: novel food authorisation in the United Kingdom post Brexit
- Conclusions

WHICH EU PRE-MARKET AUTHORISATION REGULATORY FRAMEWORK APPLIES?

Which EU Regulatory Framework ?

- Novel food or another EU regulatory framework?
  - More than one EU regulatory framework applicable?
  - Switching from wrong regulatory framework mid-way: wasted resources, significant product launch delay
- Excluded from Novel Foods Regulation (EU) 2015/2283 (under other frameworks):
  - "*containing, consisting of or produced from GMOs*" => GM Food Regulation (EC) No 1829/2003
  - Food improvement agents (additives, enzymes, flavorings) => Regulations (EC) No 1332, 1333, and 1334
- GM food additive
  - Authorisation under GM Food and Food Additive Regulations (Recital (12) Food Additives Regulation)
- Some EU pre-market authorization procedures more burdensome - e.g., GM food vs. novel food:
  - Limited 10-year authorisation period, subject to renewal
  - Labelling requirements => negatively impact EU marketability given consumer anti-GMO stance

PROCEDURE UNDER NOVEL FOODS REGULATION (EU) NO 2015/2283

Is the Product a Novel Food?

- *"Novel food"* definition (Article 3(2)) of Regulation (EU) 2015/2283?
  - Not used for human consumption to a significant degree within the European Union before 15 May 1997; AND
  - Under at least one of 10 novel food categories:
    - Novel by composition: consisting of, or produced from, micro-organisms, fungi, or cell culture; and/or
    - Novel by procedure: *" production process not used… within the Union before 15 May 1997…"*
  - Includes novel food supplements
- Food business operator ('FBO') to self-certify whether or not food is novel (Article 4(2)) – how?
  - Not necessarily self-evident – clients ask our advice regularly
  - Already authorised on EU harmonized Union (positive) List?
    - Can place on EU market without further authorization, if meets same specification, subject to data protection
  - Otherwise (indicative, but not conclusive):
    - European Commission Novel Food Catalogue (non-exhaustive)
    - EFSA novel food risk assessment Opinions
    - Published consultation request decisions (see below)

Is the Product a Novel Food?

- Consultation request procedure (Article 4(2) of Regulation (EU) 2015/2283)
- FBO may request EU Member State where first intends to market to determine if the product is novel or not
- Alternative to self-certification where novel status unclear but chance of a not novel finding
  - Some evidence of pre-1997 use
- EU Member State published decisions not always consistent or comprehensive
  - Forum shop consulted Member State to maximize chance of *"not novel"* declaration?
- Consultation not binding

Which Authorisation Procedure? : Fast Track

- Two routes:
  - *"Standard"*
  - Abbreviated, fast-track for traditional foods from third countries - full technical dossier not required
- Is product a traditional food from a third country?
  - Certain novel food categories with a *"history of safe food use in a third country"* (Article 3(2)(c))
    - 25 years in the customary diet of a significant number of people in third country(ies)
- Procedure for traditional foods from third countries (Articles 14 and 15)
  - Applicant notifies European Commission, including evidence of history of safe food use
  - Authorised by default if neither EU Member States nor EFSA submit objections within four months of receipt of notification from Commission
  - If objections received by Commission, applicant must submit substantive authorisation application addressing objections (similar to standard procedure, including EFSA risk assessment)

Standard Novel Food EU Authorisation Procedure - Overview

- Detailed EFSA guidance to follow to avoid invalid application and market access delays
- Stages:
  - Preparation of authorisation application including required safety data
    - *All* available existing scientific data (own studies, published), whether favourable or unfavourable to proving safety
    - Data gap analysis required to identify new studies required for certain end points (toxicological?)
  - Pre-submission phase:
    - Pre-notification to EFSA of studies commissioned to support application
  - Application submission and initial validity check by Commission, including EFSA
    - Substantive review begins only after validation…
  - EFSA risk assessment => EFSA Opinion (not challengeable in the courts)
  - Commission risk management authorisation decision (implementing Regulation) (challengeable)
    - Commission may rely on precautionary principle or *"other legitimate factors"* (not strictly science based)
  - Post-marketing safety monitoring conditions may be imposed by Commission (Article 24)

Preliminary Notification of Studies (Transparency Regulation)

- All studies supporting application commissioned or carried out after March 27, 2021 must be notified to EFSA prior to application submission and (where relevant) before study start date
- Same obligation for EU-based laboratories commissioned by applicants to undertake studies
- Purpose: prevent applicants withholding unfavourable studies
- Application declared invalid if does not include all, and only, the pre-notified studies, unless valid justification why not
  - Significant delay: EFSA will not (re-)commence validity assessment of any re-submitted application until 6 months after re-submission date
- Status of studies already commissioned and completed for previous authorisations in other jurisdictions?

