Compliance & Risks

Sustainable Products and Restricted Substances

A Guide to ESPR, RoHS, and China RoHS 2

Author:
Mike Kirschner, Consultant, Design Chain Associates, LLC

12 March, 2025

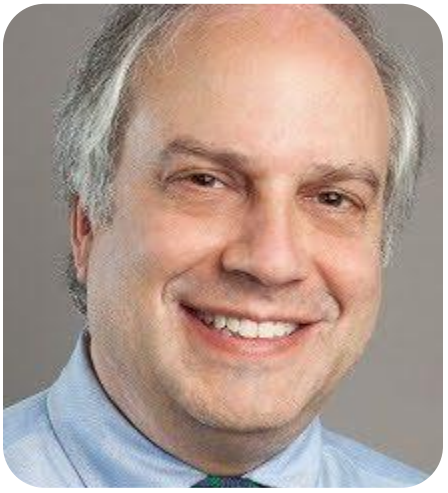
Further regulatory developments may have occurred after publication. To keep up-to-date with the latest compliance news, sign up to our newsletter.

→ | complianceandrisks.com

Table of Contents

Sustainable Products and Restricted Substances:
A Guide to ESPR, RoHS, and China RoHS 2

01. About The Author



Mike Kirschner, Consultant, Design Chain Associates, LLC

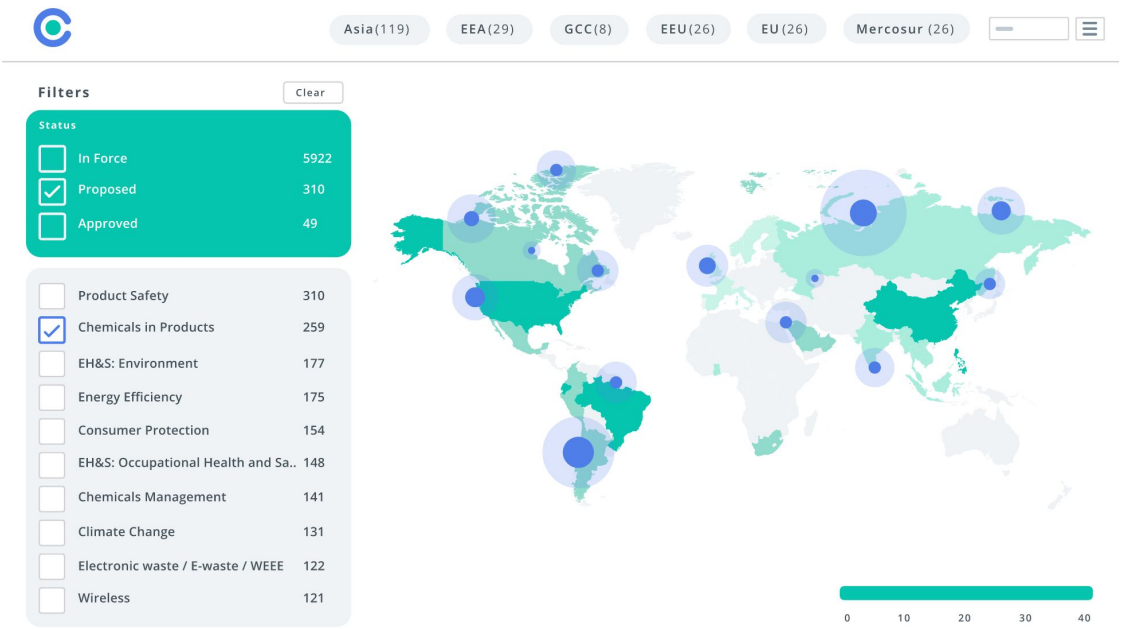
Mike helps manufacturers understand and ensure that their products comply with health and environmental regulatory, customer and market requirements.

Mike has substantial expertise in areas including semiconductor quality and reliability, software design and development, hardware design, development, and manufacturing as well as manufacturing processes and supplier/supply base management.

Prior to co-founding Design Chain Associates in 2001, Mike held engineering and engineering management positions at various manufacturers including Intel, Tandem Computers, and Compaq.

