

CRAC-HCF

13th Chemical Regulatory Annual Conference
& Asian Helsinki Chemicals Forum

REACH24H ×



Post-Forum Report

November 08-12, 2021 | Virtual Week

CRAC-HCF2021



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About CRAC-HCF 2021 Virtual Week

The Partnership That Crosses Borders

The CRAC-HCF represents the joint efforts of **Chemical Regulatory Annual Conference (CRAC)**, an annual conference that ran for 13 years hosted by REACH24H Consulting Group, and the **Helsinki Chemicals Forum (HCF)**, a leading conference organizer on the safety management of chemicals in Europe since 2009, supported by European Chemicals Agency (ECHA), the European Commission (EC) and the European Chemical Industry Council (CEFIC) and a number of Finnish Government ministries.

The strategic cooperation between REACH24H and HCF, kicked off in 2020 with over 9,000 global attendees during the [CRAC-HCF 2020 Virtual Forum](#), bringing more insights on sustainable development of chemical and market trends from a global perspective to the events.

This year the CRAC-HCF 2021 - Virtual Week offered a unique opportunity for top government decision-makers, regulatory experts, industry representatives, academic experts and the non-profit sector from all over the world, to join strategic debates and hear the top voices that shape the way forward for the chemical, pharmacy, laboratory, regulatory and related industries. The debates offered an insight into the increasing complex global equation, global market demand, environmental priorities of cleaner, safer, more reliable, and sustainable products and processes, and challenges for organizations and enterprises.

[Helsinki Chemicals Forum Official Site](#) | [REACH24H Official Website](#)

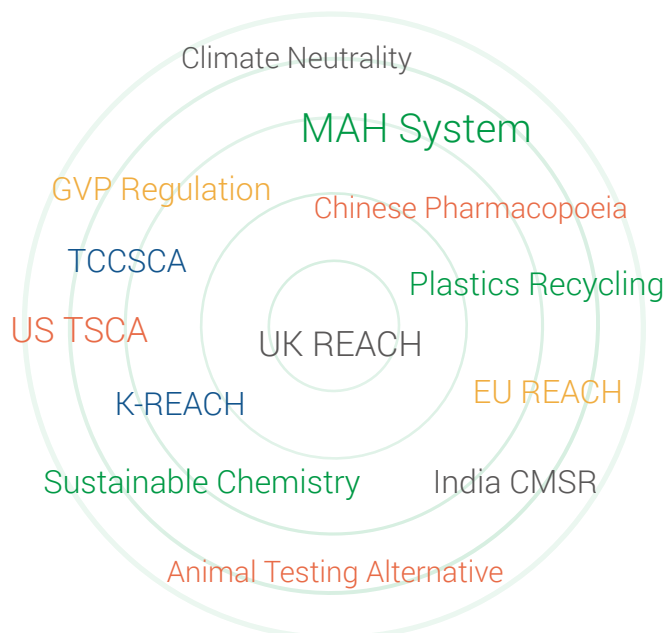
Missed Virtual Week 2021?

Visit the official website to enjoy full access to all panel discussions, and regulatory updates, leave questions and download all the slides to the presentations.

For more, visit the official website of CRAC-HCF 2021:

<https://crac.reach24h.com/crac-hcf2021/>

CRAC-HCF 2021 Virtual Week Integration of Industry Regulatory and Policy Updates





Acknowledgments

CRAC-HCF 2021 received broad attention and positive feedback from a wide range of industries.

We are indebted to our Guest Speakers who shared their knowledge and insights. We also wish to expressly thank CRAC-HCF 2021 Partners, Sponsors and Media Partners who were instrumental to the success of the Forum.

