

## **Over- Regulation is Destroying Natural Aromatics.**

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### **Abstract.**

Influential career toxicologists, using the precautionary principle as a regulatory ramrod, have been influential in forcing the aromatics trade to go through a critical period of excessive 'safety' regulation, resulting in depletion in both the range & volumes of essential oils, absolutes & resinoids actively deployed in retailed cosmetics. This has been achieved within the EU Cosmetics Sector via the Brussels Hyperbureaucratic Machine, & affects areas such as sensitisers, REACH, & 'dangerous preparations', as well as the ever more technocratic edicts from aroma-connected organisations e.g. EFFA Codes of Practice & IFRA Standards. Incredible demands have been resultantly heaped on aroma traders & producers, as well as cosmetic manufacturers, who are completely hamstrung by red tape & many of whom are unable to function without complex regulatory software programmes. As a result, many aroma ingredient manufacturers have moved out of this hostile European jurisdictional environment to relocate in more industry-friendly places such as India or China, which have the additional advantage of lower investment & operating costs. Within the aroma concerns themselves, the rise of newly important posts, like that of the 'Regulatory Affairs Manager', has further devolved focus and power away from perfumery excellence, as company executives worry more about anti-fragrance campaigners, regulatory compliance & possible litigation, than they do about the integrity of the perfumery art. . Those natural aromatic ingredient producers adversely affected by over-regulation, either inside or outside the EU, are scarcely acknowledged & certainly not compensated or helped financially to produce regulatory complaint materials. This results in social hardship for local communities dependent on income from these ingredient producers, and the loss of sustainability for some threatened species; however nobody in authority responsible for this state of affairs, seems to express either the slightest interest, let alone regret.

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## **§1. Cropwatch: A very brief description.**

Cropwatch [www.cropwatch.org](http://www.cropwatch.org) is an Independent Watchdog for the aroma trade, established between 2003-2004. Cropwatch aims to ensure the sustainability of natural product usage in our daily lives, resist threats (over-exploitation, bio-piracy) to rare & threatened aromatic species by industry, and resist regulatory threats from ill-conceived & restrictive legislation. Cropwatch has no formal membership and is non-financed, but has a Newsletter subscriber list, & we believe that the Newsletter currently reaches some 30,000 people. Cropwatch benefits from private views & evidence forwarded by many senior technical staff in the aroma industry & related professions, and this will progressively help to challenge the existing 'closed-shop' nature of aromatic ingredient regulation.

## **§2. The Demise of the Cosmetics Industry.**

### ***Size & condition of the aroma trade market.***

Accurate figures are hard to obtain, but (Wundu 2000) states that world demand for essential oils grew at an average 6.1% between 1993 to 1998. Similarly older figures for the year 1998 (taken from UN Yearbook 1999) shows the chief essential oil exporters to be the EU (52%), followed by the USA (13%), and then China, Indonesia, India & Brazil, for the year 1998.

At a press conference at IFT (2007), according to the SAFC, the global flavours & fragrances market is estimated at \$15.5 billion to \$16.3 billion, of which raw materials account for \$2 billion. Future dominance is predicted to be in natural flavours, which are expected to outstrip sales of synthetic flavours & perfumes by 2010 (through *P&F*now 2007). Redhead (2007) comments that the international flavourings industry was worth £3.6 billion in 2004. The SAFC also comment on downward pressure on pricing, & chillingly comment on fragrance & flavour houses exiting the aroma chemicals business.

Cropwatch has previously indicated that the aroma industry is currently in a desperate position, with mergers & acquisitions reducing the number of operating companies and available jobs. Advertised vacancies are for regulatory experts; nobody is looking for perfumers & technical staff. Red-tape bound Europe has become the most hostile environment for the trade on the planet, a situation which has afforded no obvious benefit to either public safety or to industry, & which has resulted in much manufacturing moving away to places like Asia, S. America & China. Whereas Europe used to benefit from gaining added value from aromatic raw materials – by producing isolates etc. – this is now being done at source.

Bleimann (2007) mentions nine factors which currently cover the market volatility & adverse operating conditions for essential oil supplies, including the rise of internal domestic markets in India & China, rises in crude oil prices (therefore leading to increased distillation cost) & steel prices (therefore rising drum costs), the profitability of growing crops other than essential oils, & the effects of severe European weather on availability.

### **US situation**

Perfume formulations are considered proprietary & therefore a trade secret in the US, and cosmetics do not have to be safety tested before placing them on the market, as the FDA in the US does not actively regulate the cosmetic industry (de Groot & Frosch 1997, Daum 2006). Ingredient restrictions or bans only apply to the following ingredients: bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes in aerosol cosmetics, chloroform, prohibited cattle materials (BSE related), methylene chloride, chlorofluorocarbon propellants, hexachlorophene, & methyl methacrylate monomer in cosmetic nail products (FDA 2006). This situation may change: a recent deal on confidential exchange of information on development & market approval procedures for cosmetic product regulation between EU Commissioners & FDA officials is reported in the trade press (Anon 2007), and from 1<sup>st</sup> Jan 2007 US companies that manufacture/market cosmetic ingredients will be asked to commit to the CTFA Consumer Commitment Code which involves manufacturers marketing only after safety testing has been undertaken & with a commitment to participating in the FDA Voluntary Cosmetics Reporting Program. This is aside from international harmonization moves under ICAP which include the US (CTFA), Europe (COLIPA), Canada (CCTFA) & Japan (JCIA).

However, for some aromatics on sale to the general public, including bottled essential oils and products containing the same, the FDA and the US CPSC (United States Consumer Product Safety Commission) do have specific authority to regulate in matters of consumer safety, as some aromatherapy suppliers are currently finding out (Kirkham 2007). The CPSC administers both the Federal Hazardous Substances Act (FHSA) and the Poison Prevention Packaging Act (PPPA)

Hazardous substances as defined by the CPSC under FHSA regulations that are not labelled in compliance with the FHSA and/or that are not packaged in accordance with the PPPA are classed as “misbranded hazardous substances”, and as such are prohibited. Incorrectly labelled oil of wintergreen (or any product containing >5% methyl salicylate) has been one recent example picked up by the FDA. “Strong sensitizers” under FHSA 16CFR1500.13 include powdered orris root, p-phenylenediamine & containing products, formaldehyde & products  $\geq$  1% formaldehyde, & oil of bergamot & products containing 2% or more of it, come under regulations for “strong sensitizers” and need to display appropriate labelling.

Turning to food flavourings, Smith *et al.* (2004a) set out the evaluation criteria for the safe evaluation of flavouring substances used by GRAS. In a further review Smith *et al.* (2004b) describe a safety evaluation procedure for natural flavour complexes as food ingredients, focussing principally on essential oils; this type of evaluation running in addition to the case-by-case evaluation scenario carried out by FEMA. In this former methodology, the safety intake from consumption of the

essential oil into a series of congenerenic groups is evaluated in the context of data on absorption, metabolism, and toxicology of members of the congenerenic group. Cropwatch has queried FEMA experts on whether this approach is flexible enough to take account of adverse drug interactions produced by natural complex substances e.g. flavanoids from grapefruit juice or furanocoumarins from grapefruit juice oil & peel oil. Further Cropwatch has queried the under-considered role of flavourings as a source of allergens and their role in atopic dermatitis & other adverse reactions.

