

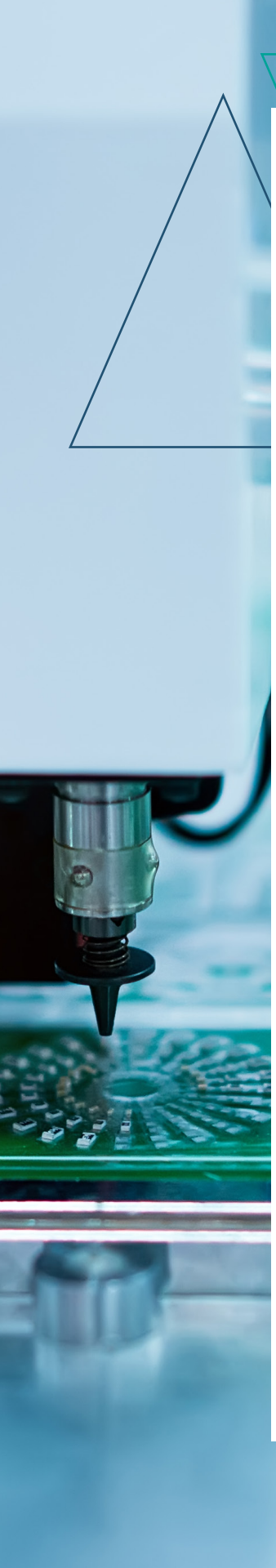
Assent

Real depth. Sustainable growth.™

eBook

The RoHS Handbook

Your Guide to Compliance



Introduction

The EU Restriction of Hazardous Substances (RoHS) Directive seeks to reduce the negative impact of electrical and electronic equipment (EEE). The substances targeted by the directive include those with the potential to compromise the natural environment, pollute landfills, and harm human health.

Under the RoHS Directive, companies must take the initiative to ensure none of the listed substances are used in their products, or, if no safer alternatives to the substances are available, that a technical exemption has been approved and published by the European Commission. Non-compliance with RoHS can result in fines and/or loss of EU market access. This is why compliance with RoHS needs a proactive approach — new substances are always being evaluated and the list of RoHS technical exemptions is constantly changing.

If you are a product or regulatory compliance manager, engineer, or quality assurance personnel and you're wondering how to stay ahead of regulatory changes, this handbook is for you.

After reading, you will:

- Understand the RoHS Directive and its requirements for your company
- Understand the technical exemptions and what their respective expiration dates mean
- Know the difference between exempted and out-of-scope substances and excluded product categories
- Be aware of the latest updates for RoHS and how they will affect your compliance program
- Gain practical insights into how to conduct proactive due diligence for continued RoHS compliance



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CHAPTER ONE

RoHS Fundamentals

This chapter covers the basics of the RoHS Directive and its impact on the electronics industry. You'll understand which substances are in scope, how to use exemptions, and the requirements for compliance.

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RoHS Enforcement

Learn about the penalties for RoHS non-compliance, the importance of the CE marking, and how to conduct defensible due diligence.

