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

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Cropwatch Newsletter No 6 – Democracy Issue.

Assembled by Tony Burfield Feb. 2007.

Editorial.

Signs that a serious rebellion was gathering from over-regulation issues in the EU cosmetics sector, started to become apparent with reaction to the somewhat naïve SCCP Opinion SCCP/0942/05, which further backed a proposal to limit furanocoumarin (FCF) concentrations in cosmetic products down to 1ppm, citing ten commonly used citrus oils, plus rue oil (rarely used in fragrances). It soon transpired that perfumers were unaware of the FCF concentrations of their common (citrus) ingredients, producers were failing to provide the relevant data, 'FCF-free' products were revealed as actually not being FCF-free, leading perfume chemists in disagreement as to whether FCF's were actually steam volatile and that the data on alleged toxicity of FCF's was incomplete. Cropwatch also pointed out to the Head of Unit of the EU Cosmetics Sector that FCF's occur in a large number of fragrance ingredients other than those few set out in the SCCP Opinion. Further, few aroma companies, apart from the industry dinosaurs, could afford the equipment and analysis time to determine FCF ingredient concentrations. To sum up the proposal was, in fact, **a monumental regulatory cock-up**, with executives of leading cosmetics companies muttering in corridors together, vowing they would quietly ignore any subsequent legislation regarding the issue.

Since then matters can only have worsened. The BFA meeting notes (14.12.06) are believed to reflect some EFFA ideals, viz. that 'essential oil producers should produce low levels of isopimpinellin & bergamottene (they meant bergamottin) in purified oils. So this is thought feasible? Oh really? We can name plenty of economically disadvantaged essential oil producers from undeveloped areas who will not be able to do this, so this looks like yet another good-old EU Cosmetic sector economically divisive policy may be coming out again soon. Up to now, of course, FCF reduction processes have produced organoleptically inferior aroma ingredients with poor keeping qualities.

The naming and shaming policy announced by IFRA, for erring members who have produced marketed fragrances which contain banned or restricted ingredients at concentrations which contravene their Standards, needs countering. Cropwatch therefore intends to name and shame those regulatory officials who:

1. Have imposed unreasonable restrictions on natural ingredients to the detriment of the perfumery art and to the denial of the basic freedom to use natural aromatic materials
2. ...or have been particularly instrumental in causing economic hardship to natural ingredient producers & the local social infra-structure that depends on this commerce
3. ... or have damaged the eco-system via any ill-thought-out policies.

Events have now moved on even further, however, with the controversial matter of the Cropwatch Boycott of the 40th IFRA Amendment to its CoP, an account of which is set out below. The authoritarian stance, secretive nature and membership exclusivity of the private little Brussels circle which determines our freedoms to use natural aromatic raw materials needs to be overhauled, and a more democratically-orientated process substituted, as angry end-users have indicated (see comments at <http://www.ipetitions.com/petition/ifra40/signatures.html>)..

Update on the Cropwatch Boycott of 40th IFRA Amendment.

1. IFRA's reaction (IFRA 2007). to Cropwatch's Boycott of the 40th Amendment to its CoP was posted on the IFRA website on 19th Jan 2007. You will see that the anonymous staff writer who penned the piece has not addressed **any** of the original proffered arguments (see Burfield 2007), but merely offers a safety-orientated justification of the QRA approach in all of its associated complexity, from what is emerging as IFRA's extremely narrow perspective of the fragrance world. The unidentified writer goes on to give us a lecture on IFRA's exclusively privileged working arrangements, and maintains the line that IFRA's main purpose is "to promote the safe enjoyment of fragrances worldwide". Any master perfumer will quickly confirm that the enjoyment of fragrances *per se* has been all but destroyed by IFRA / EU Cosmetic sector ingredient restrictions over the years, and IFRA cannot failed to have noticed the many comments made by senior players in this profession featuring in the trade press, making precisely this same observation. Any independent-minded person can only assume that IFRA is either unworldly about the consequences of its own policies, or chooses deliberately not to respond to such criticism.

