



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

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## **SCCP Opinion on Citral, Farnesol & Phenylacetaldehyde: Objection to IFRA's Divisive 40<sup>th</sup> Amendment Structure being used for EU Regulatory Purposes.**

**Cropwatch Aug 2007.**

### ***Executive Summary.***

*The request for a SCCP Opinion for a safety risk assessments of 3 potential fragrance sensitizers citral, farnesol & phenylacetaldehyde, under the guise of using the corporate toxicologist-derived QRA assessment system as a vehicle, is a way of sneaking in further controversial legislation on allergens by the back-door. Given the widespread opposition to IFRA's complex 40<sup>th</sup> Amendment, the framework of which has been used by EFFA to set out proposed restrictions, it is quite unforgivable that other interested parties have not been contacted besides EFFA, and in any case Cropwatch maintains that the correct Rules of Procedure have not been followed. To avoid further controversy, DG-Ent/SCCP need to clearly set out & review the basis on which fragrance chemicals have previously been classified as allergens, before embarking on any further restrictions for citral, farnesol & phenylacetaldehyde. The EU Commissioners need to reflect on the fact that the level of red-tape involved in rubber-stamping IFRA-EFFA QRA-based assessments like this one, will further help destroy what's left of the European perfumery industry, or further drive it out to places like India, China, South America or the Far East, where less stringent levels of health & safety regulation apply.*

### ***Introduction.***

An opinion for a safety risk assessment of 3 fragrance ingredients: citral, farnesol & phenylacetaldehyde, has been put to the SCCP, as notified on the EU website at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_q\\_173.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_q_173.pdf). The assessment is important because it is the first to use the QRA system of risk assessment. EFFA, apparently by invitation from the Brussels regulators, have provided a scheme which sets the concentration limits for these materials according to eleven categories of individual product types, largely based on extending IFRA's 40<sup>th</sup> Amendment format, itself largely derived from the assembled corporate toxicologist's schematic from the 'QRA Expert Group' (Api *et al.* 2006).

This Cropwatch objection is principally concerned with fact that the private-industry sponsored IFRA's organisation's controversial, industrially divisive and red-tape-intensive 40<sup>th</sup> IFRA Amendment cannot be used for regulatory purposes on the basis that it discriminates against SME's. As it is, Cropwatch's campaigning against the 40<sup>th</sup> Amendment earlier in 2007 forced IFRA on to the back foot, and they had to hastily provide an extensive lead-in period for SME's unable to cope with the considerable demands of the Amendment. Further, the EU website item mentioned above describes IFRA restrictions for citral & phenylacetaldehyde, and includes material from the Inventory Part II, apparently using the abandoned quenching hypothesis, which IFRA themselves have publicly indicated they do not support – a statement to this effect can even be found on the bottom of the May 2006 40<sup>th</sup> Amendment IFRA standard for citral. Although this is typical of the sort of technical sloppiness & inattention to detail we are used to seeing from Brussels, legally it renders the request for a SCCP opinion technically incompetent, and needs rewriting, as it does not honestly reflect the actual state of belief & industry best practice as communicated by IFRA, and as understood by the trade.

To further this last point above, Cropwatch was assured by Takis Daskaleros at the Cropwatch-Perfume Foundation-EU Commission meeting in Brussels on 3<sup>rd</sup> July 2007, that DG-Ent/SCCP does now possess the capability to independently conduct a literature search on regulatory matters, thereby, presumably, decreasing reliance on being spoon-fed selective information by IFRA/RIFM/EFFA and other interested industrial lobbying groups. These seem to be empty words from Dr. Daskaleros, otherwise the EU website item would reflect the fact that there is another side to the argument which has not been featured in the questions put to the SCCP. This especially relates to citral & farnesol – but only 40<sup>th</sup> IFRA Amendment-styled material is represented, and this looks like a clear bias towards IFRA policies. So, the EU website material should have included the important & widely circulated contrary opinion by Schnuch *et al.* 2004, that citral & farnesol are rarely found as allergens, so should not have attracted restrictive legislation, and over which the EU should reconsider its previous decision. Not to properly represent all available facts & opinions is an unforgivable misuse of power by Brussels, which will further destabilise traditional long-standing Industries as already previously identified by Cropwatch. As a further point, in their own terms of reference, the SCCP are looking at considering the safety of the ingredient “taking into account the scientific data provided.” Cropwatch is pointing out that If the scientific data already provided to the SCCP is selective, as is the case here, then an unbiased expert opinion cannot be reached.