02. Unlocking Market Access

At Compliance & Risks, we help you keep on top of global regulatory changes and their impact worldwide. We have the right technology, regulatory content and expertise to help you unlock market access, protect revenue and elevate the role of compliance.



Our solution includes:

- **C2P:** The most advanced product compliance and ESG compliance software on the market, helping you streamline your compliance process and unlock market access around the world.
- **Regulatory Content:** We provide the broadest and most comprehensive product compliance regulatory content on the market, monitoring 195+ countries, 20 industry sectors, 45 topics and 100,000+ regulatory sources.
- **Ask our Experts:** Direct access to our team of experts for support

Additionally, we offer:

- ✓ **Market Access Services:** Our Market Access team helps you understand your product compliance obligations by transforming regulations into actionable knowledge with tailored advice for you and your business.

Why choose C2P?

- ✓ **Stay ahead** of regulatory changes with the world's most comprehensive regulatory database
- ✓ **Avoid delays** with alerts of changes to regulations & requirements in real time
- ✓ **Improve efficiency with powerful collaboration and workflow tools** to keep compliance evidence up-to-date & live linked back to Regulations, Standards & Requirements

Contact us to speak to one of our team today to learn how you can simplify your regulatory compliance process.

For more information, please visit http://www.complianceandrisks.com

03. Introduction

Are you ready for the latest changes to EU and China RoHS regulations?

The regulatory landscape for environmental compliance is constantly evolving, and staying informed is crucial for businesses to maintain market access and avoid potential penalties.

This whitepaper provides a comprehensive overview of key updates to EU environmental regulations, including the Ecodesign for Sustainable Products Regulation (ESPR) and the latest RoHS exemptions, as well as significant changes to China RoHS.

Based on our popular webinar '**Updates on Key EU Environmental Regulations and China RoHS**,' held in February 2025, in partnership with Design Chain Associates, we highlight the top themes and trends to be aware of, as well as highlighting potential challenges and actions for companies.

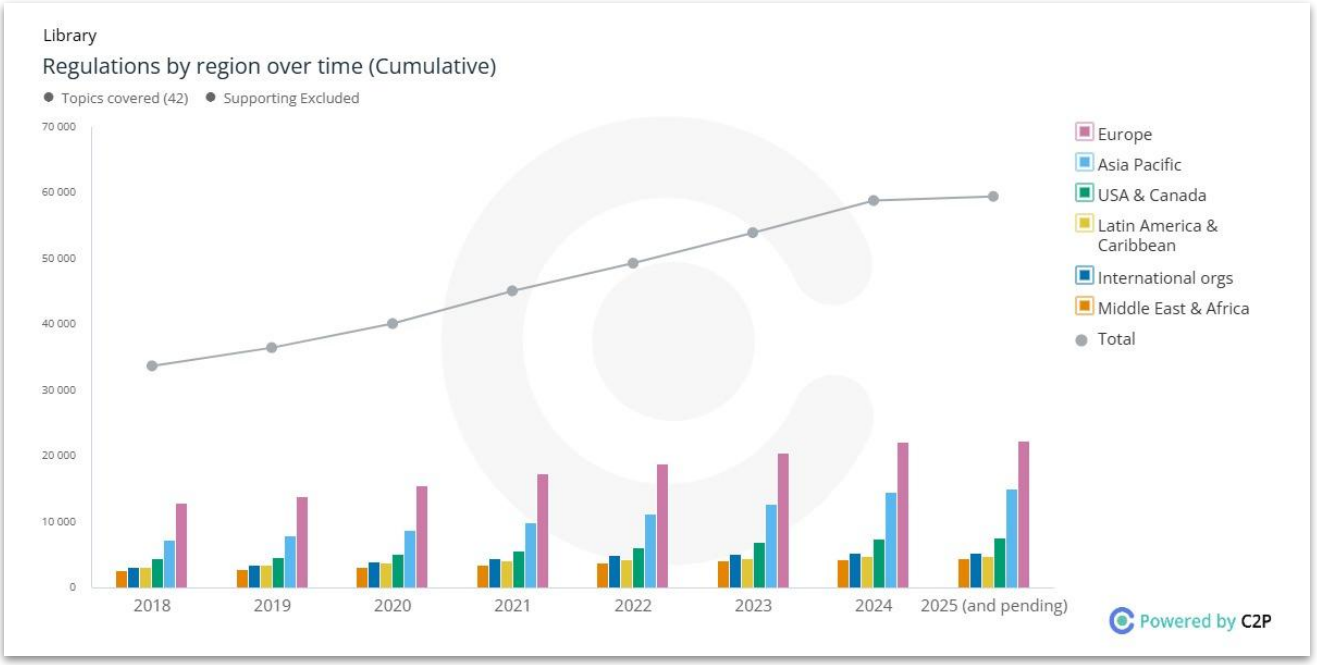
This guide provides insights and guidance on:

