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THE FIRST TRULY INDEPENDENT WATCHDOG FOR THOSE WORKING WITH NATURAL AROMATIC MATERIALS

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"Legislators & Natural Aromatics: A Modern Day Vendetta."

Talk given by Tony Burfield at *Symposium on Cosmetic Controversies –Seeing the Whole Picture,* Society of Cosmetic Scientists, May 17-19th 2009.

Abstract. Toxicologists, certain European governments, and the heads of some major international aroma concerns, contribute to an existing culture of toxicological imperialism which manifests in an over-precautionary approach to cosmetic safety legislation, and which directly affects the use of Natural Aromatic Ingredients. Fragrance buyers, concerned about possible media exposure from consumers allegedly suffering the adverse effects of harmful aroma ingredients. pressurise aroma companies to submit fragrances fully compliant with all EU & National legislatory requirements & IFRA Standards (however controversial or inappropriate they may be). The reality is, that whereas the side-effects of prescribed pharmaceutical drugs are arguably responsible for the deaths of tens of thousands of UK patients/annum, it is hard to find instances of any deaths directly caused by cosmetics or essential oils. Even close examination of the evidence for an underlying clear-cut cause effect between many alleged allergens and instances of clinical allergic contact dermatitis are absent or relatively rare. Why then, do we tolerate this safety legislation overkill, and who does this situation serve? Certainly not the interests of the consumer, nor the art of perfumery.

§1. Cropwatch: a brief description.

Cropwatch is an Independent Watchdog for *Natural Aromatic Products* used within the cosmetic, flavour, pharmaceutical, natural biocide, essential oil supply & aromatherapy industries. Core concerns include the over-exploitation of rare & threatened aromatic plants in the wild and pro-active campaigning against misappropriate regulation & codes of practice purported by the various regulatory bodies & trade-funded associations. Cropwatch has no formal membership and is non-financed, but has a *Cropwatch Newsletter* subscriber list, editions of which we believe currently reaches >30,000 people. Cropwatch continually provides free technical information to enquirers, and has detailed & continually updated data-bases on its website www.cropwatch.org .

§2 Cropwatch sets the scene.

Freedom of choice (to buy products containing natural ingredients) has been forensically removed from the public via the progressive actions of various over-

precautious safety regulators within the EU, US, Canada etc. Officials rely on 'expert' scientific opinion - which often defers to the existing culture of toxicological imperialism & corporate science, and results in over-precautionary & overly complex legislation. There is no better example of this, than that of the biocides legislation in Europe which effectively discriminates, scientifically & economically, against natural products & the SME's attempting to market them.

Industry does little to contest the validity of much of the poor & incomplete science behind the progressive over-regulation & restriction of natural ingredients. It is evidently more concerned with adhering to the existing hyper-bureaucratic system, than challenging it.

* i.e. *not* having scientific certainty is *not* a justification for *not* regulating – see Hanekamp & Bast (2007).for a detailed discussion.

§3. Biocides.

The Biocidal Products Directive (BPD) 98/8/EC, effective from the year 2000, was largely drawn up via advice from the synthetic biocide producing industry, & so predictably failed to exclude (read: protect) the low-toxicity substances for which the measure was originally designed from the scope of the regulations - low-toxicity substances like essential oils & pheromones. Some 50-odd initially notified essential oils with biocidal uses under the BPD (citronella, geranium, lavender etc) were unable to be supported by SME's on cost grounds: estimated at between 14,000 to 183,000 Euros per substance (see study on impact of BPD referenced below, completed in 2005, 5 years too late for the SME's with relevant interests). It is not difficult to for anyone to understand that the required economic outlay to support these products as active substances under the BPD was always going to be beyond the economic resources of these micro-companies. Following the impact assessment, a time extension for essential oils (as 'undefended substances') was granted under EC Regulation. No 1048/2005, but only for the supporting registrant. Under article 4.2 of EC Reguln. 1687/2002 there is also provision for a derogation for essential use, where EU Member States may apply to the Commission (up until May 2010) where they consider that an active substance is essential for them for reasons of health, safety or protection of cultural heritage, or is critical for the functioning of society, and where there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health'.

The 2nd phase of the BPD under article 16(2), carried forward under 1451/2007/EC, still does not change the situation substantially for niche products like essential oils, marketed by SME's with low annual turnovers. Neither can it be said that the acting Biocides Commissioner(s) have been unaware of this fact all along (Cropwatch has previously communicated enough times on this point!). Essential oils are still being used for their known biocidal properties, but they have to be marketed as single essential oils, rather than being advertised or packaged with the disallowed wording 'insect repellent', 'disinfectant', 'anti-microbial' or other purpose-related phrasing. In summary, the Biocides Commission cannot say they did not understand the quandary that the natural

biocides sector has been placed in, and their present market exclusion can only be viewed as exactly the outcome that the synthetic biocides industry had planned.