### **Japan.**

Japan is the 3<sup>rd</sup> largest market for cosmetics after the EU & the US & re regulated under the Pharmaceutical Affairs Law. The importation & sale of cosmetics is done under a licensing system, and a positive list of approved ingredients is used to govern formulation (there is no negative list). Labelling is carried out in quite specific way.

### **Canada.**

A new version of the Cosmetics Ingredients hot list was issued in Mar. 2007, and includes restrictions on eucalyptus oil, tagetes oil, camphor, methyleugenol & other naturals. The Canadian Cosmetics Regulations are displayed at <http://laws.justice.gc.ca/en/showtdm/cr/C.R.C.-c.869//?showtoc=&instrumentnumber=C.R.C.-c.869>

### **The EU situation.**

In contrast to the US, the EU Commission is very pro-active in the cosmetics & toiletries regulation area. Fragrance regulation in the EU has not been delineated from Cosmetics regulation, as was originally intended. An unfortunate consequence of this is that many major fragrance application areas are not regulated under any one Directive e.g. the 1976 EU Cosmetics Directive & its subsequent amendments. Therefore detergents (which come under EU Detergents Regulation EC 648/2004), household cleaning products, aerosol products, reodourants, environmental (room) fragrances, pot-pourris, scented candles, incense and more (many of these coming under the EU Dangerous Preparations Directive 1999/45/EEC) are treated separately. These non-cosmetic preparations are largely non-regulated unless they contain identified allergens (R43's) present at over 1% in which case the preparation must be labeled & classed as R43 (an allergen), or contains "allergens" (R43's) at over 0.1%, in which case the substances in the preparation must be named, and a warning given that the substance may be allergenic. Detergents which have substances classed as allergens present at over 100ppm (EU Detergents Regulation EC 648/2004) must also should appropriate labelling. Except for products designed for hand-washing, the necessity for the latter obligatory labeling seems to be arguable, since fabrics washed with fragrance allergen-containing detergents do not retain sufficient levels of residual allergens to initiate dermal sensitisation (Corea *et al.* 2006). The Human & Environmental Risk Assessment of household cleaning products group (HERA) has notably carried out voluntary program of

risk assessments on behalf of members of the International Association for Soaps, Detergents & Maintenance Products (AISE), on human & environmental risks for detergent ingredients including isoeugenol & hydroxycitronellal (HERA 2007)

There is good reason to believe that, as far as Brussels is concerned, the regulatory separation between fragrances & cosmetics has not occurred because the value of the fragrances sector market is regarded as miniscule by the EU Commission. This is a pity, because an EU Fragrance Commission could lay the framework of sensible safety policy whilst maintaining the opportunity for perfumery excellence; something denied us at present from progressive (& often nonsensical) ingredient restrictions. It could also cover & protect the art & cultural heritage aspects of perfumery, and consider the socio-economic & ecological aspects of its decision-making.

So, why has so much undue toxicological attention been paid to fragrance? The answer is simply because it has become an easy target. In Europe we hear far less about other cosmetic sensitizers such as lanolin, lanolin alcohol being one of the top ten allergens (Oppel & Schnuch 2006), latex (Poley & Slater 2000, Neugut *et al.* 2001), detergents (Poulsen *et al.* 2000) & fabric conditioner chemicals, which are designed to be substantive and therefore possibly problematic, dyes (perhaps with the exception of *p*-phenylenediamine, another of the top ten allergens, according to Oppel & Schnuch 2006) and preservatives of which several are known allergens (including methylidibromo glutaronitrile & methylisothiazolinone & formaldehyde donors such as imidazolidinyl urea & 2-bromo-2-nitropropane-1,3-diol). The failure to label these sensitizers for consumers in Europe contrasts with the US situation where some of these materials are regulated as “strong sensitizers” (see below).

Considering the prevalence of latex allergy in particular (1% to 6% of the population is allergic, rising to 10-17% amongst health care workers: AAAIA, through Kirkwood 2004), it is hardly surprising latex articles are banned in some US hospitals. Rather, the question is: why sensitization labelling is not mandatory for items such as latex gloves, condoms & balloons, like it is for some of the weak allergens enshrined in EU regulations? The SCMP did produce an Opinion on latex labelling in 2000 (SCMP 2000), but no action has resulted from this. The state of current toxicological awareness also seems to have underplayed the strong possibility that vegetable oils & fats can not only be used to reduce irritation & sensitization (Schliemann-Willers *et al.* 2002), but also that lipid-based vehicles (creams, lotions) may affect frequency of any adverse effects from alleged sensitizers themselves..

Furthermore, sensitization & allergy from dietary intake - a major subject involving many of the same alleged sensitizer chemicals as we meet in fragrance allergy - is all but unexplored, although strategies for their elucidation exist (Arcella *et al.* 2005). For some major sensitizers like Peru balsam (PB), “hypersensitivity reactions to PB from oral uptake in systemic contact allergy

cases are often overlooked.” (Pfutzner *et al.* 2003a; Pfutzner *et al.* 2003b). However evidence of the benefits of specifically avoiding flavourings in special diets, which may include the total avoidance of PB, is not clear e.g. on the one hand it has been found beneficial by Veien (1985), but not beneficial in all delayed-type allergy cases by Niinimaki (1995). Salam *et al.* (2001) publish evidence on a reported improvement in 50% of contact allergy patients on a balsam-avoidance diet.

Generally however, existing EU food intolerance data regulation is mainly concerned with whole food materials and not any individual allergenic substance. The reason for this is that the food lobby is cash-rich & powerful, and legislation in this area would be unthinkable as it would interfere with an individuals’ right to free choice. For some reason, this is not so in cosmetics, where the trade is effectively bullied by the powerful combination of career toxicologists, dermatologists & EU lawyers.

### **EU: REACH.**

As this is an ‘expanding wallets’ area for regulatory affairs consultants on both sides of the pond, we will not spend too much time on the topic as it has been well-aired already. A few points, however, will not go amiss. Firstly, that the REACH regulations, which came into force June 1<sup>st</sup> 2007, and apply to enterprises importing or manufacturing over 1 ton of chemical substances or essential oil/annum, won’t apply to food & animal food flavourings, for political, rather than scientific reasons, nor will they apply to natural aromatics used for medicinal (both human & veterinary) purposes.. Christophe Maubert of Robertet is quoted (Branna 2007), as telling the WPC audience at Cannes in June 2007 that REACH could be a death sentence for many essential oils & absolutes, a view already held by many in the trade. Currently REACH will apply to just under 150 essential oils.

