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POSITION
of the Polish Association of Cosmetic and Detergent Industry on the roadmap published by the European Commission regarding the revision of the regulation on cosmetic products

The Polish Association of Cosmetic and Detergent Industry (PACDI) represents the manufacturers of cosmetic and personal care products as well as broadly defined cleaning products in Poland. PACDI members - apart from large international companies - are mainly local SMEs for which the scope of changes provided by the revision of regulation on cosmetic products will have a significant impact on their smooth functioning and innovation of the cosmetic products they offer.

PACDI supports the actions undertaken in the framework of the Chemicals Strategy for Sustainability to enhance the protection of human health and the environment. However, these objectives should be based on sound legislation, providing predictability and stability, which will stimulate development as well as the transformation process. It should be noted that safety is a priority for the cosmetics industry and the cosmetic regulation has been successfully guarding consumer safety and health protection for many years. The highest safety standards are ensured by a strict science-based approach to risk assessment. This assessment takes into account both the recommended and foreseeable uses of the product. Therefore concepts proposed in the revision, such as essential use, should take into account both the safety assessment of a particular use and its value to the end user. It should also be noted that over the years the cosmetic regulation has become the "gold standard" for safety and a reference for legislation in different parts of the world. Future solutions under the cosmetic regulation should continue to support the EU cosmetic industry's innovation and global competitiveness, which can be achieved through robust sectorial legislation that is science-based, predictable and efficient for consumers, industry and authorities.

In PACDI's opinion, the *general approach to risk management* is only justified in a situation when a substance potentially poses an unacceptable risk and there is no specific risk assessment confirming safe use. It need to be underlined that also in this respect, the cosmetic regulation ensures the safe use of cosmetic ingredients and products using a real exposure-based approach to risk assessment. Therefore, the *general approach to risk management* should be based on the safety and allow for safeguard mechanisms such as derogations/exemptions to avoid bans on uses that are safe. It should

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be noted that a general risk management mechanism already operates under Article 15 of the cosmetic regulation and is used for substances classified as CMR. In PACDI's assessment, this mechanism can therefore be appropriately adapted for the management of substances identified as harmful under general approach to risk management (CMR, ED, persistent substances) and for the consistency and effectiveness of sectoral legislation. However, extending the general approach to risk management to additional substance categories (e.g. chemicals affecting the immune, neurological or respiratory systems, chemicals toxic to a specific organ) is not justified and PACDI calling for caution when taking this type of action. It should be noted that even within the CLP Regulation there are no exhaustive hazard classes for the classification of all types of substances.

The concept of *essential use* should be based on the principle of safe use and should become irrelevant once the use of the chemical has been confirmed to be safe. Criteria for *essential use* should be based on a case-by-case assessment of the availability of alternatives for a particular use or a particular function of the substance in the product. These criteria should include the performance characteristics, the sufficient availability of the alternative substance, its economic feasibility and overall safety impact.

The Chemicals Strategy for Sustainability introduces a number of new linkages between the horizontal chemicals legislation and existing sector-specific legislation. This type of linkage is attributed to the *one substance one assessment* mechanism. PACDI considers that this mechanism should be seen as a *one substance one hazard assessment* and as the starting point for the cosmetic-specific risk assessment, which differs significantly from the assessment carried out under the chemical legislation. It is also important to note that the cosmetic regulation imposes a complete ban on the use of animal tests for finished cosmetic products as well as for cosmetic ingredients. Therefore, the use of animal test data for the subsequent risk assessment provided under the cosmetic regulation will not be in line with existing sector-specific legislation. In these circumstances, it is necessary to eliminate the discrepancies existing in the various legislative areas and accept alternative methods. While the hazard characterisation of a chemical can be carried out horizontally, a sectors-specific risk assessment cannot be carried out in a one-size-fits-all manner. The use/exposure routes of cosmetic products are specific and differ within product groups. Therefore, the risk assessment as a basis for regulation of cosmetic ingredients requires a dedicated and experienced expert committee. In PACDI's opinion, the SCCS committee should remain an independent body operating within the structures of the European Commission. It should be noted that the SCCS committee is the scientific knowledge and experience in the use of alternative methods in risk assessment and the SCCS ingredient safety opinions are recognized worldwide.

PACDI supports efforts to align the definition of nanomaterial with the definition based on the Commission Recommendation 2011/696/EU of 18 October 2011. This approach will certainly not lead

to further divergent interpretations by authorities in Member States and will contribute to the smooth functioning of the internal market of cosmetic products.

PACDI also supports the transformation towards the use of digital means in consumer communication and welcomes the direction of the European Commission's activities. It should be noted that the current labelling system has generally not been changed since the 1970s, when the Cosmetics Directive was entered into force. In addition, the size of the labels and the associated readability of information, with significantly expanding information obligations, is increasingly limited. Increasing product packaging is also contrary to EU policy to reduce packaging material and waste production. In PACDI's opinion, the use of digital tools in product labelling is a desirable direction and will certainly streamline and accelerate the process of adapting information e.g. those subject to frequent changes.

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