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Polish Association of Cosmetics and Home Care Product's Producers Position on Endocrine Disruptors

Executive Summary

Polish Association of Cosmetics and Home Care Product's Producers remains committed to ensure the safety of cosmetic and personal care products. In accordance with the current European Cosmetics Regulation, all products undergo extensive safety assessment prior to marketing. This assessment covers all cosmetic ingredients as well as finished products. Therefore any potential health risk posed by endocrine disruptors is already considered in the existing safety assessment.

The industry welcomes the opportunity to discuss and review the European Commission strategy on endocrine disruptors and to assist in improving the European Regulatory framework. The cosmetics industry is committed to the protection of consumers and the environment from potential adverse effects of endocrine disruptors. The cosmetics industry supports the following positions:

- The application of the WHO/IPCS definitions of "endocrine disruptor" and "adverse effect" to unambiguously identify substances that produce adverse health effects via endocrine-mediated mechanisms

- A coherent, science-based approach to the identification of endocrine disruptors. The industry supports the use of scientifically agreed criteria including potency to identify, characterise and manage the potential health or environmental risks posed by such substances

- Use of best toxicological practice in order to identify dose-response curves and "no-observed adverse effect levels (NOAEL)[1]". On the basis of available data, endocrine disruptors are considered to be substances where a threshold can be defined and whereby risk can be managed similarly to other chemicals. This allows the estimation of safe exposure levels which enables the existing risk assessment approach ensuring that no health risk will be posed to consumers or wildlife

- Cosmetics Regulation already provides for risk management procedures which provide a high level of protection to consumers.

- Performance of an Impact Assessment which is relevant and proportionate to all sectors. The cosmetics industry supports a single set of criteria, including elements of hazard characterisation, e.g. potency, lead toxicity, reversibility and severity. The

[1] NOAEL – Represents the dosage at which no adverse effects are observed.

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industry is opposed to the inclusion of a multiple categorisation system (as proposed in option 3 of the roadmap).

- A single, consistent and coherent European risk based approach with regard to definition and application across the different industry sectors, avoiding national initiatives which can destabilise businesses, distort the internal EU market and at the same time compromise the safety of cosmetic products.

Definition of Endocrine Disruptors

All major international definitions stipulate that an endocrine disruptor must cause adverse effect via an endocrine-mediated mechanism. In 2002, the World Health Organisation's International Programme for Chemicals Safety (WHO/IPCS) defined endocrine disruptor as an:

..."exogenous (originating from outside the body) substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations"...

This definition stipulates that only substances that produce adverse effects mediated by the endocrine system are genuine endocrine disruptors.

A clear distinction must be made between substances that interact with the endocrine system (substances that have a biological activity) and actual endocrine disruptors (substances that produce adverse effects i.e. toxicity via an endocrine-mediated mechanism). Some substances, man-made and natural, may modulate the endocrine system (adaptive response) but only a few, very potent substances, have been shown to cause adverse health effects.

The cosmetics industry supports the WHO/IPCS definition of Endocrine Disruptors as it ensures the link between a mode of action and an adverse effect. Endocrine activity is not an endpoint by itself, but is a potential mechanism that may or may not lead to adverse effects. Furthermore, industry supports a coherent, science-based set of criteria, including potency, to identify, characterise and manage the risk posed by substances having endocrine disrupting properties.

Evaluating potential risk substances

There have been claims that certain ingredients used in cosmetics and personal care products may be endocrine disruptors according to the results of screening assays which were designed to be highly sensitive but not very specific[2]. Generally, screening assays show whether a substance has the potential to interact with the endocrine system, but they do not address the question whether the substance may produce adverse effects. Many substances, natural as well as synthetic, are active in screening assays, but very few have been shown to produce adverse health or wildlife effects. Substances with substantial