Secondly, REACH won’t, apparently, apply to turpentine oil. As Bleiman (2007) points out, the European Chemicals Agency (HQ for these functions) is located in Helsinki, Finland, and turpentine is Finland’s chief export. Bleiman has also pointed out that the main components of turpentine oil are classified as marine pollutants. Other commentator’s suspect that wood-pulping industry money is somewhere behind this exclusion, but, in any event, it is not possible to pretend this particular anomaly is marked down to any good scientific reason. Given the corruption scandals that have rocked the reputation of the EU Commission over the past couple of decades, we are all waiting to hear a mitigating explanation.

Thirdly, the amount of animal testing to meet REACH data requirements has been predicted to rise dramatically pre-introduction (although there is little time left to effect this). The Vegan Society has made the case that environmental testing of cosmetic chemicals carried out by any company using *Daphnia* (i.e. Ecover) means that the much sought-after Vegan Society labelling logo “not animal tested” cannot be used (Hellqvist 2007). A Vegan Society executive has

defined 'animal' as "the entire Animal Kingdom, that is all vertebrates and all multicellular invertebrates." (Winter 2007).

### **IFRA/RIFM**

Aside from the EU Commission, IFRA (established 1973, Geneva) is also a leading player in the fragrance ingredient regulatory scenario, claiming that 80-90% of perfume sold globally emanates from companies with IFRA membership (N.B. Cropwatch has yet to meet anyone in the trade who upholds the validity of this claim). A system of voluntary regulation to the IFRA Standards by members has operated for many years, based on recommendations following ingredient safety testing studies by RIFM of New Jersey (established 1966). Individual fragrance ingredients are evaluated in isolation, and historically have employed animal testing methodology (now apparently described as "bad science" by a senior scientist at the EU Commission, according to Antidote 2007). In contrast to the isolated evaluation of single aroma substances, a typical fragrance might contain 70 or more of such ingredients, and inter-actions, matrix effects, & toxicological effects at typical deployment concentrations are not routinely considered or evaluated.

The RIFM Materials Inventory (accessed by RIFM members only, or by members of the American Contact Dermatitis Society etc.) currently contains information on some 2600 tested fragrance materials, out of a possible 5,000 plus ingredients used worldwide. Some of these items are no longer used, and of the remainder, most are synthetic. It is alarming how such repositories of safety information are increasingly in private hands, and can only be accessed by interested parties paying money.

An IFRA Compliance Policy (policing the membership's adherence to its Standards) was initiated in May 2006. The Policy involves a programme of third-party analyses of fragrances produced by IFRA members, carried out by Batelle of Switzerland, who isolate the fragrances from retailed products marketed in various countries. Non IFRA-compliant perfumes from members may result in naming & shaming, or worse. This policy arises from not trusting IFRA members to self-police themselves, & blows apart any continuing claims by IFRA of voluntary regulation in the aroma industry.

Further, it is becoming increasingly apparent to many, including Cropwatch, that there is a lack of scientific consensus among many technically aware staff in the aroma trade, regarding the risks attributed to individual ingredients as presented by IFRA/RIFM. This is important because some of these findings are subsequently incorporated into EU Directives (after rubber-stamping by the SCCP). Cropwatch's mail bag includes many well argued private opinions disagreeing with IFRA/SCCP/EU positions, as well as helpful articles & data, from leading toxicologists, technologists, regulatory affairs staff, as well as salespeople & marketing personnel within this industry. These people feel themselves 'in denial' because they are unable to 'go public' & openly express

their opinions, and given this situation, which borders on a sort of collective trade schizophrenia. It seems incongruous therefore that an authoritarian IFRA Compliance Policy can exist in these circumstances, and it also seems incongruous that there is no mechanism for dialogue on the issues that trouble these people. The situation is dishonest, unhealthy & undemocratic. Staff in SME's feel less constrained, as is witnessed by the 928 signatories to a Cropwatch petition against the implementation of IFRA's 40<sup>th</sup> Amendment (see signatories & their comments at <http://www.ipetitions.com/petition/ifra40/signatures.html>). However, even here, the end-result is the same – IFRA did not acknowledge receipt of the petition when sent, and have remained non-communicative to any Cropwatch mail on the subject.

Those few individuals who have been brave enough to express an alternative viewpoint from RIFM in the past (e.g. Curtis 2004).have been haughtily dealt with in print (e.g. by Smith 2004). However even RIFM's stuffy put-downs, such as the reply by Ladd Smith indicated above, are capable of bringing a smile to the lips of some of us old-timers! Smith writes that “The RIFM's comprehensive, logical, and documented research methods are modelled after the National Academy of Sciences' (NRC) Elements of Risk Assessment and Risk Management (NRC 1994).” That's an improvement, then, since Opdyke's time, where he led us all a merry dance for years with the (now discredited) ‘quenching phenomena’ (Opdyke 1976) – as nobody at RIFM could find the original workers' experimental notes or reproduce their results. Even now, those of us trying to follow toxicology matters via published scientific papers, frequently encounter references which merely state author, year & “unpublished evidence to RIFM”. In our view, “comprehensive. logical & documented research methods” only have value if publicly available for study & have been properly evaluated amongst peers. Secondly, we consider that much of RIFM's work on adverse safety attributes of natural aromatic materials can be consigned to the bin – invariably the originating aromatic species has not been properly identified at source by an experienced botanist, the substance has not been audit tracked to ensure no adulteration or degradation has taken place, it has not been independently analysed to make sure that the material is 100% botanically derived and that it has the correct authenticity indicators present. For synthetics, identification of the impurities is absolutely essential, but was almost never properly carried out. This is especially relevant in today's situation, since relocation of the fragrance chemicals industry from the West to India, China, etc. may mean that raw materials now have a different spectrum of impurities to when RIFM originally tested them. It goes without saying that all too often, the minor impurities have been responsible for adverse safety effects ascribed to the whole substance.

### ***Natural aromatic ingredient traders.***

Traders of Natural Complex Substances have not helped clear the paperwork jungle either. Technical staff in trading SME's are not necessarily free to do the jobs they were originally employed to do, but spend a considerable part of their

time filling out futile & insulting paperwork (such as 20-30 page ingredient product questionnaires) which invariably accompany natural ingredient sales contracts. This endless form-filling has become a buck-passing exercise between producers, traders, customers and health officials, each attempting to absolve themselves of any responsibility whatsoever, for everyday working transactions.

As an example of this, and where aromatic ingredients are sold as food or animal feed flavourings, food Intolerance data under EU Directive 2003/89/EC (amending 2001/13/EC) may require the supplier to give details on the presence or possibility of cross-contamination of a number of food sensitizers (such as sesame seeds, gluten etc.). In practice it may mean that we all waste our time writing out certificates to the effect that our traded consignments of *Eucalyptus globulus* oil don't, in fact, contain any lupins.

### §3. The Precautionary Principle.

A communication concerning the Precautionary Principle approach was published by the EU Commission on 02.02.2000 (see [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf)) which was rapidly adopted. It requires proportionate, non-discriminatory, transparent and coherent actions be taken for the management of risk based on a structured decision-making process with detailed scientific and other objective information.