Reference: *Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products*. Study No 07010401/2006/443173/MAR/B3 Sept 2006-Sept 2007 Final Report for DG-Environment 10th Oct 2007. by Hydrotox GmbH, Risk & Policy Analysts Ltd, Ökopol GmbH.

§4. How safety regulators have destroyed the cultural inheritance & art of European perfumery.

The restriction/banning of key fragrance ingredients on dubious or over-precautious safety grounds, can easily compromise the founding elements of traditional perfumery. For instance, the crucially important fougère accord consists of a combination of bergamot, coumarin & oakmoss. Of these founding ingredients, bergamot oil usage is under threat from impending EU legislation because of its photo-toxic furanocoumarin (FC) content (see flawed SCCP Opinion 0942/05 etc.). Coumarin is an alleged sensitiser under SCCP/0935/05, and is recently restricted by IFRA. Oakmoss is proposed to be severely restricted under SCCP/1131/07, which limits the contained potent sensitisers atranol & chloroatranol to 2ppm in product (the sensitising potency of atranol & chloroatranol is currently under acrimonious dispute).

Other examples of landmark fragrances/fragrance styles which owe their conception to key natural materials include the chypre style of *Mitsouko* & *Miss Dior*, which were based on accords of oakmoss, patchouli oil and labdanum together with bergamot oil. Although patchouli is a rare example of a natural perfume ingredient without usage restrictions, labdanum qualities have sensitising properties, and oakmoss & bergamot have are restricted, as noted above.

§5. The uses of naturals in perfumery

What are the unique attributes that naturals can bring to a perfume? Naturals breathe life into an otherwise simple blend of chemicals. They add depth and sophistication-whether it is floral absolutes, woody materials or citrus oils that are used.

Whole fragrance styles/families would not exist without naturals – for example, Eau de Colognes. Many essential oils lend an incomparable radiant freshness to fragrances e.g. lime, lavender & petitgrain. It is hard to imagine a masculine fine fragrance which merely relied only on synthetic materials for its freshness. For example, accords of linalyl acetate, dihydromycenol & allyl amyl glycollate, without the presence of bergamot, lemon, lavender or rosemary oils, would be perceived as flat, lifeless & chemical.

§6. The decline of naturals in perfumery.

The usage of naturals has declined in perfumery, because of downward pressure on ingredient costs (synthetics are comparatively cheaper), & from erratic supply (weather; political events) & from stability issues. Under existing EU H&S policy,

naturals are treated as a collection of composite chemicals. The vast majority of essential oils, absolutes & resinoids contain several of the 26 named allergens, which have to be labelled under EU Directive 2003/15/EC. The desire by cosmetic manufacturers to avoid excessive product labelling has lead to some decline in the overall usage of essential oils.

The IFRA ban on benzyl cyanide & its movement into Annex III of Cosmetics Directive has virtually stopped the use of karo karunde in perfumery, and also impacts on tuberose, orange flower absolute & jasmine usage in natural perfumery. It is then, with some considerable irony that natural perfumers read about IFRA's intentions to define natural fragrance via a task force, considering IFRA's role in the consecutive banning & restriction of natural perfumery ingredients. The fact is, that natural fragrances have already been satisfactorily defined by the Natural Perfumers Guild. A corporate interpretation of the term via IFRA members, who are often more constrained on natural ingredient choices than are artisan perfumers, will be seen as inappropriate & irrelevant.

The classification of methyl eugenol as a suspected carcinogen, & safrole as a weak hepatocarcinogen, together with corresponding IFRA restrictions, has led to a great reduction in the use of those natural materials containing them, such as the methyl eugenol-containing spice oils: clove bud, pimento leaf & pimento berry. The use of rose oil has been similarly affected - it is now virtually impossible to create a 100% natural rose fragrance which complies to IFRA guidelines, formulated with >1% rose oil. Use of cinnamon leaf & nutmeg oils too, has been affected by the safrole classification, as has the use of basil & tarragon oils containing methyl chavicol. Such limitations have had significant effects on fragrance styles entering the market place: traditional aromatic masculine fougères and rich spicy notes are very difficult to achieve at so-called 'safe' levels.