Organizers



REACH24H Consulting Group



Helsinki Chemicals Forum

Partners



United Nations Environment Programme



Organization for Economic Cooperation and Development



European Commission



European Chemicals Agency



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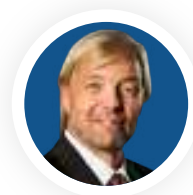


Post-Forum Report Part I: Asian HCF 2021

Opening Speech

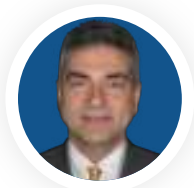
The opening session was addressed by **Mr. Bjorn Hansen, Executive Director of the European Chemicals Agency (ECHA)**.

Mr. Hansen shared some of the main achievements and challenges faced by ECHA as it developed the comprehensive and modern chemicals management system that is REACH today. From the collection of large amounts of data on chemicals, to agreeing on risk assessment principles, REACH has evidenced the level of joint effort required to develop efficient systems to ensure the safety of chemicals. As such, Mr. Hansen shared his hopes that the EU's experience in the implementation of chemicals legislation may aid other countries when developing their own systems.



Panel 1: Green Chemistry and Climate Neutrality

Moderator and Panelists



Mr. Otto Linher
Deputy Head of REACH
Unit, DG Grow
European Commission



Ms. Tatiana Santos
Policy Manager of Chemicals &
Nanotechnology
European Environmental Bureau



Mr. Joel Tickner
Professor
University of
Massachusetts Lowell



Mr. Guanglian Pang
Secretary-General
China Petroleum and
Chemical Industry Federation

Introduction

The European Green Deal is the centerpiece of European Union's ambition to tackle climate and environmental challenges, with a zero net emissions of greenhouse gas emissions (GHG) target set by 2050. The [Chemicals Strategy](#) for Sustainability launched by the European Commission represents its version of a green chemicals policy for the future, aiming to better protect humans and the environment from hazardous chemicals. This is one of the many initiatives around the world seeking to promote, incentivize and put to action greener, safer, and more sustainable chemicals strategies.

Driving Questions

- ▶ Which regulatory tools has the EU chosen to protect citizens and the environment better from the effects of harmful chemicals while stimulating innovation across the industry?
- ▶ Does Europe expect other parts of the world to follow their ambition?
- ▶ How do other world regions like Asia plan to achieve a high standard on chemical safety and waste management at the same time as circular economy and climate neutrality targets?



Highlights from the Keynote and Panel Presentations

- ▶ In the European Union, the chemical industry is responsible for 20% of total industry energy consumption.
- ▶ The new product design for circularity and tracking of hazardous substances is a priority to achieve the decarbonization of the energy system and thus reach climate objectives.
- ▶ The new EU Chemical Strategy for Sustainability includes nearly 80 actions.
- ▶ The expected REACH revision will strengthen the synergies between the management of chemicals and climate change, introducing the Essential Use concept.
- ▶ The European Commission is currently undertaking an impact assessment which will guide the REACH revision, with final adoption and implementation expected for 2023-2025.
- ▶ The environmental footprint will take a more central role in future EU legislation, asking for more information on substitution of most harmful substances from upstream and downstream.
- ▶ China covers more than 40.6% of the total chemical and production of sales globally, expected to reach 50% by 2030. In response, the central government has acted by shutting down 30% of the medium and small size polluting chemical plants and, from energy supply side, gradually shifting to natural gas, and renewables.

Challenges to Face

- ▶ The chemical industry is the sector with the highest energy demand and third largest in terms of CO2 emissions.
- ▶ While it is key to count on the chemical industry as a solution provider, it must also take ownership of the difficulties it has led to.
- ▶ The existence of different risk management systems imposes a challenge in controlling chemical substances and their effects on the environment and consumers.
- ▶ There is a lack of transparency on chemicals found in products, waste and recycled materials throughout the supply chain and to consumers.
- ▶ Only 9% of the billions of tons of plastic produced since 2000 up to 2015 have been recycled, and about 98% of single-use plastics use virgin feed stocks.