However, what has actually happened within the EU Cosmetics Commission Sector is inconsistent with the approach above. Lobbying groups, including career-motivated professional toxicologists & dermatologists, have frequently provided selective information on the alleged toxicology of specific aromatic ingredients, and the Commission has been pressurized into inappropriate action for the sake of perceived political correctness. The SCCP judges the evidence so-presented, but it is a body which collectively lacks many of the cross-disciplines needed to carry out this function satisfactorily. Further, the SCCP have been reliant on being spoon-fed the evidence, rather than carrying out their own independent literature searching to find key documents. Indeed over many issues, it is apparent that the SCCP has merely rubber stamped IFRA standards, or in one or two memorable cases, has directly adopted text from 'the Gospel according to David Basketter' (a well-known toxicologist). The evidence considered by the SCCP is not always publicly available, as is presently the case with RIFM's secretive submission to the SCCP concerning FCF's: photo-clasticity studies on isopimpinellin & bergamottin. 'Expert' committee decisions are taken without a risk-benefit analysis being conducted, and Cropwatch has been directly told that the EU is not in the business of statistically quantifying consumer health risks from individual ingredients. Cropwatch was also advised (by Takis Daskaleros, Brussels meeting, July 2007) that end-user adverse effects are also **not** considered as bona fide toxicological evidence, & this is in spite of a previous request from the Commissioners asking Cropwatch if our end-user adverse reactions survey for tea tree oil amongst aromatherapists was ready yet (correspondence Feb 2007)! It begs the question of whether we are wasting our

time partaking in some elaborate game with hidden rules, & what the point is, exactly, of submitting evidence to the EU Commissioners, if it is going to be quietly dismissed.

**Quote:** Frank Kafka: "...it must be suspected that, paradoxically, that these (scientific) fundamentalists have contributed in creating or preserving the most fearful & oppressive fictions."

Cropwatch believes that the EU Commission should apply a precautionary approach to safety risk assessment & management which highlights the areas of uncertainty and absence of information, which will then provide a much better basis for decisions about whether to proceed. At present, pressure to proceed is unrelenting, even in the absence of comprehensive toxicological or product analysis data e.g. over the intention to restrict FCF's in cosmetic products to 1ppm.

**Quote:** Fenn R.S. (2005) "Europe's obsession with the precautionary principle is stultifying our creativity" *Perfumer & Flavorist* vol 30 (Jan/Feb 2005) p 25.

#### **§4. The 26 Allergens Debacle: Bad Information = Bad Regulation.**

Some considerable space is given to this topic because of the devastating effect the EU '26 allergens' legislation has had on the trade (including relabelling & reformulating costs, computer reprogramming costs & lost revenue to essential oil producers as nervous perfume buyers initially demanded the elimination of allergens from their suppliers' fragrances).

##### ***Initial developments.***

Danish dermatologists had previously persuaded the EU authorities that fragrance allergy was a serious health issue, and that fragranced cosmetics needed to be labelled for commonly employed frequent fragrance sensitizers. This lobbying resulted in one of greatest 'jolts' to the fragrance industry: the passing of the so-called '26 allergens' legislation. Alleged allergens were identified in SCCNFP Opinion 0329/00 and passed into EU legislation under the Directive 2003/15/EC, amending Directive 76/768/EEC. This effectively required a labelling obligation for final cosmetic products containing any of the 26 identified allergens present at 0.01% in products rinsed off the skin products or 0.001% in leave-on products. Sixteen of these alleged allergens were found in Natural Complex Substances, but the EU regulators decided that no distinction would be made concerning the origin of the substances. Therefore the regulation can apply to essential oils & essential oil blends used for a cosmetic purpose, just as much to synthetic or part-synthetic fragrances, or indeed to their artifacts. As a result of their Opinion, the SCCNFP "did not consider that the production of essential oils would be threatened" by this measure, although of course they had no actual qualification in this area to predict this outcome. IFEAT famously disagreed (IFEAT 2002) and sure enough, as a consequence of perfumers employing fewer naturals due to customer pressure, volumes of traded essential oils markedly dropped in 2000-2002 and essential oil-trading companies folded.

Luckily a second list of alleged allergens mentioned in a subsequent flawed publication (Frosch *et al.* 2002), and which included the SCCP chairman, Ian White, amongst its authorship, was never actioned, because perhaps even the non-scientific staff in Brussels realized that this area was becoming highly controversial. Or maybe they had spotted some 'howlers' in the Frosch published paper, via the tendency to cite unsupported information from technically dubious references. So, for example, we learn from Frosch *et al.* that patchouli oil was claimed to contain cinnamic aldehyde, benzaldehyde & eugenol, and that Atlas cedarwood oil contains alpha-ionone! Sandalwood oil is also claimed to contain geraniol & citronellol (!), and the main components of spearmint oil are limonene, 3-octanol, methone and dihydrocarvone (but no mention of the major item carvone!). Basic errors of fact such as these, apart from reflecting poorly on the cross-disciplinary knowledge of the collective authors, also points to the low standards of refereeing in professional peer-reviewed dermatology magazines.

However Troy (2007) tells us that there are another 40-45 or so fragrance compounds which have been tentatively identified as sensitizers, waiting for eventual inclusion into IFRA Standards. It remains to be seen whether what remains of the perfume industry will have the courage to resist any more of this toxicological imperialism, and if IFRA and the EU come to realise that if they regulate this industry much more, there will be no industry left.

### ***The case of coumarin.***

Coumarin was one of the substances cited in the SCCNFP position paper for Fragrance Allergy in Consumers (SCCNFP/0017/98 final Dec 1999) as being a skin sensitiser, this also being the conclusion of previous COLIPA and RIFM opinions. A list of natural complex materials containing coumarin was previously published by Burfield (2006), and includes, flouve, foin, cassia, lavender & tonka bean qualities. Previous work by Malten *et al.* (1984), de Groot *et al.* (1988), Larsen *et al.* (1996), & Van Joost *et al.* (1985) on alleged coumarin allergenicity was reviewed by Floc'h *et al.* (2002), who commented on the lack of scientific rigour, found no statements of the purity of the materials previously used, and questioned the homogeneity and the stability of the coumarin in petrolatum suspension. Floc'h further indicated the above work failed to distinguish allergy to coumarin from cross-reaction to allergens for which coumarin might be an indicator. The SCCP Further Opinion on Coumarin as a sensitiser SCCP/0935/05 (adopted 20<sup>th</sup> June 2006) considers whether coumarin of >99.99% purity had any sensitising properties, & if it doesn't, whether the Opinion on Fragrance Allergy SCCNFP/0017/98 would need to be changed. The committee concluded that coumarin of 99.9% purity when patch tested at 2% would be able to elicit allergic contact reactions in humans, but Cropwatch suggests they only came to this conclusion because they misunderstood the data on pure coumarin from Vocanson *et al.* (2006) – also see summary attributed to Floc'h (2006). An expected further article on pure coumarin's non-allergenicity from Vocansen *et al.* should make the fact that coumarin is not an allergen, even clearer.

