knoell
worldwide registration

THINK GLOBALLY – ACT LOCALLY

RENEWAL OF ACTIVE SUBSTANCES IN THE EU

The renewal of an active substance ensures that the substance meets stringent safety and environmental criteria. It allows the evaluation of new scientific data and research to keep regulations up to date. The decision-making on the EU level serves as the basis for authorisation decisions on the national level. Furthermore, the procedure provides transparency and opportunities for public involvement.

The active substance renewal process includes:

- Notification of intended studies for renewal, including public consultation
- Renewal pre-submission advice
- Submission of the renewal dossier in IUCLID (International Uniform ChemicaL Information Database) format
- Confirmation of completeness
- Dossier evaluation by RMS (Rapporteur Member State)
- Peer review by EFSA (European Food Safety Authority) and all EU Member States, including public consultation and review of CLH (Harmonised Classification and Labelling) by ECHA (European Chemicals Agency)
- Option of 'stop the clock' to submit additional data
- Release of the EFSA conclusion
- Issuance of a draft Regulation for approval and an accompanying Renewal Report by the EU Commission
- Delivery of an opinion on the proposal by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF)
- Adoption of the Approval Regulation by the Commission if the SCoPAFF opinion is favourable

Data GAP Analysis (DGA) and preliminary risk assessments for all technical sections

These steps are required:

- Collection of all relevant data
- Provision of data to the consultancy executing the DGA, communicating expectations, timelines and deliverables to the service provider and following up
- Management of data access via a data sharing platform
- Ensurement of correctness and consistency of the DGA result and verification of their plausibility, content, and completeness
- Organisation of a meeting to discuss the results of the DGA

Dossier preparation in IUCLID

You may select one, several or all of the services below:

- Collection of all relevant data
- Provision of data to the consultancy responsible for dossier preparation, communicating expectations, timelines and deliverables to the service provider, and following up in regular meetings
- Ensurement of correctness and consistency of the dossier and results of the risk assessments and verification of their plausibility, content and completeness
- Organisation of regular status meetings
- Review and follow up on status reports
- Facilitation of strategic decisions regarding dossier content
- Organisation of the preparation of additional activities in the context of dossier preparation such as notification of studies, literature search and evaluation, endocrine disruptor (ED) assessments, kinetic evaluations
- Engagement with regulatory authorities and expert committees for all regulatory steps, including post-submission support

Scientific services

- Study concept management and monitoring
- Literature search and evaluation
- Collection and assessment of publicly available monitoring data
- Risk and exposure assessments for all relevant technical sections, ED assessments
- Environmental fate modelling including non-standard approaches, GIS analysis
- Kinetic evaluations
- Quantitative Structure–Activity Relationship (QSAR) estimates

Sanitisation

Can be performed with the following regulations:

- Regulation (EC) No. 178/2002, which establishes the European Food Safety Authority and lays down the general principles and requirements of food law and procedures in matters of food safety
- Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (the "Transparency Regulation")

Benefits of working with us

- **Expertise:** With in-depth knowledge of the regulatory framework and extensive experience in active substance renewals, our experts help you get market access.
- **Time and Resource Efficiency:** Experience a streamlined process through our expert guidance at every stage that guarantees efficient use of your time and resources.
- **Compliance Assurance:** Be assured to be compliant with EU regulations, decreasing your risk of delays or rejections.
- **Risk Mitigation:** Potential issues are proactively addressed by our expert team to mitigate risks during your renewal process.
- **Cost-Efficiency:** Cost-efficiency is maximised and renewal-related expenses are minimised according to your needs.
- **Full Service or Individual Solutions:** Take advantage of one source for your regulatory, product, and business development needs. Get assisted by us with the entire go-to-market strategy, tailored to your product, or with individual steps towards your commercialisation objectives.

knoell: your go-to partner for registration – worldwide

Think globally, act locally. Our strength is to be where it matters. Our dedicated teams support you in all phases of registration, from planning right through to the market launch of your product and beyond. In case of any questions, please do not hesitate to contact us. We would be pleased to discuss your needs in more detail and would be delighted if you choose us as your partner.

Contact us: info@knoell.com

www.knoell.com