

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

# Demonstrate Compliance to Unlock Global Market Access



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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...**



# Key Challenges

## Unclear evidence needs

*"If you take a law of about 50 pages, the evidence needed to demonstrate compliance is buried within and is not clear to everyone. We have to work through it and inform everyone of what needs to be done and what level of evidence is needed."*

## Acting on the assessment

*"We in compliance, help build the processes, templates & policies which the business needs to execute to be compliant."*

*"The challenge is bringing in the right people at the right time & getting them signed up in agreement"*

## Proving vs. being compliant

*"It is not enough to have a product that's compliant, you have to be able to prove it."*

*"We put a lot of effort and money on the table to be able to prove compliance which is sometimes even more important than being compliant."*

SORT BY DATE ▾

- ☆ C2P Alert 15/02/2020
- 📎 9 Requirements to revi... Inbox - Google  
Hi Damien, The following West Coast Future requirements may need to be r....

# Demonstrate Compliance to Unlock Market Access

Holistic Market Access Solutions

# How can I accurately demonstrate compliance?

C&R's market research highlighted the key steps to demonstrate compliance for each product

1. Determine the **required evidence** for each requirement
2. Make a **compliance recommendation** for each product & **gain agreement** from key stakeholders & decision makers
3. Communicate compliance requirements for **implementation**
4. Compile a library of evidence **documentation**
5. Report on evidence of compliance to **internal & external stakeholders**

## Poll #1

Choose the step that you have found the most challenging in your experience at your organization.

# 1. Determine the required evidence for each requirement

*"The evidence needed varies hugely. It can depend on the nature of the evidence being requested or the governing body that is setting the regulations and measuring the compliance.*

*We make products that go into military equipment, and some of those products are considered classified under DFAR which basically carries with it some very strict and rigorous evidence requirements for meeting the DFAR compliance requirements."*



# 1. Identify deliverables

- Our SME's extract **deliverables** from each regulation
- Clear action for each requirement

The screenshot displays the 'West Coast Appliances Admin' interface. The top navigation bar includes 'West Coast Appliances', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main content area is titled 'Requirements' and features a search bar, a 'Filter' button, and a 'Last updated' dropdown. The search results are sorted by 'Date Updated' and show 1 to 30 of 4,714 results. The first result is 'Energy Label in Visual Advertisements or Promotional Material for Refrigeration Appliances', dated Sep 05. The details for this requirement include: 'Labelling', 'Labelling: Ecolabeling & Energy Efficiency Declarations', 'Appliances - Wine Cabinets', 'Cooling (using refrigerant gases)', and 'European Economic Area (EEA)'. A summary text states: 'Any visual advertisement, or any technical promotional material for a specific model of refrigerating appliance must contain the energy efficiency class and the range of energy efficiency classes available on the label in accordance with Annex VII an...'. On the right side, there is a 'Saved searches' section with entries like 'My company', 'Batteries Brazil', 'Safety - Asia', and 'Machinery Directive'. At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

# 1. Define draft evidence

- Create draft evidence records for each requirement
- Collaborate with advisors & stakeholders on the level of evidence needed

The screenshot displays a web application interface for compliance management. The top navigation bar includes 'West Coast Appliances' and 'Admin'. Below the navigation, there are tabs for 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main content area shows a requirement titled 'Restriction for Cadmium in Electrical and Electronic Equipment' with a status of 'Mandatory'. It indicates that there are 6 exemptions for this requirement. The breadcrumb trail shows the path: 'Substances and Materials' > 'Cadmium' > 'Substance & Materials: Restricted Substances & Materials' > 'Fridge freezer appliances' > 'Mini Refrigerators' > 'Refrigerators' > 'India'. The interface also features a 'Linked evidence' section with a message 'No Evidence linked yet.' and an 'Add evidence' button. On the right side, there is an 'Activity' panel showing a notification: 'First published by Compliance and Risks by C2P' dated May 16. At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

## 2. Make compliance recommendation & gain agreement

*"Harmonization is a key factor. Wherever I can do something to bring the different regions and countries on the same ground, regulating the same thing the same way, is our primary goal."*

*Diversity in regulations kills the entire compliance effort because you multiply resources required, the budget needed for fulfilling the different certification testing."*



## 2. Collaborate on requirements

- Assess the same regulation to produce **unambiguous decisions**
- **Harmonise** your compliance approach across all teams, products & markets
- **Reduce** unnecessary work

The screenshot displays a web application interface for 'West Coast Appliances'. The top navigation bar includes 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main content area is titled 'Requirements for Plastic Food Contact Materials' and includes a 'Description' section with 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.