In support of the above hypothesis, the failure of coumarin to produce reactions in LLNA tests, or in Fragrance Mix II positive subjects has been noted (Frosch *et al.* 2005). Similarly, as can be seen below, several of the 26 sensitizers have been deemed too weak to justify inclusion (geraniol, benzyl benzoate, anisyl alcohol etc.). It is particularly worrying to Cropwatch that members of the SCCP who judge the evidence presented are not disinterested parties in this matter, and have applied dual standards to their Opinions on sensitizing ingredients compared with Opinions on other cosmetic ingredients (possibly to shore up their reputations).

### **Dissent against the ‘26 allergens’ issue rises**

It has never been clear on what basis the SCCNFP had decided on those allergens to be included in their Opinion 0329/00 (Storrs 2007), and indeed many contrary opinions were provided at the time e.g. by Basset (2002), Duclos (2003), Chavigny (2002), Roberts (2002), PCA (2002), Subrenat (2001), and they keep coming, even now e.g. the Hostýnek & Maibach series (2003, 2004), Basketter (2005), Schnuch *et al.* (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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| <b>Ingredient type</b>                                                               | <b>Strong potent allergens (I)</b> | <b>Less potent allergens (II)</b> | <b>Rarely found as allergens (III)</b> | <b>Risk of being allergens to small to consider (IV)</b>                                                                                    |
|--------------------------------------------------------------------------------------|------------------------------------|-----------------------------------|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Naturals</b>                                                                      | oakmoss, treemoss                  |                                   |                                        |                                                                                                                                             |
| <b>Synthetic fragrance materials also occurring in complex biological substances</b> | isoeugenol, cinnamic aldehyde      | cinnamic alcohol,                 | citral, eugenol, farnesol              | benzyl alcohol, benzyl salicylate, geraniol, anisyl alcohol, benzyl benzoate, benzyl cinnamate, citronellol, d-limonene, linalool, coumarin |
| <b>Synthetics</b>                                                                    |                                    | 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.

### **LLNA**

The ICCVAM reviewed the utility of the murine (mouse) Local Lymph Node Assay (LLNA) for hazard assessment of potential human contact sensitizers, & their findings were adopted by the SCCNFP in 2000. The ICCVAM concluded at the time that the LLNA would not replace the guinea pig assays in all cases, and would not correctly identify weak sensitizers or all strong irritants (Dean *et al.* 2001).

More recently Basketter (2007) argues that the LLNA method is (now) a fully validated alternative methodology to guinea-pig tests and the LLNA EC3 method is a way of estimating the skin potency of a sensitizer to humans. Using this technique, Lalko & Api (2006) found, for example, that the sensitizer potency classification from individual EC3 values for clove leaf, *Litsea cubeba*, lemongrass and palmarosa oils was in the weak category, & their EC3 values did not differ significantly from EC3 values for the main components of the oils. Previously, Hostynek & Maibach had reviewed animal testing procedures, including LLNA studies, in their series of reviews on published evidence for allergenicity of a number of fragrance sensitizers, using a grading system for degrees of confidence, according to criteria they previously established (Hostynek & Maibach (2003). Their findings (see below) indicate a worrying lack of scientific robustness in many cited studies.

However this is argued, the LLNA test is still an animal test, and can have no long-term future in toxicological testing within Europe.

### **26 allergens: no clinical evidence of allergy in many cases?**

Hostynek & Maibach have critically reviewed the evidence and called into question whether a number of fragrance substances can cause allergic contact dermatitis, in a series of articles e.g. for anisyl alcohol (Hostynek & Maibach

2003a), for amylcinnamic aldehyde (Hostynek & Maibach 2003b), for linalool (Hostynek & Maibach 2003c), for geraniol (Hostynek & Maibach 2004a), for citronellol (Hostynek & Maibach 2004b), for alpha-iso-methyl-ionone (Hostynek & Maibach 2004c) and more recently, for methyl heptine carbonate (Hostynek & Maibach 2006). Reviewing the scientific evidence against 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 eliciting 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 patients 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.

### ***Quantitative Risk Assessment (QRA).***

As a result of progress of the COLIPA Toxicology Advisory Group and the Joint COLIPA/AISE/EFFA/IFRA Perfume Safety Group to address dermal sensitization risk assessment for fragrance ingredients, the QRA methodology was recommended. The QRA is an exposure based methodology for dermal sensitisation risk assessment, a key component of which is consideration of the dose (of sensitizer) per unit area. This has been imposed by IFRA, in the form of the 40<sup>th</sup> IFRA Amendment, on a reluctant trade, with no discussion, and with any objection over-ruled (such as the 928 petition-signers mentioned above) and trade press coverage manipulated behind the scenes. This immensely complex system applies to eleven categories, plus sub-categories of product, instead of two previously (skin contact/ no contact). It involves costly modification of the computer systems of all IFRA-compliant companies, and the. Standards keep coming - the 14 new IFRA Standards in the 42<sup>nd</sup> IFRA Amendment impact on several essential oils, the fall out of which is set out in Annex 1 of the IFRA CoP. This means, for example, that perfumers might have to use less clary sage oil in formulations because of its minute *trans*-2-hexenal content. You might want to remember that you can liberate *trans*-2-hexenal from grass by rolling in it.

Overall we are seeing a progressive rise in conditions & restrictions which have implications on natural material usage in cosmetics & toiletries. 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. A healthy number of natural perfumers and a few perfumery organisations are not following IFRA's brand of toxicological imperialism – you can expect superior perfumes from these people!

### ***Autoxidation of sensitizers.***

There has also been investigation into the prospect that oxidized sensitizing substances (such as hydroperoxides) are responsible for sensitizing reactions, particularly in the cases of linalool (Sköld *et al.* 2004), (R)-(+)- & (S)-(-)- limonene (Matura *et al.* 2006), delta-3-carene & geraniol (Hagvall *et al.* 2007). Little is currently known about the mechanisms for the occurrence, persistence or activity of oxidized sensitizer moieties, such as linalool hydroperoxide, when they might occur in aged essential oils, such as in East European coriander oil or Bulgarian lavender oil. Further understanding of this area, via a sponsored study under Prof. Karlberg at the Univ. of Gothenburg (RIFM 2007), could contribute towards the removal of R43 risk labelling for limonene, and perhaps other monoterpene hydrocarbons, which currently cause major problems for the aroma industry. As regards mode of action however, Christensson *et al.* (2006) consider that each hydroperoxide forms a specific antigen in contact allergy, raising the prospect of multi-centered reaction sensitivity in the case of contact dermatitis from certain aged essential oils.

### ***Effects of perfume aging.***

The chemical substances within perfumes undergo complex chemical changes & inter-reactions during maturation & aging, and this can affect their allergenicity, It is worth revisiting such work as that of Fisher & Dooms-Goossens (1976) who found that a patient with allergic sensitivity to cinnamic aldehyde could tolerate cinnamic aldehyde in a perfume mixture. This illustrates the dangers of passing regulations based on testing individual fragrance ingredients purely in isolation and extrapolating the results to complex natural ingredients such as essential oils.

