

CHEMICAL REGULATORY SUPPORT

PROVIDING NOVEL SOLUTIONS FOR AN INCREASINGLY DEMANDING REGULATORY WORLD

SUPPORTING YOU WITH CHEMICAL REGULATIONS COMPLIANCE

- **Regulatory support:** compliance assessments for companies; technical support for substances that are difficult to identify or where a non-standard approach to toxicology or ecotoxicology testing, or to exposure assessment and evaluation is needed; and submission of data sharing requests
- **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH):** expert technical advice and the full package of registration services. CEA has experience of responding to dossier evaluations under the Community rolling action plan (CoRAP) and substance evaluations by EU member states.
- **Biocidal Products Regulation (BPR):** preparation and submission of active substance, single product and product family dossiers via R4BP3. CEA has experience of preparing responses to regulatory authorities and representing clients at technical meetings.
- **Risk assessments:** evaluation of the risks to human health and the environment from chemicals; assessments of product uses; building exposure scenarios; and exposure modelling and risk assessments
- **Ecotoxicology:** identification of the studies required for regulatory compliance; placement and monitoring of higher-tier, good-laboratory-practice (GLP) compliant studies when required; calculation of predicted, no-effect concentrations from study endpoints and assignment of assessment factors; data gap analysis and evaluation of data quality; data waivers and read-across arguments; interpretation of data packages; and preparation of chemical safety assessments and robust study summaries
- **Toxicology:** derived no-effect level (DNEL) estimation; data gap analysis and evaluation of data quality; data waivers and read-across papers supporting simple and complex substances; interpretation of data packages; preparation of chemical safety and robust study summaries; programme management and study monitoring; and advice on complex study designs and programmes
- **Safety data sheets (SDS) and extended safety data sheets (eSDS):** help with ensuring regulatory compliance and consistency with hazard and exposure information in registration dossiers
- **Classification, Labelling and Packaging (CLP) and Globally Harmonised System (GHS) classification, notification and labelling:** classification of substances and mixtures, notifications and support for product label design
- **Training:** education for clients and industry through seminars and specific programmes

CHEMICAL REGULATORY SUPPORT SPECIALISTS

Developing accurate scenarios is an important prerequisite for risk assessments.

CEA specialises in human health hazard and risk assessments, modelling and environmental risk assessments, environmental fate and ecotoxicology. Its regulatory and technical expertise ensure the best evaluation of the available information to give meaningful exposure modelling recommendations.

CEA can provide expert advice on addressing data gaps with expert statements and waivers, develop registration and testing strategies including alternative approaches, such as read across, QSAR and other in silico methods and can recommend and manage the appropriate studies.

We have a well-earned reputation for providing higher-tier, non-standard support for challenging products in an increasingly demanding regulatory environment. We can also provide specialist policy advice and research to government clients.

Our unique combination of expertise and experience means that our clients have access to a wide breadth of industry and regulatory specialists throughout their projects.



OUR TEAM OF MORE THAN 30 SCIENTISTS BRINGS TOGETHER EXPERTISE FROM INDUSTRY, RESEARCH AND REGULATORY AUTHORITIES, THEREBY ENABLING US TO FIND SOLUTIONS TO SEEMINGLY IMPOSSIBLE PROBLEMS.



WHAT CEA OFFERS

ENVIRONMENTAL FATE

FIELD FATE AND STEWARDSHIP

EXPOSURE AND SPATIAL MODELLING

AQUATIC TESTING AND ANALYSIS

ECOTOXICOLOGY AND RISK ASSESSMENT

TOXICOLOGY AND HUMAN SAFETY ASSESSMENT

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ABOUT CAMBRIDGE ENVIRONMENTAL ASSESSMENTS

Since 2001, CEA, an RSK ADAS Ltd company, has delivered bespoke strategic and dossier support for chemical and product registrations across Europe. Our team of more than 30 scientists brings together expertise from industry, research and regulatory authorities, thereby enabling us to find solutions to seemingly impossible problems.

Our services range from data evaluation and substance identification through state-of-the-art modelling and specialist higher-tier studies for the refinement of risk assessments to the compilation of whole dossiers or dossier sections. Our clients span manufacturers, formulators, end users, trade associations and regulatory agencies.

Visit our website or speak to a specialist to find out how we can help you to bring your products to market safely and quickly.

CONTACT

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CEA offers a range of regulatory services for REACH (1907/2006), plant protection products (1107/2009), biocidal products (528/2012), food additives (1333/2008), novel foods (258/97), veterinary medicines (2001/82/EC) and human pharmaceuticals (2001/83/EC).

CEA is part of RSK ADAS Ltd, the UK's largest independent provider of agricultural and environmental consultancy, research and development, and policy advice.

