

NUTRITION REGULATION

Inside the EU Novel Foods Revision Debate

The recent changes to the regulation have aroused concern among stakeholders on various issues.

by Liza Van Den Eede

In April 2016, over 80 representatives from the food industry, EU Member States, research institutions, non-governmental organizations and the European Commission (EC) attended a briefing by the European Food Safety Authority (EFSA) on draft guidance documents developed following the

adoption of the new novel food Regulation (EU) 2015/2283 in November 2015. The idea behind the new regulation was to make it easier to bring new and innovative foods to the EU market. Although the changes have been designed to reduce the burden of registering novel foods, they have aroused con-

cern among stakeholders on issues such as confidentiality, holder specific authorizations and transitional measures.

The Main Changes

From January 1 2018, two different procedures may be used to submit a novel food product for approval in the European Union, depending on which category the product falls under:

- The authorization procedure for novel foods.
- The authorization procedure for traditional foods from a third country.

The initial definition of a novel food is: "any food which was not consumed in the EU to a significant degree before May 15, 1997." Therefore, novel foods can be newly developed or innovative food produced using new manufacturing processes, or food traditionally eaten outside of the EU, but not commonly consumed in the EU before 1997. "Traditional food from a third country" is a food derived from primary production with at least 25 years history of safe use in a third country. It can be processed or unprocessed food consisting of, isolated from, or produced from:

- Plants/animals or their parts.
- Micro-organisms, fungi or algae.
- Cell or tissue culture derived from the above.

Examples of already authorized novel foods which could have followed this application process are noni fruit juice, chia seeds or baobab dried fruit pulp. With the new processes,

all applications will be submitted directly to the EC instead of to individual Member States, which until now were responsible for carrying out the initial safety assessments. From 2018, EFSA will conduct a scientific risk assessment for novel food applications where necessary.

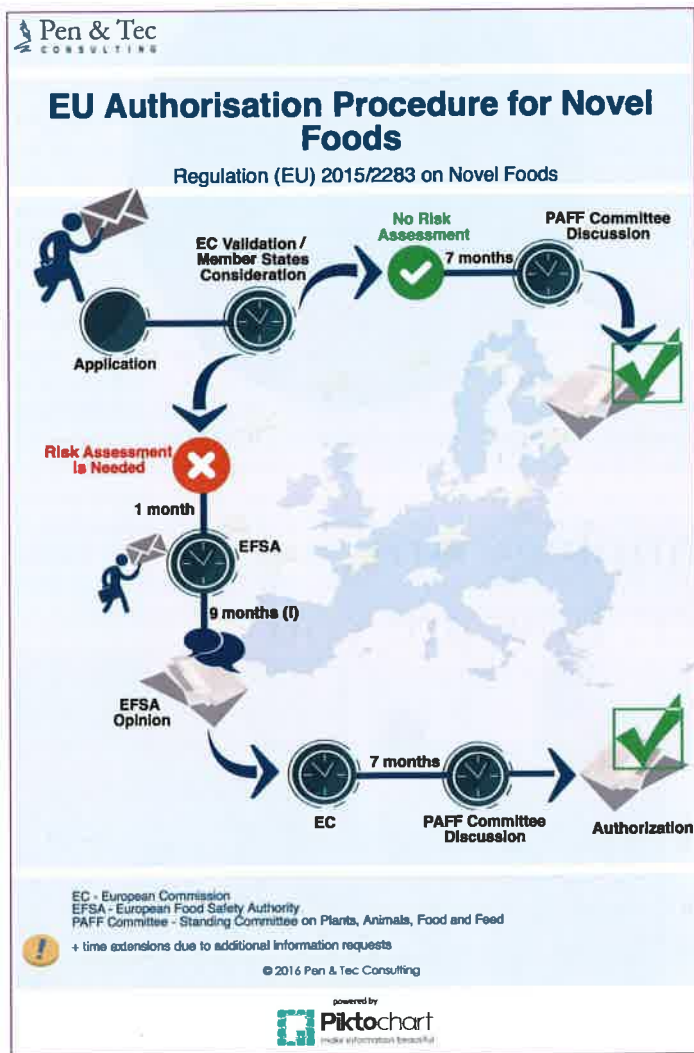
All authorizations will be generic rather than holder-specific, and once approved, will be included in the novel food Union List. Applicants may request five years of data protection in cases where proprietary data is submitted. This is only granted to novel food applications and not to notifications of novel traditional foods from third countries, who can only protect confidential information such as the manufacturing process.

