A QUICK GUIDE TO GPSR COMPLIANCE

NAVIGATING THE EU GENERAL PRODUCT SAFETY REGULATION (GPSR) WITH CONFIDENCE

ESSENTIAL KNOWLEDGE,
TOOLS AND INSIGHTS INTO
THE REQUIREMENTS FOR
LABELLING, RISK
ASSESSMENTS AND
DOCUMENTATION

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INTRODUCTION

The GPSR has a profound effect on many businesses within the EU as well as any business exporting or importing non-food products into the European Union (EU).

If your business operates within the EU or if you plan to bring non-food products into the EU market, understanding the GPSR is essential.

This guide is ideal for business leaders, compliance officers, quality assurance professionals, and any team member involved in product safety and regulatory compliance. This ebook will help you kickstart your knowledge on the GPSR.

GOOD TO KNOW

The core objective of the GPSR is to guarantee product safety during normal and foreseeable use. To achieve this, businesses are required to proactively identify potential hazards and assess risks for each product. The regulation mandates thorough documentation, robust traceability, and ongoing incident monitoring. Should any issues arise, businesses must promptly notify and warn end-users.

The GPSR outlines specific responsibilities for businesses based on their roles within the supply chain, ensuring accountability at every stage.



ECONOMIC OPERATORS & THEIR OBLIGATIONS

The **manufacturer** has the primary responsibility for ensuring that products meet all safety requirements

A manufacturer is defined as any individual or company that designs, produces, or assembles a product for sale within the EU market.

Obligations of a manufacturer:

- Ensure product safety: Guarantee product safety and comply with relevant legislation.
- **Technical documentation**: Create technical documents that demonstrate compliance.
- Affix CE marking (if applicable): and prepare a declaration of conformity.
- Ensure traceability of products: display name, registered trademark, and address on the product or packaging.
- Take corrective actions: recalling or modifying products if necessary.
- Carefully maintain complaints and incident records: and perform risk assessments.

IMPORTER

An importer is defined as any person or entity within the EU that imports products from outside the EU for sale within the EU market.

Importers play a crucial role in ensuring product safety, as they act as the bridge between non-EU manufacturers and the EU market.

Obligations of an import business:

- Verify compliance: Ensure that imported products comply with relevant EU requirements.
- **Provide information**: Ensure the name and contact details of the importer are displayed on the product.
- Retain documentation: Keep the manufacturer's technical documentation and provide it to authorities upon request.
- **Monitor products**: Conduct sample checks and monitor the safety of imported products.
- Cooperate with authorities: Report hazards and work with market surveillance authorities in case of safety concerns.

DISTRIBUTOR

A distributor is defined as any individual or entity within the EU that sells or supplies products on the market, but is not the manufacturer or importer.

Distributors are essential in ensuring that products remain compliant and safe as they move closer to consumers.

Obligations of a distributor:

- Supply safe products: Ensure that products comply with legal requirements and bear proper markings and documentation.
- Guarantee traceability: Maintain records about the supply chain (suppliers and customers).
- Report incidents: Notify the manufacturer, importer, or authorities about potential safety issues.
- Collaborate with regulators: Provide product information and supporting data when requested.
- **Avoid modifications**: Ensure products remain unaltered to maintain their safety.

PROVIDER OF AN ONLINE MARKETPLACE

Even though an online marketplace is not considered an economic operator under the GPSR, they bear significant responsibilities under the GPSR.

An online marketplace is defined as a digital platform that allows third-party sellers to offer products for sale to consumers. This includes websites, apps, or other digital interfaces where consumers can browse, purchase, or arrange the delivery of goods sold by entities other than the platform operator itself.

Obligations of an online marketplace:

- 1. **Support product safety**: Ensure that only safe and compliant products are offered on the platform.
- 2. **Ensure transparency**: Require sellers to provide information such as name, contact details, and declarations of conformity.
- 3. **Cooperate with authorities**: Remove hazardous products immediately following notification from market surveillance authorities.
- 4. **Removal obligations**: Ensure that high-risk or reported products do not reappear on the platform.
- 5. Active monitoring: Implement systems to monitor listed products and inform users about potential risks.

HOW DO I GET STARTED?

Navigating the entirety of GPSR regulations is a daunting task - and many business leaders are looking for ways how to efficiently get their organisation ready for this.

S T E P 0 1

Designate an individual or a group of individuals in your organisation to take responsibility

While this may not be the task you or your team were hoping for, it is a critical step to ensure your organization takes the necessary actions toward compliance.

This group doesn't need to handle every specific action item from the GPSR review but should oversee outstanding tasks and ensure that deliverables are completed on time.



DEFINE ROLE(S) THE ORGANISATION HAS IN THE SUPPLY CHAIN

For every product the business is involved in

As we've discussed, the requirements vary for manufacturers, distributors, importers and online marketplaces. Since a business may have different roles for different products, it's crucial to clearly identify these roles and fully understand the specific requirements that apply to each.

You can use this <u>tree diagram</u> to specify your role in the supply chain.

STEP 02

DEVELOP OR ADOPT A FRAMEWORK TO PROJECT MANAGE GPSR

To prepare your organization efficiently and effectively for GPSR compliance, it's essential to adopt a structured approach that tracks necessary changes to internal policies and manages outstanding tasks.

You can develop an internal framework or system that aligns with your preferred management approach.

Fortunately, there are tools available that can save you time and help you quickly implement a proven framework. Explore our **Templates** to see how they can assist your organization. The advantage of using a template is that it includes preselected articles tailored to your role in the market and provides clear guidance on the requirements for each one.

