

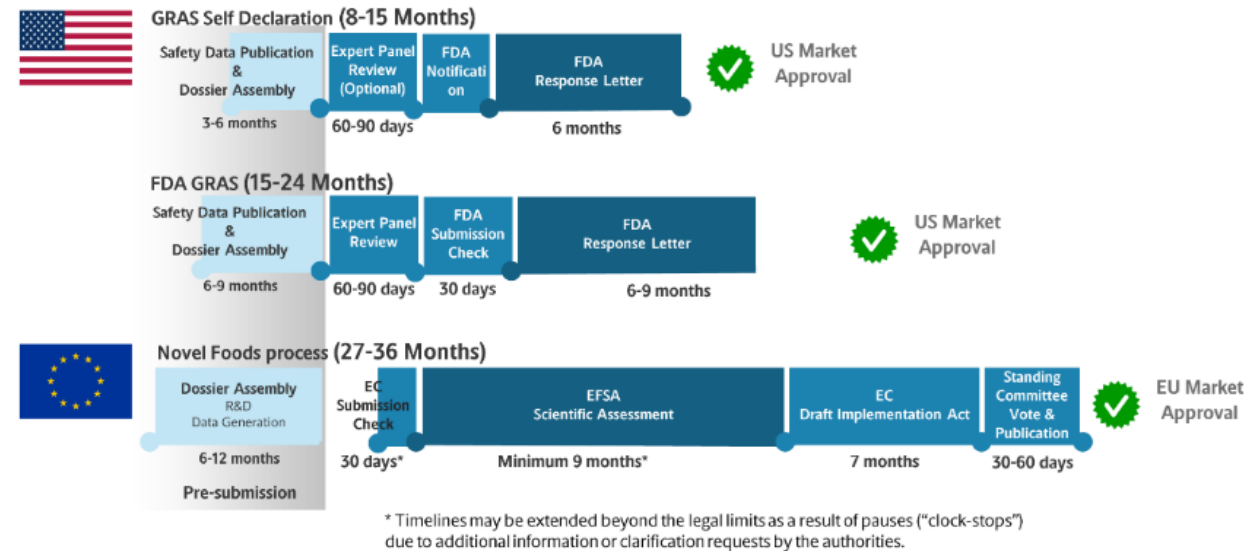
Accelerating Regulatory Success for Novel Food Startups in Europe

BioPath

BioPath – a digital regulatory support platform

Why BioPath is needed

- The green transition towards more sustainable, healthier food systems is a key EU challenge; – Novel Food is part of the solution.
- Complex EU regulation and limited regulatory capacity among innovators lead to delays, clock-stop procedures, and increases the risk of losing talent, innovation and market prioritisation outside the EU.



BioPath is proposed as a digital regulatory support platform that accelerates EU market readiness for Novel Food through better dossier preparation.

BioPath is explicitly designed to intervene upstream of submission, where intervention is most cost-effective and impactful. By supporting innovators during research planning, pilot production, and pre-submission phases, BioPath enables.....

- Determination of whether the product is categorized as a Novel Food in the EU regulatory system and thus must fulfil the requirements specified in Regulation (EU) 2015/2283
- Early identification of the applicable novel food category
- Strategic guidance on required data packages aligned to EFSA expectations
- Improved coherence between product description, production process, specifications, and safety data
- Reduced need for post-submission clarification and additional data requests – and thus a faster and more efficient risk assessment and approval procedure

First step – develop and submit the application

- Deadline for submission - July 10th 2026.
- We must demonstrate the relevance for this kind of regulatory support and thus a real need for the envisioned platform
- What is your view on the need – seen from your MS perspective?
- How do you see this project – platform? Would it be helpful for food innovators?
- Would you/your MS support the application by being listed as "supportive MS" ?
 - no obligations attached to support - only a desire to demonstrate relevance.