[2] Screening tests were developed for the purpose of prioritizing testing of substances which could be potential endocrine disruptors. Given that screening tests do not identify toxicity they cannot determine whether a substance is a genuine endocrine disruptor or not. When a substance produces changes in hormone-related parameters in screening tests, this means that the test substance may have a biological activity, but it does not mean that it is an endocrine disruptor.

endocrine activity are, for example, found in significant levels in many foods, such as soya, cabbage, cereals and even coffee. However, the majority of endocrine-active substances are not potent enough to cause adverse effects at human exposure levels. Substances that produced actual adverse effects in humans were generally potent medicines (e.g. some natural or synthetic hormones) intentionally designed for endocrine activity. The current safety assessment for cosmetic ingredients is designed to prevent that such chemicals are present at levels that would cause adverse effects. The use of best toxicological practice is absolutely necessary in order to identify dose-response curves and "no-observed adverse effect levels (NOAEL). On the basis of available data, endocrine disruptors are considered to be substances where a threshold can be defined and whereby risk can be managed. As for any cosmetic ingredients, toxicology assessments are performed for approval of ingredients by the Authorities. This allows the estimation of safe exposure levels. Taking into account the relevant exposure levels such as maximum use concentrations, the existing risk assessment approach is able to ensure that no health risk will be posed to consumers.
There is no scientific reason to assume that effects observed in the lower dose regions or non-monotonic dose response curves represent adverse effects relevant for safety assessment. Notwithstanding, cosmetic safety assessment will take into account all available information from all dose ranges to evaluate the weight of evidence and derive the most relevant thresholds.
We believe that the primary objective should be to identify potential endocrine disruptors through a coherent and science-based approach.

Polish Association of Cosmetics and Home Care Product's Producers fully supports that where science-based risk assessment indicates possible adverse effects to humans or the environment, appropriate regulatory action should be taken.

Applying the existing Regulations

EU rules require that manufacturers carry out a rigorous safety assessment by a professionally qualified safety assessor before placing a cosmetic product on the market. The existing regulation (Cosmetic product Regulation, REACH, Plant Protection Products Regulation, Biocidal Products Regulation) provide for risk management procedures such as the restriction / ban of potentially hazardous substances / ingredients.

The EU Commission's scientific advisory panel, the Scientific Committee on Consumer Safety (SCCS), routinely reviews all data regarding ingredients for which any questions are raised and provide safety ranges for the use of specific substances in cosmetic products. This includes potential endocrine disruption.

This means that substances suspected of having endocrine disrupting properties are already strictly regulated, providing a high level of protection to consumers.

Impact Assessment

While the scope of the Impact Assessment proposed by the European Commission is plant protection and biocides products, in light of the need for regulatory consistency across all sectors, the cosmetics industry supports that this initiative should also take into account the impact for other sectors, including cosmetics. In the roadmap published on 16 June 2014, the Commission sets up four different policy options concerning criteria to identify

Endocrine Disruptors. Polish Association of Cosmetics and Home Care Product's Producers clearly supports a single set of criteria, including elements of hazard characterisation, e.g. potency, lead toxicity, reversibility and severity as it ensures the identification of substances having endocrine disrupting properties which are of relevance for consumers and the environment. Polish Association of Cosmetics and Home Care Product's Producers is opposed to the inclusion of a multiple categorisation system (as proposed in option 3 of the roadmap). A categorisation scheme which includes multiple categories is likely to lead to a complex process to allocate substances and from a regulatory perspective might become a bureaucratic nightmare.

Polish Association of Cosmetics and Home Care Product's Producers supports the need for an Impact Assessment for Endocrine Disruptors that takes into consideration all industrial sectors, including cosmetics.

National initiatives

The cosmetics industry is concerned about the development of national legislation addressing potential endocrine-disrupting substances. These initiatives risk undermining the harmonisation of the European market leading to adverse impact for the industry. For similar reasons, national campaigns to raise consumer awareness of the risks posed by endocrine-disrupting substances, when there is lack or no concrete scientific evidence, should be avoided. In the absence of clear evidence and defined criteria to identify Endocrine Disruptors at EU level, such initiatives are misleading and create unjustified consumers' mistrust.

