

# 2024

VALUE IN COMPLIANCE

# ANNUAL REPORT

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# REACH24H ABOUT REACH24H



Founded in 2009, REACH24H Consulting Group specializes in delivering comprehensive product compliance consulting services, market access strategies, and sustainability solutions for companies across diverse industries.

With 8 branches worldwide, we provide professional and efficient services backed by a global team of over 300 experts. To date, we have collaborated with over 15,000 enterprises, including 103 Fortune Global 500 companies.

REACH24H has established strong connections with government agencies, industry associations, and international organizations, maintaining a robust network across 39 countries and regions. Our expertise is recognized by numerous government bodies, and we have contributed to the development of various industry guidelines and national standards.

# Industries We Serve



Industrial Chemical



Disinfectant & Biocide



Food



Pharmaceutical



Pesticide & Fertilizer



Cosmetic



Food Contact Material & Recycled Plastic



Automobile

# **Our Services**

Product Registration and Compliance Consulting

**Global Market Access Solutions** 

**Sustainability Solutions** 



EHS and Safety Management Solutions

**Chemical Inspection and Testing** 

Regulatory Alerts and Market Intelligence

# Why REACH24H

15,000+ Clients

- Trusted by 103 Fortune Global 500 Companies
- Extensive Global Network in 39 Countries and Regions

300+ Expert Team

- Over 98% of the Technical Team Holds a Master's Degree or Above
- Internationally Certified Toxicologists and Risk Assessment Experts

16 Years of Expertise

- Contributions to Industry Guidance and National Standards
- Designated Service Provider for Numerous Embassies

# Branches Worldwide

- 24/7 Services for Global Coverage
- Multilingual Support (EN, CN, JP, KR, DE, IT, + more)

# REACH24H

# HEADQUARTERS RELOCATION: A NEW CHAPTER, A BRIGHTER FUTURE



"As we step into this new chapter, we are ready to provide better service and look forward to a future with more possibilities." **Said Mr. Hong Fangwei, General Manager of REACH24H**.

In January 2025, REACH24H Consulting Group China will begin an exciting new journey by relocating its headquarters to the **Headquarters Economy Park for Alumni Enterprises**, **Zhejiang University**, located in the dynamic city of Hangzhou. Co-established by the Hangzhou municipal government and Zhejiang University—one of China's premier academic institutions, this innovative hub is a beacon of collaboration and innovation.

#### A Commitment to Excellence and Innovation

This move symbolizes more than just a change in address; it is a strategic leap forward in REACH24H's commitment to excellence. With relocation, we will have better access to advanced resources. REACH24H reaffirms its commitment to delivering smarter, more professional solutions in global market access, product compliance, and sustainable development, empowering clients to thrive in an ever-evolving regulatory landscape.

#### Looking Ahead

As we embark on this new chapter from our innovative headquarters, we extend our deepest gratitude to our partners for their trust and support. Together, we are excited to build a future filled with potential and opportunity, driving meaningful progress across industries worldwide.

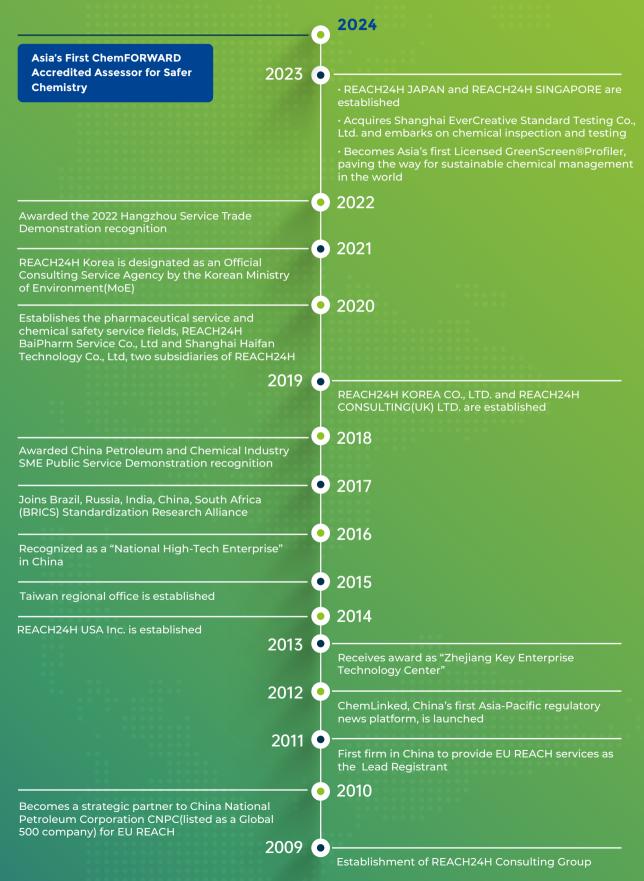
#### **NEW ADDRESS:**

10th Floor, C1, Headquarters Economy Park for Alumni Corporation of Zhejiang University, No. 76 North Longzhou Road, Yuhang District, Hangzhou, Zhejiang, China, 311121

# **GLOBAL LAYOUT**



# **MILESTONES**



# REACH24H

# GLOBAL MARKET ACCESS AND COMPLIANCE CONSULTING SERVICES



REACH24H specializes in global product regulations and market entry requirements, dedicated to helping companies achieve global trade compliance and success.

We provide professional and efficient support to ensure your products meet the regulatory requirements of targeted markets. With our customized strategies and extensive regulatory expertise, we help you navigate complex requirements and minimize risks, allowing you to concentrate on expanding your business.

# CHEMICAL COMPLIANCE & PRODUCT SAFETY CONSULTING

At REACH24H, we provide comprehensive global chemical compliance services. Our efficient and professional team offers high-quality support, ranging from market access solutions and chemical safety consulting to product registration.

We are committed to helping enterprises worldwide in ensuring their products are safe and compliant, navigating evolving regulations, and mitigating risks, thereby enabling successful market entry and growth opportunities.

## **Asia Pacific**

- China New Chemical Substance Registration (MEE Order No. 12)
- China New Pollutants Treatment Plan
- China Hazardous Chemical Registration
- "One Enterprise, One Product, One QR Code" Policy Compliance Solution
- Identification and Classification for Hazardous Chemicals
- Taiwan TCCSCA/OSHA

- K-REACH / K-BPR / K-OSHA
- Japan CSCL / ISHL
- India CMSR / BIS Certification
- Chemical Compliance in APAC Regions
- Import and Export Compliance Consultation

#### Europe & Americas

- EU REACH/F-GAS
- EU CLP/PCN Notification
- SVHC/SCIP Notification
- OSPAR HOCNF
- UK REACH/F-GAS
- Turkey KKDIK
- Ukraine REACH
- Canada CEPA
- U.S. TSCA
- Brazil REACH
- Chemicals Compliance in Latin America

# OUR SERVICES

#### Global

- Global GHS SDS & Labeling
- Emergency Phone Number Service
- CAS Number Application
- WERCSmart
- Toxicological Risk Assessment
- LHAMA Evaluation
- GreenScreen® Assessment and GreenScreen Certified™
- ChemFORWARD Assessment and SAFER™ Certified
- Transport of Dangerous Goods

# A LOOK BACK AT 2024

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES



# **Navigating New Markets and Services**

In 2024, REACH24H further deepened its research into global chemical regulations and expanded its compliance services to include the markets of Brazil, Chile, and Argentina. This expansion aims to assist enterprises in entering and growing within these promising markets.

Beyond product registration and compliance services, we provide nano-substance notification, PFAS-free certification, microplastics compliance, and EU/US biobased certification. These offerings empower companies to navigate market entry effectively and achieve sustainable transformation, thereby enhancing their market recognition.



# Overcoming Challenges in Gaseous Substance Registration under China REACH

REACH24H has successfully addressed the technical challenges of registering gaseous substances under China New Chemical Substance Registration. We have assisted enterprises in securing multiple regular registrations for gaseous substances, one of the most challenging categories for new chemical substance registration.



# Achieving Efficiency in Obtaining Taiwan PEC Standard Registration

In 2024, REACH24H significantly enhanced the efficiency of Taiwan Priority Existing Chemical (PEC) Standard Registration under TCCSCA, reducing the project period from an initial average of 1.5 years to just 2 months. This improvement ensures that all serviced enterprises receive the registration code well before deadlines.



### **REACH24H's Continued Recognition in South Korea**

For four consecutive years, REACH24H has been recognized as an officially recommended consulting service agency for K-REACH by the Korean Ministry of Environment (MoE) and the Korea Chemicals Management Association (KCMA).