Under CHIP/EU DPD (now under 1272/2008/EC), R50/53 environmental labelling (dead fish/tree symbols) and R65 labelling have had a serious impact on usage of citrus oils & their terpenes. Citrus oils have been traditionally employed in many types of perfumes for household & air care products, because of their diffusion, lift & fresh character, but perfumers now find it difficult to use them. A similar situation applies to pine needle oils. Cinnamon leaf & clove oils were used in pot pourris & candles, but R43 issues with eugenol & cinnamic aldehyde contents etc. means that their use is now restricted.

There is also a category of minor oils that IFRA has banned on predictive toxicological grounds, but has no funds to practically investigate - melissa, santolina, boldo etc. - the loss of these items also narrows the perfumer's palette of available ingredients. Natural products needing expert botanical identification & chemical analysis for QRA studies, that IFRA can no longer support (read: cannot afford to support) - such as opoponax & styrax - can also be added to the list of ingredients destined for fragrance obscurity. Styrax qualities such as styrax resinoids & essential oils, were once important perfumery ingredients - it is depressing to see these materials disappear, and the development in

Cropwatch's view shows that IFRA are not supporting the wider interests of the perfumery art, but merely reflecting the narrower business interests of their major sponsors.

§7. The media seizes on (virtually any) bad news about natural products.

Essential oils are associated in the minds of many people with alternative life styles, and Complementary Alternative Medicine (CAM). As we indicated on the Internet recently, Cropwatch is currently gathering evidence of unfair media & academic put-downs of those CAM areas which utilise aromatic plant treatments. Lippett (2009) writing in the *Education Guardian*, discussed whether Alternative Medicine should be taught as a scientific subject at all, and mentions the cyber-bullying from anti-CAM lobbyists and their influential blogs, determined to shut down CAM courses at UK universities such as Salford, Uclan, Westminster, Middlesex, Thames Valley, West of England etc., and their attempts to totally discredit the practice of homeopathy.

As an example of wrong-headed media reportage, gynecomastia in 3 pre-pubertal boys, allegedly caused by lavender/TTO-containing personal care products (Henley *et al*. 2007), received much media (national newspaper) coverage. The *New England Journal of Medicine* which ran the article, had previously announced a policy change, as it could not find independent experts for reviews, who had not been paid off in some way by industry (Newman 2002). A pity, because refutation of the robustness of the alleged gynecomastia link followed (e.g. by Nielson 2008 & Lawrence 2007 amongst others), but of course, hardly received any media attention, as the popular media seem only to be interested in 'bad news' stories.

§8. Customers object to reformulations of classic perfumes.

Reformulations of classic perfumes in order to conform to modern regulatory requirements have led to disappointment and bitterness amongst their long-term devotees, whose historical memories and emotional attachments were evoked by the odour profiles of particular fragrances, previously seen as an enduring part of their rightful cultural inheritance. Many fragrance houses seem in-denial about the whole subject, but Turin (2007) has remarked on customer anger generated during the Guerlain *Mitsouko* reformulation debacle. Internet discussions on a wider range of classic perfumes whose character has been allegedly mutilated by reformulation are available (for example see *Perfume of Life Forum* Jan 2007). As a passing thought, cultural inheritance rights (see above) over and above minor safety issues have featured in EU Commission legislation in other areas – so why has this not been introduced for perfumery? The answer may well lie with the anxiety of many fragrance customers to only purchase fragrances with comprehensive regulatory compliance (as far as is achievable), in order to escape, or as a defence against, potential media exposure highlighting any adverse effects from product ingredients. And, of course, maybe to some extent, damn what the perfume smells like.

§9. Over-regulation

Essential oils are not controlled by any one singular piece of legislation, and need to conform to, are regulated by, or are restricted by:
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- National Pharmacopoeias, ISO Stds, EOA Stds, IFRA Stds, EFFA CoP's, FEMA/GRAS, EU Cosm. Directive.
- If Biocides, under 98/8/EC. If Cosmetics 76/768/EEC.
- If flavourings, under 88/388/EEC & 199/217/EC, if food/feedstuffs 178/2002/ EC.
- If Allergic data, to Directive 2003/15/EC
- If Medicinal Products 2001/83/EC; Trad. Meds 24/2004/EC; Vetinary Medicinal products under 2001/82/EC
- GMO declarations under EC 1829/2003 & EC 1830/2003
- Limits on heavy metals, dioxins, PCB's, pesticides, 3-MCPD etc under 88/388/EEC if flavourings. Also not allowed to be present if cosmetics.
- Labelling & packaging regulations, transporting & shipping regulations. (CHIP; Classification Packaging / Labelling Directive 1272/2008/EC replacing 1999/4/EC & 1907/2006)
- REACH 1907/2006/EC

This list is the tip of the iceberg, as far as the current level of introduced hyper-bureaucracy is concerned, even for a single straightforward selling transaction for aromatic goods. Cropwatch awarded a prize in 2008 to a French trader who had requested a record 29 different pieces of paper for a single simple transaction – naturalness certificate, GMO-free certification, allergens certification, food allergens certification, food suitability certification, BSE certificate, Kosher certificate, specification, MSDS, IFRA certificate, heavy metals statement, pesticide statement, 3-MCPD statement, dioxins statement etc. etc. Truly the regulatory clerks will inherit the earth – well, if it wasn't for the required paperwork!

