in focus

US to EU cosmetics export
Unravelling the complexity of product compliance

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The EU market can be highly lucrative for US cosmetics companies. But it's vital that regulatory requirements are properly understood and factored into the export strategy. TSG Consulting's Dr Helena Eixarch sheds light on some of the complex issues that must be addressed to reduce the risk of non-compliance.

The stated value of the European cosmetics and personal care market varies across different sources. But whoever you consult, it's big. Cosmetics Europe, the European trade association for the cosmetics and personal care industry, says that based on 2017 retail prices, it's worth €77.6 billion (US$89.5 billion). That makes it the largest market in the world, ahead of the US at €67.2 billion (US$77.5 billion). Combine this with the fact that import tariffs have traditionally been low, and it's easy to see why the market is attractive to US cosmetics exporters.

However, regulatory discrepancies between the US and the EU add complexity to the trading situation. Notably, on July 11 2013, EU Cosmetics Regulation 1223/2009 came into force. This replaced the earlier EU Cosmetics Directive which had been in place for around 40 years, introducing new challenges and requirements for US exporters to contend with.

Clearly, the safety of cosmetics and personal care products is a high priority for both the US and EU markets. In the EU, stringent rules ensure manufacturers, distributors and retailers operate with care and integrity. Many of the specific challenges posed by the EU Cosmetics Regulation are rooted in the need to ensure a cosmetic product will not pose a risk to the consumer. Challenges associated with this are compounded by three core factors:

1. Allowable ingredients – while broadly dovetailing with those in the US – need to be closely monitored for regulatory updates and scrutinized for specific requirements.
2. Products must undergo a toxicological assessment, performed by a properly trained professional. Gathering the necessary information (whether via documentation or testing) can create a bottleneck in the safety assessment process.
3. Certain mandatory information must be included on the product label, and languages spoken across the EU need to be taken into account. Additionally, any product claims must comply with specific legal requirements.

In this paper, Dr Helena Eixarch sets out some of the key considerations for US cosmetics companies that already export, or want to export, to the EU. As well as looking at the robust safety assessments and extensive documentation requirements stipulated by the EU Cosmetics Regulation, Helena covers labeling and issues associated with products at the borderline between cosmetics and biocides.

Cosmetic Product Safety Reports

Central to EU Regulation No 1223/2009 is the detailed safety assessment which must be conducted and documented before products can be marketed in the EU. This goes beyond microbiological specifications, ingredient restrictions or labeling requirements followed in the US. The onus for preparing the report falls on the 'Responsible Person' taking the product to market in the EU – usually the distributor or reseller, when not the manufacturer.

The report comprises two parts: Cosmetic Product Safety Information (Part A) and the Cosmetic Product Safety Assessment (Part B). Product safety information requirements are extensive, and the required data are not always readily available. Where the information is not provided by the manufacturer, close liaison with raw material suppliers is necessary. In some cases, the finished cosmetic product may need to undergo testing, to ensure the required depth and breadth of data can be recorded.

Typically, the most challenging areas to document are raw material ingredient breakdown and information on impurities and allergens.

Raw material ingredient breakdown

The general quantitative formula from the manufacturer provides the basis for the safety assessment, but it doesn't go far enough to satisfy EU rules. Detailed information on raw materials is also required, since they may contain preservatives or additives that are not specified in the general formula. When it comes to the safety assessment stage, all ingredients present in the product must be taken into account, even if their levels in the finished product are low. Importantly, if the finished formula contains several raw materials with the same preservative, the combined total amount must be calculated to ensure levels are below maximum legal limits.

The safety assessor will request this information if they suspect a raw material may be preserved. For instance, raw materials containing high amounts of water are likely to include a preservative as they are more sensitive to microbial contamination.

Impurities

Information on impurities needs to be provided across all raw materials. However, special attention should be paid to certain ingredients which are known to contain traces of banned substances.

Some of these impurities are specifically restricted by the EU Cosmetics Regulation. For example, residual acrylamide (coming from polyacrylamide-containing raw materials) should not be present above 0.1 mg/kg in leave-on products. Likewise, nitrosamines, which can form when raw materials containing secondary amines contact nitrosating agents, are restricted to a maximum of 50 µg/kg. Both acrylamide and nitrosamines are known human carcinogens.