- Understanding the scope and requirements of the ESPR
- Identifying substances of concern under ECA's flame retardant study
- Navigating the latest RoHS exemptions
- Staying abreast of China RoHS updates
- Adapting to the evolving regulatory landscape
- And more!

04. Trends in Product Regulation

What trends are we seeing in product regulation? The graph below from C2P shows year on year growth in regulations globally.

1. **Global Increase in Regulations:** A significant upward trend in product regulations is impacting businesses worldwide, with a steady increase in the volume of product regulations globally since 2017.
2. **Regional Variations:** Some regions are experiencing more growth than others. For example, South America is focusing on building their regulatory regimes, whereas in regions like the US and South Korea where there is already a lot of product regulation, it is still growing exponentially. However, some regions are seeing a reduction in regulations, such as the UK and Canada, aiming to reduce regulatory burden.
3. **Sector Focus:** Product safety, chemicals, consumer protection and sustainability are leading the surge in product regulatory developments, driven by the need to address emerging technologies and environmental concerns.
4. **Topic Trends:** There is an increased focus on Artificial Intelligence and new technologies.



05. The Ecodesign for Sustainable Products Regulation (ESPR)

A New Era of Sustainable Product Development

The European Union is taking significant strides towards a more sustainable future with the introduction of the Ecodesign for Sustainable Products Regulation (ESPR).

This regulation represents a major shift in the regulatory landscape, aiming to make products placed on the EU market more sustainable throughout their entire lifecycle.

Unlike the previous Ecodesign Directive, which primarily focused on energy efficiency, the ESPR casts a wider net, encompassing a broader range of products and sustainability aspects.

Key Elements of the ESPR include:

- Broader Scope: The ESPR covers a wider range of products than the previous Ecodesign Directive, including textiles, furniture, and toys. It is nearly unlimited in scope and expands well beyond the energy efficiency focus of previous versions. It also provides another pathway to disclose, restrict, or control substance use.
- Digital Product Passports: The ESPR will introduce digital product passports for certain products, containing information such as the product's unique identifier, compliance documentation, and user manuals. This passport is a set of data specific to a product that includes information specified in the applicable delegated act adopted pursuant to Article 4. It is accessible through a data carrier like a barcode or QR code. The digital product passport can include a wide range of information, from compliance documentation to unique operator identifiers.
- Horizontal Requirements: The ESPR emphasizes horizontal requirements such as durability, recyclability, and recycled content, promoting a circular economy approach. These requirements aim to improve product sustainability across various categories.
- Delegated Acts: Specific requirements for product categories will be defined through delegated acts, providing detailed **obligations**. These acts will include details like commodity codes, ecodesign requirements, test standards, and conformity assessment procedures.

