

Regulatory Readiness Level

Even with a high TR level, a technology can still face market entry risks due to insufficient regulatory support. To protect and restore marine and freshwater ecosystems, the European Commission has established political packages and strategies that form the basis of a regulatory framework. These regulations can promote the adoption of new technologies by encouraging the replacement of harmful solutions with safer alternatives, facilitating secure market entry.

Considering regulations early in the innovation process is crucial; without appropriate regulations, an innovation may fail to enter the market, leading to lengthy regulatory delays. Leveraging existing regulations can offer a safer, though potentially less innovative, pathway, necessitating careful evaluation at the outset.

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Regulatory Readiness Level

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Stage 1: Conceptualise

Step 1: Define and Review the Target Market of the Innovation/Technology

Defining and reviewing the target market is crucial during the conceptualization phase of any product, service, or innovation. This understanding helps identify relevant regulations and needs the technology or application must address. It ensures alignment with regulatory frameworks and market expectations, which can vary across countries and communities. Regulatory considerations significantly influence the feasibility and acceptance of innovations, especially in sensitive sectors like marine restoration, biotechnology, and energy.

HOW TO

1. **Identify Market Segments:**

Understand market segments to identify potential customers and their regulatory needs, as different segments may face varying regulations and industry standards.

2. **Assess Regulatory Landscape:**

Examine existing regulations that affect your product's market entry and compliance requirements.

3. **Analyze Market Demand:**

Understand customer needs and preferences can help assess regulatory implications. Certain market demands may necessitate adherence to specific regulations.

4. **Evaluate Ethical Considerations:**

Consider ethical aspects that shape regulations. Societal values can drive the acceptance and implementation of regulations.

5. **Review Competitive Landscape:**

This aspect is less directly related to regulatory readiness but can provide context for how competitors navigate regulatory challenges, influencing your strategy.

6. **Explore Future Markets:**

Raise awareness of regulatory differences across regions.

EXAMPLE

A company developing new marine restoration technology starts by defining its target market, which includes local governments, NGOs, and sustainability-focused corporations. They conduct market research to identify the specific needs of these segments and review existing regulations on marine conservation across different EU countries.

During this process, they find that certain regions have stricter environmental regulations that could affect their technology's deployment. The company consults regulatory authorities to understand any additional market entry requirements.

They also evaluate the ethical considerations of their innovation, particularly its environmental impact. By considering these factors, the company effectively positions its product to meet regulatory standards and align with market demands, paving the way for a successful launch in multiple EU member states.

Step 2: Review and agree on the classification and regulatory strategy

Defining and reviewing the target market is critical for establishing a robust regulatory strategy for any innovation or technology. A well-structured regulatory strategy outlines the necessary regulatory pathways throughout the product lifecycle and aligns these with broader business objectives. Understanding the target market helps identify specific regulatory requirements, anticipate costs, and streamline the path to market approval, thereby minimizing risks and enhancing the likelihood of success.

HOW TO

1. **Set the Market and Understand Regulatory Variations:**

Identify the primary markets for your innovation. Be aware that regulations can differ significantly across regions and countries, with unique standards for your product.

2. **Gather Comprehensive Information Early:**

Collect essential data about your product, including a detailed product description, target countries, technical documentation, and existing approvals. Early information gathering can mitigate future costs and risks.

3. **Determine Approval Procedures:**

For each target market, ascertain the potential approval procedures and identify specific regulatory requirements. This understanding will aid in determining the necessary documentation and testing for compliance.

4. **Assess Risks:**

Evaluate the potential risks associated with regulatory approval based on prior experiences and assumptions. Consider factors such as time delays, costs, and the likelihood of approval.

5. **Set Goals and Milestones:**

Establish clear objectives and milestones, along with a timeline for achieving them. This structured approach helps maintain focus and allows for necessary adjustments.

6. **Regularly Review the Strategy:**

As regulations, especially for new products, can change rapidly, it's vital to review and update your regulatory strategy regularly to ensure alignment with the current regulatory landscape.