Other substances, such as ethylene oxide and 1,4-dioxane, are entirely banned in the EU. These carcinogenic impurities are carry-overs and by-products that can be present in certain ingredients including polyethylene glycol (PEG). They must only be present at trace levels in finished products. Therefore, safety assessors will request all available information to ensure allowable concentration

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thresholds are not surpassed. The same applies to impurities found in colorants or natural clays, which can include heavy metals such as mercury, lead or nickel.

If the relevant data from raw materials suppliers is ambiguous or incomplete, the end product will need to be tested to make sure impurity levels are safe. This is especially important in the case of nitrosamines, as their concentration may build up over time. Likewise, cosmetic products containing a high level of colorants need to be considered carefully. Concentrations of heavy metals in raw materials are usually provided as 'maximum possible levels' and not 'absolute values'. This introduces an element of uncertainty to the expected maximum level of impurity in the finished product.

Allergens

While plant extracts and natural ingredients are generally perceived as safe by the consumer, they can contain high amounts of allergens. This may pose a health risk to sensitized individuals. Information on allergens can be requested from the raw material supplier. If the data is not available, the finished product should be tested to assess allergen content. Stating the presence of allergens on the labeled ingredient list is mandatory under the EU Cosmetics Regulation.

Borderline products: cosmetics or biocides?

While most cosmetic products clearly fit within the definition stated in the EU Cosmetics Regulation, this might not be so straightforward when intending to use certain ingredients or claims. In some cases, there can be doubts as to whether a product is a cosmetic, a medicine, a medical device or a biocide. Importantly, the final classification of the product will determine the legal framework to be followed.

As an example, one can consider companies supplying products such as antibacterial handwash or antiseptic mouthwash. While these items are clearly cosmetic in nature, their active properties could lead to them being classified as biocides. In the EU, cosmetics and biocides are subject to standalone regulatory frameworks, and registering a biocidal product is far more complex, time-consuming and expensive than a cosmetic.

Clearly, consumer safety is always paramount. However, it has to be acknowledged that classifying a product as a cosmetic or a biocide has significant marketing and business repercussions. The correct positioning of 'borderline biocide' cosmetic products requires careful consideration. It often has to be handled on a case-by-case basis, drawing on general guidance in the absence of a specific regulatory framework.

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Practical considerations

If a product is to be marketed as a cosmetic, it must be intended for external application only. Furthermore, its composition needs to be checked. If it contains an ingredient which exceeds the concentration limits specified in the EU Cosmetics Regulation, it cannot be considered a cosmetic. Alternatively, if the product is to be classified as a biocide it must contain a biocidal active substance at an effective concentration. It is important to note that the inclusion of a biocidal active substance in a product is not necessarily an impediment for its classification as a cosmetic. Nevertheless, if the substance is present at a level sufficient to give the product biocidal activity, it is more likely to be considered a biocidal product. Product presentation, claims and target audiences can be key factors influencing the decision making process here.

Product functionality

If the main function of the product is to clean, perfume, change the appearance of or protect the skin, keep it in good condition or correct body odours, then it may fall within the cosmetics regulatory framework.

A key question is whether biocidal activities can be considered as secondary to the main cosmetic functions. In general, biocidal claims are permitted in cosmetic products as long as they are not used to 'imply that these products have characteristics or functions which they do not have', as stated in the EU Cosmetics Regulation. For instance, secondary biocidal claims like 'antidandruff' in shampoos or 'antimicrobial' in oral hygiene products are acceptable. However, claiming a 'disinfecting action' triggers a biocidal or even medicinal classification.

A handwash product whose main function is to clean, can claim a secondary antibacterial function and be classified as a cosmetic. But if the antibacterial action is intended (or implied) to be the main function, it must be then classified as a biocidal product. Therefore, proper identification of the primary and secondary functions of borderline products is essential. This is mainly achieved through the correct design of product labeling, and careful selection of any associated claims (including advertising or testimonials).

