



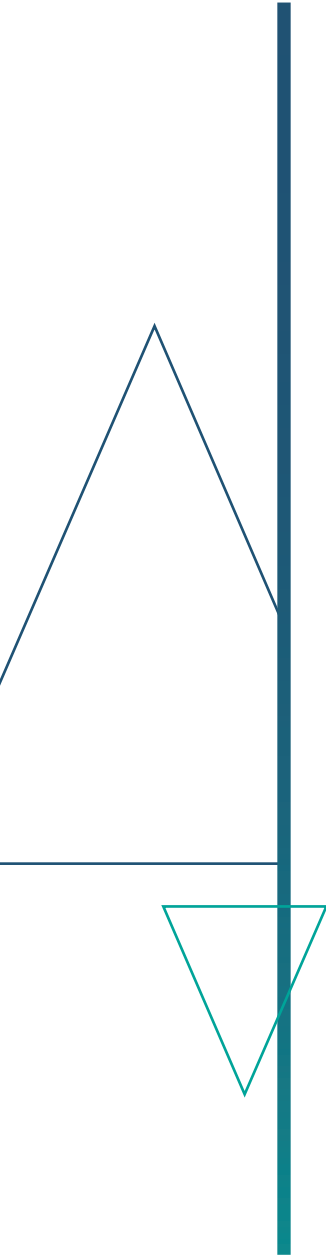
Assent[®]
Real depth. Sustainable growth.™

eBook

The RoHS Handbook

Your Guide to Compliance

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Introduction

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

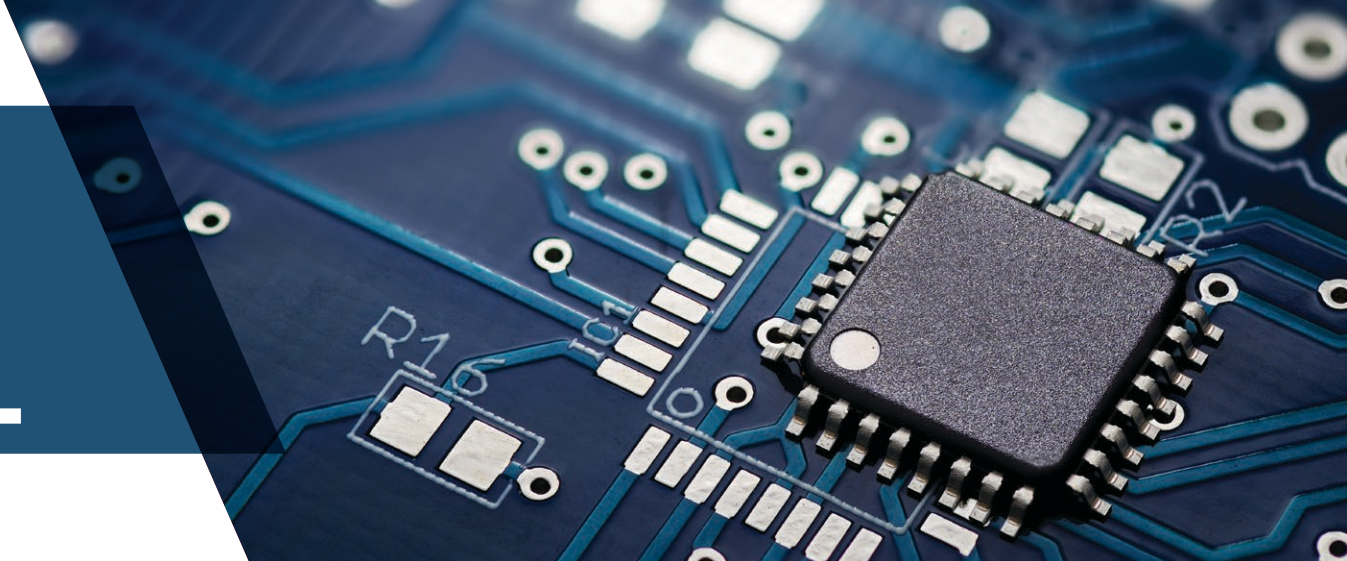
Complying with the RoHS Directive starts with strong data collection and in-depth supply chain knowledge. Companies must have comprehensive knowledge of the types and quantities of in-scope substances in their products in order to prove regulatory compliance. This eBook is for product and regulatory compliance managers, engineers, quality assurance personnel, and their colleagues seeking straightforward information about how to achieve this in a cost and time effective manner.

