

Webinar Series: Guide to **Successful Market Access**

Interpreting The Impact Of Relevant Regulations On Your Products



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Guide to *Successful Market Access*

Unlocking Market Access



Guide to **Successful Market Access**

Achieve Market Access

Coming up next...



2. Maintain Market Access



3. Expand Market Access



1. Achieve Market Access



*From a Tidal Wave of Regulation to a Compliant Product - **July***



*Interpreting The Impact Of Relevant Regulations On Your Products- **August***



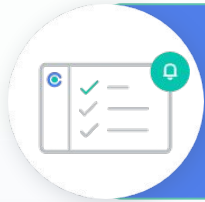
*Demonstrating a Compliant Product to unlock market access for your product - **September***

Trying to keep on top of **it all...**



A Smarter Way to Manage Product Compliance

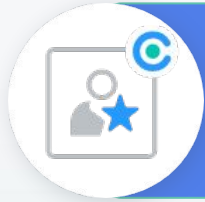
Holistic Market Access Solutions



Powerful Enterprise
Technology



Extensive Global
Regulatory Content



Team of Subject
Matter Experts

Holistic Market
Access
Solutions...



“Can I sell product X in market Y?”

→ Achieve market access



“Can I continue to sell product X in market Y when there is a change?”

→ Maintain market access



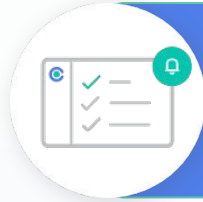
“What do I need to do to sell product X into a new market?”

→ Expand market access

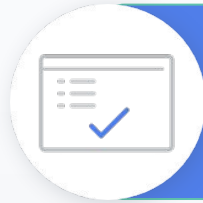
Accelerate the ability to

Achieve, Maintain & Expand Market Access for all products in all markets

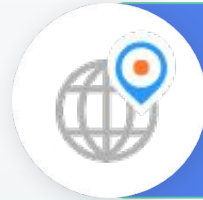
Achieve your
business
objectives,
by ...



