Webinar Series: Achieve Market Access

From a Tidal Wave of Regulation to a Compliant Product

Trish Butler
CMO
Compliance & Risks

Luis Torregrosa
Head of Product
Compliance & Risks

27th July 2022

Compliance & Risks

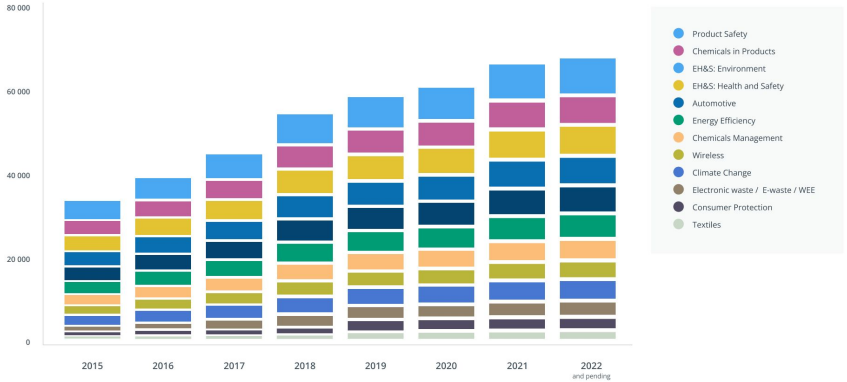
UNLOCKING MARKET ACCESS

Unlocking Market Access

GROWTH IN REGULATIONS

A Tidal Wave of Regulations hitting Product Manufacturers...

60% Growth in Regulations in the past 5 years



GROWTH IN REGULATIONS

What are the exact Regulations my Product needs to comply with?

- National regulations
- Product specific safety standards
- Mandatory standards
- Documentation
- Global regulations
- Voluntary standards
- Substance regulations
- Testing
- Labelling
- Certifications
- ESG obligations
- Harmonized standards
- RoHS/Reach
- Chemicals in your products
- Cybersecurity

Trying to keep on top of it all...

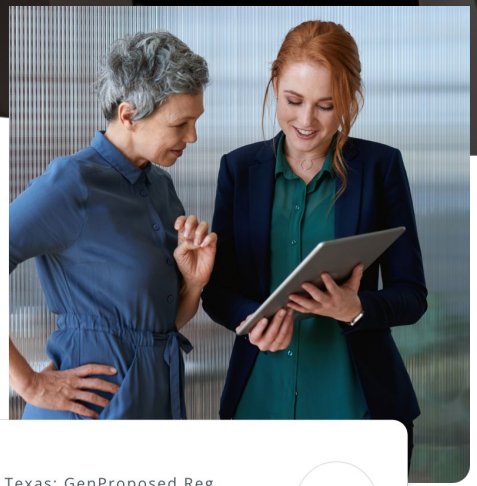
Compliance & Risks

ACHIEVE MARKET ACCESS

‘Can I sell Product X in Market Y?’

1. Identifying the right Compliance Sources
2. Clarify what applies to my Products across Markets
3. Assess Relevance & Deep Dive into exact Product Requirements

Key Challenges



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

Sep 8

Compliance & Risks

Readily identify the right regulations..

"We need to be able to readily identify emerging product-related regulatory issues around the world, and to manage them in an efficient manner"

Not enough time..

" Usually, there is not enough time to understand the regulations and act on our products to be compliant to all those regulations"

Quickly tailor to our products..

"Our compliance teams should to be able to quickly tailor the regulatory content to our specific needs"

ACHIEVE MARKET ACCESS

1. Identifying the right Compliance Sources...

"We are struggling to do this as our existing setup is somewhat ***piece-meal and dispersed among different systems and providers****.*

This makes it ***difficult to understand if we are seeing all of the regulatory information that we need.***