After reading this handbook, you will:

- ▶ Understand the RoHS Directive and your company's requirements
- ▶ Understand exemptions and what their respective expiration dates mean
- ▶ Be aware of how new updates to the RoHS Directive will affect your compliance program
- ▶ Gain practical insights into how to conduct due diligence for continued RoHS compliance



CHAPTER 01



Summary

In this chapter, you will learn:

- ▶ The history of the RoHS Directive (RoHS 1, 2, and amendments)
- ▶ What exemptions are
- ▶ The 11 categories of the RoHS Directive

EU RoHS

The RoHS Directive, also known as Directive 2002/95/EC, entered into effect on July 1, 2006. The directive restricted the use of six chemicals¹ harmful to human and environmental health in EEE and was the original foundation of RoHS 2 and its amendments. The RoHS Directive is closely linked to the Waste Electrical and Electronic Equipment

Directive (WEEE) (2002/96/EC), which outlines collection, recycling, and recovery targets for electrical goods in an effort to help solve the problem of toxic electronic waste. These six chemicals and their accepted thresholds under RoHS 1 were:

- ▶ Lead (Pb), ($\leq 0.1\%$)
- ▶ Mercury (Hg), ($\leq 0.1\%$)
- ▶ Cadmium (Cd), ($\leq 0.01\%$)
- ▶ Hexavalent chromium (chromium VI, Cr+6), ($\leq 0.1\%$)
- ▶ Polybrominated biphenyls (PBB), ($\leq 0.1\%$)
- ▶ Polybrominated diphenyl ethers (PBDE), ($\leq 0.1\%$)

A list of exemptions was created as part of an incremental implementation timeline during which manufacturers could identify and replace these substances in their products over time.

¹ RoHS 3, a 2015 update to the RoHS Directive, added four new substances to this original list. See 'RoHS 2 and RoHS 3' section.

The original RoHS Directive (2002/95/EC) included 36 exemptions applying within specific use cases for each restricted substance. These exemptions were given an expiry date, after which time that particular use would no longer be permitted.

RoHS 2 & RoHS Amendments

RoHS 2, or the RoHS Recast, was implemented on July 21, 2011, and took effect on January 2, 2013. RoHS 2 was an update to the original RoHS Directive, and involved a range of changes:

- ▶ An expanded list of exemptions, which today number approximately 150
- ▶ Requirement for periodic re-evaluations to facilitate the ongoing expansion of EEE in scope of RoHS over time
- ▶ Requirement for companies to demonstrate detailed compliance with the directive (non-compliance now labeled a criminal offence)
- ▶ Adds an automatic expiration date if an exemption is not renewed by requests from industry
- ▶ Makes it possible for new substances to be added to the list of restricted chemicals

A further RoHS amendment (2015/863) followed in 2015, 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:

1. Bis(2-Ethylhexyl) phthalate (DEHP)
2. Benzyl butyl phthalate (BBP)
3. Dibutyl phthalate (DBP)
4. Diisobutyl phthalate (DIBP)

The maximum allowable concentrations for these was set at 0.1 percent weight by weight (w/w). As of July 22, 2019, the four substances cannot be placed on the EU market in concentrations above this threshold.



What Is an Exemption?

An exemption temporarily allows a restricted substance to be used in certain applications in cases where a suitable alternative is not available. They are substance and application based, and apply for a set period of time (i.e., all exemptions have an expiration date). During the time period in which the exemption applies, industry experts research and test possible replacements for the exempted substances in various applications. If alternatives cannot be found during this period, manufacturers can request an extension or clarification of the exemption to allow further time for suitable replacements to be found. If a request for extension is rejected, the exemption will expire between 12 and 18 months after the decision by the European Parliament is made. At this time, products containing the substance will become non-compliant with the RoHS Directive.

According to a [report](#) published by the European Commission, exemption management is the most resource intensive aspect of RoHS compliance. Each year there are reviews of different exemptions and recommendations are rarely simple to resolve. This makes it difficult for businesses to keep up with the changes in requirements each year, and exemptions are often where things begin to slip through the cracks.

