

BIOCIDES

PROVIDING NOVEL SOLUTIONS FOR AN INCREASINGLY DEMANDING REGULATORY WORLD

SUPPORTING YOU WITH A COMPLETE BIOCIDAL PRODUCTS REGULATION SERVICE

A thorough understanding of a substance's properties, use pattern and exposure pathways is necessary to demonstrate safety to human health and the environment. We have a wide range of experience of various product-types and provide advice on addressing data gaps with expert statements and waivers, or can recommend and manage the appropriate studies.

Because of our multidisciplinary expertise and building on our track record of higher tier environmental risk assessment, CEA can provide a full dossier preparation and support service under EU 528/2012, the Biocidal Products Regulation, see right.

WE HAVE A WELL-EARNED REPUTATION FOR PROVIDING HIGHER TIER, NON-STANDARD SUPPORT FOR CHALLENGING PRODUCTS. OUR TEAM INCLUDES EXPERTS IN ENVIRONMENTAL FATE AND BEHAVIOUR, EXPOSURE AND SPATIAL MODELLING, ECOTOXICOLOGY AND TOXICOLOGY.

STRATEGY AND DATA GAP ANALYSIS

- Preliminary risk assessment

LETTER OF ACCESS, DATA SHARING AND DATA GENERATION

- Literature review
- Study placement, design and monitoring
- Data review and evaluation

DOSSIER PREPARATION (IUCLID 6, SPC EDITOR)

- Human health and environmental risk assessments
- Representation at meetings with the regulators
- Robust study summaries

DOSSIER SUBMISSION (R4BP 3)



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.

RISK ASSESSMENT AND HIGHER TIER SUPPORT

CEA specialises in complex human health and environmental risk assessments, with extensive experience in non-standard higher tier support.

Our regulatory and technical expertise ensure the best evaluation of the available information to give meaningful exposure modelling recommendations, including:

- extensive experience in emission scenario selection and construction for a wide range of product types
- design of bespoke product-specific scenarios (including outdoor urban and rural scenarios)
- groundwater refinement using FOCUS PEARL: direct exposure, sludge, manure, redeposition
- surface water refinement using FOCUS surface water models
- human risk assessment for a wide range of consumer and professional uses using a range of models, including ConsExpo, and expert advice on endocrine disruption issues
- risk assessment for non-target organisms including bees and bespoke field monitoring
- higher tier aquatic laboratory and mesocosm studies conducted in-house



- design of residues recovery studies for indoor emissions and bespoke fate studies in-house
- independent placing of standard Organisation for Economic Co-operation and Development studies and study monitoring on behalf of our clients
- FOCUS kinetic analysis to derive modelling and persistence endpoints

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

CHEMICAL REGULATORY SUPPORT

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.