2. Cropwatch's on-line petition against the 40th IFRA Amendment is running at <http://www.ipetitions.com/petition/ifra40/> and at this point in time is over 650 signatories. It will be formally presented to IFRA when we believe we have contacted all those widely dispersed parties, either directly or indirectly affected by the knock-on effects of IFRA's policies. The depth of feeling and the

arguments that signatories have expressed about certain issues surrounding this topic is well worth checking out (see petition comments section <http://www.ipetitions.com/petition/ifra40/signatures.html>).

3. Perfumer & Flavorist ran an IFRA vs. Cropwatch poll on the 40th Amendment Boycott issue. The results announced on 7th Feb 2007 gave Cropwatch a **landslide victory at 85.1% of the votes cast, to IFRA's 13.4%**. The result can be viewed at <http://www.perfumerflavorist.com/newsletter/5620826.html>. Cropwatch understands from Jed Gleason at Allured that the poll will be reopened very shortly for a further period, the next results to be featured on the P&F website on 7th March 2007.

4. Media Reaction to Cropwatch Boycott. This story was well reported in general, but some of the media which normally run Cropwatch articles have not run this particular story.

5. Artisan Natural Perfumers Guild (ANPG) have issued a press release on 8th Feb 2007 fully supporting Cropwatch on this issue (see full text at http://artisannaturalperfumers.org/cropwatch_ifra.htm) and asking for a moratorium on the 40th Amendment implementation until the policy process can be opened up and given the opportunity for a more widespread public debate. The ANPG have constructed, together with some international-based help, a 19 point FAQ on which can be viewed at http://artisannaturalperfumers.org/cropwatch_ifra.htm, which more fully explains some basic issues around this matter. Cropwatch is pleased to see declarations on this issue from the ANPG, who represent a formerly unheard (and as far as some are concerned, probably an unrecognised-) sector of the perfumery spectrum.

Cropwatch Comments.

As a few Cropwatch supporters have remarked, **cosmetics & natural products regulation in Europe up to now has been all about money**. Now the worm is turning, and hopefully there are signs that it should become **all about democracy**. Only this week are reports of the UK government being visibly shaken by the power of public opinion – over 1 million people have signed a Downing Street e-petition website about road user charging (Oliver 2007). Although this latter figure belittles the 650-odd signatures collected so far by Cropwatch from those affected by IFRA policies over the 40th Amendment, the principle remains the same. The power of opinion means that no longer can undiscussed, uncriticised & unchallenged precautionary principle-based policies dreamed up by toxicologists & EU lawyers, be allowed to dominate the regulation of the fragrance & essential oil industries, as these regulations are slowly strangling standards, creativity & freedom in fragrance creation & usage.

It is a fact that reading the restricted membership mails from officials of EFFA, RIFM, IFRA etc., that these people quite precociously regard & term themselves,

as “the industry” – and lay people would be shocked by this arrogance, we are quite` sure. In fact, of course, they are not the whole industry. They are merely a seriously-advantaged part of it.

Over the past few weeks a group of us, from househusbands to doctors & professors, have started to look more closely at the science behind various RIFM reports, IFRA policies, articles in *Contact Dermatitis*, SCCP Opinions etc. We are starting to ask questions about the quality of science put forward & the basis of the decisions taken, and a sense of extreme frustration is developing that the valid opinions of any persons outside of these privileged ‘expert’ committees, or trade associations,. counts for absolutely nothing. Something has to change before fragrance regulation descends into anarchy, based on lack of respect for regulatory decisions, which are both impractical (e.g. the on-going FCF issue), unenforceable (internet sales; the myriad numbers of small cosmetics & essential oil producers), not believable (such as the long running 26 allergens issue), or require staff & equipment beyond the economic reach of small companies (red tape & various analytical issues). .An initiative needs to be made by regulatory authorities before disaffected groups make up their own more realistic & down-to-earth Codes of Health & Safety Practice.

