Among cosmetics, the category of sunscreens is certainly a fascinating one for a cosmetologist (the sort of expert that supposedly has knowledge of chemistry, toxicology, dermatology, rheology, and even marketing, etc.). The development of sunscreens brings along many technical and toxico-logical issues, which stem from the requirement of having contrasting ingredients for opposite needs in the same formula. Good spreadability is in contrast with water resistance, and the proper level of filters is in contrast with the quality of the texture and solvents needed for product stability.

Once a potential solution is found for these issues, the development process of a new product is usually further complicated by marketing and regulatory issues. Many useful and practical - and in fact safe - ingredients cannot be used due to a bad reputation they have in web-based blogs and forums or simply because there has been scare mongering, which leads the developer to avoid parabens, alumina and nano ingredients (1). The other side of the coin is the burden of regulations that classify sunscreens in very different ways in different areas of the world.

From the regulatory perspective (2), we can identify some major geographic areas to consider, though the European approach (and this is reasonable due to the dimension of that market) is paving the way for many other areas, which have eventually adopted the same concept and set of rules.

We can broadly identify:

- European Union and EEA (Switzerland, Norway, Iceland)
- USA
- Canada
- Japan
- South Korea
- Brazil
- China
- Taiwan
- ASEAN countries
- MERCOSUR Countries
- RUSSIA
- Australia
- New Zealand
- Middle East/Arabic countries (Turkey, Emirates, Morocco, Egypt)
- India
- African countries (South Africa, Nigeria, Tanzania)
- Ecuador
- Others

It’s not easy to compare the different regulations available, largely because cosmetics are defined in different ways. Moreover, in the case of sunscreens, these are classified as “over the Counter” (OTC) products in the USA (this means they are regarded as drugs and not as cosmetics) or according to specific provisions like in Australia.

The classification is not the only critical point or main hurdle in the development of an internationally-recognised formula, since each authority has developed specific lists of allowed UV filters and their own systems to calculate, test and label the SPF factor.

It is quite an extensive task to go into detail for each of the aforementioned world areas. Therefore, we will provide an overview of the main markets which should be interesting for those companies that are looking to take their products to the global market.

EUROPEAN UNION, SWITZERLAND, NORWAY AND ICELAND

We can start with the European Union. The current EU Regulation (3) EC/1223/09 replaced the previous system based on Directive 76/768 providing all member states with the same legal framework, based on the negative and positive lists of ingredients. The same framework is also applied in New Zealand, some of the Middle East/Arabic countries, Turkey and ASEAN countries. In these areas the EU regulation is accepted and applied as it is or with minor changes. The main point in this case is to check whether the local legislative status of some of the ingredients is updated.

According to the definition given by the Regulation, a “cosmetic product!” means any substance or mixture which is intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with the sole purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. Among these functions, the protection of skin from damage due to sun exposure is referred to as a cosmetic action. Therefore, in Europe, sunscreens are considered as cosmetics. In Europe, the system is constantly updated as technical progress evolves, on the basis of the Scientific Committee on Consumer Safety’s (SCCS) recommendations on safety of ingredients. The Committee provides recommendations on
health and safety risks (chemical, biological, mechanical and other kinds of physical risk) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products, etc.) and services (e.g. tattooing, artificial sun tanning, etc.).

These recommendations usually lead to an update of regulations, whose annexes have to be considered for formulating a sunscreen. These are:

I. Cosmetic product safety report
II. List of substances banned in cosmetic products
III. List of substances which cosmetic products must not contain according to restrictions
IV. List of colourants allowed in cosmetic products
V. List of preservatives allowed in cosmetic products
VI. List of UV filters allowed in cosmetic products

The current list has 28 filters listed along with specific limits of concentration and with some specific warnings for the labelling of the products. The testing and labelling is also included in the Commission Recommendation of September the 22nd, 2006 on the efficacy of sunscreens and the claims made relating thereto. This recommendation sets some specific guidelines regarding the UVA/UVB ratio of protection, specific labelling warnings and the labelled category of protection starting from low protection (SPF 6) to very high protection (SPF 50+).