Confidentiality

- EFSA publishes all information supporting the application (including submitted data) once application validated
- Applicant can apply for confidential treatment of limited categories of information (production process, detailed composition, etc.)
- Requirement of *"verifiable justification"* why disclosure would harm applicant's interests
- EFSA's decision whether to grant - refusal?
  - Confirmatory application (appeal) procedure
  - Ultimately challengeable before the Court of Justice

Data Protection

- Authorisations are generic => competitors may in principle rely on previous authorisation
- Initial authorisation-holder may request protection of its proprietary data supporting application to prevent competitors "*free riding*" on its investment (Article 26)
- Conditions for grant by European Commission of data protection:
  - Designation as proprietary at time of application
  - Applicant had exclusive right of reference at time of application
  - Data critical for EFSA assessment (decided in EFSA Opinion)
- Five year (non-renewable) *"quasi-exclusivity"* period during which only initial authorisation holder may place product on the market, except where:
  - Another operator obtains authorisation of same product using own (rather than authorisation holder's) data; or
  - Authorisation holder agrees to license data to another operator (letter of access)
- Published data cannot benefit from data protection (controversial)
- Statutory confirmation that publication of data by EFSA will not undermine exclusivity (Article 38 (1a)

MARKET ACCESS ISSUES FOR ALTERNATIVE PROTEINS IN EUROPE

Market access issues for alternative proteins in Europe

- Alternative proteins are significant contributor to sustainability agenda and feeding exploding population…yet considerable EU regulatory market barriers
- Ability for Europe to compete with other jurisdictions (US, China)?
- Protectionism regarding agricultural (meat, dairy) industries versus substitute products' importance for sustainability (agriculture contributes a third of GHG emissions) and food security

Alternative protein - precision fermentation

- Genetically modified microorganisms ('GMM') (microbial hosts as cell factories) produce specific proteins
  - Human-identical milk oligosaccharides produced by fermentation of GM *Escherichia coli* (Regulation (EU) 2023/948)
  - Article 3(2)(a)(ii) *"food consisting of, isolated from or produced from microorganisms, fungi or algae…"*
- The rDNA issue: GM Food Regulation (EC) NO 1829/2003 rather than Novel Food Regulation (EU) 2015/2283?
  - Recital (16) GM Food Regulation *"The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed"*
  - SCoFCAH meeting September 24, 2004: includes recombinant DNA ('rDNA') or GMM "*totally or partially, whether alive or not*"
  - GMMs normally filtered out in processing, but rDNA traces may remain
  - *De minimis* rDNA threshold: less than 10 ng/ml (2019 EFSA Statement 2019.5741)
  - Controversial legally: GMM is GM processing aid; therefore, rDNA is residue outside of GM Food Regulation
- Manifest and policy recommendations of The European Biosolutions Coalition, 21 February 2024
  - *"Absence vs. presence of recombinant DNA shall not be used as a regulatory criterion but shall be an integral part of the safety assessment required under product-specific legislation."*
- 20 March 2024 Commission Communication on EU Biomanufacturing (Com(2024)137 final) fails to address

Alternative protein - cell cultured meat

- Cells from animal (e.g., feather), fed with nutrients (amino acids, carbohydrates) and grown in a bioreactor to replicate conventional meat
  - *"Slaughter-free animal proteins"*
  - GM techniques not required
  - Much lower carbon footprint than traditional meat
- Article 3(2)(a)(vi) of EU Novel Food Regulation (EU) 2015/2283 *"food consisting of, isolated from or produced from cell culture…derived from animals…"*
- Approved in US, Australia, Korea and Singapore but…
- Still no EU novel food authorisation? Why?...

