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HEALTH, ENVIRONMENTAL & REGULATORY SERVICES

UNDERSTANDING THE EU COSMETICS REGULATION & ATTAINING COMPLIANCE

Author: Chris Brennan
Manager, Toxicology Assessment

White Paper

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INTRODUCTION

It has been almost three years since the EU Cosmetics Regulation was put in force across Europe, replacing the preceding EU Cosmetics Directive. From the perspective of a service supplier to the cosmetics industry, it is evident that this has become a real challenge for the cosmetic industry - even global brand leaders - to meet the robust regulatory requirements of the regulations. Even now, we are witnessing many providers of cosmetic products supplying products that do not fulfil all of the robust regulatory requirements of the cosmetic regulation.

This white paper examines the bulk of changes and main points surrounding the EU Cosmetics Regulation including Safety Assessments, GMP, Marking and Labelling Requirements, Product Information File requirements and the role of the Responsible Person.

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Regulatory Drivers

The aim of the regulation was to simplify and harmonise the regulatory requirements across each member state and it is clear this has essentially worked. With simplification and improved clarification of the regulatory details, this offered the potential to improve product safety and reduce costs for businesses as well as to minimise legal uncertainties and inconsistencies in order to avoid the divergence in national transposition. However, there is still differing interpretation across some member states. This continues to create difficulties for the cosmetics industry to easily supply and market their products across the whole of the EU.

Regulation Recast - The Highlights

The definition of a cosmetic product has not really changed under the Regulation, except for some minor editorial changes.1 As defined, a 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body - such as the epidermis, hair system, nails, lips and external genital organs - or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them or keeping them in good condition, or correcting body odours.

The recast was intended to bring clarification in regard to the definition of 'Responsible Person', Good Manufacturing Practice (GMP) and improve safety reporting. There is no doubt this new regulation certainly has assisted in implementing consistency across the EEA with regard to notification, allowing for a central commission to be developed and tightening the requirements for the product information file.

As an example, definition, notification, labelling and safety assessment became necessary for nanomaterials but only for those which are not already restricted in the cosmetic product regulation. Substances classified as carcinogenic, mutagenic or toxic for reproduction continue to be prohibited and currently need to be reviewed by the Scientific Committee on Consumer Safety (SCCS) before use is granted. Some chemicals classified as 'CMR' (defined as being 'carcinogenic, mutagenic or toxic for reproduction') are now banned including boric acid derivatives, some of which have already prompted a RAPEX recall of cosmetic products.

New criteria have now been published for product claims in the form of Commission Regulation (EU) No 655/201 which lays down common criteria for the justification of claims used in relation to cosmetic products and alongside these are guidelines to the justification of claims used in relation to cosmetic products.

In addition, we also saw the long awaited publication on the guidelines of Annex I which was implemented with a view to helping the process of the safety assessment. This would be expected to be carried out by a competent scientific expert (safety assessor) able to identify, understand and critically evaluate toxicological information, endpoints and other physico-chemical data. Furthermore, progress towards the clarification of packaging material information requirements and how these impact the considerations made in the safety assessment is also being made.

Responsible Person

The definition of a "Responsible Person" (RP) was less well-defined under the Directive and is now much improved under the Regulation.

By default, the manufacturer or importer assumes the identity of the "responsible person". The distributor within the EEA could also be the responsible person, if they were to place a cosmetic product on the market under their own name or trademark or if they were to modify a product already placed on the market in a way which may affect its compliance.

Alternatively, a person or authorized representative within the EEA who is appointed by the manufacturer or importer to act as their responsible person, could be used. The mandate request and acceptance to appoint an authorized representative should be carried out in writing.

The obligations of a responsible person are detailed in Articles 4 and 5 and include:

- Ensure overall safety and compliance of the cosmetic product
- Notify their products to the central commission using the notification portal
- Ensure the product information file is current and complete
- Ensure a safety assessment is completed
- Comply with Good Manufacturing Practice
- Ensure compliance with the Regulation of any animal testing
- Maintain accurate and compliant labeling
- Ensure claims are substantiated
- Notify the presence of any nanomaterials
- Identify the supply chain and immediate distributors
- Co-operate with the competent authorities (CA)
- Monitor compliance with the Regulation
- Manage any reported incidents of undesirable effects and serious undesirable effects

The Product Information File

The Regulation (EC) No 1223/2009 introduced changes to the existing Product Information File (PIF); however, the majority of the content remains much the same as the previous Directive. Structurally, the product information file is now defined by the following components: a description of the cosmetic product, description of the method of manufacture and compliance with GMP, proof of effect and data on any animal tests completed after September 2004, and of course, the cosmetic product safety report (CPSR) which will include Part A, safety information and Part B, the cosmetic product safety assessment.