06. ECHA's Study On Flame Retardants

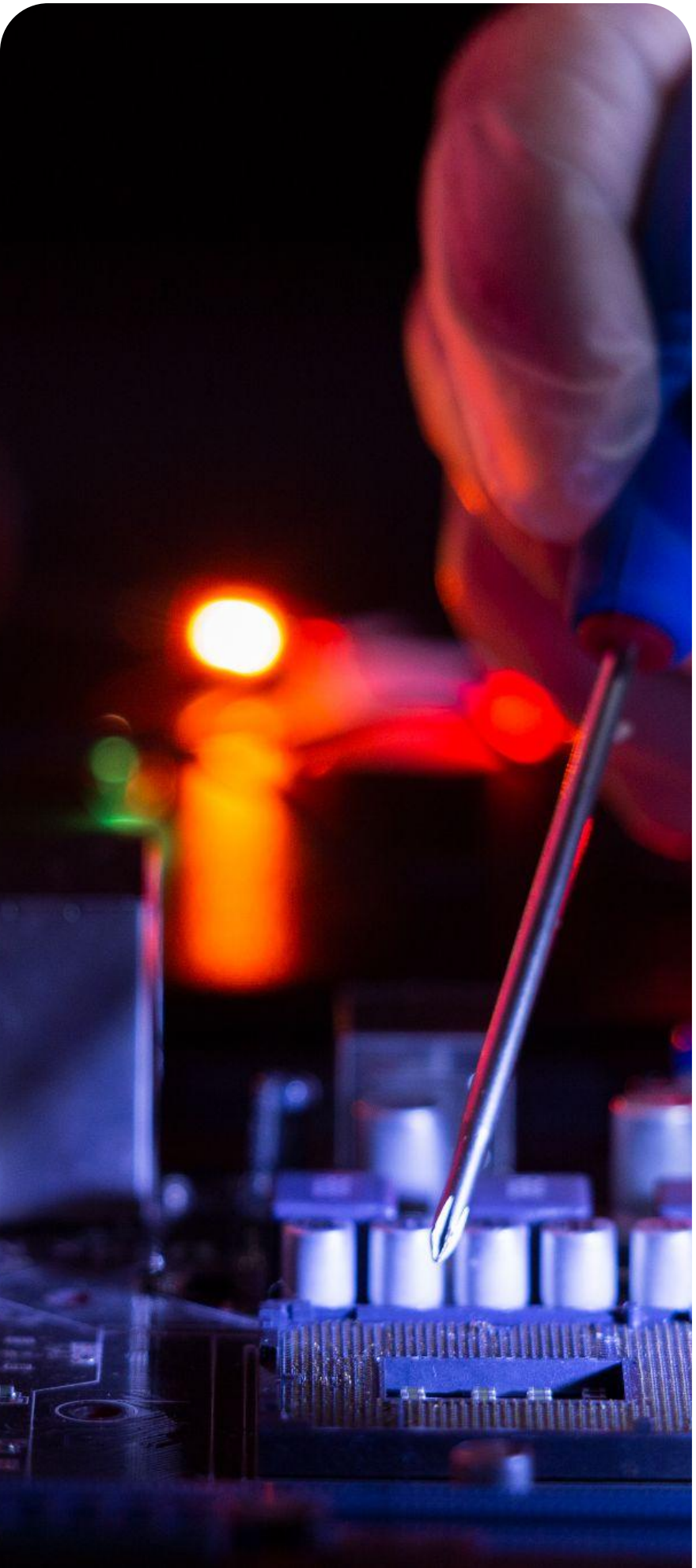
Identifying and Addressing Substances of Concern

Flame retardants are necessary to meet product safety standards when flammable materials are too close to a potential ignition source, but they can also pose risks to human health and the environment.

The European Chemicals Agency (ECHA) is conducting a comprehensive study on flame retardants, so far identifying five substances of concern due to their persistent, bioaccumulative, and toxic properties. These substances are likely to be restricted under REACH, impacting industries that utilize them in their products. The study currently focuses on aromatic brominated flame retardants, which are typically used in electronics, automotive, construction, and textiles.

ECHA's study also highlights:

- **Emissions from Flame Retardants:** The study raises concerns about emissions from flame retardants throughout the product lifecycle, particularly migration out of plastics.
- **Waste Stream Differentiation:** The need for better differentiation of waste streams containing different flame retardants is emphasized to facilitate recycling and disposal.
- **Potential ESPR Actions:** The study's findings could lead to future actions under the ESPR to address the risks associated with flame retardants. This is because ESPR Annex I includes "Use of Substances of Concern" as a potential area of control.