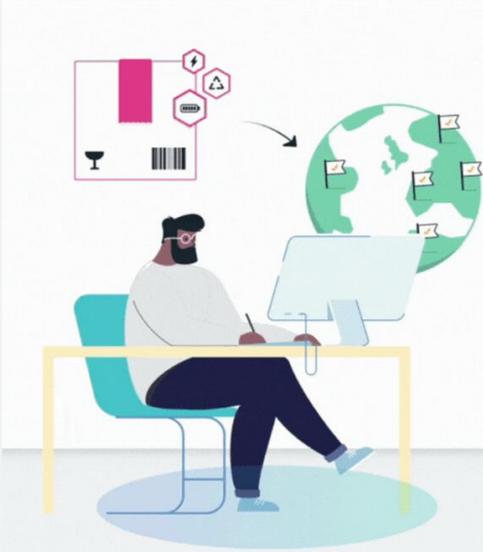
On the right side, there is an 'Activity' panel with a search bar and a list of updates:

- New step in test for all products** by Karic&R Dowling (Jun 24)
- Description updated** by Karic&R Dowling (Jun 24)

Buttons for 'Ask our Experts' and 'Help' are visible at the bottom right of the activity panel.

## 2. Product Compliance Specifications

- Easily create a **product focused** outcome
- All relevant **requirements & evidence** need to be compliant
- Produce **reports** to gain agreement & start implementation



The illustration shows a person with a beard and glasses sitting at a desk, working on a computer. Above them is a globe with several location pins. To the left of the globe is a product specification card with a barcode, a lightning bolt icon, a recycling symbol, and a speech bubble icon. An arrow points from the product card to the globe.

**Begin your compliance journey**

Achieve, maintain and demonstrate compliance for all products in all markets with C2P Product Compliance. Get started by adding your first spec.

[+ Add a spec](#)

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# 3. Communicate compliance requirements for implementation

*"We in compliance, help build the processes, the templates, the policies that allow us to be compliant, and then the business needs to execute. **The challenge is bringing in the right people at the right time, getting them signed up that, yes, in fact, we need to do all of this. You need to build it in as part of your process at the beginning, as opposed to afterwards.**"*



# 3. Collaboration & Decision Making

- Task management & discussions
- Fast and effective collaboration between stakeholders
- Record activity provides transparent decision making

The screenshot displays the 'West Coast Appliances' software interface. The main document is titled 'Requirements for Plastic Food Contact Materials'. It includes a 'Description' section with 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.

The interface also features a navigation bar with 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. A right-hand sidebar shows an 'Activity' log with 19 items and 'Discussions' with 1 item. The activity log includes entries such as 'New step in test for all products' and 'Description updated'. At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

# 3. Watching for updates

- Watch your Product Compliance Specs
- Get alerts on new or updates requirements
- Insights into any changes during implementation

The screenshot displays the 'Product Compliance' section of the West Coast Appliances (WCA) system. The interface includes a navigation bar with 'West Coast Appliances', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. Below this, there are tabs for 'Specs', 'Requirements', and 'Evidence'. A search bar and '+ Add Spec' button are located at the top right of the main content area. The 'My specs' section is active, showing three product specification cards:

- WCA Air Fryers**: Includes Australia, France, United Kingdom (UK), and United States of America. Categories: Food Contact, Heating Technology, Product Packaging, Recycled. Updated Sep 27, 2022.
- WCA Coffee Machines**: Includes France, Germany, and Spain. Categories: Brewing Chambers, Pressure Equipment, Product Packaging. Updated Sep 27, 2022.
- WCA Microwave Ovens**: Includes Canada and United Kingdom (UK). Categories: Food Contact, Product Packaging. Updated Sep 27, 2022.

Each card features a product image, a list of countries, a list of categories, an update date, and an 'OWNER' field with a user profile icon. At the bottom of the page, there is a footer with '© Compliance & Risks | C2P Version 2022.9.2(e30deb2) | Terms & Conditions' and two buttons: 'Ask our Experts' and 'Help'.