EXAMPLE

A biotech company developing a novel environmental restoration technology identifies the European market as its primary target. It starts by reviewing regulations related to biotechnology and environmental impact in various EU countries. The company collects essential information, including technical documentation and existing product approvals. After analyzing the regulatory landscape, it determines the approval procedures for each target country and identifies specific requirements for documentation and testing. The company assesses potential risks, such as delays in approval, and sets a timeline with milestones for each regulatory step. Finally, the company commits to reviewing its regulatory strategy biannually to adapt to any changes in regulations or market conditions. This proactive approach enables streamlined product development and timely market entry while ensuring compliance with relevant regulations.

Step 3: Establish intended use and key performance

In the regulatory process, defining the intended use and establishing key performance metrics for an innovation or product are critical steps. These elements guide the product's development, regulatory submission, and market introduction. A clear understanding of intended use helps ensure the technology's compliance with regulatory requirements, while key performance indicators (KPIs) demonstrate how the product performs against its goals. Together, these steps allow companies to assess whether their product meets customer needs and regulatory standards.

HOW TO

1. **Define the Intended Use:**

Outline the product's main function, primary application, problem solved, and target users to support regulatory filings. Define whether the technology is aimed at environmental restoration, industrial efficiency, or another purpose, ensuring the intended use complies with relevant industry regulations.

2. **Establish Key Performance Indicators (KPIs):**

Identify measurable KPIs that demonstrate the product's success in its intended use to ensure the product meets legal standards. These should be quantitative metrics, like performance levels, environmental impact reductions, or efficiency improvements, tailored to the product's functionality and regulatory expectations. KPIs.

3. **Align KPIs with Regulatory Requirements:**

Ensure the KPIs are relevant to customer needs and comply with industry-specific regulatory standards. In the marine restoration sector, for instance, regulators might require performance metrics around biodiversity restoration or ecosystem health.

4. **Test and Validate Performance:**

Conduct controlled testing to verify the product meets its intended use and achieves the established KPIs. This involves rigorous trials, including stress tests, to ensure functionality under various conditions. Such data demonstrates the product's reliability in delivering its intended purpose for regulatory approval.

5. **Document for Regulatory Submission:**

Prepare detailed documentation of the intended use and performance tests. Regulatory bodies need thorough records that support the product's claims. This documentation should clearly state how the product meets the regulatory guidelines and why it's fit for its intended market.

6. **Review and Adjust if Necessary:**

Make necessary adjustments to the product design or intended use, if testing reveals discrepancies between the intended use and actual performance.

EXAMPLE

A company developing a seagrass restoration technology defines its intended use as the "restoration of coastal seagrass ecosystems to improve water quality and enhance biodiversity." The company establishes key performance indicators, such as the percentage of seagrass coverage restored within a year, reduction in water pollution levels, and the number of marine species returning to the restored habitat.

The device undergoes field tests to validate these KPIs, and the results are documented. The company submits the documentation to the appropriate regulatory body, demonstrating that the device can perform as intended, comply with environmental regulations, and achieve the desired outcomes in its target market.

Stage 2: Prototype

Step 4: Plan of required regulatory submissions and establish implementation plan in compliance with applicable regulatory requirements

Planning for regulatory submissions is crucial for ensuring that your product complies with all applicable regulations throughout its lifecycle. A well-structured submission plan helps streamline the approval process, identifies potential challenges early, and ensures alignment with regulatory requirements. This step involves understanding the specific submissions needed for each target market and creating a timeline for implementation.

HOW TO

1. Identify Required Regulatory Submissions:

Research and compile a list of all regulatory submissions needed for your product in each target market. This may include pre-market notifications, registration documents, and detailed product descriptions.

2. Understand Regional Variations:

Be aware of the differences in regulatory requirements across regions. Regulations can vary significantly, and understanding these nuances is essential for compliance.

3. Establish a Timeline:

Create a detailed timeline for your regulatory submissions. This should include milestones for each phase of the approval process, ensuring that all necessary documents are submitted in a timely manner.

4. Develop a Resource Plan:

Allocate resources, including personnel and budget, to manage the regulatory submission process effectively. Ensure your team is equipped with the knowledge and skills to navigate the regulatory landscape.

5. Implement a Tracking System:

Set up a system to monitor the status of each submission. This will help you stay informed about any updates or requirements from regulatory bodies.

6. Review and Adjust if Necessary:

Regularly review your submission plan and adjust it as needed. Regulatory environments can change, so staying adaptable is key to maintaining compliance.