Moving Forward

- ▶ The chemical industry must undergo a deep transformation to reach global detoxification and decarbonization targets, with innovation and investment as critical priorities.
- ▶ Trade-offs should not be assumed, instead be seen as innovation challenges.
- ▶ Need to rethink production and support innovation not just in developed but also in industrializing countries.
- ▶ To NGOs, production and consumption need to be scaled down.
- ▶ Industry should approach new chemical designs by including environment and sustainability as a performance characteristic equal with cost and performance.
- ▶ Safe and sustainable chemicals by design must involve the whole value chain, from the retailer to the chemical manufacturer.
- ▶ As chemicals do not offer high margins, required investment by the chemical industry will have to be supported by strategic community investment.
- ▶ Governments should offer clear and transparent guidance, ensuring a long-term vision in all processes.
- ▶ Both incentives for clean production, green economy, etc. and disincentives for uses of chemicals found to be less safe are equally necessary.
- ▶ Assessment of the environmental footprint along the whole life cycle is a game changer for decision making.
- ▶ International cooperation to promote safe and sustainable development of chemical industry is essential.
- ▶ In China, serious measures have already been taken to reduce carbon emission and waste, promote renewables and unconventional fuel, and support technology innovation.
- ▶ With China's 2019-2020 coal consumption levels estimated at 57%, it will aim to achieve carbon neutrality in coal consumption by 2060.
- ▶ Examples such as the U.S. Green Chemistry and Commerce Council where companies along the value chain are actively seeking to exchange experiences and learn about challenges and opportunities faced highlight the need for greater global support through SAICM, OECD, and other types of scientific exchanges.
- ▶ China openly endorses international cooperation and training opportunities. The UN Orange Book on Dangerous Goods was translated into Chinese, and there are joint initiatives with UNAPP, WPC, ICCA, and AEPW, among others.



Panel 2: How to Accelerate the Replacement of Animal Toxicity Testing

Moderator and Panelists



Ms. Patience Browne

Principal Administrator
Organization for Economic
Cooperation and
Development (OECD)



Ms. Erin Hill

President
Institute for In Vitro
Science



Ms. Kristie Sullivan

Vice President of Research
Policy
Physicians Committee for
Responsible Medicine



Ms. Xiaoting Qu

Deputy Secretary General
The Society of Toxicity Testing
and Alternative Methods, Chinese
Environmental Mutagen Society

Introduction

Global regulations increasingly aim to limit or eliminate the use of animal testing in the safety evaluation of chemicals used across industries such as agriculture, personal care products, cosmetics, food contact materials, etc. In addition to the interest of replacing animal toxicity testing for humane reasons, animal testing is time consuming, costly, and may not accurately predict chemical effects in humans. Advances in biotechnology have produced a variety of new methods that can be used in lieu of animal test data.

Driving Questions

- ▶ How can we assure these approaches are as protective of human health as the animal models they replace?
- ▶ How can these approaches be applied across chemical sectors?
- ▶ Are there obstacles to harmonizing these approaches globally, similar to what has been done for animal toxicity tests?

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Challenges to Face

There's an agreed need to demonstrate the variability of the animal test, especially in regions that still cling to it as the gold standard.

- ▶ While OECD methods and standards are useful, there is an issue with international harmonization, and more than 50% of the chemicals coming out are from non-OECD member countries.
- ▶ To introduce methodologies and support the transition across regions, local needs and different government roles must be considered.
- ▶ While in Europe and China it is now more common to find public funds used to fund the development of methods, in the US and other regions, public funds mostly go to researchers working with animals, such as the NIH.

Moving Forward

- ▶ Need to shift the focus away from comparing alternative methods to animal testing but rather by aligning them with the goal of protecting human health and the environment.
- ▶ China continues to strengthen the interface for authorities, academics, and the industry to share knowledge, further capacity building, training and dissemination.
- ▶ Where there are not good human reference chemicals, the application of adverse outcome pathway (AOP) can be useful to show how the non-animal approaches or in-vitro methods use.
- ▶ Engagement strategies need to be multifactorial, including method developers, scientists, regulators, and trainees with encouragement.
- ▶ It is necessary to build comfort with new approaches, include them in university syllabus, and prioritize training and sharing of case studies and new concepts as early as possible to support regulators.
- ▶ The translation and dissemination of materials, including not only OECD guidelines, but also good in-vitro method practices, and virtual global forums offer an opportunity for knowledge sharing.



