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

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Editorial.

So far, 2009 has been a busy year for Cropwatch. Following criticisms by supporters that the Cropwatch website was becoming difficult to navigate, the Cropwatch website is undergoing a prolonged make-over. The *Cropwatch Files* section at http://www.cropwatch.org/cwfiles.htm already contains an alphabetical listing of most of the features and data-bases related to the work we do/have done in trying to preserve natural materials from commercial over-exploitation, and the restriction/banning of natural products on over-precautionary grounds by regulators, or by trade bodies. As you may be aware, the *Cropwatch Files* section is continuously expanded & updated as new information is received.

This present newsletter tracks new developments in areas which Cropwatch has maintained a campaigning presence (*Furanocoumarins in Citrus Oils*, and the '*26 Allergens' debacle*). We also reveal where to find the content of Cropwatch's presentation "Legislators & natural aromatics: a modern day vendetta." – a talk given by Tony Burfield at the Symposium on *Cosmetic Controversies – Seeing the Whole Picture*, organised by the Society of Cosmetic Scientists, Grantham UK, May 17-19th 2009. We take a look at oxidation & essential oil components; consider the effects of some of IFRA's latest restrictions of natural/nature identical ingredients; and more….

§1. Furanocoumarins & E.O.'s: letter to Cropwatch from the EU Commissioner.

The European Cosmetic Commissioner, Mrs. Sabine Lecrenier, wrote to Cropwatch last week (27th May 2009) giving details of a requested re-consultation with the SCCP, over new proposals for furanocoumarins (FC's) in cosmetics, which now more specifically relate to the position of essential oils. The letter can be seen in full at http://www.cropwatch.org/09-05%20Letter%20to%20Cropwatch%20signed.pdf. Essentially the re-consultation proposes the following:

Furanocoumarins should be banned for cosmetic use except where they are present in natural essences. Then for natural essences, the FC limits are proposed to be set using the following seven markers: bergapten (5-MOP),

bergamottin, byacangelicol, epoxybergamottin, isopimpinellin, oxypeucedanin and xanthotoxin (8-MOP). The limits would be:

5 ppm of the 7 furanocoumarins in leave-on products;

50 ppm of the 7 furanocoumarins in rinse-off products,

And each of the seven furanocoumarins should not be present in higher concentration of 1 ppm*.

[**We will approach the Commissioner to clarify the precise meaning of these conditions, as they can be interpreted ambiguously in their present form*].

It is to be generally welcomed that the SCCP will have to re-consider the FC situation in light of the case put by Cropwatch regarding the effects of FC regulation on the perfumery art. Although the SCCP is being asked to consider a new policy which makes some form of limited concessions for essential oils, Cropwatch cannot accept that essential oils should be specifically singled out for penalisation in this way, whilst other commonly used cosmetic ingredients, which similarly show photo-toxic properties, escape unregulated. Apart from this, we still have the situation of the privately-held evidence commissioned by RIFM on FC's, for which Cropwatch will make a repeated request that it be placed in the public domain. It is frankly quite unacceptable that EU legislation is proposed which relies in some part upon safety data which the public is not allowed to see. Further, Cropwatch also feels that if the SCCP had been able to devote the time to properly consider the data shown in Cropwatch's 118 page *Furanoucoumarins data-base* presented at http://www.cropwatch.org/FC's%20A-Z%20listing%20in%20Natural%20Ingredients%20v%201.04.pdf, they could not possibly have come to their present conclusion.

Some larger aroma concerns (including Capua, Treatt and others) are making certain low FC-content citrus oils commercially available to the trade. Differing views (many of which are negative) are held on their perceived odour quality and performance in product by perfumers & flavourists. And as Cropwatch has previously pointed out, there is a danger that in the wrong hands, low FC products potentially represent a license to adulterate; as it stands the presence of the natural furanocoumarin content can make a contribution to estimates of ingredient authenticity. This is illustrated by the situation came about last year, where the diminished supply of lemon oil dictated that the authentic product was difficult to find, but adulterated lemon oil was plentiful [virtually no studies exist on the toxicological implications of adulteration – industry doesn't like to talk about it, and toxicologists are either unaware of it, chose to ignore the situation or wrongly assume the ingredients used to extend oils are nature identical & therefore harmless]. The more important point is that fragrance customers/consumers should not accept any further reduction in achievable standards in the perfumery art, as a result of fragrance manufacturers being forced to employ "safe" natural ingredients which may be pale olfactory shadows of their unprocessed equivalents.

Cropwatch has the following concerns about the situation:
Since the technology to reduce/eliminate FC's in essential oils is not available to all essential oil producers on cost grounds, nor yet is the equipment to analyse essential oils for FC contents available to most ingredient buyers, or perfume manufacturers, the above proposals are essentially non-workable, and present a dilemma for the regulators:

1. How does the Commission make sure that their policies do not economically discriminate against SME's? [As far as Cropwatch can see, there is no mechanism in place to gauge this situation].

2. The more general point: how does the Commission make sure that lobbying for commercial advantage has not taken place by concerns which have the technology to deliver products which suit the (known) Brussels policy direction? [Cropwatch thinks that the DG-Ent may have already been taken advantage of in this regard, although not necessarily on this issue].

These two points are very important, and we already have situations where EU policies have led to unregulated situations and a distortion of the cosmetic ingredients market (more on this later, perhaps).

Cropwatch will send a considered reply on the SCCP's new proposals for furanocoumarins in cosmetics, to the EU Commissioner/SCCP, before the Sept 4th 2009 closing deadline.

§2. '26 Allergens' Situation to be Reconsidered by SCCP.