ACHIEVE MARKET ACCESS

2. Establish what Applies to my Products Across Markets

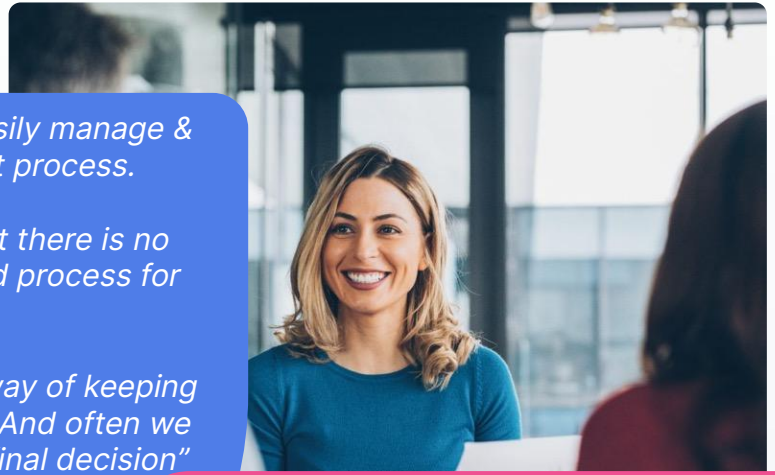
*"We need to cross-identify all **Regulations & Standards** for my **Product X** in **Market Y** of interest.*

*But the challenge is that **I need the time and skills** to navigate through an **overwhelming amount of information**."*

"Working across multiple industries we need to interpret the applicability of regulatory changes to our product portfolio & develop systems to ensure we are compliant."

ACHIEVE MARKET ACCESS

3. Assess Relevance & Deep Dive into Exact Product Requirements



"I need to be able to easily manage & maintain an assessment process.

But the challenge is that there is no streamlined coordinated process for our team's work.

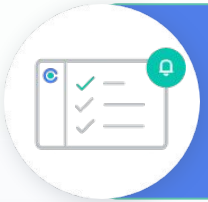
There is no organised way of keeping the corporate memory; And often we are not sure about our final decision"

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

A Smarter Way to Manage Product Compliance

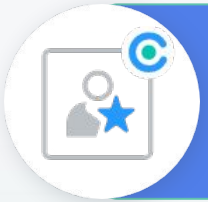
Holistic Market Access Solutions

Compliance & Risks



Powerful Enterprise Technology - C2P

Curated Global Regulatory Content



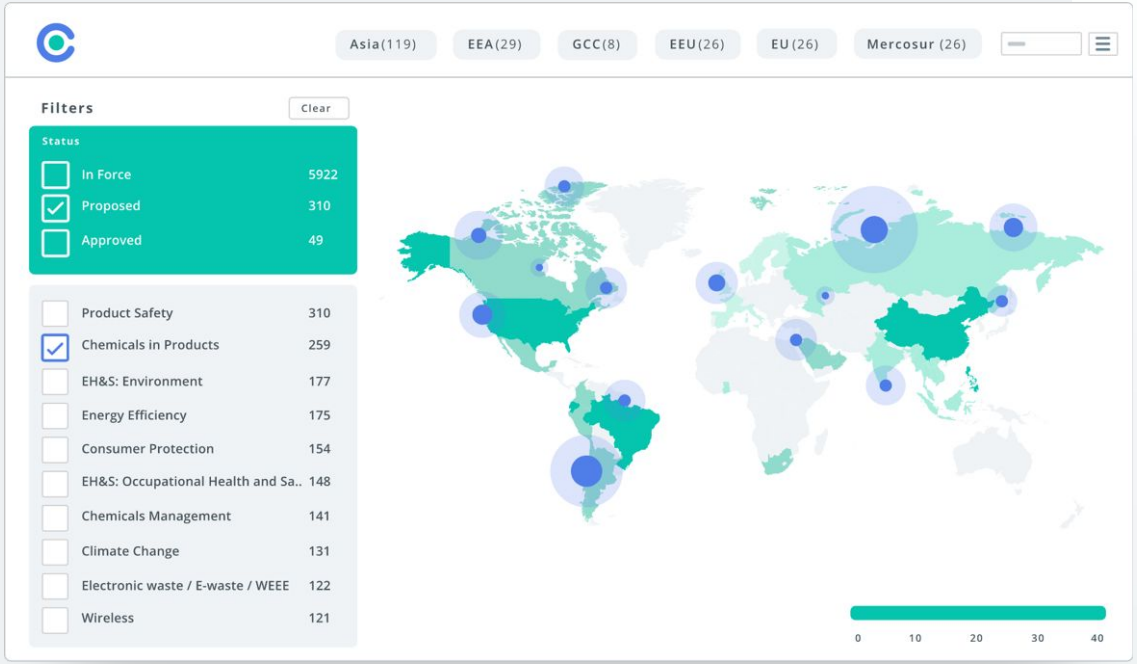
Team of Subject Matter Experts

Holistic Market Access Solutions...

