L'OBSERVATOIRE DES COSMÉTIQUES

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THE COSMETICS REGULATION 1223/2009

- MASTERING THE KEY POINTS
- BE AWARE OF ONE' S OBLIGATIONS
- PREPARING THE PRODUCT INFORMATION FILE
- MANAGING NANOS, EDS, CMRS
- SET UP ONE' S COSMETOVIGILANCE
- BE IN COMPLIANCE WITH GMP

LES ÉDITIONS DE L'OBSERVATOIRE DES COSMÉTIQUES

Collection The Essential

Introduction

European Cosmetics Regulation 1223/2009 was implemented in full on 11 July 2013, replacing the previous Directive.
If the overall spirit of cosmetics regulations has remained unchanged, the new text has come with important changes, as well as new responsibilities and obligations for the different players of the cosmetics industry. And, given its nature (a Regulation rather than a Directive), it is directly applicable in all European Union countries, without the need to be transposed on the national level. The same goes for all its amendments.

Six years after the Regulation came into force, it appears that it is sometimes still poorly known or mastered by the different actors in the sector, a fact that the market control authorities constantly observe… and punish.
How to comply with Regulation 1223/2009? How to formulate in such a way as to meet all the requirements defined for ingredients and raw materials, when they change regularly? How to build the Product Information File, mandatory before any marketing? How to establish the Product Safety Report? How to deal with such particular ingredients as nanomaterials, CMRs, endocrine disruptors? How to set up the cosmetovigilance? Where and when should the various declarations and notifications be made? Or, in short, how ensure the safe marketing of cosmetic products, without risking a recall or compliance injunction?

This ebook, intended for manufacturers, importers, distributors, formulators, regulatory affairs officers, safety assessors, quality managers… This ebook, intended for manufacturers, importers, distributors, formulators, regulatory affairs officers, safety assessors, quality managers… presents the provisions of the Cosmetics Regulations and the obligations of each party, with key concepts and practical sheets to meet its requirements, as well as the latest developments and news in the text.

Structure of the Regulation

Just like any other European regulation, Regulation No 1223/2009 is divided into several parts.

THE “WHEREAS”

They make up the introduction of the text and define its spirit, explaining its framework, principles and objectives, which determine the obligations of the various actors involved in its implementation.
The Cosmetics Regulation counts 71 of them.

THE TEXT

40 articles define the actors’ obligations and the procedures for implementing the text. They are structured around ten chapters:

- Chapter I: Scope and definitions
- Chapter II: Safety, responsibility, free movement
- Chapter III: Safety assessment, Product Information File, notification
- Chapter IV: Restrictions for certain substances
- Chapter V: Animal testing
- Chapter VI: Consumer information
- Chapter VII: Market surveillance
- Chapter VIII: Non-compliance, safeguard clause
- Chapter IX: Administrative cooperation
- Chapter X: Implementing measures, final provisions

THE ANNEXES

These are the technical parts of the Regulation, which counts ten of them. The first six, which have to do with the safety report and conditions of use of the ingredients, are especially important to keep in mind.

Annex I: Cosmetic product safety report

This annex is divided into two parts and lists all the elements that must be included in the cosmetic product safety report.

Annexe II : List of substances prohibited in cosmetic products

It is the exhaustive list of substances whose use is prohibited. Each of them is identified by its chemical name, CAS number, and EC number.

Annex III: List of substances which cosmetic products must not contain except subject to the restrictions laid down

These substances subject to restrictions are not prohibited, but their use must satisfy the conditions listed in this annex, in particular:

- The types of products in which they can be used
- Their maximum concentration in finished products
- The specific restrictions depending on the substances
- The wording of conditions of use and warnings that must appear on the label

Annex IV: List of colorants allowed in cosmetic products

This exhaustive list contains the colorants that may be used, each with their own chemical name, CI number (the Colour Index used by the INCI nomenclature), CAS and EC numbers, colour, types of products in which they may be used, and the other conditions of use (maximum concentration authorized, purity criteria…).

Note

Hair dye colorants are not part of cosmetics colorants, but they are included in Annex III on the substances subject to restrictions.

Annex V: List of preservatives allowed in cosmetic products

It is another exhaustive list set up according to the same principle: each substance is identified by its chemical and INCI names, CAS and EC numbers, with the types of products in which they can be used and the other conditions of use (maximum concentration authorized, specific restrictions, wording of conditions of use and warnings…).

Annex VI: List of UV filters allowed in cosmetic products

Likewise, the UV filters and screens allowed are identified in an exhaustive way by their chemical and INCI names, CAS and EC numbers, with the various conditions of use to which they are subject.

ANNEXES UPDATES

Annexes II to VI are regularly amended by regulations that modify Regulation 1223/2009, depending on the assessments carried out by the SCCS (Scientific Committee on Consumer Safety) to evaluate the safety of ingredients, and on the transcription of its Opinions by the European Commission into the regulatory framework. As a result, these lists are far from set, and have already known several adaptations since the initial text entered into force.

Annex VII: Symbols used on packaging/container

It is the reference that must be used for the symbols indicating the “reference to enclosed or attached information”, the “period-after-opening”, and the “date of minimum durability”.

Annex VIII: List of validated alternative methods to animal testing

This annex lists the alternative methods validated and specifies whether they can fully or partially replace animal testing.

Annex IX: Reference to the former Directive

It is divided into two parts: the “Directive repealed with its successive modifications” and the “List of time-limits for transposition into national law and application”. Today, it only serves as a history reminder.

Correlation table

This last annex indicates the references of the various parts of the text in the former Directive and new Regulation. Designed to make it easier to go back and forth between the various paragraphs, it is no longer very useful today.