07. Navigating the Latest EU RoHS Exemptions

The EU Restriction of Hazardous Substances (RoHS) Directive plays a crucial role in regulating the use of hazardous substances in electrical and electronic equipment.

However, a significant regulatory shift is underway with a proposed mandatory testing requirement that could drastically alter how companies demonstrate RoHS compliance.

Key draft updates include:

- **Mandatory Testing**: The European Commission is proposing mandatory testing for RoHS compliance, potentially impacting industry practices and costs. This proposal stems from the Commission's belief that more technical evidence in the form of test reports can improve compliance. However, there is debate on whether testing is meaningful for series production..
- **Exemption Changes**: The draft Delegated Directives propose changes to several RoHS exemptions, including the bifurcation and narrowing of certain exemptions. These changes are based on a study to assess requests for renewal of exemptions.
- **Implementation Timelines**: The comment period for the draft delegated directives ended in February 2025, with adoption expected in March 2025 and entry into force around June 2025. The actual expiration of exemptions would be 12 to 18 months later, unless renewal applications are submitted in time for exemptions with that option.

08. China RoHS

Understanding The Latest Developments

China RoHS is another significant regulation that either restricts the use of hazardous substances in electrical and electronic products or requires their disclosure.

China is taking a stricter approach to hazardous substances with its updated RoHS framework. The recently proposed changes to China RoHS Phase 2 introduce mandatory testing requirements for high-risk components in products listed in the Catalog, aligning more closely with the possible direction of the EU RoHS Directive, but with distinct national implementation differences.

These changes signal China's intent to strengthen enforcement and align more closely with global regulatory standards. Companies exporting to China must prepare for increased documentation demands, higher testing costs, and potential delays in certification as regulatory authorities implement these new requirements.

Key changes include:

- **Mandatory Standard**: The updated China RoHS is transitioning to a mandatory GB standard, increasing the compliance requirements for businesses.
- **Phthalates and Testing**: The four phthalates already restricted by EU RoHS are being added, along with mandatory testing for high-risk components. This testing must be conducted annually, and test reports are required.
- **Digital Labeling**: QR codes, screen displays, and other digital indicators are being added to labeling information methods. Additionally, the regulation explicitly allows for online placement of the hazardous substance table.

09. Mitigation Strategies

So what can you do to protect yourself?

The regulatory landscape for hazardous substances and product sustainability is becoming more complex, requiring a proactive approach to compliance management.

Businesses must move beyond reactive compliance strategies and integrate regulatory foresight into product design and supply chain decisions.

Here are our steps to help you minimize product regulatory and litigation risk:

1. **Research and Analysis:** Conduct thorough research to understand the impact of new regulations on your products and supply chain. This includes understanding how new design and product constraints may affect your business model.
2. **Industry Engagement:** Work with or join industry associations to stay informed and influence regulatory developments.
3. **Technical Expertise:** Invest in technical expertise, such as chemists and toxicologists, to support compliance efforts.
4. **Track Regulatory Developments & Litigation Risks:** Utilize tools like the C2P platform to monitor global regulatory changes, track emerging trends, and proactively assess potential litigation risks.

Interested in future-proofing your business? Start a conversation with our experts.

10. Webinar Q&A

During the live webinar, numerous questions were sent in by our engaged audience. Our webinar presenter from Design Chain Associates, **Mike Kirschner** has provided expert answers to the most popular queries below.

Q) Are there any regulatory plans to regulate halogens in printed circuit boards more strictly or even ban them?

"TBBPA is currently on the candidate list of SVHCs, and will probably be placed into REACH Annex XIV, but that won't affect its ability to be used (particularly outside the EU) in PCB manufacturing. It's consumed in the process and does not appear in the finished PCB. There are non-halogen alternatives to use of TBBPA in PCBs that can be considered. I think it's low on the list of bans in the FR strategy for reactive uses."

Q) is there any guidance available, how to choose the correct EFUP label under China RoHS?

"See SJ/Z 11388-2009. DCA sells an English translation of it at chinarohs.com."