Novel food regulatory challenges

- Slow and cumbersome (under resourced) procedure
  - Period from submitting application until any Commission authorisation 2 years, plus…
  - No statutory maximum time limits for certain stages
  - Possible information requests (EFSA, Commission) => *"stop the clock"* until applicant files response
  - Food Fermentation Europe: need for revision of *"lengthy and opaque"* regulatory framework for fermentation products
    - Compare US GRAS clearance (no questions letter) of precision derived protein within average of 14.5 months, notwithstanding DNA in final product
- Arbitrary "*whether or not it was consumed in the EU before May 1997*" criterion in novel food definition, irrelevant to risk profile of post 1997 products
- Delays in application procedure caused by failure to prenotify to EFSA all studies supporting application prior to submission and (where relevant) before study start date (Transparency Regulation)
- Risk management (Standing Committee) stage of application procedure subject to political influence (EU countries currently banning cell cultured meat!)

Novel food regulatory challenges (2)

- What constitutes placing on the market of a novel food (triggering pre-market authorisation requirement)?
  - Wide definition of placing novel food on the market (Article 3(8) of Regulation (EC) No 178/2002)
    - Includes *"holding of food for the purpose of sale",* any transfer to another EU entity
  - Does a sensory evaluation/tasting panel prior to commercialisation require authorisation?
    - Limited (and differing) national guidance
  - Do novel foods produced in EU but exported for sale in third countries require authorisation?
    - *"Accidental"* placing on the market in EU prior to export?
    - Is authorisation requirement limited to placing on EU market?
- Lighter touch regime?: carve out from full authorisation where alternative protein equivalent to conventional products (extend rationale of NGT proposal and UK Precision Breeding Act)
  - Precision fermented milk (and/or oligosaccharides) equivalent/identical to human milk?
  - Cell cultured meat identical to traditional meat?

Use of Dairy Terms on Substitute Products

- Dairy denominations ("*milk*", "*butter*", "*cheese*") prohibited for non-(mammary) milk products under harmonised EU legislation (Regulation (EU) No 1308/2013), subject to limited national "*traditional use*" exemptions
  - Irrespective of use of qualifiers (for example, "*Veggie Cheese*" or "*Tofu Butter*") (Case C-422/16, *Tofutown*)
  - Aim: protecting dairy industry and consumer protection (substitute products lack same quality characteristics)
- European Parliament Amendment 171 banning dairy terms like "*creamy*" or "*buttery*" for non-dairy plant-based products withdrawn
- Contrast: US FDA draft guidance: "*consumers generally understand that [plant-based milk alternatives] do not contain milk and choose to purchase [those products] because they are not milk.*"
- Specific precision fermentation product name issues:
  - Can you claim "*obtained from cattle*" for artificial milk proteins produced by GMMs using genetic information from cattle genes?

Use of Meat Terms on Substitute Products

- EU Law definition of *"Meat"* limited to animal products (Regulations (EC) 853/2004 and 1169/2011)
- No harmonised European level prohibition of meat related terms ("*sausage*", "*burger*") on substitutes (contrast dairy)… but some national (non-EU harmonised) restrictions
- **Italian** ban (Law No. 172 of 1 December 2023) on:
  - Production and marketing of food or feed consisting of cell cultured meat [**total sale ban! proportionality**?]
    - Application of precautionary principle to protect *"human health and the interests of citizens and to preserve the agri-food [national livestock] heritage"*
    - But cultured meat health risks already addressed through EU novel food framework!
  - Designation as meat of processed products containing predominantly vegetable proteins
    - Vague scope – in addition to chicken, beef, etc., *"specific terminologies of butchers, … fisheries"*?
  - Notification of draft legislation to European Commission (2023/049/IT) later withdrawn by Italy (therefore unenforceable?)