(Slightly modified from feature first published on *Aromaconnection* March 21st 2009).
Cropwatch was assured by the EU Cosmetics Commissioner on the occasion of the Cropwatch-Perfume Foundation-EU Cosmetics Commission meeting at Brussels back in 2007, that our views on the 26 allergens would be (re-) considered by the SCCP. Cropwatch has been campaigning for a number of years to change the legislation regarding the 26 alleged allergens (16 of which occur in natural products), which carry a labeling obligation where the concentration of any one identified fragrance substance in the final cosmetic product is 0.01% or above for products rinsed off the skin, or 0.001% or above in leave-on products. This requirement was incorporated into Council Directive 2003/15/EC, whereby these materials were moved into Annex III of the Cosmetics Directive. The basis for the inclusion of these substances as allergens has never been explained by the SCCP (Storrs 2007).

Independent papers/peer-reviews/comments (e.g. Schnuch (2004), Vocansen (2006 & 2007), and several papers by Hostynek & Maibach) 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) had openly asked the EU to rethink their policy.

In a new move, a request for an updated scientific opinion on the labelling of 26 fragrance substances has been made by Brussels to the SCCP, apparently being

described as a spin-off from the public consultation (Nov 2006) on the Commission proposal of regulation of some fragrance substances.

"Scientific information of general and specific nature has been submitted to DG ENTR in order to ask the SCCP for a revision of the 26 fragrances with respect to further restrictions and possible even delisting."

"At that time there were not sufficient scientific data to allow for determination of dose response relationships and/or thresholds for these allergens."

…And that's presumably the nearest we will ever come to an apology from Brussels, for the imposition of over-precautionary and unnecessary legislature, which cost the aroma industry millions of Euros in reformulation and labeling costs at the time, and presumably will again, with any new 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; resultant job losses occurred in many parts of the trade Depressed usage arose from the fact that the large majority of essential oils, absolutes & resinoids contain several of the 26 named allergens, and cosmetic manufacturers wished to avoid excessive product labeling. The decline in the overall usage of essential oils in fragrances from this cause is still felt today.

What is needed now is an independent impact assessment, sponsored by DG-Environment, to find out the damage caused to industry, and especially to SME's and natural ingredient producers, over the whole '26 allergens' legislatory debacle. Cropwatch identifies one of the problems as the chemophobic attitudes of some European government advisers (Denmark springs to mind), who have been led by the nose by career toxicologists, who have exaggerated the ingredient risks posed by allergens. This pressured situation has pushed the EU Cosmetics Commissioner into over-hasty legislation over this matter. What has been missing in this situation is a realistic overview and the application of common sense, and we can only hope that lessons have been learned In Brussels, before the aroma industry, or parts of it, are totally bankrupted.

References

Schnuch A. (2008) – remarks attributed to Schnuch by the trade media during the IFRA workshop on Allergy Prevalence in Fragrance Nov. 2008 e.g. by Montague-Jones in *Cosmetics-Design Europe* 18.11.2008

Storrs F.J. (2007) "Allergen of the year: fragrance." *Dermatitis* **18**(1),3-7

§3. Cropwatch at the SCS.

Tony Burfield gave a talk entitled "Legislators & Natural Aromatics: a Modern Day Vendetta" at the *Symposium on Cosmetic Controversies –Seeing the Whole Picture* organised by the Society of Cosmetic Scientists, Grantham UK May 17-19th 2009. The talk is too large to reproduce here (a pdf version is available in the *Cropwatch Files*; a Power Point version is also available at http://www.cropwatch.org/Legislators%20&%20Natural%20Aromatics%20on%20PowerPoint.ppt), but includes new material on biocides, examples of the direct

effects of legislation on the ingredient use and perfumery styles, the subject that career toxicologists don't want to talk about (hormesis), tea tree oil and the rodent carcinogens safrole, estragole & methyl eugenol (for which IFRA and the EU have different limits). Matthias Vey of IFRA spoke immediately after Cropwatch, his talk being entitled "How Safe are Fragrance Raw Materials? The IFRA Principles for Safety Assessment."

Cropwatch was fairly happy with the presentation, as we felt that we were preaching to the converted (to some extent anyway) and we have come away with many new leads obtained by talking to some of the more independent-minded attendees. Cropwatch would like to thank the SCS for being brave enough to create a forum for discussion on controversial matters – a rare occurrence in these difficult times.

§4. The Trouble with Theories About the Oxidation of Essential Oils.

by Tony Burfield.
[Extended & modified slightly from first publication on *Aromaconnection* Feb 8th 2009].

Judging by the response from Cropwatch supporters, many of you may have already read about a doctoral thesis and remarks made by Lina Hagvall of the University of Gothenburg, Sweden, distributed via the cosmetics trade press. Many trade professionals have found the reported remarks condescending, as we are well aware, and may even have a wider understanding, of the context of oxidized aroma materials than the source of the remarks. But I digress.

The thesis in question is entitled "Formation of skin sensitizers from fragrance terpenes via oxidative activation routes: Chemical analysis, structure elucidation", and Katie Bird (Bird 2009) recently covered the story for *Cosmetics Design Europe*, although, as with any news knocking natural products, the article is being very widely circulated on websites dealing with health interest, chemophobia and related matters. Many of us have found the Bird-penned article makes for confusing reading: for example what is 'geraniol oil'? A better recourse is maybe to download the thesis itself from the University of Gothenburg website at http://gupea.ub.gu.se/dspace/handle/2077/18951. You will then be able to gather that the thesis is primarily concerned with the consideration of substances without contact allergenic properties, but which can be activated either via autoxidation in contact with air, or via cutaneous metabolism involving skin enzymes, to reactive products which can cause contact allergy. Primarily the study looks a five published articles with which the author has had a major involvement, studying the oxidation of geraniol, geranial (a conformational isomer of citral), linalool, linalyl acetate & lavender oil. For convenience these articles are referenced below (Hagvall *et al*. 2007; Hagvall *et al*. undated; Hagvall *et al*. 2008; Skold *et al.* 2008; Hagvall *et al*. 2008a). Much of the linalool & geraniol used as fragrance ingredients is, of course, synthetic, stored and distributed in a way that prevents oxidative deterioration, and the peroxide content is subject to prescribed limits at the point of sale. Aaberg, the Information Officer at the University of Gothenburg chooses to emphasise however, that even natural perfumes may cause allergies, pointing to the natural geraniol content in rose oil