§10. Legislation-compliant ingredients – a new opportunity.

Cropwatch has a large A-Z data-base of articles in the *Cropwatch Files* section of its website, listing the various furanocoumarin (FC) contents of natural products following FC phototoxicity issues (raised under SCCP/0942/05 etc.). Companies like Treatt, Capua etc. now market a range of FC-free citrus oils, but small traditional producers of citrus oils are potentially disadvantaged without huge technological investment. And for what reason exactly? The safety case for reducing FC's to the minute levels the EU proposed in finished cosmetic products is not robust, and although essential oils are always singled out for particular examination, other commonly used cosmetic ingredients also show photo-toxic effects (again, see the *Cropwatch Files* reports on Furanocoumarins for further information).

To date, other especially processed legislation-compliant ingredients, such as safrole-free nutmeg qualities, methyl eugenol-free rose oil, IFRA compliant oakmoss qualities, furanocoumarin-free bergamot oil etc. etc. have all proven to be more-easy-to-adulterate, pale olfactory shadows of traditionally produced natural products. This reduction in ingredient quality compromises the art of the

possible in perfumery practice and opens the door to the possibility of even more adulteration (once again, see *Cropwatch Files* for data-base on essential oil adulteration)

§11. Compare & Contrast: Pharmaceuticals and Cosmetics.

- Laurance J. (2003) "Reactions to common medicines kill 10,000 each year." *Independent* Fri 2 July 2004 p8.
- Vioxx (a drug marketed by Merk used to control blood pressure) has killed between 88,000 and 119,000 patients. *Lancet* 365(9458), 475–81 (2005).
- No reported deaths from application of cosmetics in EU in 2008. Or in 2007, or in 2006… Some concern over lead ingredients in eye cosmetics from Pakistan (2009) and lead levels in lipstick generally (disputed: 2008)…but no fatalities reported in the literature. N.B. lead products are still allowed in hair dyes in EU.
- Only 1 well-documented clinically relevant case of allergy to coumarin has ever been reported (Mutterer *et al*. 1999). Similar low numbers of clinically relevant cases for many other alleged allergens listed under EU Directive 2003/15/EC. The legislation clearly lacks proportionality.

The conclusions from above are self evident. Ever since the removal of arsenic, lead and mercury from cosmetic formulas of earlier times, the actual hazards from cosmetics use have become are relatively slight. The bureaucratic burden associated with the marketing of cosmetics & cosmetic ingredients in the EU, however, remains enormous.

§12. Shortcomings of the EU Cosmetic Commission's H&S CoP.

The EU Cosmetics Commissions' existing CoP is a museum-piece. It does not offer a definition of safety, does not quantify individual ingredient risks, does not allow ingredient risk / benefit considerations, does not allow in-use considerations, & does not allow for consumer adverse reactions (or lack of them) to affect safety policy.

This 'risk-only' scenario leads to the situation of toxicological imperialism, where a misguided bias for precaution & scare-mongering predominate, and where the lobbying of pharmaceutical & chemical companies disadvantages competitive natural products. Worrying situations of vested interest (e.g. individual SCCP members acting as witness, judge & jury over issues like oakmoss & treemoss sensitisation), remain unaddressed (see *Cropwatch Newsletter* Aug. 2008, Jan 2009).

Part of the problem lies with the lack of cross-disciplinary ability within the EU Cosmetics Commission, the SCCP, and those organisations which spoon-feed them information (EFFA, IFRA etc.). For example the unforgivable refusal of a risk / benefit scenario to assess ingredient safety (which is the norm. in many other industries & professions) mostly reflects on the inability of the Commission to deliver on such a policy. The rationale for disallowing the risk / benefit

approach given by the Commission, relates to the objective of allowing cosmetic effects for marketed cosmetic items, but differentiating them from medical effects, which are disallowed. Since many cosmetic ingredients are added solely for their beneficial effects, being in-denial about advancing cosmetic scientific progress leaves the Commission looking increasingly irrelevant, & rather similar to King Canute - still on the throne, but drowning in the incoming tide.

§13. Hormesis.