Furthermore, innovative technologies are being developed to help businesses track and trace their products from origin to end of life. These technologies enable the creation of a **Digital Product Passport** for the products you manufacture or sell. With future regulations anticipated in the EU, this could be an important area for your business to explore.

STEP

REVIEW EVERY ARTICLE THAT IS RELEVANT

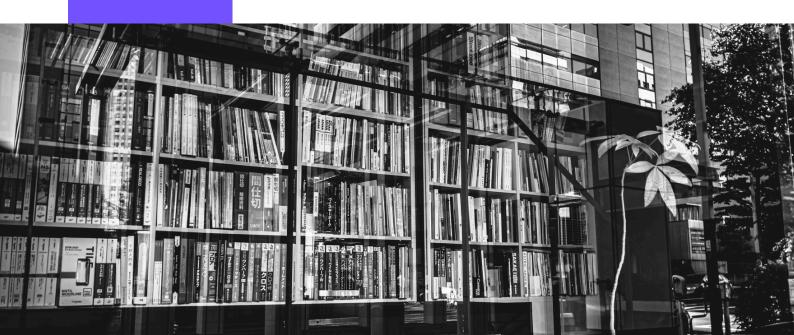
This is the heavy load of work needed to prepare your business and there is no avoiding it.

When reviewing the articles, assess your organization's gaps in compliance with the regulation and evaluate the associated risk level.

Where applicable, define specific action items to meet the requirements of each article and set clear deadlines for completion.

Appoint someone to take responsibility for implementing the necessary changes within your organization.

Note: Depending on your organization's role in the supply chain, you will need to review different articles.



MONITORING

It is crucial to closely track progress in addressing gaps with the GPSR regulation to ensure full compliance.

S T E P 0 5

Implement a regular review cadence to adapt your compliance practices as regulations evolve.

Consider establishing a monthly project meeting schedule to review and complete all action items identified to address gaps in compliance with the regulation.

Once all action items are finalized, shifting to quarterly or semi-annual meetings may be helpful to assess any organizational changes and their impact on your product safety responsibilities.

At GPSR Templates we aim to update you of important news regarding GPSR. Subscribe to our newsletter to stay in the loop.

CHECKLIST

- DESIGNATE AN INDIVIDUAL OR A GROUP OF INDIVIDUALS IN YOUR ORGANISATION TO TAKE RESPONSIBILITY
- **✓** DEFINE ROLE(S) THE ORGANISATION HAS IN THE SUPPLY CHAIN
- DEVELOP YOUR OWN OR ADOPT A PROVEN FRAMEWORK TO PROJECT MANAGE YOUR INTERNAL GPSR REVIEW
- REVIEW EVERY ARTICLE THAT IS RELEVANT
- IMPLEMENT A REGULAR REVIEW CADENCE TO ADAPT YOUR COMPLIANCE PRACTICES AS REGULATIONS EVOLVE.



HOW TO DO A RISK ASSESSMENT

The GPSR mandates that organizations conduct a risk assessment for the products they offer on the market.

A risk assessment should evaluate potential risks to the health and safety of consumers, considering the typical use of the product. This evaluation must address physical, mechanical, chemical, digital, and other relevant hazards.

Additionally, the assessment should pay special attention to risks faced by vulnerable groups, such as children, the elderly, or individuals with disabilities.

Risks should be assessed in line with applicable European standards relevant to the specific product category.

The outcomes of the risk assessment must be documented, including a complete technical description of the product.

Any newly identified risks should be incorporated into the documentation.

Organizations are required to implement corrective actions where necessary, based on the findings of the risk assessment.



HOW TO LABEL PRODUCTS

These are essential elements on the labels of your products

Identification of the product: your label should include comprehensive information that can be used to identify the product. Amongst others, this can be a serial number or identification number.

Information about the economic operator: The label should include the address of the manufacturer. For products imported into the EU, the label must also include the address of the importing business.

Additionally, when a responsible person is required —typically for non-EU manufacturers exporting to the EU— their name and address must also appear on the label.

Safety information: the label should include all safety warnings and instructions relevant to the specific group of people using the product.

Options to provide further digital information: (e.g. you can also choose to provide this information through a QR code).

Application on changed products: when a product changes significantly, it should be treated as such with a matching label.

Traceability: all information across all your sales channels (whether physical or digital) regarding your products has to be consistent.

HOW TO DOCUMENTATION

Documentation must serve as evidence that products are safe and that the organization has taken the appropriate risk assessments and measures. Here is how organizations should maintain documentation based on the regulation

Technical documentation: this should include a description of the product, a risk assessment, norms that were used to judge conformity with regulations, and safety measures.

Cooperation with local regulatory authorities: documentation should be accessible for local authorities. In case of dangerous goods, the economic operator should proactively inform authorities and actively seek cooperation.

Monitoring product changes: any changes need to be documented, as well as its impact on the safety of the product and its risk assessment.

Access and availability of documentation: documentation must be available on request. This can either be digital or in print.

Corrective measurements: documentation should include any incidents that have been reported, alongside any corrective measures that have been taken for it. Documentation should also feature specific plans in case of recalls, including communication plans.

Storing documentation: usually for a period of 10 years.

CONCLUSION

If your business operates within the EU or intends to introduce non-food products to the EU market, the GPSR directly applies to you.

We hope this e-book has offered valuable insights and clarified the expectations for you as a economic operator within the EU.

Compliance is an ongoing process, and leveraging tools, templates, and collaborative efforts can make your journey easier and perhaps even allow you to turn compliance into a competitive advantage.

For further support, feel free to reach out to our team through GPSR-Templates.com.

DISCLAIMER

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