TECHNOLOGY - C2P

Manage everything in One Place...

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



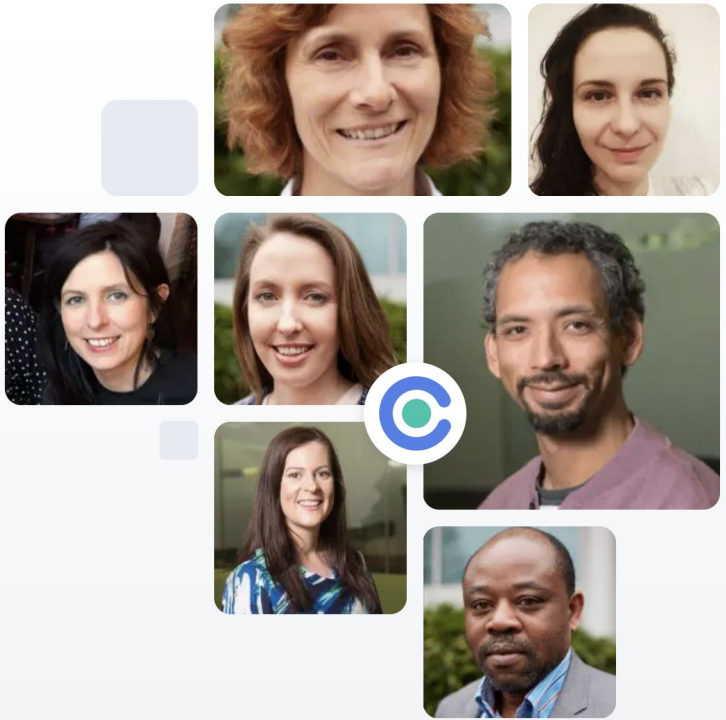
C2P - The Key to Unlocking Market Access

EVIDENCE	Procure & link evidence records to relevant requirements to prove compliance
REQUIREMENTS	Capture, analyze & manage in the platform “live” linked to regulations & standards. Build customized sets of requirements covering your products & countries
STANDARDS	Contextual linking to regulations & requirements Searchable versions & equivalences of standards
REGULATIONS	Stay in control of the evolving regulatory landscape with access to 70,000+ proposed & enacted regulations & documents

SUBJECT MATTER EXPERTISE

Global Regulatory Expertise

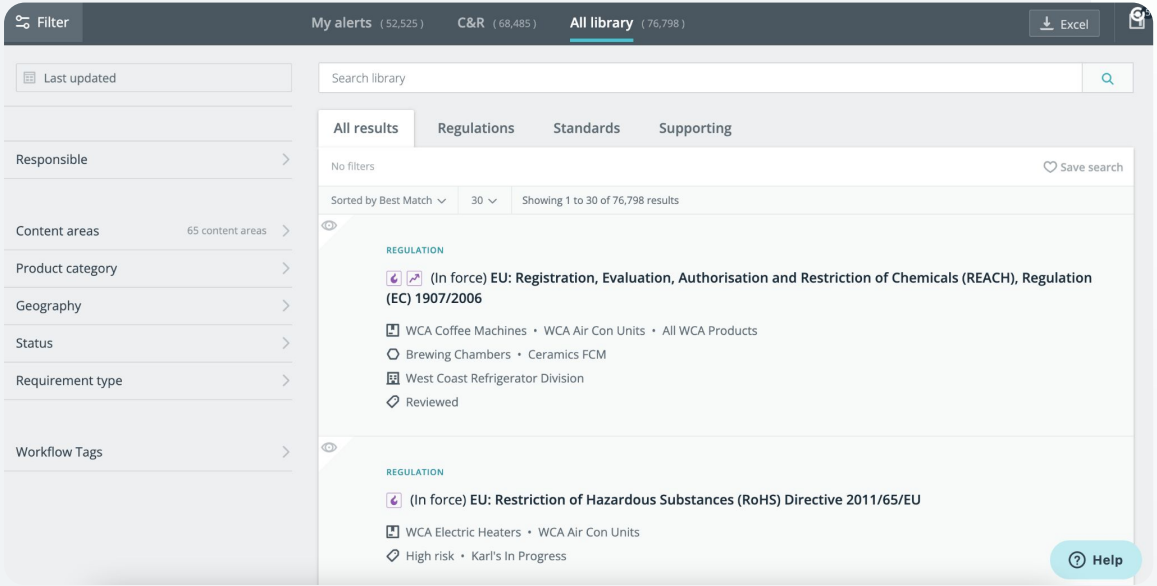
- 40+ Subject Matter Experts around the globe gathering necessary compliance information
- Almost 30 languages spoken to understand the local complexity
- Extensive Knowledge Partner network
- Expertise across products, geographies & policy areas