as a potential problem (Aaberg 2009). To be frank, considering the high cost of rose oil, and the downward pressure on fragrance ingredient costs, I doubt if many perfume manufacturing companies are going to add rose oil in amounts that risk consumer safety in the manner described by Aaberg. Studies involving lavender oil may be more realistic, but again, lavender oil is stored and transported in a way that prevents oxidative deterioration, and the peroxide limit at point of sale or use is subject to restriction by the internal standards of many cosmetic companies. It is of particular note that the autoxidation of synthetic derivatives of linalool used as fragrance ingredients (such as ethyl linalool) were not investigated by Hagvall *et al*., adding to the perceived anti-naturals inclination of the studies.

If I were one of Hagvall's invigilators, I would have insisted on a re-write of a number of parts of the thesis, where the science as presented is dubious, incomplete, or, most importantly, does not present an accurate context & overview of the topic. Some knowledge of industrial practices would have aided its general acceptability as well, and a collection of these points will constitute a future article from this author.

Overall this author is not saying that the elucidation of underlying mechanisms whereby oxidized essential oils, which may be the cause of type IV allergy and acute contact dermatitis, is not important. But an overview which puts this work in perspective is importantly missing. Further, the mention of Axel Schnuch's work in this area (Schnuch *et al.* 2007) is selective, and not to include mention of Hostynek & Maibach's toxicological reviews of geraniol & linalool (Hostynek & Maibach 2004; Hostynek & Maibach 2008) is almost unforgivable, however inconvenient the conclusions in these articles may be to the thrust of Hagvall's work. The reader is thus left to form his/her own independent opinion on the relevance of the study, especially against a background of an increasing number of published studies on the anti-oxidative properties of essential oils, the declining concentrations & use of essential oils in fragrances generally, the use of cold-storage & nitrogen-blanketing (amongst other measures) to prevent the oxidative deterioration of stored essential oils, natural isolates & synthetic ingredients, and the addition of anti-oxidants, UV-filters and stabilizers to finished fragrances & cosmetics to extend their integrity & shelf-life. One is also tempted to mention that a major contributor to the cost of the studies was RIFM, a primary instigator to the culture of toxicological imperialism which has overtaken the regulation of cosmetics/fragrances in the West, to the general detriment of the perfumery art.

How does the publication of this thesis change anything? The lack of evidence of a clear cause-effect relationship between geraniol and linalool and cases of allergic contact dermatitis has been previously emphasised by Hostynek & Maibach (2004 & 2008), and Cropwatch would guess from its' own experience that adverse end-user effects would tend to support the same conclusion for lavender oil. Hostynek & Maibach (2008) also comment on the relative stability of linalool, its low oxidation rate kinetics and speculate negatively about how readily

linalool would oxidize in fragrances & cosmetics, as well as low consumer exposure levels to the ingredients. We are the, really left with the concept of the creation of 'powerful' sensitisers from linalool, geraniol etc. by skin enzymes (Cropwatch disputes that a number of these metabolites are actually the powerful sensitisers they are made out to be) in a dynamic situation of decreasing bio-availability of substrates to these dermally-located enzymes (from mass evaporation of the perfume from the skin over time). Elucidating a pathway for potential dermal sensitisation by bio-metabolites of these terpene alcohols, either added as synthetics or as contained in natural products, would seem a long way from proving the effect poses a risk to consumers. Great store seems to have been put on the Hagvall investigations by the IFRA/RIFM toxicology juggernaut, but considering the importance of the sensitiser issue to the perfumery trade, and its impact on the use of natural ingredients in perfumery, the sponsoring of just one researcher to look (mainly) at the oxidation of geraniol & linalool / lavender oil seems an exceptionally disproportionate response to the problem. Unless of course you believe that IFRA & RIFM sees the future of perfumery as entirely synthetic.

Cropwatch is trying to work towards the sponsorship of toxicological research that emphasises a risk/benefit approach towards the elucidation of the safety of natural products. Otherwise we will all drown in a sea of over-cautious toxicological negativity and chemophobia, which, it is becoming clear, has little relevance in terms of safety risks presented to the general public from natural-product containing products.

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Sköld M., Hagvall L. & Karlberg A-T (2008).”Autoxidation of linalyl acetate, the main component of lavender oil, creates potent contact allergens.” *Contact Dermatitis* **58**, 9-14.

§5. Bio-Piracy, Bio-Prospecting, Local Treatments & Ayurvedic Medicine.

[Article first published on *Aromaconnection* 1st March 2009].

