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

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## **Melissa Oil & IFRA Policy (cont'd): The Further Details.**

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### **Pre-amble.**

Those of us who have worked in the aroma trade for most of their working lives, have, at times, been highly skeptical of the knowledge & abilities of those unelected officials who would impose baffling & seemingly nonsensical regulations and codes of practice upon the trade. Sometimes we felt that we were being regulated by those who had little in-depth knowledge or experience of the subject - a feeling which has never really gone away.

Perhaps safety-orientated organisations like IFRA would have gained more credibility from some of us old-timers if they had more openly owned up to their previous errors. Yes, we accept that with improvements in experimental design and better techniques, many of IFRA's earlier (nineteen seventies') findings on ingredient toxicology are now suspect, or have been superseded. Most importantly, the failure to use rigorously purified aroma chemicals for toxicology testing by researchers reporting to RIFM, and the use of complex botanical materials from non-expertly identified botanical sources, has thrown large sections of IFRA's previous toxicological findings into doubt since impurities and adulterants have often been responsible for adverse effects rather than the pure ingredients. From a personal standpoint, when you have been drenched in perfume & essential oils on a daily basis for 30-odd years, as many of us at the coalface have, you may feel some intuition (rightly or wrongly) for what aroma materials might be posing any handling risks. This is `why many of us laughed openly over IFRA's Quenching Hypothesis (now discredited). It is why we are still cynical over the disproportionate IFRA classifications of many materials which are supposed to be sensitising, according to the corporate-toxicological methodology involved in the QRA approach. But many of these ingredients indicated as sensitisers have failed to produce any significant numbers of adverse reactions amongst the end-users of fragranced cosmetic & household products in which they occur.

### **Melissa Oil: Lesson Learned.**

The curious` case of the previous banning of Melissa oil as a fragrance ingredient by IFRA, gave Cropwatch an opportunity to explore IFRA's ingredient

policies in detail (see previous Cropwatch reports). In so many instances, a veil of secrecy obscures the detailed experimental facts on which IFRA/REXPAN ingredient status decisions are made. Following requests by Cropwatch, Robertet Grasse, to their immense credit, were willing to share their toxicological findings on Melissa oil testing, referred to in the RIFM data-base but otherwise not available to the general public. Subsequently we can now clearly see (in our opinion) that there was no good reason to ban Melissa oil from perfumery use in the first place, and a case for its continued restriction is heavily based on Robertet's evidence, which was not comprehensive across a range of dosages, but based on a strategy to reduce costs. This involved contriving experiments at doses which were likely to produce a positive safety outcome, rather than the prospect of funding a more extensive range of tests proving its skin safety at higher dosages. That's OK - we can easily deal with this, because it represents the truth. It's just that IFRA didn't previously reveal these particular facts about the economic restraints which have materially affected the testing strategies, for this particular ingredient.

Where do we go from here? It is apparent that we need an independent body to openly ascertain the facts about 'pure' toxicological science – as against the corporate-funded version of toxicology which we are forced to follow. It is also apparent from the mail that Cropwatch receives that there are other expert opinions out there – why must these individuals be sidelined and denied places on expert committees? Above all, Cropwatch is concerned that the low standards set out in many IFRA commercial standards may be rubber stamped & adopted by the EU Commission, as of course has happened previously, and which may come to be an increasing trend.

### **Melissa Oil – the Further Details.**

With a few minor punctuation changes, the reply from Catherine Gadras is set out below (we had asked for the exact botanical identification of the *Melissa* spp distilled for essential oil (since IFRA had failed to properly define it), and for its' geographic origin & compositional details. We had further asked the Robertet team for any views on the presented HRIPT & EC3 data. We also had an exchange of mails with Michel Meneuvrier of SAPAD who provided the oil for testing (see below) & who confirmed that the Melissa plants distilled for oil were produced organically from Diois region plants.

Catherine writes: "As I mentioned below Melissa EO used for testing is *Melissa officinalis* subsp. *officinalis* L cultivated in the South East of France in the region of Di (Drôme). This genuine essential oil has been provided to us by the SAPAD (Société Anonyme des Plantes Aromatiques du Diois). The sample was taken from the crop 2008. 7 to 8 levels of fresh leaves plus the flower part are used for the distillation. Please find below the range of the main constituents provided to us by SAPAD and the composition of the sample used in the most recent tests. (See attached file: Melissa-EO Composition.pdf).