TECHNOLOGY - C2P

1. Relevance Increase

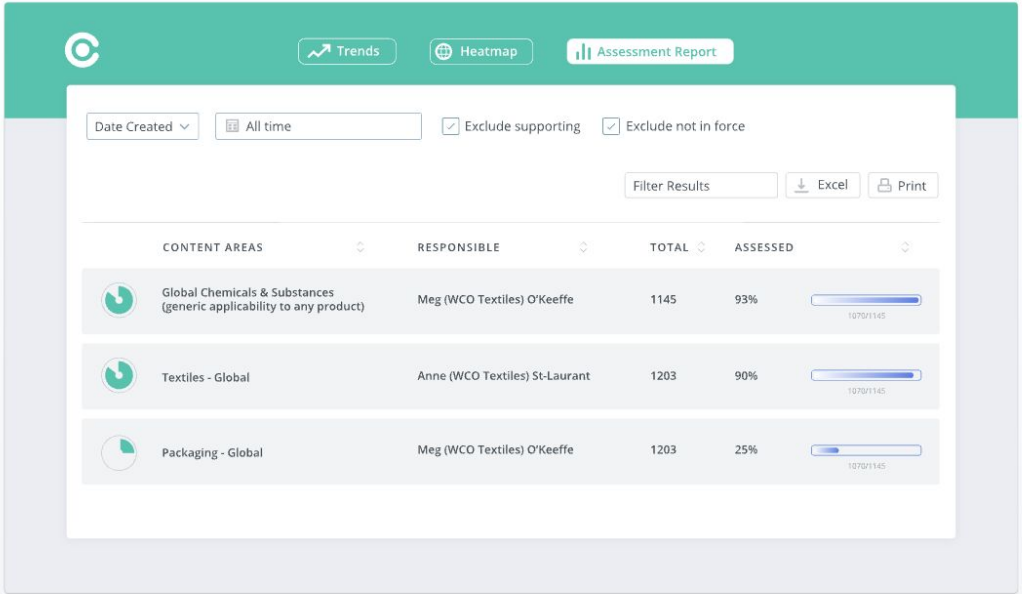
- Eliminate noise
- Tailor C2P to your products
- Filtered alerts



TECHNOLOGY - C2P

2. Search & Filter Regulations

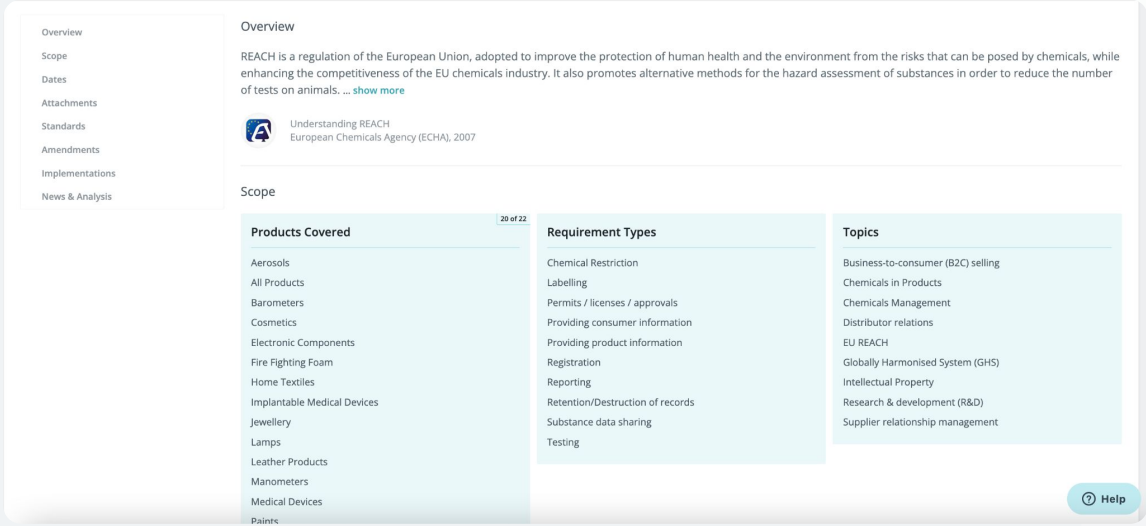
- Easy navigation through regulatory content
- Intelligent search engine
- Easy to filter information