Panel 3: The Tension Between Plastics Recycling and Energy Recovery

Moderator and Panelists



Mr. Mark Radka

Chief, Energy and Climate
Branch
UN Environment
Programme (UNEP)



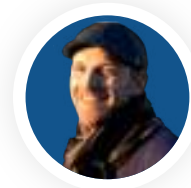
Dr. Andrea Hinwood

Chief Scientist
UN Environment
Programme



Dr. Nanqing Jiang

Secretary General
Committee of Green Circular
and Inclusive of All China
Environment Federation



Mr. John Duncan

Circular Economy Expert

Introduction

Many Asian cities have a problem disposing of municipal solid waste and face growing demands for energy. Proponents of waste to energy plants see the technology as offering a solution to both problems. Much of the energy value in MSW, however, lies in its plastics content and incineration precludes the recycling of plastics.

Driving Questions

- ▶ Are there net benefits to society in the burning of plastics to recover their energy content?
- ▶ Does the practice discourage or encourage recycling and a circular economy approach to the use of plastics, which requires separating recyclable plastics from the plastic waste stream before it is incinerated?
- ▶ How does the introduction of biodegradable plastic affect the technology and economics of both incineration and recycling?

Highlights from the Keynote and Panel Presentations

- ▶ 2.1 billion tons of municipal solid waste was generated in 2020, projected to reach 3.4 billion tons by 2050.
- ▶ 50% of waste in Asia is land filled. 25% of waste is incinerated, yet it holds a poor global record on recycling and composting.
- ▶ Of the total 8300 million metric tons of plastics produced since 1950s, vast majority have been discarded (49M), and only a fraction (600M) has been recycled or incinerated (800M).
- ▶ Plastics and additives can degrade to form other chemicals and micro plastics enabling environmental and human health exposure.
- ▶ The three R's – Refuse or Reduce, Reuse, and Recycle – are the core of waste management.
- ▶ Waste to energy has a large carbon footprint, second only to coal in terms of GHG emissions.



- ▶ UNEP has developed guidelines, identifying mandatory, strongly advisable, and advisable criteria that need to be met before considering waste to energy.
- ▶ Biodegradable plastics can be bio-based plastics yet have a similar environmental fate and behavior as other plastics and are thus not the long-term solution to plastic waste.
- ▶ In China, in the last 10 years' municipal solid waste in China reached 200 million tons per year.
- ▶ China produces 30% of the world's plastic and holds the world's 30% production capacity of biodegradable plastic.

Challenges to Face

- ▶ Waste to energy facilities require a steady supply of the waste material which discourages waste reduction and recycling efforts.
- ▶ To ensure sustainability of the investment, high calorific value plastics are needed for energy supply. Additives can be problematic.
- ▶ While incineration can reduce leakage of plastics into natural ecosystems, it leads to other pollution which can often be more toxic and more difficult to manage, especially in developing country settings.
- ▶ In China, the lack of efficient waste sorting systems has hindered recycling efforts, with increasing subsidies going towards incineration plants.

Moving Forward

- ▶ At present, waste to energy is not able to fully manage the general issue of plastics in the environment.
- ▶ Waste to energy is not a circular solution so should not be a first option as it is intrinsically linked to fossil fuels.
- ▶ Regulators must enable a sound regulatory environment that emphasizes the three R's and support this hierarchy as a priority.
- ▶ Plastics have an energy and a materials value, the energy can be recovered but materials value should prevail.
- ▶ Better organic waste management systems are needed, specifically in Asia and developing regions, so as to help decrease the contamination of the recyclable components of municipal waste systems.
- ▶ Waste to energy plants require process control to ensure correct pollution control, maintenance and sustained investment.
- ▶ It remains critical to develop emission standards and ambient air quality standards for the air toxics or hazardous air pollutants that are emitted from these facilities,
- ▶ For single-use plastic so far there's still no extended producer responsibility (EPR).

