PRODUCT SAFETY & STEWARDSHIP
BUILDING TRUST THROUGH MANAGING RISK
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SAFETY & STEWARDSHIP – THE NEW IMPERATIVES

**Consumer** concerns regarding potential chemical exposures from products are reflected in increasing global regulatory pressures: from additives in food, to chemicals for industrial applications, to components of toys.

**Companies** are seeking solutions to address the range of concerns – from known burdens to unintended and unanticipated risks – that threaten brand and bottom line.

**Industry leaders** are realigning their thinking – from the boardroom and across every function from R&D to customer support – around product safety.

**Ramboll** resolves the concerns of manufacturers and marketers of products through robust risk management, helping them confidently succeed in the market.
IN THE PRODUCT LIFECYCLE

Ramboll offers expert support when:

• You want to enter new markets and uses
• Your supplier changes production (but didn’t tell you)
• Regulatory scrutiny focuses on your product
• Allegations appear in social media
• The science changes for your key ingredient
• You acquire a portfolio (but don’t know all that’s in it)
• You want to gain competitive advantage through sustainable products
YOUR PARTNER FOR PRODUCT SAFETY & STEWARDSHIP

From product development to post-market, Ramboll supports you throughout the product lifecycle with strategic and technical services, optimising competitive advantage and reducing liability.

• Strategic stewardship programmes
• Alternatives analysis and substitution
• Supply chain communication and control
• Registration and notification
• Worker, consumer and environmental risk assessment
• Crisis and recall management
• Global compliance
APPLYING EXPERTISE TO PRODUCT USES

With global reach and local expertise, we bring strategic insight and practical technical solutions for:

- Industrial chemicals
- Biocides, pesticides and plant protection
- Consumer products
- Toys and children’s products
- Cosmetics
- Pharmaceuticals and medical devices
- Food additives and contaminants and food-contact substances
WHY RAMBOLL?

Resolving complex issues
Ramboll partners with your teams to solve your most pressing issues. Every day our dedicated product safety and stewardship team provides globally integrated breadth and depth of expertise to address our clients’ most challenging issues.

Delivering innovative solutions
In 1982 we pioneered the chemical risk assessment process subsequently used around the world. Today we are pioneering new risk-based tools to evaluate safe and sustainable alternatives, demonstrate compliance and reduce uncertainty for products in the market.

Inspiring trust
We build confidence and consensus amongst stakeholders - including consumers, regulators and business leaders - through credible communication and application of sound science.
ADDITIONAL INFORMATION

The following pages describe some of the individual services that we offers and some of the sectors for which we regularly work.
REACH REGULATION

Around the world, manufacturers, importers, distributors and users of chemicals and products face a multitude of complex and challenging obligations and business implications arising from the REACH regulation. As the authorisation and restriction processes that seek to manage the risk associated with the most hazardous substances gain pace, the registration and evaluation regime brings more substances under regulatory scrutiny.

Ramboll has unparalleled experience working with industry to intelligently resolve these unique challenges, drawing on our breadth and depth of regulatory and technical expertise to provide comprehensive REACH support.

SERVICES

• Preparation and submission of robust registrations
• Strategic and technical support to guide firms successfully through authorisation or restriction
• Optimally managing the evaluation process
• Consortia management and only representative
• REACH programme management and auditing
• Classification, labelling and packaging (CLP)

REGISTRATION

We have prepared over 100 lead and numerous co-registrations under REACH. We are often called in to troubleshoot and rapidly update existing dossiers – in the wake of a draft decision following evaluation – to align and strengthen the dossier in line with ECHA’s expectations.

AUTHORISATION

Ramboll secured the green light from the ECHA’s Committee for Risk Assessment and Socio-Economic Analysis for the use of two phthalates by Roxel under the authorisation process, the third such recommendation under REACH. We are preparing authorisation applications for chromates, TCE and aprotic solvents.
The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is intended to standardise the classification and communication of the hazardous properties of chemical substances and mixtures.

In today’s rapidly evolving regulatory environment, it is more important than ever for companies to stay informed of the nature and timing of regulatory changes impacting their products and supply chains around the world. Ramboll Environ provides expert implementation services to assist with OSHA’s GHS program and similar regulations around the world.

