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

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05.05.07

Dear Sabine Lecrenier,

Thank you for your electronic mail to Cropwatch of 26.04.2007. Cropwatch is deeply concerned about the lack of fairness in dismissing/ignoring our main points in the FCF citrus oil crisis situation, and we doubt strongly that it is actually in your brief to potentially destroy the stability of the perfume industry by effectively banning citrus oils on the basis of flimsy and largely unproven concerns about FCF phototoxicity. In view of the wide-spread concerns from our members and the industry as a whole on these points we have taken the decision to copy this mail to the EU Ombudsman which we will follow up shortly in a visit to Brussels. .

In your mail of 26.04.2007 you indicate that evidence over what you term 'the safe use' of the furanocoumarins (FCF's) angelicin, bergapten, xanthotoxin, psoralen, oxypeucedanin and epoxy-bergamottin has not been provided to the SCCP, and that you invite Cropwatch to submit evidence before April 2007 end, or face regulation of FCF's to 1ppm in final cosmetic products. We also understand from your mail that 'part of industry' has submitted evidence to the SCCP on isopimpinellin & bergamottin, although we are apparently not permitted to see it.

Several matters arise from the unworkable regulatory position described above.

1. Cropwatch has been actively speaking with citrus producers, but the current round of talks will not end until May end 2007 - as you will appreciate much of the

citrus industry is not European-based, and communications with non-European citrus producers cannot always be quickly arranged. It is not until this on-going round of talks ends, that the next move can be decided.

2. The basis on which many individually purified FCF's are concluded to be potentially photo-carcinogenic in SCCNFP/SCCP Opinion's such as SCCP 0942/05, is not sufficiently scientifically robust, the data is sparse & incomplete, and does not, for example, allow for the matrix effects in complex biological materials in which they occur, thought to be particularly important here. The SCCP has been swayed by a conventionally-fashionable suspicion of FCF photo-carcinogenesis, rather than any solid proof. This is an insufficient basis for any form of proposed regulatory restriction and from my experience in dealing with a large number of prominent aroma concerns, it won't be widely accepted.

2. In general, we consider these regulatory proposals for restriction of FCF contents in finished cosmetics to be over-hasty, ill-conceived and inappropriate. This is not helped by the fact that there is no comprehensive data source which indicates the actual distribution of FCF's with respect to variations across oils from citrus varieties, geographic, climatic & seasonal factors, and expected concentrations of FCF's in single expressed oils (pellatrice, sfumatrice, scorzella, machine process etc), the various concentrated (partially deterpenated) oils, terpeneless oils, sesquiterpeneless oils, solvent extracted oils, distilled oils, reclaimed oils etc. etc. Industry therefore is not equipped & cannot adhere to these restrictions because of a basic lack of information about FCF levels in aromatic ingredients.

3. If these proposals do go ahead, the measures spell the end of traditionally prepared natural citrus oils as perfumery ingredients. The new proposals may create some demand for 'FCF-free' processed citrus oils, which we now understand are anyway generally not FCF-free as claimed, and which are just pale olfactory shadows of real cold-pressed citrus oils, their performance in product does not substitute for cold-pressed oils, & neither are their keeping qualities as good. Furthermore, FCF-free oils are frequently adulterated with synthetics - something that your expert committees (whom we believe are completely reliant on what industry tells them), will probably not be aware of. FCF-free bergamot oil is a particular case in point - and in adulterated form, the ingredient is simply not acceptable in Natural Perfumes.

4. In your letter to Cropwatch 11.12.2006, you personally undertook to ensure a public consultation on the economic impact of these measures because of the threat of financial discrimination against small citrus producers. We will hold you to this promise. Can you confirm that you intend to keep this promise and if so, have any moves in this direction yet been taken?

5. If individual FCF's are found to be present in cosmetics on analysis, it is not technically possible in all instances to ascribe a citrus or non-citrus origin for

them (possible exception: angelicin). Therefore the SCCP's proposal to limit FCF's to 1ppm in finished cosmetics potentially affects all other natural ingredients from the Apiaceae & Rutaceae, and a social impact assessment on non-citrus FCF-containing aromatic ingredient producers and possible effects on their livelihoods & dependents needs to be carried out, in line with the European Union's commitments to Human Rights..

In recent days, Cropwatch's attention has been drawn to data which extends the occurrence of FCF's in natural ingredients considerably further than our previous summary at <http://www.cropwatch.org/newslet3.htm> which at the time we believe was the most comprehensive available. We intend to analyse and confirm this data, and issue an update if necessary

6. The European Commission previously handed out funds to Italian bergamot growers in 2002, at a time when phototoxicity issues surrounding bergamot oil usage were as clearly appreciated & understood as they are now. Your new proposal to limit certain naturally occurring FCF's in cosmetics will, of course, include those present in bergamot oil.

These two developments above are at cross-purposes – and your latest restrictive proposals on FCF contents will clearly put immense pressure on the Italian & Ivory Coast bergamot industries, and the local S. Italian fragrance industry which features high proportions of Italian citrus ingredients.

7. We would like an explanation as to why Cropwatch's independently assembled proposal for labeling warnings for cosmetics containing FCF's has been ignored, rather than rely on expensive technological processing to give a physical reduction in concentration (the only option to not using FCF-containing ingredients at all). Accepting for a moment that there is the immeasurably small theoretical transitory risk to fragranced cosmetics users of developing photocarcinogenesis from FCF's from natural aromatic ingredients, why isn't a warning label to avoid actinic light for 12-24 hrs after dermal application of a FCF containing cosmetic deemed to be sufficient in this situation?