### ***Conclusion (on alleged allergens)***

Cropwatch has called for a review of the workings & competence of the SCCP in all disciplines (a direct written request in 2006 which initially drew a response from Brussels officials, but which seems to have stalled). Cropwatch has also been gathering evidence for the EU Ombudsman for some time over a number of issues (including the 26 allergens debacle) to see whether a charge of maladministration can be proven over the way this legislation has been administered – for example we are encouraged to believe that EU Commission staff may have breached their own Code of Conduct. Whichever way these developments progress, to decline to act now on eliminating non-allergens/weak allergens from the 7<sup>th</sup> Amendment of the Cosmetic Directive seems indefensible.

Although the legislation had an immense initial effect on industry, most perfume buyers will now accept perfume submissions which requires the labelling of, say, a maximum of six alleged allergens. This may then permit the incorporation of many of the natural ingredients which the formulator intends to add.

### ***Environmental labelling.***

Whereas the '26 allergens' situation is annoying because it is just plain unfair, environmental hazard classification labelling is presently more of a concern for

the future of natural products usage – especially for citrus oils & oils of the Pinaceae. This classification under Annex III of the Dangerous Preparation Directive is now includes labeling saying Very Toxic to aquatic organisms (R50), Toxic to aquatic organisms (R51) and ‘May cause long-term effects in the aquatic environment’ (R53). No company wants any obligatory labelling incorporating these risk codes above which shows a dead fish and a dead tree symbol on their product.

Citrus oils have traditionally been used in many types of air fresheners, particularly wicks & gels, for their diffusion lift & character but perfumers now find it difficult to use them at useful levels because of the R50/53 labelling. There is drive therefore towards using synthetics to give the required citrus character, although these products do not generally produce the same radiance as natural citrus oils. Pine oils suffer the same problems with respect to R50/53 labelling, but are used less, partially due to their greater cost.

Technical problems with implementing the 2<sup>nd</sup> ATP to the Dangerous Preparations Directive (DPD) 2006/8/EC into UK law have held up its implementation, The issue is not so much with neat substances but with preparations. Under the Control of Major Hazard Accident (COMAH) Regulations up to 200 tons of R51/53 substances (e.g. *Eucalyptus globulus* oil) could be stored before COMAH Lower Tier Controls come into play. But since COMAH relates to the weight of a preparation, 10Kg of Eucalyptus oil in 200 tons of water would trigger COMAH requirements, whereas 199 tons of neat oil would not! All this flows from the 2<sup>nd</sup> ATP of the DPD, and in the absence of a Specific Concentration Limit (SCL) for the substance) the generic concentration limit applies:  $C_n$  (the concentration of the substance in the preparation) for substances classified as N, R51/53 being  $2.5\% \leq C_n \leq 25$  and for substances classified as N, R50/53,  $C_n$  is  $\geq 25\%$  (thanks to Paul Howath at the International Chemicals Unit for this information). The second ATP will extend the generic limits used to classify substances harmful to the Environment. The aim is to classify products containing small quantities of powerful biocides etc. that are typically present at concentrations around 0.1 to 0.5 % in water based products such as standard emulsion paints and perfumes’. Therefore under the 2<sup>nd</sup> ATP above, it is expected that more substances will gather R50/53 status as more comprehensive information on L(E)C<sub>50</sub> values of fragrance ingredients appear.

### **Citrus oils – further troubles.**

Apart from eco-hazard R50/53, irritancy (R38), sensitization (R43) & hydrocarbons content (R65) labelling, the other cloud hanging over the future of traditionally prepared (cold-pressed) citrus oils in perfumery relates to their furanocoumarin (FCF) contents. It alleged that some individual FCF’s may be linked to photo-toxicity and photo-mutagenicity.

Banning citrus oils from perfumes would be a drastic move from which perfumery would never recover. But this unthinkable step is precisely the outcome which the

EU Cosmetics regulators have decided upon – by placing a restriction on certain furanocoumarins (FCF's) such that their content in finished cosmetics cannot collectively exceed more than 1 ppm, in line with the previous recommendations of the 2001 SCCP Opinion & SCCP Opinion 0942/05. Already IFRA restricts FCF's to 15ppm, but this is a regulation which, it seems, few fragrance companies adhere to, primarily because perfumers & formulators are unaware of the FCF content of the ingredients they employ..

Head of Cosmetics Unit, Sabine Lecrenier, denies that all FCF's will be banned, but then goes on to specify six furanocoumarins (FCF's) which will be severely restricted, because they are allegedly linked with photo-carcinogenic potential. These six (psoralen, angelicin, bergapten, xanthotoxin, oxypeucedanin and epoxy-bergamottin) are all found to a greater or lesser extent in the major citrus oils used in perfumery, and are to be collectively regulated to 1ppm concentration in finished cosmetics. Apart from the fact that there is no technological process available which can efficiently remove all of the FCF's, the case proving human carcinogenicity from the effects of individual FCF's, as presented in previous SCCP Opinions such as SCCP 09542/05, remains scientifically non-robust. There is a lack of supporting knowledge, understanding & experimental & technical data. For FCF's occurring in natural aromatic products, matrix effects & the anti-carcinogenic potential of other co-occurring substances remains unclear.

The restrictive legislation proposed by Lecrenier *et al.* (Head of Cosmetics Commission) as described above is actually unworkable since no comprehensive data on the distribution of FCF's across the range of perfumery ingredients, citrus or otherwise, is available in the public domain. In any case, any minutest health risk which might be present to fragrance-wearing consumers is best approached by labelling, advising the wearer to avoid actinic light for 12-24 hours after FCF-containing fragrance application.

Most disappointingly, whilst health risks from FCF's in cosmetics remain so minute as to be virtually incalculable (provided reasonable precautions are taken), Lecrenier *et al.* seem to have completely ignored the catastrophic effect to the perfumery art by removing citrus ingredients from the perfumer's palette, as outlined in Cropwatch's April 2007 *Newsletter*. This is because nothing other than safety issues are in the remit of Brussels officials, a situation that urgently needs to change.

## **.§5. The Demise of the Perfumery Industry.**

### ***Fear culture.***

The dread of media attention, & being featured in national newspapers by a chemophobic journalistic culture, causes sleepless nights for the world's fragrance buyers. All manner of possible ills have been ascribed to perfumes in the past few years, from allergy & asthma (Millqvist *et al.* 1999; Norback *et al.* 1995) to respiratory illness and ocular damage (Elberling 2005), raising the possibility of litigation from supposedly affected fragrance end-users. Buyers

believe, because of a long history of brainwashing, that unless their fragrances comply with IFRA Standards, that their companies are 'at risk', and they put pressure on fragrance producers to ensure that their purchased fragrances comply to every possible regulatory requirement. The perfumer's job is to point out that removing every ingredient showing some evidence of an adverse effect or another detracts from the art of the possible – rather like paint a picture without using green and yellow paint and wondering why it doesn't look like the scene in front of you.