**SERVICES**
- Strategic planning and global implementation surveillance
- Development of multi-national GHS classification positions
- Safety data sheet (SDS) authoring systems and tools
- SDS and label content development and guidance
- Extended SDSs - Europe
- Classification, Labelling and Packaging of Substances and Mixtures (CLP) notification - Europe
- Training on GHS classification and outreach to suppliers

**DEVELOPMENT OF CLASSIFICATION POSITIONS**
Ramboll’s expert human health toxicologists, ecotoxicologists and epidemiologists assist clients in assigning thorough, data-based classifications. GHS classifications require extensive data gathering and technical analysis that addresses various endpoints included in the regulation.

We provide support with literature research, classification position development and justification documentation, development of read-across and quantitative structure-activity relationship (QSAR) strategies, and professional scientific judgment and data interpretation to identify the most scientifically, legally defensible GHS/CLP classifications.

**SDS & LABEL CONTENT**
Ramboll develops high-quality SDSs and labels in country-specific formats and languages. We maintain a thorough SDS authoring procedure with rigorous quality care and sign-off by a certified toxicologist and/or industrial hygienist, depending on client requirements.
The strength of a business is rooted in the quality, integrity and reputation of the products it sells: future market acceptance of these products, from a regulatory and public perspective, are a primary determinant of current and future success.

Acquisition and divestiture activities that evaluate product safety, compliance and customer perceptions provide a strong and transparent basis for informed investment decisions and competitive advantage.

SERVICES

Multi-nationals, local firms, private equity firms and financial investors turn to us to evaluate the risks and opportunities associated with the raw materials and product portfolios as part of due diligence during M&A activity.

- High-level assessment to identify red flag issues
- Detailed evaluation of product safety, compliance and emerging concerns, as well as legacy issues
- Strategic and technical advice

Acquisition of specialty coatings firm

The acquisition of an international specialty coatings business completed smoothly after has delivered a focused review of the global regulatory status of the product portfolio and provided assessment of the ongoing market for the buyer.

Divestiture of medical device manufacturer

Ramboll Environ’s product due diligence review – included within our comprehensive support for the divestiture of part of a group of companies – provided confidence to prospective buyers of the compliance and future regulatory climate for the product portfolio.
Manufacturers and marketers of chemicals find themselves navigating an increasingly complex world of emerging issues, policies and regulations.

Ramboll provides solutions to these daily challenges, drawing on our global reach and depth experience.

**SERVICES**

**Regulatory compliance:** providing comprehensive support for registration, notification, classification and labelling.

**Supply chain and quality management:** evaluating and ensuring control and effective communication with suppliers to manage business risks.

**Safety, substitution and sustainability:** assisting global product improvement across your business.

**Troubleshooting:** supporting your products in the marketplace with local language and insight.

**Vigilance:** interpreting the implications of emerging issues and anticipating policy and regulatory changes.

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**Expedited global product launch**

Ramboll’s Environment & Health team determined regulatory requirements for market entry in 57 countries, including 13 in Asia, on an unanticipated 10-week turnaround. The properties of this consumer product necessitated specific labelling to avoid pitfalls regarding marketing claims. We identified appropriate terminology allowing the launch to proceed on schedule and recommended a minor reformulation to greatly simplify regulatory obligations.

**Registration/Notification**

We have notified or registered hundreds of substances under regulations in Europe, US, Canada, China, Korea, Japan, the Philippines and Australia.
Manufacturers and marketers face increasing pressures from customers and regulators to evaluate alternatives and develop safer processes and products.

Alternatives assessment requirements force a higher level of complexity, extending ingredient substitution to include additional technical aspects, economic impacts and sustainability.

Ramboll’s integrated team of scientists, engineers, economists and process specialists navigates companies through this new level of scrutiny.

**SERVICES**

**Alternatives assessment:** identifying and evaluating potential substitutes for safety across the lifecycle, process modification, applicable use and technical and economic feasibility.

**Regulatory compliance:** providing applications for authorisation under REACH, evaluations under California Safer Consumer Products Regulation (CASCP) and support for other regulatory programmes that restrict or ban use of existing chemicals.

**Value chain evaluation:** mapping impacts through the supply chain.

**Authorisation under REACH**
We prepared one of the first authorisation applications under Annex XIV (for DEHP and DBP), and are preparing submissions for chromates, TCE and aprotic solvents.