TECHNOLOGY - C2P

3. Regulatory Summaries

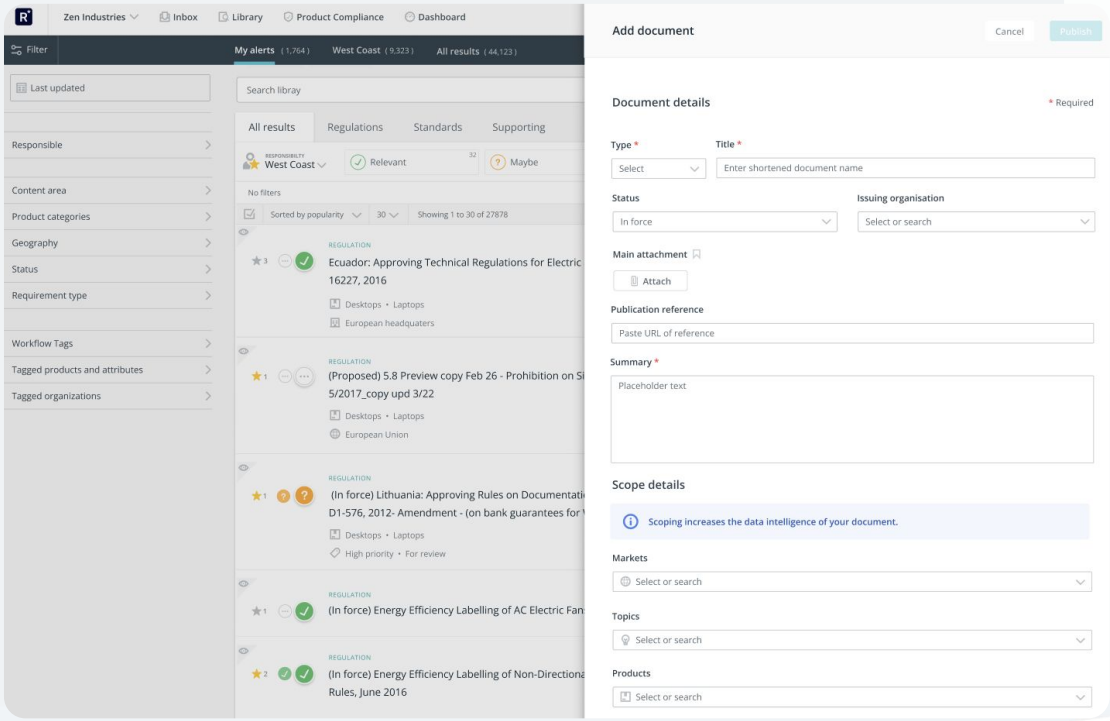
- Readily available
- Extracted from regulatory text to give quick insight
- Essential metadata for faster decision-making
- Local language documents summarised into English



