Cosmetics Europe
the personal care association

The Israeli Chambers of Commerce
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To Whom It May Concern:

Cosmetics Europe, is the European Personal Care Association. We welcome the will from the Israeli Government to align the Pharmacist Regulations (Cosmetics) 5777-2017 with the EU Cosmetics Regulation 1223/2009 as have many other countries outside the EU e.g. Switzerland, Turkey, ASEAN etc… To this extent we would like to share some clarification on some specific requirements part of the EU Cosmetic Regulation.

Identification, Role and Responsibility of the Responsible Person

Cosmetics Europe welcomes that Israel is introducing the concept of Responsible Person (RP) in its updated regulation. To ensure full compatibility between the systems in Israel and in the EU – thus facilitating trade between the two regions, we would like to explain how the concept is implemented in practice in the EU.

In Europe, the Responsible Person (RP) can be a natural person (i.e. an individual) or legal entity (i.e. a company). In the vast majority of cases the RP is actually a legal entity (company) and only in rare cases (e.g. micro-companies) the RP is a natural person. The RP must be established in the EU and his name and address must be labelled on the product.

As a default, the RP is the manufacturer (company who manufactures or orders the manufacturing and places on the market under his name/trade mark) or the importer. However, the 'original' RP may appoint a third party to become responsible for the product by a written mandate. This means a 100% transfer of all responsibilities, a partial transfer or split of responsibilities is not possible.

The main responsibilities of the RP are:

- Safety
- Good manufacturing practice
- Safety assessment
- Product Information File
- Sampling and analysis

- Notification
- Restrictions for substances listed in annex
- CMR substances
- Nanomaterials
- Traces of prohibited substances
- Animal testing restrictions
- Labelling
- Product claims
- Access to information for the public
- Communication of serious undesirable effects
- Information on substances
- Contact with the competent authorities in the frame of in-market control

Given that the cosmetics portfolio of an RP can cover thousands of products it is usually not feasible for a single natural person to have all the technical competences and time to personally carry out all duties for each and every product. Hence, the RP responsibility is taken by the company (legal person) rather than an individuum and the duties distributed to the most competent staff members. One of these duties would be to act as the first physical contact person to the authorities in case of questions. We encourage that RPs would provide such contact details to the authorities – without, however, this individuum the RP.

In a similar logic, we welcome the Israeli initiative to carry out trainings on the RP obligations and agree that any RP should have undergone such training (i.e. in case of the company being the RP, they should have at least one staff person who is adequately trained).

CE suggestion: The Responsible Person can be a natural person or a legal entity. Requirements for training of RP should be formulated in a way that both types of RP are considered.

Product Information File (PIF) Access

As one key obligation, the Responsible Person must be in a position to demonstrate that the product placed on the market meets the safety and technical requirements under the EU Cosmetics Regulation. In order to fulfil this role, the RP needs to maintain specific information on the product in the PIF.

The PIF contains the information that enables the RP to answer most of the enquiries made by the control authorities and to provide evidence that the product is in compliance with the Cosmetics Regulation. The PIF contains a huge amount of data and need to be systematically updated, every time there is a change in the data (change of suppliers, modification of characteristics of raw material, cosmetovigilance …). Therefore, the information is usually maintained in electronic database format. In addition, because of the confidentiality and business sensitivity of certain parts (e.g. formula, manufacturing process, or claim support data), the full set of information is often kept and maintained by the original manufacturer.

We understand the position of the Israel authorities that, in order to take his responsibilities in a meaningful way, the RP based in Israel has to be sure that the PIF and safety information is complete prior to placing a product on the market.

However, it is not necessary nor relevant for the RP to examine the entire PIF, including the Safety Assessment, in all technical details. Indeed, the Safety Assessment contains very large amounts of toxicilogical studies/data whose full understanding requires specific toxicological training and experience (similar for details on microbiological quality, trace impurities, etc). The role of the RP is not duplicate the work done by the technical experts and safety assessor, but rather to ensure that such work has been carried out by suitably qualified persons.

CE suggestion: According to the EU Cosmetics Regulation the RP should make the PIF available in case of inspection. Rather than requiring that the RP has 'read the PIF', it should be acceptable that prior to placing a product on the market, the Responsible Person has ascertain that the PIF as per the Regulation exists, has been done by suitably qualified experts and will be made available in case of inspection.

Regarding Notification of the product, the EU requires that this be done prior to placing the product on the market. Indeed, the notification requirement is separate from the requirement to establish a PIF and a notification can be made at a time when the PIF is not yet finished. Only when the product is placed on the market, both requirements (notification and PIF) need to be fulfilled. This is why in the EU Cosmetics Product Notification Portal (CPNP), the RP can indicate whether the product is already on the market or not.

CE suggestion: To de-couple the obligation for PIF and notification and clarify that a notification can be made prior to the availability of the PIF – provided that both obligations are fulfilled at the time of placing the product on the market. To make the situation clear in the notification database, a field could be added to identify whether the product is already on the market when notifying.

We also understand the position of the Israel authorities that the RP must be in a position to ensure that the PIF information can be made accessible without undue delay in the case of an inspection by the control authorities.

In the context of the in-market control, when the EU control authorities request to have access to the PIF, they are not expecting to have an immediate access to the entire PIF. Unless the inspection is triggered by a major safety issue, companies will be given sufficient notice ahead of the inspection. This is captured in the notion of "readily accessible" stated in the EU Cosmetics regulation.

Indeed, the detailed support documentation for the PIF may not necessarily be in the RP premises. All or part of the information could be stored at the relevant company departments (e.g. laboratory, quality department, toxicology department…) or a subcontracting laboratory or

consultant. This is why in case of a routine inspection, the RP in the EU will be provided between 48h and 72h to provide the requested part of the PIF. This ensures a reasonable period of time for the RP to gather the information but not enough time to build a PIF from scratch.

It is very important that the RP is fully aware of his obligations to provide the PIF information to the control authorities and has processes in place if the information is not physically stored at the address. Awareness raising and training of RP is essential in this respect.

CE suggestion: Adding in the Legislation that the PIF "is readily accessible" in electronic or other format.

Good Manufacturing Practices

In the EU, any cosmetic product placed on the market must have been manufactured according to GMP. ISO GMP 22716 is a relevant reference but the choice of an adequate standard to follow remains voluntary. Demonstration of compliance with GMP is part of the PIF where all the control and quality documentation must be kept. In the EU an external validation is not required because the RP, as manufacturer or contracting a third-party manufacturer, is the best placed to demonstrate to authorities that the standard is indeed implemented and applied properly. Therefore, the RP can choose to audit personally the manufacturing sites – be they their own or third-party subcontractors - or to outsource such audit.

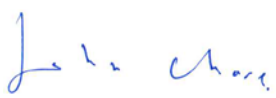
EU Member States carry out GMP inspections as part of the in-market control, but usually do not deliver a GMP certificate to local manufacturers.

The proposed requirement for importers into Israel to provide a GMP certificate by the authorities from the country of origin will have an impact on business continuity and some companies may be in the incapacity to provide such document and therefore to not have access the Israeli market.

CE suggestion: Third-party audit and authorities' certificates should not be mandatory for GMP.

Cosmetics Europe and its experts stand ready to answer any question you may have in relation to our comments.

Sincerely yours,



John Chave

Director General