The PIF still also needs to be held accessible at the address on the packaging. This simply means that the PIF must be available to the enforcing authorities from the address specified on the product label, and that address alone. The PIF does not need to be held physically at that address and can be accessed electronically. It can even be held outside of the EEA often dependent on commercial arrangements between the RP and their suppliers; nevertheless, the CA should be able to gain access and receive it typically within 72 hours. This address can only be within the EEA.

It is noteworthy that the requirements of the Regulation's PIF are also applied to those products that were under the previous Directive. This meant that for all cosmetic products approved for supply under the old Directive, the PIF would need to have been updated with additional information before 11th July 2013.

Safety Assessments for Cosmetic Products

The cosmetic product safety assessment was introduced as part of the 6th amendment to the Cosmetic Products Directive. This allowed the experienced safety assessor to identify any potential problems with a cosmetic formulation taking into account the foreseeable use and the information provided in the product information file (PIF). The Directive lacked clarity on the prerequisites for the cosmetic product safety assessment, such that the new Regulation now introduced some of the general requirements from the SCCS Notes of Guidance and putting into legal text what should fundamentally already have been considered in the safety assessment.

These considerations shall be accompanied by the cosmetic safety report in the product information file and include the results of microbiological specifications and preservative challenge testing, purity specification of the raw materials and packaging and also packaging material compatibility; these shall be provided at the time of the safety assessment for the safety assessor to consider before signing off.

In addition, a clear understanding of the product usage under normal and reasonably foreseeable conditions is expected with exposure scenarios to the cosmetic product and its ingredients. This exposure data must include the site of use, area, amount, frequency and/or duration, intended use, target population (e.g. children, pregnant woman, those with skin conditions). The assessment must also include any other information supporting the safe use of the product (e.g. existing studies on human volunteers). Crucially, the toxicological profile of the substances in the cosmetic product now includes specific reference to nanomaterials. Margins of safety shall also be assessed and discussed where relevant. This means that the competent expert needs to correctly identify a suitable NOAEL/NOAEC to make that judgement. To help within this, guidance to Annex I was finally published at the end of November 2013 in the form of Commission Implementing Decision 2013/674/EU2. Supplementing this, the SCCS notes of guidance are available3. Guidance is also readily available regarding labelling, role of the responsible person and the product information file (PIF) from the Cosmetics Europe website.

Good Manufacturing Practice

Good Manufacturing Practice (GMP) has always been a mandatory requirement under the previous directive, and remains so under the Regulation. The main difference is the reference to the harmonised standard, EN ISO 22716:2007 and its presumption of conformity to the Regulation's GMP requirements offered by compliance. Although EN ISO 22716 is not a mandatory standard, your GMP system should ideally be at least be equivalent to it.

Notable Issues

Whilst the publication of the regulation was welcomed by industry, it did create some confusion and uncertainty with the inclusion of many inconsistencies or errors in the text, which included a description of purity requirements for pigments which should have had none, and failing to correctly add complete regulatory restrictions of additional uses for some preservatives.

Some pigments are controlled for their purity and subject to the purity requirements of Directive 95/45/EC . However it is important to highlight that this directive was in fact repealed and the purity specifications for cosmetic products therefore had to follow the Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

There have so far been 15 amendments to the regulation during this time and notable examples include the restrictions and prohibition of the paraben preservatives, prohibition of methylchloroisothiazolinone: methylisothiazolinone in leave-on cosmetic products and further restrictions upon the use of some hair dyes.

Marking & Labelling Requirements

There are no major changes to the labelling requirements under the Regulation; however, a new "egg timer" symbol has been included for use alongside the best before date and there is clearer guidance on when dates of durability are not required, when irrelevant to the product type, e.g. for aerosols. The presence of a nanomaterial must also be identified by the suffix '(nano)' next to the ingredient on the ingredients listing.

Notification

The major change employed under the Regulation is the notification requirement. A new electronic notification portal was set up and went live on 11th January 2012. The intention is to harmonise the procedure for notifying the intention to supply cosmetics in the EEA through to a centralized commission and ensuring cosmetic products can be traced back to the responsible person. As part of the notification procedure, poisons centres will be automatically included in the notification process.

