European Commission

Towards an EU-US trade deal
Making trade work for you

The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues

EU position on cosmetics

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 ICCR (International Cooperation on Cosmetics Regulation).

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

- mutual recognition of lists of allowed and prohibited cosmetic substances
- collaboration in good manufacturing practices and mutual recognition of inspection results
- collaboration in, and regulatory acceptance of, validated alternative test methods to animal testing
- harmonization of test methods (based on ISO standards) and test requirements
- approximation of labelling requirements
- strengthening the harmonization work carried at international level under ICCR
- reinforcing regulatory cooperation on emerging areas.

The discussions are at a relatively early stage and therefore the specific actions that may be decided cannot yet be determined.
But 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
- more efficient testing, and
- greater international harmonisation of cosmetics regulations and practices.

This could 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. Mutual recognition of lists of substances that can be used in cosmetic products (positive lists) and of lists of substances that are prohibited or restricted in cosmetic products (negative list)

The EU Cosmetics Regulation contains lists of substances authorized 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). The EU Regulation contains also lists of prohibited substances in cosmetics (Annex II) and substances subject to specific restrictions (Annex III).

Both Parties could explore possibilities for the approximation and mutual recognition of cosmetic ingredients that are allowed 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 thorough safety assessment and authorisation. Both Parties could discuss possibilities to mutually recognize scientific findings on the safety of UV-filters used in sunscreens.

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 as in the US manufacturers have to comply with cosmetics good manufacturing practices. The European standard on cosmetics GMP is fully aligned with the international standard ISO 22716 on cosmetics GMP. 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 OTC drugs in the US, compliance with pharma GMP is required as well as factory inspections carried out by FDA. In this context, the acceptance of GMP inspections carried out by the other Party could be explored.

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 for animal testing. The overall objective is to encourage the US to formally accept validated test methods for regulatory purposes for cosmetics, in particular for products being classified as OTC drugs in the US.

Both sides could share scientific knowledge on the matter including 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. Harmonization of other test methods and of test requirements

Both sides should further cooperate on the harmonization of test methods on 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 (EU allows those on the list of authorized colorants without further testing. US-FDA has to approve all colour additives (ingredient pre-approval) and for certain colour additives batch testing is required).

The possibility to waive 'batch testing' of OTC drugs manufactured with ingredients 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 (e.g. acceptance of the term *aqua* as alternative to water).

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 emerging issues such as allergen labelling. For instance, scientific opinions underpinning regulatory decisions on fragrances allergen labelling could be shared.

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 on emerging areas

Both Parties could cooperate in good regulatory practices on emerging issues, for instance with respect to nanotechnology or alternative test methods, 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.