# India BIS Certification: Comprehensive Services Across Industries

REACH24H has developed a comprehensive service system for India's Bureau of India Standard (BIS) certification, encompassing both Scheme-I Indian Standards Institution (ISI) Certification and Scheme-II Compulsory Registration Scheme (CRS) Certification.

Our services cover a range of industries, including chemicals, personal care products, electronics, electrical appliances, and equipment, assisting enterprises in streamlining their BIS compliance processes.



## Promoting a Safe Future for E-commerce Platforms

The rapid growth of e-commerce has led to products with excessive toxic chemicals, like children's toys and clothing. This has made chemical management on E-commerce platforms a new focus of concern.

Invited by the NGO-Toxics Free Corps, REACH24H contributed to the drafting and release of the "Guidelines for Chemical Management in E-commerce Platforms". These guidelines help e-commerce platforms develop proactive chemical management strategies, promoting a green, safe, and sustainable consumer environment.

# COMMITMENT TO STRENGTHEN INDUSTRY EXCHANGE & COOPERATION

To further refine the "Guidelines for Preparing Socio-Economic Benefit Analysis Reports for High-Hazard Chemical Substances (Discussion Draft)," the Solid Waste and Chemicals Management Technology Center of the Ministry of Ecology and Environment organized a meeting with industry stakeholders. REACH24H was invited to participate, offering insights and recommendations.



REACH24H was invited to attend a workshop focused on the Chinese National Standard *Test Methods for Transport Packaging for Dangerous Goods*. By contributing our expertise and insights, we aim to enhance the safety management of dangerous goods.



REACH24H organized seminars on the latest chemical regulatory trends, with attendance from China's government authority representatives.



REACH24H was a Platinum Sponsor, hosted a training session on "Overview of China TDG Regulations", and presented an "International Regulatory Briefing - China Update". During the event, we engaged in detailed discussions with representatives from the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) regarding regulatory landscapes and their potential impacts on corporate operations in both countries.



REACH24H was invited to share insights on product compliance and sustainable solutions with Japanese enterprises.



REACH24H organized CRAC Japan 2024 and brought together industry leaders, regulatory experts, and stakeholders from Japan and around the world to discuss critical issues surrounding chemical management. The event focused on key topics such as hazardous chemicals management, the "One Enterprise, One Chemical Product, One QR Code" policies, and the sustainable development of the chemical industry.





REACH24H organized CRAC Europe 2024 and brought together industry experts to share strategies for navigating regulatory challenges across the Asia-Pacific region and beyond. CRAC Europe 2024 - Chemical Session stood out as a landmark event, building on over 15 years of expertise in APAC chemical compliance while addressing pressing topics for European companies.





# AGROCHEMICAL & BIOCIDES COMPLIANCE

At REACH24H, we offer comprehensive services in agrochemical registration and biocides compliance. Our expert team assists global companies in managing the intricacies of product registration, empowering them to capitalize on new market opportunities.

#### Global Pesticide Registration

- China Pesticide Registration
- China New Pesticide Registration
- EU PPP Regulation Compliance
- EU BPR Regulation Compliance
- UK Pesticide Registration
- US EPA Pesticide Registration

- US EPA Inert Ingredient Registration
- US EPA Pesticidal Device Registration
- Canada Pesticide Registration
- Australia Pesticide Registration
- Compliance Consulting in Other Regions

## ▲ Fertilizer & Biostimulant Registration

- China Fertilizer Registration
- China Biostimulant Registration
- EU Fertilizer Registration
- EU Biostimulant Registration

### Technical Support

- Pesticide Regulatory Analysis Report
- Pesticide Market Analysis Report
- GLP Lab Screening and Test Monitoring
- QSAR and Computational Toxicology
- Risk Assessment Report
- Customized Training

#### ■ Disinfectant & Biocide Compliance

- China Disinfectants Registration
- Korea BPR Compliance
- EU BPR Compliance
- US EPA Registration

- US FDA CGMP Compliance
- Laboratory Screening and Test Supervision
- Disinfectants/Biocides Market Landscape and Consulting
- Customized Training









# A LOOK BACK AT 2024

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES

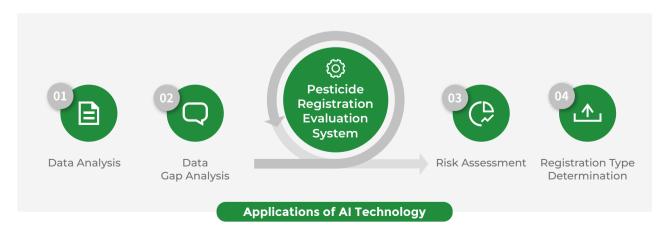
#### **R&D Support for New Pesticide Development**

REACH24H offers R&D support that includes conducting safety assessments to identify potential risks. By leveraging advanced biotechnology and our extensive experience in pesticide registration safety assessments, we develop scientific, phased testing strategies to optimize lead compound structures.

#### Al Integration in Pesticide Registration

REACH24H has integrated AI technology into pesticide registration through the development of the Pesticide Registration Evaluation System.

This system modularizes complex segments of the registration process, providing an intelligent framework that covers the core steps of pesticide registration. It enables enterprises to assess feasibility from the project initiation stage, thereby enhancing efficiency and success rates.



### Achieving U.S. Pesticide Registration Across All U.S. States and Washington, D.C.

In the U.S., pesticide products must be registered with state pesticide regulatory offices for sale and distribution, each having its own set of requirements and fees.

REACH24H has utilized its technical expertise to assist numerous companies in securing over 200 state registrations, encompassing a wide range of product types and achieving comprehensive coverage across all 50 states and the District of Columbia (DC).

# Achieving Rapid Approval in Australia Pesticide Registration

In2024, REACH24H has effectively assisted enterprises in completing Australia pesticide registrations, achieving active substance approval in just seven months.



## Fertilizer Compliance Expertise

Our extensive expertise in fertilizer compliance has empowered numerous enterprises to successfully complete EU biostimulant registrations and China microbial inoculant registrations.

# REACH24H's Continued Recognition for K-BPR Service

For three consecutive years, REACH24H has been officially recognized as a recommended consulting service agency by the Korean Ministry of Environment (MoE) and the Korea Chemicals Management Association (KCMA).

# 2024년 화평법 및 제품법 중소기업 지원시업 수행기관 선정결과

(2024.2.29, 한국화학물질관리협회)

2024년 화평법·제품법 중소기업 지원사업 수행기관 선정결과를 아래와 같이 공지합니다.

구분	기업명	선정결과
1	남앤드남인터내셔널	선정
2	《리이치24시코리아》 REACH2	4H 선정
3	리켐프로	선정

# COMMITMENT TO STRENGTHEN INDUSTRY EXCHANGE & COOPERATION

Visit to the Italian Ministry of Health



Representatives from Brazil's Ministry of Agriculture and CropLife America Invited to CRAC China 2024.







REACH24H organized CRAC Europe 2024 to enhance communication and collaboration between China and Europe on Global Pesticide Registration.





Engaged in comprehensive dialogues with European pesticide companies, the International Biocontrol Manufacturers Association (IBMA), and representatives from the French Biocontrol Association.





REACH24H was invited to present at global industry conferences, sharing the latest updates and insights.

以安全性为导向的 新农药可行性评估与登记策略 第88 PhD 技术专家 第88 PhD 技术专家











# **GLOBAL COSMETICS COMPLIANCE**

With decades of experience and an in-depth understanding of cosmetic regulations, REACH24H has successfully assisted thousands of enterprises, including many Fortune 500 companies, in entering their target markets. We are also the designated compliance service provider for the embassies and consulates of Switzerland, France, the United Kingdom, New Zealand, and others.

#### China

#### New Cosmetic Ingredients (NCI)

- NCI Registration / Notification
- Toxicological Data Gap Analysis and Customized
   Formula & Packaging Review Registration Proposal
- Ingredient Safety Assessment Report
- Ingredient Safety Information Submission
- Test Monitoring

#### Toothpaste

- Formula & Packaging Review
- Toothpaste Notification
- Testing & Efficacy Evaluation
- Safety Assessment

#### Cosmetic Products

- Product Registration / Notification
- Product Safety Assessment Report
- Cosmetic Efficacy Evaluation

#### Others

- RP Agent in China
- Adverse Reaction Monitoring
- Regulatory Report
- Customized Training

#### **ASEAN**

- Formula & Packaging Review
- CPSR Compilation
- PIF Compilation
- Cosmetics Notification
- License Holder service

# Japan & South Korea

- Formula & Packaging Review
- Cosmetics Notification
- Evaluation and Reporting of Functional Cosmetics
- RP Agent Service
- Quality Inspection of Imported Cosmetics

## EU & UK

- Formula & Packaging Review
- CPNP & SCNP Notification
- CPSR Compilation
- PIF Compilation

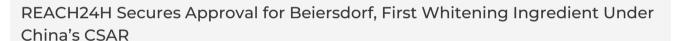
#### US

- MoCRA Cosmetics Registration
- Formula & Packaging Review
- Product Listing & Annual Renewal
- Facility Registration & Renewal
- OTC Drug Registration
- INCI Name Application

Global Cosmetics Compliance

# A Look Back at 2024

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES



REACH24H successfully assisted Beiersdorf in obtaining approval for a new whitening ingredient, Thiamidol (630). This marks the first whitening ingredient to be approved under the Cosmetic Supervision and Administration Regulation (CSAR), a key milestone for the industry.