### ***Hyperbureaucratic technocracy.***

With apologies to Frank Kafka, this term can easily be applied to the red-tape-strangled profession we now inhabit. The EU Cosmetics Directive has undergone some 50 revisions since instigation, although it is now to be simplified, so we understand. However the *raison d'être* of the EU Commission is to continually pass legislation, fed by risk assessment data (as opposed to risk-benefit data) from career toxicologists, many of whom work inside the big trans-continental companies. This situation is killing the aroma profession – as witnessed by the fact that many ingredient companies are closing down, or have moved out of Europe to countries with a less restrictive bureaucracy. The big trans-continental companies are rubbing their hands together in anticipation – for only they have the resources to cope with the immense regulatory burden which is eliminating the smaller companies. The regulators themselves are impotent & bemused – whilst they don't want to be blamed for destroying the industries they are supposed to be administering, their only concern is to be seen to be politically correct over EU chemical safety policy, and it is only corporate-sponsored science which can provide the sophisticated toxicological data that they completely rely on.

**Quote:** Nietzsche: "Madness is rare in individuals, but common in parties, groups & organisations."

### ***Toxicological imperialism.***

The pressure from fragrance customers for their supplied goods to keep within all possible regulatory edicts, & the new expanding power of the 'regulatory affairs manager' within the aroma trade, keeps the culture of toxicological imperialism in place. Industry contributes to this too – by fanatical adherence to red-tape, in order not to be found responsible for any adverse effects of goods. As industry has appointed so many regulatory affairs staff, support for complex & unnecessary legislation will no doubt be popular – these people are hardly going to campaign for measures which may downsize their jobs.

Religious freedom & human life-style choices are threatened too – even the 'holy smoke' from incense is being studied for harmful chemical content by the Danish EPA who have declared incense burning a health risk. We know from various studies that smoke from incense may contain irritants, particulates & heavy metals (Lu *et al.* 2006) as well as alleged carcinogens such as benzene &

polyaromatic hydrocarbons (Yang *et al.* 2007) from the incomplete combustion process occurring during incense use (Pors & Fuhlendorff 2003, Eggert & Hanson 2004, Guo *et al.* 2004). Eliminating nitro-musks & phthalates from incense might be desirable, but not traditional ingredients which have religious significance, such as myrrh & benzoin.

### **Chemophobia**

Dermatologists & toxicologists have managed to create a scare-mongering culture, with the EU Commission's explicit blessing, by exaggerating the safety risk aspects of many individual cosmetic ingredients. Many of us believe that we have already weeded out all the most dangerous items from perfumery inventories – e.g. neurotoxins such as musk ambrette for example. But now we have new categories of risk to worry about. – the environmental degradability of cosmetic ingredients for example. Rain falling on orange groves, dropping pine needles in forests, piles of rotting fruit and vegetables worldwide, brassica crops which load the soil with isocyanates & sulphides, have all failed to create disaster scenarios for local flora & fauna. Many authorities describe essential oils as a category which presents negligible risk to the environment. So why are we faced with absurd legislation for environmental risk of these materials? Where has common sense gone? .

The new toxicological scare culture apparition is inhalation toxicity. Will we soon be worrying about scent from carnations, stocks & rose buds contributing to our annual methyl eugenol body-loading, or the amounts of alpha- & beta-pinene we are inhale as we walk through the local leafy woods? I calculate that I personally already receive thousands of times more benzyl cyanide annually from living close to rapeseed fields in full bloom than I ever did from application of any cosmetic – but then farmers' activities are impossible to regulate are, and cosmetics are an easy target.

Living is a risky business. Eliminating all possible risk actually devalues the quality of our lives, but the regulators have not properly got this into perspective, or found the right balance to deal with it. We accept the fact that they are still learning on the job, but they are affecting our working lives and leisure time whilst so-doing.

### **§6. The problem with the EU Cosmetics Commission.**

1. There is a point-blank refusal by the EU Commission to define 'safety' in context to cosmetic ingredients (Cropwatch 2007). Since the European tax-payer supports the salaries of the Commissioners specifically in order to manage Cosmetics' safety on behalf of European consumers, this situation is bizarre.

2. There is a refusal to quantify cosmetic ingredient risks. What are the chances of adverse effects from a specific banned perfumery ingredient affecting an average perfume-using individuals' health? Are we not entitled to know? Would it be, for example, more or less likely than being hit by a meteorite?

3. Risk-benefit analysis. The refusal of Cosmetics Commission regulators to instigate this classic form of safety assessment used in many, if not most, other professions, (agriculture, pharmacology etc.) is extraordinary, but probably highlights the absolute dependency of the EU expert advisers on big industry data input. As a demonstration of the poor performance by leading figures in this area, one of the classic industry texts entitled *Fragrances - beneficial & adverse effects* (Frosch *et al.* 1998) skims over the topic of benefit itself (approx 5% of the text), and offers little, if any, human biochemical/physiological data, although if you want to know anything about chemical communication between robber bees - this is the book for you! Equally IFRA's website article on the same subject looks as if it were penned by a young schoolchild. This situation draws attention to the cross-disciplinary crisis within the power-brokers in this industry.

### **Ethanol**

Ironically the 'benefit to industry' argument may have to be used by Brussels officials over the regulatory stalemate concerning ethanol and its CMR 1 status (Carcinogenic, Mutagenic or Reproductive toxin - see EC Directive 67/548). You may recall that the French independent occupational safety group, the *National Institut de Recherche et de Securite*, had submitted a proposal in 2006 to classify ethanol as a category 1 CMR substance (motivation unknown – was it embarrass the regulators who would be 'hoisted by their own petards'?) Their intention was interpreted as being that classification was required for ethanol under EC Directive 67/548/EEC – a Directive which relates to the classification, packaging and labeling of dangerous substances. Under the 7th Amendment to the Cosmetics Act 76/768/EEC, categorization under this move would have required the European Commission to ban ethanol in cosmetics (and therefore perfumery) as CMR 1 substances are banned in cosmetics. Additionally the European Chemicals Bureau had on its original agenda for Oct 7<sup>th</sup> 2006, a proposal to classify ethanol as a CMR material.

COLIPA have also submitted an opinion on this matter pointing out the socio-economic implications of this ban, which would require the banning of perfumes, after-shaves, colognes, eau de toilettes, some mouthwashes etc. etc., and they pointed out that this move if enacted would require many workers to wear gloves & respirators to avoid contact with ethanol i.e. when working in bakeries (ethanol is produced by panary fermentation in bread dough), in bars etc. etc.

As far as Cropwatch understands the current situation, the primarily affected alcoholic beverage industry is not about to go out of business, and in the cosmetics area, there seems to be reluctance on the part of the regulators to enter into any further hasty moves on this issue.