## 4. Compile a library of evidence documentation

*"We don't use any management system to structure our folders, it is a bit haphazard e.g. folder by model, energy efficiency certs, etc. random folder names.*

*This makes it very difficult to locate the exact documents because we don't know if a document is about to expire, or will expire or should expire."*



# 4. Documenting evidence records

- Single place for all evidence documentation
- Linked to requirements
- Track evidence expiration

The screenshot displays the 'Evidence' management interface. The top navigation bar includes 'West Coast Appliances', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. The main header has tabs for 'Specs', 'Requirements', and 'Evidence'. A search bar is present with the text 'Search for Evidence'. Below the search bar, there are filter options for 'Complete' (Yes/No), 'Evidence type' (Certificate, Test Result, Registration, Supporting document), 'Product model', and 'Geography' (Expiry dates, Include archived). The main table shows a list of evidence records with the following columns: TITLE, DOCUMENT TYPE, PRODUCT MODEL, GEOGRAPHY, NOTE, EXPIRY DATE, COMPLETE, and LAST UPDATE.

TITLE	DOCUMENT TYPE	PRODUCT MODEL	GEOGRAPHY	NOTE	EXPIRY DATE	COMPLETE	LAST UPDATE
FDA- 3881	Registration	All WCA Products	European Union (EU)			No	Aug 22
test demo	Certificate	All WCA Products	European Union (EU)		Jul 27, 2022	No	Jul 05
DOC - USA	Certificate		United States of America (USA)		Jun 28, 2023	No	Jun 27
Test For FCM Composition	Test Result	WCA Coffee Machines	European Economic Area (EEA), European Union (EU)		Jun 11, 2027	No	Jun 24

At the bottom right, there are buttons for 'Ask our Experts' and 'Help'.

## 4. Missing evidence for each product

- Evidence scoped to **products** & **requirements**
- Identify **gaps** in evidence
- Confidence all products are **compliant**

The screenshot displays the 'West Coast Appliances' Product Compliance dashboard. The interface includes a top navigation bar with 'West Coast Appliances', 'Inbox', 'Library', 'Product Compliance', and 'Dashboard'. Below this is a secondary navigation bar with 'Specs', 'Requirements', and 'Evidence'. The main content area shows a grid of product specification cards under the 'All specs' tab. Each card includes a product icon, title, region, update date, and owner information. A search bar and '+ Add Spec' button are located at the top right of the grid. A 'Learn more about Product Compliance' link is visible above the grid. At the bottom right, there are 'Ask our Experts' and 'Help' buttons.

Product Name	Region	Updated	Owner
All WCA Consumables	Asia	Jun 14, 2022	MH
All WCA Products	United States of America (USA)	May 09, 2022	KD
Childrens Power Toothbrush	Canada • European Economic Area (EEA) • United Kingdom (UK) • ...	Dec 08, 2021	KD
WC Baby Bottles	Canada • European Union (EU)	Aug 22, 2022	KD

## 5. Report evidence to key stakeholders

*"Providing too little or too much evidence information of the compliance of a product can open the company up to potential liability issues, or further questions from regulatory bodies.*

*Therefore, we need to ensure our reporting is accurate and is key for maintaining audit deadlines."*



# 5. Demonstrating compliance

- Provide **stakeholders** access to evidence records
- Provide access to **auditors**
- **Quickly respond** to requests to prove compliance

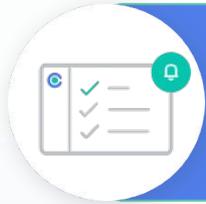
The screenshot displays the 'West Coast Appliances' Product Compliance interface. The main content area shows a table of evidence records with the following columns: TITLE, DOCUMENT TYPE, PRODUCT MODEL, GEOGRAPHY, NOTE, EXPIRY DATE, COMPLETE, and LAST UPDATE. The table contains three rows of data:

TITLE	DOCUMENT TYPE	PRODUCT MODEL	GEOGRAPHY	NOTE	EXPIRY DATE	COMPLETE	LAST UPDATE
FDA- 3881	Registration	All WCA Products	European Union (EU)			No	Aug 22
test demo	Certificate	All WCA Products	European Union (EU)		Jul 27, 2022	No	Jul 05
DOC - USA	Certificate		United States of America (USA)		Jun 28, 2023	No	Jun 27

