// Product Compliance

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What is product compliance and why is it a challenge for manufacturers?

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Summary

Many companies would like to enter foreign markets and sell their products globally. Among numerous issues they should take care of (such as customs, taxes, logistics, etc.), it is easy to forget the topic of product compliance, comprising national certification and marking requirements for products, technical regulations and standards and a number of other regulatory requirements.

In order to avoid pitfalls and place products on foreign markets in accordance with the law, a sound understanding of product compliance, its different aspects, and methods of ensuring it is necessary.

The article will introduce you to the area of product compliance and give you a good overview of its different aspects such as:

- Different types of product requirements
- Regulated products
- Conformity assessments procedures
- Compliance markings
- Examples of different approaches to product conformity
- Main challenges related to product compliance

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As consumers, we would like the products we buy and use not only to meet their purpose and be durable but also to be safe. We have the right to expect that our laptop charger will not start burning or that the windscreen of our car will not burst into pieces when hit by a stone. What we often do not think of is how it is ensured that products placed on the market meet all the legal requirements and technical standards, or in other words, that they are compliant. This is where the term 'product compliance' (or 'product conformity') comes into play.

DEFINITION

Product compliance describes a set of regulatory requirements, rules, and standards that a product must meet in order to be placed on the market in accordance with the law. These requirements differ from product to product and from market to market and cover various aspects such as: electrical safety, electromagnetic compatibility, radio frequency, chemical composition, eco-design, energy efficiency, mechanical safety, restrictions on hazardous substances, children safety, artificial intelligence, cybersecurity, safety labelling, consumer information, packaging, extended producer responsibility, etc. As you can see, product compliance is a very complex area and manufacturers need a comprehensive understanding of its different aspects in order not to make costly mistakes.

Very often, there exist different laws regulating respective aspects of products, so in order to bring your product to the market in a compliant way, you don't need to know only one regulation, but for example ten. Some of the 'famous' product laws from the EU are e.g. Radio Equipment Directive (RED), Low Voltage Directive (LVD), Restrictions on Hazardous Substances (RoHS), Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Waste of Electrical and Electronic Equipment (WEEE), General Product Safety Directive (GPSD) and many others. Americans also have a soft spot for such abbreviations, like for example Consumer Product Safety Act (CPSA), Toxic Substances Control Act (TSCA) or California Proposition 65 (Cal Prop 65). And just imagine that each country has its own regulations and abbreviations...

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SCOPE

Basically, countries are free to choose which product aspects they want to protect via regulatory requirements and which product categories should be covered by them. Whereas most countries of the world regulate electrical household appliances and radio devices, the remaining categories of regulated products tend to differ a lot between different markets. Among the most commonly regulated goods are for example: machinery, toys, vehicles and their parts, medical devices, personal protective equipment, construction products, equipment for potentially explosive atmospheres or laboratory equipment. You can say that these are safety-relevant products. However, it is an individual decision of each country which products are safety-relevant and should be subject to a conformity assessment.
We published a separate article dedicated to the product compliance for vehicle parts – to access it please go to: *Legal challenges for European OEMs.*

CONFORMITY ASSESSMENT PROCEDURES

Similarly, the methods of proving that the product meets regulatory requirements can differ between countries. To the most common conformity assessment procedures/ schemes belong:

- Self-certification / declaration of conformity: where the manufacturer of the product is exclusively responsible to ensure that it meets the regulatory requirements and standards; he may (but is not obliged to) have his product tested by a third-party; the manufacturer may be required to issue a declaration of conformity in which he declares the compliance of the product with the applicable laws and standards; this method can be called a first-party conformity assessment
- Registration: where the manufacturer is required to register products at a designated authority before they can be imported or sold;
- Third-party testing: where the manufacturer must have his products tested by an independent accredited body to obtain official test results;
- Certification: where the product not only gets tested by an independent testing body but is also required to obtain an official certificate based on the test results.

The list is not exhaustive and above-mentioned procedures may be supplemented by additional requirements such as factory inspections or certification of the quality management systems (to ensure, among others, the conformity of production). All of them may exist in one country at the same time and, for example, apply to different product categories.

There also exist a second-party conformity assessment of products. This procedure means that your client may want to have your products tested in his own way before he buys them. This mostly involve very large, important, or demanding customers such as governments or other major buyers. The second-party assessment is in this case not required by public law but by the contract with your contracting party.

COMPLIANCE MARKINGS

One of characteristic elements of product compliance are also the so-called compliance labels or markings. Whereas a consumer normally does not peruse product regulations nor technical standards, nor is he aware of all test and certification procedures that products we buy must undergo, what they usually see are different signs and symbols situated on the product or package labels. The symbol that European consumers see most often are the letters “CE” standing for “Conformité Européenne” in French (or European Conformity in English). However, other countries do not content themselves with such simple logos and go for more sophisticated forms (resembling Egyptian hieroglyphs sometimes...). There is a plethora of such national compliance markings worldwide – the author of this article counted at least 25 on his laptop charger...