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CHAPTER THREE

A Proactive Approach to RoHS Compliance

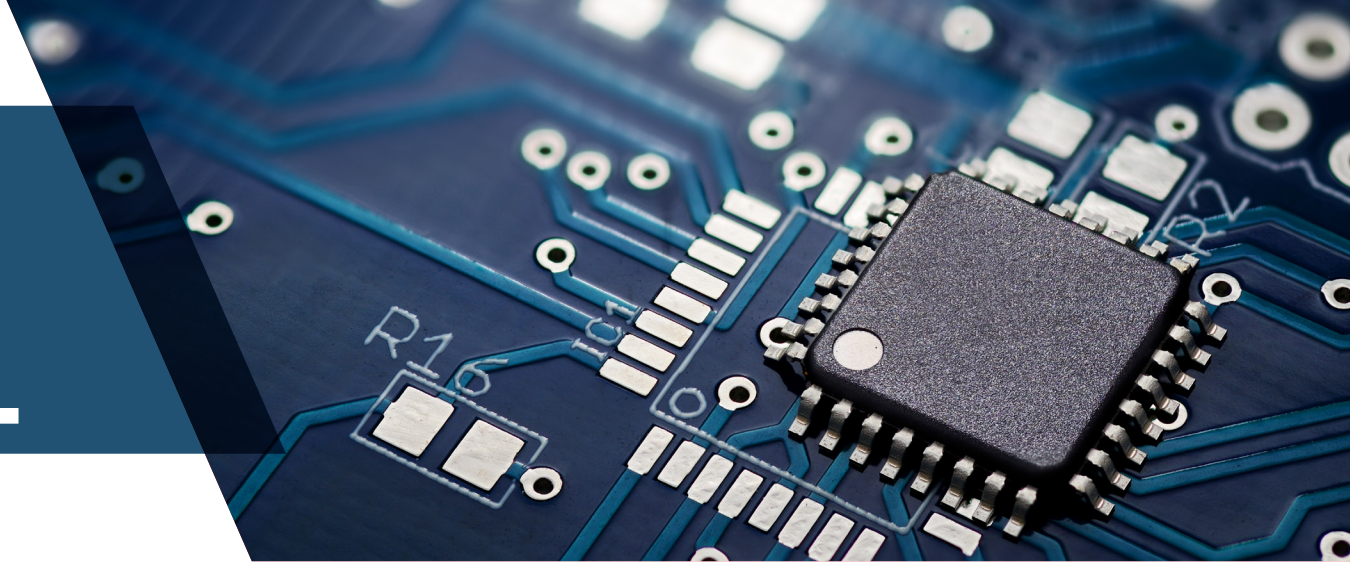
See why an internal solution to RoHS compliance may not be the answer, and get strategies for proactive compliance.

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Book a demo of Assent's RoHS compliance solution to start improving your data quality and risk management.