Perhaps the most controversial toxicological topic to have come up in recent times, as attested by the publication of several thousand scientific papers, the subject of hormesis and its place in precautionary regulatory culture creates a huge potential divide for regulators and toxicologists alike. The old-school idea that the toxic effects of a chemical show a dose-dependent linear relationship ending at a threshold level is now challenged. At low levels adaptive, non-adverse or even beneficial effects can occur (hormesis), and have been soundly shown for >6,000 chemicals (Calabrese 2004). This raises a 'serious misreading of the term toxic' charge for the EPA*, and the ECHA over the REACH legislation, and suggests that the estimated 50-100 million Euros spent on the witch-hunt of synthetic chemicals exercise is wasted, and will not save a single life.

However the proponents of the hormetic model are far from unworldly, and predict that industry will resist the hypothesis (Hanekamp & Bast 2007). Earlier, Calabrese (2004) had stated "Of course, a protectionist philosophy dominated by a linear dose-response model and obsessed with achieving zero risk will have difficulties accepting this notion", and again "If only zero risk is acceptable to the public, then it is easy to call for the complete abolishment of a product or activity that carries with it some risk, no matter how large the costs or benefits."

Cropwatch, too, imagines the corporate science-career toxicologist-regulatory lawyer alliance will resist the acceptance of the hormetic hypothesis. Perhaps Jostman sums it up best (Jostman 2007): "Absolute reassurance & 'no risk' policy is, however, contributing to the risk adversity of our society and triggers biased regulation, which will not deliver substantial environmental or health benefit."

*N.B. This reference to the EPA needs to be seen as what appears to be a gagging order, mentioned a document prepared by the EPA in 2004, which states that the purpose of a risk assessment is to identify risk (harm, adverse effect etc.), effects that appear to be adaptive, non-adverse or beneficial may not be mentioned. Through Calabrese (2007)"Belle newsletter: Introduction." *Human & Experimental Toxicology* **26**, 845.

§14. Cropwatch despairs of the 'experts'.

Many experimental safety studies have been carried out on plant extracts / distillates from plants which were not expertly botanically identified at source, were not batch-tracked & not tested as being 100% derived from the named botanical (i.e. may well be adulterated). Individual chemical constituents used in

studies have often been impure synthetics purchased from companies like Fluka, Sigma-Aldrich or Extrasynthese, rather than 99.99%+ pure components worked up from the natural source. These facts alone suggest much of the historical work on natural product toxicology is non-robust. Neither is Cropwatch the first to point out these inadequacies: Hostynek & Maibach, in a series of articles that forensically examine the evidence for designating certain aroma chemicals are allergens, also point out the shortcomings in experimental design of many toxicological studies, which invariably includes criticisms about the chemical purity of the materials used.

Coming back to the general situation, recommendations on safety are made by 'expert committees' populated by academics with no industrial experience, which lack cross-disciplinary skills, & cannot foresee the socio-economic and other consequences of their actions. Staff from the EU Cosmetics Commission previously admitted (Brussels 2007) that the SCCP lack botanical expertise & only had access to independent literature searching in 2007 for their Opinion-forming duties **(!)**. Now we read that a pool of 160 'experts' is to be made available to Brussels staff….

§15. Vendettas against natural products: the case of tea tree oil (TTO).

TTO is added to cosmetics for its known beneficial properties (anti-inflammatory, biocidal etc.) & not for any other reason - certainly not for its odour value, which many people dislike. But the EU does not accept risk/benefit scenarios in health & safety assessments ("Opinions") carried out by the SCCP, and so is in-denial about its function in a finished cosmetic. The BfR (BfR 2003) imply that because there is no pharmacological proof of efficacy of TTO, it therefore must be a cosmetic material by default (?).

(Almost) nobody is investigating the medical / pharmacological properties of TTO, because the pharmaceutical industry is unable to profit from natural products, by issuing patents etc. So, in spite of 80 years of the demonstrable safe use of TTO, the pharmaceutical / chemical industry could theoretically lobby Brussels, alleging stability & sensitisation problems, and hope to remove TTO as a competitive product. But of course this would never be allowed to happen…

Common sense tells us that tea tree oil is no more unstable or 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 questioned in SCCP/1155/08), diluted TTO might be unstable in cosmetic formulations, skin & eye irritation have not been assessed by adequate methods. SCCP 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 on 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.