Assent's RoHS solution is managed by a team of compliance experts with deep knowledge of ongoing regulatory updates. We ensure your RoHS program is updated with the latest exemption rules to protect you from falling out of compliance.



Get in-depth knowledge on exemptions and expirations in our whitepaper, *European Union RoHS Directive: Understanding Exemptions.*

[Download Whitepaper](#)



EU RoHS: Are You in Scope?

The RoHS Directive applies to all companies selling EEE finished products in Europe, but there are a number of goods that are out of scope of the RoHS Directive. Get a deep dive into RoHS scoping, complete with flow charts to help you determine the RoHS obligations for your product with Assent's *EU RoHS Scoping Guide*.

[Download Guide](#)

Implementation Categories

The RoHS Directive applies to 11 equipment categories. As per the directive's incremental implementation timeline, these categories came into scope at different times, which culminated in the full implementation of all categories (minus explicit exclusions) in July 2019.



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

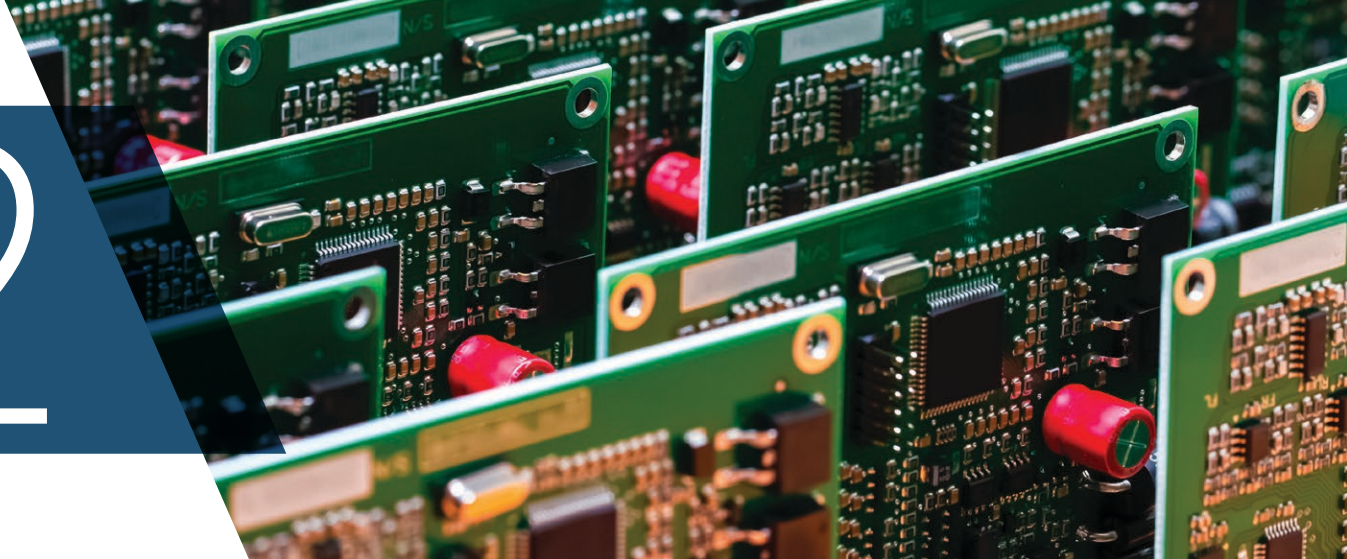


Category 11: EEE Not Covered by Above Categories

As of July 22, 2019, the scope of the RoHS Directive has officially been extended to all EEE, except those explicitly excluded under Article 2, Section 4. This includes the four new phthalates as listed above.



CHAPTER 02



Requirements & Enforcement for Companies in Scope of the RoHS Directive

In this chapter, you will learn:

- ▶ Who is considered a “producer” under RoHS
- ▶ How to demonstrate RoHS compliance through CE marking
- ▶ Avoiding enforcement action through due diligence

Producers of EEE in scope of the RoHS Directive are responsible for ensuring their products meet the requirements of the directive. In fact, the simple act of placing your product on the market signals the producer’s declaration that the product complies with the RoHS Directive.