**Substitution**
Following European restrictions on flame retardant chemicals, Ramboll evaluated potential substitutes for use in the US market for a leading manufacturer. We determined the relative safety and environmental characteristics of multiple candidate alternatives, resulting in a reformulation suitable for both the European and US markets.
Under the Toxic Substances Control Act (TSCA), US manufacturers and importers of new chemical substances must notify USEPA prior to manufacture. USEPA can require testing of new and old chemical substances and mandate companies to report data on substances posing a risk of injury to human health or the environment. Importers must certify that chemicals comply with all TSCA requirements.

SERVICES

- New chemical notifications, by preparing and shepherding pre-manufacture notices (PMNs) and low volume exemptions (LVEs) through the USEPA review process
- Exemptions, by evaluating and substantiating requirements (eg for polymer exemption (PE) and research and development (R&D) exemption)
- Corporate management and compliance, by auditing TSCA-related activities and through comprehensive support for systems to improve and demonstrate compliance
- Import and export compliance, by reviewing supply chain communication and compliance and assisting with ongoing importation and exportation compliance

Comprehensive support for TSCA compliance

A leading advanced structural materials producer for the aerospace industry required TSCA compliance support. We provided comprehensive support including reviewing TSCA inventory listings, evaluating PMN and various exemptions, preparing PMN for chemical intermediates, evaluating Notice of Commencement (NOC) requirements, providing Inventory Update Rule (IUR) support, conducting TSCA training for R&D staff and meeting with USEPA to discuss PMN compliance issues.
NANOSCALE MATERIALS & TECHNOLOGIES

As nanotechnology moves from an emerging technology to one used for general purposes, its applications are transforming industries, bringing significant technical and economic benefits. Nanoscale materials can behave differently from larger particles of the same substance, requiring additional evaluation to characterise and manage risks to human health and the environment. Regulations are evolving in different parts of the world to account for substances in nanoform, and scientific knowledge on the fate and behaviour of nanomaterials is increasing rapidly.

SERVICES

• Support for regulatory compliance (REACH, TSCA, cosmetics, national registers)
• Strategies for testing and/or interpreting data
• Hazard assessment
• Exposure assessment
• Procedures and training to manage exposure
• Risk communication (scale of risk)

Nanomaterials under REACH
Ramboll has reviewed the current capabilities of nanomaterials safety testing and provided input into the EU impact assessment on the evolution of REACH regulation for nanomaterials.

Remediation technology
Ramboll is active in NANOREM, a collaborative research project investigating novel applications of nanomaterials in contaminated land remediation.

Exposure in the workplace
Carbon black (CB) particles in the workplace require further characterisation. We conducted an industry-wide epidemiology study of CB manufacturing employees to evaluate lung cancer mortality in relation to inhalable CB.

Separately, we designed nanomaterial management training programmes for the research and development facility at a multinational corporation.
POST-LAUNCH SURVEILLANCE

Post-launch surveillance (PLS) is increasingly used by firms as they synthesise available data to make confident statements regarding the safety of the consumer products they place on the market. It integrates pre-market safety data with real-world effects, distinguishing between rumour and fact, anecdotes and evidence, to identify and quantify true hazards.

Covering the entire product life cycle, PLS is viewed by leading firms as a critical tool in responsible product stewardship, regulatory compliance and risk management programmes.

Increasingly stringent regulatory requirements demand thoughtful and comprehensive post-launch surveillance plans. Ramboll Environ integrates scientific specialty disciplines to provide tailored programmes for PLS that meet individual client needs and product demands.

SERVICES

• Responsible roll-out of new products
• Validating pre-market test results under real-world conditions
• Design, management and analysis of passive and active surveillance systems
• Communications programmes for a range of stakeholders

Leading in implementation
Ramboll’s Environment & Health team is supporting major PLS programmes across several sectors where safety assurance is vital for public wellbeing and brand reputation.

• Novel foods (eg modified fats and modified organisms)
• Cosmetovigilance including botanicals and essential oils
• Over-the-counter pharmaceuticals and nutritional supplements such as DMAA and energy drinks
• Modified risk tobacco products
Emerging regulations around the world drive various – sometimes conflicting – requirements for companies placing cosmetic products and ingredients on the market.

In-depth knowledge of regulations and experience of key cosmetic ingredients safety is a prerequisite for assuring compliance, to confidently manage risks and respond effectively to regulatory requirements (e.g. for European cosmetics regulation).