You may note this suggested labeling approach has been adopted elsewhere to indicate phototoxicity risk e.g. in Tasmania in 2001 where the statement "Application to skin may increase sensitivity to sunlight" exempts the product from National Drugs & Poisons scheduling.

The Commissioners Needs to Explain.

Cropwatch supporters have repeatedly made the following points to us, to put to you directly.

1. The Brussels regulators need to demonstrate to an immensely skeptical public, using a proper risk analysis based explanation, why putting a couple of dabs of a citrus oil-containing perfume behind the ears or across the wrists is

suddenly putting EU citizens at risk of a photo-carcinogenic health development, when the fragrance-using public believes that they already indulge in far more 'dangerous' activities, such as peeling an orange, slicing out a grapefruit or pressing a lime. Is the act of preparing home-made marmalade or making real home-made lemonade now going to be banned in the EU as an unacceptably dangerous activity, via FCF exposure to bare hands and arms? Are citrus fruit pickers at occupational photo-carcinogenic risk from FCF's and if so what measure are in force to protect these workers? Do citrus groves or orangeries, or indeed spiceworks & herb farms, which all have FCF-secreting plant parts need to be marked off with warning Hazchem symbols? The answer is 'of course not' - so why apply these illogical restrictions to fragrances?

2. Could we be given even one clear cut case-study, where a perfume wearer has developed a photo-carcinogenic health problem through wearing a modern citrus oil containing fragrance? The fragrance companies we have privately contacted have been unable to provide a single instance of such an occurrence, and there is a concern that these proposed restrictions refer purely to sophisticated toxicological constructs which are purely in the land of fantasy.

3. In aromatherapy general practice, in a global context, some tens of thousands of people per annum receive a whole or part body massages with diluted citrus oils in vegetal carrier. This practice hasn't caused a documented photocarcinogenic risk – massage recipients are merely told to keep away from actinic light fro 12-24 hours. So why does a dab of citrus oil containing cosmetic/perfume present more of a risk, than this unregulated and apparently safe practice? It makes no sense.

Previous matters.

Cropwatch would also like to re-present & ask for follow up on some points from its previous mails & reports, which the Cosmetics sector regulators seem to have been ignoring.

1. The regulators & 'expert' committees need to clearly spell out, why they do not carry out a risk-benefit analysis on individual cosmetic ingredients, and merely concentrate on an exaggerated form of precautionary-principle based risk assessment. It appears that the EU Cosmetics sector is quite out of step with best available practice in not carrying out this type of analysis, as is currently applied to other industries & professions (this week, for example, risk-benefit analyses are being applied to novel agricultural crops).

Mr Carvalho, in his letter to Cropwatch of 15.02.2006 suggested that "It is up to the European Commission, on the basis of SCCP Opinions (risk assessments) to take the appropriate measures related to cosmetic ingredients after discussion with the authorities of Member States (risk management). It would be in this framework that the precautionary principle would be applied by the risk manager, as would be a risk-benefit analysis." However, after a depressing talk with

Brussels insiders, I have yet to be convinced that a risk-benefit for any single cosmetic ingredient has ever yet been carried out - certainly I cannot find evidence of one within any EU Cosmetic sector material available in the public domain.

2. Whilst EU Commissioners have pledged their faith in SCCP 'expert' Opinions, many parts of industry have the direct opposite view, & after a series of errors and instances of lack of cosmetic industry knowledge, Cropwatch previously asked for a review of the SCCP Opinions by an independent expert committee. In reply, you (Sabine Lecrenier) in a letter to Cropwatch on 11.12.2006, stated "within the SCCP rules of procedure hearings with industry or other special interest groups are foreseen. I will therefore pass on your request to the secretariat of the SCCP (Directorate General Health and Consumer Products)." We would like to know the outcome of this eventuality please.

3. The regulators need to explain why cosmetic ingredients are so heavily over-regulated compared with flavouring ingredients, when so many ingredients are identical to both industries, and cause the same adverse atopic reactions whether taken orally or applied to the dermis. We can only conclude that the SCCP/DG Ent is unfairly biased against the cosmetic ingredient industry, or is over-zealous & unbalanced in its regulation of this same industry. This situation needs urgent independent appraisal, not ignoring or "sweeping under the carpet".

4. We maintain that European citizens have the inalienable Human Right to buy 100% natural perfumes should they so wish, and this matter should be tested in law. The increasing demand for natural perfumes (and even organic perfumes – see trade press) is living proof of this growing consumer demand which reflects individual lifestyle preferences. The European Cosmetics regulators are consistently regulating against natural aromatic products via their obsessional pre-occupation with precautionary principle based safety legislation, which is leading to an ever-increasing synthetically based, ecologically unsound and non-green orientated scenario for perfumery.

Since consumers of natural commodities are aware that 'natural' doesn't always equate with 'safe', a new set of rules or a specific EU Directive needs to be urgently drawn-up for this type of natural product, otherwise manufacturers will produce perfumes which do not conform to restrictive European regulations (as is already starting to happen). My personal view is that this situation is a wake-up call to the European Commission - otherwise it will become increasingly irrelevant to modern European society.

I hope to get the opportunity to discuss these matters with you in person at some point – certainly it is widely agreed that the FCF issue is the most important matter ever to affect the perfumery trade.

Yours sincerely,

Tony Burfield
Co-founder of Cropwatch
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