EXAMPLE

A biotechnology company identifies the need to submit pre-market notifications to regulatory bodies across several EU countries. To streamline this process, the company uses the [EU's Access2Markets database](#) to identify applicable product requirements and harmonized standards. This ensures that their product meets health, safety, and environmental regulations across the EU.

To begin, they consult the **Trade Assistant feature** in the Access2Markets database, which helps simulate importing the product into the EU and provides detailed guidance on regulatory standards and the necessary documents. These documents include safety assessments and efficacy studies for the product's approval.

The company then creates a submission plan, setting a timeline to submit documents well in advance of the product launch to account for potential delays. They allocate a team with expertise in regulatory affairs to manage the process and establish a tracking system to monitor submission statuses.

By proactively addressing regulatory requirements, including complying with **EU harmonized standards**, the company positions itself for smoother market entry. These standards enhance transparency and simplify the approval process across EU member states.

To introduce a product or service on EU-markets, the [EU Product Compliance Overview](#) is helpful to meet the regulatory requirements.

The following screenshots show an example of introducing algae for human consumption on the EU market:

Access2Markets

Home Goods Services Investment Markets Toolbox Contact

Single Entry Point for Trade Barriers

My Trade Assistant
Goods + ROSA (Rules of Origin Self-assessment tool)

How to use this form Disclaimer

Product name or HS code Country from Country to

algae Japan Belgium Search

[Access2Markets - Home](#)

Seaweeds and other algae

12 12 210000 - 290000

Show in list of goods

Vegetable products > Oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder > Locust beans, seaweeds and other algae, sugar beet and sugar cane, fresh, chilled, frozen or dried, whether or

[Access2Markets - Search](#)

Seaweeds and other algae

12 12 21 00 00 - 29 00 00

Fit for human consumption

12 12 21

[Access2Markets - Results](#)

Results for product code 1212.21 from Japan to Belgium

Tariffs

Rules of origin

Rules of Origin Self-Assessment (ROSA)

Origin documentation and verification

Taxes

Import requirements

Overview

General

Specific

Control of contaminants in foodstuffs

Control of pesticide residues in

Import requirements

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This section presents:

- A general overview of the European Union requirements to be met when importing countries. These measures are adopted to protect public health, environment, etc. and apply the most relevant EU policies on food safety, animal health, environmental standardisation, import restrictions, marking and labelling.
- General requirements are the general formalities and documents required for importing third countries into the EU irrespective of the country of origin.
- Specific requirements on non-tariff measures that are applicable per country of origin.
- National competent authorities and legislation (when EU legislation is not directly applicable, specific requirements are provided for the selected Member State of destination).

Product requirements

Information on EU rules and requirements for your product.

[Access2Markets - Results information](#)

Example EU's Access2Markets database

Step 5: Contact regulators and establish mechanisms/processes for applicable regulations and standards

Engaging with regulators early in the development process ensures that the product aligns with current standards and minimizes the risk of delays due to non-compliance. Establishing clear communication channels with regulatory bodies can help identify necessary conformity assessments and approvals, avoiding potential regulatory pitfalls. These interactions are essential to understand how regulations apply to the product and how to implement the required compliance processes effectively.

HOW TO

1. **Identify Relevant Regulatory Authorities:**

Identify the regulatory authorities responsible for approving and overseeing your product in the target market. For products being introduced in the EU, Notified Bodies listed on the [NANDO Website](#) (New Approach Notified and Designated Organizations) are the designated organizations that assess compliance.

2. **Establish Communication Channels:**

Set up formal communication with these regulatory bodies early on. Engaging with them ensures that you are updated on any changes in regulatory requirements and allows you to ask for clarifications, submit questions, or seek pre-approval guidance.

3. **Understand Conformity Requirements:**

Different products require different assessments for conformity. Notified Bodies conduct conformity assessments for specific product categories, ensuring that the product meets legal and safety standards before entering the market.

4. **Document Processes and Compliance Pathways:**

Create an internal mechanism for tracking compliance progress and submissions. Develop clear documentation for all interactions with regulatory bodies, outlining submission timelines, required documentation, and responses from authorities.

5. **Assign a Compliance Team:**

Designate a dedicated team or personnel responsible for maintaining ongoing communication with regulators and managing the submission of regulatory documents.