Companies placing in-scope EEE products on the market must be ready to demonstrate that the products comply with the RoHS Directive by ensuring they have the relevant technical documentation on hand. While the ultimate scope of the directive only applies to finished products, this final product is likely comprised of a number of components and sub-assemblies that come together to form the product. In order for the final product to remain compliant, these components and sub-assemblies must themselves not contain any of the 10 restricted substances in quantities above the threshold concentration values.

Instead of testing every component and sub-assembly for RoHS compliance individually

(which is costly and time intensive), producers can request certification from their suppliers that the parts supplied are RoHS compliant. Producers should also perform selected audits to confirm the compliance of these parts, as deemed necessary.

How to Demonstrate EU RoHS Compliance: CE Marking

In addition to having technical documentation on hand, RoHS 2 (i.e., as of 2013) requires all EEE in scope to have a CE marking, and to feature a reference to RoHS 2 on the product's Declaration of Conformance (this is not a specific form). All CE marking directives require the manufacturer of the product to create a technical file containing the analysis and component data required to demonstrate that product's compliance with the regulations relevant to it. This technical file must be kept for a minimum of 10 years after the product is put on the market (as per article 7d). Should a product's compliance be questioned by enforcement authorities, this technical file must be produced within 28 days of the request. Manufacturers are not required to make this file available to the public or to customers.

Enforcement Action

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 U RoHS Directive. At a minimum, these powers include the ability to:

- ▶ Carry out unannounced site inspections and/or physical product checks
- ▶ Prohibit products from accessing 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

Who Is a Producer?

According to Article 3 of Directive 2012/19/EU on WEEE, a "producer" means any person who, irrespective of the selling technique used, including by means of distance communication:

- (i) Manufactures and sells EEE under their own brand;
- (ii) Resells under their own brand equipment produced by other suppliers, a reseller not being regarded as the "producer" if the brand of the producer appears on the equipment, as provided for in sub-point (i); or
- (iii) Imports or exports electrical and electronic equipment on a professional basis into a member state.



- ▶ 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 will also drive the implementation of a new shared database known as the Union Product Compliance Network (UPCN). This database will enable EU regulators to share data on products manufactured and imported into the EU.

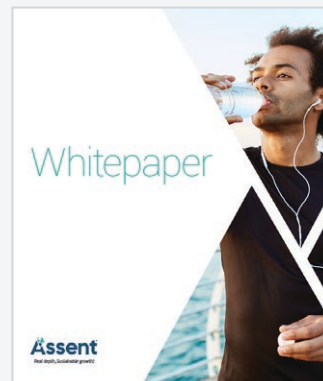
Compliance with RoHS 2 requires manufacturers to create technical files in alignment with CE marking requirements. These files (to be maintained for 10 years after the product has been placed on the market) should include:

- ▶ 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

What to include in your declaration of conformity:

- ▶ The unique identification number of your EEE
- ▶ Your business name and address or that of your authorised representative