- Minimum efficacy - lowest allowed claim SPF 6
- UVA protection must be at least 1/3 of UVB protection [UVA/UVB ratio]
- Critical wavelength for testing is at least 370 nm
- Precautions and usage instructions – recommendations for protection must be shown in labelling
- 4 protection categories (4) (see extract from recommendation)
- Testing made according to SPF + UVA method (in vitro systems preferred for ethical reasons)

USA

The sunscreens are classified in the USA as “over the counter” (OTC) drugs and the main reference documents are the Final Rule (5) published in 2011 and the Sunscreens Innovation Act published in 2014. The classification as OTC means that all the limits due to the approval process and strict definition of labelling have their effect in this category of products. The Sunscreen Innovation Act has been approved with the declared purpose to make some of the new filters already in use in the EU and in other countries available to the US market. The Act has also been developed according to the “material time and material extent concept”, meaning that active ingredients that have been marketed “to a material extent” in a foreign market and are obviously supported by safety data can be added to an OTC (therefore to sunscreens) drug monograph. The decision made in 1970 by the FDA to place sunscreens products in the OTC category is actually blocking some of the new sunscreens available in Europe, it has been a long time since the FDA has approved a new sunscreen due to the lack of safety data, as well as insufficient funds. The Sunscreen Innovation Act didn’t change the situation too much and the prospect of seeing miloxate, bemotrizinol, bisoctrizole, drometrizole trisiloxane, ecamsule, enzacamene, iscotrizinol, and octyl triazone approved in the US market is still far away. The complex work of developing sunscreens is certainly not easy due to the fact that some of the allowed filters are not particularly useful for the textures being developed today due to their technical characteristics.

Many of the aspects of the Final Rule deals with are mostly labelling matters. Label wording is strictly regulated, such as where and how to write relevant information like water resistance or, in the case of sunscreens with a broad spectrum (SPF >15), which products can bear the claim: “if used as directed with other sun protection measures, (the product) decreases the risk of skin cancer and early skin ageing caused by the sun”.

One part of the regulatory system for sunscreens is represented by the monograph, which essentially provides a standard for active ingredients. If a monograph has been issued for a product, all a company has to do is to be allowed to market it is to demonstrate that it has met the standards of that monograph. This method allows new formulas to be introduced to the market and is different from the aforesaid regulations on new ingredients.

Twenty-four ingredients are currently regulated by the FDA through its various final monographs.


- Aminobenzoic acid (PABA) up to 15%
- Avobenzone up to 3%
- Cinoxate up to 3%
- Di oxybenzone up to 3%
- Homosalate up to 15%
- Mentholanthranilate up to 5%
- Octocrylene up to 10%
- Octyl methoxycinnamate up to 7.5%
- Octyl salicylate up to 5%
- Oxybenzone up to 6%
- Padimate O up to 8%
- Phenylbenzimidazole sulfonic acid up to 4%
- Sulisobenzone up to 10%
- Titanium dioxide up to 25%
- Trolamine salicylate up to 12%
- Zinc oxide up to 25%
- Ensulizole up to 4%
- Homosalate up to 15%
- Meradimate up to 5%
- Octinoxate up to 7.5%
- Octisalate up to 5%
- Octocrylene up to 10%
- Oxybenzone up to 6%
- Padimate O up to 8%

A new monograph is underway, but we’ll have to wait until 2019-2020 to anticipate solving some of the open questions relating to sprays and other forms (powders, wipes), ingredients, high SPF values, etc.

In some cases, single states, e.g. California, have specific state rules that make it more complex, such as the PROPOSITION 65 of the State of California of January the 1st, 2015, requiring to print the following warning on labels of products containing the cancer-causing chemical benzophenone: “WARNING: This product contains benzophenone, a chemical known to the State of California to cause cancer.”
The typical label for a sunscreen is depicted in Figure 1.

**Canada**

Health Canada has issued a regulatory framework for cosmetics which is a blend of the EU and US regulations. Cosmetics are regulated under a framework that resembles the European one (e.g. with a hotlist of ingredients), while sunscreens are classified in different ways according to the single ingredient and may fall either under the Natural Health Product or the Drug Products regulations.