## Enhancing Safety Assessment Capabilities with Innovative Strategies

With China's comprehensive cosmetic safety assessments nearing full implementation, REACH24H is proactively supporting enterprises in strengthening their safety assessment capabilities. Our solutions incorporate innovative strategies that avoid animal testing, such as Threshold of Toxicological Concern (TTC) and Read-Across methods.

## **Expanding Cosmetic Compliance Services in ASEAN Markets**

REACH24H has conducted an in-depth analysis of cosmetic compliance requirements across various countries, extending our services to Malaysia, Singapore, Vietnam, and other ASEAN markets. By successfully overcoming technical and language barriers, we have enabled global enterprises to capitalize on international market opportunities.

#### Facilitating Market Entry: Supporting Enterprises in Expanding into Japan

REACH24H Japan has obtained the "Marketing Authorization Holder (MAH) License for Quasi-drugs," allowing REACH24H to offer comprehensive support to enterprises entering the Japanese market.

# Recognition for Excellence in Sustainability and Cosmetic Compliance Services

REACH24H Korea was commended by the Korean Ministry of Food and Drug Safety (MFDS) and the Korea Cosmetic Association (KCA) for their outstanding contributions to sustainability and safety management in the cosmetics industry.





## REACH24H Assists Global Cosmetic Companies with MoCRA Implementation

REACH24H USA acted as the U.S. Agent and assisted numerous foreign companies with its cosmetic facility registrations and product listings under the U.S. Modernization of Cosmetics Regulation Act (MoCRA).

# COMMITMENT TO STRENGTHEN INDUSTRY EXCHANGE & COOPERATION

## Global Collaboration in Cosmetics Compliance and Market Trends

In 2024, REACH24H Korea hosted the CRAC Korea seminar in Seoul, focusing on global cosmetics compliance and market trends. Key representatives from industry associations and companies, such as the Korea Cosmetic Industry Institute, China Association of Fragrance Flavor and Cosmetic Industries, Independent Beauty Association, ASEAN Cosmetics Association, KAO Corporation, and MINTEL, gathered to discuss regional management requirements and market dynamics.





REACH24H was invited to participate in the Cosmetics Europe Annual Conference 2024, hosted by Cosmetics Europe. During the event, REACH24H shared insights and engaged in discussions on the technical requirements for the safety assessment of cosmetic products.



For two consecutive years, REACH24H has partnered with the China Association of Fragrance Flavor and Cosmetic Industries to host the International Cosmetics Forum. The event includes participation from global industry organizations like Cosmetics Europe, the Personal Care Products Council, and the Japan Cosmetic Industry Association.







REACH24H hosted the Cosmetics Toxicology Forum in collaboration with the Shanghai Society of Toxicology.



REACH24H participated as a judging panel member at In-Cosmetics ASIA.



# DEACH21H

# ONE-STOP FOOD COMPLIANCE CONSULTING

REACH24H is committed to providing one-stop market access consulting services to businesses worldwide. With extensive industry expertise, we have successfully assisted thousands of food companies in reaching their target markets. We are also the designated regulatory service provider for embassies, consulates, and business associations.

In 2024, REACH24H expanded its services to Southeast Asia, Japan, Europe, the US, Australia, and New Zealand. We offer comprehensive compliance consulting and technical services to help enterprises bring their products to the global market successfully.

### >> China Food Registration

- China Health Food Filing and Registration
- China Infant Formula Registration
- China Food for Special Medical Purposes
   Registration
- China New Food Ingredient & Additive Registration
- China Pet Food/Feed Registration

### >> China Market Entry Compliance

- Overseas Manufacturers Registration
- Label Review and Preparation
- Product Formula Review
- Food Safety System Construction

#### » APAC/EU/US Food Compliance

- US FDA GRAS Service
- Product Formula Review
- Product Registration
- Label Review and Design
- Regulatory and Market Access Report

#### Customized Solutions

- 1-on-1 Regulatory Consultation
- Customized Training
- Regulatory and Market Access Reports
- Market Analysis and Consumer Research
- Regulatory and Market Intelligence
   Monitoring

# **A LOOK BACK AT 2024**

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES

# Enhancing Market Access with US GRAS Certification Services

REACH24H has developed robust capabilities in US GRAS certification. We provide comprehensive market access assessments and GRAS certification services to a diverse array of enterprises.



# Empowering Enterprises to Enter the Chinese Pet Food Market

REACH24H has successfully assisted several enterprises in obtaining China import registration certificates for feed and pet food.

### REACH24H Shares Insights at China Business Forum

As the sole compliance consulting agency, REACH24H was invited to the "China Business Forum," celebrating the 60th anniversary of China-France diplomatic relations. We offered valuable insights on how French enterprises can leverage China's regulatory environment to successfully enter the market





## Trusted by International Institutions for Regulatory Guidance

REACH24H has earned the trust of international institutions such as Invest Nova Scotia, the Australia-New Zealand Infant Nutrition Council, Advantage Austria, and the British Consulate-General in Shanghai. We have been invited multiple times to present on the latest Chinese food regulations to local enterprises in Canada, Australia, New Zealand, and Austria, providing precise guidance for entering the Chinese market.









Invited by the Austrian Consulate-General in Shanghai to present on China's import food regulations and market overview. Invited by the British Consulate-General in Shanghai to share insights on China's food compliance requirements with British enterprises.





# DEACU21U

# FOOD CONTACT MATERIALS & RECYCLED PLASTIC COMPLIANCE

REACH24H is well-versed in the management requirements for food contact materials (FCM) and recycled materials across China, the US, the EU, Canada, and MERCOSUR.

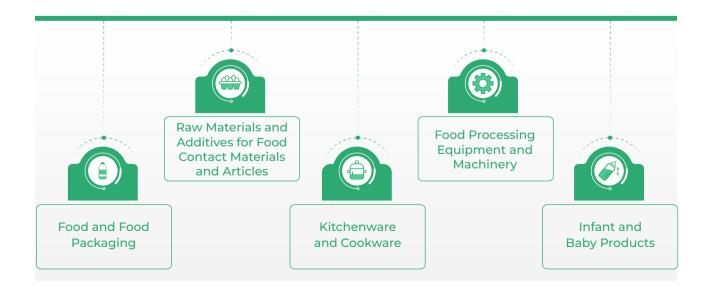
With over 10 years of success in new substance applications in these regions, we have a deep understanding of the specific application requirements for each product category. Our technical and service capabilities encompass raw materials, new ingredient applications, intermediates, and end-product compliance throughout the product lifecycle.

#### Food Contact Material

- Product Compliance Analysis
- Regulatory Status Inquiry Service
- Compliance Test Arrangement and Supervision
- Declaration of Compliance (DoC)
- U.S. Food Contact Notification (FCN) Application
- EU Food Contact New Substance Application
- China GB New Food-related Product Application
- Supply Chain Management
- Customized Training

#### Recycled Plastic

- Compliance Analysis Report
- U.S. No Objection Letter (NOL) Application
- EU Scientific Opinion Letter (SOL) Application
- Challenge Test Arrangement and Supervision
- FDA & EFSA Official Communication and Consultation
- Regulatory Monitoring Service
- Customized Training

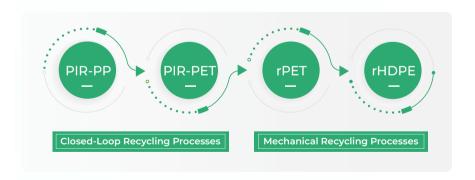


# **A LOOK BACK AT 2024**

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES

# Achieving US FDA Approvals for Recycled Plastic Processes

REACH24H successfully secured multiple US FDA No Objection Letters (NOL) for various recycled plastic processes, including PIR-PP and PIR-PET closed-loop recycling, rPET mechanical recycling, and rHDPE mechanical recycling. Some projects were approved in as little as six months from initiation, with one project receiving approval just 18 days after dossier submission.