Demonstrating Compliance



For what is required

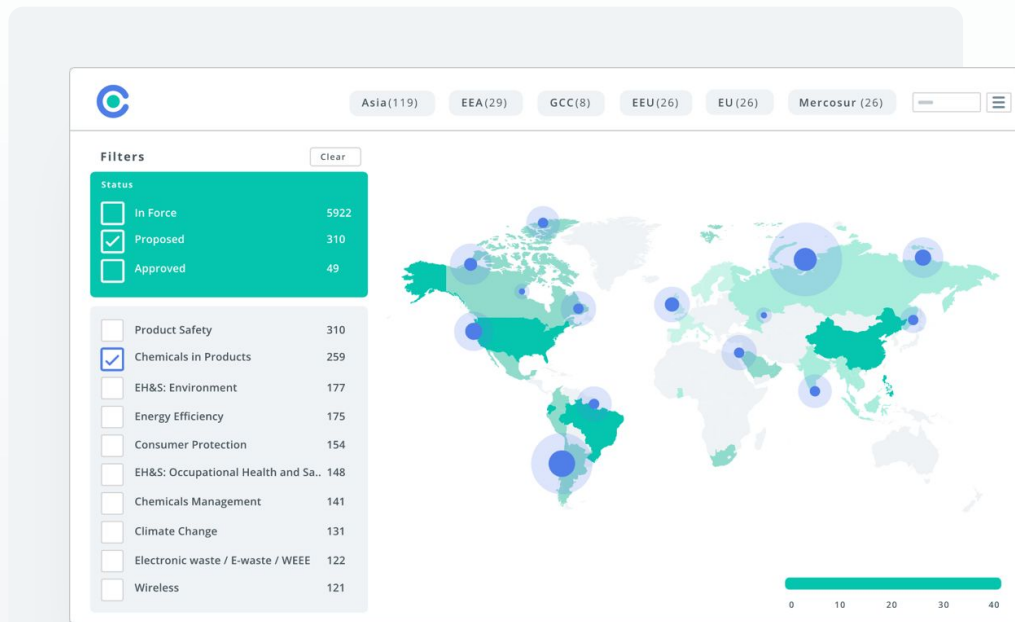


Driven by Global
Regulations & Standards

TECHNOLOGY - C2P

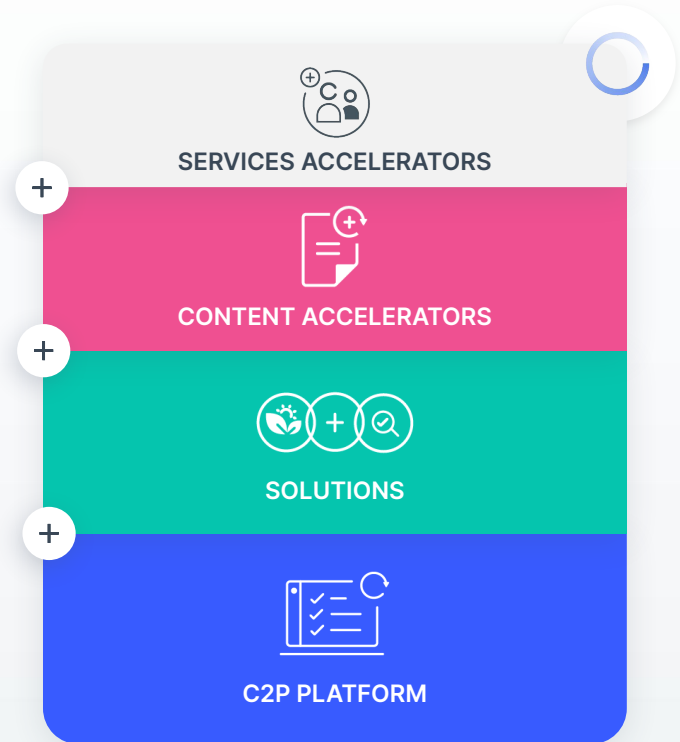
C2P - The Key to Unlocking Market Access

- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



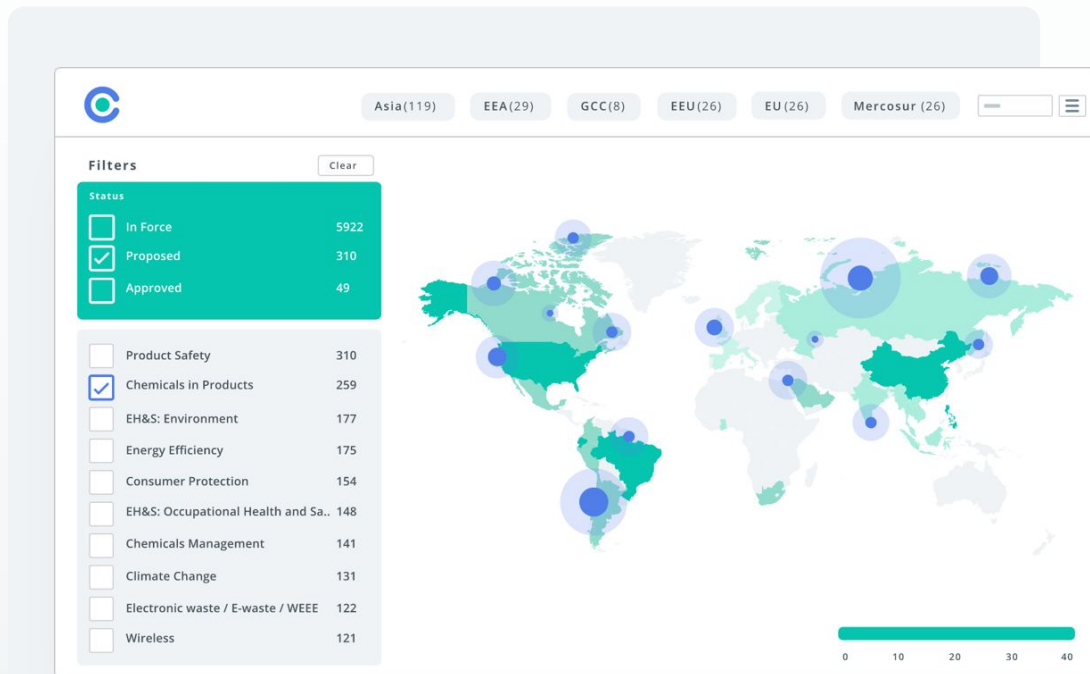
Tailored to meet your needs...

- **Product focused** experience that reduces noise and enables your team to focus on what matters most
- Add-on packages to **accelerate market access** through:
 - Use-case specific solutions
 - Global regulatory content
 - Professional services



Manage everything in One Place...

