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

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Cropwatch Claims Victory Regarding "26 Allergens" Legislation.

[Modified from article originally written for *Aromaconnection*, Feb 2008].

Pre-amble. Cropwatch has been campaigning for a number of years to reverse the EU's "26 allergens" legislation, founded as it is on "bad science". Cropwatch was assured in a face-to-face meeting with the EU Cosmetics Regulator in Brussels in late 2007 that this subject would be re-examined, and it appears that this is now the case, as the EU Commission have reportedly agreed to consider the Schnuch evidence (see below). If this is all the evidence on alleged allergens that the Commission is going to review, it will be a disappointment, since further scientific papers on fragrance chemicals originally misclassified as allergens by the SCC(NF)P are piling up, as indicated below.

To recap (Burfield 2008), 26 alleged allergens, 16 occurring in natural complex substances, were identified in SCCNFP Opinion 0329/00 (rubber stamping previous IFRA-RIFM information) and passed into EU legislation under the Directive 2003/15/EC, amending Directive 76/768/EEC. **The criteria for the inclusion of these materials as allergens by the SCCP has never been satisfactorily explained.** The legislation requires a labeling obligation for finished cosmetic products containing any of the 26 identified allergens present at 0.01% in products rinsed off the skin, or 0.001% in leave-on products.

Several years on from the passing of Directive 2003/15/EC and the publication of Schnuch's opinions in 2004, we learn that EFFA have (at last) contacted DG-Enterprise asking for labeling requirements for ten allergens to be reconsidered. These ten substances are **benzyl alcohol, benzyl benzoate, methyl heptine carbonate, hexyl cinnamal, anisyl alcohol, linalool, benzyl salicylate, amyl cinnamal, limonene & γ-methyl ionone**. This is apparently in the light of Scnuch (2007) identifying these materials extremely rare sensitizers, and in 3 cases, not sensitizers at all.

The Schnuch Evidence (taken from Burfield 2007). The July edition of the German consumer magazine *Öko-Test*, No. 7/2004, 55, reported on studies done by the IVDK, an information network association of dermatologists, headed up by Prof. Schnuch. It concluded that not all the 26 allergens identified by

SCCNFP Opinion, and enshrined in the 7th Amendment to the Cosmetics Act, bear the same risk, and criticises the EU Commission for treating them all as equal. The report classifies allergens accordingly.
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Ingredient type	Strong potent allergens (I)	Less potent allergens (II)	Rarely found as allergens (III)	Risk of being allergens to small to consider (IV)
Naturals	oakmoss, treemoss			
Synthetic fragrance materials also occurring in complex biological substances	isoeugenol, cinnamic aldehyde	cinnamic alcohol,	citral, eugenol, farnesol	benzyl alcohol, benzyl salicylate, geraniol, anisyl alcohol, benzyl benzoate, benzyl cinnamate, citronellol, d-limonene, linalool, coumarin
Synthetics		HMPCC, hydroxyl-citronellal	lilial, methyl heptine carbonate	amyl cinnamic alcohol, hexyl cinnamic aldehyde, alpha-keton

Table 1. Classification of the '26 allergens' according to IVDK, 2004

The Oko-test report for July 2004 gives details on criteria & an internal ranking system for allergic fragrance ingredients. This penalises the presence of strong allergens (column I above) by two points & penalizes less potent allergens by one point (column II above). Weaker (column III) allergens do not gather points but must be named. Non-allergens (column IV) do not gather points or have to be named.

Schnuch *et al.* (2007) report in a further study conducted in four periods of six months from Jan 2003 to Dec 2004, on the frequency of sensitisation to the 26 allergens. The authors conducted the patch-testing studies with a large number of consecutive, unselected patients with suspected allergic dermatitis to these 26 compounds. Schnuch *et al*. concluded that for some of the alleged allergens amongst the 26, neither restriction nor labeling seem justified, and that EU regulators should review the previous decisions taken.

Further Evidence (taken from Burfield 2007). Hostynek & Maibach have critically reviewed the evidence on SCCP alleged allergens, and called into question whether a number of fragrance substances can actually cause allergic contact dermatitis, in a series of articles:

Anisyl alcohol (Hostynek & Maibach 2003a)
Amylcinnamic aldehyde (Hostynek & Maibach 2003b)
Linalool (Hostynek & Maibach 2003c)
Geraniol (Hostynek & Maibach 2004d)
Citronellol (Hostynek & Maibach 2004e)
Alpha-iso-methyl-ionone (Hostynek & Maibach 2004f)
Methyl heptine carbonate (Hostynek & Maibach 2006).