Cropwatch has previously featured articles concerned with the fact that intellectual property relating to traditional treatments & medicines, and other exploitable properties of useful plants, has been looted or otherwise misappropriated. These acts have been carried out by multinational companies, and in some instances by unscrupulous individuals or teams within universities. The pharmaceutical industry, of course, has a long history of bio-piracy - you have only to think of well-known long-standing drugs such as reserpine & vincristine where no recompense was paid to the communities where the drug was found. Some examples of misappropriation for nine Indian medicinal plants were given in a discussion-only document by UNCTAD India Team (2005), which was reproduced in Cropwatch’s *Updated list of threatened aromatic plants used in the aroma & cosmetic industries v.11 March 2009.*

Plant name	**Patents Revealed (use similar to Traditional Knowledge).**
Acorus calamus L. (Vacha)	3 granted, 7 applied
Adhatoda vasica Nees (Vaska),	1 granted
Andrographis pinacualta Nees (Kalmegh)	3 granted
Commiphora mukul Engl. (Guggul)	11 granted
Curcuma longa L. (Haldi)	20 granted
Phyllanthus amarus L.	4 granted
Rauvolfia serpentina Benth. (Sarpagandha)	19 granted
Swertia chirata Buch. – Ham. Ex Wall (Chirata).	None directly mentioned, but 3 applications need study.
Terrminila chebula Retz (Harar)	3 granted
Withania somnifera Dunal (Aswaganha)	1 granted, 1 applied

Table 1. Medicinal plants with patent claims possibly similar to Indian Traditional Knowledge (adapted from UNCTAD 2005 discussion document).

Quoting from the Cropwatch article: “The authors of this document (UNCTAD) point out, that for most USA patents relating to native Indian plants, the inventors are often Indian people of Indian origin, patenting uses of plants already used for the same purpose in Ayurvedic medicine. This surely must raise questions on whether these particular patenting authorities are “fit for purpose” by ‘mis-granting’ patents based on traditional knowledge, & in so-doing, failing to

establish whether acts of misappropriation have occurred. A spokesperson for the US Govt. defended the performance of the US patenting authorities on this issue in 2001, stated: “The fault lies not with the patent system, however, but with the inaccessibility of the knowledge involved beyond the indigenous community” (Anon 2001). This feeble excuse for not spotting bio-piracy when it stares US officials in the face is simply not an acceptable position for a competent authority to maintain, but it certainly illustrates the need for recruitment of the appropriate expertise in this area.”

In a new departure, the Indian Government has effectively licensed 200,000 local treatments as “public property” which is intended to limit their use as a brand. This move was taken after Delhi scientists identified 5,000 bio-prospecting patents taken out by companies outside India. Dr Vinod Kumar Gopta, who heads the Traditional Knowledge Digital Library, was reported in the *Guardian* newspaper (Ramesh 2009) as saying more than 2,000 of these treatments belong to the seven Indian systems of medicine, and he wonders why so many millions of dollars are being spent by multi-nationals, when so many lobbies deny they work at all. Gupta’s remarks on these doubters brought a particular smile to the face of the author, as Cropwatch is currently gathering evidence of media & academic put-downs of those Complementary Alternative Medicines (CAM’s) which utilise aromatic plant treatments. This comes in a week when in an *Education Guardian* article, Lipsett (2009) 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.

Returning to the Ramesh-penned article, Gupta further mentions the granting of 285 patents in Brussels, which involve the properties of traditional Indian medicinal plants, and he would like these patents lifted. It will be very interesting to see the outcome, given the activities of the estimated 16,000 corporate lobbyists with very large cheque books, known to lurk in Brussels. Readers may remember however that Indian officials have previously been to court to successfully nullify patents taken out on the neem tree (which took them ten years), and on turmeric derivatives (which only took one).

You don’t have to look hard to find evidence of Ayurveda as the current buzz-word in cosmetics trade magazines. For example, an article on “Ayurvedic Beauty – here’s how to formulate beauty products based on the ancient Indian discipline” by Shyam Gupta of Bioderm Research (Gupta 2009) takes us through the principles of the Ayurvedic beliefs and describes topical treatments, Ayurvedic anti-aging ingredients, Ayurvedic skin-whitening ingredients, Ayurvedic arthritis, muscle & joint-pain relief ingredients & treatments, and a list of Ayurvedic herbs for further development together with their potential for ‘inside treatments’, as cosmaceutical agents, and for ‘outside treatments’. I am not a lawyer, I just believe in a fair world and treating people properly. I therefore have

serious doubts about the operational ethics, & ultimately the legality of marketing certain products from companies such as Bioderm and Sabinsa (the latter company previously featured in Cropwatch articles). If the Indian Government start using their large financial resources to defend traditional plant uses and to stop their unlicensed exploitation by foreign companies, we could see a big shake-down in the cosmetics sector.

References.

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Lippett A. (2009) "The opposite of science." *Education Guardian* 24.02.09 p8

Ramesh R. (2009) "India acts to stop foreign drug companies seeking patents on traditional remedies." *Guardian* 23.02.09 p22.

§6. IFRA (Partly) Reveals its Toxicological "Evidence" against Melissa Oil.

***Pre-amble*.**

It has always been something of a curiosity that IFRA has previously seen fit to prohibit melissa oil (lemon balm oil) which derives from *Melissa officinalis* L. ssp *officinalis,* as an ingredient of fragrances. The reasoning behind this, according to the published IFRA Standard for melissa oil, issued on16-07-2008, was said to be:

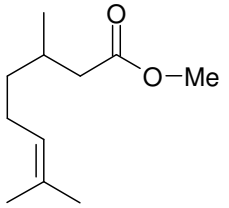
1) presence of structural alerts as defined in the Human Health Criteria Document (Ford *et al.,* 2000) and/or
2) adverse data on the material itself and/or
3) adverse data for a structurally related material based on toxicological concerns about its contained components from structural point of view.

Whilst melissa oil enjoys a considerable reputation in aromatherapy for its alleged beneficial properties, the usage volume of melissa oil in corporate perfumery nowadays has to be vanishingly small, perhaps running to no more than a few kilos per annum, since many perfumers consider the high cost of the ingredient is not justified by any contained unique notes, overall odour value, stability, or performance in product. In the days of early perfumery, the situation may have been different, for example *Melissa officinalis* was said to be an ingredient of the 17th Century cordial Eau des Carmes. Melissa extracts on the other hand contain classes of compounds not found in the essential oil, which may have acetylcholinesterase inhibiting, anti-oxidant, anti-viral (e.g. exhibit action against herpes simplex viruses: Wolbling & Leonhardt 1994). and other useful properties Melissa leaf (under 'lemon balm') is official in the European Pharmacopoeia.