#### Securing US FDA Approvals for Food Contact Materials

We assisted global enterprises in obtaining US Food Contact Notification (FCN) approvals for coatings, plastic resins, biodegradable PHA plastics, various plastic additives, and novel food contact materials—all sanctioned by the US FDA.







# Contributing to Policy on Recycling Food Contact Plastics

REACH24H was invited to participate in a policy research seminar on "Primary-level Recycling of Food Contact Plastics Packaging," organized by China's National Development and Reform Commission, the National Health Commission, and the State Administration for Market Regulation. We provided scientific evidence and recommendations to inform policymaking and enhance recycling practices.



# DEACH24H

# PHARMACEUTICAL REGISTRATION AND COMPLIANCE CONSULTING

BaiPharm, a wholly-owned subsidiary of REACH24H, specializes in pharmaceutical regulatory consulting and supply chain services. Our team comprises seasoned experts in pharmacodynamics evaluation, drug development, regulatory affairs, and international business. BaiPharm offers market access services and post-marketing regulatory support for drug formulations, active pharmaceutical ingredients (APIs), excipients, and packaging materials.

## DMF Filing

- Active Pharmaceutical Ingredients
- Pharmaceutical Excipients
- Packaging Materials

## Product Registration

- Abbreviated New Drug Application (ANDA)
   New Drug Application (NDA)
- Application for Clinical Approval: CTA/IND, BLA, BE Studies and MRCTs
- eCTD Compilation and Submission

# Pharmacovigilance

- ICSR Case Processing
- Aggregated Safety Report
- Literature Screening
- Risk Management: RMP, US REMS
- Signal Management and Detection
- PV Consulting and PV Auditing

## Regulatory Support

- GxP Consulting and Auditing
- Domestic Agent for Overseas MAH
- Professional Translations
- Regulatory Due Diligence

# A LOOK BACK AT 2024

# ENHANCING TECHNICAL AND SERVICE CAPABILITIES



## Pioneering PDE Toxicological Assessment in China

BaiPharm has independently developed China's first Permitted Daily Exposure (PDE) Toxicological Assessment Database, creating an internationally aligned methodology system. With thousands of PDE/OEL professional reports, this database plays a crucial role in enhancing safety management in multipurpose pharmaceutical manufacturing.





#### Excellence in Pharmaceutical Toxicology Assessment

As one of the first companies in China to offer pharmaceutical toxicology assessment services, BaiPharm has helped several renowned Chinese pharmaceutical enterprises successfully pass cross-contamination audits related to GMP by European and US officials. Our PDE/OEL reports have been highly recognized by international auditors.

# Leadership in Developing Industry Standards

As the leading drafting unit, BaiPharm was instrumental in developing the "Pharmaceutical Permitted Daily Exposure (PDE) Assessment Methodology" group standard in China. This standard provides a vital reference for scientific and standardized PDE assessments within China's pharmaceutical industry.



# Facilitating Risk Management through Industry Forums

In collaboration with CPHI China, BaiPharm organized an offline forum to assist enterprises in achieving precise risk management for multipurpose production.





# REACH24H

# SUSTAINABILITY SOLUTIONS



We help enterprises and high-quality products take the initiative to innovate toward a sustainable future. We offer customers comprehensive and diversified carbon neutralization and sustainable solutions, empowering companies to achieve green transformation and sustainable development. Together, we drive positive change and contribute to a more sustainable future.

# SUSTAINABILITY SOLUTIONS

## **Carbon Neutrality & Sustainability Solutions**

- Environmental Product Declaration (EPD)
- ESG Assessment & Report
- > EU CBAM
- CDP Reporting
- > EcoVadis Rating
- Green Chemical Screening and Assessment
- Science-Based Targets initiative (SBTi)

- GHG Emissions Accounting
- > ECO Label / Environmental Label
- CCER Investment & Development
- Sustainability Strategy & Roadmap
- Product Carbon Footprint
- Carbon Neutrality Strategy for Events

## **Green Chemical Screening and Assessment**

- GreenScreen Evaluation and Certification
- > Toxicological Risk Assessment (TRA)
- ChemFORWARD Evaluation and SAFER Certification > EU Safe and Sustainable by Design (SSbD)

# **Other Services**

- > Life Cycle Assessment (LCA)
- Industry Researching Report
- > Emission Reduction Path Planning
- Customized Training and Research Services
- Policy Tracking and Interpretation



In 2015, UN Member States translated their vision of sustainable development into a blueprint for achieving it: the 2030 Agenda for Sustainable Development.

### **A LOOK BACK AT 2024**

## ADVANCING EXPERTISE AND FOSTERING INDUSTRY COLLABORATION







## REACH24H: Asia's First ChemFORWARD Accredited Assessor for Safer Chemistry

Following GreenScreen certification, REACH24H became Asia's first and currently only ChemFORWARD Accredited Assessor. We provide a comprehensive suite of ChemFORWARD substance evaluation and SAFER™ label application services, aiding companies in their sustainable transformations.





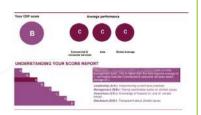
## Assisting an Enterprise in Securing EcoVadis Gold Rating

In 2024, REACH24H helped enterprises develop a clear sustainability strategy by providing detailed and precise supporting documents and data. This professional guidance enabled a company to successfully achieve the EcoVadis Gold Medal, thereby enhancing its global market competitiveness and expanding its market opportunities.



#### **Elevating CDP Scores Across Industries**

REACH24H successfully assisted multiple enterprises in achieving significant improvements in their Carbon Disclosure Project (CDP) scores across various industries. Notably, we helped a leading cosmetics supplier improve its score from a D in 2022 to a B.





#### Delivering In-Depth Sustainability Research Reports

We provided tailored sustainability research reports to multiple enterprises, offering comprehensive analyses of global sustainability policies, industry standards, and best practices. These reports equip companies with the insights needed to understand global sustainability trends and strategically prepare for the future.

#### Offering Insights in Safer Chemicals at the BizNGO Annual Meeting

REACH24H was honored to participate in the BizNGO Annual Meeting, hosted by the Clean Production Action (CPA) in the US. We engaged in discussions with government representatives, leading consumer goods companies, and financial institutions on topics such as green assessments, chemical footprints in supply chain management, and integrating UN chemicals management programs and indicators.





## REACH24H

# EHS CONSULTING \*\* & SAFETY MANAGEMENT SOLUTIONS

## **EHS CONSULTING & SAFETY** MANAGEMENT SOLUTIONS

With over 20 years of experience serving globally renowned chemical enterprises, Haifan Technology Co., Ltd. (a subsidiary of REACH24H) specializes in providing EHS consulting, process safety risk assessment, and digital solutions for the chemical industry.

#### CHEMWISE: Intelligent Chemical Management System

70,000+ Chemical Substances 150+ Models

Contained in the chemical database

Supported for Chemical Safety Assessment

Offering integrated solutions for the "One Enterprise, One Product, One QR Code" Policy

#### RISKWISE: Intelligent Risk Management System



#### **EHS Compliance**

- EHS Compliance Auditing
- EHS Regulatory Database
- · Laboratory Safety Management
- Supplier Compliance Audit

#### Process Safety Management ...



- Hazard Zoning Services
- PSM Audits and Training
- PSM Services
- Static Electricity and Ignition Source Analysis
- Dust Hazard Assessment
- · HAZOP, LOPA, and SIL

#### **Transport and Storage**



- · Lithium Battery Transport and Storage **Compliance Consulting**
- · Comprehensive Lithium Battery Safety Management
- Cargo Hazard Assessment and Transport Certification
- DG Packaging/Transport Consulting and Training
- Chemical Incompatibility Analysis

#### **A LOOK BACK AT 2024**

## ADVANCING EXPERTISE AND FOSTERING INDUSTRY COLLABORATION

#### Establishing Standards for Hazardous Chemical Management

Collaborating with the National Registration Center of Chemicals (NRCC) of China's Ministry of Emergency Management, Haifan has helped develop group standards for hazardous chemical coding and labeling. By integrating QR code technology and practical examples, they co-released the "Technical Specifications for Hazardous Chemicals Coding and Labeling" (T/CCSAS 047-2023).

This standard is now a key reference for managing hazardous chemicals in China using electronic QR codes. It outlines the principles and structure for coding, information labeling, and usage requirements across production, storage, transportation, operation, and use.



## Government-Recognized Innovation in Chemical Management

Haifan completed Shanghai's first "One Enterprise, One Product, One QR Code" application case. We were invited to share this case study and system demonstration with hazardous chemical enterprises. Our project, "Integration of QR Code Technology to Enhance Enterprise Chemical Management," was shortlisted for the Best Case Award by the Chinese government.