EXAMPLE

A company developing a marine restoration technology identifies that it must work closely with Notified Bodies to ensure compliance with EU market regulations. Using the NANDO website, the company locates the relevant bodies based on legislation and submits an initial query. It assigns a team to manage ongoing communication with these bodies and begins the conformity assessment process by preparing detailed technical documentation. By actively engaging with the regulatory bodies, the company ensures that it remains aligned with all regulatory expectations, paving the way for smooth market entry.

Stage 3: Develop & Test

Step 6: Complete initial regulatory submissions and evaluation plan

Completing the initial regulatory submissions and outlining an evaluation plan is crucial for obtaining product approval and market entry. These submissions are necessary to demonstrate that the product complies with all applicable legal, safety, and environmental requirements. Conformity assessments, testing, and certifications ensure the product aligns with legislative standards. The process may also involve a Notified Body, which is responsible for carrying out the conformity assessment if mandated by the product's regulatory classification.

HOW TO

- 1. Conduct Conformity Assessment:**

Before placing a product on the EU market, conduct a [conformity assessment](#) to verify that it meets all applicable legislative requirements. This involves testing, inspections, and certification to ensure the product is compliant.

- 2. Determine Notified Body Involvement:**

If the product's regulations require third-party validation, involve a Notified Body from the [NANDO list](#). They will assess whether the product meets EU safety and quality standards.

- 3. Prepare the Declaration of Conformity (DoC):**

Create a [Declaration of Conformity](#) (DoC) to confirm that the product complies with relevant EU legislation. The DoC should include detailed information such as product identification, applicable legislation, manufacturer details, the involvement of any Notified Body, and references to harmonized standards or other normative documents.

- 4. Submit Required Documentation:**

Submit all necessary documents to the relevant regulatory bodies, including safety assessments, test results, and the DoC. Each regulatory body may require different documentation depending on the product and market.

- 5. Create an Evaluation Plan:**

Outline a plan to evaluate the regulatory submission process and ensure that all necessary requirements are met. This plan should include timelines for submission, monitoring of regulatory body responses, and tracking compliance updates.

- 6. Prepare for Post-Submission Evaluation:**

Once submissions are complete, be prepared for follow-up queries or requests from regulatory authorities. Adjust the evaluation plan accordingly to address any feedback and ensure swift progression through the approval process.

EXAMPLE

A marine restoration company submits its new technology for EU market approval. It conducts a conformity assessment to ensure the product meets all safety and environmental regulations. Since the technology falls under specific legislation, the company involves a Notified Body to carry out third-party validation. It prepares a Declaration of Conformity (DoC) listing the product details, legislative standards, and the involvement of the Notified Body. The company uses the Access2Markets database to verify the standards that must be met and submits the required documentation, including the DoC and technical reports, to regulatory bodies. The company also establishes an evaluation plan to monitor the approval process and adjust its strategy based on feedback.

Step 7: QMS Certification and technical File Preparation

In the EU, certain products must adhere to strict quality management systems (QMS) to ensure compliance with safety, health, and environmental standards. The [CE](#) marking is one of the most significant certifications, required for products ranging from medical devices to industrial machinery. Additionally, other certifications and [labels](#), such as energy labels and the EU Ecolabel, provide further guarantees of a product's environmental performance. Proper documentation, including technical files, is essential to demonstrate compliance and to justify the EU Declaration of Conformity.

HOW TO

1. **Identify Applicable Directives and Harmonized Standards:**

Determine which EU directives and harmonized standards apply to your product. This step ensures that your product aligns with the correct regulations.

2. **Verify Product-Specific Requirements:**

Confirm any additional product-specific requirements. These could be related to the industry, country, or type of product being developed.

3. **Assess the Need for Notified Body Involvement:**

Determine whether your product requires independent [conformity assessment](#) by a notified body, as detailed in steps 5 and 6. This is often necessary for more complex or high-risk products.

4. **Conduct Product Testing:**

Perform the necessary testing to check your product's compliance with EU directives. This includes safety, health, and environmental protection standards.

5. **Prepare the Technical File:**

Create a comprehensive technical file containing all required documentation that proves your product meets the necessary requirements. This file should include descriptions, test results, a list of parts, and other essential [documents](#).

6. **Affix the CE Marking and Prepare the Declaration of Conformity:**

affix the CE marking and prepare the EU Declaration of Conformity. The manufacturer is responsible for ensuring the marking is correct and complies with regulations.