Meanwhile the SCCP's critical questioning about tea tree oil safety destabilised & unsettled the Australian TTO industry, plantations closed & the TTO price/Kg rose. This situation let in competition from Chinese TTO, often inferior in quality & different in composition. The BfR joined in the scare-mongering. 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 unsafe & recommended a 1% concentration limit in cosmetics - a concentration at which, anyway, they doubt TTO would have a pharmacological effect. COLIPA (2002) similarly suggested a 1% conc. limit in cosmetics, but then promptly withdrew from the debate. Consumer demand for TTO-containing products fell, and Cropwatch has evidence from one German tea tree oil toothpaste manufacturer, 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 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, the EU Cosmetics Commission does not allow adverse consumer 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 show no significant problems associated with TTO use in aromatherapy. We conclude the regulatory action sequence against TTO to be misguided, unfair, to have arisen purely because of industrial lobbying, and does not serve the public interest.

§16. Vendettas against natural products: Safrole, a weak hepatocarcinogen?

Public resistance to over-precautious safety legislation gets little media attention. The use of sassafras qualities in sassafras tea, root beer, filè powder etc. was banned in 1976 by the FDA in the US, as the main constituent, safrole, is a mild rodent hepatocarcinogen. There is, even today, little new evidence for its human carcinogenicity. Many sassafras tea drinkers & root beer makers in Eastern US regard the right to use sassafras flavouring ingredients as part of their cultural inheritance. They regard the 1976 FDA ban as purely political; brought about by the fact that safrole is a precursor for illicit drug manufacturing (Ecstasy etc). A Texas study is reported to exist showing no decrease in hepatic carcinoma occurrence since the sassafras ban.

In terms of restrictions on use, safrole as an added ingredient is banned as such by IFRA. The limit for safrole from safrole-containing essential oils in fragranced cosmetic products is 0.01%.

§17. Vendettas against natural products: Some very inconvenient classifications.

- **Safrole**: carcinogen cat. 3 mutagen cat. 2 (EFFA 2008). Occurs in sassafras, nutmeg, mace, star anise & cinnamon leaf oils.
- **Methyl chavicol:** Possible weak genotoxic hepatocarcinogen (SCF 2001). Occurs in star anise, exotic basil, fennel, tarragon oils.
- **Methyl eugenol:** Possible carcinogen (US). Calif. Prop. 65 carcinogen. Occurs in rose, basil, bay W.I., cananga, citronella Sri Lanka, pimento, lovage & betel oils etc. Human exposure levels normally several magnitudes below bioassay levels for rats, mice; relevance of rodent data questioned (Robison & Barr 2006).
- **Lilial® (BMHCA):** Reproductive toxin cat 3. REXPAN: OK to use it up to conc. limits in IFRA Standard.
- **Ethanol:** CMR cat 1. Cosmetic manufacturers currently withdrawing ethanol from mouthwash formulations. Indispensable ingredient to cosmetics trade.

Although not strictly cross-comparable, this data suggests that if the ingredient is synthetic (e.g. Lilial), a different set of rules apply. And if the ingredient important enough (e.g. ethanol) no rules apply at all. Amongst the losers in this game of double standards are methyl-eugenol-containing naturals as listed above. And if that's not confusing enough, several ingredients have different EU and IFRA limits, methyl eugenol included:

Product type	IFRA Standard Max %-age	EU Standard Max %-age
Fine fragrance	0.02%* *Conc in fragrance compound	0.01%
Eau de toilette	0.008%	0.004%
Fragrance cream	0.004%	0.002%%
Other leave on:	0.0004%	0.002% for leave-ons & oral hygiene products
Rinse off	0.001%	0.001%
Non-skin (see IFRA Std)	0,02%	
Other non cosmetic products not covered above	0.001%	

Table 1. IFRA vs. EU Cosmetic Directive limits for methyl eugenol in various product categories.

N.B. IFRA Standard also applies to household products

Cropwatch concludes that the Standards for methyl eugenol are too severe, based on the available evidence, which Cropwatch has been reviewing for the last 18 months.

§18. Fragrance regulation – what can be done?

Fragrance is used in other areas than just cosmetics: e.g. household products, aerosols, environmental fragrancing, candles & incense, reodourants etc. By

bringing all these application areas together, Cropwatch believes there would be considerable support within the European Parliament for a separately established **Fragrance Commission** which would preserve the art, culture & heritage of European fragrance. Cropwatch also believes that the Ombudsman would take up the issues of non-transparency, 'invisible' lobbying and social non-accountability within the EU Commission. As it is, the fact that the SCCP has been too over-worked to deal with major aroma issues (such as citrus FC's; TTO) within a reasonable time-frame, the case is strengthened for an independent body of experts who are experienced with (& just deal with) aromatic materials.

§19. Vendettas against natural products: The case of coumarin.

The established views on the toxicity of certain ingredients can be difficult to counter - It becomes almost heretical to believe that certain substances may not be the hazardous materials they have been made out to be. One of these is coumarin. But in fact EFSA (2004) concluded that coumarin is non-genotoxic, and any human carcinogenicity issues may only be relevant to very small sub-section of human population (Lake 1999).