Book a Demo

CHAPTER 01



RoHS Fundamentals

Overview of EU RoHS

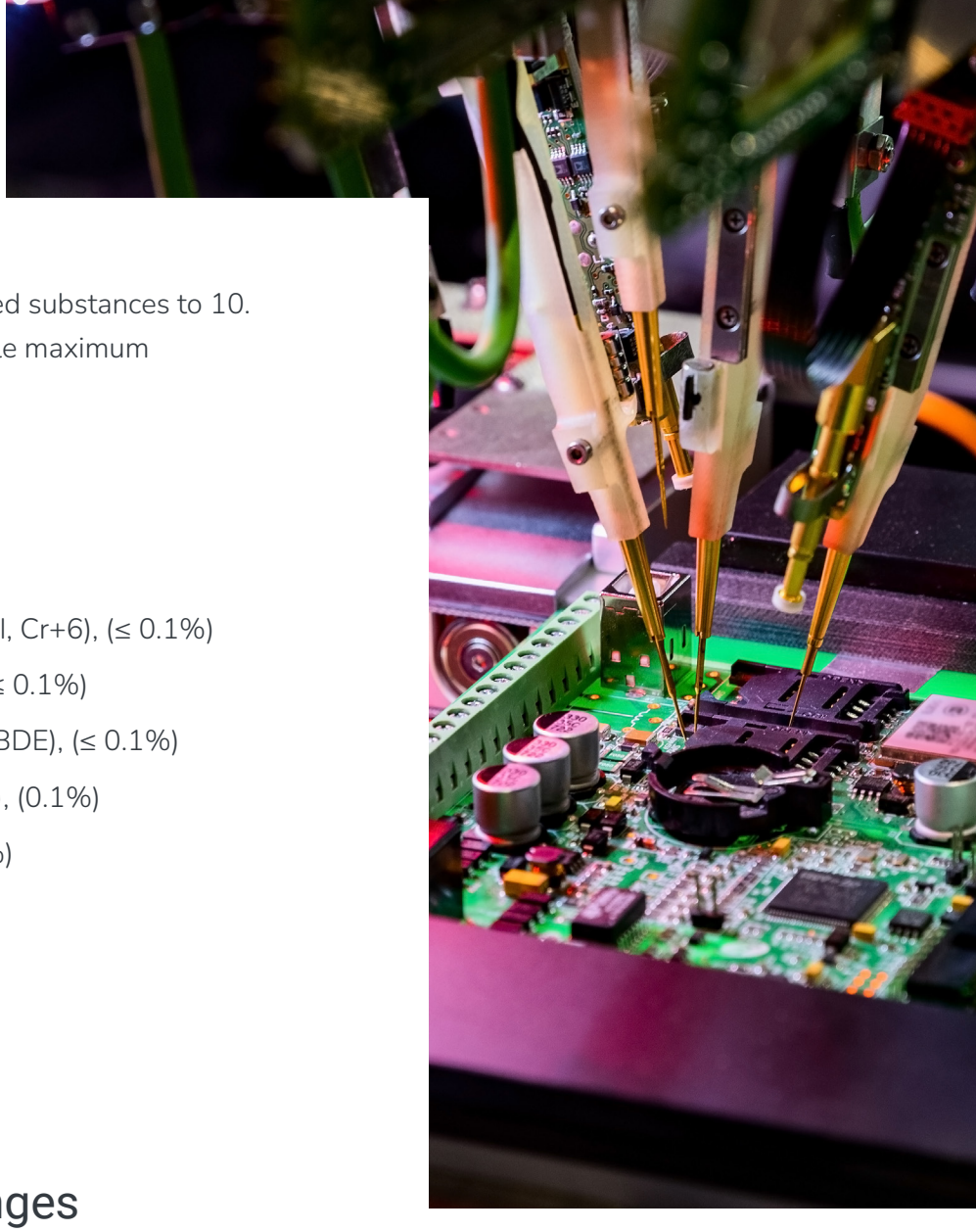
The RoHS Directive, also known as Directive 2002/95/EC, originally went into effect in July 2006, but has been significantly updated twice since then.

RoHS 2 (Directive 2011/65/EU), a recast or replacement of the original RoHS Directive, came into effect on January 2, 2013.

It involved a range of changes, including:

- An expanded list of technical exemptions, which today number over 150
- A requirement for periodic re-evaluations to facilitate the ongoing expansion of EEE in scope of RoHS over time
- A requirement for companies to demonstrate detailed compliance with the directive (non-compliance now labeled a criminal offense)
- Adding an automatic expiration date if a technical exemption is not approved for renewal following the submission of requests from industry
- Making it possible for new substances to be added to the list of restricted chemicals

An amendment to RoHS (Directive (EU) 2015/863) followed two years later, adding four more substances (all phthalates) to the list of restricted chemicals under Annex II.



This brought the total number of restricted substances to 10. They are listed below with their allowable maximum concentrations, weight by weight (w/w).

