

REGULATORY AND STRATEGIC CONSULTING FOR HUMAN
NUTRITION AND ANIMAL HEALTH



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REGULATORY CONSULTING FIRM WITH EXPERIENCE ACROSS GLOBAL MARKETS

Pen & Tec is a specialist consultancy with over 15 years' experience advising companies on the regulatory requirements for the food and animal feed industry in Europe.

Pen & Tec was founded in 2000 by Dr Elinor McCartney to meet the needs of companies faced with the growing complexity of food chain legislation and increasingly stringent requirements for regulatory submissions in the EU.

Since incorporation, Pen & Tec has established a history of success in guiding clients through their regulatory affairs challenges for products including food and feed additives, novel foods and nutrition and health claims.

We are based in Barcelona, Spain and have expanded our global reach by increasing our network of associates, allowing us to offer regulatory services for food and feed products in other leading global markets such as the USA, China, Brazil, India.

Dr Elinor McCartney has over 30 years' experience in product development and EU regulatory affairs of the food chain. Elinor is a graduate of the Royal (Dick) School of Veterinary Studies, University of Edinburgh, where she also obtained a PhD in enteric diseases of piglets. She has an MBA (with distinction) and has tutored Finance and Marketing for the Open University Business School.

Elinor mainly provides strategic advice to clients on legal status and best regulatory options to accelerate time to market and enable key business decisions. Elinor's in-depth knowledge of the legal requirements and working procedures of regulators at both national and EU level enables her to give expert advice and tactical options to reduce unnecessary delays in the registration process.



Dr Elinor McCartney

*EU Food Chain Legislation Expert
President of Pen & Tec Consulting*



OUR TEAM

We know that having the right people managing our clients' projects is the key to our continued success. We also know that it takes a team effort to provide the exceptional service our clients expect and deserve, which is why we pride ourselves on our long-standing client relationships.

Our multi-disciplinary team have extensive backgrounds and many years of experience working with EU food chain legislation, specialising in registrations for food and feed additives, enzymes, probiotics and novel foods. With a proven track record for successfully gaining approval for multiple food and feed products, we are ideally equipped to offer you a full regulatory affairs support service.

We offer advice and support at all levels and stages of registration projects, from initial planning and budgeting, through to full project management and dossier submission. We work with in-house regulatory teams to define the optimum regulatory strategies, and help deliver selected solutions within agreed time-frames.

We can deliver training targeted to your needs, and expert assistance when in-house resources are stretched. We tackle small and big tasks, so that your team can operate at maximum efficiency to meet key objectives. We specialise in helping to rescue dossiers in trouble with regulators.

STRATEGIC ADVICE TO ENSURE FASTER MARKET ACCESS

Our solutions are based on the most accurate and up-to-date information available, ensuring that our clients get the best outcome possible.

Pen & Tec provides strategic advice to senior managers to inform and enable key business decisions.

We can rapidly assess projects and commercial objectives, helping to outline available registration options and estimate the probability of meeting both regulatory and commercial targets, together with associated costs and timelines.

Our expert support of projects from inception through to approval cuts time to market and ensures rapid return on investment.

A COMMERCIAL APPROACH TO REGULATORY AFFAIRS

▪ STRATEGIC ADVICE

Handled correctly, the time it takes to bring a new product to market can be significantly reduced. We offer strategic advice on the fastest and most cost-effective registration pathways, enabling senior managers to make key business decisions and achieve a faster recuperation of investment.

We also offer advice on broadening product usage or prolonging the lifetime of authorised products.

▪ MANAGING THE APPROVAL PROCESS

Registering a food or feed product can be a time consuming and challenging task. Managed in the right way, product registration can be achieved without setbacks.

Our regulatory specialists can take overall project responsibility from initial stages of product development through to regulatory approval, ensuring a smooth evaluation process. Alternatively, we can support internal departments when time and resources are limited, so that your team can operate at maximum efficiency and meet corporate objectives and deadlines.

We can also advise on application dossiers that have run into difficulty, helping them get back on track to successful approval.

We help companies accelerate return on investment by bringing new products to market as quickly as possible



FROM R&D TO PRODUCT APPROVAL

We help scientists bridge the gaps between research, product development, and legal requirements for product authorisation and market access.

If your remit is innovative research, we can help you determine the key data that need to be generated for successful product approvals. We can help you to produce compliant study designs, protocols and reporting templates that will meet registration requirements, and so speed up evaluation and approval by regulators.

