EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO, Legal Affairs and Trade in Goods
TRADE F.3 Tariff and Non–Tariff Negotiations, Rules of Origin

Phone call between Cosmetics Europe and European Commission 10/03/15

List of attendees:

- [redacted] (DG TRADE)
- [redacted] (DG GROW)
- [redacted] (Cosmetics Europe)

Objective:

Discussion on technical details on the TTIP negotiations in particular as regards EU and US approaches on cosmetics safety assessment methods.

UV filter pilot project:

1. The project should entail a detailed comparison of the EU and US requirements as well as data which is to be submitted for an ingredient approval in the EU and in the US

2. A concrete UV-filter already approved in the EU (including the data submitted) should be selected (which UV filter has not yet been decided)

3. Experts from US FDA and EU SCCS should assess jointly the complete dossier and the reasons that led to the EU approval.

4. Ideally the pilot would comprise also, as outcome, recommendations on possible alignment of EU and US requirements.

US FDA interested to interact with EU experts to better understand why EU regulates sunscreens as cosmetics instead of over the counter drugs and the historical background of EU regulation and cosmetics classification.

Video Conference (VC) on safety assessment of ingredients

VC is scheduled for 24/03/2015 with FDA drug experts (not linked with the pilot project). Not yet decided who will attend VC from the EU SCCS. [redacted] would be welcomed, but it is not possible as she is not a member of SCCS anymore.

Several questions in the past arising from the **assessment of the long term exposure** considering the fact that the extent of exposure is significantly higher than it was before. (remark: EU safety assessment guidelines assume a 18g daily use as a maximum amount on full body which is an over estimation of probable real exposure)

Main objectives of the DVC:

1. to demonstrate to FDA that our assessment system is detailed and appropriate

2. to present the different aspects that are looked at by SCCS experts as defined on SCCS guidance

3. to present data needed to substantiate the safety

4. To present EU pharmacovigilance/cosmetics vigilance

According to the US post market data is not sufficient. Adverse reaction reporting does not give appropriate information on carcinogenic long term effects. We have new legal obligation now. Report from DE (UV filters were not on top of the list).

EU updates often list of allowed ingredients and new bans in light of new scientific evidence becoming available. For instance, several endocrine disruptors have been actively replaced/removed from list of allowed ingredients in the EU due to SCCS scientific opinions.

Remark: Ideally US should be asked to consider daily use products containing small quantities of UV-filters (e.g. facial creams) as cosmetics instead of sunscreens.

Minimum amount to test should be determined (likely higher than what is used daily in practice) – to make sure results are reproducible

New US Cosmetics Innovation Act:

- Draft guidelines developed by FDA will be assessed by Cosmetics Europe.

International Cooperation on Cosmetics Regulation (ICCR):

- Cosmetics Europe would like to see formal recognition of ICCR as a fora having high technical value (and strong mandate given to DG GROW to implement those guidelines in EU legislation). Issues discussed by ICCR should inform/input into the EU debate. How to make sure that EU and SCCS would take on board ICCR recommendations?.

- As regards ICCR and animal testing, several alternative test methods (ATMs) have been validated and adopted in the EU. However, for some areas implementation in the EU would be more difficult (e.g. ICCR discussions on traces)