EBOOK
2025

LES ÉDITIONS DE L'OBSERVATOIRE DES COSMÉTIQUES

USA

REGULATORY FRAMEWORK AND MARKET TRENDS

Introduction

Increased customs duties or not, France is the leading exporter of cosmetics to the United States. And, according to a recent study by Astérès on behalf of Cosmetic Valley, US consumption is set to remain buoyant over the next few years.

The regulatory environment is also extremely dynamic. With the passage of the MoCRA (Modernization of Cosmetics Regulation Act), the FDA (Food and Drug Administration) has been granted new powers to manage and control the cosmetics sector. Henceforth, manufacturing establishments must be registered, products notified, adverse effects documented and reported to the authorities, labels to include a US-based contact, factories (even outside US territory) to be prepared for inspection…
And there's still more to come, since we're still waiting for additional measures, such as a list of allergens to be labelled, to be published by the FDA.

It's also important to understand that, when you go to the United States, you can't stop at federal law. Each state has the right (and some do, like California and Washington) to adopt its own additional cosmetic requirements. Lists of prohibited ingredients, labeling requirements, product declaration obligations… may thus vary from state to state, and add to the rules with which we must comply.

When it comes to spending, Americans have habits all their own. True "beauty addicts", they spend an average of $100 a month on beauty products (according to investment bank Harris Williams). In the United States, cosmetics are everyone's business: men, women, teenagers, children… all demographic cohorts like to take care of themselves and expect products adapted to their needs.

CosmeticOBS has designed this Ebook to help you keep abreast of regulatory requirements and the latest market trends. A tool to help ensure compliance, and put on your side all the chances of a successful export venture to this country.

Regulatory framework

MOCRA, THE NEW COSMETIC DEAL IN THE US

Voted by the US Congress on December 29, 2022, the Modernization of Cosmetics Regulation Act (MoCRA) will profoundly change the regulatory framework for cosmetics in the United States from the end of 2023. During the International Meetings organised by Cosmed on March 22, 2023, Béatrice Muhl, in charge of European clients at Registrar Corp, an American firm specialised in all aspects of compliance with the US FDA, gave an overview of the new rules to follow.

The United States was known until now for having very few rules for cosmetics (except for those applying to dyes or OTC which will remain in force), and for having an authority (the Food and Drug Administration - FDA) with very few enforcement powers. MoCRA will change this, by establishing a comprehensive framework to regulate all cosmetic products.

This law has therefore been passed by Congress and signed by the President of the United States. But it is still largely a "work in progress".
Indeed, although the MoCRA already contains some very concrete elements, many others will be specified by the FDA through "Regulations". It is to be expected that the administration will issue "Proposed rules" which will give rise to open comment periods before the "Final rules" are adopted. Each will contain an implementation date and a date by which companies must comply with the new rule.

Key definitions of MoCRA

Responsible Person

The Responsible Person is not strictly speaking a person, but rather an entity. It is the manufacturer, packager or distributor whose name appears on the label of the cosmetic product.
It is this entity that will be in charge of:

- The registration of products, according to a system that will replace the VCRP (Voluntary Cosmetics Registration Programme) by the end of 2023
- The prevention and reporting of adverse events, which will therefore become compulsory whereas it was only optional until now
- The substantiation of product safety
- The additional labelling requirements
- Themanagement and communication to the FDA in relation to allergens, as the FDA is mandated to establish a list of allergens, which will have consequences for labelling
- The archiving of certain data, particularly in relation to adverse reactions

Facility

The term "facility" refers to any establishment that manufactures, processes or packages (in case of primary packaging only) cosmetic products distributed in the United States, which also includes subcontractors if they meet this definition.
This facility must be registered with the FDA and comply with published US Good Manufacturing Practices.

Safe Cosmetic

The term "safe cosmetic" means that the cosmetic product and its ingredients are not hazardous to the user under the conditions of use recommended on the label or used in a routine and customary manner.
The FDA will not consider a cosmetic ingredient to be hazardous to users solely because it may cause minor and temporary skin reactions or irritations.

Serious Adverse Event

The term "serious adverse event" means an adverse event that results in or requires medical intervention to prevent:

- Death or a life-threatening situation
- An infection or hospitalisation of the patient
- A persistent or significant disability or infirmity
- A congenital anomaly or malformation
- A significant cosmetic harm other than that expected under the usual or customary conditions of use, such as serious or persistent irritation or infection, second- or third-degree burns, significant hair loss, or persistent or significant change in appearance

In all such cases, the FDA must be notified within 15 days of the event.