Notwithstanding, the Federal Institute for Risk Assessment (BfR) had to be publicly corrected in 2007 on alleged risks with coumarin toxicity from cosmetics. The BfR had wrongly maintained that the TDI (0.1mg/d) for coumarin could be exceeded by application of cosmetics. Commentators are on record as saying that Prof. Hensel had, additionally, not understood species differences relevant to coumarin metabolism.

Confusion and misinformation reigns over the status of coumarin as a sensitiser Coumarin is regulated by EU Directive 2003/15/EC, such that coumarin requires labelling as a sensitiser if present at concentrations of >10ppm in fragranced leave- on products, or >100 ppm in fragranced products washed off the skin. Cropwatch maintains that in the SCCP Opinion /0935/05 on 99.9% pure coumarin, the expert committee had misunderstood the data, incorrectly concluding that pure coumarin is a sensitiser. Schnuch *et al* (2004), Floc'h *et al* (2002), Vocanson *et al* (2006 & 2007) and many others seemingly have opposing views. Cropwatch's submission to DG-Ent. on coumarin was never acknowledged. What is evident is that *minor impurities* in *some* commercial grades of *synthetic* coumarin used for allergy testing (dihydrocoumarin; 6-chlorocoumarin etc.) *may* be sensitising. The fact remains that only 1 well-documented clinically relevant case of allergy to coumarin has ever been reported (Mutterer *et al*. 1999), so again we in the area of disproportionate response.

Full details can be found in 'Coumarin: the Real Story' (updated Jan 2009) in the *Cropwatch Files*.

§20. Vendettas against natural products: The oakmoss/treemoss debacle

Oakmoss – foundation of Coty's *Chypre*, Guerlain's *Mitsouko*, Dior's *Miss Dior*. Fragrant lichen extracts are the cornerstones of both the chypre & fougère accords, and are immensely important to the perfumery art. SCCP Opinion

1131/07 limits the potent sensitisers atranol & chloroatranol to 2 ppm in oakmoss, treemoss (& cedarmoss) products. But the conclusions reached in SCCP Opinion SCCP/1131/07 appear to be unsafe from a failure to consider all the available evidence. Cropwatch was easily able to find this evidence via a literature search (see the corresponding bibliography in *Cropwatch Files*). There is also a question of partiality by individual SCCP members who were also paid researchers (according to documents seen by Cropwatch). These members did not exclude themselves from the Opinion, & are thus unethically operating as witness, judge & jury in this matter.

§21. Vendettas against natural products: Peru balsam qualities..
The bête noir of allergenic aroma ingredients for many dermatologists, Peru balsam has medically important role in difficult-to-heal wounds (see Peru balsam articles in *Cropwatch Files*). Several perfumery companies removed Peru Balsam qualities from their inventories following confusion over their safety status, due to errors in 2006 made by EU regulatory clerks. This, together with effects of previous 1982 IFRA Standards, has reduced the use of Peru Balsam qualities (oil, absolute etc) in fragrances. Curiously, as production volumes have decreased to 50% at source, positive patch-test frequency reactions to Peru Balsam have mysteriously increased.

Now help is needed to save the declining forest in El Salvador, the balsam producing industry itself and the communities dependent on it. The EU's attitude is that the socio-economic consequences of their legislation are 'not within their remit'. Facts not generally appreciated about Peru Balsam include the following:

- Much/most of the Peru balsam oil on the commercial market is adulterated. Dermatologists do not use a standardised, authenticity-tested product for patch-testing etc..
- RIFM have previously failed to identify the major allergens in Peru balsam / Peru balsam oil (such as the relatively unstable coniferyl benzoate 1-9%, benzyl isoferulate to 0.4% etc.).
- Cropwatch has been working with Peru balsam manufacturers to try to reduce the occurrence of the major allergens in Peru balsam qualities without affecting their odour profile. Finding funding for this sort of work is problematic.

§22. The 26 Allergens Debacle.
SCC(NF)P in Opinion SCCNFP/0017/98 & 0329/00 identified a number of fragrance chemicals (16 of which occur in natural products) having a labelling obligation for allergens where conc. in the final product is <0.01% in products rinsed off the skin products or <0.001% in leave-on products. This was incorporated into Council Directive 2003/15/EC. The basis for the inclusion of these chemicals as allergens has never been explained by the SCCP (Storrs 2007), The chairman of the SCCP (Ian White) has co-authored a number of research papers on alleged allergens, cannot be said to be a disinterested party in this matter.