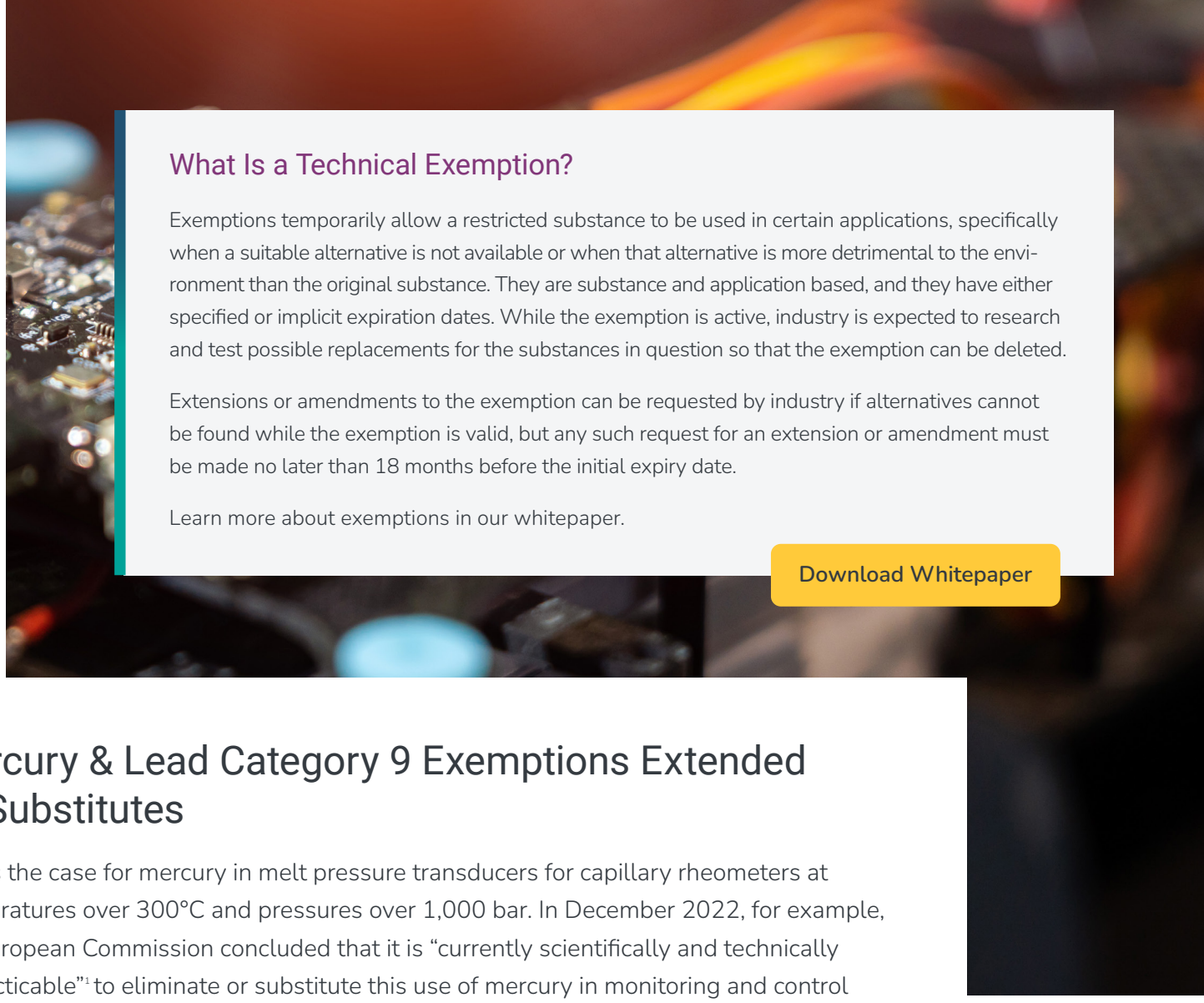
1. Lead (Pb), (≤ 0.1%)
2. Mercury (Hg), (≤ 0.1%)
3. Cadmium (Cd), (≤ 0.01%)
4. Hexavalent chromium (chromium VI, Cr+6), (≤ 0.1%)
5. Polybrominated biphenyls (PBB), (≤ 0.1%)
6. Polybrominated diphenyl ethers (PBDE), (≤ 0.1%)
7. Bis(2-ethylhexyl) phthalate (DEHP), (0.1%)
8. Benzyl butyl phthalate (BBP) (0.1%)
9. Dibutyl phthalate (DBP) (0.1%)
10. Diisobutyl phthalate (DIBP) (0.1%)

RoHS Exemptions

Exemption Process Changes

In July 2023, the European Commission released a proposal to shift the responsibility for key scientific and technical tasks to the European Chemicals Agency (ECHA). One of the key changes will be the transfer of the process to receive, consider, and accept or reject industry requests for new technical exemptions or extensions of existing exemptions.

