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The EU's Peru Balsam Fiasco: A Sorry Tale of Regulatory Incompetence.

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[Assembled from various Cropwatch sources].

This file is resurrected from the Cropwatch archives, as a testament to the fact that mistakes & misinformation made by regulatory officials can result in loss of confidence & destabilisation of the affected ingredient producing industry. In this case, users of Peru balsam qualities, trying to adhere to the regulations, became so confused, that many eliminated or substituted for the ingredient in their fragrance inventories, resulting in an overall downturn in demand. No apology, economic compensation or technical help has ever been offered by Brussels bureaucrats to 'right the wrongs' done to this industry, to the declining Peru forest & to the peoples socially dependent upon it. Legislators surely have a duty of socio-economic accountability for their actions, but as things stand they seem to exist isolated in mid-air in their Ivory Castles.

Pre-amble.

It must be very frustrating for the officials of aroma trade organizations who have to be polite and respectful to Brussels officials who have totally screwed-up over an EU fragrance ingredient regulatory issue. This has had unfortunate (but hopefully short-term) economic consequences for an already beleaguered Central American producing industry, who have never received an apology. This is not the first time such a situation has arisen.

Peru Balsam: Some Facts.

Crude Peru balsam, according to Burfield (2005) is "...produced by slashing and removing strips of the scorched and wounded bark of the tree *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royale) Harms syn. *Myroxylon pereirae* (Royle) Klotzsch, that grows to 25m. Peru balsam is produced mainly in El Salvador, with some former production in Guatemala and Honduras. Sometimes trees are individually worked to give several (usually 3) tappings, and the exudate is collected on rags, which are subsequently boiled to recover the balsam, the various tappings being combined to give a uniform quality product. To refine the raw material, (according to Retamar, 1986) the balsam was reportedly alcohol-treated, and the neutral solution of the resinoid in benzene then could be decolourised in part with activated charcoal, followed by extraction

with freon 12 at 21 °C. This method replaced the older method of heating over a fire to evaporate any remaining moisture and sieving whilst still hot, to remove organic matter. [You will note the former use of the carcinogen benzene in this process, quoted by Retamar as late as the year 1986]. However, Peru balsam manufacturers that Cropwatch has talked to in El Salvador, have no knowledge of this process.

A better description of the Peru balsam production process is set out below, quoted from *The Right of Reply of a Peru Balsam Manufacturer* document within *The Cropwatch Files*.

Production of Peru balsam is carried out after the rains in November/December until May, by fire-scorching and wounding the bark of the tree, leaving approx. 1 week, before slashing and removing rectangular strips of outer layers of bark (typically some 30cm. x 15 cm.), which are crushed, boiled into hot water and pressed (giving 'Balsam of Cascara', Balsam of the Bark). As well as the bark, the tree is also worked – according to Poucher (1936), after the outer layers of bark are removed, exposing the wood. This is covered with cloths or rags to collect the exudates over 15-20 days, the cloths or rags being subsequently boiled to recover the balsam and pressed in a rope press, (giving 'Balsam de Pañal', the major part of the yield). In a few days a third exudation ('Balsam de Contrapique o Tacuazonte ') is collected with cloths that are boiled and pressed to recover the resin. In the pressing process the balsam sinks to the bottom (S.G. 1.150 to 1.170) and the water is decanted off and the resin strained. A combination of these three tapping in definite proportions is a 'Raw Balsam' that then is boiled to evaporate the residual water (this called the "Purification Process"). This "Purification" gives Peru balsam as we know it commercially. The tree may be tapped in this way at fortnightly intervals up to 8-9 months per year. Average yields have been reported to be between 0.25 to 0.50Kg per tree per annum around 60 years of age giving maximum yields (Manual of Good Practice in the Production of Balsam of El Salvador, OIRSA 2006).

The balsam has been traditionally used for "warmth" and sweetness in perfume compositions, particularly as part of oriental themes. It also has significant uses in incense perfumes, being blended with musks, coumarin and animal notes." Sensitisation to Peru Balsam exudates will often lead to complex multiple allergies, varying according to the individual (Hjorth 1959).

A Regulatory Screw-Up.

Crude Peru Balsam exudates have been listed in many trade publications as CAS No 8007-00-9, and are the subject of an SCCNFP Opinion (SCCNFP/0771/03), in consequence being added in the last Technical adaptation (Dir. 2005/42/EC) to Annex II of the Cosmetics Directive (76/768/EC). For those of you unfamiliar with this legal jargonese, it effectively means that it was recommended that Crude Peru Balsam exudates cannot be used in fragrances because of their alleged skin sensitising potential.