Independent publications (e.g. Schnuch (2004 & 2007), & several articles by Hostynek & Maibach (see references listed in Appendix I), have indicated that there is no robust clinical or experimental evidence to support many of these 26 ingredients as allergens. Up to now there has seemed to be no mechanism to independently review the SCCP's Opinion, or undo Directive 2003/15/EC, although Schnuch (2008) publicly asked the EU to rethink their policy. It is a little ironic too, that Hostynek & Maibach's (2008) detailed article, the latest entitled "Allergic contact dermatitis to linalool: Allergen status disqualified" has appeared in various slightly different forms in three consecutive journals / trade magazines, reflecting the level of concern for industry.

In a new development (March 2009) a request is made by the EU Commission to the SCCP for an updated scientific opinion regarding the labelling of 26 fragrance substances that were introduced into Annex III of the Cosmetics Directive by 2003/15/EC on the basis of the SCCNFP draft opinion (SCCNFP/0017/98). This is passed off as a spin-off from the public consultation (Nov 2006) on the Commission proposal of regulation of some fragrance substances.

The older Opinion SCCNFP/0017/98, actually divided fragrance chemicals as most frequently listed allergens (list A), or infrequently listed allergens (List B), but curiously, the recent request to the SCCP makes no reference to the work of Schnuch *et al.* (2007), who called for a slightly different list of substances to be reviewed as allergens, on the basis of his published work indicating no safety concerns to consumers for a number of fragrance chemicals.

Overall, the imposition of the over-precautionary and unnecessary 26 allergens legislature, cost the aroma industry millions of Euros in reformulation and labelling costs at the time, and presumably will yet again, with any new regulatory situation. The passage of the original legislation depressed the production of some essential oils worldwide for at least two years afterwards, reflecting their reduced usage in cosmetics. This arises from the fact that the vast majority of essential oils, absolutes & resinoids contain several of the 26 named allergens, and cosmetic manufacturers wished to avoid excessive product labeling. As mentioned previously, the decline in the overall usage of essential oils in fragrances from this cause is still operative today.

§23. Past promises.

Quote from Ian White (1998) "Fragrances – Future Aspects" in *Fragrances, Beneficial and Adverse of Effects*" ed. P.J. Frosch, J.D. Johansen & I.R. White, publ. Springer 1998:

"A think tank has been set up consisting of a balanced representation of dermatologists, fragrance compound manufacturers and users to address aspects of the problems and needs."

The above quote describes a situation which seems to have little resemblance to the SCCP, of which Dr. White is chairman, or any other committee which we are

aware of. Note absence of 'independent scientists with requisite cross-disciplinary skills', on the 1998 wish-list.

§24. The suppression of scientific dissent.

These quotes are included because they mirror the elitist & secretive workings of some regulators and trade associations, which effectively operate as a closed shop.

"For any group that is able to acquire a disproportionate share of society's wealth, power, or status, it is advantageous for this inequality to be seen as legitimate. One of the key bases or supports for legitimacy in contemporary societies is scientific and technological expertise."

" …wherever legitimacy supported by technical expertise is important …. there is a reasonable chance that some cases may be found of the exercise of power to suppress dissent from dominant views."

Brian Martin (1999).

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Appendix II – List of Acronyms.

- BfR – Federal Institute for Risk Assessment
- BPD - Biocidal Products Directive
- CoP - Code of Practice
- DPD - Dangerous Products Directive
- ECHA - European Chemicals Agency
- EFFA - European Flavour & Fragrance Association
- EFSA – European Food Safety Authority
- EPA - Environmental Protection Authority
- FC – Furanocoumarin syn. Furocoumarin
- GMO - Genetically Modified Organisms
- H & S - Health & Safety
- IFRA - International Fragrance Association
- ISO - International Standards Association
- MCPD - 3-monochloropropane-1,2-diol
- PCB - Polychlorinated Biphenyls
- QRA - Quantitative Risk Assessment
- REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals
- RIFM - Research Institute for Fragrance Materials
- SCCNFP - Scientific Committee on Cosmetic Products and Non-Food Products. Now SCCP (q.v.)
- SCCP Scientific Committee on Consumer Products
- SCF – Scientific Committee on Food
- SME - Small & Medium Enterprises
- TDI – Tolerable Daily Intake
- TTO - Tea Tree Oil

Appendix III – EU Definition of a cosmetic product.

This comprises any substance or preparation intended to be placed in contact with the various external parts of the human body including the skin, hair, nails, lips and external genital organs, or with the teeth or mouth. The exclusive purpose should be to clean, to perfume, to change appearance and/or correct body odours and/or protect or keep those parts in good condition.