Currently, to acquire an exemption or an extension, a company must submit an application to the European Commission. The Commission then appoints a technical consultant and asks them to provide findings and recommendations for consideration. When this new proposal is agreed upon, those seeking exemptions will need to make their submissions to ECHA.



What Is a Technical Exemption?

Exemptions temporarily allow a restricted substance to be used in certain applications, specifically when a suitable alternative is not available or when that alternative is more detrimental to the environment than the original substance. They are substance and application based, and they have either specified or implicit expiration dates. While the exemption is active, industry is expected to research and test possible replacements for the substances in question so that the exemption can be deleted.

Extensions or amendments to the exemption can be requested by industry if alternatives cannot be found while the exemption is valid, but any such request for an extension or amendment must be made no later than 18 months before the initial expiry date.

Learn more about exemptions in our whitepaper.

Download Whitepaper

Mercury & Lead Category 9 Exemptions Extended as Substitutes

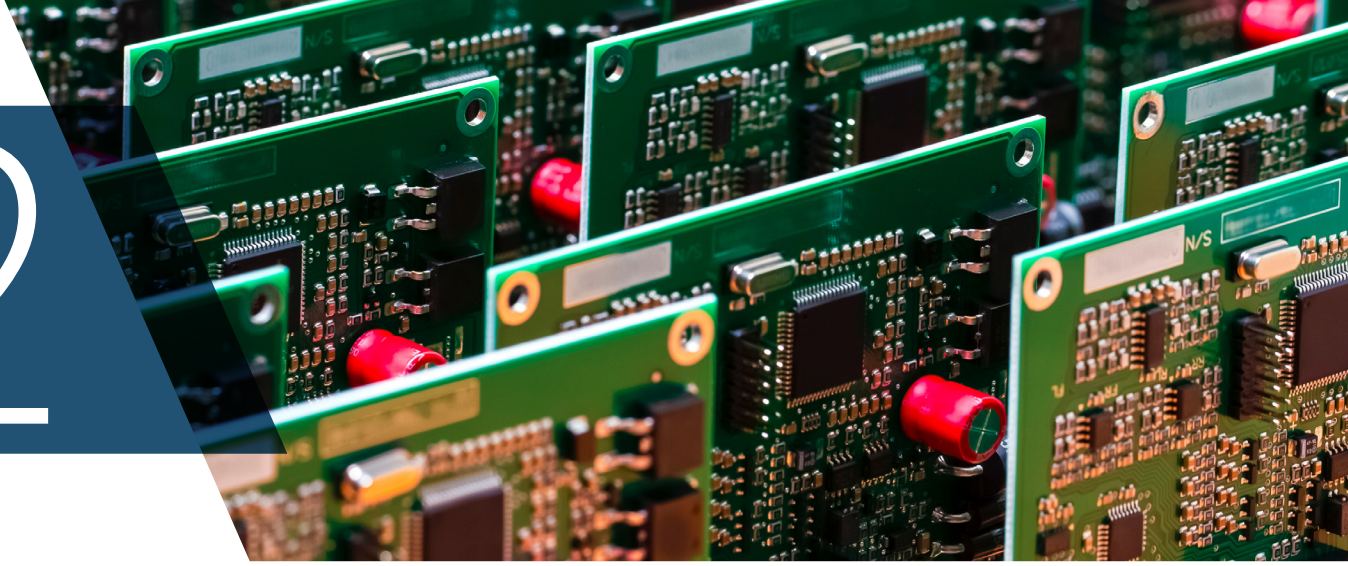
This is the case for mercury in melt pressure transducers for capillary rheometers at temperatures over 300°C and pressures over 1,000 bar. In December 2022, for example, the European Commission concluded that it is "currently scientifically and technically impracticable"[1] to eliminate or substitute this use of mercury in monitoring and control instruments that fall under category 9 of RoHS Annex I.

As a result, under a RoHS amendment published in July 2023, an exemption for mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and pressures over 1000 bar came into force with a specified validity period. This exemption applies to Category 9 equipment and was originally due to expire on December 31, 2025. In April 2024, however, industry submitted a request to extend this date. That request is still under consideration (as of July 2025) and, until a final decision is made, the December 2025 expiry date is no longer relevant.