TECHNOLOGY - C2P

4. Integrate Internal Documents

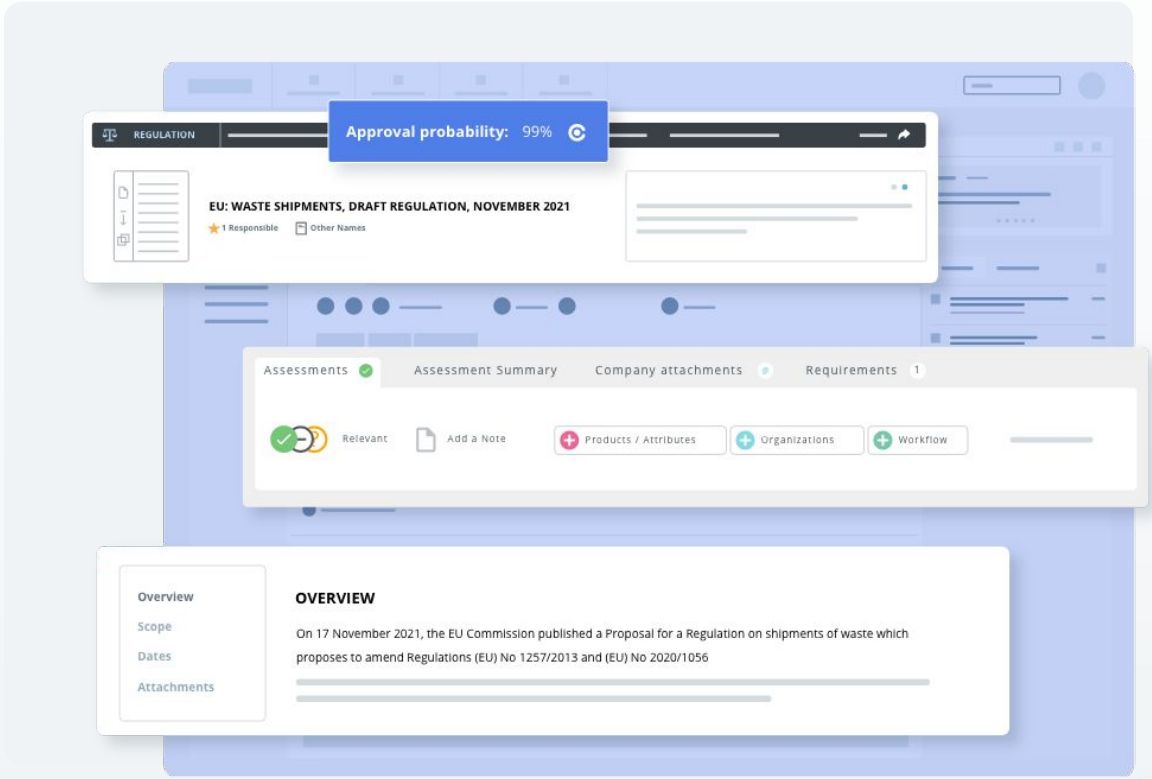
- Include internal policies
- Add internal documents and integrate them with C2P



TECHNOLOGY - C2P

5. Probability Analysis

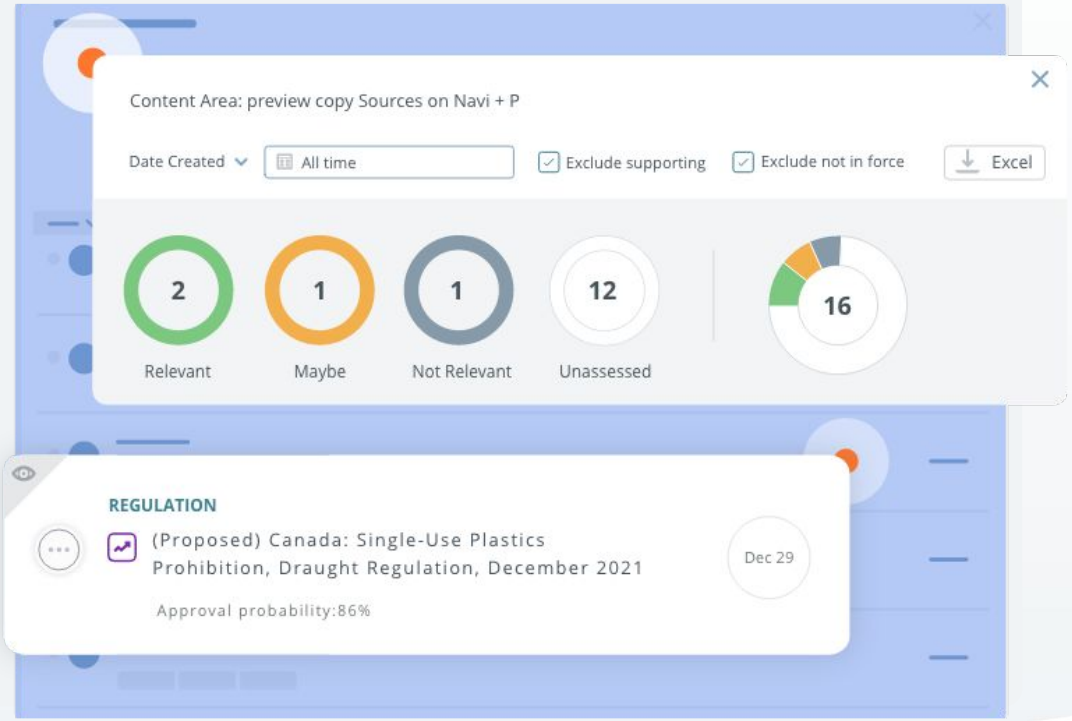
- Know what's coming beforehand
- Draft regulations included
- AI powered probability of approval