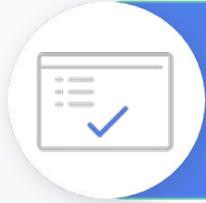
The interface also includes a sidebar with filter options for 'Complete' (Yes/No), 'Evidence type' (Certificate, Test Result, Registration, Supporting document), and 'Product model'. A 'Product Compliance' dropdown menu is open, showing options for 'Specs', 'Requirements', and 'Evidence'. The URL at the bottom is <https://www-12.compliance2product.com/c2png/product-compliance>.

# A Smarter Way to Manage Product Compliance

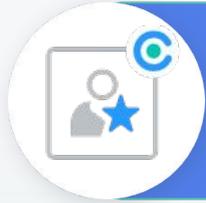
Holistic Market Access Solutions



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



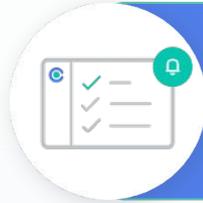
*“What do I need to do to sell product X into a new market?”*

→ Expand market access

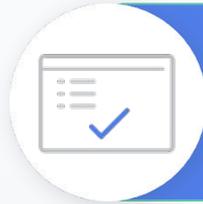
# Accelerate the ability to

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

Achieve your  
business  
objectives,  
by ...



Demonstrating Compliance



For what is required



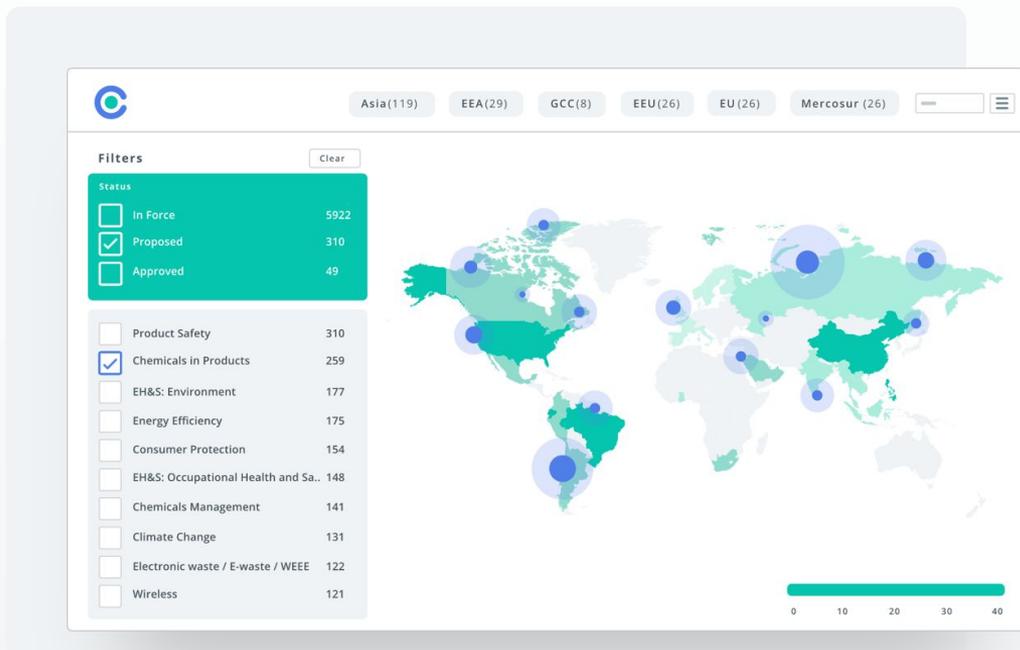
Driven by Global  
Regulations & Standards