7. **Identify and Document Potential Risks:**

In the technical file, identify all potential risks associated with your product and describe how these risks are managed or mitigated.

EXAMPLE

A company manufacturing marine restoration equipment identifies that its product must comply with EU environmental protection and safety regulations, requiring CE marking. After determining the applicable directives and harmonized standards using the Access2Markets database, the company confirms that an independent assessment by a Notified Body is required.

They conduct tests to ensure that their product meets environmental and safety standards, documenting the results in the technical file. This file includes detailed descriptions, test results, a list of parts, and a comprehensive risk assessment.

Once the product passes the necessary conformity assessments, the company affixes the CE marking and prepares an EU Declaration of Conformity, enabling it to enter the EU market.

Stage 4: Commercialise

Step 8: Regulatory submissions and market approval

After ensuring a product meets the necessary regulatory requirements, the next step is to prepare and submit the product for market approval. For products sold in the EU, this often involves obtaining a CE marking, which certifies that the product meets EU safety, health, and environmental standards. Achieving this approval allows for the legal commercialization of the product within the EU market. Additionally, manufacturers must fulfill traceability and labeling requirements to ensure transparency and consumer safety.

HOW TO

1. Submit the Technical Documentation:

Submit the product's technical documentation to the relevant authorities. This file includes information like test results, safety assessments, and conformity declarations.

2. Provide Instructions and Safety Information:

Once approved, the product must include clear instructions and safety information. These must be provided in a language understood by consumers and end-users in the target market, ensuring compliance with EU language requirements.

3. Ensure Product Traceability:

Comply with traceability regulations:

- Preserve the technical documentation.
- Provide a clear product identification, such as a type, batch, or serial number.
- Indicate the manufacturer's name and address on the product itself.

4. CE Marking:

Affix the [CE](#) marking to the product. The CE marking signifies compliance with applicable regulations and enables market approval across the EU.

5. Maintain Records:

Ensure that all technical documentation and submission records are preserved for future regulatory audits or market surveillance.

EXAMPLE

A manufacturer seeking to introduce a marine monitoring device in the EU first compiles its technical documentation, including safety assessments and compliance with environmental standards. After submitting the necessary files, the device undergoes the approval process, and a CE marking is granted.

The company includes instructions and safety guidelines in multiple languages to accommodate various EU markets. Each device is labeled with a batch number and the manufacturer's contact information. These steps ensure that the device is fully compliant and traceable within the EU.

Stage 5: Sustain

Step 9: Post market surveillance, (Vigilance) and Reporting

Once a product has entered the market, the responsibility doesn't end with regulatory approval. Ongoing post-market surveillance (PMS) and vigilance are critical components of ensuring the continued safety and compliance of the product. The company must monitor the performance of their products, stay informed about any legislative changes, and report any safety issues or non-conformities that arise. Post-market activities ensure that products remain safe, reliable, and compliant throughout their lifecycle.

HOW TO

1. **Monitor Legislative Changes:**

The company must remain vigilant about any changes in regulatory legislation that may impact their products. The EU often provides a transition period for adapting to new rules, enabling companies to adjust their products or find replacements if necessary.

2. **Establish a Post-Market Surveillance System:**

Develop a PMS plan that includes continuous product performance monitoring and feedback collection from users. This system helps to identify potential issues early and ensure ongoing compliance.

3. **Report Safety Issues:**

If any product defects or safety concerns are identified, companies must report them to the appropriate regulatory bodies and take necessary actions, including recalls if needed. This process ensures consumer safety and adherence to regulatory standards.

4. **Document Non-Conformities:**

Keep detailed records of any deviations from expected performance, including product failures or safety incidents. This documentation is essential for demonstrating compliance with post-market regulations.

5. **Adapt and Respond:**

If new regulatory requirements are introduced, the company must adapt products accordingly or face the risk of a product ban. The transition period provided by the EU should be used to make the necessary adjustments or find suitable replacements.

EXAMPLE

A company producing marine restoration equipment in the EU is informed of an upcoming legislative amendment affecting environmental impact regulations. During the transition period, the company re-evaluates its product, making necessary modifications to comply with the new standards. They also monitor customer feedback to ensure ongoing product performance and report any detected safety concerns to the appropriate regulatory bodies.



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