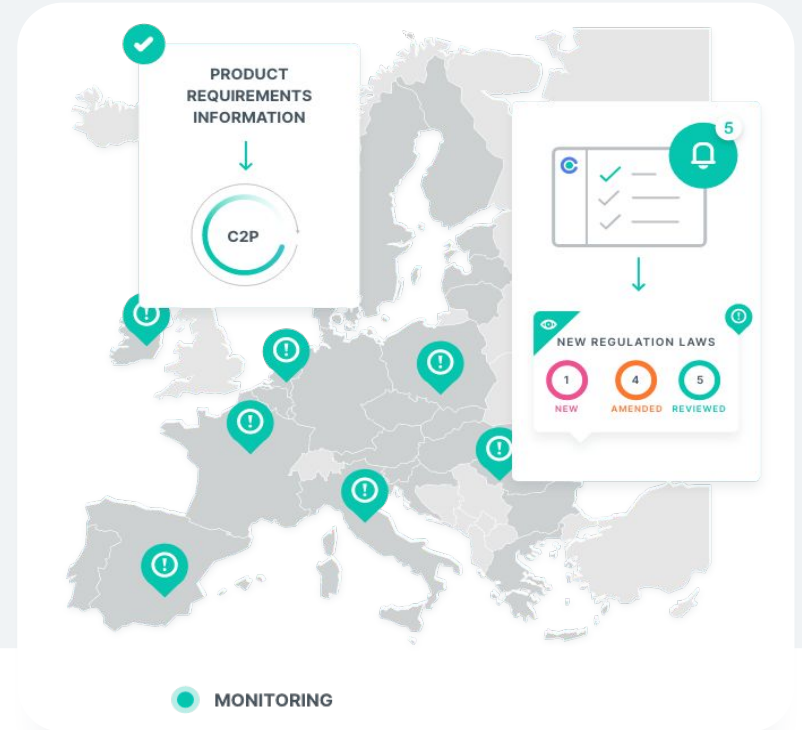
- Design, build, and collaborate on new products with confidence
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements
- Continually monitor regulatory changes & keep ahead of proposed changes before they happen



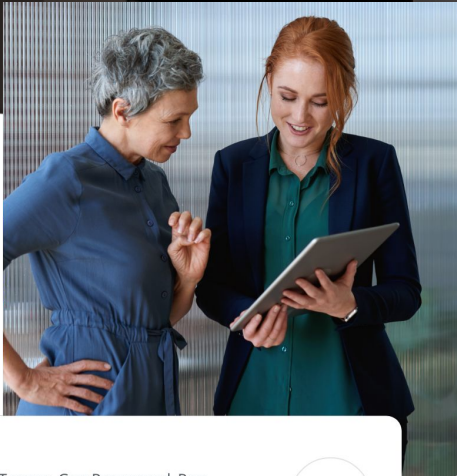
WHY C2P?

Why Invest in a Technology Platform?

- Accelerate time-to-market
- Reduce non compliance risks
- Enable business continuity
- Improve efficiency
- Save time



Interpreting relevant regulations is complicated..



Products need to meet updated legislation..

"We need to ensure our products meet current, stringent environmental compliance legislation, as well as be prepared for regulatory changes coming down the line"

Need to interpret quickly..

"We need to interpret the applicability of regulatory changes to product portfolio and develop systems to ensure we are compliant"

Repeated assessments done..

"It may not be obvious, but companies spend a significant amount of time assessing the same law, which wastes time and resources."

REGULATION

(Proposed) Texas: GenProposed Reg
Sources Sep 8 with Deadline for comments
- preview copy

Sep 8

Interpreting The Impact Of Relevant Regulations On Your Products

Holistic Market Access Solutions

How can I properly interpret regulations?

C&R's market research highlighted key questions when trying to interpret regulations

1. How can I get **translations** of all relevant compliance sources not in English?
2. What are the **key dates** for when regulations and standards take effect?
3. What are the impacted **products** & associated **requirements** for each compliance source?
4. How can I determine the **penalty** for non compliance?

Poll #1

Choose the question that represents the biggest challenge for your team when interpreting regulations?

1. Get access to translations for relevant Regulations and Standards

"If you are operating in the Chinese market, these documents are written in Chinese..."

Without translations you need to have a local partner to discuss what is basically meant or what is definitely required by the authorities."



1. Get the correct translations of the relevant Regulations and Standards

"Sometimes we come up with different translations of the same statement. So, we have to seek advice from within the industry."

Seeking experts based out of the countries of the regulation slows us down and can lead to confusion on how to interpret the regulation."