Closing Remarks

The Asian HCF 2021 Forum ended with Closing remarks made by Mr. Geert Dancet, Secretary General of Helsinki Chemicals Forum, who thanked everyone present and all those who had contributed to the success of the Forum, and then officially declared the Asian HCF 2021 closed.





Post Forum Report Part II: Global Chemical Compliance Management

Keynote Speakers



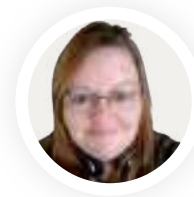
ECHA's 2021 Report on The Operation of EU REACH and CLP

Ms. Catherine Cornu
Senior Scientific Officer
European Chemicals Agency
(ECHA)



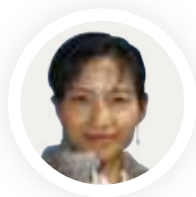
EU Nanomaterials Registration and Oversight

Mr. Abdelqader Sumrein
Scientific Officer
European Chemicals Agency
(ECHA)



Year One into UK REACH: Developments and Regulatory Direction

Ms. Julie Mayhew
Senior Policy Adviser
Department for Environment,
Food and Rural Affairs (Defra)



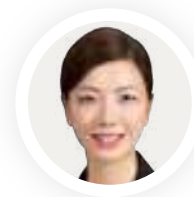
Advances in Chemicals Management in Taiwan Region

Ms. Yahui Ni
General Manager
Environmental Resource
International Co., Ltd



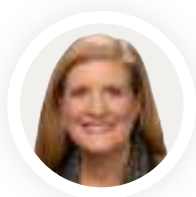
The Latest Development of Indian Chemical Regulation

Mr. Shisher Kumra
Executive Director
Global Product Compliance
Group



K-REACH Registration, Evaluation of Existing Chemical Substances and Future Prospects

Ms. Dahee Lee
K-REACH Expert
Korea Chemicals Management
Association



TSCA at 5: Rules of the Road for Unpredictable Times

Ms. Alexandra Dapolito Dunn
Partner
Baker Botts Law Firm



Topic Highlights

Looking Back at 15 Years of Operation of EU REACH

ECHA published the Report on the operation of REACH and CLP 2021 in June 2021, looking back at 15 years of operation of REACH with special attention to the last five years. Ms. Catherine Cornu from the European Chemicals Agency shared the findings of ECHA's analysis on this Report.

Over the last five years, the operations of REACH and CLP have advanced the protection of worker health, consumer health and the environment in the EU. They have also positively contributed to innovation, competitiveness, and the functioning of the internal market within the EU.

Despite this, synergies between REACH, CLP and other legislation have often failed to materialize and much still needs to be done to achieve the levels of protection envisaged by the legislators.

On EU Nanomaterials Registration: Current Status and Challenges

Mr. Abdelqader Sumrein, Science Officer from European Chemicals Agency (ECHA) introduced the current situation of nanomaterials registration in EU. As of October 2021, ECHA has received nanomaterial registrations or updates of dossiers for 130 substances, covering 441 different nano forms. Although this number may be considered below expectations, it is meant to increase, with the European agency offering more support, currently updating its IUCLID, manuals and guidance documents, including the Human Health Nano Guidance, Environmental Nano Guidance and Guidance on Registration and Substance ID.

[READ MORE](#)

India Expects to Notify WTO of Draft CMSR

Mr. Shisher Kumra, representing Global Product Compliance Group, one of the only two non-governmental organizations involved in reviewing India's much anticipated CMSR regulation, shared details on the internal process that led to this regulation, and the new obligations that may affect enterprises across industries. Due to Covid-19 the legislation process slowed down, yet it is now speeding up to notify WTO of the draft proposal for public consultation, adding concrete advice to stakeholders on their need to notify on quantities above 1 tonne per year during the initial notification period to support the creation of a new national inventory.