The Composition / Authenticity of Melissa Oil.

There is a considerable amount of scientific literature on the composition & authenticity of melissa oil, and this brief review should only be taken as merely

illustrative rather than fully comprehensive. Melissa oil rarely been commercially available in unadulterated form in the past, and was often a construct of citronella oil, litsea cubeba oil, lemon oil and various isolates & synthetics (Burfield 2008). Tisserand & Balacs (1995) had only identified possible toxicological concerns for melissa oil via its citral content, which they maintained was in the range 35-55%, concerns which presumably also apply to other high-citral containing oils such as lemongrass oil & litsea cubeba oil. Previously Schultze (1992) had investigated melissa flower oil, and found the corolla oil (yield 0.002%) to be different from the calyx oil, the latter resembling more the oil of the leaves. The main constituents of melissa leaf oil (Schultze 1989) were found to be citronellal (36.2%), germacrene D (13.5%), β-caryophyllene (10.9%), geranial (7.6%), and methyl citronellate (4.9%). Clery (1992) drew up some pointers to distinguish authentic melissa oil (including estimation of the geranial: citronellol ratio), in order to distinguish it from lemon-scented catnip oil from *Nepeta cataria* var. *citriodora*; this same topic was subsequently re-investigated by Klimek *et al.* (2000). In addition Clery indicates that the β-caryophyllene: geranial ratio is also important for the verification of authenticity, and the author cites a checklist of components normally found in genuine melissa oil. The position is further complicated by the ratio of top leaves to bottom leaves gathered, as the neral / geranial content is higher in the top leaves, whereas the sesquiterpenes are relatively higher in the bottom leaves – a topic further investigated by Mrlianova *et al*. (2001), who investigated essential oil composition at various harvest cut heights. Further, oil produced from the dried herb is claimed to be higher in neral & geranial, and lower in β-caryophyllene & caryophyllene oxide, than the fresh herb (Salaby *et al.* 1995). Melissa plants grown near the equator usually only grown in vegetative (non-flowering) form and so slight compositional differences may also arise from this consideration.



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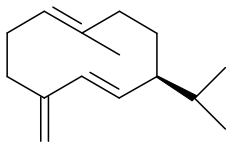
germacrene D

The evaluation of criteria for melissa oil authenticity was also discussed by Hener (1995) who used enantioselective gas chromatography, isotope ratio mass spectroscopy on-line coupled with capillary gas chromatography. Soresen (2000) reviewed the analysis, composition and pharmacological uses of *Melissa officinalis* extracts. Later, Lawrence (2008) reviewed a number of publications on melissa essential oils showing differences in composition due to the effect of different geographical sourcing, differing stages of maturity etc. Other melissa oils produced commercially include *Melissa romana* Mill.

Melissa Oil under IFRA's 44th Amendment.

Under the draft proposals for IFRA's 44th Amendment, melissa oil (which they describe as 'genuine *Melissa officinalis* L.') has been downgraded from an

outright ban in fragrances, to a concentration restriction in the fragrance compound (as opposed to the finished cosmetic product). QRA data for melissa oil, which is categorised as a weak sensitiser, is presented by IFRA for the various established product categories, based on a No Expected Sensitization Induction Level (NESIL) of 1400µg/cm^2. The problem for those of us who like to consider the robustness of the "evidence" supporting these proposed restrictions, is that it is alluded to in the form of 3 unpublished reports, not available in the public domain. These are as follows:

RIFM (Research Institute for Fragrance Materials, Inc.), 2001. Human repeated insult patch test. Unpublished study from Robertet, 21 February. Report number 36641. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2008. Local Lymph Node Assay. Unpublished study from Robertet. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2008. Human repeated insult patch test. Unpublished study from Robertet. (RIFM, Woodcliff Lake, NJ, USA).

Cropwatch has written to Robertet, Grasse, and to RIFM N.J., requesting that they make these reports publicly available, in the interests of transparency. We feel that this is particularly important in this case, in view of the devastating criticisms concerning the use of the QRA technique outlined in SCCP Opinion SCCP/1153/08, which directly related to the submitted RIFM / IFRA-generated data concerning citral as an alleged sensitiser (see feature on SCCP Opinion SCCP/1153/08 in *Cropwatch Newsletter* August 2008).

Update 27th May 2009.

Further to the proposed IFRA restriction for Melissa oil, and the non-availability of the relevant evidence in the public domain, Cropwatch made separate requests to the holders of the withheld information (Robertet & RIFM). Catherine Gadras, in charge of the regulatory and safety department of Robertet, Grasse, has mailed promising to forward a summary to Cropwatch by 15th June 2009, in respect of the LLNA and HRIPTs tests that have been conducted on behalf of Robertet, 'in order to allow the use of this EO for perfumery use'. This is a welcome development. RIFM have not, as yet, either replied or acknowledged the request.

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§7. What to do about IFRA’s Discredited QRA Policy.

In a somewhat surprising new development, Matthias Vey of IFRA, speaking at the SCS Symposium (Grantham, May 2009) mentioned the fact that there are to be discussions on the QRA between the SCCP and IFRA*. Previously Cropwatch had been told in a meeting at Brussels in 2007 with the European Cosmetics Commissioner, that communication between the SCCP and third parties (like Cropwatch) was not permitted, in order not the prejudice the SCCP, and to defend the committee from any criticism of partiality. We now seem to be in a situation where IFRA, a trade-funded business organisation, whose main activity is to sell scientific information on fragrances, is to have privileged access to a supposedly independent EU scientific committee, to discuss an inherently contentious safety technique. Of course, IFRA has a lot to lose if the SCCP continue to discredit the QRA technique as the flawed piece of corporate-contrived science which, in our opinion, it is (see devastating SCCP Opinion SCCP1153/08), since IFRA have adopted this methodology as a tool to distinguish & restrict the use of any allegedly sensitising fragrance ingredients. Cropwatch wrote to the Cosmetics Commissioner on 26th May 2009 asking that this situation of unique access be either reversed, or that in the interest of fairness & to prevent possible bias, other interested parties should be granted similar opportunities to interact with the SCCP. Failing this, again in the interests of transparency, other parties should at least be granted observer status at important meetings which determine future cosmetics policy in this area.