The crop results from the distillation of 3 "cuts: one at the end of May and the two

others from the beginning of July and at the end of August/beginning of September. The producers finds that the citral content is maximum in the third cut (greater than 50%) and that citronellal is below 10%.

2) Comments regarding safety data (HRIPT and EC3)  
The LLNA has been made to determine a level of concentration at which one begins to observe induction of sensitisation. In our case 4500µg/cm<sup>2</sup>. Considering the high cost of this EO (5 to 7 tons of fresh plants to produce 1 Kg of essential oil) on one hand and the fact that we did not want to risk a positive reaction in the HRIPT, we have chosen this conservative 1470µg/cm<sup>2</sup>. This is more than adequate for perfumery use which is our business. It is quite possible that a higher safe limit for melissa EO exists but in my opinion it must be verified by testing my opinion it must be verified by testing.

PS: I take advantage of our e-mail exchanges to make some comments concerning the Cropwatch report on Melissa (page 3) that I found on internet :

I have 2 comments on this sentence below: :

"Under the draft proposals for IFRA's 44th Amendment, melissa oil (which they describe as 'genuine *Melissa officinalis* L.')

has been downgraded from an outright ban in fragrances, to a concentration restriction in the fragrance compound (as opposed to the finished cosmetic product). QRA data for melissa oil, which is categorised as a weak sensitiser, is presented by IFRA for the various established product categories, based on a No Expected Sensitization Induction Level (NESIL) of 1400µg/cm<sup>2</sup>."

1) Did you really mean "downgraded" ? My poor English would have expected "upgraded". (**Cropwatch comments:** downgraded from a negative position (a ban) but upgraded to more positive position (just a restriction) - it all depends on how you look at it!).

2) I confirm to you that the QRA limits are in finished consumer products and not in fragrance compounds." (**Cropwatch comments:** on this latter point we stand corrected. Thank you Catherine!).

**Addenda** – Analysis Data received from Robertet.

**Analysis of Melissa EO sample used in HRIPT test.**

Component	% FID CW
Myrcène	0,16
Limonène	0,37
Cis Ocimène	0,12
Trans Ocimène	1,14
Para cymène	0,15
Methylheptenone	1,76
Octène 1 ol 3	0,4

Citronellal	1,3
Alpha copaene	0,34
Beta bourbonene	0,4
Linalool	1,38
Cis + Trans Isocitral	1,6
Beta Caryophyllene	14,2
Neral	23,8
Methyl geraniate	0,32
Germacrene	4,3
Geranial	33
Geranyl acetate	2,2
Delta Cadinene or delta Amorphene	0,7
Citronellol	0,2
Nerol	1,1
Isogeraniol (cis+trans)	0,24
Geraniol	1,7
Epoxydes de caryophyllene (cis+trans)	1,8
Germacradienol	0,3
Muurolol T	0,4
Thymol	2,1
carvacrol	0,25
Alpha Cadinol	0,6
Neric acid	0,1
Geranic acid	0,3
<b>TOTAL 96,73</b>	

#### Information Stat from SAPAD

	Mini %	Maxi%	Moyenne %	Escart Type %
<b>Methyl heptenone</b>	<b>1.05</b>	<b>3.36</b>	<b>1.8</b>	<b>0.7</b>
<b>Limonene</b>	<b>0.04</b>	<b>0.48</b>	<b>0.18</b>	<b>0.13</b>
<b>Citronellal</b>	<b>0.6</b>	<b>19</b>	<b>4.9</b>	<b>4.4</b>
<b>Neral +citronellol</b>	<b>6.4</b>	<b>28</b>	<b>18.7</b>	<b>5.4</b>
<b>Geranial + Geraniol</b>	<b>9</b>	<b>38.3</b>	<b>25.6</b>	<b>7.4</b>
<b>Caryophyllene beta</b>	<b>10.1</b>	<b>29.6</b>	<b>18.3</b>	<b>4.4</b>