TECHNOLOGY - C2P

6. Assessments

- Earmark the regulations that need to be actioned on
- Maintain your corporate memory with a uniform criteria



TECHNOLOGY - C2P

7. News & Analysis

- Clarity on implications of a new/revamped regulation
- Analysis from our team of experts

Expert Commentary preview 6 of 30 Print Share

The New Blue: EU Updates Key "Blue Guide" to Products Laws

Tracey Bischofberger and Edward Turtle of Cooley LLP

The European Commission has published its revised 2022 Blue Guide (available here). The Blue Guide is a key guidance document for EU product rules and the Commission describes the revision as "a substantial update". In this blog, we provide a quick summary of some of the headline changes.

Background

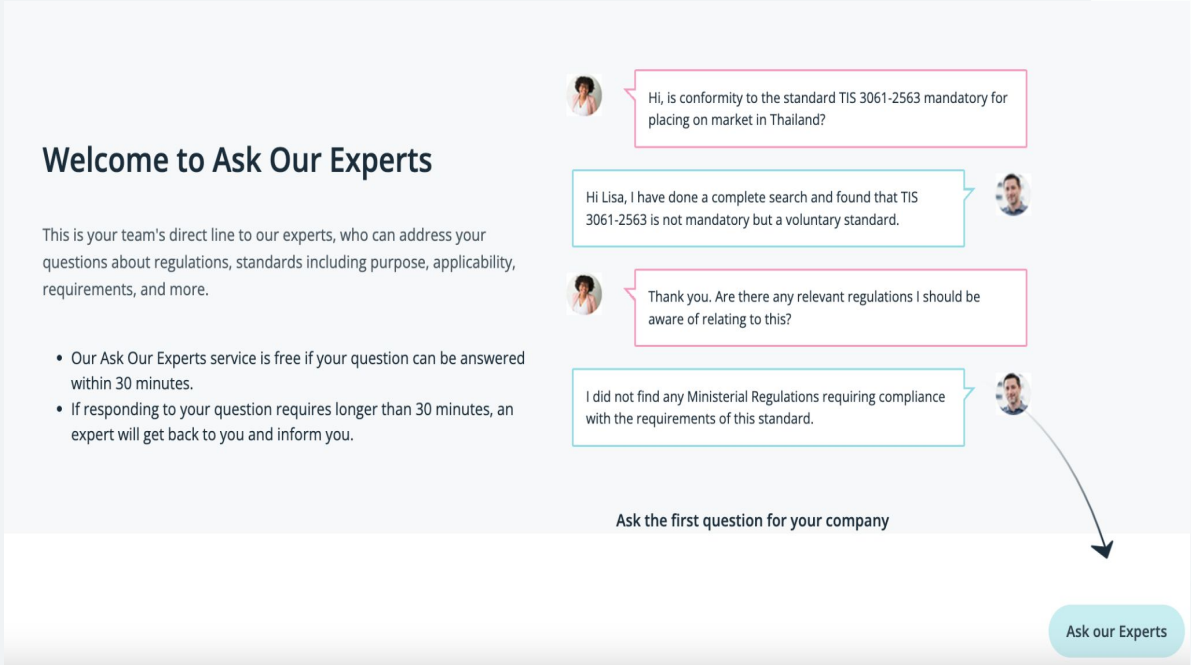
The Blue Guide is a key European Commission guidance document for EU product rules and applies to a wide range of products covered by Union harmonisation legislation (i.e., generally, CE-marked products). These include radio equipment, electrical and electronic equipment, medical devices, toys, machinery and PPE, amongst many others. More information can be found in our bitesize introduction to the Blue Guide.

The Blue Guide's broad scope and detailed guidance also make it influential in other areas. Whilst not legally-binding, it provides meaningful interpretation guidance on many areas of product regulation, and in practice is relied upon heavily by market surveillance authorities. The Blue Guide was first published more than two decades ago, in 2000, and was updated in 2014 and 2016. The latest revision has been a while in the

TECHNOLOGY - C2P

8. Ask Our Experts

- Get a second opinion
- Direct access to our team of subject matter experts



WHY C2P?

Greater ROI for the Compliance Team

- Optimize your compliance process with C2P & reduce Time-to-Market
- Improve your team's efficiency by focussing on decision making rather than on bookkeeping & firefighting

Q&A