

From uncertainty to action: practical steps to navigate EU Novel Food approval



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Moving from awareness to action, this guidance helps you make early, informed decisions on whether and how to enter the EU Novel Food pathway.

Start by confirming if your product is actually a novel food.

- Check if it falls under exemptions or existing legislation
- Search the Union List to see if it is already authorised
- Collect evidence of pre-1997 consumption if applicable
- Use tools like the Novel Food Catalogue and Article 4 consultations with Member State competent authorities (Reg. (EU) 2018/456).

If your product is likely a novel food, plan your strategy early.

- Prepare a strong dossier from the start, taking into account both safety and labelling requirements, to avoid delays
- Anticipate high costs for data, safety studies, and regulatory support
- Factor in long timelines and possible requests for additional data

Reduce risks through smart business choices.

- Protect your data and consider applying for data protection
- Explore partnerships to share costs and expertise
- Learn from similar applications and engage early with authorities

Key takeaway: do not treat regulation as a final step.

Use it as a strategic filter early on to decide whether to proceed, adapt your product, or choose a faster market route.