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Summary Report from the public consultation on Methylisothiazolinone in the framework of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products

Background

A 12-week public consultation took place from 29 July to 23 October 2015 whereby the European Commission proposed the following modification to Annex V (authorised list of preservatives) of the EU Cosmetics Regulation (No. 1223/2009):

- (1) To ban the use of methylisothiazolinone as a preservative in leave-on cosmetic products;**
- (2) To maintain the current authorisation of methylisothiazolinone as a preservative in rinse-off cosmetic products up to a maximum concentration of 100 ppm.**

During the public consultation, numerous comments were received from various regions and a wide range of stakeholders. The majority of comments came from individual consumers followed by two member states, industry stakeholders as well as a medical institute. Strong support was observed on the European Commission's proposal to ban the use of methylisothiazolinone in leave-on products, while many respondents went a step further to suggest an immediate restriction in concentration for rinse-off cosmetic products.

Respondents

Individual consumers (U.K., Ireland, and U.S.) reported on allergic reactions they had encountered using cosmetic products containing methylisothiazolinone including eye irritation -such as swelling, itchiness and redness - but also skin irritation and dryness. In more serious cases, severe nerve pain, temporary vision loss, muscle spasms, eczemas, respiratory distress and intolerance for heat were reported. Respondents from the U.S. pleaded for the EU to take action thereby setting a precedent for other countries worldwide to follow.

Consumers also highlighted that particular attention should be paid to certain category of cosmetic products such as baby care, 'green', and 'sensitive' skin products.¹

An **online international support group (consumer association)** on Methyl/Chloro/Isothiazolinone consisting of approximately 6 000 individuals worldwide proposed extending the ban of methylisothiazolinone to rinse-off cosmetic products while strongly taking into the account the entire cohort of variants – methylchloroisothiazolinone, benzisothiazolinone and octylisothiazolinone – when gathering data and carrying out future risk assessments related to any of these substances.

Members of the support group shared their personal stories (including pictures) showing that reactions to methylisothiazolinone go beyond a simple rash and can often include both physical and psychological suffering if not hospitalisation.

A recurrent problem encountered was the time taken to make a correct diagnosis as there is a lack of information concerning allergic reactions to methylisothiazolinone making it hard for specialists to start looking at an allergic reaction straight away.

The group reported on the alarming rise in sensitivity to methylisothiazolinone (even as regards to consumers who had not shown any prior allergy) over the past two years and warned of the risk of an epidemic which is already present in third world countries.

There was also a request for stricter labelling and increased educational awareness of allergic reactions linked to methylisothiazolinone. It is often the case that this substance is not listed in the ingredient list while actually being present and even in higher concentrations than currently authorised.

Member States (Finland and The Netherlands) showed strong support to the European Commission's proposal to ban the use of methylisothiazolinone from leave-on products. Furthermore, Finland strongly disagreed maintaining the authorisation of methylisothiazolinone in rinse-off products and hair leave-on products and proposed a significant concentration reduction if not ban.

The Institute of Environmental Medicine, Karolinska Institutet (Sweden) reinforced the urgency to ban methylisothiazolinone in leave-on products since the incidence of allergies have increased dramatically in the last two years and since two opinions from the Scientific Committee on Consumer Safety (SCCS) clearly conclude that it is dangerous. The Institute further highlighted their disagreement with a delay in the reduction of methylisothiazolinone in rinse-off products as evidence shows that the population already sensitised to this substance have allergy contact dermatitis following the use of a rinse-off product. Therefore, according to clinical and experimental studies, the concentration should be immediately reduced to 0,0015%.

¹ Individual consumers also raised concerns regarding the presence of MI in many house-hold products such as household liquids and detergents, sprays, paint, toilet paper, and air cooling systems – but as these are outside the scope of this public consultation (which focuses on cosmetic products only), they are only mentioned as a footnote.

Industry stakeholders (Spain, Brazil, and the ASEAN Cosmetic Association) requested longer transition periods comprising of at least 24 months to implement the proposed measure, which will be extremely costly and burdensome, especially to SMEs. The ASEAN Cosmetic Association informed that the use of methylisothiazolinone in leave-on cosmetics, including wipes, had already been proactively eliminated since January 2014 in its region, but more time should be given to carry out a proper safety assessment for rinse off products; it was recommended to wait for the QRA methodology to be re-evaluated under the IDEA project.