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Sent: Tuesday, January 15, 2013 11:39 AM
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Subject: HLWG; reg issues ; meeting with Cosmetics Europe on 14 January)

Meeting of TRADE colleagues with Cosmetics Europe (Part 4.1b), who was informed about state of play in HLWG, organisation of Forum meeting in the spring and the follow-up work on the joint submission with PCPC. Cosmetics Europe provided additional explanations on the submission.

Cosmetics Europe is confident that a convincing case can be made in the area of cosmetics, which would provide benefits to industry and regulators on both sides, and ensure a viable package. CE also highlighted that we need to take into account that the EU and US have different approach to regulating cosmetics and this extends also to the definition (i.e. some personal care products in the EU are treated as non-prescription drugs in the US and subjected to regulation applied to OTC drugs). Also, US attitude toward international standards differs from EU.

Cosmetics Europe highlighted the critical and delicate dossier of animal testing, the ban which would enter into force on 11 March and requires careful handling to prevent a major trade conflict. Recognition by the US of the EU's positive list of cosmetics and ingredients as well as close upstream cooperation on the cross-cutting issue of nanotech were also mentioned.

In general, our impression was that the submission needs to be completed and restructured in order to get to a meaningful "package" which could interest regulators on both sides.

As a follow-up to this meeting, Cosmetics Europe will provide additional information to the Commission on its individual proposals, including the legal situation on both sides (i.e. which products are covered by what legislation) and how to get to convergence, possible legal and other obstacles as well as the economic case for greater convergence for the EU and US industries. **Cosmetics**

Europe will meet representatives of PCPC on 22 February and engage in discussions on further refining their joint position, and the presentations by the industry at the forthcoming HLRCF meeting.

Main messages from CE:

- **US should recognise the EU's positive list of cosmetic s and ingredients.** The FDA monographs are usually outdated when published while the EU list captures the products adequately.

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Cosmetics Europe also mentioned the new regulation on cosmetics which will come out in the summer and further contribute to harmonisation of enforcement of rules on cosmetics – can US set similar steps?

- **Test methods:** In general, Cosmetics Europe highlights that there would be a case for recognising each other's testing protocols and accepting each other's validation methods. The new EU legislation on animal testing is a sensitive trade issue- not only with US, but also other nations applying animal testing to cosmetics (China). This legislation could affect international trade once the ban (applied to imports) will enter into force in March. *NB: CE explained its position on animal testing as regard the trade aspects. CE does not seek to reverse the situation but pleads for flexible interpretation, i.e. that, where no alternatives exist, animal testing results carried out legally under REACH and other regimes (biotech, food and feed regulation) by EU and US and internationally on substances (97% of substances are multi-use) and ingredients can be used for cosmetics. In essence the ban would thus only cover tests carried out specifically for cosmetic products (at present 1/10 of animals used for testing can be attributed to the cosmetics industry, i.e. 1500). CE also calls for the application of OECD arrangements in this area. CE main argument is that any other approach would risk a trade war but also suffocate research activity in the cosmetics industry (the only industry investing large sums in finding alternatives).*
- **Restructuring of EU Negative list:** Annex II of the cosmetics directive should be restructured. This effect will not be achieved with the new regulation (which mainly covers product notification, supply chain issues). The annex is outdated. Smaller companies in particular would benefit from this cleaning exercise (many substances in the annex are not any more used).
- **Nanotech:** CE explained it would be very beneficial if EU and US could strengthen their cooperation in this field, in particular on the definition, to avoid that our approaches become too divergent. This does not only concern cosmetics but also other areas (chemicals, pharma). CE prepared to engage in the discussion and provide more information from the business side, economic aspects, etc.