[READ MORE](#)



UK HSE Rolls Out Work Plan to Better Support Activities Under New UK REACH

This year marks the first year for the implementation of UK REACH, which entered into force on January 1, 2021. As UK REACH comes into force, issues and concerns faced by industry inevitably continue to increase. Julie Mayhew from UK's Department of Environment, Food and Rural Affairs shared many of the efforts made to help the industry adjust to the change. The UK Government has extended the time needed to submit DUINs and advises on a temporary reactivation of grandfathering window. A new Work Plan has been published and expected to come into effect soon to providing a comprehensive picture of all activities conducted under UK REACH. Including the identification of priority restrictions for the use and/or sale of lead ammunition.

[READ MORE](#)

TSCA Briefing: Compliance Challenges and Preparation for Future Restrictions

In 2016 under the Obama administration, the Lautenberg Chemical Safety Act was signed into law, effectively amending the Toxic Substances Control Act (TSCA). Alexandra Dunn, former Assistant Administrator for the U.S. EPA's Office of Chemical Safety and Pollution Prevention shared some of the main challenges and progress achieved since then. Among others, risk evaluations for existing chemicals identified as "high priority", a new requirement under the 2016 amendment, now require even longer review times under the Biden administration, since it has been determined to now require additional exposures, such as from air, water, and soil. Also, EPA plans on withdrawing previously granted LVEs for PFAS, and pre-manufacture notice (PMN) may now require more processing time from the government agency, demanding patience from the side of enterprises.

[READ MORE](#)



Post Forum Report Part III: China's Pharmaceutical Regulation and Market Overview

Keynote Speakers



Interpretation of Chinese Pharmacopoeia 2020 Edition

Ms. Qiaofeng Tao

Vice President
Zhejiang Institute for Food and Drug Control



China Market Entry Strategy for Overseas Pharmaceuticals

Mr. Feng Zhou

Director of Business Development
Haisco Pharmaceutical Group



Decoding China's Good Pharmacovigilance Practices (GVP)

Mr. Daniel Yu

Associate PV Director
Zhejiang Taimei Medical Technology Co., Ltd



Interpretation of China's Marketing Authorization Holder (MAH) System

Ms. Manlu Xia

Industry Expert



Focused Areas and Targets of Innovative Drug Research in China

Mr. Liang Hong

General Manager
Ruiou BaiPharm Service Co.,Ltd



Topic Highlights

Interpretation of the 2020 Chinese Pharmacopoeia

Chinese Pharmacopoeia (ChP) is at the core of China's national-level drug standards, said Ms. Qiaofeng Tao, vice president of Zhejiang Institute for Food and Drug Control, an affiliate of Zhejiang Medical Products Administration.

She mentioned that drug registration standards should comply with ChP's general technical requirements, as China's National Medical Products Administration stipulates it. So international companies also have to obey ChP to export drugs to China.

How Can Foreign Medical Products Embrace the Chinese Market?

As the second largest pharmaceutical market in the world, Mr. Feng Zhou from Haisco explained, Chinese companies have found themselves increasing in numbers at such a pace that has demanded that businesses turn to innovative drugs to face the fierce competition and low profits in generic drugs market. Mr. Zhou also advised international companies them to understand cultural differences better so that the cooperation with Chinese partners could go smoother.

Decoding China's Good Pharmacovigilance Practices (GVP)

Mr. Daniel Yu, from the Zhejiang Taimei Medical Technology, reminded international companies that China's GVP would take effect on Dec. 1, 2021 and that international companies have the opportunity to outsource pharmacovigilance activities such as the processing of individual case study reports (ICSR) to local Chinese service providers.