The following information must be included in the notification:

- Category of cosmetic product
- Name/address of responsible person where the PIF held
- Contact details of physical person to contact in case of necessity
- Country of origin, if imported
- Member State where product is first put on the market
- Presence of nanomaterials (separate notification also required)
- Name/CAS No of each substance classified as CMR category 1A or 1B
- Frame formulation (Cosmetics Europe to revise the frame formulations)
- Original labelling and photograph of the packaging
- Poisons centres now included in the notification process and disseminated

Undesirable Effects and Serious Undesirable Effects

Also introduced is a new requirement to report any serious undesirable effects (SUE). Whilst it was a requirement that any undesirable adverse effects were included in the product information file, there are now also obligations on the responsible person and distributor to communicate any serious undesirable effects to the competent authority and to list corrective measures. There are three forms that are available to complete.

SUE Form A: Responsible Persons or Distributors notifying SUEs to the Competent Authorities;

SUE Form B: This form is completed by the Competent Authority and attached to SUE Form A to provide a brief summary and perspective of the case when the Competent Authority transmits SUE Form A to other Competent Authorities and to the Responsible Person. The transmission to the Responsible Person is mandatory when the initial notification comes from a Distributor and it is highly recommended in follow-up and final transmissions when the initial notification comes from the Responsible Person;

SUE Form C: Competent Authorities transmitting SUEs reported by health professionals or end users to other Competent Authorities and the Responsible Person.

Product Claims

An additional objective of the new regulation is to strengthen the criteria for the justification of products claims. Article 20 of the regulation was written to prevent cosmetic products from implying claims for characteristics or functions that cosmetic products do not have. Examples where this may occur include text, names, trade names, pictures, figurative and other such signs. Consequently Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products was published.4 According to this new regulation, claims on cosmetic products shall conform to the following common criteria:

1. Legal compliance
2. Truthfulness
3. Evidential support
4. Honesty
5. Fairness
6. Informed decision-making

Manufacturers need to be conscious of the claims they choose to make either on the product itself or in commercial advertising and ensure these can be substantiated. Claims denigrating competitors or ingredients that have an otherwise safe history of use will also be scrutinized as will claims stating that the product does not contain specific ingredients that are already prohibited according to law.

Conclusion

The EU Cosmetics Regulation has had a positive impact on the cosmetics industry. There has been a noticeable increased number of training and workshops which have been made available to support the stakeholders. There is a still a great deal of work ahead for the cosmetics industry to ensure practices and procedures are harmonised, the interpretation of the regulation is consistent across all member states, that safety assessment is robust and that as a live document the product information file remains up to date. Industry, together with the competent authorities, must also ensure that both post market surveillance and cosmetovigilence remains sufficient in its aim to ensure only safe cosmetic products remain in the marketplace.

Intertek Health and Beauty Products Services

Our experts can help you to understand your responsibilities under the EU Cosmetics Regulation. Contact us today to start your conversation.

Intertek has over 30 years' knowledge & experience of providing safety and efficacy services for the health and beauty product industry. We support R&D requirements through to manufacturing and marketing claims. Partnership with Intertek brings you access to expertise that facilitates a faster route to market through cost effective services: a convenient 'one-stop shop'.

Intertek Health and Beauty Product Services provide a comprehensive range of services aimed at ensuring the quality, safety, and efficacy of your products, including:

- Cosmetic Safety Assessments
- Product Information file
- Notification
- Regulatory support
- Safety & Quality Testing
- GMP ISO 22716
- Human Clinical Studies
- Efficacy & Performance
- Due Diligence
- Nanomaterials
- Stability Studies
- REACH
- Claims Support
- Packaging Testing
- Supply Chain Audits

MEET OUR EXPERT

CHRIS BRENNAN, MANAGER, TOXICOLOGY & REGULATORY ASSESSMENT

Chris Brennan has extensive experience in Organic, Medicinal, Combinatorial and Analytical Chemistry gained within the pharmaceutical industry. He has been involved in designing the lead optimisation chemistry programmes for a number of potential drug candidates that have since moved on to preclinical stages.

He was appointed as a Postdoctoral Fellow at the CNRS in Gif-sur-Yvette and has published a number of scientific papers and patents in international journals. He is currently Manager of the Intertek Toxicology group based at Leicester and is one of Intertek's global experts in cosmetic safety assessment and regulation.

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FOR MORE INFORMATION

Centre Court
Meridian Business Park
Leicester, Leicestershire
LE19 1WD
United Kingdom

+44 161 721 5247

health.beauty@intertek.com

intertek.com/cosmetics

intertek
Total Quality. Assured.