Draft Guidance Documents

Under the new regulation, a novel food can be classified into one of ten different categories. Depending on the category, relevant information should be provided to the authorities to prove that the food is safe. The draft EFSA guidance document, which was shared with the industry in February 2016, does not currently offer much detail and mainly covers general data requirements with a few specific recommendations.

In theory, this could provide the applicant with much improved flexibility, provided any alternative approach is thoroughly described and supported by strong arguments. Even though the EFSA Panel on Dietetic Products, Nutrition and Allergies gave assurances that each food would be assessed on a case-by-case basis, inexperienced applicants could fall into "clock-stop" traps, if they choose an ineffective strategy or omit information thought crucial by EFSA in their safety evaluation.

Botanicals and their extracts raised the most concern during the discussion with EFSA and stakeholders. EFSA noted that more clarity would be needed in this area and gave assurances that this would be better described in the final guidance,



which should be published in summer/autumn 2016. Stakeholders also heavily questioned EFSA's proposed method of estimating anticipated dietary intake as being too similar to that used for food additives. EFSA claimed that the guidance offers flexibility, but advised that intake estimates would always need to be assessed in a conservative manner and that background exposure should always be taken into account, regardless of the method used.

What to Expect

Timelines and deadlines are clearly set out at each stage of the evaluation process, which should result in a more predictable and hopefully faster

approval process. Additionally, authorization procedures and corresponding timelines are different for novel food applications and notifications of traditional foods from third countries. The EC hopes to reduce the approval process for novel food applications from 3.5 years (which is currently the average approval period) to around 1.5 years for novel foods. However, stakeholders believe that it will still take 2-3 years to access the European market due to supplementary information requests and other regulatory hurdles. The best-case scenario for the approval time of novel traditional foods from third countries is expected to be 8-14 months.

Pitfalls Under Evaluation

Applicants whose dossiers are currently being evaluated by Member States or EFSA and obtain an approval before January 2018 are at a disadvantage. They will not be able to profit from a holder-specific authorization, as their authorization will shortly be transformed into a generic authorization when all approved novel foods are added to the Union List. Furthermore, they cannot apply for a five-year data protection period, since the approval will have been granted under the old regulation (EU) No 258/97, unless the European Commission introduces certain transitional measures. Meanwhile, applicants whose evaluation process is still ongoing in January 2018 will be able to apply for a five-year data protection period. Even though the regulation will only be applicable from January 1, 2018, food business operators need to be aware of the crucial changes which the regulation brings.