Ramboll aims to clarify the complexity around cosmetics – from colourants, hair dyes, fragrances and preservatives to the challenging new functional actives – providing leading science and innovative thinking to manage and respond effectively to emerging issues (e.g. nanomaterials and endocrine disruption).

**SERVICES**

- Global regulatory compliance (including acting as ‘responsible person’ in EU)
- Human and environmental safety dossiers (and Product Information Files)
- Development and evaluation of non-animal testing methods
- Supply chain management
- Post-market cosmetovigilance approaches
- Packaging and sustainability

**Regulatory status of cosmetic ingredient**

Ensuring familiarity with new regulation and identifying an appropriate course of action can be a major area of uncertainty for manufacturers, formulators and retailers of cosmetics. Understanding the connection between scientific panel recommendations and regulatory changes is also critical for strategic planning and ingredient sustainability. We identify and explain the imperatives for cosmetics industries, to develop and implement pragmatic strategies.

**Non-animal testing methods in safety assessment**

We successfully apply new types of information and data analysis for adverse outcome pathways (AOPs) to support robust globally harmonised safety decisions. We have used physiologically based pharmacokinetic modelling to elaborate safety assessments in internationally harmonised safety dossier for cosmetics to place concerns regarding substance toxicity in context.
Our long partnership with the aerospace and defence industry is rooted in resolving issues resulting from the specification and use of substances hazardous to health or the environment.

Recent introduction of new regulations aiming to track, tightly manage or phase-out the use of the most hazardous substances coupled with stakeholder expectations for safe workplaces, clean environments and sustainable products have driven product safety to the top of the agenda. The aerospace and defence sector is responding proactively, leading efforts to ensure safe use and secure the supply chain.

**Securing the supply chain and safe use**

We know first-hand the challenges that sector-specific regulations and protocols, complex supply chains and global markets pose to companies across the sector. We work closely with clients, their suppliers and customers to:

- Map and evaluate impacts through and provide certainty and assurance in the supply chain
- Demonstrate and improve safe and sustainable use of critical substances and products
- Evaluate alternatives and assist substitution planning
- Support sensible policy development and risk management

**Authorisation under REACH**

Inclusion of several chromium VI substances on Annex XIV of REACH presents a substantial issue for the industry. We are currently preparing complex applications for authorisation under REACH of several CrVI substances for an aerospace led consortium. We also secured an early authorisation for use of two phthalates in rocket motor manufacture for Roxel.

**Strategy for compliance**

An aircraft manufacturer sought certainty that its systems, procedures and tools would allow it to continue to operate in compliance with product safety regulations around the world. Our review facilitated this, providing clear, prioritised recommendations for action.

**Comparative risk assessment**

Our detailed regulatory, human health, environmental risk assessment of alternatives informed a critical strategic investment decision for a major client.
Expanding product and environmental regulatory requirements and increased customer demands are presenting manufacturers of commercial and industrial goods with the challenge to improve their compliance programmes as their products come within scope. From motors to meters, stakeholders expect robust compliance systems that will deliver safety, minimise liability and optimise market acceptability.

**Improving performance**
A thorough knowledge of regulatory requirements and processes across the product lifecycle is necessary to identify, define and implement approaches, systems and tools. Our team brings strategic and technical experience, enabling us to offer the following services to manufacturers of commercial or industrial goods:

- Business process gap assessment
- Focused training and education
- Regulatory baseline and ongoing market monitoring
- Data collection management
- Data management software assessment and selection
- Ongoing technical and strategic advice

**Navigation instrument manufacturer**
With our guidance, our client was able to move from a reactive approach to customer service and regulatory compliance that was costly, tedious and frustrating, to a proactive initiative that involved smart data collection, education and guidance, and put in place a product environmental compliance programme that added value to the top and bottom line.

**Industrial sensor and controller manufacturer**
A division of a large multi-national was concerned about its awareness and understanding of regulatory requirements in markets around the world. We identified the compliance requirements with significant implications for our client’s products and global markets and implemented a programme to successfully communicate relevant issues to various tiers in the organisation.
**FOOD INGREDIENT SAFETY — GRAS**

Ingredients added to foods in the US must be approved as food additives by the US Food and Drug Administration (USFDA) or established as generally recognised as safe (GRAS) for food use. GRAS status is established based on the views of ‘experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food’. The predominant method of GRAS determination involves scientific procedures requiring the same quantity and quality of scientific evidence as is required for approval of a food additive regulation for the ingredient. Nonetheless, the GRAS determination process is much quicker than the formal food additive petition process, making it the favoured path to market for food ingredients in the US.