BENEFITS OF CHOOSING THE RIGHT REGULATORY ROUTE

Selecting the best route to approval in the shortest time possible allows the most efficient use of research resources. Whether you are involved in in-house research or your team supplies contract research, it is essential to design studies that will achieve maximum success, meeting both product performance and regulatory objectives.

We offer guidance on how to design studies and prepare a technical applications to achieve successful regulatory approval. We can help you during the initial stages of a project when developing a new product, and give advice on selecting suitable feed or food additive candidates, highlighting potential project killers at an early stage (e.g. unacceptable antibiotic resistance in candidate probiotic strains).

We can help you identify the key data necessary for the registration of innovative products, and advise on the impact of data requirements when registering a product that is a genetically modified microorganism (GMM), qualified presumption of safety (QPS), highly purified or with many identified impurities.

REDUCING UNNECESSARY DELAYS

We have been advising clients on regulatory affairs for over 15 years, working in close contact with the European Food Safety Authority (EFSA) since its creation in 2002. Our in-depth knowledge of EFSA requirements and working procedures enable us to provide expert advice and tactical options to reduce unnecessary delays in the evaluation and approval process.

For best results, we work with clients during the early stages of product development to identify the correct legal status and fastest route to market. We can also act as project managers to help avoid errors that slow down time to market.

We help to bridge the gap between R&D, marketing and regulatory to achieve approval



REGULATORY AFFAIRS EXPERTS

PROFESSIONAL ADVICE WHEN YOU NEED IT

Our creative approaches can save significant time in regulatory projects, and offer fast-track alternative routes to market, where these are available. Alternatively, our team can also advise on options for broadening the usage of a product or manage renewals as existing approvals expire. We are experienced in providing key advice on labelling and claims, allowing clients to exploit marketing opportunities within legal boundaries.

WORKING WITH INTERNAL REGULATORY TEAMS

We work with clients to define optimum regulatory strategies, and help deliver selected solutions within agreed time frames. Our managers are equipped to support client regulatory teams when time and internal resources are in short supply. We can review scientific and regulatory documents before submission to relevant authorities, identify gaps and anticipate potential pitfalls. We can also deliver training targeted to individual needs and expert advice at any stage of your project.

STRATEGIC ADVICE

We help bridge the gap between commercial and regulatory departments so that senior managers can meet business objectives. We not only provide advice on data required to build a technical dossier, but can also help you justify which data could be omitted, or provide tactical options to reduce delays in the registration process.



Tailored support and advice, from assistance when internal resources are stretched, to full project management

SERVICES

Our experts offer strategic advice on the optimum route to market by evaluating existing data, focusing on the legal requirements and guiding you through the regulatory procedures. Helping your product reach its commercial potential is at the heart of what we do.

1. STRATEGIC ADVICE FOR FASTER MARKET ACCESS

- Analysis of market entry options
- Rescue of “problem” dossiers

2. DATA ASSESSMENT, COST & TIMELINES

- Identification of legal status
- Evaluation of existing data
- Construction of regulatory plans
- Cost analysis, budget estimates
- Estimated time to market

3. REGULATORY AND PROCEDURAL GUIDANCE

- Life cycle management of projects
- Design and organisation of studies
- Best practices for conducting studies
- Dossier preparation and post-submission support

4. GENERAL REGULATORY CONSULTING

- Monitoring EU legislation and changes
- Communication, mediating with EU authorities and Member States
- Literature searches
- Statistical analysis & meta-analysis
- Training and in-house workshops
- Conference presentations

5. BUSINESS DEVELOPMENT

- Regulatory feasibility studies
- Market entry strategy
- Local office set-up
- Partner/investor research
- International public relations
- Trade missions/in-country market visit
- Trade show support
- Bridging cultural gaps
- Representation services
- Distributor research

A close-up photograph of a hand moving a red chess king piece on a chessboard. The hand is positioned at the top of the frame, with fingers gripping the top of the piece. The chessboard is in the foreground, with other pieces visible in the background, some of which are out of focus. The lighting is soft, highlighting the texture of the wood and the skin of the hand.

We help companies take food and feed products to market quicker by overcoming legal obstacles and optimising return on investment

FOOD EXPERTISE

Pen & Tec has expertise in EU food regulations to help overcome regulatory barriers and ensure the fastest route to market.

Our services are tailored to your needs and we are available to offer assistance at any phase of a project or evaluation process.

Pen & Tec work with applicants to identify the most appropriate strategy for obtaining authorisation. Our regulatory and scientific experience also means we can often anticipate regulatory questions and potential pitfalls in order to reduce delays before a product can be taken to market.