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1 RoHS Directive. European Commission. (n.d.). https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en

CHAPTER 02



RoHS Enforcement

Show Compliance With the CE Marking

RoHS requires all EEE within its scope to have a CE (Conformité Européene) marking, which is to be placed on the product whenever possible. The product's Declaration of Conformity (DOC) must also include a reference to RoHS 2, along with:

- Your business name and address or that of your authorized representative
- The unique identification number of your EEE
- A statement that the DOC is issued under your sole responsibility
- Information, such as the serial number, to identify your EEE and ensure that it is traceable
- A statement that your EEE complies with the relevant RoHS requirements
- References for the relevant harmonized standards or technical specifications you used, if applicable
- Additional information:
  - Place and date of issue
  - Name, function, and signature

All CE marking directives also require manufacturers to create and maintain a technical file for each specific product. This file contains the analysis and component data needed to demonstrate the product's compliance with applicable regulations. It should include:

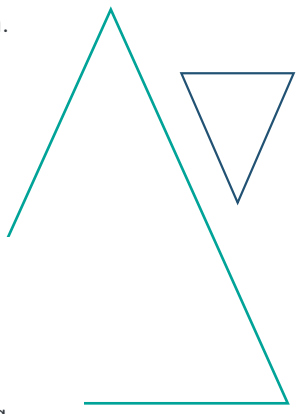
- A general description of the product and how it operates
- Conceptual, design, and manufacturing drawings, and schemes of components, subassemblies, and circuits, with descriptions and explanations
- A list of harmonized standards and/or other relevant technical specifications used.
- The results of design calculations and examinations
- Relevant test reports

The file must be kept for a minimum of 10 years after the product has been put on the market (as per article 7d). Manufacturers are not required to make this file available to the public or to customers. Should a product's compliance status be questioned by enforcement authorities, this technical file must be produced within 28 days of the request.

Enforcement Action

RoHS enforcement can vary, as it falls within the jurisdiction of individual EU member states, but penalties must be "effective, proportionate and dissuasive." The European Commission has, however, published a Frequently Asked Questions document to help manufacturers and other key stakeholders interpret the requirements of the directive, achieve compliance, and avoid enforcement becoming an issue.

The member state enforcement authorities have a range of powers available to them. These include:



- The power to make test purchases
- Powers of entry
- The power to request technical documentation and other evidence
- The power to inspect, seize, and detain EEE
- A range of sanction powers, including taking forward court action and imposing fines on companies placing non-compliant products on the market



RoHS & the EU Market Surveillance Regulation

With main provisions that apply as of July 16, 2021, the EU Market Surveillance Regulation (Regulation 2019/1020/EU) gives member state authorities additional powers to ensure products in the EU market are compliant with all current product regulations dating back to 1967, including the EU RoHS Directive. These powers include the ability to:

- Carry out unannounced site inspections and/or physical product checks
- Prohibit products from being placed on the EU market
- Order a product withdrawal or recall
- Require economic operators to take appropriate actions to bring instances of non-compliance to an end or otherwise reduce risks
- Order the removal of a product from an online interface, or to have a product displayed with an explicit warning for the end user, assuming that no other means to eliminate serious product risks exist
- Allow authorities to reclaim the full costs of their activities from economic operators

The regulation has also driven the implementation of a new shared database known as the Union Product Compliance Network (UPCN). This database was established on January 1, 2021, and enables EU regulators to share data on products manufactured and imported into the EU.

What Are the RoHS EEE Categories?

The RoHS Directive originally applied to 10 categories of EEE. Additionally, as of July 22, 2019, the scope of the RoHS Directive was extended to all EEE through the addition of a new "catch all" category 11, except those explicitly excluded under Article 2, Section 4.