Peru Balsam 'Oil' (generally encountered as ex- molecular distillation or very high vacuum distillation of the crude Peru Balsam, which offers yields of >50%), is/was identified under the same CAS No. 8007-00-9, and is the subject of an SCCP Opinion (SCCNFP/0392/00) which concludes that "Extracts and Distillates of Peru Balsam should not be used such that the total level exceeds 0.4% in cosmetic products." **Cropwatch comments:** It thus appears that the SCCP merely rubber-stamped the previous IFRA Dec 1991 Standard based on RIFM's original work (including that of Opdyke (1974)]. Again the bottom line for those who need a simpler translation: It was recommended that Peru Balsam Oil was safe to use in cosmetics/fragrances at 0.4% maximum final concentration in the product.

The Confusion arises here because in the Technical adaptation (Dir. 2005/42/EC) to Annex II of the Cosmetics Directive (76/768/EC), in using the term CAS No 8007-00-9 as descriptor, it could be interpreted that both the banned (allegedly sensitising) Crude Exudate and the concentration restricted Peru Balsam oil (which is presumed safe at <0.4%) were all included in the Annex indiscriminately.

Memo to EU legislators: Crude Peru Balsam exudate needs to be separately identified (perhaps via a separate CAS No.) to distinguish it from Peru Balsam Oil, and the exact position clarified in Annex II above. Otherwise some might consider that the fragrance industry is placed in a legal 'no man's land' over the legitimate use of Peru balsam oil. Already, as we write this (March 2006), fragrance companies fearful of being 'caught out' by this technicality are producing reconstituted synthetic versions of Peru Balsam Oil to substitute in their existing internal formulae which stipulate the ingredient.

The length of time it takes for the legislators to sort out these mistakes is quite unforgivable, bearing in mind the cost & inconvenience to industry, and the fact that Peru Balsam producers and traders face a period of uncertainty. As it is, expert committees/DG Enterprises are still scampering about trying to clarify the exact position (March 2006).

Update April 2006: Industry Loses Respect For EU Lawmakers.

The troubled Peru balsam saga took another turn for the worse this week. It seems that the 'expert' EC committees & advisors simply cannot get their heads around a concept which would not seriously trouble a beginner-trainee in perfumery.

Briefly, on the 1st April 2006, Commission Directive 2005/42/EC (20th June 2005) which amends EC Directive 76/768/EEC concerning cosmetic products, for the purposes of adapting Annexes II, IV and VI to technical progress, came into force. Under Annex II (prohibited materials) now have we have, under reference 1136:

1136. Peru balsam (INCI name: Myroxylon pereirae; CAS No 8007-00-9), when used as a fragrance ingredient.

DG Enterprises had previously asked the SCCP for clarification about whether the ban in the Opinion in SCC(NF)P/0771/03 applied to crude Peru balsam only, and whether extracts and distillates are safe under restriction set out in SCCNFP/0392/00 (i.e. IFRA's previous restriction to 0.4% concentration max.).

The outcome is that Commission Working Document 06/COS/ENTR/05 presented at the December is believed to contain the following position, that the ban on Peru Balsam should only apply to:

Exudation of *Myroxylon pereirae* (Royle) Klotzch (Peru balsam, crude); CAS No 8007-00-9) when used as fragrance ingredient”.

Problems with this position.

1. It appears that the Chemical Abstracts Service is maintaining that CAS numbers are not assigned to exudates, as these are considered natural unprocessed materials. Cropwatch believes this news probably come as a bit of a shock to compilers of technical information to the natural products and vegetable drugs industry, which has used these numbers for decades. Cropwatch invites comments from companies & individuals who may be affected by this revelation.

2. It also appears that by including the CAS number bundled with the term 'Exudation of Peru balsam' (in spite of requests that the CAS number should be dropped), some parts of industry at least, are assuming that this will in fact be interpreted as Peru balsam oil (to which the term actually applies) in spite of EFFA's pleas that the word should be spread that the ban will only apply to the crude exudates.

We'll have to see how this situation progresses, but already there are those that have lost patience with the whole situation and are substituting reconstituted Peru Balsam for Peru Balsam qualities in fragrance & flavour formulations. This situation hands another triumph to the synthetic chemical industry, and once more the EU Commission – for no good reason - puts pressure on what remains of the beleaguered natural products industry.

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