### ***Rules of Procedure Not Observed.***

Cropwatch would also like to point out that the Legal Procedure Re: Requests for SCCP Opinions in relation to Risk Assessment (C7 2004 D/370235) have not been observed in this current request.

The Rules of Procedure for a Request of a Scientific Opinion put to the SCCP chair via the Secretariat require not only a Terms of Reference statement, but further requirements to state the Community Interest and the Scientific Background. It seems that neither of these requirements have been fulfilled on the EU website item about this matter, to date anyway.

The Rules of Procedure also state under rule 17 (b) “Diverging Scientific Opinions” that when the Secretariat is informed of “divergence or risk of divergence between the opinions of one of the scientific committees and an International or community body”, the chairs will seek to either “avoid or resolve the divergence”. The rule further states that “in particular the chairs should make a preliminary assessment of the nature of the divergence, advise on the need for a joint meeting with the parties concerned and on the committees and members to be involved.”

Cropwatch has a problem here with the SCCP continuing to use as chair-person of the SCCP, someone who is clearly not a disinterested party (namely Ian White) particularly over the subject of allergens, and judging by remarks made in the public domain, is not impartial in this matter either. Further, since Ian White authors/co-authors published papers on allergens, Cropwatch maintains that he is not an appropriate person to judge evidence which is essentially competitive or conflicting to his own findings or views. We therefore believe that Ian White should stand down from committee work involving SCCP Opinions which involve allergens, to avoid any public perceptions of the possibility of bias.

The “26 allergens” legislation as enshrined in the 7<sup>th</sup> Amendment to the Cosmetics Directive remains one of the most controversial & poorly scientifically justified pieces of regulation which the EU Cosmetics Commission has had the misfortune to be responsible for, and any further compounding of the situation by passing more legislation about sensitizers is to be strongly resisted. This current request for a further SCCP Opinion, potentially regulating more alleged fragrance sensitizers, clearly qualifies under the Diverging Scientific Opinions, set out under Rule 17 (b) above. Further the Oko-Test results of Schnuch *et al.* (2004) represent a challenge to the existing “26 allergens” legislation, which needs to be reviewed. Cropwatch’s popular campaign against the 40<sup>th</sup> IFRA Amendment, the public support & press coverage on the matter cannot be ignored. Since Cropwatch is clearly amongst the principle players in this issue, we would like to take this opportunity to formally ask DG-Ent why they have not have not asked for our input.

### **Additional Information.**

*Citral* is a mixture of two acyclic monoterpenoids, neral & geranial, which can be regarded as branched chain aliphatic unsaturated aldehydes (*cis*- and *trans*-3,7-dimethyl-2,6-octadien-1-al). Citral occurs widely in varying component isomer ratios in natural products including citrus oils, lemongrass oils, *Litsea cubeba* oil, black pepper oil, verbena oil, melissa oil etc. etc. In layman’s terms, most people

are regularly exposed to citral - hand exposure occurs when peeling & cutting citrus fruits like oranges & lemons, and citral is regularly imbibed as a natural or synthetic flavouring component of fruit-based or fruit flavoured soft drinks.

*Farnesol* a common sesquiterpene alcohol component of many essential oils, the isomers of which may be typically be found to 4.5% in neroli oil, and to 1% in rose oil. *E,E*-farnesol also occurs in *Santalum spicatum* extract (Australian sandalwood “oil”) to approx 5%, which distinguishes it from the lower concentrations found in the oil of *Santalum album* (E.I. Sandalwood).

*Phenylacetaldehyde* has a piercing green odor, which on dilution is reminiscent of hyacinths, and is a minor component of many essential oils and fruits – for example it occurs at up to 5% in the headspace of the sweet-pea blossom, *Lathyrus odoratus*.