Polish Association of Cosmetics and Home Care Product's Producers supports the need for a single, consistent and coherent European risk based approach, avoiding national initiatives that can destabilise businesses and distort the internal market.

Clarifying the Scientific data on Endocrine Disruptors

Effects in Humans

Some researchers have suggested that human fertility is declining in modern industrial societies. It has been claimed that the presence of endocrine disruptors in the environment have led to decreasing sperm counts and increasing incidence of birth defects linked to the male reproductive system. These elements have been linked into a single hypothesis, the so-called "Testicular Dysgenesis Syndrome" (TDS = increase incidence of hypospadias[3], cryptorchidism[4] and testical cancer in the population). However, there is no firm evidence to support a general decline in sperm count in industrialised countries. For example, a recent study, the largest, longest and best controlled investigation ever performed on this question, found no changes in the sperm count of more than 5000 Danish military recruits over a period of 15 years.

In addition there is no scientific evidence for a general increase in the incidence of cryptorchidism or hypospadias. Also, these two pathologies appear to have different mechanisms, casting doubt on a common origin or a common causal agent. Whereas in some studies an increase in these diseases has been reported, in others the incidence was

[3] Hypospadias – Birth defect that involves an abnormally placed urinary opening.
[4] Undercended testicles

stable with no significant changes reported. In Europe, studies suggested an increase in certain testicular cancers in Denmark, but no similar effects were observed in other European population, some of which are geographically close (e.g. Finland)[5]. The reason for this discrepancy remains unknown. Overall, there is no clear evidence to support the hypothesis that TDS-related diseases are increasing due to exposure to chemicals. It is unclear whether TDS actually exists and even less clear whether man-made chemicals play any role.

There is no evidence that permits the conclusion that there is a widespread increase in diseases caused by chemicals disrupting the endocrine system.

Effects in the Environment

A number of studies in wildlife have reported adverse hormone-mediated effects in a number of different species such as fishes or alligators. However, these effects were found in areas with extreme levels of environmental pollution. Where pollution was absent or properly controlled, no adverse effects were observed. For example, several studies showed adverse reproductive effects in freshwater fish exposed to human-derived oestrogens (residues of the contraceptive pill) in effluent of sewage treatment facilities. In this case, the inappropriate treatment of these waste waters was the main cause for the modifications observed.

Adverse endocrine-mediated effects in wildlife were found at sites of high environmental pollution – after remediation and/or removal of the pollution the effects disappeared. At normal environmental levels of chemicals, no hormone mediated effects are observed in wildlife.

Conclusions and expectations

Polish Association of Cosmetics and Home Care Product's Producers welcomes the debate on endocrine disruptors. We consider this debate as an opportunity to review the scientific data in order to maximise the safety of the consumer and the environment. We look forward to a science-based discussion with the relevant stakeholders, including the European Institutions, Consumer Organisations, NGO's and involved industries, in order to ensure the safety of cosmetic products and to minimise their effects on the environment.

[5] The Weybridge +15 (1996-2011) report – EEA Technical Report No 2/2012.

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Polish Association of Cosmetics and Home Care Product's Producers key messages on Endocrine Disruption are:

- *Endorse the WHO/IPCS definition of Endocrine Disruptors;*
- *Establish a set of science-based, agreed criteria to identify substances with endocrine disrupting properties;*
- *Maintain the existing risk assessment approach which ensures that no health risk will be posed to consumers or the environment;*
- *The Cosmetics Regulation already provides risk management procedures that provide a high level of protection to consumers;*
- *Support a single set of criteria, including elements of hazard characterisation, e.g. potency, lead toxicity, reversibility and severity to identify endocrine disruptors as it ensures the distinction of substances which are of high regulatory concern;*
- *Develop a single, consistent and coherent European approach that prevents individual Member States initiatives;*