- NOVEL FOODS
- NUTRITION AND HEALTH CLAIMS
- FOOD ENZYMES, PROBIOTICS, ADDITIVES AND FLAVOURS
- FOOD INGREDIENTS, SUPPLEMENTS
- FOODS FOR SPECIAL MEDICAL PURPOSES
- COMPLIANT LABELS AND PERMITTED CLAIMS

FOOD SERVICES

Our services cover all of the following categories:

NOVEL FOOD:

- Assessment of the regulatory status and correct regulatory pathway to market the product
- Evaluate existing data, identify gaps and provide **expert advice**
- Assist collecting additional data, monitor studies and review study reports
- Compile, write and submit **novel food dossiers**
- **Post-submission support**

HEALTH CLAIMS:

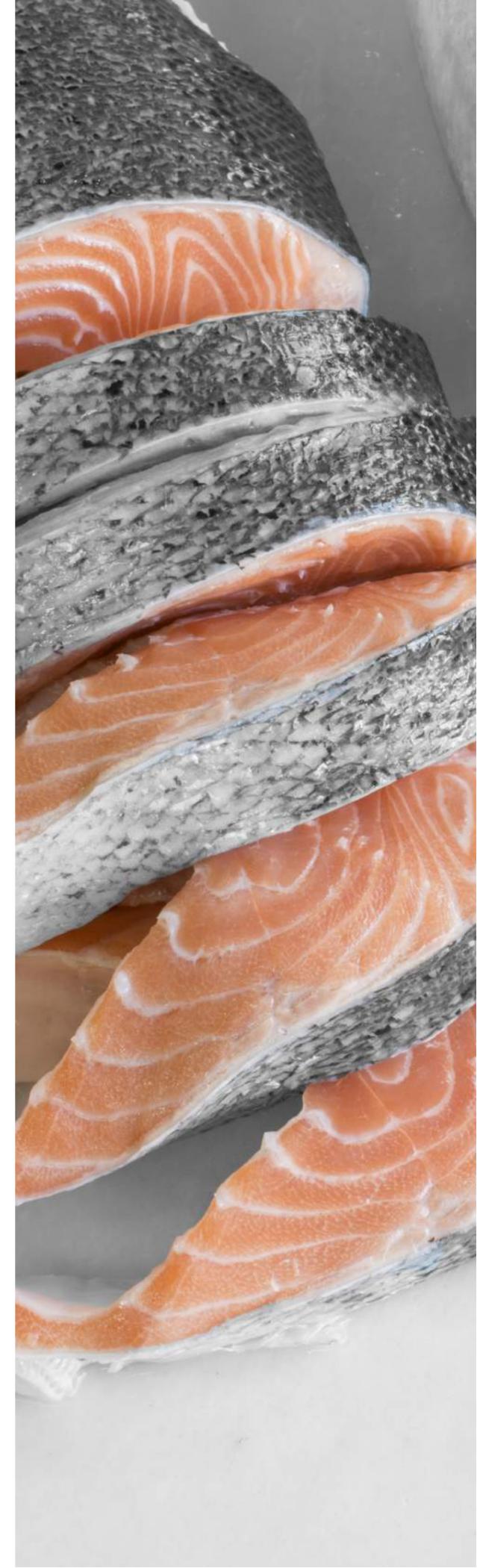
- Assess the **wording of label text** to ensure approved claims are used
- **Review clinical studies** to determine if they qualify for a health claim and identify probability of success
- Perform thorough **literature reviews**
- Compile, write and submit **health claim applications**
- **Post-submission support**

FOOD SUPPLEMENTS:

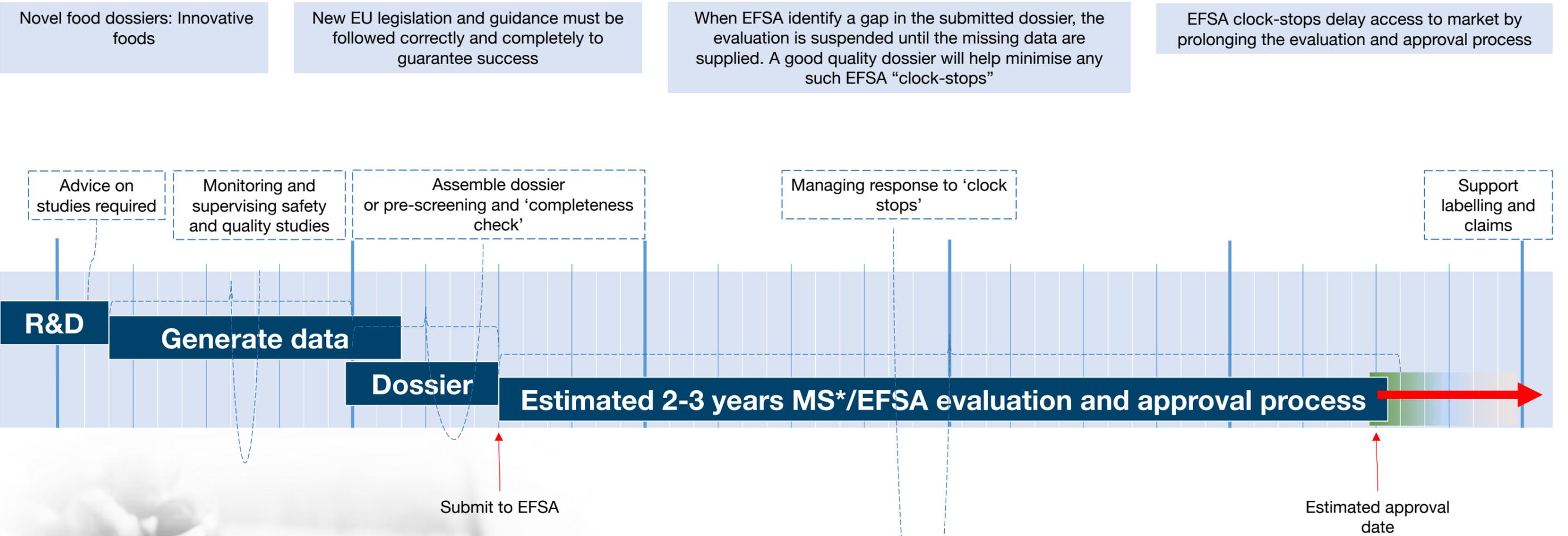
- **Formulation review:** verify legal status of ingredients and maximum permitted limits, in target EU countries
- **Ensure label compliance**
- Assess permissibility and wording of claims
- **Translate** label text to main EU languages
- Advise and assist with **notification process**

FOOD FOR SPECIAL MEDICAL PURPOSES:

- **Assess the legal category** of the product and identify whether it qualifies as an FSMP
- Assist with the **notification process**
- Evaluate existing data, identify gaps and provide **expert advice**
- Compile, write and submit **FSMP dossiers** to EFSA



HOW WE WORK – TYPICAL NOVEL FOOD TIMELINE



* Member States





FEED EXPERTISE

Whether you have an enzyme, a micro-organism or a chemically defined feed additive, Pen & Tec can assist in gaining authorisation for your product. Our in-depth knowledge, strategic insight and ability to interpret the EU Regulations and Directives means that your product will be placed on the market as fast as possible.

Pen & Tec have a proven track record in assisting companies seeking authorisation for feed additives.

Our dedicated team have many years' experience working on various types of feed additives as well as feed materials, compound feed, medicated feed and dietetic feed.

▪ FEED ADDITIVES AND PREMIXTURES

- ✓ TECHNOLOGICAL ADDITIVES
- ✓ SENSORY ADDITIVES
- ✓ NUTRITIONAL ADDITIVES
- ✓ ZOOTECHNICAL ADDITIVES
- ✓ COCCIDIOSTATS AND HISTOMONOSTATS

▪ OTHER FEED CATEGORIES

- ✓ FEED MATERIALS
- ✓ COMPOUND FEED, COMPLETE FEED AND COMPLEMENTARY FEED
- ✓ MEDICATED FEED
- ✓ DIETETIC FEED (PARNUTS)



FEED SERVICES

FEED ADDITIVES AND PREMIXTURES SERVICES

- **Product classification** based on the characteristics, intended use and legal status
- Evaluation of **data requirements, financial planning and timelines**
- Help with designing and monitoring **animal studies** as well as review of results and reporting
- **Literature searches** and expert reports
- Preparation and submission of **feed additive dossiers**
- Help with answering **post-submission questions**

OTHER FEED CATEGORIES:

- COMPOUND FEED
- MEDICATED FEED
- DIETETIC FEED (PARNUTS)

GENERAL FEED SERVICES:

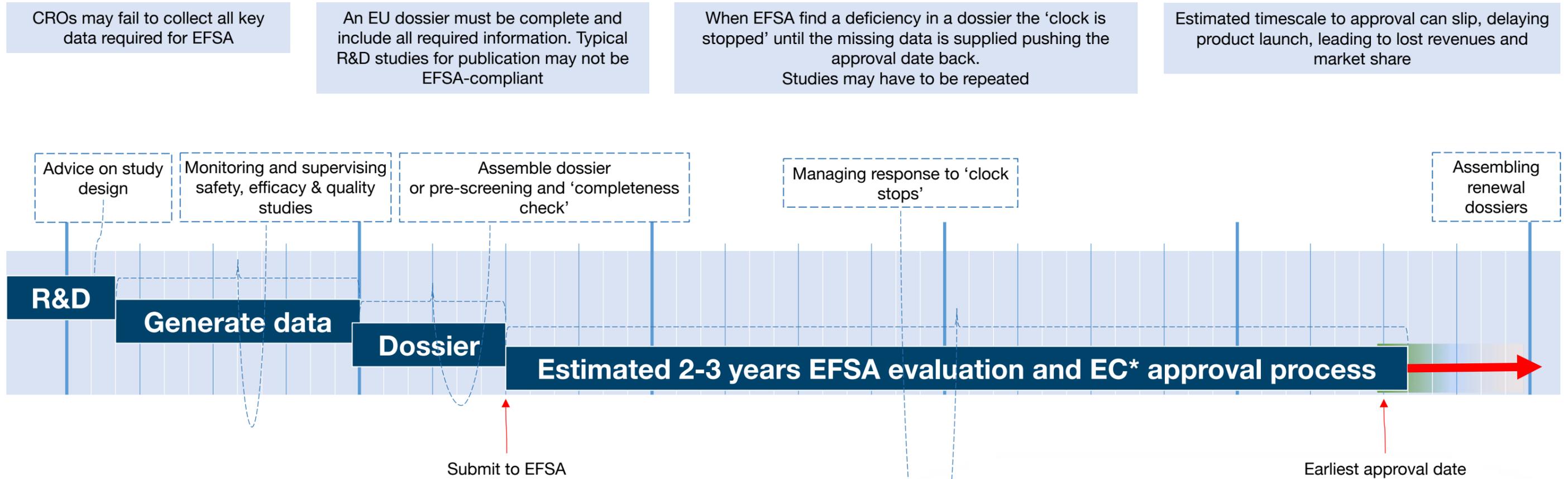
Legislation and guidance documents are updated regularly taking into account technological progress, EFSA's experience in handling applications and input from stakeholders. Pen & Tec can help identify and interpret the latest Regulations and Guidelines, contributing to a faster registration process.

The services that we offer are tailored to client needs, but if you are unsure how to enter the European feed market we may suggest the following approach, taking into account regulatory, commercial and scientific matters:

- **Identify the feed category** and distinguish from other products such as veterinary drugs
- Verify **legal status** and assess if the feed meets the conditions for marketing associated with a particular intended use
- Assist with a **new application**, and liaise with competent authorities
- Ensure correct information is included on the **label**, to avoid misleading the user



HOW WE WORK - TYPICAL FEED ADDITIVE TIMELINE



* European Commission

COMPETITIVE ADVANTAGE

EXPERIENCE

- We have worked in close contact with EU regulatory authorities for over 15 years, with in-depth knowledge of the requirements and working processes at both Member State and EU level
- Our knowledge enables us to provide our clients with tactical options to reduce unnecessary delays in the registration process

IT'S NEVER TOO LATE – RESCUE DOSSIERS

- We can advise on and implement recovery strategies for applications that have run into difficulty with EFSA, the EU Commission &/or Member States

WE SPEED TIME TO MARKET BY AVOIDING DELAYS, FOCUSING ON:

- Precise planning – identification of exact data requirements
- Accuracy – ensuring data reported in studies are complete, correct and coherent
- Effective project management
- Timely communication via a named project manager



PEN & TEC WORLDWIDE

Pen & Tec works closely with our international partners to identify the **OPTIMUM & MOST EFFICIENT** regulatory strategy to obtain a legal status for food/feed additives and ingredients globally.

Since 2000, we have expanded our international presence by increasing our network of associates and forming working partnerships in the USA, Canada, China, India, Japan and Brazil.

We will continue to form new partnerships and alliances in new geographies. Please contact us if you need support in a particular country or region – we may be able to help you.

OUR GLOBAL EXPERIENCE

USA:

- FAPs – food additive petitions for feed enzymes;
- GRAS – self-affirmed or notified Generally Recognised as Safe (GRAS) for feed & food ingredients
- AAFCO – Direct-Fed Microorganisms (DFM) taxonomy updates & feed ingredient notifications
- DIETARY SUPPLEMENTS – for humans, pets, horses, companion/sport animals

Latin America:

- Registration of feed and food additives in Brazil



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