Q) Mike can you comment on the footnote in the draft of 6(c) aiming at harmonizing REACH and ROHS? Why are the exemptions of the REACH restriction not also included in the draft?

"The text of the Explanatory Memorandum for this draft says "Provided that a footnote is added to the respective exemption entries, the evaluation results show that the exemption, would not weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU." This makes the exemption consistent with REACH Annex XVII entry 63, paragraph 7.

REACH Annex XVII entry 63, para. 8(k)(iv) excludes EEE, as lead is already is restricted under RoHS. I'm not sure what the second question is referring to."

Q) When can we expect the restriction of ABFRs under REACH ? 3-5 years away, or sooner?

"I expect to see a draft regulation amendment to REACH sometime this year for the five confirmed PBT/vPvB ABFRs and the actual restriction come into effect maybe 2-5 years later."

Q) By when the companies will be mandated to test RoHS top risk components? It is in force? If not, when it will be in force? Thank you.

"Hard to say. I hope it's never and I would like to see the industry fight this so make sure your company joins Digital Europe, IPC, ITI, or some other industry association that supports the industry on EU RoHS.

If that doesn't happen it's probably at least 3 years away since the Commission has to issue a request to CENELEC, which will then take probably 18-24 months to develop the protocol and release the updated standard, and then another 6-12 months for that to come into effect."

Q) If the China and EU RoHS testing requirements are adopted, is it instant application or is there are run-up period?

"Nothing is "instant" in the EU. See the answer to previous question.

Regarding China, same as the first paragraph of the answer to Q6. Otherwise, "For products manufactured or imported before the implementation date of this document, they shall comply with the requirements of this document starting from the 13th month after its implementation date." I'm not sure this is meaningful or helpful; it's unclear to me so merits comment during the remaining WTO TBT comment period, which runs to March 6, I believe."

Q) Under ESPR, does incorporating recycled materials that contain SVHCs (e.g., lead) contribute to a product being considered sustainable? If not, how can the industry strike a balance between increasing recycled content and maintaining overall product sustainability? Additionally, given that recycled raw materials are often more expensive than virgin materials, how can companies navigate this cost challenge?

"This is hard to answer right now, even for the JRC. See section 2.3.2.2.4 of the JRC study. I expect that the development processes of the individual "delegated acts" will, among other things, identify areas where post-consumer recycled materials can be used and where they may cause a problem without further processing."

Q) While Rohs is law we are stuck with it to correct?

"Of course. It has not been repealed or recast so it remains in force."

Q) The problem is with small <$20mm sales company they don't have the $ to test and have to rely on supplier certification

"Yes, if the Commission is successful in changing the requirement in EN IEC 63000, small manufacturers are going to have to work closely with suppliers to make sure they do the testing, or help share the cost. Keep your eyes on the EU and make sure to comment about the cost vs. your budgets vs. the lack of actual value and credibility testing adds to RoHS compliance when the Commission brings it up for stakeholder comment periods again."

Q) For a small U.S. company manufacturing research-use-only scientific equipment, where systems are assembled and tested using components from suppliers who certify RoHS compliance, but no in-house testing is conducted before selling in the EU or China—does this approach remain valid for compliance? Given that fewer than 100 systems are sold per year, are there any additional requirements to consider?

"If the EU successfully changes EN IEC 63000 (or if your product is in the China RoHS catalog and they actually end up requiring testing), you are probably going to want your suppliers to do the testing; they may want you to help share the cost (especially for low volume custom parts). Keep your eyes on the EU and make sure to comment about the cost vs. your budgets vs. the lack of actual value and credibility testing adds to RoHS compliance when the Commission brings it up for stakeholder comment periods again."

Q) When is the amendment to IEC 63000:2018 expected to take effect?

"Hard to say. I hope it's never and I would like to see the industry fight this so make sure your company joins Digital Europe, IPC, ITI, or some other industry association that supports the industry on EU RoHS.

If that doesn't happen it's probably at least 3 years away since the Commission has to issue a request to CENELEC, which will then take probably 18-24 months to develop the protocol and release the updated standard, and then another 6-12 months for that to come into effect."

Q) Does REACH impose a complete ban on substances, or does it set limits on the amount of material that can be placed on the market?