The key points of the MoCRA

Registration of facilities

Existing establishments that manufacture or process cosmetic products distributed in the United States must be registered with the FDA by December 29, 2023. New establishments will have 60 days following the marketing of a product to do so.

The procedure is not yet known as the FDA has to set up the system to submit these registrations.

They will in any case have to be renewed every two years.

Establishments outside the US will have to appoint a US Agent for Registration, to whom the FDA can turn with any questions, be it a health emergency, an adverse reaction, or to facilitate communications for a possible inspection.

Product registration

The Responsible Person must submit a record for each product, called "Product Listing".

"Attention! This is not a product list," Beatrice Muhl stressed, *"but a registration for each individual product, even though the term may be confusing."*

The MoCRA says that the FDA needs to put in place a flexible system to allow different versions (shades, flavours, strengths) of the same product to be grouped together in a single submission. Again, this must be done by 29 December 2023, even though the new registration system is not yet open.

And the Responsible Person will have to renew the Product Listings every year as well as make updates in case of changes.

The new labelling requirements

In connection with the new cosmetovigilance system, cosmetic product labels must be updated to indicate either:

- A full US address
- A telephone number in the United States
- An electronic contact information through which a Responsible Person can receive an adverse reaction report (this can be an email or an online form on a website), so that a consumer can submit a report For existing products, the deadline for compliance is 29 December 2024.

"It is better to wait a little while before re-labelling," Beatrice Muhl advised,* "to be sure of what the FDA will specify, because it may be necessary to add an additional sentence such as 'To report a serious adverse event' or 'contact'…"*

Another novelty: cosmetic products that contain allergens in their fragrance ingredients must update their labelling to list them.

But to do so, they will have to wait for the FDA to establish the list, in order to check if it is identical (or not) to the European list. And even though the MoCRA specifies that the FDA should be guided by international regulations, especially European ones, there may be some differences in the end.

Finally, the labelling of cosmetic products for professional use must include a clear and visible statement that the product is to be administered or used only by authorised professionals and is in compliance with the existing labelling requirements for cosmetic products.

Adverse event reporting

Until now, it has been voluntary. With MoCRA, it becomes mandatory, according to the same system.
From the end of 2023, in case of a serious adverse event (a priori only if it occurred on the US territory) associated with a cosmetic product, the Responsible Person must submit within 15 days a report to the FDA, together with a copy of the labelling on or in the packaging.

Archiving of adverse events

Adverse event reports must be kept for six years and the FDA has a right of access to them, particularly during inspections. The FDA may request details of the formula and a written list of all ingredients in a fragrance or flavouring in a product if it suspects that they may be the cause of a serious adverse event.
It should be noted that for companies classified as "small businesses" (average turnover in the USA of less than 1 million dollars over the last three years), the time limit for keeping these reports is shortened to 3 years.

Good Manufacturing Practices

Until then, the subject of GMPs was dealt with by rather vague guidelines of less than 10 pages dating from 2013.
The MoCRA requires the FDA to establish a real regulation, at the latest by 2025. And this will not necessarily be a copy and paste of the ISO 22716 standard, as the US administration can certainly draw inspiration from it, but also add new elements. This regulation will allow the FDA to inspect facilities and audit any records it deems necessary to determine compliance with GMP.
And products will be considered "adulterated" if they are not manufactured in a GMP compliant facility.

The elements of product safety

Companies must maintain the necessary documentation to establish the substantiation of the safety of their cosmetic products, and clarification from the FDA is awaited.
Again, a product will be considered "adulterated" if this requirement is not met.

Product recalls and inspections

The FDA will have enhanced authority over product recalls.
It will thus be able to initiate a mandatory recall (which was not previously within its competence) as soon as:

- There is a reasonable probability that a cosmetic product is adulterated or mislabelled
- That the use or exposure to this product may cause serious adverse events

Inspections

Until then, the FDA only inspected OTC manufacturers, the only ones it knew of since they were the only ones registered with it. Now that all cosmetic companies must be registered, *"we can expect that in the future, the FDA will come to inspect, not systematically but by sampling, as it already does for food, medical devices and pharmaceutical establishments,"* Betrice Muhl warned.

Cosmetics containing talc or PFAS

Any product containing talc will have to comply with a standardised test method to be defined by the FDA to detect and identify asbestos.
As for the use of PFAS, it will have to be evaluated and scientific review elements concerning their safety of use and the associated risks will have to be included in the evaluation.

So we can only wait for the FDA regulations (which have already announced that **they will no longer accept submissions to VCRP**)… and be ready to adapt as quickly as possible!