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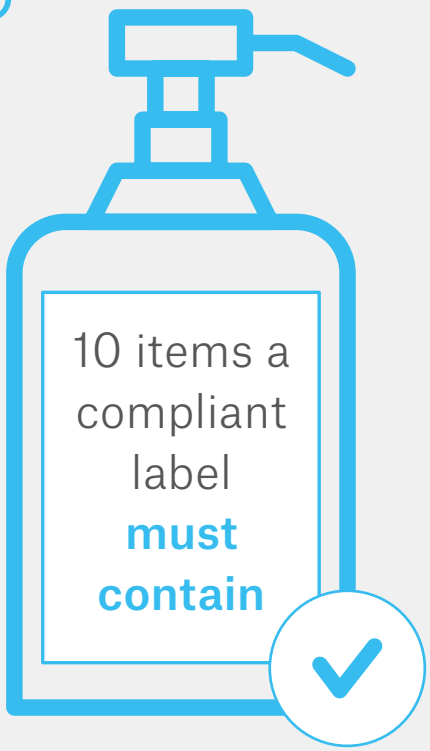
Ten legal requirements for cosmetics labels in the EU

Any cosmetic product marketed in the EU must bear specific information on the container (e.g. bottle, jar) and packaging (e.g. outer box, if applicable). It must be indelible and easily legible.



Name and address

of the responsible person.

Country of origin

for imported products.

Directions for use and precautions

If the container and/or packaging are too small to include this information, a leaflet or tag can be enclosed; this must be referred to by specific wording or by the open book symbol.

For products with a minimum durability equal to or below 30 months

the date of minimum durability must be stated, preceded by the words 'best used before the end of' or by the hourglass symbol.

Function of the product

unless it is clear from its presentation.

For products with a minimum durability above 30 months

the period after opening (PAO) must be indicated by the open jar symbol. Exemptions apply to certain product types.

Nominal content

Exemptions apply to small volumes, free samples, single-application packs or packages containing a number of items.

1010 Batch number

May only appear on the external packaging if containers are too small.

List of ingredients

preceded by the term 'ingredients'.

This information may be indicated on the packaging alone. There are specific rules governing which ingredients must be declared, the order in which ingredients are listed and the ingredient names used. If the packaging is too small to include this information a leaflet or tag can be enclosed; this must be referred to by specific wording or by the open book symbol. Specific rules apply to soap, bath balls and other small products.

The information referring to the nominal content, the minimum durability of the product, the directions for use and precautions, and the function of the product

must be translated to the language

determined by the Member State where the product is being sold.