02

#### Advancing Process Safety with Customized Digital Risk Management Solutions

03

We provided customized RISKWISE risk management systems for over 30 chemical enterprises, enabling the digitalization of HAZOP (Hazard and Operability Study) reports. This allows enterprises to independently conduct HAZOP risk analyses, making analysis results easily accessible and updatable for engineers and staff at all levels. This significantly improves process safety management across entire industrial parks.

Wise HAZOPing



Wise Embedding



Wise Managing







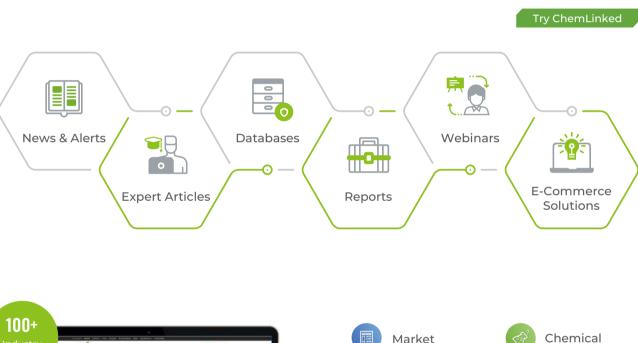
## REACH24H

# REGULATORY ALERTS \* AND MARKET INTELLIGENCE - CHEMLINKED



As a leading service provider of comprehensive regulatory information and compliance solutions, REACH24H launched ChemLinked in 2012, targeting global companies, professionals, government bodies, etc., pharmaceutical: involving the chemical, food, cosmetic, agrochemical and pharmaceutical industries, to meet the growing demand for clear and concise regulatory advice and market intelligence in Asia, especially China.

ChemLinked boasts a multidisciplinary team of scientists, compliance specialists, and language experts backed by the vastly experienced technical teams at REACH24H ensuring the members acquire authoritative information and dependable consultancy services from highly experienced regulatory experts.





#### A LOOK BACK AT 2024

## ADVANCING EXPERTISE AND FOSTERING INDUSTRY COLLABORATION

#### .

#### Building an Integrated Business Service Platform

Over years of development, ChemLinked has evolved from a simple information provider to a comprehensive service platform, offering regulatory alerts, market research, and compliance support. It has become an integrated hub that combines media insights with business services.

In 2024, ChemLinked supplied regulatory alerts and market research reports to leading international companies across more than 10 countries. With its global perspective and expertise across diverse sectors, it offers robust support for their international market strategies.

#### Innovative Tools for Global Food Compliance

Leveraging its technical expertise and IT development capabilities, ChemLinked boosts user efficiency and accuracy by providing rapid access to product compliance conclusions and references via its regulatory database.



#### Try FoodCheck

To assist companies in efficiently navigating global food compliance challenges in 2024, ChemLinked has introduced two innovative tools: the Al-driven compliance Q&A system, QME, and the comprehensive global food compliance search tool, FoodCheck.



## REACH24H

## GLOBAL CONNECTION: CRAC GLOBAL 2024





## 16TH CHEMICAL REGULATORY ANNUAL CONFERENCE

In 2024, REACH24H successfully hosted the 16th Chemical Regulatory Annual Conference (CRAC Global 2024), drawing over 600 participants from government agencies, global organizations, media, and businesses worldwide. The conference centered on key topics such as global chemicals, pesticides, cosmetics, and green sustainability. Attendees exchanged insights on industry developments and market trends, exploring sustainable and innovative growth pathways.

The CRAC, organized annually by REACH24H, aims to foster industry exchange and collaboration. It seeks to partner with industry leaders to explore new development opportunities and models, promoting extensive global cooperation to address worldwide challenges.

Click to Download the Report

#### CRAC China















#### CRAC Korea





#### CRAC Japan





#### • CRAC Europe









#### **CRAC 2024 IN NUMBERS**

Key Topics	<ul> <li>Global Chemical Compliance Management</li> <li>Safer Alternatives and Sustainable Development</li> <li>Global Pesticides Registration and Market Analysis</li> <li>Global Cosmetics Regulatory Compliance Strategy</li> </ul>
Global Conferences	<ul> <li>CRAC China - Nanjing, China</li> <li>CRAC Korea - Seoul, South Korea</li> <li>CRAC Japan - Tokyo, Japan</li> <li>CRAC Europe - Agrochemical Session - Cologne, Germany</li> <li>CRAC Europe - Chemical Session - Munich, Germany</li> </ul>
Guest Speackers	Oovernment Agencies     Industry Associations     International Organizations      Academic Representatives     High-Profile Companies
600+ Global Participants	<ul> <li>Government Officials</li> <li>Industry Associations</li> <li>International Organizations</li> <li>Academic Representatives</li> <li>Enterprise Representatives</li> <li>Media Representatives</li> </ul>



Industries of Conference Attendees

Organizations of Conference Attendees

# REACH24H\* REACH24H\* RESPONSIBILITIES

## SAFEGUARDING CLIENTS INTERESTS

Trade secrets are essential to an enterprise's competitiveness and are directly tied to its market position and growth potential. REACH24H places strategic emphasis on protecting corporate business information and trade secrets through robust measures.

In 2024, REACH24H Consulting Group was recognized by the Chinese government as a Trade Secret Protection Model Company.

#### Trade Secret Protection Model Company

REACH24H Consulting Group, acknowledged by the Chinese government as a Trade Secret Protection Model Company, underscores its commitment to high service standards and the protection of business interests.







#### Specialized Trade Secret Protection Team

We have established a Trade Secret Protection Task Force, a dedicated team tasked with designing, implementing, and monitoring trade secret management strategies. This involves defining roles and responsibilities for all employees, establishing detailed operational workflows, and preparing emergency response plans.

To ensure seamless implementation of safeguards, we have hired trained specialists who conduct regular audits, compliance checks, and employee training sessions. This approach fully protects client information and secures business interests.

Furthermore, we have a Trade Secret Protection Office specifically designed for high-level projects, equipped with stringent security measures to ensure robust information protection.



#### Comprehensive Confidentiality Policies and Measures

- Comprehensive Policies: We have established robust confidentiality policies that include employee confidentiality agreements, contract management systems, information security protocols, and crisis-handling measures. These guidelines ensure every team member understands their responsibilities and adheres to strict standards.
- Risk Assessment Mechanisms: We perform regular risk assessments and compliance checks to identify potential risks. This process involves evaluating workflows, addressing risks, and implementing preventive and corrective actions to maintain system integrity.
- Legal Support from Lawyers: We collaborate with legal experts to ensure our policies and procedures comply with the latest regulations and align with industry standards.



#### Advanced Technological Safeguards

- Cutting-Edge Security Tools: We utilize advanced technologies, including data classification, encryption, access control, and robust network security measures, to protect sensitive data. These systems are specifically designed to effectively prevent unauthorized access and data breaches.
- Real-Time Monitoring: Our real-time monitoring system continuously tracks the access and sharing of sensitive information. This capability enables us to immediately detect any irregularities and swiftly implement corrective actions when necessary.



#### Continuous Employee Training and Engagement

- Industry Engagement: We actively participate in trade secret protection forums and industry events to exchange insights, adopt best practices, and stay ahead of evolving challenges.
- Employee Training and Awareness: We provide employees with regular training on confidentiality measures, ensuring staff remain aware of and equipped to handle changing information security needs. Through internal newsletters, posters, and other communication tools, we foster a workplace culture that values confidentiality and actively prioritizes the protection of trade secrets.

#### **CARING FOR EMPLOYEES**

At REACH24H, we have long embraced a people-oriented management philosophy, fostering a culture of sincerity, unity, trust, and efficiency. We are committed to creating a diverse, equitable, and inclusive workplace where every employee is respected and valued. To support this, we implement measures and systems to protect employee rights and offer long-term career development strategies that facilitate personal and career growth.



#### **Comprehensive Learning and Training Opportunities**

#### Onboarding and Skill Mastery Program

We provide customized courses designed to help new employees acclimate to the work environment and master essential workflows and skills.





#### **Enhancing Professional Expertise and Skills**

We consistently create learning opportunities to foster continuous development. Annually, we offer training and encourage our employees to pursue toxicologist certification.

In 2024, we have six newly certified toxicologists who will support businesses across various industries by conducting toxicological evaluations and risk assessments, thereby enhancing global compliance standards.



#### **Customer Service Training**

We prioritize the "Think Customer" philosophy by utilizing diverse training programs to enhance our employees' customer service skills.

Our annual "Moment of Truth" (MOT) training emphasizes effectively managing each customer interaction to ensure clear communication and exceptional service.

