

New market entry compliance checklist

Launching a new product, or opening a manufacturing site in a new market, means working through five compliance domains: **product safety, chemical substances, site EHS, labeling, and ongoing monitoring.**

This practical checklist brings all five domains into one place. Work through it domain by domain to catch potential non-compliance issues early.



Product safety

- ☐ Which product safety legislation or standard applies to this product in the destination market?
- ☐ Does the product require pre-market registration, type approval, or certification before it can be sold or imported?
- ☐ Which conformity assessment procedure applies, and which body must conduct or witness it?
- ☐ Are existing test reports, technical files, and declarations of conformity valid here, or must they be reissued?
- ☐ Is there a local authorized representative or importer of record requirement?
- ☐ What are the post-market surveillance obligations once the product has market access?



Chemical substances

- ☐ Which restricted substance lists apply in the market for this product category?
- ☐ Has the product BOM been screened against current versions of all applicable restricted substance lists, including recent update cycles?
- ☐ Are substance concentration thresholds consistent across all components, or does this require deeper, homogeneous material-level screening?
- ☐ Have supplier declarations been verified against current regulatory lists, not just accepted at face value?
- ☐ Are any substances of very high concern present above 0.1% w/w, triggering REACH Article 33 communication obligations to customers?
- ☐ Are there chemical authorization or restriction requirements beyond the major frameworks?
- ☐ Is any currently permitted substance scheduled for restriction here within 12 to 36 months?



EHS at the manufacturing site

- ☐ Does the site hold all required environmental permits under local law?
- ☐ Are occupational health and safety requirements, including exposure limits, PPE standards, and incident reporting, current and implemented at site level?
- ☐ Are chemical storage, handling, and emergency response plans compliant with local regulations, including any site-specific thresholds that trigger additional obligations?
- ☐ Has the site completed required EHS registrations or notifications with local regulatory authorities?
- ☐ Are EHS management systems, such as ISO 14001 or ISO 45001, in place where required or expected by the market's buyers or regulators?
- ☐ Does the site's EHS compliance status meet due diligence requirements under applicable supply chain legislation here?
- ☐ When were EHS requirements at this site last reviewed?
- ☐ Is there a process for tracking regulatory changes at site level?



Labeling and marking

- ☐ Which conformity or approval marks are required on the product or its packaging?
- ☐ What are the mandatory language requirements for labeling, instructions for use, and safety warnings?
- ☐ If the product contains hazardous substances, does the label comply with the applicable GHS adaptation, including hazard pictograms, signal words, and precautionary statements?
- ☐ Are there product-category-specific labeling requirements, such as energy labeling, recycled content disclosure, or battery chemistry marking?
- ☐ Does the label include all required importer, manufacturer, or authorized representative contact information?
- ☐ Are there digital labeling requirements, such as QR codes linking to product passports or extended safety data, that apply to this product category?
- ☐ Has the label been reviewed by a local regulatory expert to confirm compliance?



Ongoing monitoring

- ☐ Is there a defined process for tracking regulatory changes in the destination market across all five domains?
- ☐ Who owns regulatory monitoring for this market?
- ☐ What is the escalation path when a relevant change is identified?
- ☐ Are restricted substance list updates automatically reviewed against the product BOM?
- ☐ Is there a process for reviewing exemption expiry dates and reapplication needs?
- ☐ Are EHS regulatory changes tracked at the national, regional, and local level?
- ☐ Is there visibility into proposed regulatory changes, not just enacted legislation, so that product or process changes can be planned ahead of enforcement dates?
- ☐ Is there a defined review cycle for reassessing compliance across all five domains for each active market?

Compliance doesn't end at launch

A product or site that's fully compliant on day one can fall out of compliance within months if regulatory change isn't tracked. Enhesa's specialists can help sense-check a market entry plan across all five domains.

Speak to an
Enhesa expert