*In fairness, re-reading the notes of Matthias Vey’s presentation, the relevant slide says”IFRA engaged with DG ENTR and DG SANCO. Industry was encouraged to continue implementing and validating the QRA and co-operation with DG Sanco was offered in addressing the concerns expressed by the SCCP.” There are several problems here:

(a) It is important to realise that, in spite of the hype, IFRA isn't "the perfume industry" - most small perfumery companies can't afford to join because they cannot afford IFRA's membership fees. Many do not even support iFRA's policies.
(b) We utterly refute the subsequent allegation that "There is full trust from the fragrance industry and its customers regarding the application and use of the QRA". The QRA is an unmitigated bureaucratic disaster, which has turned working perfumers into bean-counters for IFRA, when they should be devoting time to making perfumes. Before, up to the 39th IFRA Amendment (with the leave on/wash off system), perfumers could commit all the ingredient restrictions to memory. Now with over-complexity of the introduced QRA system, most perfumers have completely lost track of the regulatory status of individual fragrance ingredients. In order to check & modify fragrance compositions for regulatory compliance, they are forced to rely on the integrity of their company's software programs, to check & modify fragrance compositions, and are thus effectively one more step divorced from current safety awareness. I've yet to meet anyone working at the coal-face of the fragrance industry who supports the QRA system, although there are, of course, many fragrance buyers who insist on their fragrance suppliers' compliance to every piece of health & safety regulation going, because of a fear of the media getting hold of some ingredient scare story which might implicate them and thereby affect turnover. These people drive the whole chemophobic situation, and it was the education of fragrance buyers (to the reality of the allergens situation) Prof. Axel Schnuch drew attention to in 2008 (Schnuch 2008).

Reference.

Schnuch A. (2008) – remarks attributed to Schnuch by the trade media during the IFRA workshop on Allergy Prevalence in Fragrance Nov. 2008 e.g. by Montague-Jones in *Cosmetics-Design Europe* 18.11.2008

§8. IFRA's 44th Amendment - What's bin did and what's bin hid*

*with sincere apologies to Donovan!

We are looking below at three further proposed IFRA Standards under the forthcoming 44th Amendment, which have recently been circulated to IFRA membership groups for comment, with a 3rd June 2009 deadline. During the course of these examinations we continue our efforts to bring privately held evidence on health & safety legislation into the public domain, in order that decision-making the process becomes transparent.

Vanillin – Some Brief Notes.

The first consideration is a proposed new IFRA (restrictive) Standard for vanillin. Readers will be aware that amongst flavour & fragrance ingredients, vanillin is possibly the most important aromatic aldehyde, with its easily recognisable & attractive powdery sweetness. It is available as a natural product via isolation from the vanilla pods of *Vanilla planifolia* G. Jacks, in which it occurs at up to 23,000 ppm, & via various biofermentation routes from natural starter materials. The production of vanilla itself was estimated at 2,000 tons in 2001 (Biolandes

2001), with 70% of the total production going to the US & Canada. Production rose to 3,600 tons in 2008 (Manceau 2009), but there are problems ahead, including pricing & compositional issues for vanilla from Uganda & Papua New Guinea, the effects of Madagascar's political crisis, and from the damage caused by the fungi *Fusarium oxysporum* & *Phytophthora* spp. infecting Malagasy vanilla vines (see Gleason 2009; Manceau 2009). This is sufficiently serious that Dominiques Roques of Biolandes (through Gleason 2009) estimates a 1,200 ton/annum vanilla production loss from *Phytophthora* infection. Perfumery ingredients produced from *Vanilla* spp. (absolute, oleoresin, tincture, oil, CO_2 extract etc.) are too familiar to describe in detail here. Vanillin also occurs as a minor component of a number of essential oils (e.g. star anise, clove bud & asafetida oils), and in absolutes, and balsams (e.g. Peru balsam, benzoin Siam, benzoin Sumatra).

The production volume of the cheaper & more easily available synthetic vanillin (which has previously run at approx 1% of the price of natural vaniilin) has been estimated at about 6,000 tons/annum, & the material has been historically prepared from feedstocks such as guaiacol, catechol, *ortho*-dinitrochlorobenzene & lignin. Opdyke (1977) previously found vanillin to be relatively non-toxic, non-irritant & non-sensitising. The OECD SIDS report on >99% pure vanillin (20.08.1996) concluded that in animal tests, vanillin was sensitising in 5 out of 10 studies, but was not sensitising in the only test conducted under GLP. Vanillin was also said to be non-sensitising at 2% in maximisation tests carried out on 25 human volunteers.

According to information seen by Cropwatch, the true situation may be even more complex, since in trials with human volunteers >99% pure vanillin ex lignin was found to be non-sensitising, whereas vanillin ex guaiacol. or via the former *ortho*-nitrochlorobenzene process, provoked sensitising reactions in some individuals. Vanillin prepared from certain natural sources may also be slightly sensitising [of the 110 separate *Vanilla* spp., only 3 are cultivated: *V. planifolia* G. Jacks (Bourbon or Indonesian vanilla), *V. tahitensis* Moore (Tahitian vanilla), and *V. pompona* Schneide (Guadeloupe vanilla; vanillons; W. Indian vanilla). Eighty percent of vanilla production occurs in Madagascar; other producing areas include/have included Uganda, Papua New Guinea, Comoros & Reunion (the latter producing vanilla "Bourbon"), Java, Tahiti, Martinique, India (production hit by *Fusarium* infection), Sri Lanka, Tanzania & the Seychelles].