1. Translations

- Attach and store internal translations for easy access
- Publicly available translations are captured in C2P
- Translation service to provide you with a full legal English translation of the source

The screenshot displays the 'West Coast Appliances' C2P interface. The main content area shows a regulatory document titled 'Ukraine: Technical Regulation on Energy Labelling of Energy-consuming Devices, Regulation, Order No. 164, 2022'. The document is marked as 'Approved' and 'coming into force on Aug 01, 2023'. The interface includes a navigation menu on the left with options like 'Overview', 'Scope', 'Dates', 'Attachments', and 'News & Analysis'. The main content area is divided into sections: 'Overview' (text describing the regulation), 'Scope' (with sub-sections for 'Products Covered', 'Requirement Types', and 'Topics'), and 'Dates'. The 'Products Covered' section lists 'Electrical and Electronic Equipment (Abbrv: EEE)'. The 'Requirement Types' section lists 'Labelling', 'Providing product information', 'Registration', and 'Retention/Destruction of records'. The 'Topics' section lists 'Energy Efficiency'. The interface also features an 'Activity' sidebar on the right with a notification from 'Meg O'Keefe' and buttons for 'Ask our Experts' and 'Help'.

2. Identify the timeline when compliance sources will take effect

"Our top priority is to ensure that we comply and to make sure that it's not done retrospectively.

So if we know there's any changes coming to legislation, then we need to be proactive."



2. Upcoming dates on Regulations

- Our team of SMEs extract **all key dates** from regulations and standards
- **Faster and better** decision making with valuable insight on key dates
- Report on **upcoming dates** for all relevant regulations and standards

The screenshot displays a software interface for 'West Coast Appliances' with a navigation bar including 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main content area is titled 'REGULATION' and features a header for 'EU: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006'. Below the header, there are tabs for 'Assessments', 'Assessment summary', 'Company attachments', and 'Requirements'. A 'Relevant' status is indicated with a green checkmark and a right-pointing arrow. A sidebar on the right shows 'Activity' and 'Discussions' sections. The 'Overview' section contains a description of REACH and a link to 'Understanding REACH' by the European Chemicals Agency (ECHA), 2007.

ACHIEVE MARKET ACCESS

3. Determine the products & associated requirements for compliance

"We need to identify emerging product-related regulatory issues around the world, & manage them efficiently.

We were struggling to do this as our previous setup was dispersed among different systems & providers.

This made it difficult to understand if we were seeing all of the regulatory information needed."



3. Documenting Compliance Requirements

- Leverage regulation metadata to **identify and extract** requirements faster
- **Single location** for all product compliance requirements
- **Clear audit trail** on requirement decisions

The screenshot displays a web application interface for 'West Coast Appliances'. The main content area shows a document titled 'Requirements' with the following details:

- Overview:** On 27 April 2022 the Ukrainian Ministry of Energy approved Order No. 164 approving Technical Regulation on Energy Labelling of Energy-consuming Devices. This Technical Regulation is modeled on Regulation (EC) No 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling... [show more](#)
- Scope:**
 - Products Covered:** Electrical and Electronic Equipment (Aber: EEE)
 - Requirement Types:** Labelling, Providing product information, Registration, Retention/Destruction of records
 - Topics:** Energy Efficiency
- Dates:** Jun 30 **Compliance deadline:** suppliers must enter information in the product database for products placed on the EU market between 1 August 2023 and 1 January 2025. [Show all dates](#)

The interface includes a navigation menu with 'Assessments', 'Assessment summary', 'Company attachments', and 'Requirements'. A sidebar on the left lists 'Overview', 'Scope', 'Dates', 'Attachments', and 'News & Analysis'. A right-hand panel shows 'Activity' and 'Discussions' with a recent entry: 'Meg O'Keefe set relevance to 'Yes''. At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

3. Collaboration & Decision Making

- Activity, Task management & Discussions
- Fast and effective collaboration between SMEs
- Transparent decision making

The screenshot displays the 'West Coast Appliances' software interface. The main content area is titled 'Requirements for Plastic Food Contact Materials' and includes a 'Plastics FCM' restriction for the 'European Union (EU)'. Below this, there are tabs for 'Attachments', 'Linked regulations and standards', 'Evidence', and 'Specs'. The 'Description' section contains the following text:

Only the substances included in the Union list of authorised substances set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

Substances which are used must comply with 'Specific Migration Limits' (SML), the maximum amount of substances allowed to migrate to food.