Reviewing the scientific evidence for geraniol, for example, Hostynek & Maibach conclude that they found no cases where a patient had been brought to a clinic directly because of geraniol contact dermatitis. The authors go on to discuss patch-testing mixtures in general, where concentrations of elicitating chemicals are deemed too high, which decreases specificity without greatly affecting sensitivity. Consumers, they argue, may acquire benign allergies after everyday exposure to low doses of geraniol, which are only revealed under patch-testing conditions.

Storrs (2007) also comments that dermatologists help patient's needs most, when they critically evaluate patients reactions. Storrs concludes that positive reactions to patch-testing (using fragrance mixes) rarely indicates clinical contact dermatitis caused by specific fragrance ingredients.

The position of **pure coumarin** as non-allergen has been extensively reviewed by Cropwatch at http://www.cropwatch.org/Coumarin%20-%20the%20real%20story%20update.pdf Aroma trade associations have tried to belittle the finding that pure coumarin in not an allergen, by stating that the situation of coumarin's non-allergy may only apply to (pure) Rhone-Poulenc derived material. However the status of coumarin-containing natural materials, like lavender absolute & tonka bean absolute (previously found non-sensitising by RIFM, remember), is far from clear. Is it safe that finished fragrances containing these coumarin-containing substances as ingredients, have to be labeled to show the presence of allergens, as required under the EU Cosmetics Directive, or not? The EC's regulations may have advanced, but the necessary scientific credibility is not there.

Friedrich *et al.* (2008) looking at a number of **monoterpenes** using the rat Popliteal Lymph Node Assay (PLNA) concluded that although citral, α-terpinene, β-myrcene and (-)-α-pinene induced a clear immuno-stimulatory response due to their irritant properties, no monoterpene proved to be a sensitizing agent in the PLNA. Further work may reinforce the hypothesis whereby weak irritants such as citral above are often misclassified by techniques such as the LLNA as weak or moderate sensitizers. Again it underlines the point that we may have been misled by a culture of toxicological imperialism, into forms of precautionary fragrance ingredient legislation which may not ultimately prove to be scientifically robust.

SCCP 'Out of Touch'.

Although the chairman of the SCCP was quoted as saying words to the effect that he expected the 26 allergens legislation to have little effect on industry, it subsequently lost the industry € millions in labeling & reformulating costs, computer reprogramming costs & lost revenue to natural ingredient producers, as nervous perfume buyers initially demanded the elimination of all allergens from their suppliers' fragrances, on the basis that by operating this policy, they would escape media attention in the event of any adverse effect complaints about their products. When fragrance houses started offering substandard perfumes as a result of leaving out natural materials containing those dreaded allergens, perfume buyers started to realise that they would have to allow at least some allergens to be present. Although it may not generally realised, a second list of alleged allergens (Frosch *et al*. 2002) was quickly drawn up by some prominent toxicologists 'jumping on the bandwagon' (the authorship team including Ian White, the Chairman of the SCCP). This paper included a number of ingredients rarely used in perfumery, and the paper itself was riddled with scientific errors of fact. So, this further list of alleged allergens was quietly dropped, following the industry storm that the original 26 allergens legislation had created.

Trade Bodies Now Show Signs of Schizophrenia over Allergens.
Cropwatch believes corporate toxicologists and industry-funded-bodies such as EFFA are still actively trying to-, sneak further allergens into the Cosmetics Directive by the back-door, under the guise of 40th IFRA amendment / QRA methodology. As evidence of this, you will remember that EFFA recently submitted evidence to the SCCP on farnesol, phenylacetaldehyde & citral using QRA based methodology (see Cropwatch objection at http://www.cropwatch.org/objectcitral.pdf). It is difficult to see whose interests they are serving by doing this, and why the sudden volte-face by EFFA now, over 10 of the 26 alleged allergens.

If EFFA had supported Cropwatch to change the 26 allergens legislation over the past 5 years that we have been campaigning, we might have saved a lot of damage to the perfumery art, & to the fragrance industry in particular. Perhaps then, it is time for EFFA to support Cropwatch on citrus furanocoumarins issue too, before we have a similar situation of EFFA having to conduct a publicly embarrassing U-turn in 5 years time on that issue as well.

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