MOT (Moment of Truth), introduced by Jan Carlzon, former CEO of Scandinavian Airlines, refers to brief but impactful moments during customer interactions that significantly influence overall impressions.



Moment of Truth (MOT) Training

#### **Diverse Courses and Trainings**



**Business English Training** 





First Aid and Safety Training



**Practical Life Skills Workshops** 



#### Creating a Healthy Work Environment

#### RFACH24H Book Club





#### Company Outing





#### REACH24H Activities









#### **CONTRIBUTING TO SOCIETY**

REACH24H actively participates in various charitable activities, consistently supporting rural education development and caring for left-behind children and the elderly living alone. We strive to give back to society and contribute to social progress through tangible actions.



In 2023, REACH24H visited Xinxing Primary School in Yunnan Province, China, to conduct volunteer teaching activities, sharing courses, books, and love to inspire hope and dreams in the children.



In June 2024, we received a heartfelt gift from the school: handmade mugwort sachets crafted by teachers and students. This thoughtful gesture traveled 2,500 kilometers from Yunnan to Hangzhou, filled with care and blessings.

Throughout 2024, REACH24H has maintained contact with the school, offering support in various ways.



For two consecutive years, REACH24H has supported farms in overcoming the challenge of unsold fruit by donating to sanitation worker rest stations and offering it as employee benefits.





In 2024, REACH24H responded to the government's call by donating to the "Great Love Fund" project, aimed at addressing the living difficulties faced by food delivery workers, couriers, and ride-hailing drivers.



In June 2024, REACH24H held a "Lighten the City" charity hike, where employees picked up litter along the way.

REACH24H is dedicated to green operations by implementing energy-saving measures and encouraging staff to adopt eco-friendly habits like green commuting and going paperless.





## REACH24H

# 2025 REGULATORY \* INSIGHTS: KEY UPDATES FOR INDUSTRIES



## China: Legislative Progress on Environmental Risk Management of Chemical Substances Under New Pollutants Treatment

China continues to prioritize the environmental risk management of chemical substances, as emphasized by the *Action Plan for New Pollutants Treatment* and the Legislative Work Plan of the State Council in 2024. The Ministry of Ecology and Environment (MEE) has been working with the Ministry of Justice to advance the "*Regulation on Environmental Risk Management of Toxic and Hazardous Chemical Substances*" (Draft). The final regulation will introduce differentiated management measures for new and existing chemical substances based on environmental risks.

#### **Compliance Alert:**

Stay ahead of regulatory changes in 2025. Assess your compliance requirements early to minimize risks, especially those affecting your supply chain.

## China: Proposed "Law on Hazardous Chemicals Safety (Draft)" Expected to Impact Chemical Handling in 2025

In 2024, China released a draft of the "Law on Hazardous Chemicals Safety" for public consultation. The law, once enacted, will impose stricter safety management requirements for entities involved in the production, storage, use, and transport of hazardous chemicals. Key measures include safety condition reviews, license management, emergency response protocols, and online monitoring of major hazard sources.

#### **Compliance Alert:**

Companies must conduct self-assessments and ensure full implementation of safety production measures to avoid potential legal and financial risks from non-compliance.

## China: New Mandatory National Standard for Road Transport of Dangerous Goods to Take Effect in 2025

China's *Vehicle Mark for Road Transportation Dangerous Goods* (GB 13392-2023) standard will come into effect on April 1, 2025. This new regulation mandates specific labeling for vehicles transporting dangerous goods.

#### **Compliance Alert:**

Review the content and marking criteria of the GB 13392-2023 standard to ensure compliance before the mandatory implementation date.

## Taiwan Region: Potential Update to Prohibited Chemical Substances List in 2025

Taiwan Region is expected to update its list of prohibited chemical substances in 2025, impacting industries such as cosmetics, medical devices, and electronics. These changes may align with international standards such as the EU REACH regulation.

#### **Compliance Alert:**

Monitor closely updates to the Taiwan Region's prohibited substances list. Adjust formulations and supply chains as needed to ensure compliance with new restrictions.

#### Korea: Changes to K-REACH New Substance Notification Requirements in 2025

As of January 1, 2025, the tonnage threshold for new substance notifications under K-REACH has increased from 0.1 tons/year to 1 ton/year. Additionally, Korean authorities are set to implement more detailed classifications for existing toxic substances, including their acute human toxicity, chronic toxicity, and environmental risks.

#### **Compliance Alert:**

For substances previously registered under the lower tonnage threshold, or those that require new notifications, companies should ensure they meet the updated requirements. Pay attention to the classification and validation rules from Korean authorities.

#### India: BIS Certification Requirement for Electrical Appliances Starting March 2025

India has issued the 2024 Quality Control Order (QCO) for household, commercial, and similar electrical appliances, requiring BIS certification for products entering the market. The QCO will come into effect on March 17, 2025.

#### **Compliance Alert:**

Ensure your electrical appliances are BIS-certified before export to India to avoid market entry delays and disruptions. Review the Indian standards and complete certification in advance.

#### EU: ECHA's 2025 Enforcement Priorities Focus on Imports and Online Sales

The ECHA's Enforcement Forum has set out its plan and enforcement priorities for 2025, including controls on imports, online sales, and the classification and labeling requirements for mixtures, including biocides. The Forum also started work for the next EU-wide harmonised enforcement project (REF-14) that focuses on ensuring compliance with classification and labeling requirements for hazardous mixtures in consumer products like electronic cigarettes or air fresheners.

The Forum also agreed that its next pilot enforcement project will focus on only representatives (OR) who register imported substances, including those in mixtures.

## EU: New CLP Regulation Requires Hazard Classification for Endocrine Disruptors and PBM Substances by 2025

The updated *EU Classification*, *Labelling*, *and Packaging (CLP) Regulation*, which includes new categories for Endocrine Disrupting Chemicals (EDCs) and substances with Persistent, Bioaccumulative, and Mobile (PBM) properties, is now in effect. Substances must be classified according to these new categories by May 1, 2025.

#### **Ukraine: REACH Regulation Comes Into Force in 2025**

Ukraine's *Technical Regulation on Chemical Safety* (Ukraine REACH) will officially take effect on January 26, 2025. Pre-registration will begin on that date and last for one year, with a deadline of January 26, 2026.

#### **Compliance Alert:**

Companies trading in Ukraine should prepare for the pre-registration process, especially for substances requiring high-tonnage registration. Engage with service agencies early to ensure compliance and avoid registration delays.

#### USA: TSCA Reporting Requirements for PFAS Begin in 2025

Under the final PFAS reporting rule of the *Toxic Substances Control Act* (TSCA), companies must report information regarding PFAS or PFAS-containing products manufactured or imported between 2011 and 2022. The reporting period will begin on July 11, 2025, and will last for six to twelve months.

#### **Compliance Alert:**

Companies should trace all trade records for PFAS-containing products and confirm their content. Ensure timely submission of PFAS data to the US EPA to meet reporting deadlines and mitigate compliance risks.

#### USA: GHS Hazard Classification and Labeling Update Due by 2026

The U.S. Federal Register has updated the *Hazard Communication Standard (HCS)*, including provisions for reduced-size hazard labels for small containers. SDS and labeling updates must be completed by January 19, 2026.

#### **Compliance Alert:**

Companies must revise Safety Data Sheets (SDS) and labels according to the new HCS standards. Additional modifications may be required for proper classification and labeling of hazardous substances like flammable gases or explosives.



#### China: Expected Amendments to Pesticide Registration Regulations in 2025

In November 2024, China's Ministry of Agriculture and Rural Affairs proposed amendments to key pesticide regulations, including the "*Measures for the Administration of Pesticide Registration*," "*Administrative Measures for Pesticide Production Permits*," "*Administrative Measures for Pesticide Labels and Instructions*," "*Administrative Measures for Pesticide Registration Studies*," and "*Administrative Measures for Pesticide Business Permits*."

#### **Compliance Alert:**

Track these regulatory updates and ensure that your business complies with any new requirements set to take effect in 2025.

#### EU: New Pesticide Regulations on Safeners and Synergists

The European Union has introduced new evaluation criteria for safeners and synergists in plant protection products, aligning approval requirements with those for active substances.

- Notifications for additional safeners or synergists used in plant protection products authorized in at least one Member State must be submitted by 19 December 2024.
- Applications for the approval of safeners or synergists listed in the non-exhaustive list can be submitted for inclusion in the gradual review program by 19 June 2025.

#### **Compliance Alert:**

Safener and synergist data are anticipated to become as critical as active substance data. Companies should proactively develop compliance strategies and adhere to key regulatory timelines to stay competitive.