Interpretation of China's Marketing Authorization Holder (MAH) System

The Drug Marketing Authorization Holder (MAH) System also matters in China's drug regulatory framework. In Ms. Manlu Xia's presentation, she elaborated on the main features of China's MAH system, stressing that it would be better for an international company to know the moves of competitors.

Focused Areas and Targets of Innovative Drug Research in China

Mr. Liang Hong, general manager of Ruiou BaiPharm, who shared with the audience many of the latest trends, making a special mention of antineoplastic drugs which are finding increasing market opportunities due to the rise in cancer cases in China, e.g., EGFR-TKIs and ALK small-molecule targeted drugs. In terms of the anticancer drugs, some Chinese drug makers have already obtained marketing approval, while some are eyeing the pending approval. Therefore, international companies need to consider carefully before joining the keen competition.



Behind Every Great Forum There's Great Organizers



Helsinki Chemicals Forum

The Helsinki Chemicals Forum (HCF) is an independent non-profit forum founded by the Finnish Fair Foundation and the City of Helsinki aimed at promoting chemicals safety and chemicals management globally. HCF has held annual high-level conferences in Helsinki every year since 2009, supported by European Chemicals Agency (ECHA), the European Commission (EC) the European Chemical Industry Council (CEFIC) and a number of Finnish Government ministries. Over the years, the Helsinki Chemicals Forum has gradually evolved from debating the multiple challenges that the global chemical industry is facing to becoming the priority platform for debating how approximation of regulatory systems around the globe and multilateral cooperation can contribute to a safer and greener environment world-wide.

REACH24H Consulting Group

Founded in 2009, REACH24H is a consulting company specialized in providing one-stop global market access services to companies in the fields of industrial chemicals, agrochemicals, cosmetics, food and food contact materials and Pharmaceutical.

We are proud of our diverse team, from our technical experts to our international trade and market specialists across our headquarters in Hangzhou, China, branches in Taiwan, China, South Korea, Ireland, UK and the U.S., and our business representatives in Japan, UK, EU and South America. We continuously work to expand our networks to businesses, associations and government authorities across all regions to anticipate compliance needs and provide full-cycle strategic planning.

By offering a 24-hour global consulting service network and a technical expert team, REACH24H helps enterprises and high-quality products take an initiative to trade, improving their understanding of technical barriers and assisting international trade departments and businesses to move from passive to active in the global market. To date, REACH24H has helped nearly 9,000 companies worldwide overcome technical trade barriers to smoothly navigate the global market.

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- Successful completion of tens of thousands of regulatory cases
- First choice of over 9,000 companies for our regulatory expertise and experience



Product Registration and Consulting Services

REACH24H offers one-stop global market access services for businesses in the industrial chemicals, pesticides and disinfectants, cosmetics, food and food contact materials as well as pharmaceutical industries.



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Contact Us

REACH24H Consulting Group

customer@reach24h.com

www.reach24h.com/en

China

14th Floor, Building 3, Haichuang Technology Center,
1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86-571-8700-7555 Fax: +86-571-8700-7566

Taiwan, China

9th Floor, 898 Jing Guo Road, Luzhu District,
Taoyuan, Taiwan
Tel: +886-3-3466936 Fax: +886-3-5167038

South Korea

Room 908-909, 7, Heolleungno, Seocho-gu,
Seoul, 06792, Republic of Korea
Tel: +82-2-3497-1610

USA

11921 Freedom Drive, Suite 550, Reston,
Virginia 20190 USA
Tel: +1-703-596-8055 Fax: +1-703-776-9462

Ireland

Paramount Court, Corrig Road Sandyford,
Dublin 18, Ireland
Tel: +353-1-8899-951 Fax: +353-1-6865-683

UK

45 Stanway Gardens, Edgware, Middlesex,
England, HA89LN
Tel: +44-203-582-2996



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REACH24H Consulting Group

14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)

Tel : +86 571 8700 7555 Fax: +86 571 8700 7566 Email: customer@reach24h.com

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