COSMETICS EUROPE:

CERTIFICATE OF FREE SALE FOR COSMETICS IN THE EUROPEAN UNION

COSMETICS EUROPE QUESTIONS AND ANSWERS DOCUMENT

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Introduction

EU cosmetic companies exporting to third countries are often asked to provide a Certificate of Free Sale (CFS) as part as their export dossier. This certificate is a declaration attesting that the product intended to be imported is compliant with the EU Cosmetic Products Regulation and may therefore be freely sold across the EU.

The EU Cosmetic Products Regulation came into force on 11 July 2013 and is a safety-based regulation. It regulates the production, labelling and import of cosmetic products; its main objective is the safeguarding of human health.

Since many years Certificates of Free Sale provided by EU companies have been accepted by third countries. A CFS is also regarded as a "Certificate of Manufacture" or a "Health or "Safety Certificate by certain non-EU countries.

This Questions and Answers document provides information on the Certificate of Free Sale practice in the EU. It is also aimed at clarifying that in the EU the country of origin of the CFS may be different from the country of manufacture.

Questions and Answers

1. **What Information does a CFS contain ?**

- The most important basic information is a statement that the product(s) may be freely sold across the EU. This allows the product to circulate freely within the EU single market.
- A statement that the product complies with the EU Cosmetic Products Regulation (EC/1223/2009) is normally included.

It is not necessary to attach the formulation to a CFS because the statement of compliance implies that the formulation complies with the regulation.

2. **Does a CFS also acts as a certificate for compliance with EU Regulations and cosmetic Good Manufacturing Practice?**

All companies manufacturing or placing products on the market in the EU are obliged to comply with the EU Cosmetic Products Regulation. Such statements are therefore normally automatically covered within the scope of a CFS.

If a cosmetic product is compliant with the EU Cosmetics Regulation, cGMP requirements, as laid down in the Regulation, are also fulfilled. Products sold in the EU must be produced in accordance with cGMP. Third party certification of cGMP compliance is not mandatory in the EU. It is therefore unnecessary to request for a cGMP compliance certificate for imported products from the EU in addition to CFS. A CFS should also be accepted as a cGMP certificate.

3. **Why is a CFS issued in an EU Member State important for international trade?**

Many countries outside the EU have a system of pre-market product registration, which requires specific documentation to guarantee that a product is safe and complies with international cosmetic regulations. A CFS is the main document that provides assurance that the product is formulated and manufactured in accordance with the EU Cosmetic Products Regulation. Since the European Union has a well-structured and efficient regulatory system for cosmetics, a CFS issued in an EU Member State is widely accepted internationally.

4. Who in Europe can issue a CFS?

Different organisations are recognised as competent authorities for issuing CFS of equivalent standard in the EU.

Certificates of Free Sale can be issued by (i) the Responsible Person[1] or by (ii) a relevant organisation[2] other than the Competent Authority in any EU member state as arranged by the Responsible Person if this is the normal practice for that market. These have an equivalent weight in terms of the EU market as the Responsible person, not the third party, is responsible for compliance with the EU regulations.

5. Is it necessary for CFS to be authorised or authenticated through any other authorities or processes?

No, additional authorisation or authentication is not necessary, since a CFS is an original document, issued by authorised bodies. Additional authorisation or authentication provides no extra guarantee or legal endorsement of product safety or compliance.

6. Why are CFS issued in different formats and by different organisations in the EU?

Historically, the different countries have followed different systems. Depending on the country, the national competent authorities may issue the certificate, or alternatively, they can authorise trade associations or other agencies (eg chambers of commerce) to issue CFS on their behalf.

7. Is there any difference in CFS issued by Member States?

No, the CFS document may have variation in format, text, style and the issuing body, but the fundamental certification that the product complies with the EU Cosmetic Products Regulation and may be freely sold throughout the EU is the same.

[1] The Responsible Person is defined in Article 4 of the EU Cosmetic Products Regulation (EC/1223/2009).
[2] 'Relevant organisation' could be a Trade Association or Chamber of Commerce, as examples. This list is not exhaustive.

8. **Does Cosmetics Europe issue CFS?**

No, Cosmetics Europe does not issue CFS. Of course, through co-operation with national associations and regulatory agencies, Cosmetics Europe plays a very important role in promoting the understanding of the CFS and the harmonisation of the regulation across all Member States.

9. **Can a central department issue documents for CFS even if it is not in the country of manufacture of all products?**

Yes, this is a recognised process for the Responsible Person to issue CFS documents. The country of origin may be another country.

10. **Why is a CFS not always issued in the country of manufacture?**

The EU is a single market and companies marketing internationally may choose to locate the Responsible Person in many Member States which may not be the same as the country of manufacture. Issuing CFS centrally in the country of the Responsible Person, regardless of manufacturing location, is the accepted practice.

For operational and logistic reasons, many companies produce different products and ranges in several countries.

- Products manufactured in one Member State (and therefore complying with the EU Cosmetic Products Regulation) may not necessarily be sold in that country.
- The European Union is a single market for cosmetic regulations. This means control can be centralised in one EU location (as indicated by the address on the product copy). A CFS issued in any Member State therefore covers production throughout the EU.
- A EU CFS covers products manufactured outside the EU on behalf of an EU based Responsible Person. As according to the EU Cosmetic Products Regulation the Responsible Person is fully responsible for placing products on the EU market and maintaining the PIF in accordance with Article 11 of the Regulation.
- If a company sub-contracts the manufacturing of a finished product, production must also comply with the requirements of the European Cosmetic Products Regulation. The CFS for such products can be issued in any Member State where the marketing company acting as the Responsible Person operates, irrespective of where their products are manufactured.

11. What are the marketing implications of specific wording in a CFS?

A product might be manufactured in one Member State, but this does not necessarily mean that it will be sold in that particular country. The EU is a free market and international companies might decide to transfer product from one country to another for strategic or business reasons. Certain products might not even be sold within the EU if they were developed for specific overseas markets, however a CFS would only be issued for products that comply with the EU Regulation.

In addition, since many countries have long registration time-scales, a CFS is often requested before the product launch. However, a CFS would not be issued until the product was assessed as safe and compliant with the European regulations. Following this principle is important to ensure that new and innovative products are rapidly accessible to consumers worldwide.

12. Why do shipments sometimes arrive from a country that is not necessarily the same as the country of origin of the product?

Companies do not necessarily distribute from every country of manufacture and/or may have centralised distribution. Origin of manufacture should not be confused with origin of shipment. As mentioned earlier, the European Union is a single market for cosmetic regulations.

13. Can a company obtain a CFS for products manufactured outside the EU?

Yes, since the company responsible for placing the product on the EU market is obliged to comply with the requirements of the European Cosmetic Products Regulation, this company can obtain a CFS from the authority in the EU country in which it operates. Of course, the company must be established within the European Union.

Where can I get more information?

Please contact the Cosmetics Europe national association members for more information.

Their contact details can be found on the Cosmetics Europe website:

www.cosmeticseurope.eu .

COSMETICS EUROPE IS THE EUROPEAN TRADE ASSOCIATION REPRESENTING THE INTEREST OF THE COSMETICS, TOILETRY AND PERFUMERY INDUSTRY

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