#### EU: Withdrawal of PPP Authorisations on Active Substances by 2025

- Acibenzolar-S-methyl: Approval expires on January 10, 2025
- Fenpyrazamine: Approval expires on January 15, 2025
- Flumetralin: Approval expires on January 15, 2025
- Tritosulfuron: Approval expires on May 7, 2025
- Metribuzin: Approval expires on May 24, 2025

#### **Compliance Alert:**

Review your product formulations to ensure that they do not contain any banned substances and adjust formulations as needed to remain compliant.

#### EU: Potential Expiration of Approvals for Three Active Substances in 2025

Several active substances, including Bentazone and Propyzamide, will see their approval expire in 2025.

- Bentazone: Approval review expires on May 31, 2025
- Propyzamide: Approval review expires on June 30, 2025
- Sulfoxaflor: Approval review expires on August 18, 2025 (use restricted to permanent greenhouses only)

#### **Compliance Alert:**

No renew applications have been submitted for these substances to date. Without industry support, these substances will transition to "non-approved" status upon expiration. Companies are advised to check if their EU-bound pesticide products contain these substances and prepare accordingly to avoid trade disruptions.

## USA: EPA Updates and Implements Endangered Species Act Workplan to Accelerate Pesticide Review

In 2024, EPA issued several reports that provide scientific assessments and risk management strategies for addressing potential risks to endangered species from herbicides, insecticides, and rodenticides. Updates to the evaluations of the pesticides are expected to continue throughout 2025.

#### **Compliance Alert:**

Businesses must monitor the EPA's updates on pesticide evaluations, revise product labels accordingly to include endangered species protection requirements and risk mitigation measures, and reference the EPA's quidance resources to ensure regulatory compliance.

#### USA: Enhanced Pesticide Drift Management Restrictions in 2025

Pesticide drift risk evaluation will remain a focal point of the EPA's human health and ecological risk assessments in 2025. As part of its updated pesticide registration process, the agency now requires earlier protections for people from pesticide spray drift during new active ingredient registrations and new use decisions.

#### **Compliance Alert:**

- Adjust Product Portfolios: Develop drift-reducing pesticide products based on local crop cultivation and pesticide application scenarios.
- Revise Product Labels: Modify labels in line with EPA risk assessments to reduce pesticide drift risks effectively.
- Monitor Regulatory Dynamics: Stay informed about the latest federal and state regulatory policies and adjust business strategies timely.

## DISINFECTANTS & BIOCIDES

## Korea: New K-BPR Regulations for Household Chemical Products to Take Effect on January 1, 2025

The Ministry of Environment in Korea has announced the implementation of the revised "Amendment to Safety and Labeling Standards for Consumer Chemical Products" (MOE No. 2024-139), effective January 1, 2025. The update expands the scope of restricted and banned substances and introduces changes to labeling standards.

#### **Compliance Alert:**

Companies must comply with the new regulations when declaring or updating products under the K-BPR framework to maintain market access in Korea.

- Existing products must adhere to the new rules upon their next update or declaration.
- For new products, full compliance with all requirements of the amended regulation is mandatory after the effective date.

#### **UK: Potential New Regulatory Requirements for Disinfectant Products**

Post-Brexit, the UK has been gradually introducing new regulatory requirements for disinfectant products, and the Health and Safety Executive (HSE) is working to update the regulatory framework. These changes are expected to include targeted requirements tailored to the UK market.

#### **Compliance Alert:**

Companies may need to make additional adjustments to product registration and compliance strategies to ensure that their disinfectant products meet the UK market's specific requirements.



## China: Full Version of Cosmetic Safety Assessment Dossiers Required from May 1, 2025

Starting May 1, 2025, all cosmetic registrants and notifiers in China will be required to submit a full version of safety assessment dossiers in compliance with the *Technical Guidelines for Cosmetics Safety Assessment* (2021) and other relevant regulations during registration or notification applications.

## China: 2025 Compliance Preparation for Simplified Notification of Toothpaste Products

For toothpaste products subject to simplified notification, notifiers must complete the following requirements before December 1, 2025:

#### • Notification Dossier Organization:

Products launched before January 1, 2021, may self-archive their notification materials; however, for products launched after this date, notifiers must submit complete materials via the notification platform.

#### • Efficacy Claim Evidence Publication:

Except for toothpaste products claiming only cleansing effects, notifiers must upload and publish evidence supporting efficacy claims on the platform.

#### China: New Testing Methods for Cosmetics Effective July 1, 2025

Effective July 1, 2025, five new and replacement testing methods will be implemented for cosmetic registration, notification, and sample testing in China:

- New supplementary testing method: For azelaic acid and its salts, phenacetin, and hydroxycapric acid.
- Revision of testing method: For Asbestos, and glucuronic acid & 14 other ingredients.

#### EU: Multiple Substances to be Prohibited or Restricted in Cosmetics from 2025

#### Nanomaterial Restrictions:

From February 1, 2025, cosmetics containing the following nanomaterials will no longer be allowed on the EU market:

- Styrene/acrylates copolymer (and its sodium form)
- Copper, colloidal copper, colloidal silver, gold, colloidal gold, thioethylamino hyaluronic acid gold, acetyl heptapeptide-9 colloidal gold, platinum, colloidal platinum, acetyl tetrapeptide-17 colloidal platinum.

These substances must be removed from the market by November 1, 2025.

#### • Retinol and Derivatives (retinol, retinyl acetate, retinyl palmitate):

Non-compliant products will be prohibited from market placement from November 1, 2025, and from sale after May 1, 2027.

#### • Triclocarban and Triclosan:

Products on the market before December 31, 2024, that comply with the April 23, 2024, conditions can be sold until October 31, 2025.

#### Homosalate:

Non-compliant products will be prohibited from market placement starting January 1, 2025, and from sale by July 1, 2025.

• Other Restricted Substances (e.g., hydroxyapatite, genistein, daidzein, kojic acid, alpha-arbutin, arbutin): Products containing these substances will be prohibited from market placement from February 1, 2025, and from sale after November 1, 2025.

#### **Compliance Alert:**

Verify whether your cosmetic products for export to the EU contain any of these prohibited or restricted substances, and make the necessary adjustments before the deadlines to avoid trade disruptions.

#### EU: 21 CMR Substances to be Prohibited in Cosmetics from 2025

As part of the amendment to the EU CLP Regulation (EU 2024/197), 21 new Carcinogenic, Mutagenic, or Reprotoxic (CMR) substances will be banned in cosmetics starting September 1, 2025.

#### **Compliance Alert:**

Companies should review their product formulations and ensure compliance with the new CMR substance restrictions to avoid market access issues. For detailed substance information, please contact REACH24H at customer@reach24h.com.

#### **USA: 2025 MoCRA Regulatory Updates**

• FDA Proposed Rules on Asbestos Detection in Talc-Containing Cosmetics (Deadline: March 27, 2025):

On December 26, 2024, the FDA issued proposed rules outlining testing methods for detecting asbestos in talc-containing cosmetics. Companies are encouraged to submit comments by the deadline.

#### FDA MoCRA GMP Draft Delayed:

The release of the MoCRA Good Manufacturing Practices (GMP) draft and fragrance allergen disclosure rule has been postponed until October 2025.

#### MoCRA Product Listing Requirements:

Companies must ensure timely annual updates of product listings in 2025, as part of the requirements under MoCRA.



#### China: First National Standard for Food Contact Adhesives to Be Implemented in 2025

In 2024, China introduced its first national standard for food contact adhesives, GB 4806.15-2024, titled *National Food Safety Standard Adhesives for Food Contact Materials and Articles.* The regulation will come into effect on February 8, 2025.

#### **Compliance Alert:**

Adhesives used with food-contact materials must be safety evaluated, considering both the adhesive and substrate interactions, to ensure regulatory compliance.

#### Japan: Revised Standards for Food and Food Additives to Be Released in 2025

Japan has released a draft revision of the *Specification and Standards for Food, Food Additives, Etc.* in 2024. The updated standards will address food simulant liquids, testing methods, and material specifications. The final version is expected to be published in mid-2025.

## Japan: Transition Period for Positive List of Food Contact Synthetic Resins Ends in 2025

The Japanese Ministry of Health, Labour, and Welfare (MHLW) has established a five-year transition period for the positive list of synthetic resins used as primary materials in food utensils, containers, and packaging. This transition period will end on May 31, 2025, at which point Japan will have completed safety evaluations for all "existing substances" and updated the final Positive List.