References.

Burfield T. (2007) – see <http://www.cropwatch.org/40thpetition.htm>

IFRA (2007) - see

<http://www.ifraorg.org/Enclosures/News/IFRA%20reply%20to%20Cropwatch%20boycott%20re%2040th%20amendment%2019%20January%202007.pdf>

Oliver J. (2007) “Now MP’s join road toll revolt” *Mail on Sunday*.” 11.02.07 p16-17.

Cropwatch Statement : Lavender, TTO & Prepubertal Gynecomastia.

It is possibly a truism that academics, toxicologists etc. researching the effects of natural products have never had their work widely criticized, except perhaps by their own peers. There are signs that things are changing, as a more informed public follow their own callings & interests, and gain an increased access to scientific literature via the media & the Internet etc. and start to ask awkward questions. This is in contrast to the attitude of the popular media, which seems to take an obscene delight in publishing anything which puts alternative medicine & natural products in a bad light without questioning the robustness of the data behind the stories.

A case in point is illustrated by the latest work from Derek Henley and his chums who have produced a hypothesis (Henley *et al.* 2007) allegedly linking the application of cosmetics containing lavender & tea tree oils to the development of prepubertal gynecomastia in 3 young boys who exhibited normal hormone levels for their age. This link is, again allegedly, ‘supported’ by *in vitro* experiments

where lavender & tea tree oils turned on estrogen-regulated genes and inhibited an androgen-regulated gene in the human breast cancer line MCF-7. This story has been very widely featured in the media at face value, with almost no investigative reporting.

Henley *et al.* do not satisfactorily prove cause and effect for any identified substances in the applied cosmetics, nor have they isolated, analysed & authenticated the manufacturer's claim for the alleged presence of essential oil ingredients as being 100% derived from the named botanical source. The minute doses of essential oils received by the boys, derive from the low concentrations allegedly present in the soap, shampoo (products which are washed off the skin), hair gel & and the leave-on fragranced lotion - although the latter (reportedly) did not affect the twin of one of the affected boys in the study when used just by itself.

Many activists have been looking further into this matter, and new information is shared between interest groups on a daily basis. For example the *Randall Neustaedter Natural Health Newsletter* refers to an article (Neustaedter 2007) which identifies the manufacturer of the hair gel & shampoo (allegedly via information from Clifford Bloch, the pediatric endocrinologist from Denver) which caused the problem for all 3 boys as, again allegedly, being manufacturing under the Paul Mitchell brand name. This product is apparently supposed to contain both lavender and tea tree oils, although the above cited *Newsletter* reports that an analysis found little evidence of the presence of tea tree oil in the cosmetics.

A particularly galling aspect to natural product sympathisers, is to be found at end of the Henley paper. Here one of the authors, Clifford Bloch, reports receiving grant support and lecture fees from Eli Lilly, Genentech, Novo Nordisk, Pfizer, Tercica, & Serono, and the rider is added that "No other potential conflict of interest relevant to this article was reported". Given that a considerable proportion of natural product end-users popularly believe that pharmaceutical & chemical companies are funding negative campaigning to put competitive natural products in a bad light, this quite remarkable declaration will appear, rightly or wrongly, as an English 'two-fingered salute' to many in the essential oil industry. Cropwatch believes that further totally independent-based investigation to further establish or to disprove this tenuous hypothesis is urgently needed here.

