

5 September 2012

AmCham EU's Position on the 2013 Ban on Animal Testing

Europe remains a premium choice of investment for cosmetic and personal care companies from the United States, who contribute to the success of the industry in Europe and help make the EU a world leader in the sector. The high export value of the cosmetics industry is an asset to the EU, and encouraging a favourable environment for innovation in this sector is crucial as it will permit to deliver important continuous economic, societal and health benefits.

The cosmetic industry is a leader in life sciences and the development and scientific acceptance of alternative methods to animal testing that also benefit other sectors. This investment in research for alternatives allowed the industry to phase out animal testing ahead of the Cosmetic Directive requirements (2004). However, it is clear that a full set of alternatives is not yet ready and maintaining the 2013 marketing ban on animal testing in absence of any validated alternative would negatively impact the cosmetic industry.

Trade impact

The EU must ensure that products developed outside the EU in compliance with local regulatory requirements are not prevented from being sold in the EU market.

- The goal of the testing and marketing bans of the Amendment 7 to the Cosmetic Directive was to eliminate the use of animals for EU cosmetics legislation purposes. The legislator has explicitly specified that the bans apply only to animal tests carried out '*in order to meet the requirements of this Directive*' (emphasis added).
- There will be no positive impact on animal welfare by banning or refusing data that has been developed to meet EU non-cosmetic or third country regulatory requirements in line with applicable animal welfare standards.
- Refusing this data could run counter to OECD and WTO rules.
 - The principle of mutual recognition is enshrined in the **OECD** decision of 1981 concerning the mutual acceptance of data (MAD) in the assessment of chemicals. When the European Commission proposed the animal testing ban in 2000, it stated, '*This prohibition... does not apply to testing carried out for the purposes of meeting other regulatory requirements if the same chemical ingredient is also used in other applications... outside the scope of*

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Emanuele Degortes; Emanuele.degortes@amchameu.eu +32 2 289 10 36

[the Cosmetics Directive]', adding that data from animal tests may be used as supporting data for cosmetic ingredients. The Commission added that *'...it would be inappropriate for the [EU] to demand the repetition of a test using alternative methods, as this would set up a barrier to trade'*.¹

Application of the ban to tests not carried out for the purpose of the EU's cosmetics legislation would imply a restriction of the free movement of cosmetic products. The free movement of cosmetic products would be hindered and compliance with WTO agreements would be in question (which have to be used as guidance when interpreting EU legislation) if animal testing and marketing bans prevent imports into the EU of cosmetic products containing ingredients tested on animals for other regulatory purposes. The GATT agreement (Article III.4) precludes discrimination between physically identical products based on differences in the basis of production. Producers who make use of established animal-based test protocols may therefore claim that their methods of evaluating product safety have no material effect on the final products, and that their cosmetic products may consequently not be discriminated against in the EU market on the basis of the safety testing protocols employed.

- AmCham EU believes that **the mutual recognition and acceptance of data generated for other regulatory purposes than the EU cosmetics legislation is crucial** to enable the import into the EU of innovative products and the placement on the EU market of safer and better performing products.

Impact on innovation and science within the EU

Maintaining and enhancing the capacity of the cosmetic and personal care industry to innovate within the EU improves consumer's health and wellbeing by providing them with better performing and safer products. Innovation is critical in a fast-moving sector where most products take over five years to reach the market, the majority of products have a lifetime of less than five years and in which about 25% of products are reformulated or replaced annually. Consequently, the development of new ingredients – and the ability to assess their safety – is at the heart of cosmetics innovation, which is highly depending on the scientific data generated.

- The rapid progress in chemical, biological and dermatological research produces opportunities for new ingredients that allow the industry to deliver greater quality and performance to consumers, to respond to societal challenges, such as ageing, to create products with better skin compatibility, and to develop products that are more sustainable.

¹ Explanatory Memorandum in COM (2000) 189 final, 5 April 2000.

- New ingredients and reformulations need to be developed to replace ingredients that are withdrawn due to safety concerns, high costs or because new ingredients are more sustainable, for example. In 2010, companies removed 120 ingredients out of 2,000 from their portfolios, and this trend is expected to continue.
- The ability to generate new scientific data on existing ingredients is equally crucial to confirm the safety of these ingredients in the light of newly identified health risks or in the case of an increased focus on a new scientific issue such as endocrine-disrupting properties. Additional tests may be required to ensure the continued use of ingredients when such problems arise.
- In 2010, the value of exports of cosmetics products from the EU was €12.5 billion, with up to 62% of products placed on the export market. This value would be likely to fall as 'commoditised' EU-made products are less appealing to consumers in foreign markets than innovative products made elsewhere. US companies would look to manufacture their products elsewhere in order to be closer to these developing markets, and the EU would lose out on export duties and workplaces

Consequently, AmCham EU calls for the development of a pragmatic and workable derogative scheme for testing specifically for EU cosmetics legislation purposes, which should allow:

- **The generation and use of data to prove the safety of new innovative ingredients (for cosmetics application only) or existing ingredients with an innovative new use.**
- **The ability to generate and provide data to EU regulatory bodies in case safety concerns arise on existing ingredients.**
- **Any derogative scheme must remain workable for SMEs.**

Impact on the economy and employment

The cosmetics and personal care products industry brings economic benefits to the EU. In 2010, the €66 billion European market represented one-third of the global market share. American companies contribute heavily to the success of the European cosmetics industry, including through research and development and other employment opportunities in Europe.

- Approximately 1.7 million jobs are dependent on the cosmetics industry, both directly and indirectly. Of the 177,000 people working directly in the cosmetics industry, 25,000 are scientists; their employment in Europe depends on innovation and, in turn, on the development of new ingredients (and the ability to assess their safety).
- If the incentives or the ability to innovate are removed, companies will look to move their R&D activities nearer to other markets for which new products can be developed under more 'innovation-friendly' national regulatory obligations. Despite the high level of scientific knowledge available in Europe, R&D would be likely to move if the

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Emanuele Degortes; Emanuele.degortes@amchameu.eu +32 2 289 10 36

political and regulatory climate in Europe becomes less favourable – and pioneering research into alternatives to animal testing would join this ‘brain drain’. The impact would also be felt by national governments in tax revenues: US companies operating in Europe contribute to VAT and tax revenue on industry profits, which amounts to an industry-wide total of around €10bn per year.

- **In the current economic situation, one of Europe’s most successful and most competitive industries, needs to remain competitive and the inward investment that the industry brings from the US and elsewhere must be maintained and encouraged.**

CONCLUSIONS

AmCham EU calls on the European Commission to come forward with a proposal that effectively balances ethical leadership, consumer safety, innovation and growth in a manner that continues to take science as guiding principle.

The current situation favours a ‘regional approach’ rather than a ‘data quality approach’, which is especially problematic for US and other non-European companies as it fences off the European market and has negative consequences for R&D and trade. It also imposes a significant cost – in terms of availability of products, industry costs, and employment – for a very small (if any) benefit to animal welfare, given that tests will continue elsewhere in the world.

We believe that a proposal should at least recognise the possibility to use data that are generated to meet third country or EU non-cosmetic regulatory requirements in line with applicable animal welfare standards. In addition, there is a clear need for a pragmatic and workable derogative scheme for testing specifically for EU cosmetics legislation purposes, thus avoiding condition creating a ‘de facto’ restriction.

* * *

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate U.S. investment in Europe totaled \$2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

* * *

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Emanuele Degortes; Emanuele.degortes@amchameu.eu +32 2 289 10 36