"No. Among other things, REACH either restricts the use of substances (Annex XVII) or requires that their use be disclosed (Article 33 - the candidate list of SVHCs). Some people mistake Article 7 for putting a limit of how much of a particular substance a manufacturer can place on the EU market in a year. That's a significant mis-reading of the Article. While complex, for articles it simply says that if you put over one metric ton of an SVHC on the EU market in a year across all the products you've sold in that year, AND if the substance is not registered for that use under REACH, you have to notify ECHA. The obligation kicks in 6 months after a substance is placed on the candidate list. This is going to be a very rare situation for a EEE manufacturer."

Q) Could you share your insights on the upcoming PFAS restriction decision expected this year? Should companies take proactive measures to prepare, or is it better to wait and see which substances will be prohibited and which will be restricted?

"I have no special insight. I think manufacturers should be working on understanding where PFAS are used in their products and manufacturing processes, learning which are particularly problematic and trying to find out whether there are alternatives to the substances, materials that use them, or parts or systems that they're in. That'll help you understand the impact whenever they get around to PFAS in electronics, because they're used all over the place. It could be very problematic."

Q) During the presentation, I noticed a reference to CE marking, and it seems that its scope may have been expanded under ESPR. Is that correct? This is the first time I've heard CE marking mentioned in connection with ESPR, so I want to ensure I understand its implications.

If the scope has indeed been expanded, does this mean that all textiles will now require a CE mark of conformity by a specific date? Additionally, does the CE mark need to be directly on the product label, or is it acceptable to include it on a hang tag or packaging?

Was CE marking discussed in any of your other webinars covering ESPR? Any clarification you can provide would be greatly appreciated.

"CE Mark and all related NLF requirements apply to ESPR. This is not new; the previous EcoDesign Framework Directive 2009/125/EC is also an NLF Directive, as was its predecessor, the EuP Directive 2005/32/EC. What is new is the expanded scope. So the focus on textiles per the JRC does indeed potentially add a CE Mark requirement for whatever particular textiles are in the scope of a future "delegated act".

So when the "Delegated Act" covering textiles, which I can tell you work for is already in progress, is in place it will tell you about what is needed and how to mark the product. It will also give you the scope and timeline as well as all the other requirements. If you are unaware of this I recommend contacting your favorite industry association. I know that AFIRM Group is on top of this. https://afirm-group.com/.

I recommend that you review the regulation, the FAQ, and the JRC report. Links to all are included in the webinar slides."