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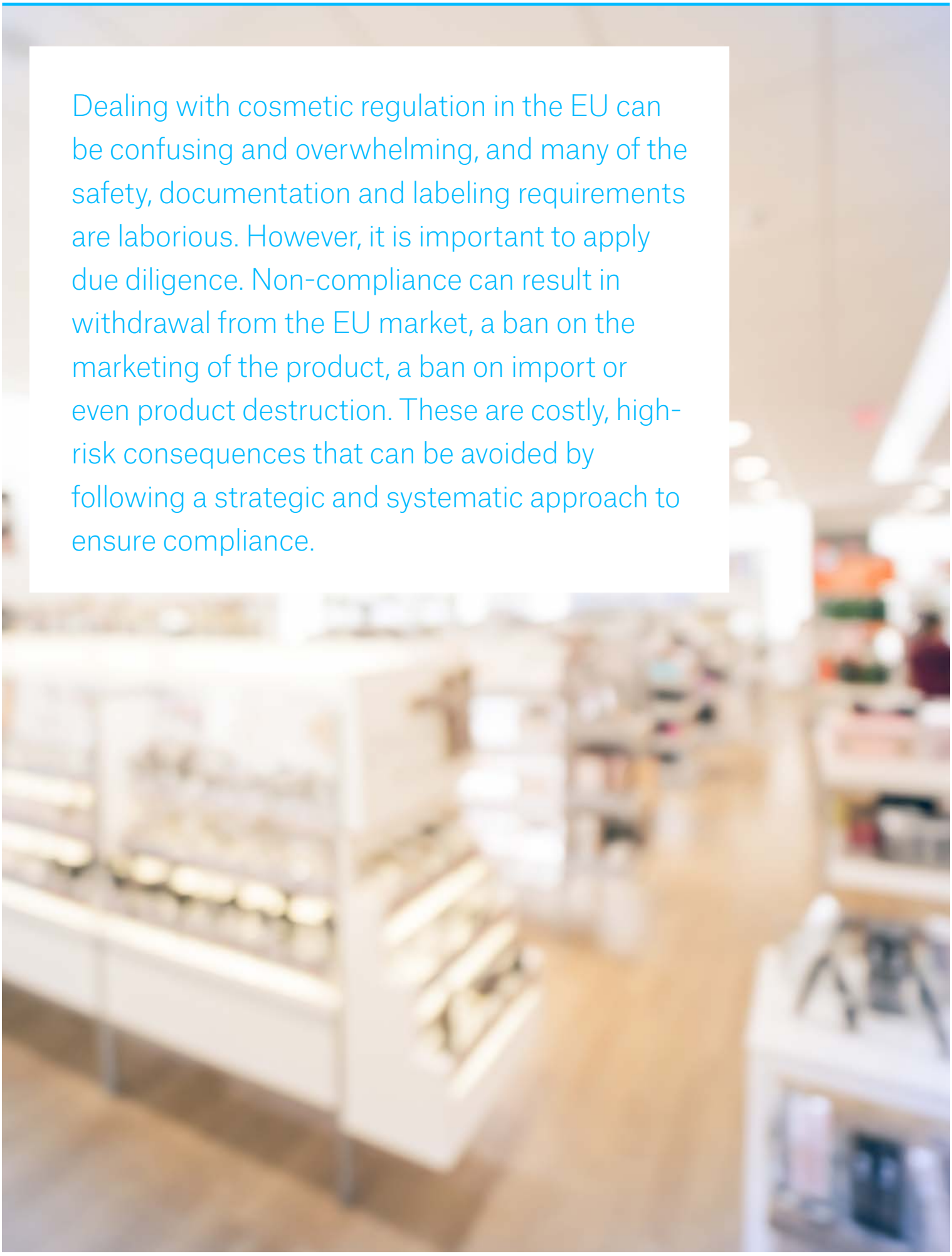
Ten stages of compliance with the EU Cosmetics Regulation

Before exporting a cosmetic product to the EU, the product formula, safety assessment and PIF, labeling and notification must fulfil legal requirements.

Follow these steps to ensure compliance:

1. An EU-based Responsible Person must be designated.
2. The Responsible Person must ensure the product is classified as a cosmetic, especially when dealing with borderline cases.
3. A formula check is recommended to ensure compliance with ingredient restrictions.
4. A Cosmetic Product Safety Assessment (CPSR) must be performed according to the provisions of the EU Cosmetics Regulation.
5. Labels must be checked for compliance.
6. The relevant evidence to support claims related to the product must be gathered.
7. The product must be notified to the Cosmetic Product Notification Portal (CPNP).
8. A PIF (Product Information File) must be collated.
9. The Responsible Person must ensure cosmetovigilance is properly performed, that is, adverse effects related to the product must be monitored and notified to the authorities if appropriate.
10. Close monitoring of regulatory changes is recommended to ensure products remain compliant once they are on the market.

Dealing with cosmetic regulation in the EU can be confusing and overwhelming, and many of the safety, documentation and labeling requirements are laborious. However, it is important to apply due diligence. Non-compliance can result in withdrawal from the EU market, a ban on the marketing of the product, a ban on import or even product destruction. These are costly, high-risk consequences that can be avoided by following a strategic and systematic approach to ensure compliance.



How TSG can help

For almost 30 years, TSG Consulting has provided companies around the world with regulatory guidance and scientific expertise. Our experts are highly knowledgeable in the core sciences and the public policy decisions that are used to structure and implement environmental and chemical regulations. By combining this knowledge with our industry experience, we provide companies with comprehensive services from the early stages of product development to marketplace entry and ongoing compliance.

Interested in discussing a potential project?

Get in touch:
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About the author

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Helena provides support to clients, advising on all aspects of regulatory compliance with the EU Cosmetics Regulation. Prior to joining TSG Consulting, Helena worked as a regulatory toxicologist for a major cosmetics retailer. Helena has both a degree and a PhD in Biochemistry, holds a Diploma on Cosmetic Products Safety Assessment, and is a European Registered Toxicologist.

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TSG Consulting provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (AIM:SAG) company.

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