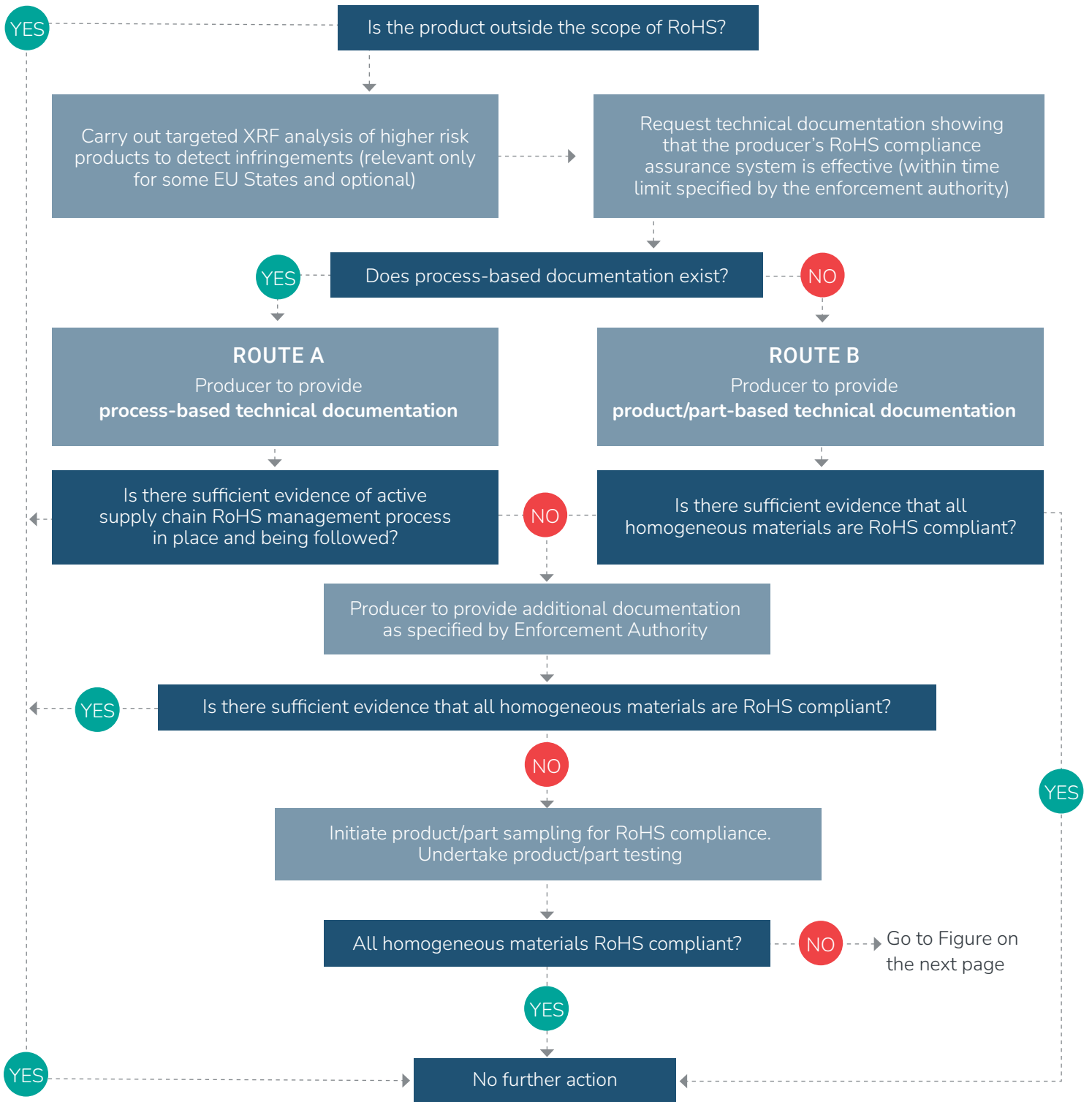
- ▶ A statement that the DoC is issued under your sole responsibility
- ▶ Information, such as the serial number, to identify your EEE and ensure that it is traceable
- ▶ A statement that your EEE complies with the relevant RoHS requirements
- ▶ References for the relevant harmonised standards or technical specifications you used, if applicable
- ▶ Additional information:
 - ▷ Place and date of issue
 - ▷ Name, function, and signature



Learn More

Find out how the EU Market Surveillance Regulation will impact your business in our whitepaper, *The EU Market Surveillance Regulation & the New Enforcement Landscape*.

[Download Whitepaper](#)