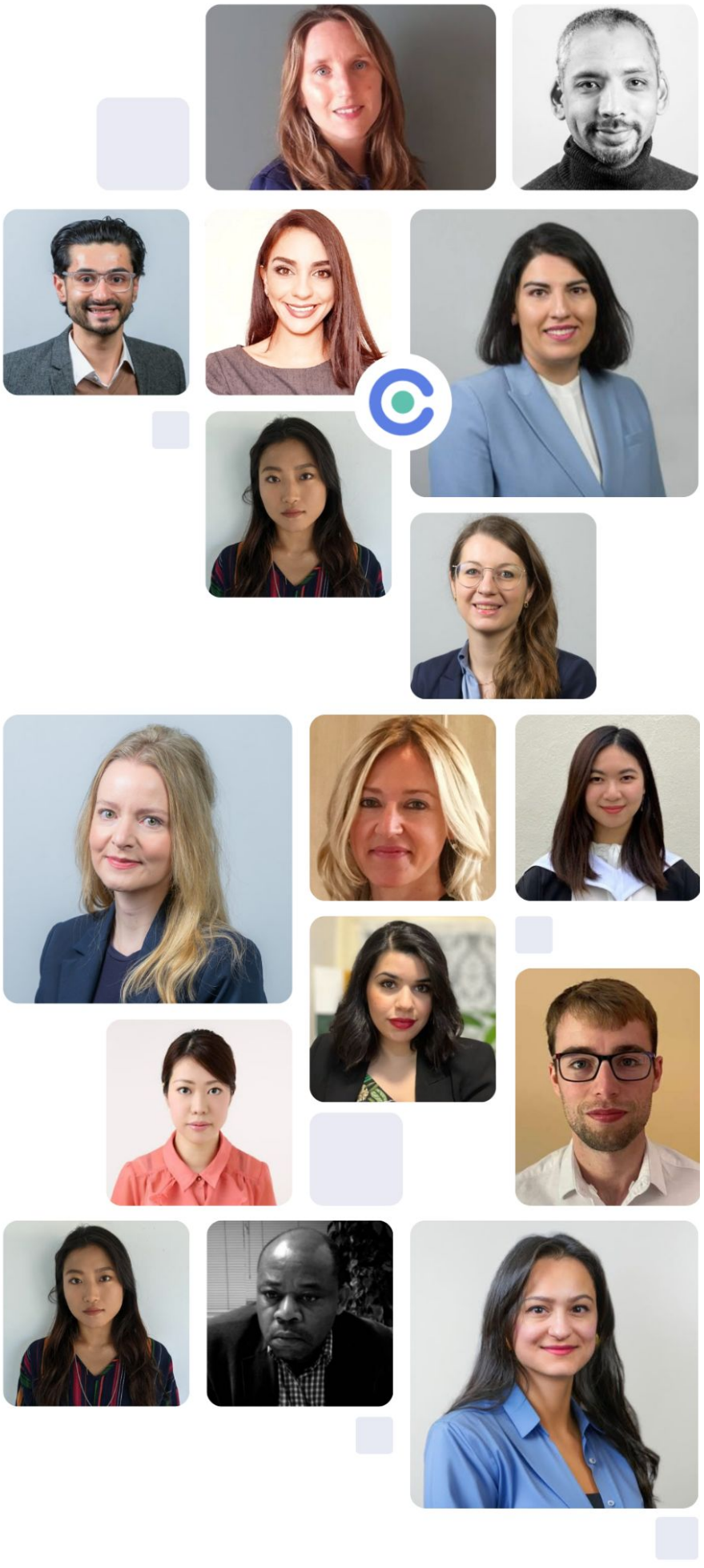
11. Conclusion

The changes to EU and China RoHS, ESPR, and hazardous substance regulations underscore a global shift towards stricter environmental compliance and product sustainability.

As regulatory bodies expand their oversight, companies must adapt by reassessing material choices, implementing stronger supply chain controls, and leveraging digital compliance tools.

By staying informed and proactive, businesses can turn compliance challenges into competitive advantages, ensuring continued market access and leadership in sustainable product innovation. The regulatory landscape will continue to evolve, but those who embrace compliance as a strategic priority will thrive in this new era of environmental responsibility.

Empower your business today - begin your journey and speak to a regulatory expert.



12. Ask Our Experts

Stop Drowning in Regulatory Updates and Get Back to Business.

Feeling overwhelmed by the ever-changing world of global regulations? You're not alone. Keeping up with complex legislation like ESPR, RoHS, and China RoHS can feel like a full-time job, draining valuable resources from your core business.

What if you could add **80+ compliance experts** to your team?

With our Ask the Experts service, you can. Our global team of 50+ subject matter experts and 30+ knowledge partners provides unparalleled expertise across a diverse range of products, geographies, and policy areas. We monitor regulatory changes daily and provide clear, concise answers to your most pressing compliance questions.

Gain instant access to:

- **In-depth, localized knowledge:** Our experts possess a deep understanding of complex global regulations, including ESPR, RoHS, and China RoHS.
- **Rapid response:** Get quick answers to your questions, often within 30 minutes, freeing up your team to focus on other priorities.
- **Confidence and clarity:** Navigate regulatory complexities with assurance, knowing you have a team of experts backing you up.

Boost your compliance capabilities without expanding your headcount.

Submit your question today and experience the power of having a dedicated compliance team at your fingertips.

Your question will be answered free of charge if we can research it within 30 minutes.

Compliance & Risks

OUR NUMBERS

300+

CUSTOMERS WORLDWIDE

195

COUNTRIES COVERED

100,000+

REGULATIONS

→| complianceandrisks.com