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PRODUCT COMPLIANCE AS A TRADE BARRIER

As mentioned in the very beginning of the article, the rationale behind the concept of product compliance was first to protect the consumer from dangerous products. However, countries discovered very quickly that product compliance can be also used as a trade barrier and a tool to protect their own markets. Requirements such as local representative, local in-country testing or national technical standards can impede the import of goods and significantly increase its costs. Whereas some obligations might be understandable (such as a local representative to which authorities or consumers could turn to in case of problems), some others, like the necessity to test the product twice according to the same standards can be seen as pure economic harassment.

The technical barriers to trade (so-called TBTs) linked with product compliance requirements are a useful tool for states for one more reason. The average tariff rates have been falling worldwide for several decades as a part of the trade liberalization. Therefore, their usefulness as a protectionist measure has also been decreasing. Technical barriers to trade, on the contrary, are more difficult to detect and to contest – they can often be justified under cover of product safety or consumer protection.

EXAMPLES OF DIFFERENT APPROACHES TO PRODUCT CONFORMITY

To illustrate how different countries address and regulate the issue of product conformity, several chosen examples from the biggest markets may be useful. The short descriptions below are meant to provide the reader with a general overview and a basic understanding and do not include too many details for the sake of simplicity. To get a deeper insight, please do not hesitate to contact the author of this article directly.

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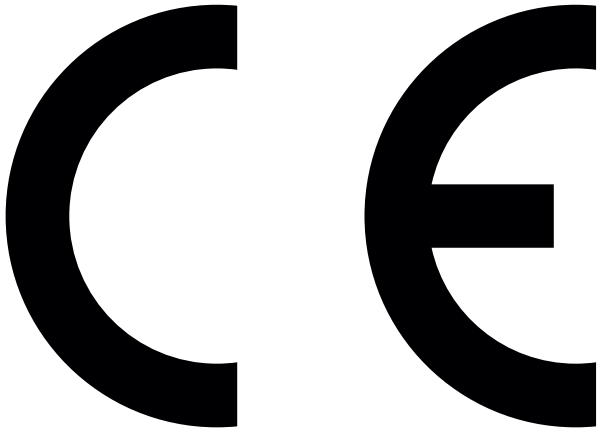
EUROPEAN UNION AND ITS CE

In the European Union, the CE conformity assessment is predominantly based on the so-called CE declaration of conformity (DoC). In this document, the manufacturer declares which EU product directives his product meets (there are over 20 CE directives covering different product groups, such as low voltage equipment, radio devices, lifts, toys etc., some were mentioned in the beginning of the article). Moreover, he also declares which harmonized standards the product fulfils (these are standards published in the Official Journal of the EU which provide the presumption of conformity with the essential requirements of the EU product directives). Of course, the manufacturer must make sure that the product meets all the requirements indeed (not only declare it). Nevertheless, in most cases he is not legally to obliged to go to a third-party testing body or have any official product certificate issued.



The EU declaration of conformity is one of the final steps of the whole process, though. First, before placing the product on the EU market, the manufacturer identifies the EU directives which are applicable to his product (there are no official lists of products covered by the CE conformity – the manufacturer must assess the applicability himself based on the, not always unambiguous, definitions from the directives). Then, from the applicable directive(s) (more than one can apply) he derives the product-specific requirements and identifies an appropriate route for conformity. As the next step, he complies the technical documentation of the product, issues the aforementioned CE declaration of conformity and marks the product with the CE marking.

Interestingly, this homogenous approach to product regulation in the EU was not always the case. Only in the last 10-15 years, as a part of the creation of the single market, product requirements and standards were harmonized. In the further past, major trade barriers existed between the present EU members and each country had its own conformity marking, e.g. for electrical products (imagine over 20 pictograms on electrical plugs, destined only for the European market...). Thanks to the Brexit, the new British product label UKCA and the recent legislative chaos linked with it we can at least imagine how Europe was back then, before the harmonization.

CHINA AND ITS CCC

The Chinese CCC certification (China Compulsory Certification) is partly similar to the EU system, however, there are important differences. Like in the EU, there is a structured and universal conformity assessment system with regulations for specific product groups and a national conformity label (there exists even an official catalogue of affected products). On the other hand, the two most important elements of the CCC certification and, at the same time, differences from the European CE system are obligatory in-country product testing (products that are undergoing the certification must be sent to test laboratories in China) and factory audits (product manufacturers' sites get inspected by delegations of Chinese auditors).

After passing the tests and the audit, products obtain a CCC certificate.

Recently, China has been adopting some elements of the system based on the manufacturer's declarations of conformity (like in the EU). The concept of the so-called CCC Declaration of Conformity has been extended to cover more and more product groups. Nevertheless, this topic will not be elaborated on in this article for the sake of simplicity, to avoid unnecessary confusion.

