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The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues

EU position on cosmetics - update

Update. Due to a technical issue, the previous version of this document, dated 6 March 2015, was published without the last page. This updated version now includes this last page. Points 2.5 to 2.7 can be found on page 4 below.

The European Commission apologises for any inconvenience caused.

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Trade

1. Introduction

The final report of the US - EU High Level Working Group on Jobs and Growth of February 2013 highlights that as regards regulatory aspects TTIP should contain, in addition to cross-cutting disciplines and TBT plus elements, provisions concerning individual sectors.

This paper outlines the main elements of a possible approach under TTIP to promote regulatory convergence in the cosmetics sector. These elements build on existing cooperation between EU and US regulators under the International Cooperation on Cosmetics Regulation (ICCR).

It contains preliminary ideas that can be complemented and refined at later stage. The TTIP could cover:

- collaboration in scientific safety assessment methods,
- collaboration in good manufacturing practices and mutual recognition of inspection results
- collaboration in, and regulatory acceptance of, validated alternative test methods to animal testing
- harmonisation of test methods (based on ISO standards) and test requirements
- approximation of labelling requirements
- strengthening the harmonisation work carried out at international level under ICCR

- reinforcing regulatory cooperation on emerging areas.

The discussions are still ongoing and therefore the specific actions have not yet been decided.

In any case, these proposed items could result in gains not only for industry arising from reduction of diverging requirements, but also in:

- a wider range of cosmetics products available to the consumer
- more efficient testing, and
- greater international harmonisation of cosmetics regulations and practices.

This would be achieved without compromising the protection of public policy interests such as health or animal welfare.

2. Possible elements for a cosmetics annex in TTIP

2.1. Convergence of data requirements and scientific safety assessment methods

The EU Cosmetics Regulation contains lists of substances authorised for use in cosmetic products as colorants (listed in Annex IV), as preservatives (listed in Annex V), and as UV filters (listed in Annex VI).

Both Parties could endeavour **to align their data requirements and scientific safety assessment methods** for cosmetic ingredients that

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must be assessed and authorised for use in cosmetic products.

For instance, only **assessed and authorised UV filters can be used in sunscreens in the EU**. In the US, sunscreens are classified as over-the-counter (OTC) drugs requiring also thorough safety assessment and authorisation. Both Parties could discuss possibilities to share scientific findings on the safety of UV-filters used in sunscreens.

The idea would be to **facilitate the authorisation procedure for UV-filters** in one market that are proved to be safe and therefore allowed in the other market.

2.2. Good Manufacturing Practices (regulatory recognition of the international standard ISO 22716 on cosmetics, and recognition of GMP inspections for OTCs)

Both, in the EU and the US manufacturers have to comply with cosmetics good manufacturing practices. The European standard on cosmetics Good Manufacturing Practices (GMP) is fully aligned with the international standard ISO 22716 on cosmetics GMP.

US Food and Drug Administration (FDA) guidance has been recently modified so as to align it with ISO 22716.

Both Parties should **agree on formally recognising that compliance with ISO 22716** is

sufficient for regulatory purposes and work towards elimination of any differences between own standards/guidance and ISO 22716 if at all existent.

For products classified as over-the-counter (OTC) drugs in the US, compliance with pharma GMP is required as well as factory inspections carried out by the FDA.

In this context, it would be useful to explore whether the compliance with **ISO GMP standard for cosmetics would be sufficient also for cosmetic products classified as OTC drugs**, or whether the results of GMP Pharma inspections carried out by authorities in the EU could be accepted as an alternative.

2.3. Formal regulatory acceptance of validated alternative tests methods to animal testing

Several alternative tests methods (ATMs) to animal testing have been validated and adopted as OECD test guidelines.

Both Parties could agree on further **fostering the development of alternative methods to replace animal testing**. The overall objective is to promote the use of validated and OECD accepted alternative test methods for regulatory purposes for cosmetics.

Both sides could **share scientific knowledge** on the matter including

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existing technical assessments and guidance documents, and could collaborate in the development and implementation of the 'read across data approach and integrated testing strategies' that use all available information and data.

2.4. Harmonisation of other test methods and of test requirements

Both sides should further **cooperate on the harmonisation of test methods** on the basis of ISO standards (e.g. ISO 24445 - test methods to determine the sun protecting factor).

Both sides could **explore possibilities for the approximation of requirements regarding colour additives** (The EU allows those that are on the list of authorised colorants without further testing. In the US for certain colour additives batch testing is required).

The possibility to waive 'batch testing' of colorants considered safe by both sides (including purity levels), could be explored (in case existing legislation allows it). In that case, safety compliance could be checked via inspections on a random basis.

2.5. Approximation of labelling requirements

Both sides could work on further aligning **labelling requirements** on the basis of the International

Nomenclature for Cosmetic Ingredients (INCI system) in particular as regards trivial names.

Other labelling requirements could be harmonized (e.g. sunscreen protection factor (SFP) based on common ISO test methods) as well as the labelling of colour ingredients (FDA using INCI names and EU requiring colour index number).

In addition, both parties could pursue **collaboration in new issues such as allergen labelling**.

2.6. Reinforce cooperation within ICCR

Both parties could commit to further **strengthen their cooperation within ICCR** and discuss ways to implement ICCR decisions in their jurisdictions, as well as bringing a political commitment to reinforce the impetus of ICCR work.

2.7. Reinforce regulatory cooperation in new areas

Both Parties could cooperate in new issues and consider developing disciplines and principles aimed at **good regulatory practices specific to the cosmetics sector**, without duplication of the work done in the ICCR.