COSMETIC AND PHARMACEUTICAL PACKAGING

SAFE SUSTAINABLE SOLUTIONS

The cosmetic packaging…

The European regulation governing the cosmetic sector is Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 (Cosmetics Regulation).
This text replaced the Cosmetics Directive 76/768/EEC and all relevant national laws after 37 years, eliminating the legal inconsistencies produced by the national adoptions of the previous legislation.
A single regulation valid across all EU countries benefits both consumers and companies. Consumers are assured of uniform protection, while producers and distributors of cosmetic products benefit from the free movement of goods within the market.
This regulation came fully into effect on July 11, 2013.
The Regulation maintains the fundamental principles of the Directive, the most important being the obligation to provide consumers with a safe cosmetic product.

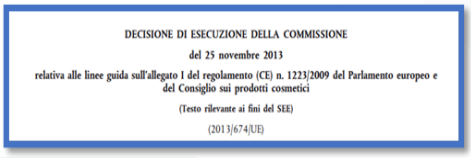

22.12.2009 IT Gazzetta ufficiale dell'Unione europea L 342/59

REGOLAMENTO (CE) n. 1223/2009 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO
del 30 novembre 2009
sui prodotti cosmetici
(rifusione)
(Testo rilevante ai fini del SEE)

Among the aspects of the Directive retained in the Regulation text are:

- a broad definition of cosmetics;
- an in-market control system by the Member States;
- the responsibility of the person placing the cosmetic on the EU market concerning compliance with legal requirements;
- a system that regulates specific ingredients through inclusion in positive or negative lists.

In order to ensure the safety of the final consumer, Regulation (EU) No. 1223/2009 concerning the production and marketing of cosmetic products requires that the Safety Assessor considers all ingredients, including possible traces of substances, foreseeable conditions of use, and the characteristics of the packaging material, as well as any possible interactions with the cosmetic product.
Section 4 of Annex I states, "The safety report for cosmetic products contains, at a minimum, the following elements: …4) Impurities, traces, information on packaging materials," which has created many concerns for both cosmetic companies and primary packaging manufacturers.


DECISIONE DI ESECUZIONE DELLA COMMISSIONE
del 25 novembre 2013
relativa alle linee guida sull'allegato I del regolamento (CE) n. 1223/2009 del Parlamento europeo e del Consiglio sui prodotti cosmetici
(Testo rilevante ai fini del SEE)
(2013/674/UE)

To this end, the European Commission published guidelines for Regulation (EC) No. 1223/2009 on cosmetic products (Decision 2013/674/EU of November 25, 2013), aimed at providing greater clarity and thus better understanding of the requirements set by the regulation so that the Safety Assessor can prepare a safety report for cosmetic products that meets legislative requirements.
Since substances can migrate from packaging to formulation, the relevant characteristics of the packaging material must be considered.

Some traces have concentration limits clearly defined by regulations. For the presence of traces of substances that are not prohibited, and for which there are no defined concentration limits at the regulatory level, but which could affect consumer safety, it is necessary for the Safety Assessor to perform a safety evaluation. As a starting point, reference can be made to the FCM regulations; in fact, point 3.4.3 of the Decision "Relevant characteristics of the packaging material" states that "Packaging material refers to the container (or primary packaging) that is in direct contact with the formulation. The relevant characteristics of the packaging material in direct contact with the final product are important for the safety of the cosmetic product. Reference to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council (OJ L 338 of 13.11.2004, p. 4) may be useful.

COSMETIC AND PHARMACEUTICAL PACKAGING

"IT IS ESSENTIAL TO RECOGNIZE THAT COSMETICS ARE DIFFERENT FROM FCM;
our laboratory specializes in testing those materials intended to contain specific cosmetic matrices,
with characteristics that are absolutely different from the food simulants used so far for FCM.
In synergy with the technical committees of the Italian Packaging Institute, new approaches and simulants (alkaline, oxidative, surfactants...) have been defined.... **and pharmaceuticals**

In addition to the aspects defined by the Pharmacopeia in specific Monographs dedicated to individual materials, risk assessment is increasingly based on typical rules for food contact compliance. In fact, while in the food contact area, the investigation of unintentionally added substances refers to the acronym NIAS (Non-Intentionally Added Substances), in the pharmaceutical sector, the same types of contaminants are defined as Leachables & Extractables.

- Extractables are organic and inorganic chemical substances that can be released from a packaging or drug release system, from a component of packaging or packaging material under specific conditions during laboratory tests.
- Leachables are organic and inorganic chemical substances that can be released from a packaging

or drug release system, from a component of packaging or packaging material under normal storage and use conditions or during accelerated stability studies of the pharmaceutical product.

Leachables are generally a subset of extractables or derive from extractable substances. It should be noted that chemicals can also migrate from packaging or release systems to patients through direct contact.

OUR SOLUTION

Food Contact Center specializes in validating packaging intended for contact with cosmetics and actively collaborates in the technical committee held under the Italian Packaging Institute (institutional) regarding the validation of cosmetic packaging. The company is capable of developing a suitable analytical plan focused on a thorough evaluation study of the formulation of cosmetics, the materials used in contact, and the simulant that must be used during testing.Food Contact Center is also specialized in validating packaging intended for contact with drugs or pharmaceutical forms, and in this case, it actively collaborates in the technical committee held under the Italian Packaging Institute regarding the validation of pharmaceutical packaging. In this context, FCM rules are proving to be a reference. It should be noted that the Pharma sector sometimes continues to refer to international standards (ASTM and ISO) and especially to pharmacopeia rules. Therefore, the company is able to develop an analytical plan proposing analyses according to both FCM rules and pharmacopeia for evaluating the compliance of materials used for pharmaceutical packaging.

The Laboratory Management