NOVEL FOOD AUTHORISATION: THE STARTING PONT

Member States of the European Union are not the only jurisdiction to operate a system which seeks to manage what novel food and novel food ingredients can be made available to their citizens, but they do operate probably the most stringent system and require the most comprehensive data submissions in order to gain successful market authorization.

A core and critical difference between Member States and other jurisdictions is the location of the "starting point" for their decision-making process. Other jurisdictions, such as the USA, start from the premise that a food or ingredient is ***safe*** unless they have cause to believe otherwise, the European Commission begin with the assumption that the food or ingredient is ***unsafe*** and will maintain that position until satisfied, through the provision of independently validated scientific data, that such a position is incorrect and can be relaxed.

While it is tempting to think that these two approaches represent two sides of the same coin, such that they are not that dissimilar, that it is not the case and the manner in which they manifest themselves means that the volume of data required to achieve Market Authorisation will be significantly in excess of that which is likely to be currently in the possession of organisations which may already be marketing their product elsewhere.

NOVEL FOOD AUTHORISATION: THE PRINCIPLE

The premise behind the authorisation process is that any company who is intending to place on the market a food which falls into certain criteria, must satisfy the European Commission that the food (including the process by which it is created) is safe for consumption by the population.

Furthermore, what must be proven to be safe is not the novel food/ingredient in its ***generality*** but, amongst other things:

- that the novel food/ingredient is safe, on its own, in the ***specific manner*** in which it is delivered and in which it is intended to be consumed in the manufacturer's product;

- that the novel food/ingredient is safe, on its own, in the ***specific quantity/volume/ strength*** in which it is delivered and in which it is intended to be consumed in the manufacturer's product; and,

- that the novel food/ingredient is safe, in the context of the ***delivery mechanism*** in which it is intended to be consumed, i.e. the manufacturer's product.

NOVEL FOOD AUTHORISATION: THE PRACTICAL EFFECT

It is therefore necessary to submit scientific data in respect of all aspects of:

- the ingredient "simpliciter" (our phrase) and the process through which it was created;
- the ingredient in the context of the product and the process through which it was created; and,
- the ingredient in the general food environment/consumption context.

Anecdotal "evidence" and contentions that there have been no reported issues raised in other jurisdictions will not necessarily rate highly in the context of the scientific decision concerning the Authorisation application. The decision is based on safety as established through scientific study and evidence, and the data submitted must establish the case in its own merits.

NOVEL FOOD APPLICATIONS: THE SEQUENCE

This sequence describes the current position where an applicant seeks to market their product in any European jurisdiction, including the United Kingdom. Brexit will have an impact upon the application procedure, which is highlighted below, but which cannot presently be incorporated within the sequence because the UK Food Standards Agency has not yet indicated the substance of the procedure that it will invoke from 1st January 2021..

STAGE 1: Confirming the Application and Requesting Information

(a) The Applicant submits their Novel Food Authorisation Dossier to the European Commission.

(b) The Commission send any requests for information to the Applicant as may be necessary for the Commission to address the Validity of the application.

(c) The Applicant provides such information as is requested to the Commission, in order that a decision may be made upon the Validity of the application.

STAGE 2: EU Commission Provides the Application to Member States and EFSA

(a) The Commission seeks to verify whether the application falls within the scope of the Novel Food Regulations and whether the requirements set out in Article 10(2) and 10(4)(if applicable) of that Regulation (by reference to the associated Guidance) are met, by:

(i) Making the application available to the Member States; and,

(ii) Consulting with the European Food Safety Authority (EFSA) and seeking its opinion as to whether an update to the Union List (of Novel Foods) is liable to have an effect on human health.

STAGE 3: EFSA Provides its Views on the Suitability/Validity to the Commission, or Requests further information from the Applicant

(a) EFSA, within a period of 30 working days following the receipt of the consultation request (and full supporting documentation, whichever is the latter), provides the Commission with its views on whether the application fulfils the relevant requirements set out in Article 10(2) and 10(4)(if applicable) of the Regulation; or,

(b) EFSA requests such further information as it desires in order for it to make its assessment of the suitability and Validity of the application.

(c) Upon (a) above being satisfied, whether on the first occasion (or subsequent occasions), EFSA confirm that the application is suitable and Valid.

