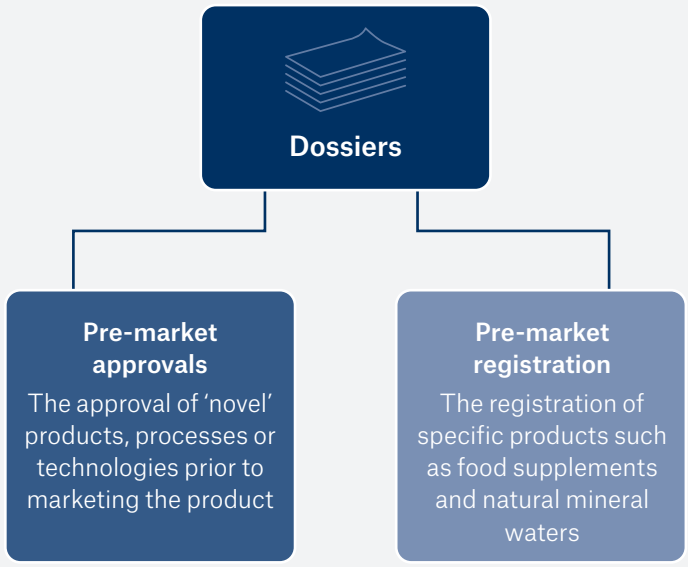
Dossier service

Qualification, preparation and submission of pre-market approvals and registrations

The rapid evolution of consumer demand and technological capability are driving innovation at a pace that is stretching the limits of regulation. Across markets worldwide, an increasing number of products are requiring formal approval as 'novel' products, processes or technologies. Leatherhead's dossier services provide an end-to-end solution, guiding clients throughout the process. Our services encompass qualification, preparation and submission of dossiers for human and pet foods. We also work closely with the regulatory authorities post submission, handling questions on our clients' behalf.



leatherhead food research

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How our pre-market dossier service works

Leatherhead's food and pet food dossier projects are split into six go/no-go stages to provide clarity on progress and to put you in control of your investment.

Stage 1	Stage 2	Stage 3	Stage 4**	Stage 5	Stage 6
Dossier qualification*	Full data review & gap analysis	Roadmap & design of experiments (DoE) for additional data	Data collation & monitoring	Dossier compilation	Dossier submission & stewardship

* Includes collation of evidence from literature for health claims dossiers

** Optional for the pre-market approval dossier service. Leatherhead may act as the Study Monitor for pre-clinical and clinical trials, review and advise on study protocols and resulting data. Leatherhead does not contract for, attend or participate in trials.

How Leatherhead can help

Leatherhead Food Research can help with pre-market approvals of your new ingredient, food additive, enzyme, flavouring or health claim, as well as registration of specific products:

- Our dossier qualification stage enables us to provide a realistic estimate of the resources required to submit your application prior to further investment
- Let us do the hard work. We can prepare and submit EU/UK pre-market approval dossiers, US GRAS dossiers and pre-market registration dossiers on your behalf
- Our experienced team includes ex-regulators with first-hand experience of navigating approvals, plus toxicologists who can advise on and monitor relevant safety studies

Contact our team to discuss your dossier requirements. Remember, if you are a full Leatherhead Member (Bronze or above) you can benefit from project discounts.

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