**Expertise in safety assessment**
Ramboll provides strategic advice and technical assistance to manufacturers and marketers of food ingredients with our work on certain ingredients or for key clients recognised globally.

- GRAS feasibility assessments (data sufficiency and gap analysis)
- Guidance, oversight, interpretation and presentation of safety studies to support GRAS status
- Preparation of complete GRAS dossiers including dietary exposure assessments
- Establishing, managing and consulting with the expert panels to review and affirm GRAS status
- Submitting GRAS notifications (GRNs) to USFDA

**New ingredient approvals**
Psyllium was proposed as a potential source of soluble dietary fibre in a ready-to-eat breakfast cereal. We critically and objectively reviewed extensive scientific data comprising human, animal and *in vitro* studies addressing general toxicity, vitamin and mineral absorption and availability, allergenicity, carcinogenicity, and reproductive effects. Our safety assessment for a major food company supported a conclusion that the use of psyllium seed husk in cereals is GRAS.

Safety dossiers, including critical reviews of safety data on two ingredients and the estimated daily intake (EDI) in various consumer groups, were prepared for potential ingredients in an energy drink. Ramboll’s Environment & Health team also participated in the expert panels that reviewed these safety data and affirmed the use of these ingredients as GRAS.
Bringing clarity through science
From strategy to implementation, our scientific insight and long regulatory experience helps companies around the world place their active substances, products and treated articles on the market. Whether our clients seek guidance through the process, technical support for borderline, new or difficult issues, or resources to support in-house activity, we work to provide focused, robust and reliable support.

Triclosan
Our robust and leading-edge hazard, exposure and risk assessments of Triclosan for human health and the environment across many uses (textiles, plastics, personal care products and pharmaceuticals) have been instrumental in supporting the continued use of this biocide for many years.

Treated articles
Many products are treated with or intentionally contain biocidal products, creating regulatory implications. Our team has worked with manufacturers including those of coating and clothing to clarify associated regulatory and technical implications.

Bringing products to market
We offer global support for the listing of active substances and authorisation of biocidal products including one or more active substances.
Around the world, people understand that children are not just small adults when it comes to exposures from the products around them, and expect an extra degree of regulation to protect them.

Current attempts to harmonise multiple programmes within regions such as the EU, as well as the differing requirements of individual countries have implications for local producers and global distribution networks.

Individual states in the US are working to provide regulatory programmes specifically geared towards the exposure of children to consumer products. These varying approaches and requirements create complexity for manufacturers, distributors and the producers of chemical ingredients used in these products.

Ramboll global reach and local presence
We develop coordinated quality assurance and testing and monitoring programmes to allow toy and children’s product companies to address regional, national and local regulatory requirements in a coordinated, cost-efficient programme.

With regulatory experts, chemists, toxicologists and materials specialists across the US, the EU and in China, we offer scientific and technical excellence on the ground in areas where local knowledge makes a difference.

SERVICES
Alternatives analysis/ingredient substitution: successes with alternate flame retardant, ink and plasticiser formulations

Compliance programme development and oversight: guiding transitions from restricted substance lists to active management of suppliers and ingredients

Adulteration and unanticipated component investigations: effective chemical, exposure and process analyses to characterise risks to consumers and brand, and to guide responses, recalls, compliance and litigation needs
ABOUT RAMBOLL

Ramboll is a leading engineering, design and consultancy company employing 13,000 experts. Our presence is global with especially strong representation in the Nordics, UK, North America, Continental Europe, Middle East and Asia Pacific.

We constantly strive to achieve inspiring and exacting solutions that make a genuine difference to our clients, end-users and society at large.

Environment & Health

A globally recognised environmental and health practice, our 2,100 experts have earned a reputation for technical and scientific excellence, innovation and client service. Advances in science and technology and evolving regulatory, legal and social pressures create increasingly complex challenges for our clients. We evolve to keep pace with these changes – by adding new services, contributing to scientific advances or expanding geographically.

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