A monograph (last revision issued on 23/06/2015) entitled “Sunscreen monograph” collects all the points referred to this class of products. For the marketing of a product a Product Licence Application must be filed.

Canada’s monograph includes sprays and powders. It refers to all products including those referred to as secondary sunscreens. In fact, specific provisions are given for labelling broad spectrum and UVA protection, whereas certain claims are not allowed, unless supported by existing scientific data.

**ASEAN**

As previously stated, the cosmetic directive for ASEAN (7) countries is quite the same as the EU regulatory framework. Differences may arise due to a delay in adopting the EU approach and decisions and because of a specific warning that is mandatory, i.e. “Do not stay too long in the sun, even while using a sunscreen” that must be put onto products sold as primary sunscreens. The ASEAN scientific committee act like the SCCS, but the adoption of the directive is not homogeneous over the Member Countries.

It must be highlighted that no claim should be made that implies that a “100% protection against UVA and UVB radiation” is guaranteed and that “reapplication of the product is unnecessary” e.g. whole day protection.

Examples of recommended warnings:
- Do not stay too long in the sun while using a sunscreen
- Re-apply frequently to maintain protection, especially after sweating, swimming or towelling
- The use of sunscreens is one way to reduce the dangers from sun exposure
- Instructions for use to ensure that sufficient quantity is applied, e.g. pictogram, illustration, etc
- Over-exposure to the sun is a serious health threat

The following SPF classifications are recommended to the JCIA self-regulating standards. The UV filters are among the ingredients that are regulated.

The minimum SPF may even be as low as just 2 while the maximum is 50+. The request to add specific warnings such as “reapply every 2-3 hours and reapply after towelling” is
still in discussion. Some attention must be paid to claims like “prevents wrinkles”, which is not permitted, while the claim “prevents fine lines caused by dryness of skin” may be allowed provided it is substantiated by testing.

CHINA

The rapid change of the regulatory profile for cosmetics is due to many aspects: the growing market, the needs of protection, the request for quality exports and the change of the governing body from MOH to the more structured SFDA. China has approved many changes, such as the approved ingredients list (now under further revision) and has identified a classification as “special use cosmetics” for sunscreens. This means that registration of a product with the State Food and Drug Administration (SFDA) will check the safety and efficacy of the product, along with the SPF and other parameters. The list of permitted filters is the same as the EU, which is due to the close exchange between the EU commission and Chinese authorities looking for harmonisation of regulations. The maximum level is SPF 50 while for UVA the rates are PA +, ++, +++.

An issue which is always in discussion is China’s request (in general for cosmetics) for animal testing and, in this case, the in-vivo UVA mandatory testing.

HONG KONG

Surprisingly, it is the easiest country to register cosmetics in since no specific rule is in place for import, and customs normally require the products to meet the regulations in one of the “developed countries” e.g. EU, USA, China, Australia.

KOREA

Korea distinguishes different classes of cosmetics (their system resembles the Chinese regulations) and classifies sunscreens as “Functional Cosmetics” with specific provisions. Products must be sampled for registration and reports on test methods for both active ingredients and finished products must be provided. The dossier must include information of the origin, development and final formulation. The maximum allowed SPF is 50+ and the result of SPF or efficacy data and testing must be provided by a test supervisor (similarly to the safety assessor in EU regulations) with more than 5 years of experience.

A specific process is required for new sunscreen active ingredients, which need to be supported by a dossier that must include extensive safety data. In Korea the manufacturer must also provide all information on the fragrance used, including a components list of the fragrance.

TAIWAN

Like many Far East Asian countries, in Taiwan sunscreens are classified as medicated cosmetics. This means registration requires a GMP certificate. The labelling regulations are similar to other systems worldwide, with the SPF numeric value (max 50+) and the UVA protection grade that can be up to PA ++++

The list of allowed filters is the same as in the EU, but with different allowed concentrations.