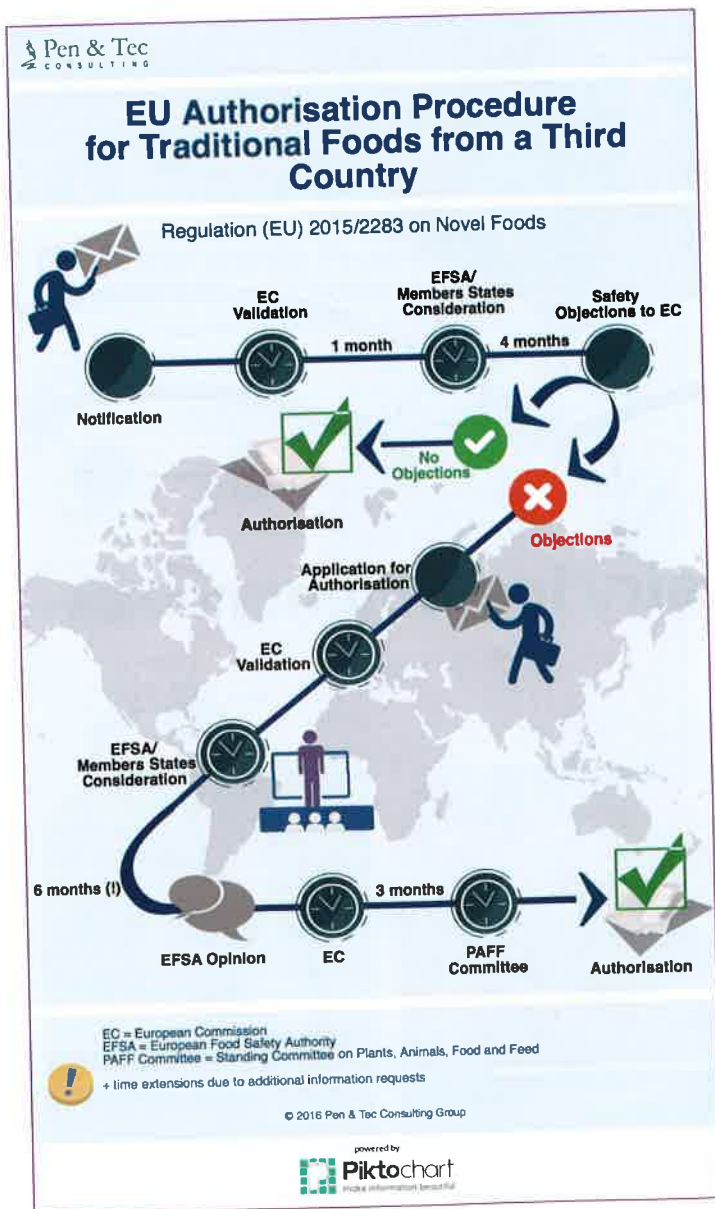
How to Take Advantage

The authorization procedure will vary according to the type of novel food seeking approval. This process is dynamic and the underlying dossier must be prepared carefully to ensure that scientific progress and new regulatory requirements are respected in order to avoid unnecessary and costly delays in the evaluation process. Crucial steps include:

- Drafting a proper and accurate application dossier.
- Opening a dialogue with the authorities and monitoring progress as the application is evaluated.
- Handling "additional information requests" promptly and professionally.

It is essential to decide on a realistic strategy to gain authorization under the new rules. Consultancy firms such as Pen & Tec can help with this. ▼

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› **Brexit: Potential Regulatory Impact**

The Pen & Tec Consulting group has been tracking the legal and political situation in the UK and EU since the unexpected and disappointing Brexit referendum outcome. It may be too early to comment - indeed we hope that the UK will not implement Brexit, since the referendum result itself is not legally binding, and the UK government is yet to invoke Article 50.

This is a complex issue, and it is clear that the UK do not have a Brexit plan in place. The current government is undergoing a leadership contest, the opposition are in turmoil and the 48% of the British population that voted to "remain" are contesting the outcome. There is a serious political vacuum, and whether or not the UK implement Brexit still remains to be seen.

Whatever the outcome, the UK will want to trade with the EU, and this is a good reason to suppose that UK legislation post-Brexit will mirror EU legislation. Secondly, in the event of Brexit, the UK government legal system will be tied up for years to come, preparing new arrangements with the EU and reforming the parts of the legislation pertaining to EU membership (or non-membership, in the case of Brexit). UK legislators can either copy-paste EU legislation, or use this opportunity to criticize each law and assess its value. The latter may be the most desirable option but it is also a time-consuming and expensive process. Pen & Tec Consulting therefore believes that UK food chain legislation will overall remain unchanged, and will continue to reflect EU legislation. ▼