

www.cropwatch.org



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

E: info@cropwatch.org

T: ++44 (0)7771 872 521

Mrs. S. Lecrenier,
European Commission,
Head of Unit F3,
Cosmetic & Medical Services,
DG Enterprise,
BREY 10/169,
1040 Brussels.

3rd September 2009

Dear Ms Lecrenier,

I am responding to your mail to Cropwatch of 27th May 2009, regarding the proposed regulation of furanocoumarins (FC's) within the Cosmetics Directive. The proposals contained in your mail have caused some confusion for the industry, since the line restricting the seven proposed FC markers (bergapten, bergamottin, byakangelicol, epoxybergamottin, isopimpinellin, oxypeucedanin & xanthotoxin) to 1ppm is in apparent conflict to the other lines in the proposal, which limit the concentration of the sum of these markers from natural essences to 5 ppm in leave-on products, and 50 ppm in rinse-off products. Further, we consider that the inclusion of chemically unstable FC markers (such as byakangelicol, and to a lesser extent, bergamottin) is of dubious safety value, and that this proposed legislation is over-hasty, since the overall risk/benefit effects of many FC's have not been adequately evaluated by the Commission - SCCP Opinion 0942/05 for example failed to provide any direct evidence whatsoever of in-vivo human photo-carcinogenicity from FC's, and its conclusions are at variance with the findings of other researchers such as Chouroulinkov et al. (1989), Dubertret et al. (1990) & the EMEA (1990)(see attached file). Moreover, it is still the case that no single in vitro test currently exists which can predict the photo-carcinogenicity of furanocoumarins, and that photoclastogenicity has

been associated with other very commonly used cosmetic materials such as zinc oxide and titanium dioxide (see attached file). Cropwatch does not understand why investigations into the risks posed by these inorganic materials has not been undertaken, and why it always natural aromatic ingredients which seem to be selectively singled out for investigation.

Cropwatch is opposed in principle to any proposal to regulate the FC contribution from natural ingredients within fragranced products, & our view includes the opinions of much of the natural perfumery trade (which is largely unrepresented within organisations such as IFRA, EFFA & within corporate perfumery). We feel that a labelling solution, advising users to cover up affected skin areas from actinic light for 12-24 hrs after application of FC-containing fragrances would adequately address any alleged photo-toxicity concerns. This is already best practice in aromatherapy where massage clients are treated with FC-containing citrus oils (up to 2.5% in carrier). Further, a labelling solution would also prevent accusations of 'cultural vandalism' by the EU Cosmetics Commission, if these proposals to drastically limit FC's in fragranced products result in the effective removal of indispensable natural (citrus) ingredients. This outcome would cause the disappearance of complete classes of fragrances such as Eau de Colognes, Eau Fraiche and citrus-based compositions. Further, we have identified officials within the EU Parliament who are very concerned about the effect of such proposals on the cultural heritage and art of perfumery, a topic which we believe needs to be further considered by the EU Commission.

Since there was little comprehensive information available within the public domain on FC contents of natural perfume ingredients, and we found little knowledge of the subject amongst the professional perfumers that we contacted, Cropwatch has assembled some databases on the subject (one such is attached) which additionally contain some critical comments & over-views. Even now, only the larger aroma concerns have the (expensive & sophisticated) equipment required to accurately determine FC concentrations in natural ingredients and finished perfumes. So these proposals, if passed into EU legislation, would be very divisive, since they will economically discriminate against small citrus oil producers and SME's (- COLIPA has, we believe, previously commented on the socio-economic responsibilities of the Cosmetics Commission when considering the passage of this type of legislation). Cropwatch has further looked into claims made by leading aroma companies that the flavouring industry had solved the problem of FC removal from citrus oil ingredients

several years ago, and found that the claim was largely unsubstantiated.

Lastly Cropwatch is concerned that evidence may be submitted to the SCCS, which is not freely available within the public domain, and that the SCCS may use such unseen evidence on which to base their opinions. One such piece of evidence (on DNA-bergamottin interactions) by Prof. David Kirkland of Covance Labs, commissioned by RIFM, has been summarised in an IFRA newsletter, but the experimental details have not been fully disclosed. Both the author of the work and RIFM have refused requests by Cropwatch to view the data. We feel that the non-publication of any such secret safety data which may be submitted to the SCCS (for their eyes only), would be completely unacceptable where matters of public safety are concerned, and would not fulfill the requirements of complete transparency.

Best regards,

Tony Burfield
Co-founder Cropwatch
www.cropwatch.org