AUSTRALIA

The sunscreen regulations in Australia are full of important requirements that reflect the high level of attention towards sun protection in Australia. This specific need is due to the geographical and meteorological position of this country. Sunscreens are classified mainly as therapeutic and cosmetic sunscreens (8).

Therapeutic sunscreens include:
- primary sunscreens with SPF 4 or more
- secondary sunscreens – except those regulated as cosmetics
- primary or secondary sunscreens with SPF 4 or more that contain an insect repellent
- products containing sunscreen agents with SPF less than 4 that are currently defined as listable sunscreens (specific situation to be checked in detail)

Cosmetic sunscreens are products that contain an ingredient with sunscreen properties but the primary purpose of the product is neither to be a sunscreen nor a therapeutic molecule. These products are regulated as cosmetics by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS) rather than therapeutic goods, which are classified by the TGA.

Among the specific rules for Australia, a norm regulates the allowed filters and their amount, and there are a number of specific rules for claims. These are different between the two categories. Therapeutic sunscreens with a broad spectrum protection (SPF of 30 or higher) may have these indications on the label:
- ‘May assist in preventing some skin cancers.’
- ‘May reduce the risk of some skin cancers.’
- ‘Can aid in the prevention of solar keratoses.’
- ‘Can aid in the prevention of sunspots.’

In Australia nano titanium dioxide and zinc oxide are commonly used in sunscreens and the labels of therapeutic sunscreens are not required to declare the particle sizes of ingredients.

For the labelling of secondary sunscreens, which limits the SPF to under 15 (and for make-up up to 50+), a broad spectrum activity is mandatory and the levels are as usual - Low, Medium, High, Very High - but there is a wider range of SPF values in the low class (4, 6, 8, 10).

NEW ZEALAND

In New Zealand sunscreens are classified as cosmetics and the standards for cosmetics is clearly linked to the EU regulation, which is usually applied (updated) as it is. Otherwise, the recommendation is to market sunscreens that comply with the Australian Standard (AS/NZS 2604).
refer to water resistance, sunblock, broad spectrum along with SPF value and the UVA protection expressed as PA++.

A specific rule [9], recently passed, regards packaged goods. Packaged goods require cosmetics to bear a red or brown dot for non-vegetarian products and a green dot for vegetarian products. The application is still not very clear as there is no definition of “vegetarian cosmetics”- this point has to be checked during the registration process.

RUSSIA

The growing market of Russia has seen the regulations being updated quite a lot. It has to be noted that there is a common market known as the Single Customs Union (10), which includes Russia, Belarus and Kazakhstan. Sunscreens are classified as cosmetics according to the Technical Regulation for the Safety of Cosmetic Products that resembles the EU regulation. Registration is obligatory according to the GOST standards and allowed filters are in the annex V of the regulation, which is similar to the EU annex. Also the labelling has guidelines similar to the EU regulations, with a products required to show a maximum SPF of 50+, the PA +++ and the broad-spectrum feature. Due to the climate conditions, products needs to be evaluated for stability.

MERCOSUR

As occurs in Europe, Russia and Asia, South America also has a Common Market Group. The MERCOSUR includes Argentina, Brazil, Paraguay and Uruguay and a technical regulation establishing labelling and safety requirements for sunscreens has been in place since 2012 (even if the application in some countries, namely Brazil, may be different).

According to regulations, a sun product is a preparation intended to be in contact with the skin and lips with the objective of providing protection against UVB and UVA radiation by dispersing or reflecting the radiation. Products that claim protection against UV radiation as an added benefit rather than as their main objective fall under the scope of the regulation, too. The technical framework is derived from the 2006 EU recommendation and requires the sun protection factor, the water resistance feature and that UVA protection is at least 1/3 of the UVB.

Products must be registered, while labelling has a separate set of rules. The sun protection factor is marked as “FPS” or the words “Factor de Protección Solar” plus the UVA logo. In the case of products that have the sunscreen protection as an added benefit the minimum SPF must be 2 and FPUVA also 2, while a specific warning is needed: “this product is not a sunscreen”. Rules on claims require that they do not contain language suggesting total protection from solar radiation nor can they be labelled with statements claiming to provide 100 percent protection against UV radiation, or stating that the product does not need to be reapplied under any circumstances.