To ensure the overall quality of the plastic, the Overall Migration Limit (OML) must also be observed.

On the right side, there is an 'Activity' panel with 19 items and a 'Discussions' panel with 1 item. The activity feed shows a 'New step in test for all products' by KarlC&R Dowling on Jun 24 and a 'Description updated' by KarlC&R Dowling. At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

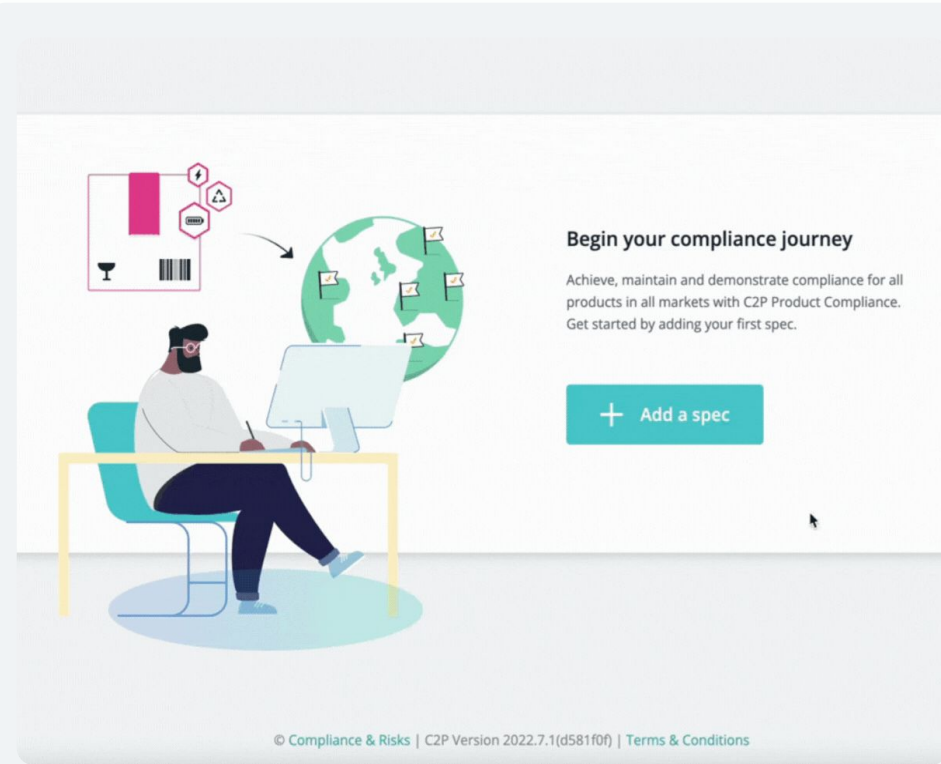
3. News & Analysis

- Expert commentary & analysis from our team of experts and network of knowledge partners
- Clarity on implications of a new/revamped regulation

The screenshot displays a web application interface for 'West Coast Appliances'. The top navigation bar includes 'West Coast Appliances', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. Below this, a secondary navigation bar features 'My Alerts', 'News & Analysis' (which is highlighted), 'Upcoming Dates', and 'Discussions'. The main content area is divided into a left sidebar and a central feed. The sidebar, titled 'FILTER', includes sections for 'Type' (with 'Regulatory Update' at 10651 and 'Expert Commentary' at 2005), and 'Author' (listing various firms and individuals with their respective article counts). The central feed, titled 'Search for News & Analysis', shows a search bar and a list of results. Two results are visible: 'Low Voltage Directive' by Cooley LLP (dated Aug 11) and 'UK REACH updates on restriction, SVHCs, and authorisation plus consultation on pushing back registration deadlines' by Chris Robertson of RINA (dated Aug 08). A right-hand sidebar contains a featured article titled 'Compliance & Risks Launches ESG Solution To Help Global Brands Meet Regulatory Obligations'. At the bottom right, there are buttons for 'Ask our Experts' and 'Help', along with a 'Show all' link.

3. Predefined Legal Compliance Requirements

- **Additional** requirement content offerings and services
- Help **accelerate** a company's ability to interpret regulations
- Increase the **productivity** of your SMEs & focus on supporting product growth



4. Determine the Penalty for Non Compliance

“Determining the penalty for non compliance is critical for us to be able to make the appropriate interpretation for our business and we will invest time to understand the sanctions if needed.”



Hop on the Product Development Journey with us..

Agree or disagree with the following statement based on your experience in your industry.



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Q&A