TTIP - Cosmetics Europe Meeting with European Commission
03/07/2014

Attendance:

- DG TRADE ([**Art. 4.1b**])
- DG SANCO ([**Art. 4.1b**])
- Cosmetics Europe

Topics Covered:

A. Mutual Recognition of Safety Standards
B. Approved Colorants List
C. Colourants Labelling
D. Harmonisation of Future Regulations
E. Animal Testing Ban in 3rd Countries

A. Mutual Recognition of Safety Standards:

Stakeholder Engagement

- Annex II (list of substances prohibited in cosmetics products) in Cosmetics Regulation won't be touched by the EU. There has already been a great deal of concern from civil society on perceived relaxing of EU safety standards. Cosmetics Europe says gain is not that great anyway.

Cosmetics Europe:

- Explained benefits of converging regulatory requirements: consumer gains a wider range of cosmetics and understandable, aligned safety standards across the Atlantic.

UV Filters:

- 28 approved in EU; 16 authorised in US. Of 16 approved in US, 10 authorised in Europe, 3 not: PABA (banned in EU) and 2 authorised in EU but not as UV filters.
- Thus, 18 authorised in EU are not allowed in US .
- Extremely long approval process. US says reason for lack of progress is that industry does not submit complete applications.

Cosmetics Europe:

- Need for convergence of safety assessment principles. It needs to be understood how the FDA carries out safety assessment.
- In EU, safety data used for key decisions in chemicals and UV filters were generated with animal tests before the ban.

Next Steps:

- **Cosmetics Europe** to give info on how long the UV filters approval process takes.

B. Approved Colorants List:

Diverging Lists

- **US:** 65 allowed colourants. 36 require batch testing; 29 have exclusions from this rule through a "process of petition".
- **EU:** has 150 allowed cosmetics colourants.

Cosmetics Europe:

- Not worth aiming at mutual recognition of lists. Better to focus on the approach to safety assessment (i.e. batch testing).

Batch Testing:

- Batch testing is a statutory requirement which cannot be elimminated in US legislation but fast-tracking could be considered/asked for.
- European legislation for food and cosmetics relies on legal manufacturer responsibility that trace levels are safe and technically unavoidable during the manufacturing process, whereas US has pre-defined purity levels in their legislation, verified by batch testing.

Cosmetics Europe:

- EU cosmetics companies use principally colorants exempted from batch testing in the US.
- When they have to go through batch testing, it is a very burdensome process.
- **Batch testing is not considered useful by the industry because:**
    - Any batch tested would represent only a single batch from that supplier –not representative of line of cosmetics in general.
    - Risk batch testing penalises smaller companies who can't assure the purity of their products.
    - Costly – new legislation might introduce a new fee for batch testing. CE recommends the EU explains to FDA that batch testing is overly resource intensive.
- The US approach amounts to a 'pre-market registration system'
- **Data instead of batch testing:** Industry could give raw data to FDA on grounds of strict confidentiality. But don't want to do this unless the potential win is big enough.
- **EU should not focus on persuading US to increase their list of authorised colorants:** Don't believe it is worth at this stage discussing mutual authorisation of lists, better to recognise common principles of safety assessment.

C. Colourants Labelling

Current Labelling Requirements:

- **EU legislation:** " *The CI (Colour Index) nomenclature shall be used, where applicable.*"
    - Legislation won't allow us to move away from CI labelling for colorants.
- **US legislation:** Prefer colour coding. Take INCI name and add 'trivial name' (red, blue...)
    - US also reluctant to change things. For example, on replacing 'water' with 'aqua', says EU should provide study showing that American consumer understands terms such as "aqua."
- **Current Industry Practice:** manufacturers tend to place both EU & US name on same label.

Cosmetics Europe:

- Advantages of move to single label details: common identifier for consumer, and less work for companies.
- However, Sunscreen monograph took 12 years to update. Unless there is serious political will, not much will change.
- Could solution be for EU to switch to using INCI?

US Pilot for Common Labelling

- US has proposed a pilot project for colorants labelling, by verifying molecular structures of colorants with European CI numbers against molecules of US colorants with "common and usual" names. US proposed next steps:
    - Names – identify 20/30 commonly used names.
    - Batch Testing – EU to provide samples of colorants to US for batch testing.

- The Commission asked CE for their advice on selecting suitable colorants including their samples for the pilot.

Cosmetics Europe: Batch testing should not be necessary to determine molecular structure existing already in ICID Dictionary. All colorants are listed with a US name and often with a CI name too, so most of this work has already been done.

Next Steps:

1) Should find out the names of 65 colorants on the US list
2) Ask US what they want to achieve with the pilot project?
3) CE to reach out to members and get the molecular information required directly from them.

D. Harmonising Future Regulations

Allergen Labelling:

- US intends to regulate this area ("priority regulation area") and wishes to get the EU perspective.
- Commission: Next step to discuss first key principles for preventing allergies.

Cosmetics Europe: Not keen to include this issue into TTIP. Firstly, it needs to be understood how the risk of allergens is assessed in cosmetics?

Other Future Regulations:

Cosmetics Europe:

- Regulatory Cooperation: When considering approaches for regulation of cosmetic ingredients (i.e. UV filters, nanos), involve the US from the beginning.
- Treat the US as a privileged partner rather than a stakeholder – send them draft legislation before such legislation is made public (*NB: Sending draft legislation to the US before is sent to MS and EP is though not possible)*.

E. Animal Testing Ban:

- CE asked EU to inform 3rd countries that some of them are "wrongly following EU testing ban" as they omit important parts of the the EU interpretation and scope of the ban in the EU.