#### EU: BPA Ban in Food Contact Materials to Take Effect in 2025

The European Commission has formally adopted a regulation banning the use of Bisphenol A (BPA) in food contact materials, which will come into force on January 20, 2025, with an 18-month transition period. This ban will impact products such as metal can coatings, plastic beverage bottles, and adhesives in contact with food or beverages.

#### Switzerland: Updated Food Contact Materials Regulation Effective in 2025

On December 9, 2024, Switzerland's updated two annexes in the nation's food contact materials regulation (SR 817.023.21), came into force on January 1, 2025. This revision aligns Switzerland's food contact material legislation with the latest EU regulations, particularly *Regulation (EU) No. 10/2011* concerning plastics.



#### China: New Food Labeling Standards to Be Released in 2025

China is expected to release the revised versions of two important food labeling standards in 2025:

- GB 7718 General Standard for the Labeling of Prepackaged Food
- GB 28050 General Rules for Nutrition Labeling of Prepackaged Foods

These revisions will likely be accompanied by the Regulations on Food Labeling Management. The new standards aim to update and refine food labeling requirements for both domestic and imported food products.

#### EU: New Novel Food Application Guidelines to Take Effect in 2025

The European Food Safety Authority (EFSA) has updated its guidelines for novel food applications. These revised documents clarify definitions and data requirements to improve the quality of submitted dossiers and streamline safety risk assessments. The new guidelines will officially come into effect on February 1, 2025.

#### USA: FDA's Revised "Healthy" Claim Rule to Take Effect in 2025

On December 19, 2024, the FDA issued a final rule updating the definition of the "healthy" nutrient content claim, aligning it with current nutritional science and the Federal Dietary Guidelines. Manufacturers choosing to use this claim have three years to comply but may adopt the new criteria sooner.

The new rule will take effect on February 25, 2025. Manufacturers choosing to use this claim have three years to comply but may adopt the new criteria sooner. The FDA plans to release additional guidance by February 2028 to assist businesses with compliance.



#### China: Health-Based Exposure Limits (HBEL) for Co-Production Risk Assessments

Health-Based Exposure Limit (HBEL) based risk assessments are gaining prominence in China due to their scientific rigor. The use of HBEL allows for more reliable evaluations and can reduce the risk of secondary assessments. Ensuring comprehensive and accurate HBEL reports will be crucial for the smooth progression of production and research projects.

#### **Compliance Alert:**

Pharmaceutical companies should ensure including PDE (Permitted Daily Exposure) reports in the risk assessment when manufacturing medicinal products in shared facilities and that these PDE reports adhere to the required standards. Ensuring compliance now will avoid complications during GMP audits.

#### China: 2025 Edition of the Chinese Pharmacopoeia to Be Released

The 2025 edition of the *Chinese Pharmacopoeia* (Pharmacopeia of the People's Republic of China) is expected to be published in March 2025 and implemented in October 2025. This updated version will introduce new standards and requirements for drug production and testing.

#### **Compliance Alert:**

Pharmaceutical companies should closely monitor the release of the 2025 edition and adjust their operations in line with the new requirements to ensure full regulatory compliance once the new edition is implemented.

## China: New Regulations on Pharmaceutical Excipients and Packaging Materials to Be Enforced in 2025

On January 2, 2025, China's National Medical Products Administration (NMPA) released two appendices to the *Good Manufacturing Practice for Pharmaceutical Products (2010 Revision)*, specifically targeting **pharmaceutical excipients** and **packaging materials** respectively. These appendices will come into effect on January 1, 2026.

#### **Compliance Alert:**

Pharmaceutical companies involved in the production of excipients and packaging materials should begin updating their facilities and quality management systems to meet the new regulatory requirements before the January 2026 deadline.

#### China Standardizes Requirements for Domestic Responsible Persons Designated by Overseas MAHs

On November 14, 2024, China's National Medical Products Administration (NMPA) issued the *Interim Provisions on the Management of Designated Domestic Responsible Persons by Overseas Marketing Authorization Holders (MAH) of Drugs.* 

The Provisions establish a comprehensive framework for the qualifications and requirements of domestic responsible persons designated by overseas drug MAHs and provide clear guidelines for reporting information about domestic responsible persons.

Effective July 1, 2025, all overseas-manufactured drugs must adhere to the Provisions, including the inclusion of the domestic responsible person's name, address, and contact details on the drug package insert.

## China: New Re-registration Requirements for Domestic Manufactured Drugs Starting in 2025

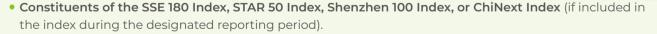
On October 11, 2024, China's National Medical Products Administration (NMPA) published the *Application Procedures and Documentation Requirements for the Re-registration of Domestically Produced Drugs*, effective January 1, 2025.

## SUSTAINABILITY DEVELOPMENT

#### **China Issues Corporate Sustainability Reporting Guidelines**

In April 2024, all three of China's securities exchanges issued their respective *Corporate Sustainability Reporting (CSR) Guidelines*, which took effect on May 1, 2024.

These guidelines require:



• Dual-listed companies in both China and abroad (referred to as "Covered Companies").

These companies are required to prepare and publicly disclose a **corporate sustainability report** covering the 2025 calendar year by April 30, 2026.

The CSR Guidelines also encourage other listed companies on these exchanges to voluntarily adhere to the guidelines. The guidelines align with international standards while addressing specific considerations relevant to China.

#### **Compliance Alert:**

- Establish ESG governance structures and develop an ESG indicator system based on the *Guidelines* and *Sustainability Report Preparation Guide (Draft)*.
- Collect relevant information and prepare to disclose the sustainability report alongside the annual report in 2026.

#### EU: CBAM Transition Period Ends in 2025

On December 17, 2022, MEPs and EU governments reached a deal to reform the Emissions Trading System. As determined by the agreements, the transition period for CBAM will end by the end of 2025. The definitive period will start on January 1, 2026.

This transition will involve additional verification steps, where companies must submit data to down-stream customers that will be subject to third-party verification. Furthermore, customers must purchase CBAM certificates based on the implied carbon emissions of imported goods.

#### **Compliance Alert:**

- Develop data monitoring systems to ensure accuracy and verifiability.
- Engage professional agencies for training on calculating implied carbon emissions and smooth third-party verification.
- Identify key areas for emission reduction and implement energy-saving measures to lower product carbon footprints and enable broader international market access.

## EU: New CO<sup>2</sup> Emission Performance Standards for Cars and Vans Starting in 2025

In January 2025, the EU will implement new CO<sup>2</sup> emission standards for passenger cars and light commercial vehicles (vans). Under *Regulation (EU) 2023/851 and Regulation (EU) 2019/631*, the EU fleet-wide CO<sup>2</sup> emission target for new passenger cars is set at 95g CO<sup>2</sup>/km, while the target for vans is 147g CO<sup>2</sup>/km.

#### **Compliance Alert:**

- Develop vehicles that meet new EU environmental standards, with increased focus on electric and hybrid vehicles.
- Adopt advanced emission monitoring technologies for real-time tracking.
- Build long-term supplier partnerships to drive sustainable technology development

#### EU: New Battery Regulation to Replace the Batteries Directive in 2025

The New Batteries Regulation, *REGULATION (EU) 2023/1542*, which came into effect on August 17, 2023, will officially replace the existing *Battery Directive 2006/66/EC* by August 18, 2025. This regulation imposes stricter sustainability requirements on battery manufacturers, including the calculation and disclosure of carbon footprints, with a focus on light means of transport (LMT) batteries.

#### **Compliance Alert:**

- Adopt official methods for calculating and disclosing greenhouse gas emissions across the battery lifecycle.
- Ensure upstream suppliers provide accurate carbon footprint data.
- Comply with new standards for hazardous substances, CE labeling, electrochemical performance, and durability.

#### EU: New EU Deforestation Regulation Delayed to 2025-2026

In 2023, the *Regulation on Deforestation-Free Products (EUDR)* entered into force, targeting the consumption of deforestation-free products to reduce the EU's impact on global deforestation and forest degradation.

The primary driver of deforestation is the expansion of agricultural land for commodities such as **cattle**, **wood**, **cocoa**, **soy**, **palm oil**, **coffee**, **rubber**, and related derived products.

The implementation dates are set for late 2025 for large enterprises and June 30, 2026, for small and micro enterprises.

#### **Compliance Alert:**

- Companies should determine whether their products are directly affected by the EUDR based on the CN codes.
- Record all relevant information regarding product production and supply chains, including raw material sources, manufacturing processes, and transportation methods.
- Collect documentation such as land use certificates and environmental compliance certifications and submit due diligence statements.
- Establish strong communication and cooperation mechanisms with the value chain to promote green and sustainable production practices.



## VALUE IN COMPLIANCE

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