STAGE 4: Risk Assessment Performed by EFSA, or EFSA requests further information from the Applicant concerning the Risk Assessment being Undertaken

(a) EFSA, ***within 9 months*** from the date of the receipt of the Valid application (and full supporting documentation, whichever is the latter), performs the risk assessment and provides its opinion; or,

(b) EFSA requests such further information as it desires in order for it to make its Risk Assessment on the application.

(d) Upon (a) above being satisfied, whether on the first occasion (or subsequent occasions), EFSA informs the Commission of its opinion as to whether the Union List should, or should not, be updated to include the food which is the subject of the application.

STAGE 5: Risk Management

(a) From the date of publication of EFSA's opinion, the EU Commission then has ***7 months*** to draft an implementing act authorizing the placing on the market within the European Union of a novel food and updating the Union List accordingly.

TO WHOM ARE NOVEL FOOD SUBMISSIONS MADE?

The Novel Food (Amendment) (EU Exit) Regulations 2019 (SI 2019/702) indicate that submissions should be made to the Food Standards Agency (as regards England, Wales and Northern Ireland) and Food Standards Scotland (as regards Scotland). These Regulations state that they come into force on "Exit Day".

The European Union (Withdrawal Agreement) Act 2018 defined "Exit Day" as 31/1/20, however, the similarly named Act of 2020 introduced the concept of the "Implementation Period", which saves EU authority until the "Implementation Period completion day". The "IP completion day" is 31st December 2020.

Thus, *presently* (and at least until 31/12/20), Novel Food submissions can only be made to the EU Commission. After that date submissions will need to be made to the UK FSA for products intended for sale in England, Wales and Northern Ireland, to Food Standards Scotland for products intended for sale in Scotland and to the EU Commission for products intended for sale in the European Union.

We say *presently* because it may be that the date from which the FSA will adopt responsibility will move backwards depending upon the progress of the politico-economic Brexit negotiations.

THE IMPACT OF THE FSA ANNOUNCEMENT AND CHANGE IN RESPONSIBILITY/LIABILITY FOR RECEIPT AND ASSESSMENT OF NOVEL FOOD APPLICATIONS

As currently defined, in order to benefit from the UK FSA exemption (which is applicable only to the UK), any application must be "Validated" by 31/3/21 (i.e. ***reach Stage 3(c)*** as identified above).

The UK FSA is currently inviting organisations who make submissions to the EU Commission to provide a copy to the FSA:

> "*In addition to submitting them to the European Commission as usual, we strongly recommend businesses also send them to us to allow us to consider them. We can then give businesses guidance and answer any queries we may have, in order to ensure they progress at pace through our UK authorisation process from 1 January 2021.*"

Any submission made before 31/12/20 has to be a submission to the EU Commission, who will have responsibility for the validation assessment. However, when applications are made to the EU Commission, as they will have to be until that date, then the UK FSA cannot control the timing of when applications will be declared "Valid" and the applicant is at the mercy of the EU Commission's timing.

This gives rise to key questions: What will happen if the EU Commission fails to validate a pre-31/12/20 application by the 31/3/21 in circumstances where the submission was made to them sufficiently in advance of 31/3/21 to afford them reasonable opportunity in which to validate it?

a. Will the UK FSA extend the period further for such applications, until a point defined by the date of the validity decision?

b. Will the UK FSA "passport" the application to the UK and accept responsibility for the validation, as far as the UK is concerned?

c. Will a new, and parallel, application ***have*** to be made to the UK FSA?

For applications made after 31/12/20 then the UK FSA is responsible for the validation process, and the duration of that process. If the UK FSA is unable to make the validity assessment by 31/3/21, will it extend the validation period (which would also be the exemption period) until a point defined by the date of the validity decision?

In a post-Brexit environment, we believe that it is likely to be politically unacceptable for "UK Businesses" to be prejudiced by the conduct of a European body who, by then, would hold no power or responsibility over the "UK Business". Therefore, we believe that it is likely that, in the circumstances described (i.e. where the submission was made sufficiently in advance of 31/3/21 to afford the EU Commission reasonable opportunity in which to validate it), then 31/3/21 deadline will be extended to the date of the Commission's validity decision for that individual application.

Equally, we do not necessarily believe that the UK FSA will, by 1/1/21, have the systems and/or resources in place to assess the validity of applications (which by definition could only have been submitted to them on or after 1/1/21), by 31/3/21. Therefore, for equally politically expedient reasons, we believe that the deadline is likely to be extended for those who submit their applications to the UK FSA by a date (in advance of 31/3/21) which afforded the UK FSA sufficient time to conduct the validation process on the application.