- **Category 1:** Large Household Appliances
- **Category 2:** Small Household Appliances
- **Category 3:** IT & Telecommunications Equipment
- **Category 4:** Consumer Equipment
- **Category 5:** Lighting Equipment
- **Category 6:** Electrical & Electronic Tools
- **Category 7:** Toys, Leisure & Sports Equipment
- **Category 8:** Medical Devices
- **Category 9:** Monitoring & Control Instruments
- **Category 10:** Automatic Dispensers
- **Category 11:** EEE Not Covered by Above Categories



There is a provision in the RoHS Directive allowing for the invocation of "due diligence" as a possible line of defense in the face of enforcement action. Using this claim in a defense means a company must be able to show they took all possible steps to comply with the requirements of the directive.

Such steps must involve some form of positive, proactive action taken to mitigate supply chain risk. This may include identifying and assessing the risks specific to the nature of the goods produced or the setting in which they are produced, and creating a plan or system to deal with these risks in a manner proportional to the size and scope of the business. This system should be kept up to date and should be documented so that evidence of due diligence can be presented to an enforcement authority upon request.

Besides the "reasonable due diligence" claim, enforcement authorities consider a number of other factors when making a determination on a case. These factors include the size of the business under investigation and the perceived level of risk of the non-compliant product, relative to the possible impact it could have.

While there is no set definition of what due diligence for RoHS compliance looks like, the next chapter outlines some best practices for creating an effective and defensible RoHS program.

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CHAPTER 03

A Proactive Approach to RoHS Compliance

Why Building an Internal RoHS Solution Is Difficult

RoHS is complex and remains one of the most challenging directives for manufacturers placing products on the EU market. As such, it requires proactive, diligent, and consistent focus. This is not a static directive; there is always the possibility of a new amendment or even a new recast, particularly when substances are evaluated for inclusion.

But proactive compliance isn't just a requirement – it can also be a competitive advantage. By staying on top of new RoHS requirements, knowing if your products are in scope, and pursuing solutions to maintain market access, you can stay a step ahead of your competitors.

The difficulty in doing this is often twofold.

First, compliance is dependent on understanding the composition of affected products. This requires data – not just from internal sources, which could be easy to acquire, but also your suppliers. You also need to deep-map your supply chain, evaluate it for compliance issues, and know the appropriate steps to take to remain compliant.

Second, you need to be aware of where the RoHS Directive is going. Reactive compliance is not a winning strategy. In short, a proactive approach to compliance requires insight into the directive's future direction.

It's not impossible to build an internal solution that handles all facets of RoHS compliance. But it requires near limitless resources to build out compliance teams and hire experts specializing in RoHS who have on-the-ground knowledge of what's going on. Oh, and don't forget deep-mapping your supply chain.

That's where Assent comes in.

Assent's RoHS Solution

Our RoHS solution provides:

- Insight into your products, so you can see if in-scope substances made it into the equation somewhere along the line
- Continuous mapping and monitoring of your supply chain, so you can go to market knowing you're in compliance and will stay compliant
- In-house regulatory experts who are familiar with RoHS, from its conception to its current state and beyond

Remember how you need a proactive approach to RoHS compliance? This solution sets you on the right path.

