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THE FIRST TRULY INDEPENDENT WATCHDOG FOR THOSE  
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## **Regulatory Vendettas against Natural Products: the Case of Tea Tree Oil (TTO).**

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TTO is a complex natural substance added to cosmetics as an ingredient known for its beneficial properties (anti-inflammatory, biocidal etc.), & not for any other reason - certainly not for its odour value, which many people find unpleasant. But, according to existing guide-lines, the EU Cosmetics Commission would not be able to accept any risk / benefit scenarios generated by its health & safety 'expert' advisers, even if they were capable of generating them. The SCCP you will recall is a group of academics with no experience of the cosmetics industry, which, the EU Commission has previously admitted, lacks some forms of cross-disciplinary expertise. They generate a series of assessments of the toxicology of single cosmetic ingredients in isolation, in the form of SCCP Opinions, when directed to do so by DG-Enterprise. Thus it comes about, that, according to the existing guide-lines, the SCCP has to be 'in-denial' about the formulatory purpose of including TTO within a cosmetic product.

The Federal Institute for Risk Assessment (BfR) imply that because there is no pharmacological proof of efficacy of TTO, it therefore must be a cosmetic material by default (BfR 2003). But TTO finds itself in a Catch-22 situation in this regard, since (almost) nobody is investigating the medical / pharmacological properties of TTO, simply because the pharmaceutical industry is unable to profit from investigating natural products, with a view to issuing defensible patents. So, let us imagine a scenario where, in spite of 80 years of the demonstrable safe use of TTO, the hugely influential pharmaceutical / chemical industry could theoretically lobby Brussels officials, alleging stability & skin sensitisation problems, and thereby hope to remove TTO as a competitive ingredient to their in-house synthetics. But of course in our fair and just society, this would never be allowed to happen. Would it?

Common sense, or even a faint familiarity with terpene chemistry, tells us that tea tree oil is actually no more unstable. or any more unsafe than a large number of other commonly used essential oils, but:

- SCCP Opinion SCCP/0834/04 concluded that undiluted TTO used for a cosmetic purpose might not be safe (cosmetic purpose later questioned in

SCCP/1155/08), diluted TTO might be unstable in cosmetic formulations, skin & eye irritation have not been assessed by adequate methods. The SCCP believed they had identified data-gaps relating to subchronic toxicity, percutaneous absorption, genotoxicity/carcinogenicity & reproductive toxicity.

- The ATTIA (& RIRDC) made the big mistake of submitting a safety dossier to the SCCP relating to these shortcomings, at a cost of £200,000 Australian, thus creating a precedent for the whole essential oils industry. The SCCP took nearly 2 years to evaluate their data, and were still not satisfied (see SCCP Opinion 1155/08).

Meanwhile the SCCP's critical questioning about tea tree oil safety destabilised & unsettled the Australian TTO industry and its customer-base: plantations closed, & the TTO price/Kg rose. This rising cost situation led to competition from Chinese TTO, often inferior in quality & different in composition which led to blends of Australian & Chinese TTO becoming common in the essential oils marketplace, and also made profitable the possibility of adulteration with monoterpene hydrocarbons such as  $\alpha$ - &  $\gamma$ -terpinenes. Because the SCCP has not commissioned independent advice, these factors have so far been ignored. The BfR joined in the scare-mongering, and in a statement dated 1st Sept 2003, it declared 100% TTO used for a cosmetic purpose (what cosmetic purpose is served by 100% TTO?) as being unsafe, & recommended a 1% concentration limit in cosmetics - a concentration at which, anyway, they doubt TTO would have a pharmacological effect. COLIPA (2002) had similarly suggested a 1% conc. limit in cosmetics, but then promptly withdrew from the debate. As a result, consumer demand for TTO-containing products fell in some countries, and Cropwatch has evidence from one German tea tree oil toothpaste manufacturer (submitted 2008-9), whose annual usage went down from 4 tons/annum pre-2003, to 500Kg/annum presently.

Cropwatch spent 18 months investigating where the pressure for any need to establish an SCCP Opinion on TTO originated. We now have the answers we need, and conclude there is little evidence of transparency over lobbying within Brussels, as has been previously identified by the *Corporate Europe Observatory* (Wesselius 2005). We also note that adverse end-user reactions from sales of tens of millions of small bottles of TTO by major distributors run at > 0.0015% (Cropwatch, unpublished data), but you will remember that the EU Cosmetics Commission does not allow adverse end-consumer reaction data as admissible evidence for safety evaluations of cosmetic ingredients. Meanwhile Cropwatch has been running a website questionnaire for aromatherapists on TTO for several years. This is expected to report in summer 2009, and to show no significant problems associated with TTO usage in aromatherapy.

### Conclusions.

We conclude that TTO is indeed in a Catch-22 situation where the benefits for its inclusion in cosmetics cannot be officially acknowledged, since these benefits are pharmacological/medical/biocidal rather than cosmetic. As it is, benefits for the

inclusion of TTO as a cosmetic ingredient potentially outweigh any identifiable risk. The safety case against TTO has not included near-zero end-user adverse effects data, and so once again we see the familiar pattern of regulators solving theoretical toxicological problems, which don't actually exist in practice. The sequence of regulatory actions against TTO therefore can only be seen as misguided, unfair, and to have arisen partly because the Health & Safety Code of Practice adopted by the European Cosmetics Commission to investigate the toxicity of single cosmetic ingredients is antiquated and urgently needs modernisation. Most worryingly, elements of corporate influence (if not bullying) have yet to be officially revealed. It is clear that the outcome of this affair has not served the public interest, who continue to regularly use tea-tree oil in their millions, unabatedly.

### **Reference.**

Wesseliuss E. (2005) "High time to regulate EU lobbying." *Consumer Policy Review* **15**(1), 13-18.