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USA

The philosophy of product compliance in the USA is quite different than in Europe or in China. There is no state-backed, universal conformity assessment scheme for all products. No lists of product regulations exist nor are there any catalogues of regulated products. In fact, very few product categories are required by law to have their conformity assessed (an example are radio transmitters requiring the FCC approval). Similarly, there is no national compliance marking like the European CE or the Chinese CCC. That does not mean, however, that there is a free-for-all in the USA.

The requirement to have a product tested often comes from the market and from clients. There exists a few private testing and certification schemes for different product categories (the most famous being probably the UL aka Underwriters Laboratories). Such certification may be required by your American business partners, may make it easier to market your product by raising the consumer's trust and might also give you the confidence that your product is safe and meets American standards.

OTHER COUNTRIES

What about the other countries of the world? There exists a range of different solutions, from restrictive conformity assessment systems with mandatory in-country certifications to no conformity assessments at all (and a plethora of intermediate forms in between). Among the countries with well-structured, universal systems, based on national certifications are for example (in brackets are the names of the systems, often derived from national standardization bodies): Eurasian Economic Union (EAC - Eurasian Conformity), Brazil (INMETRO - Instituto Nacional de Metrologia, Qualidade e Tecnologia), Indonesia (SNI – Indonesian National Standard), India (BIS – Bureau of Indian Standards), South Korea (KC – Korea Certification), Chinese Taipei (BSMI - Bureau of Standards, Metrology and Inspection), Saudi Arabia (SASO - Saudi Standards, Metrology and Quality Organization), United Arab Emirates (ESMA - Emirates Conformity Assessment Scheme) or Mexico (NOM - Norma Oficial Mexicana).

These systems cover various product groups (i.e. are not limited to one specific product category), require in most cases a specific national mark to be placed on products and are based on national testing bodies and institutions which carry out certifications. Obviously, a specific testing infrastructure and technical expertise that not all countries have is necessary to create and run such a system. Therefore, many of other countries, instead of having a comprehensive conformity assessment scheme, decide to regulate via national laws only a few chosen product categories (especially those most relevant for consumer safety like electrical household appliances or radio devices).

Another solution (which e.g. many African countries use) is to outsource the conformity assessment of imported products to accredited private companies. There are several such companies worldwide which run the so-called PVoC (pre-export verification of conformity) programs. They verify products before the export to their destination and then issue certificates which allow the import (very often for each shipment). The problem with PVoC programs is that they miss a clear legal basis which would publicly describe what technical requirements and standards imported products should meet. These details are often transferred to the exporter only in bilateral communication with the accredited company, which does not provide for much transparency.

CHALLENGES OF PRODUCT COMPLIANCE

What are the biggest challenges related to product compliance that manufacturers wanting to market their products internationally face? First of all, there are no two identical conformity assessment systems worldwide. Every country has its own specificities which manufacturers should know and understand in advance in order not to make costly errors. Likewise, scopes of affected products differ a lot between different markets: that a product is not covered by the CE marking requirement in the EU does not mean that it is not regulated e.g. in China. Sometimes it is a challenge at all decide if the product is regulated or not. If a country has a comprehensive catalogue of affected products (preferably with their HS codes), good for us. If, on the other hand, we must interpret some vague and unclear legal definitions in order to decide whether to have our product certified or not, the assessment gets trickier.

Another challenge, which actually should be taken into consideration at the product design stage, are diverging technical requirements and standards between countries. Even though numerous harmonization attempts are made at the international level (e.g. in organizations such as ISO - International Organization for Standardization or IEC - International Electrotechnical Commission), many countries still decide to go their own way and develop their own standards. And very often, even if they adopt international standards, they force importers to undergo an additional national testing procedure anyway (which re-doubles the same product tests).

On top of all aforementioned challenges, manufacturers must deal with the fact that the regulatory landscape is changing permanently. Countries keep issuing new laws containing new technical, certification, labelling and import requirements for different products. New conformity assessment systems are created, and existing ones are being modified. Product scopes affected by regulations are also regularly changed. Without a permanent monitoring of new requirements and timely analyses of new regulations affecting their products, manufacturers may very quickly fall out of compliance and end up being unable to supply foreign markets. The question is whether they should build up manpower to deal with all these laborious tasks and requirements by themselves or whether to outsource at least some parts of these activities to reliable experts.

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EFS IN GENERAL

EFS provides you with a comprehensive overview and support you in the area of Automotive Regulatory and Product Compliance.

Thanks to our 25 years of experience in the automotive industry, we have an extensive know-how in automotive regulatory and product compliance. Our international and multilingual team of experts combines crossindustry legal expertise with the necessary knowledge of processes and tools to ensure conformity of products.

Our competences are:

- Comprehensive and in-depth law understanding
- Conceptual and procedural Know-how
- Operational excellence

We value a partnership and close cooperation with our customers and look forward to supporting you with overcoming global challenges and answering questions related to product compliance and automotive regulatory – so that you can focus on your core Business.
Contact us on a non-binding basis if you are interested in an initial consultation or if you have questions regarding product approvals, import restrictions or certifications

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