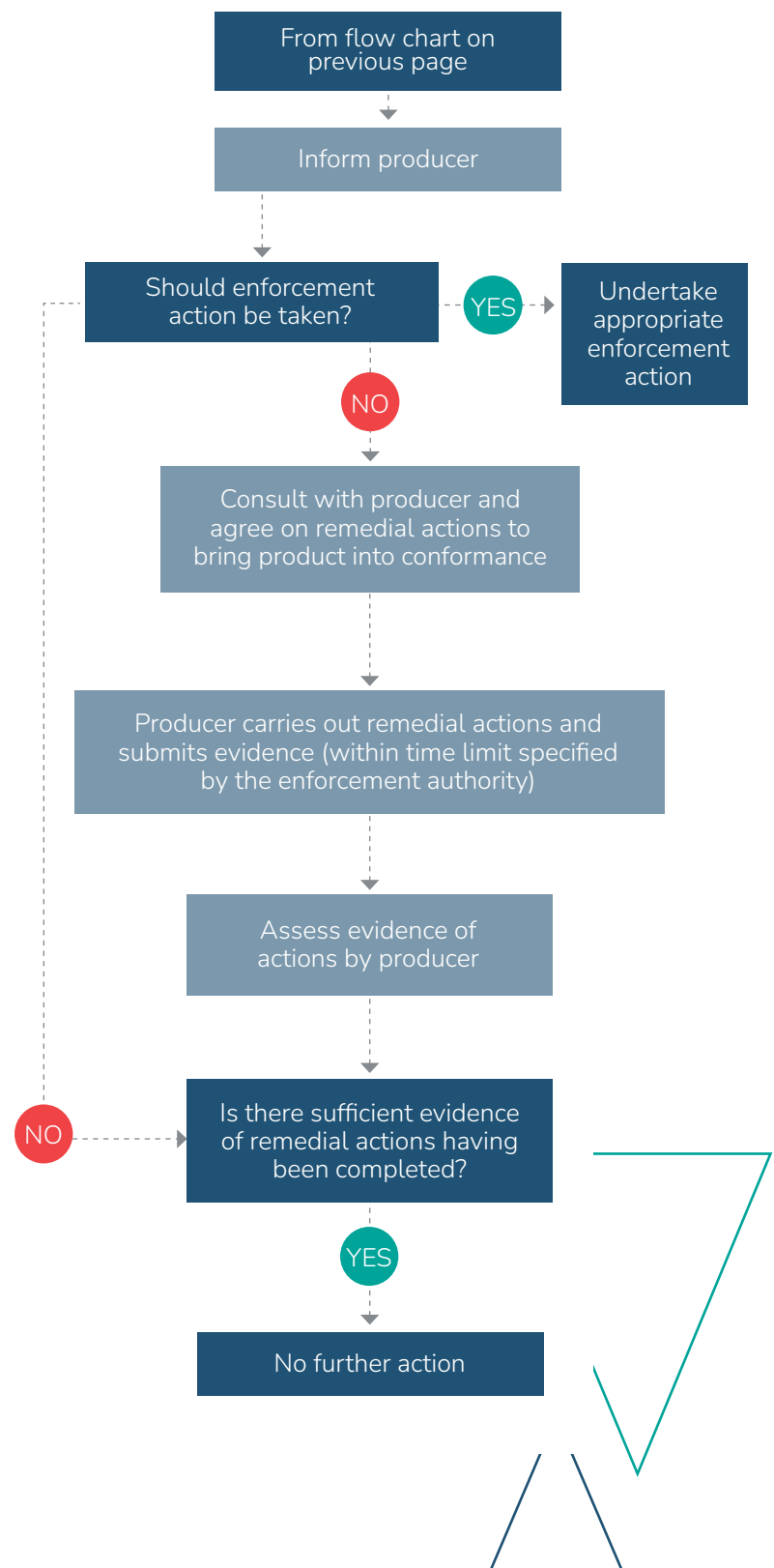


There is a provision in the RoHS Directive allowing for the invocation of “due diligence” as a possible line of defense in the face of a regulatory enforcement action. Using this claim in a defense means a company must be able to show they took all possible steps (i.e., conducted maximum reasonable due diligence) to avoid committing a violation of the directive.

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

Besides the “reasonable due diligence” claim, there are a number of other factors considered by enforcement authorities 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-compliance in question, relative to the possible impact it could have.

Flow Chart for RoHS Enforcement Action



CHAPTER 03

Leveraging a Supply Chain Data Management Solution

Complying with the RoHS Directive and similar regulations is entirely dependent upon your understanding of the product and its composition. You need to leverage data from internal sources and suppliers to deep-map your supply chain and evaluate it for compliance issues.

By leveraging the right supply chain sustainability management platform, you can reach out and collect data from your suppliers, organize and analyze that data, and clearly identify problem areas and next steps from one central location. Assent helps you gain an actionable view of your supply chain so you can be smarter and obtain your sustainability goals.

For more information on automating your RoHS compliance program, and for details on how working with Assent will help your company win, contact us at info@assent.com.