Use of Meat Terms on Substitute Products (2)

- French ban (décret 2022-947) on meat denominations for products containing over a certain threshold of vegetable proteins (similar to Italy)
- Similar Polish draft legislation restricting meat denominations; Romanian draft law to ban cultivated meat
- Switzerland Administrative Court 2022 judgment found, contrary to national guidance, that word "*chicken*" on pea protein product did not mislead average consumer (appeal pending)
  - *Absolute* prohibition on use of animal names *in all circumstances* illegal
  - Intended use of product may refer to food of animal origin (e.g. "*use as alternative to chicken*")
- 22 January 2024 note to Council of 13 EU Member States against cultured meat ("*not… a sustainable alternative*"), https://cutt.ly/nw1vxAlc
- Contrast with substantial investment in alternative proteins in UK, Germany, Denmark and Netherlands

New CJEU caselaw concerning meat/fish terms on plant-based substitute products

- European Court of Justice judgment in Case C-438/23, 4 October 2024
  - EU Member State national law cannot restrict terms like "*sausage*", "*steak*" or "*filet*" for plant-based substitute products, except where a legal name is established for the product under EU law
  - Prominent indicator on plant-based substitute products of substitute ingredient (Point 4 of Part A of Annex VI of Regulation (EU) No 1169/2011) creates **rebuttable** presumption that consumer protected but…
  - An EU Member State national authority may find this presumption rebutted (consumer has been misled) where *"nonetheless…the actual manner in which the food is sold or promoted is misleading the consumer"*
  - Depends on the presentation of the product as a whole on a case by case basis

COMPARE AND CONTRAST: NOVEL FOOD AUTHORISATION IN THE UNITED KINGDOM

Review of UK novel food regime

- Retained EU Novel Foods Regulation (EU) 2015/2283 still law in Great Britain *(mutatis mutandis)*
  - European Commission and EFSA replaced by Secretary of State and Food Standards Agencies
- Brexit as opportunity for UK strategic divergence from EU regulatory barriers (novel foods, gene editing)
- UK Government, Pro-innovation Regulation of Technologies Review - Life Sciences, May 2023
  - *"A particular growth sector is alternative proteins…developing and manufacturing alternative proteins in the UK could create around 10,000 new factory jobs…" (page 16)*
  - Regulatory sandboxes - need for *"a well-defined relaxation of rules, to allow innovators…to experiment with new products or services under enhanced regulatory supervision without the risk of fines or liability."*
- UK HM Government Response to Review, May 2023
  - *"The alternative proteins sector is currently being held back by regulation inherited from the EU. A [new regulatory approach] will allow the UK to make rapid progress in this space..." (paragraph 28, page 11)*
- UK government creates new regulatory sandbox for cultivated meat (with £1.6 m funding) to encourage innovation; October 2024
- FSA currently reviewing 4 cultivated meat novel food applications (approval recently granted for pet food)

Review of UK novel food regime (2)

- UK FSA Novel Foods Regulatory Framework Review – independent Deloitte report 7 June 2023
  - Current FSA novel food assessment system overwhelmed with surge of CBD (cannabidiol) applications
  - Changes to system needed if it is *"to keep pace with innovation"*
  - Considers alternative models for "*tactical efficiency*" (possibly in combination)
    - Triaging: grouping applications and relevant procedure according to risk level; criteria for *"fast track"* procedure (e.g., *"alignment with net zero national objectives"* – cultured meat?)
    - Conditional authorisation with ongoing monitoring (echoes CBD transitional approach)
    - Global collaboration: *"recognising the evidence base of decisions of regulators in other jurisdictions"*
  - Replace precautionary approach with reasonable certainty of no harm (U.S.) approach
  - Recognition of importance of regularly updated guidance and early stakeholder engagement
- September 18 2024 FSA Board Meeting: public register of novel foods replacing requirement for authorisation statutory instrument (which currently adds 6 months to timeline) post Ministerial decision to be introduced in 2025
- Is that it? Or other changes in line with review?

Take home messages

- Ensure you are pursuing market access under the correct regulatory framework – could be the difference between requirement for pre-market authorisation or not (for example, flavourings)
- Identify the best strategy for assessing if your product is or is not a novel food (self-assessment, Article 4 consultation request?)
- Follow (voluminous) application submission guidance carefully to avoid unnecessary delays in authorisation timeline
- Preliminary notification of studies prior to submission of application important
- Consider at initial stage if want to apply for data protection – must state this at time of submission and have exclusive right of reference
- Many market barriers for alternative proteins inherent in EU novel food regulatory framework and in the regulation of marketing of substitute products
- Could the UK lead the way with a streamlined, more user-friendly regulatory framework?

Thank You!

Any questions?

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