Assuming for a moment that the conclusions of the paper are scientifically proven, and not a spoof as has been unkindly suggested, then the situation leaves many questions unanswered – essential oils components are only bioavailable here via skin absorption or by the inhalation of volatiles, and we know from previous animal studies that that the concentrations of the major components of lavender oil at least (linalool and linalyl acetate) where inhaled via a pre-dosed air supply, can not only be easily determined (Jirovetz *et al.* 1991), but can also proven to be rapidly eliminated from the bloodstream. Nevertheless, from many studies, we know that even at these minute levels, blood-borne

lavender oil volatiles can affect cognition skills (e.g. Sakamoto *et al.* (2005). *In vitro* dermal bioaccumulation & elimination studies for linalool & linalyl acetate have been conducted by Cal & Sznitowska (2003), and for the dermal penetration considerations for tea tree oil, the studies of Cal *et al.* (2006), featuring skin absorption & elimination of terpinen-4-ol might be relevant. From these studies we can speculate that depending upon their chemical structure, terpene bioaccumulation in the dermal layers does not in all cases necessarily indicate their subsequent wholesale availability to the organism via the bloodstream. We also have to remember that, amongst other factors, evaporation from fragrances applied to the dermis, limits their bioavailability, and that the absorption of terpenes is influenced by the vehicle in which they are applied (Cal 2006) as well as matrix effects etc.

Returning to the main subject, further, **Henley *et al.* do not eliminate the effects of other hormone-disrupting chemicals from diet, home & environmental exposure to chemicals or from other components in the cosmetics used. Further, they do not explore whether other materials (vegetable oils, soya products etc.) are capable of also producing the observed reactions.** Cropwatch has already reviewed the alleged estrogenic effects of essential oils from the scientific literature (Cropwatch 2006) after Henley *et al.* presented the same findings earlier to the Endocrine Society (Henley *et al.* 2006). Here Cropwatch found some evidence that some terpenes & derivatives weakly interact with estrogen receptors under certain conditions (e.g. Howes *et al.* 2002) but little overall evidence for any specific & relevant estrogenic effects for lavender & tea tree oil. It is difficult, therefore, to explain the results of Henley *et al.* (if confirmed) from our existing knowledge of essential oil composition, bioabsorption, pharmacokinetics and human physiological metabolic processes. Certainly, if true, a scientifically robust confirmation of these findings would have serious implications for essential oil & fragrance usage – the occurrence of linalool for example, is ubiquitous in commodities derived from aromatic plants. However many of us who have spent a lifetime working with natural aromatic products are a very long way from accepting that this sequence of anecdotes & observations as currently presented, even adds up to a hypothesis, let alone a theory. We will reserve judgment until we see some properly designed scientifically rigorous studies, which, we understand are already underway.

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Peru Balsam oil, Annex II/III issues of the EU Cosmetic Directive and the Public Consultation.

Peru balsam producers in El Salvador have reported declining demand in recent years which is threatening the quality of life of local balsam gatherers and the infrastructure of local communities dependent on this income source, and the viability of the actual Peru balsam forest itself (see <http://www.cropwatch.org/peru2.htm>). Much of this production volume decline stems from the banning of Peru balsam as a perfume ingredient by IFRA in 1982, and the unprofessional regulatory muddle which recently engulfed the EU Commission & its advisers in attempting to move PB qualities into an Annex of the Cosmetics Directory (see <http://www.cropwatch.org/peru.htm> & update). As a

result of this, a completely confused fragrance industry has many instances dropped Peru balsam qualities from their raw material inventories.

A more technically competent EU administration might have sought to find a way to work with industry to manufacture a product with fewer adverse dermatological effects – from purely humanitarian considerations if nothing else - since it has played a part in the actual hardship which ensued. Cropwatch, with its limited resources, thinks that manufacturing such a product might be feasible (see article link above), and is seeking funds for the El Salvadorian Peru balsam industry, to try to help it devise such a process.

Meanwhile Cropwatch is not expecting a favourable reaction to its report in support of the Peru Balsam industry in El Salvador from DG Enterprise. This is because the scope of the Public Consultation was so narrow that the actual term “Public Consultation” is quite derisory in our opinion, and Cropwatch was forced to go beyond its limits. Further, the period allowed for submissions was so short (with Xmas & New Year intervening) that a properly representational document was impossible to assemble.

TB. Feb 2007.