Cropwatch believes that there is more to learn about the alleged weakly sensitising properties of vanillin, and the effects of minor impurities, just as was about coumarin, although this has still to be recognised by the legislators.

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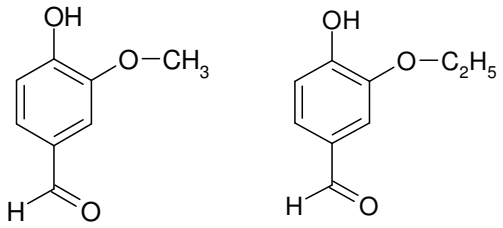

vanillin ethyl vanillin

Vanillin – Uses in Perfumery.

Vanillin, the key odorous material of vanilla pods, has played a major role in perfumery since it was first synthesised in 1876. It has been the foundation of the oriental fragrance family formed from accords of vanillin, balsams, spices, patchouli, woods, salicylates and citrus oils. *Jicky,* created in 1889 by Guerlain was the first major oriental fragrance founded on this accord; a family of wonderful oriental fragrances, employing large amounts of vanillin, soon followed. Some of the landmark fragrances in the oriental family, both male and female, are listed below:

Emeraude (Coty 1921)
Shalimar (Guerlain 1925)
Old Spice (Shulton 1937)
Youth Dew (Estee Lauder 1952)
Opium (YSL 1977)
Samsara (Guerlain 1989)
Obsession (Calvin Klein 1985)

In the early to mid 1990s a major vanillic trend was founded on an overdose of vanillin and vanilla. Beginning with *Vanilla Fields* (Coty 1993), a host of sweet vanllic floral and vanillic floriental fragrances were launched e.g. *Tocade* (Rochas 1994), *Loulou Blue* (Cacherel 1995), *Le Male* (J. P. Gautier 1995), *Allure* (Chanel 1996), *Ghost* (2000). This trend of the 1990s has lead to a general sweetening of fragrance styles, (and consequently a generally higher use of vanillin), which is apparent today in the myriad of oriental masculine styles (e.g. *212 Sexy for Men* 2006) and fruity floral feminine types and fruity florientals (e.g. *Delicious Night* DKNY 2007).

Vanilla themes, with vanilla as the key ingredient, have universal appeal in home fragrances: candles, pot pourris, reed and aerosol air-fresheners. Sweet foody themes such as chocolate, cookies, toffee, and even berry notes, which are widely found in foam baths, shower gels and shampoos are heavily dependent on the use of vanillin.

Vanillin under IFRA's 44th Amendment.

IFRA's newly proposed restrictions under the 44th Amendment for the extremely weak sensitiser, vanillin, seem to be largely based on three reports, two of which are internal RIFM reports (and one of which is only in draft form). These are not freely in the public domain. These are as follows:

Basketter D.A., Wright Z.M., Warbrick E.V., Dearman R.J., Kimber I., Ryan C.A., Gerberick, G.F., White I.R. (2001). "Human potency predictions for aldehydes using the local lymph node assay." *Contact Dermatitis*, **45**, 89-94.

RIFM (Research Institute for Fragrance Materials, Inc.), 1970. Maximization study with vanillin. RIFM report number 1760, October 7. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2009. Human repeated insult patch test. DRAFT REPORT. (RIFM, Woodcliff Lake, NJ, USA).

It is impossible for fragrance companies to approve or make comment on the scientific robustness of the evidence for making these restrictions, if they cannot see all the evidence. It would seem important therefore IFRA/RIFM to make these studies available in the public domain, especially since the newly reported evidence flies in the face of previous conclusions about the sensitising potential of vanillin. It is slightly unclear, too, whether the newly proposed IFRA Standard just refers to deliberately added vanillin in fragrance compounds, or to the total vanillin content of the fragrance (i.e. including contributions from vanillin-containing natural materials).

Restrictions on vanillin concentrations in fragrances will further limit the art of the possible in fragrance creation – and for what reason? Fashionable fragrances employing high levels of vanillin (see above) have not resulted in a spate of adverse consumer reactions or queues at dermatology clinics.

As a final point, many have written in to Cropwatch pointing out that the toxicological investigation / restriction of components which are found in natural complex materials, is being pointedly pursued, whereas the toxicology of closely related & commercially available synthetic materials is being ignored. In this particular case, no mention is made of the any investigation of closely related synthetic, **ethyl vanillin**. Good to see people are thinking for themselves, but previous investigators [e.g. Patlewicz *et al.* (2001) & Basketter *et al*. (2001)] found ethyl vanillin to be non-sensitising, which may rather deflate the argument! Other investigations which show a similar lack of breadth in the selection of natural & synthetic ingredients to investigate, include the studies made by Hagvall *et al*. regarding possible mechanisms for dermal sensitisation by linalol & geraniol (see updated Cropwatch article at http://www.cropwatch.org/The%20Trouble%20with%20Oxidation%20of%20Essential%20Oils.pdf). We have also been treated by the academics concerned, via the trade press & websites dealing with health matters, to opinions about what these studies indicate for the users of cosmetics containing linalol- & geraniol-rich essential oils. Regarding the linalol studies, to our knowledge no investigation has been made of the widely-used & closely related synthetic, **ethyl linalol**, and many have concluded, rightly or wrongly (& bearing in mind their reported remarks in the press) that these researchers are riding on an anti-naturals ticket. Cropwatch considers a more likely explanation is that the academics concerned have a limited experience of the cosmetics trade & the available choices of commercial aromatic ingredients.

