

EU Novel Food dossiers

Schuttelaar & Partners, The Netherlands

Contact person: Marjolein van der Spiegel (e-mail: mvanderspiegel@schuttelaar.nl)

Schuttelaar & Partners is an advisory agency for a healthy and sustainable world. One of our activities is our support to innovative companies to compile and submit EU novel food dossiers to prove the safety of these products and to bring more innovative and sustainable products on the market. We can offer the following activities:

Preparation and submission of EU novel food dossiers

We support innovative companies (from start-ups to multinationals) to prepare and submit novel food dossiers with all required information to show that the new product or ingredient is safe.

For this, we carry out the following studies:

- Gap analysis
- Coordination of laboratory analyses
- Literature review according to the EFSA methodology
- Intake assessments
- Discussions with authorities, laboratories, scientists

With this information we prepare the novel food dossier and submit it, together with all related documents, to the European Commission (EC) for a risk assessment by the European Food Safety Authority (EFSA).

We also help companies that want to compile their novel food dossier themselves with a second opinion, general feedback, but also with support or coaching.

Information request by EC and EFSA

After submitting the novel food dossier, more information can be requested by EC or EFSA. We assist in the follow-up process to answer these questions.

Strategy and costs estimation

In addition to preparing, submitting and the follow-up process, we support companies to provide an overview of the process to submit a novel food dossier:

- Is our product novel?
- When is our product not novel?
- Which procedure for a novel food dossier should I follow?
- What is the best moment to submit my application?

- How much will this cost?
- When would I be able to bring my product on the market?
- What information is needed for my dossier?

Expertise

We have broad experience in compiling novel food dossiers for both vegetable and animal novel foods under the new Novel Food Regulation (EU) No. 2015/2283.

Our Food Compliance team consists of experts in the field of food technology, food safety, toxicology, laboratory analyses, nutrition and health, intake assessments, food quality management, and novel food legislation.

Using this broad expertise, we can demonstrate the safety and nutritional value of novel foods according to the guidelines, case-by-case and in cooperation with the customer. In addition, we are aware of the latest developments regarding legislation.

Budget

Depending on the information that has already been collected, the expertise within the company and the activities you want us to execute, we can send you a tailored proposal. The range of a typical budget for supporting an EU novel food dossier lies between € 50,000 - € 90,000 excl. VAT. This budget is only for the work done by Schuttelaar & Partners, so excluding the costs for laboratory analyses.

For more information, please contact Marjolein van der Spiegel (e-mail: mvanderspiegel@schuttelaar.nl).