4. **Natural fragrances.** The public wants natural fragrances; big industry doesn't, and the regulators are busy reducing the number of natural ingredients with restrictions e.g. citrus oils, traditional oakmoss, traditional Peru balsam & styrax materials. Natural ingredients are a nuisance to modern industry managers – they are often seasonal, prone to price volatility, prone to shortage due to political

situations or adverse weather conditions, & they can vary greatly in quality due to a number of other intrinsic & extrinsic factors. Being complex mixtures, they have toxicological complexity. Definitions of 'natural' fragrance are still evolving. Cropwatch is working with 'natural' meaning 100% botanically-derived. However other opinions differ, and in a situation similarly to the degradation of meaning of 'natural cosmetics' (where now several many organic certifying authorities allow certain synthetics are allowed), so Grimshaw (1991) came up with the following quote, which has stuck with some people:

**Quote:** Grimshaw (1991) ...(a) common request is for a “natural” fragrance containing at least 50% of materials, with the latter being nature-identical, however the latter may have been obtained.”

### **7. The Demise of the Professional Essential Oil Associations.**

The working margins of natural products traders are so squeezed due to downward pressure on pricing by key industry buyers, that many have closed down in the past few decades. Downward pricing has also resulted in lowering of traded product quality and a rise in adulteration. Essential oil organisations themselves are non-technical in the sense that they rarely fight the science behind progressive restrictive regulation. Sadly they are also over-deferential to the regulators, an attitude which has only plunged them inescapably towards humiliation over several recent matters. Finally they are almost impossible to communicate with, non-transparent, and are expensive to join. As a group, they rarely allow independent observers at their meetings.

### **8. The Demise of the Natural Aromatic Ingredient Producers.**

Natural ingredient producers from far-flung parts of the world may find themselves a little “out of the loop” when it comes to coping with the outfall from natural aromatic product ingredient regulation. Essential oil traders primarily look after their own business interests, not those of their remote raw material suppliers. Even worse, essential oil organizations act like an arm of the EU, helping them (by providing masses of technical information) to pass legislation which directly affects the trading status of producers, who find themselves in a Catch-22 situation – they have to be friendly with the very people (traders in professional organizations) who they see are helping put them out of business. As regards socio-economic fall-out, the EU Commissioners, who seem completely detached from worldly realities, wash their hands of any responsibility for their actions.

Cropwatch believes that when ingredients are banned or restricted, the next requirement is a process whereby the application of science & technology can provide a technical fix, so that these ingredients can be reinstated. It is not just the responsibility of private industry to organise this, we all need to play a part. Cropwatch has been unable, so far, to find a body which could potentially be a source of funding for this prospect (suggestions welcome!).

## 9. The Demise of a Banned Ingredient Producer.

Cropwatch sent the following information on behalf of Peru Balsam producers in El Salvador, to the Brussels regulators, in response to a Public Consultation exercise:

“..... the banning of Peru Balsam (PB) as a perfumery ingredient by IFRA in 1982 (RIFM 1982) may have been an important factor in the resultant halving of global production in the last two decades.”

| Year      | Annual Production |
|-----------|-------------------|
| 1976-1980 | 143 tons/annum    |
| 1985-1989 | 146 tons/annum    |
| 1996-2000 | 91 tons/annum     |
| 2001-2005 | 73 tons/annum     |

**Table 2 Peru Balsam Annual Production Figures (for years where figures are available). Source: Centrex, El Salvador**

Considerable economic damage was done to the PB industry by the recent regulatory muddle over PB qualities which involved non-perfumery cognescent Brussels officials making clerical errors (so that Peru balsam oil was wrongly indicated to be moved to Annex II of the Cosmetics Directive). The knock-on effect resulted in many perfume companies becoming so confused by the issue that they removed Peru balsam oil from their inventories altogether. This, in turn, reduced demand for Peru balsam at source. Although it's too much to hope for that the Commission will ever apologise for any errors such as this, they could help with getting finance for a technical fix to combat the underlying PB allergenicity problems. Otherwise the PB industry in El Salvador may all but disappear, with loss of employment, loss of maintained PB tree forest, and loss of local community infrastructure.

Apart from an acknowledgement of the original submission, Cropwatch has not heard anything further on this matter from EU officials, & apart from a reminder of the EU regulations over PB, neither have the El Salvadorian producers.

**Quote:** Félix de Azúa: "Nobody is safe from bureaucratic error, and every day, fewer & fewer citizens can be sure of getting or keeping a job."

## Conclusions.

Bullied by Megacorporation scientists and over-influential career toxicologists, the EU's regulators for cosmetics & toiletries, & general household products, have been led by the nose into passing inappropriate & over-cautious ingredient legislation in the name of the Precautionary Principle. The effect of this is destroying the opportunity for perfumery art & excellence because of the inappropriate restriction of natural ingredients, which were such important constituents of finished fragrances. Although Cropwatch appreciates that some trade people are starting to stand up & be counted, we need a lot more

individuals to openly express their private opinions & doubts about the existing state of cosmetic regulatory affairs. The members of essential oil trading organisations have forgotten that if they intend to survive, they need to look after the hard-pressed producers, rather become extensions of the Brussels regulatory machine.

Cropwatch maintains that IFRA, the EU and bodies for cosmetics regulatory affairs do not have the monopoly on approaches to safety policy - there is still room for common sense, appropriateness and proportion to figure in the equation. .

*Thanks to Nigel Back, Martin Watt, Kendra Kirkham and others who cannot be named for their help in assembling this lecture.*

### List of Acronyms

AAAIA - American Academy of Allergy, Asthma & Immunology  
AISE - International Association for Soaps, Detergents & Maintenance Products  
ATP – Adaption to Technical Progress  
BEOA – British Essential Oil Organisation  
CCTFA - Canadian Cosmetic, Toiletry and Fragrance Association  
COLIPA – European Cosmetic, Toiletry & Perfumery Association  
CoP – Code of Practice  
CPSC (US) - United States Consumer Product Safety Commission  
CTFA – Cosmetics, Toiletries & Fragrance Association  
EPA – Environmental Protection Agency  
EU – European Union  
FCF – Furanocoumarins  
FEMA- Food Extract Manufacturers Association  
FHSA - Federal Hazardous Substances Act  
HERA - Human & Environmental Risk Assessment of household cleaning products group  
HMPCC - (4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde or Lylal  
ICAP – International Cosmetics Alignment Process  
ICCVAM -  
Interagency Coordinating Committee on the Validation of Alternative Methods  
IFEAT - International Federation Of Essential Oils and Aroma Trades  
IFRA – International Fragrance Association (the “R” is silent!)  
IVDK - the Information Network of Departments of Dermatology for the surveillance and scientific evaluation of contact allergies  
JCIA - Japanese Cosmetic Industry. Association  
L(E)C<sub>50</sub> – Median Lethal Effective Concentration  
LLNA – Local Lymph Node Assay  
NRC – National Research Council  
PPPA – Poison Prevention Packaging Act  
REACH – Registration, Evaluation, Authorisation & Restriction of Chemicals.

RIFM – Research Institute for Fragrance Materials  
SAFC – A division with Sigma-Aldrich.  
SCCNFP – Scientific Committee on Cosmetic Products & Non-Food Products  
SCCP – Scientific Committee on Consumer Products  
SME – micro, small & medium sized enterprises

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