TECHNOLOGY - C2P

# C2P

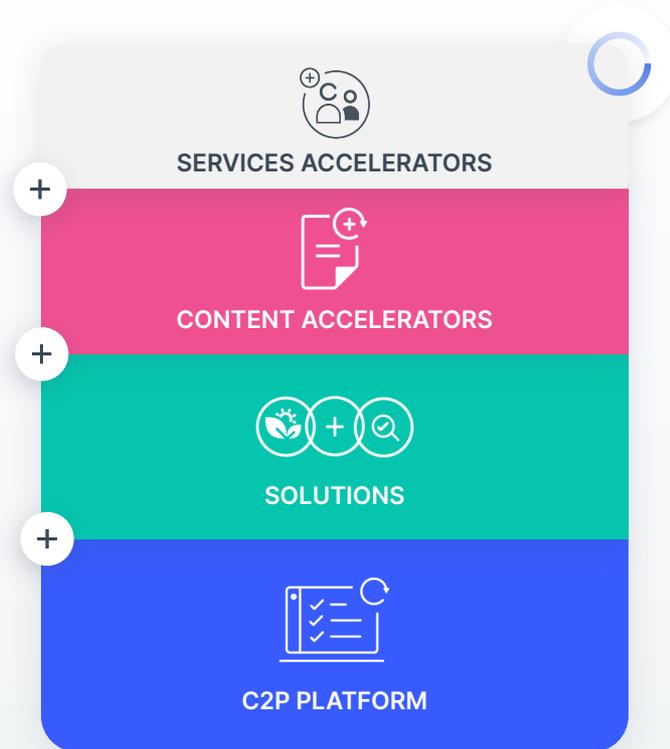
## The Key to Unlocking Market Access

- 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



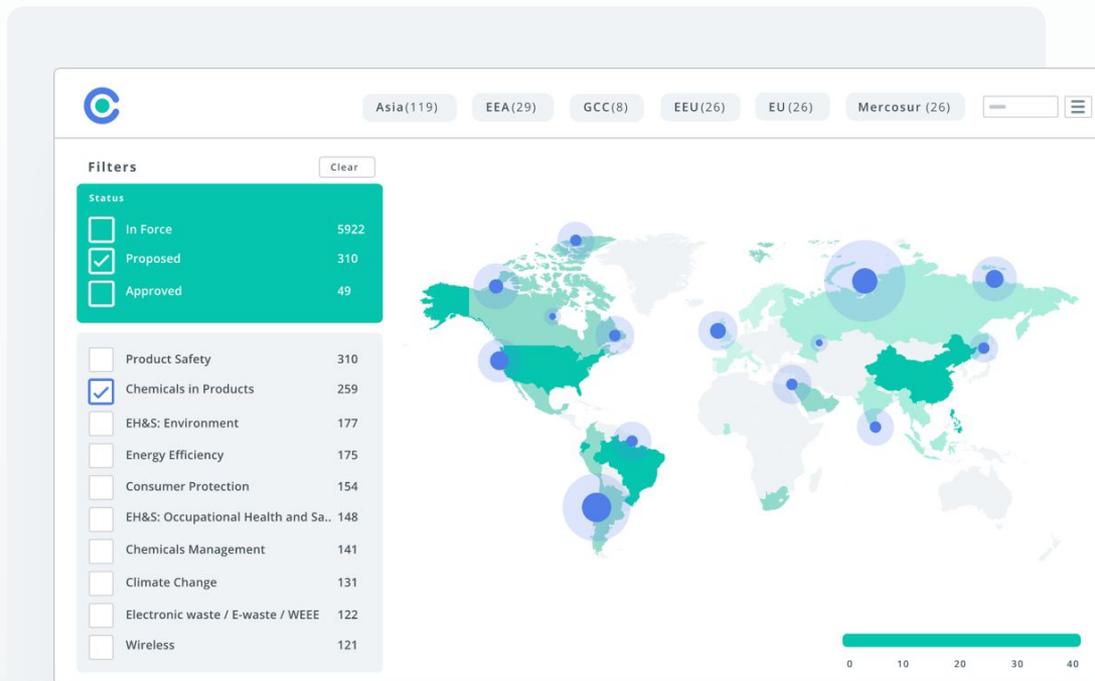
# Tailored to meet your needs...

- Comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence
- 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
- Integrate with other systems to enable [streamlined business processes](#)



WHY C2P?

# Why Invest in a Technology Platform?

- Accelerate time-to-market for products
- Reduce non compliance risks that impact your ability to meet business goals and cause reputational damage
- Enable business continuity by digitizing your compliance process and building corporate memory
- Improve efficiency and enable your team to focus on business critical initiatives rather than manual tasks
- Save time with access to Compliance & Risks' extensive Knowledge Partner network



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# Q&A