### **Background.**

Quantitative Risk Assessment (QRA) methodology was recommended as a result of progress of the COLIPA Toxicology Advisory Group and the Joint COLIPA/AISE/EFFA/IFRA Perfume Safety Group to address dermal sensitisation risk assessment for fragrance ingredients. The QRA is basically an exposure based methodology for dermal sensitisation risk assessment, a key component of which is consideration of the dose (of sensitiser) per unit area to determine sensitiser potency. The QRA methodology is enshrined in IFRA’s 40<sup>th</sup> Amendment, which is an immensely complex system applied to eleven categories of fragranced products, plus sub-categories, instead of two previously (skin contact/no contact). It involves costly software modifications for the computer systems of all IFRA-compliant companies, and IFRA modifications keep on coming. No-one is quite sure why the previous, simple & eminently satisfactory leave-on/wash off system for skin exposure of fragrance chemicals was supplanted. Under the complex QRA system, no perfumer can keep the safe usage levels of ingredients in their heads like they used to be able to under the old leave-on/ wash-off rules. Perfumery has thus become a software operation and perfumers merely drones, operating the software. We can only assume that the pressure to change to the 40<sup>th</sup> Amendment methodology has been for political reasons rather than any pretence of improving consumer safety, best summed up by Cropwatch’s conjecture that aroma industry regulation has been hi-jacked by a culture of toxicological imperialism. The styled questions to the SCCP are a manifestation of this culture.

### **Opposition to 40<sup>th</sup> IFRA Amendment.**

Europe is already a hostile environment for perfumery, and the imposition of the 40<sup>th</sup> IFRA Amendment on the perfumery community has been met with large-scale opposition, since it gives a profound advantage to the aroma Megacorporations. This is because only these large companies have the resources to cope with the immense amounts of red-tape generated by IFRA, EFFA & the EU, and they are rapidly growing by swallowing up the smaller

companies who are unable to cope. Indeed Bleimann (2007) has remarked with words to the effect that at this rate that there will soon only be four or five large corporates left in the aroma business.

In spite of bullying & coercion of the trade press & identifiable trade organisations into supporting these measures, opposition to the 40<sup>th</sup> IFRA Amendment has been such that 928 perfumers, soap-makers, small crafters and essential oil sellers & end-users have signed a petition against it (see <http://www.ipetitions.com:80/petition/ifra40/index.html>); and many have privately resolved not to implicate it. Any potential use of IFRA's 40<sup>th</sup> Amendment by the EU Commission therefore would be seen as the EU supporting big industry against the SME's in a most economically divisive manner. And if this measure for citral goes through according to the IFRA blueprint, another 40-45 other alleged sensitizers are poised to follow (Troy 2007). It therefore poses the question of how much further perfumery ingredients can be regulated by the EU before the perfumery industry collapses altogether. Already fragrance industry sales have been essentially flat for a number of years, speaker after speaker took the podium wringing their hands over the on-going situation at the World Perfumery Congress in 2007, whilst international companies are locating their major functional operations to locations outside Europe, where fragrance regulation is more proportional to the actual safety risks presented.

***Cropwatch Recommendations for Investigation of Citral, Farnesol & Phenylacetaldehyde as Sensitizers.***

1. Before considering regulating further sensitizers such as citral, farnesol & phenylacetaldehyde, the SCCP needs to clearly & comprehensively set out the basis on which fragrance substances are classified as allergens (Storrs 2007) from its present haphazard approach, which caused so much turmoil in the industry when the "26 allergen" legislation was first introduced under Directive 2003/15/EC, amending Directive 76/768/EEC. The SCCP also needs to review its previous opinions on allergens SCCNFP/0017/98 & SCCNFP/0421/00 to regain its credibility, since it previously included non-allergens, and allergens too weak to be classed as allergens, in its previous Opinion (Schnuch *et al.* 2004). In particular it should be noted that few, alleged allergens identified by the SCCNFP (apart from isoeugenol, cinnamic aldehyde, treemoss & oakmoss) have been directly connected with cases of clinical allergy.

2. The SCCP needs to pro-actively seek out **all** the opinions on the potential of citral, farnesol & phenylacetaldehyde as sensitizers, rather than be spoon-fed & eventually to rubber-stamp the evidence as provided by career toxicologists assembled under the IFRA/EFFA umbrella. For example, the authors of a recent publication on phenylacetaldehyde as a sensitizer (Sanchez-Politta *et al.* 2007) indicates that there is little independent peer-reviewed evidence to support such a classification. On the other hand there are several cosmetic materials classed as strong sensitizers in the US (Burfield 2007) which are unrestricted by the EU

Cosmetics regulators, possibly because of the latter's over-obsession with dermatological matters in general, & alleged allergens in particular.

Cropwatch Team.  
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