Example 1: Application to the EU Commission

a. An application is lodged with the EU Commission on 1/12/20. If the Commission assess the validity of the application prior to 31/3/21, then there is no issue and the application will either be:

    (i) validated, in which case (and subject to passporting provisions), it can continue to be marketed (in the UK) after 31/3/21 and during its risk assessment period; or,

    (ii) rejected as invalid through failing to meet the necessary criteria.

b. However, if the Commission does not assess the validity of the application prior to 31/3/21, then by expiration of the exemption period (31/3/21), the application has not been validated because it has not yet been assessed by the Commission for validation purposes.

c. Under the UK FSA's presently announced structure, the application has not been validated by the end of the exemption period and the applicant is therefore unable to continue to market the product (either in the UK or European Member States), after 31/3/21, which it would be able to do if the application had been validated and had progressed into the risk assessment period.

Example 2: Application to the UK FSA

a. An application is lodged with the UK FSA on 1/1/21. If the UK FSA assess the validity of the application prior to 31/3/21, then there is no issue and the application will either be:

    (i) validated, in which case it can continue to be marketed (in the UK) after 31/3/21 and during its risk assessment period; or,

    (ii) rejected as invalid through failing to meet the necessary criteria.

b. However, if the UK FSA does not assess the validity of the application prior to 31/3/21, then by 31/3/21 the application has not been validated because it has not yet been assessed by the UK FSA for validation purposes.

c. Under the UK FSA's presently announced structure, the application has not been validated by the end of the exemption period and the applicant is therefore unable to continue to market the product after 31/3/21, which it would be able to do if the application had been validated and had progressed into the safety assessment period.

HOW LONG DOES THE VALIDATION PROCESS TAKE?

What can be seen from the process Stages identified above is that the applicant can be asked to provide additional data during the Validation Stage, and so in some senses the maximum period is uncertain and case-specific.

Perhaps what is most relevant in the current circumstances is what is the shortest duration over which the Validation Stage can take place, because at present this would inform potential applicants as to the date by which they must submit their application in order for it to be Validated by 31st March 2021?

We are aware of an application that was submitted to the EU Commission via its Novel Food Application Portal (as all applications must be until 31/12/20), in December 2019 which has still not even been acknowledged as having been received by the Commission. By this we do not mean that it has not yet been Validated (i.e. either progressing to the Risk Assessment Stage or rejected as being invalid), but that its receipt has not even been acknowledged, some 3 months after it was provided to the Commission.

If that is a timescale typical of applications, and we believe that it is, then one can immediately see the implications for when applications must be submitted in order to have any chance of being Validated within the timeframe necessary in order to continue to benefit from the exemption being offered by the UK FSA.

THE BIG QUESTION: WHEN SHOULD AN APPLICATION BE MADE AND WHY?

As indicated, we believe that there will come a point at which the UK FSA will announce a "submitted for validation by" date as its new de-facto deadline, and in addition to which there will need to be "passporting provisions".

Without these two measures, the UK FSA is compelling market participants to make applications to itself, over which it will hold no *vires* (authority/power) until 1st January 2021 and, as presently resourced, we do not believe that it will have the necessary capability to validate the glut of applications between that date and 31st March 2021, a period of only 64 working days.

Therefore, we believe that the introduction of a "submitted by" date will:

(a) provide greater certainty than present for market participants/potential applicants;

(b) ensure that the UK FSA, even if swamped with applications in January 2021 (most of which we expect to be doomed to failure), will have a "release valve" for those in respect of which it is unable to conduct the validity assessment by 31st March 2021.

Such a date will also have the added advantage of "weeding out" all of those companies who are listening to unprofessional and/or inexperienced advisors, or self-interested medical or supplement trade groups, and being led to believe that 31st March 2021 is the date which they must submit "something" (however perfunctory), rather than a backstop date by which ***all*** of the necessary data must have been provided in order for it to be assessed and a validity decision made.

It cannot be guaranteed that any such announcement will be made, when or if it will be made or what the de-facto "submitted for validation by" date might be. Time is of the essence in terms of submitting an application with competent and adequate data in order to be afforded the UK marketing exemption.

We repeat what is necessarily becoming our well-worn phrase: ***Be Careful Who You Listen To***.