Table 3. Permitted active ingredients for therapeutic sunscreens.

<table>
<thead>
<tr>
<th>Australian Approved Name (AAN)</th>
<th>Synonyms, Abbreviations, Trade Names, CAS Number</th>
<th>Maximum Concentration (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berodetrizol</td>
<td>Bis-ethylenoxyphenol-metohexyl tetrazine [INCI name]</td>
<td>10%</td>
</tr>
<tr>
<td>Benzoil salicylate</td>
<td>Benzyl salicylate</td>
<td>6%</td>
</tr>
<tr>
<td>Butyl methoxydibenzoylmethane [INCI name]</td>
<td>4-tert-butyl-4-methoxydibenzoylmethane</td>
<td>5%</td>
</tr>
<tr>
<td>Camphor benzalkonium methosulfate [INCI name]</td>
<td>N,N,N′,N′-Tetramethyl-4-isoxazolin-5-ylmethyl methyl sulfonate</td>
<td>6%</td>
</tr>
<tr>
<td>Cinoxate</td>
<td>2-Ethoxyethyl para-methoxynapthalene</td>
<td>6%</td>
</tr>
<tr>
<td>Diethylaminoethanol benzylbenzoate [INCI name]</td>
<td>Benzonic acid 2-(4-diethylamino-2-hydroxyethyl) hexyl ester</td>
<td>10%</td>
</tr>
<tr>
<td>Dioxybenzone [INCI name]</td>
<td>Benzophenone 8 [INCI name]</td>
<td>3%</td>
</tr>
<tr>
<td>Oxietilaminozolinacetato [INCI name]</td>
<td>1-[2-hydroxy-4-sulfinyl] propionic acid</td>
<td>10%</td>
</tr>
<tr>
<td>Drometacril trisiloxane [INCI name]</td>
<td>2,2′,4-Trimethylbenzyl 2,4,6-trimethylstyryl triisiloxane</td>
<td>15%</td>
</tr>
<tr>
<td>Ecamamine [INCI name]</td>
<td>Terephthalidilacenil diphloron acid</td>
<td>10%</td>
</tr>
<tr>
<td>Homosalate [INCI name]</td>
<td>Homosalicylate 3,3′,5-trimethylcyclohex-2-yl cyclohexanecarboxylic acid</td>
<td>15%</td>
</tr>
<tr>
<td>Isomyl methoxy-cinnamate</td>
<td>Isomyl p-methoxy cinnamate [INCI name]</td>
<td>10%</td>
</tr>
<tr>
<td>Isomyl 4-methoxycinnamate</td>
<td>Isomyl 4-methoxycinnamate [INCI name]</td>
<td>10%</td>
</tr>
<tr>
<td>Methylbenzylidene camphor [INCI name]</td>
<td>3-4′-Methylbenzylidene-diaminopropyl Enzymamer [INCI name]</td>
<td>4%</td>
</tr>
<tr>
<td>Oxybenzone [INCI name]</td>
<td>Benzophenone 3 [INCI name]</td>
<td>10%</td>
</tr>
<tr>
<td>Padimate O [INCI name]</td>
<td>Ethylhexyl dimethyl PABA [INCI name]</td>
<td>8%</td>
</tr>
<tr>
<td>PEG-20 MPA [INCI name]</td>
<td>Ethylhexyl 4-methoxybenzilate</td>
<td>10%</td>
</tr>
<tr>
<td>Phenylbenzimidazol sulphonate [INCI name]</td>
<td>3-Phenyl-5-sulfonylamidazole</td>
<td>4%</td>
</tr>
<tr>
<td>Polypicoline-11 [INCI name]</td>
<td>Dimethyloctahydrobenzaldehyde</td>
<td>10%</td>
</tr>
<tr>
<td>Salicyl benzene [INCI name]</td>
<td>Benzoic acid 4- [INCI name]</td>
<td>10%</td>
</tr>
<tr>
<td>Salicyl benzene [INCI name]</td>
<td>5-Benzoyl-4-hydroxy-2-methylenbenzene sulfonic acid</td>
<td>10%</td>
</tr>
<tr>
<td>Sulfosalicylic acid [INCI name]</td>
<td>Toluidine sulfonate [INCI name]</td>
<td>25%</td>
</tr>
<tr>
<td>Triacontanol [INCI name]</td>
<td>Palmitic acid</td>
<td>12%</td>
</tr>
<tr>
<td>Zinc cece [INCI name]</td>
<td>Pigmint white 4</td>
<td>No limit</td>
</tr>
</tbody>
</table>