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

[Download Guide](#)



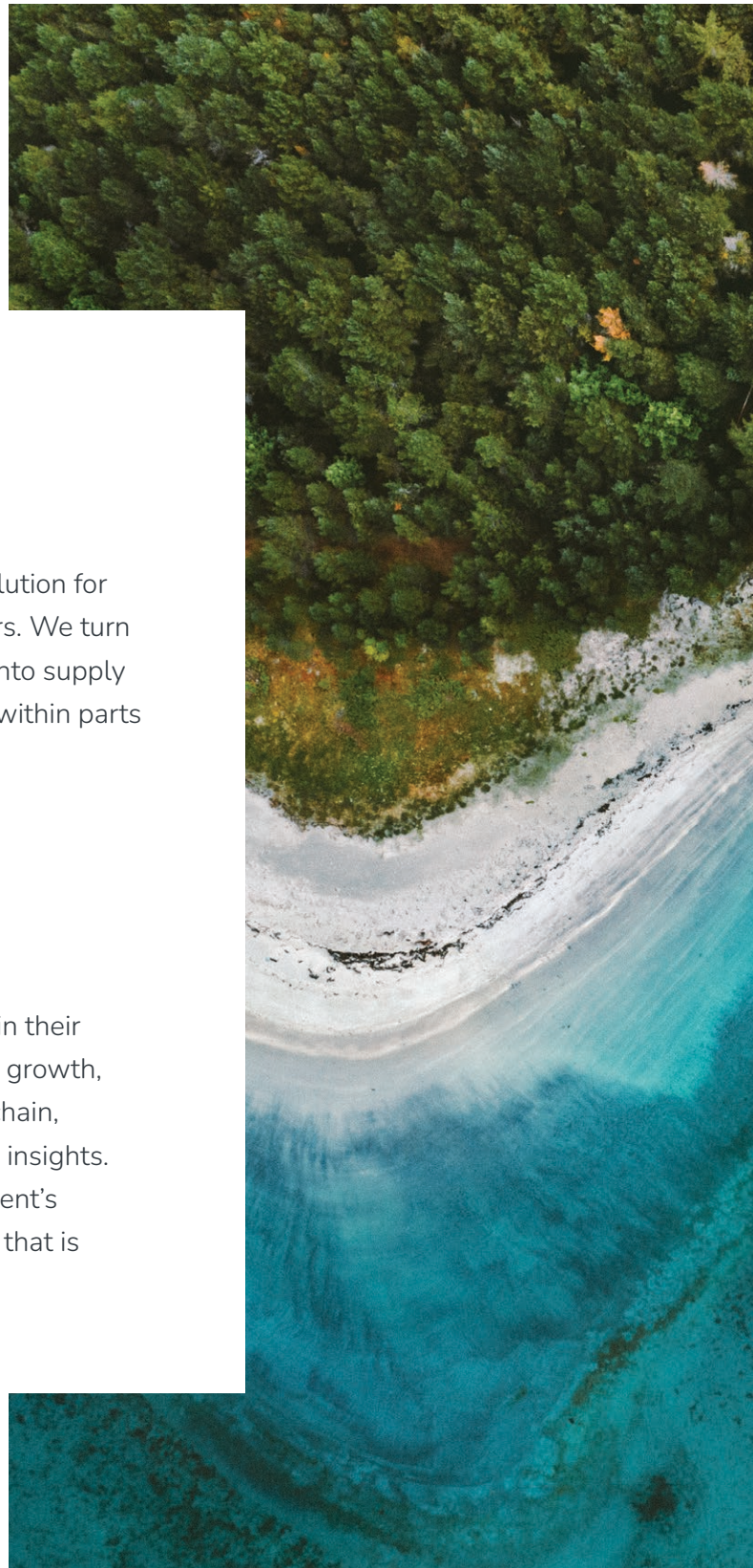


Who Is Assent?

Assent is the supply chain sustainability management solution for the world's most forward-thinking complex manufacturers. We turn sustainability goals into tangible action by delving deep into supply chains, identifying suppliers, parts, and even substances within parts to map the entire complex manufacturing genome.

What We Do

We help companies spot sustainability risks hiding deep in their supply chains and identify new areas of focus to enhance growth, efficiency, and value. By digging deep within the supply chain, we pull and validate more actionable data to provide real insights. Guided by regulatory experts with a diverse skill set, Assent's solution delivers a cross-enterprise view of sustainability that is necessary for true leadership in the field.





[Assent is] a low touchpoint program with very high results and program growth, year in and year out.

— Ryan Zelhofer, Former Product Compliance Manager, Plexus

Over **200,000**
parts managed

80% reduction in staff
management hours



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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