P&G input into consultation on regulatory issues for possible future trade agreement between the EU and US

General remarks

The EU and US are both mature democracies where citizens share the same values and expect the same high standards of regulatory protection for consumers and the environment. We should therefore accept that regulatory procedures in the field of chemicals, cosmetics and biocides have compatible and functionally equivalent approaches.

This would allow companies in this sector, which represent an important leverage for growth and job creation, to trade goods more effectively while reducing the financial and administrative charge of public authorities, with no negative consequences for consumer health and environmental protection

An ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries' regulatory systems, in particular of BRICs countries.

Specific remarks

Chemical sector

Issues: There are important differences between the EU and US in terms of approach to chemical regulation (both existing and prospective) which often result in duplication of effort by government and industry, inefficiencies and unnecessary costs for all stakeholders.

Impact: Differences between TSCA and REACH create a barrier to our business model which is to innovate on a global scale, look into worldwide supply of raw materials. Speed to market, which is key in the Fast Moving Consumer Goods area, is significantly hampered.

Potential benefits: From an industry perspective, the most value-added would be to focus on more efficient and effective operation of the chemical regulatory systems in the EU and the US, to include common principles for information sharing, for prioritizing chemicals, for review and evaluation, and for coherence in hazard and risk assessment. A common approach to data assessment would simplify the chemical review process, improve transparency and be more efficient for companies to develop their chemical dossiers in both economies.

Suggested actions: We would like the EU and US to establish mutual recognition of compatible regulatory regimes for control of chemicals. Creating a mechanism that allows regulatory agencies to recognize that they have functionally equivalent approaches would avoid affecting each region's existing regulatory framework while allowing for the production, sale and use of chemicals that are lawful in one continent to also be lawful in the other.

Secondly, the EU and US should agree on objectives and governing principles of chemical control laws, as well as on a common template and equivalent or compatible IT systems to submit registration dossiers.

Thirdly, a mechanism which would allow physico chemistry, health, and environment data submitted under one regulatory regime can be acknowledged under the other without re-submitting would help business immensely. This would avoid unnecessary animal testing and save costs for companies and public authorities. This process should not threaten confidential business information and data compensability, otherwise data owners would risk losing competitive advantage when entering new markets to the benefit of free riders taking advantage of data owners' financial expenditure.

A way to protect against inadvertent loss of CBI or data compensation rights is to incorporate a requirement for notification to the data owner prior to one geography sharing with the other. A data owner could use that opportunity to object to the sharing of information to protect CBI or data compensability, or allow the data exchange to proceed between government agencies.

Cosmetic sector

Numerous regulatory differences prevent the application of "approve once, accepted everywhere" in this sector. Specific ingredient and labelling regulations prevent the free interchange of US and EU produced cosmetics and fragrances.

1) INCI labelling only with PCPC inventory is not acceptable for the EU market

Acceptance of EU trivial names in the US (e.g. Aqua) would be a major step in harmonization without impact on the consumer.

Impact: As ingredients must be listed only by their PCPC-INCI names, companies are obliged to apply both English and Latin INCI name on their products' packaging. This discrepancy also creates difficulties for trade with other countries.

For example, according to the Canadian multilingualism regulation, in the case of companies using the two harmonised INCI terms "AQUA / WATER", both terms being part of the International Cosmetic Ingredient Dictionary, the addition of the French word "EAU" would also become mandatory simply because of the presence of the INCI name "WATER".

Another example is colorant names used in Color Cosmetics. US requires color name "Red 6, iron oxides" while EU requires CI numbers (CI XXXXXX). As cosmetics are often composed by multiple colours the final result is cumbersome for industry and unfriendly to consumers.

Potential benefits: Companies would be able to use only one INCI name, which would result in more effective trade flow between regions, lower costs for industry and ultimately wider choice for consumers.

Suggested actions: We encourage authorities to work toward harmonization of INCI labelling.

2) OTC Classification

Several cosmetic products that are classified as OTC in the US (anti-dandruff shampoos, toothpastes, antiperspirants, sunscreens etc.) are safely marketed as cosmetics in the EU. This prevents free movement of such products due to heavy labelling and unnecessary claim and formulation restrictions.

Impact: OTC Cosmetic Drug products require 6 months accelerated stability testing to assure 3 year product stability prior to launch; For OTC products not meeting OTC Monograph requirements compulsory tests on animals in the framework of an NDA or a TEA.

Potential benefits: Harmonizing the approach towards OTC cosmetic drugs would reduce significantly extra costs and red tape both for enterprises and authorities without compromising the safety of consumers.

Suggested actions: We call authorities to shift the borderline between the cosmetics and OTC drugs so that more products could be efficiently marketed as cosmetics in both regions.

3) Standardization of cosmetic colour specifications

Differences persist in approved cosmetic colours between the US and EU without technical reasons (i.e. purely historical).

Impact: Both the EU and the US have specific purity criteria for some cosmetic colours. These criteria differ for the same colour material and are sometimes mutually exclusive. As a result the same product must have multiple supplies for each colorant and separate productions driving cost and complexity upward.

Potential benefits: Move to single set of purity criteria for cosmetic colorants would allow for an identical product to be manufactured for both markets allowing or both free movement and scale benefits.

Suggested actions: Engage in discussion with US authorities with the intent of agreeing common standards.

4) Exploit harmonization potential of the International Cooperation on Cosmetics Regulation (ICCR)

The International Cooperation on Cosmetics Regulation (ICCR – EU, USA, Japan, Canada) is an important platform for regulatory convergence, but so far has no strong mandate to address issues that would require changes in legislation.

Potential benefits: Given its multilateral framework, the ICCR would provide the best forum to align cosmetics regulations in order to maintain the highest level of global consumer protection while minimizing barriers to international trade.

Suggested actions: Formalize ICCR's role as a significant tool for further harmonization and support increased and meaningful engagement by the EU and US.

Biocidal products

Issues: Most of the biocidal products approved in the US are not compliant with EU regulations, and vice-versa. This requires reformulation, additional efficacy testings, different toxicology tests, new supply chain, etc.

Impact: The lack of harmonization results in higher costs and longer lead times leading to fewer products available for commercial customers (that service hospitals and restaurants) and consumers. The additional cost for companies of our size exceeds several millions €.

Potential benefits: Industry would gain the ability to formulate with a global mindset, with a focus on the performance of our products and the environmental footprint rather than meeting the specific requirements in each geography. Overall this would lead to better and cheaper biocidal products.

Suggested actions: In this sector as well, mutual recognition of registration and approval procedures would undoubtedly increase the regions' industry competitiveness while preserving the same degree of safety.