INDIA

The cosmetic regulation in India dates back to rather old regulations and the marketing of products must deal with a lot of bureaucracy (a typical statement you can hear in India is that “the British invented bureaucracy, the Indians perfected it!”), in some cases with standards and laws that conflict themselves. Cosmetics in India must be registered and the claims allowed

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The definition “Broad Protection” is not accepted. Specific warnings are (refer to the EU recommendation) that (1) sunscreens need to be reapplied to maintain their effectiveness; (2) they help prevent sunburn; (3) a doctor should be consulted if applied to children under six months; (4) prolonged sun exposure by children should be avoided; (4) they do not provide any protection against sunstroke; (5) they should be applied abundantly before sun exposure; (6) they should be re-applied after sweating profusely, bathing, swimming, drying oneself with a towel and exposure to the sun; and (7) if the applied quantity is not sufficient, the level of protection will be significantly reduced. Also the categories are the same of those in Europe with Low, Medium, High, very High, with the maximum SPF allowed being 50+.

It must be underlined that in Brazil the list of allowed sunscreens is broader than in the EU and in the US and that for the cosmetic products the age limit for children is up to 12 years old.

ISRAEL AND THE MIDDLE EAST

Laws in this area have recently undergone many changes, with the basic structure of the European regulation EC/1223/09 being adopted to establish a system of local laws and technical standards. Yet, due to many bureaucratic burdens, each country had previously gone through its own process of developing regulations. However, the main aspects related to the allowed filters and SPF values are now the same.

ECUADOR

Recently, this country has adopted a specific standard that is mainly based on regulation EC/1223/09, including the technical part in the annexes.

TESTING

Testing of sun care products is according to local regulations and, due to historical reasons, it can appear rather complex. A more detailed description of each standard would require more space than this short overview allows.

Sun protection factor (UVB)

The ISO 24444:2010 is in fact applied in Europe, Israel, Canada, Mercosur, Mexico, Chile and Andean, Australia, South Africa, Korea, Taiwan, Asean and Russia. The US FDA 2011 is accepted in USA, Canada, Mercosur, Mexico, Chile and Andean, Korea, China, Taiwan and ASEAN. China, Korea and Mercosur have also their own standards, but also accept others, so hopefully in the future there will be only one system. All systems provide a measurement that can be used to label the SPF value. With regard to UVA testing, the situation is almost the same since we can count on the ISO 24443 (or 24442) and the corresponding US FDA broad spectrum test from the 2011 monograph. As for water resistance testing for packaging claims (water proof is no longer accepted), this is more diverse around the world and mainly reflects the different approach of each governing body - this topic has substantial importance as it may greatly affect the safety of consumers, as it may offer the illusion of being protected also while bathing.

CONCLUSION

As stated above, it’s not possible to provide detailed information on sunscreens regulations in a few pages, as each geographic area has its peculiarities. In the case of sunscreens, regulatory departments and the R&D must cooperate at a very early stage of the project for a new product (this is recommended anyway) in order to clearly identify the boundaries, potential problems and solutions. Given the variety of situations, it’s certainly not easy to claim to have an internationally-accepted formula and it may be better to have a framework structure with a standard set of filters one can adapt to each situation. R&D must maintain enough flexibility during development to adapt the formula in case of changes to rules and the regulatory affairs department should be able to spot changes to laws as soon as they are enforced. Certainly, the ability of a company to develop a sunscreen that is successful when placed on the global market is a difficult task and, when achieved, shows the skills of the people that work there.

REFERENCES AND NOTES

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