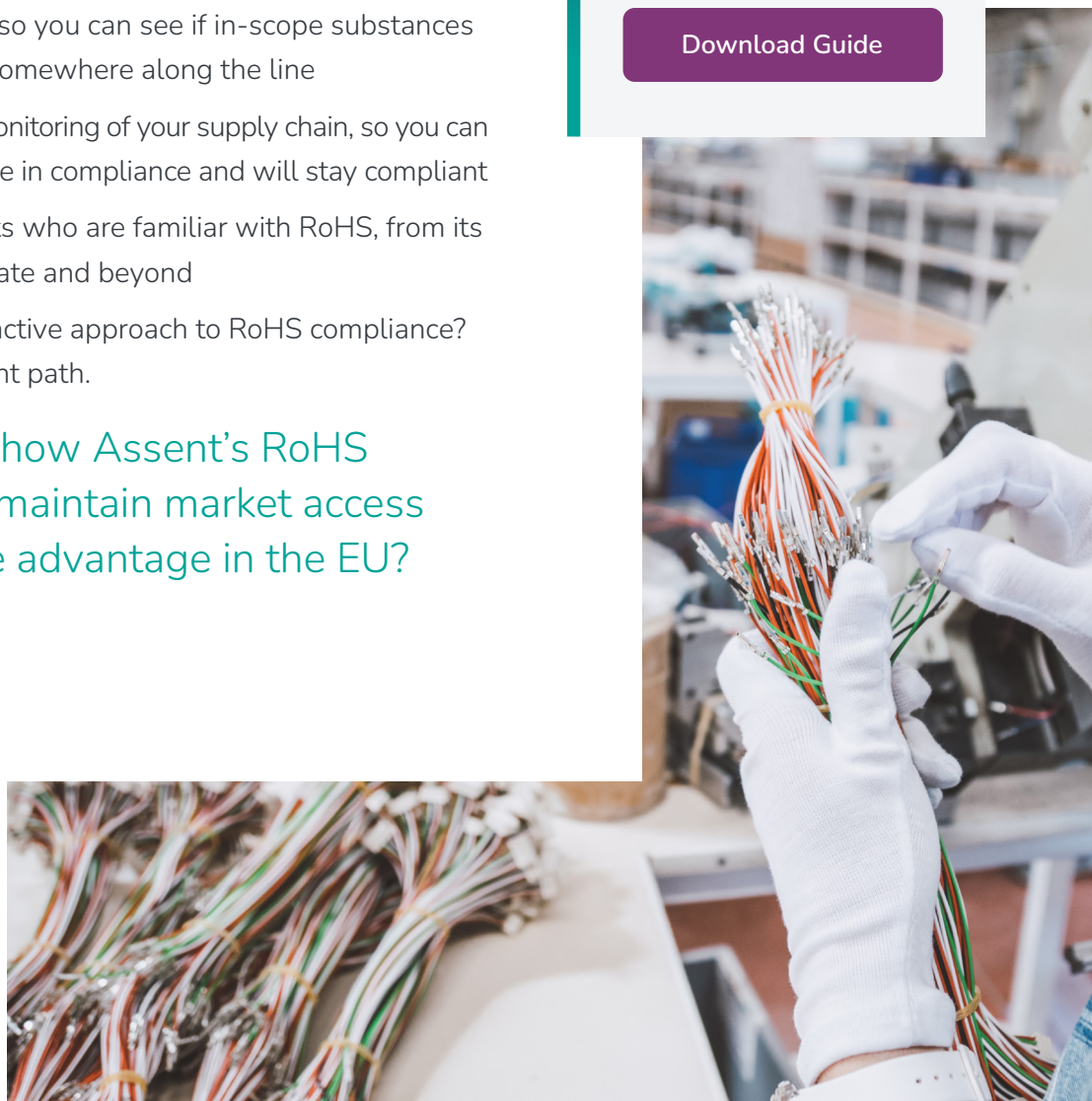
Want to see firsthand how Assent's RoHS solution can help you maintain market access and gain a competitive advantage in the EU? **Book a demo today.**

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For more information on Assent's RoHS solution, download our guide, *Managing Supply Chain Data With the Assent Compliance Platform.*

Download Guide



The Assent Solution

The journey toward sustainability demands a new way of thinking about supply chains. Assent turns your supply chain data into a critical tool to make safe, sustainable, and ethical products by providing:

- Clean data collected from the source using automated engagement techniques that dive deeper into supply chains
- Crucial, at-a-glance supply chain sustainability data through streamlined dashboards
- An adaptable program that evolves alongside regulations and industry trends

People are the beating heart of any sustainability program. Assent combines its leading technology with expert guidance, ensuring each program is tailored to your specific needs. Dedicated customer success managers make sure you have a familiar face to speak to about changing program goals or enhancements.

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