Estragole (methyl chavicol).
The draft document showing the IFRA proposal for the restriction / prohibition of **estragole** to 0.02% in fragrance compounds looks like an unfinished piece of work. The grounds cited for the restriction / prohibition, are those of alleged carcinogenicity, but, somewhat surprisingly, no supporting evidence or references are supplied in the circulated draft of the new Standard.

The restrictions, if applied to the total estragole content of a fragrance compound, including naturally-occurring estragole from natural ingredients and not just to added estragole, will severely impact on the use of those essential oils in which estragole naturally occurs in cosmetic products. These include star anise (to 6.4%), exotic basil (to 90%), fennel sweet (to 6.4%) and tarragon (to 82%), as well as more minor amounts in bitter fennel, cananga & ylang ylang oils & absolutes, and the oils from certain *Pinus* spp. The point was also made by Cropwatch at the SCS Symposium (Burfield 2009) that limitations on substances like safrole, methyl eugenol & estragole have already had significant effects on the fragrance styles entering the marketplace - traditional aromatic masculine fougères and rich spicy notes are very difficult to achieve at the so-called 'safe' levels for these materials. There is little prospect of substitution either – the contribution of estragole, for example, to the odour profile of naturals and finished fragrances, is virtually irreplaceable. So here we have another prospect of IFRA further restricting the art of the possible in the fragrance art with the progressive introduction of their restrictive Standards.

So what is the evidence? Animal experiments using high doses of estragole have led to its classification as a possible weak genotoxic hepatocarcinogen (SCF 2001). Other expert committees have come to different conclusions. The FEMA Expert Committee concluded that dietary exposure to estragole did not constitute a cancer risk, and ventured that a non-linear relationship exists between dose, profiles of metabolism, and covalent binding of estragole to protein and DNA (Smith *et al*. 2002). We in the aroma industry do not need to be caught in the crossfire of differing toxicological opinions anymore – rather we need firm evidence that this same situation (of zero cancer risk) does not similarly apply to bio-available estragole from the application of estragole-containing fragrances to human skin.

Benzaldehyde.
Continuing the potential damage to the usage of natural aromatic products, IFRA are also introducing a new Standard limiting benzaldehyde concentration in fragrance compounds. Benzaldehyde is, of course, the major component in bitter almond oil, and is used to create almond and cherry notes in perfumes & flavours. Because of its pungency and odour character, it is also used in reodourant perfumes. Benzaldehyde is a minor component of many other natural products, including cinnamon leaf oil; cassia oil; cassie, narcissus & champaca absolutes; some cistus oils; clove oils & rosewood oil. Natural benzaldehyde is available from peach, cherry & plum stone processing, and via biofermentation routes e.g. starting from natural cinnamaldehyde ex cassia oil.

The grounds for the proposed restriction of benzaldehyde in perfume compounds by IFRA are based on the alleged weak sensitising properties of benzaldehyde, for which three references are quoted by IFRA:

Basketter, D.A., Wright, Z., Gilmour, N.J., Ryan, C.A., Gerberick, G.F., Robinson, M.K., Dearman, R.J., Kimber, I., 2002. "Prediction of human sensitization potency using local lymph node assay EC3 values." *The Toxicologist,* **66**(1-S), 240.

RIFM (Research Institute for Fragrance Materials, Inc.), 1973. Maximization study with benzaldehyde. RIFM report number 1802, October 11a. (RIFM, Woodcliff Lake, NJ, USA).

RIFM (Research Institute for Fragrance Materials, Inc.), 2009. Human repeated insult patch test. DRAFT REPORT. (RIFM, Woodcliff Lake, NJ, USA).

Again, the clincher for many of us in being able to judge the robustness of the scientific evidence necessitates the public availability of the draft RIFM report listed above.

Comments.

In conclusion, these three IFRA proposals appear to be incompletely assembled and over-hastily produced. As we previously noted, until we know any further judgement from the EU legislators on the acceptability of the corporate-science styled QRA technique (following the SCCP's severe criticisms in SCCP/1153/08), it would seem expedient to hold back on the implementation of this further set of IFRA Standards, if only to avoid unnecessary industry costs. Any communication on these matters from the authors of documents cited above, from RIFM or from the EU Cosmetics Commissioner, will be circulated by Cropwatch.

References.

Basketter D.A., Wright Z.M., Warbrick E.V., Dearman R.J., Kimber I., Ryan C.A., Gerberick G.F. & White I.R. (2001) "Human potency predictions for aldehydes using the local lymph node assay." *Contact Dermatitis* **45**(2), 89-94.

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(Burfield 2009) – see
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Smith R.L., Adams T.B., Doull J., Feron D.J., Goodman J.I., Marnett L..J., Portoghese P.S., Waddell W.J. *et al.* (2002) "Safety assessment of alkyloxybenzene derivatives used as flavouring substances –methyl eugenol & estragole" – *FCT* **40**,851-870

§9. Herbal Medicine Petition.

The following 'round robin was received by Cropwatch as we go to press. For obvious reasons, we thought it worthy of inclusion. The text reads as follows:

“The Government wish to further regulate Herbalists by bringing them under state control, protecting both the function and title of a Herbalist. Alongside this regulation they wish to change the Herbal Medicine laws again to prevent anyone, other than a state regulated herbalist (or possibly other health professional), from prescribing herbs. This, coupled with a previous change to our herbal medicine laws, will take Herbal Medicine away from the people, with state regulated Herbalists and pharmaceutical companies claiming Herbal Medicine as their own. http://www.gopetition.com/petitions/support-herbal-medicine.html

Please pass this link and information onto as many people (patients, family, friends, practioners, MP's, MEP's, media) as possible. Thankyou.”