US regulations for cosmetic products

Trouble free exporting to the USA

Michael Pfeiffer and Melanie Cummings from Pfeiffer Consulting explain the challenges to consider before marketing products from the EU to the US and what pitfalls to avoid.

The obstacles for an EU company entering the US market are manageable

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With over 300 million inhabitants and US$58bn[1] (compared with Germany's approx. 80 million inhabitants and just over € 13bn[2], the US is one of the top-selling cosmetic markets in the world. Cosmetic products that are "Made in Germany" are highly valued. Many German and European companies are successfully represented in the US market. These companies profited from the increase in sales which amounted to 5.8% in 2014. For 2015, sales are expected to be characterised by a similar increase. If exports to the US are to be successful, it is vital to be well prepared. When legal requirements are violated and mistakes are made, local US authorities react. Such mistakes can cause long waiting times for Customs clearance or even result in mandatory destruction of products or return of the delivery without compensation. This brief overview provides regulatory background knowledge based on our many years of experience in supporting exporting companies at a regulatory level.

Differences in classification

Products that are categorized as cosmetics in the EU may be subject to other legal regulations in the USA. For example, sunscreens, dandruff shampoo, antiperspirants, and fluoride toothpaste are classified as OTC (over the counter) drug products – that is to say they are available without prescription. Other product groups can fall under the category of "medical devices". Violations in this field can be punished as a violation of the pharmaceutical law – in the US as well as in the EU – which entails serious consequences for the company and its future entry to the US market.

Identification and promised effectiveness

Requirements for labelling do not differ as much. Labelling, according to EU standards, requires adaption to the US regulations; for example, the net quantity declaration (ml and fl. oz.) also has to be positioned on the front of the product covers. However, there are differences in the interpretation of claims that have to be carefully attended to, see table below. If you fail to take these differences into account, it can result in serious consequences.

Different interpretations of claims

Not allowed in US	Allowed in US
Wrinkle reduction	Reduces appearance of wrinkles
Eliminates dandruff	Eliminates flaky scalp
Eliminates/reduces puffiness around the eyes	Reduces appearance of puffiness around the eyes

The use of ingredients

The US uses a "negative" list, not a "positive" list like in the EU and some other countries. The US allows the use of chemical names or common names if a US INCI name has not been assigned. The list below is not necessarily all inclusive, but is an example of common cosmetic ingredients that have different INCI names and/or labelling requirements in the EU. Restricted ingredients can be found in the CIR compendium[1]. The CIR does not review colourants. Regulatory information for colorants can be found in 21 CFR part 70 EU[2].

- Aqua — Water
- Parfum — Fragrance
- Cera Alba — Beeswax
- Paraffinum Liquidum — Mineral Oil

Most waxes (Carnauba, Candelilla, microcrystalline) use "cera" in the EU and "wax" in the US.

Colourants are always listed last (regardless of quantity used).

US INCI names have to be included with the CI numbers.

As colourants allowed in the EU may not be allowed in US cosmetics, this is something that needs to be checked carefully.

California-specific regulations

The EU Cosmetic Directive 1223/2009 is a standard Europe-wide regulation which does not apply to the US. The regulations may differ from one individual state to the next. One example is the so-called **Prop. 65** (this is a clean water initiative implemented years ago with a list of ingredients that have been grown to include CMR and which require a warning on the package) and the **California Safe Cosmetics Act** (which requires product registration if a cosmetic contains ingredients that meet the criteria on the published list) in the US State of California. Prop. 65 Warnings in California are common (they are printed on every bottle of wine sold in the state), but the placement of such a warning on a cosmetic product is avoided, in general[3].

VOC 2013 research of CARB

The **California Air Resources Board (CARB)**[4] started a survey on all consumer products, including cosmetics. This survey has been mandatory for companies who sold cosmetic products in California in 2013 and 2014. Deadline for submission was March 2, 2015. The purpose of the survey is to determine whether there are products on the market containing VOC's (Volatile Organic Compounds) that should be added to the list of regulated categories. Current cosmetic categories include hair styling products, antiperspirants and deodorants, toners/astringents, and certain nail treatment products. These products require a specific batch code structure printed on the container (or notification to CARB of the deviation).

Optional FDA[3] registration – yes or no?

Basically, approval or notification of cosmetic products is not required in the USA. However, it may be an advantage to submit an optional **VCRP**[4] with the **FDA**[3]. This does not constitute an official approval, although it can have a positive effect on customs clearance, on market entry, and on the related acceptance of products with the distributors. It is a good final check to confirm that product ingredients are allowed in a particular type of product. Unfortunately, registration is not permitted until after a product is first sold in the US.

Prerequisites for marketing in the US

Compared to Europe, the procedure of distributing products in the US is much easier. The basis for marketability in the USA is the verification of the following aspects:

- Is it a cosmetic product and not an OTC product or a medical device?
- Are the ingredients approved in general and with reference to the individual states (in particular California) and the related necessary warning notices or product registration?
- Identification of primary and secondary packaging
- Verification that colourants used in cosmetic products are approved
- Advertising claims

Products that meet all legal EU requirements don't usually have to be modified, or only have to be slightly modified according to US regulations. The next step would be the above mentioned optional VCRP[4] registration with the FDA[3].

Differences in product liability

The US is known for many legal procedures in the field of product liability, which are not easy to understand for Europeans. It is recommended to get legal advice from an expert attorney in order to evaluate the individual risks and to find the corresponding protection. There are expert attorneys in the USA who can be consulted directly or can be engaged by correspondence.

What costs are incurred?

It is difficult to calculate the exact costs, as this depends on many individual factors. Basically, it can be assumed that the costs for the verification of the aspects mentioned, the preparation of a statement and the VCRP[4] registration can be approx. 40 to 60% lower than the costs common in the EU for the preparation of a safety assessment, a **PIF (Product Information File)** and the notification.

The US market – a challenge?

The US is a very interesting market, in particular with the current $/€ exchange rate. The obstacles for an EU company entering the market are manageable. There are very good marketing possibilities for the appropriate products or product groups. However, without meeting the local legal requirements – in the USA as well as in the EU – marketing attempts to market will fail.

References:

1. German Trade & Invest — www.gtai.de
2. IKW — www.ikw.org
3. FDA: Food and Drug Administration — www.fda.gov
4. VCRP: Voluntary Cosmetic Registration Program — www.fda.gov/Cosmetics/RegistrationProgram/RegistrationHelp/default.htm

[1] www.cir-safety.org/ingredients

[2] www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=70

[3] http://oehha.ca.gov/prop65/prop65_list/Newlist.html

[4] www.arb.ca.gov/consprod/regact/2013surv/2013main.htm

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