# Evaluation Summary of Vanilla Bean Extract for Use as a Cigarette Ingredient

Vanilla extract (or vanilla bean extract) is generally recognized as safe (GRAS) by United States Food and Drug Administration (FDA), and is also approved as a food additive (21 CFR § 182.20). Vanilla extract is also listed as GRAS by the Flavor Extract Manufacturers Association (FEMA No. 3105)[1] and is approved for use in food by the Council of Europe (CoE No. 474).[2]

Vanilla extract is the pure essence of the vanilla bean, dissolved in alcohol.[3] Vanillin is the predominant component of the flavor profile of vanilla bean extract and vanilla oleoresin (a semi-solid concentrate obtained by removing the solvent from the vanilla bean extract).[4-9]

Vanillin is perhaps one of the most recognizable aroma chemicals in the world. Its desirable characteristic flavour and aroma have led to its widespread use in the food industry.[4-9] In addition to its use in food, vanillin is used extensively as a fragrance in cosmetics, personal care products air fresheners and as a masking agent for otherwise odorous chemicals. It is also used in confectionery industries, and as a pharmaceutical excipient in oral solutions, tablet coatings, syrups and in powders to mask otherwise unpleasant tasting pharmaceutical preparations.[10]

Toxicity studies have shown that vanillin is of low toxicity with lethal oral doses in rodents of approximately 1-1.5 g/kg.[11-17] Short term and chronic studies have demonstrated the safety of daily exposure to vanillin in food.[17-20] Teratology studies with rats have not demonstrated any danger to the fetus.[21-25] Genotoxicity studies in bacterial and mammalian cell systems did not reveal any mutagenic properties at µM concentrations but mM concentrations induced sister chromatid exchanges in normal human lymphocytes.[12,25-47] Vanillin has been reported in many studies to possess anticarcinogenic qualities.[11,48-52] Evaluation of biochemical systems reveals that vanillin can suppress many of the enzymes that are required for the metabolic activation of known mutagens and carcinogens.[53-65] *In vitro* studies with bacterial and mammalian cells demonstrated that, in the presence of some mutagens, vanillin would reduce their genotoxicity but that it can also promote the genotoxicity of others.[25,41-46,65-68] Antimutagenic studies *in vivo* have described a similar dual effect of vanillin, which also proved to be dependent on the mutagen used. [11,48-50]

Vanilla bean extract is currently used worldwide at levels below 100 ppm in selected cigarette brands manufactured and/or distributed by Philip Morris USA Inc. (PM USA) and/or Philip Morris Products SA (PMP SA). Vanillin, the major flavoring component of vanilla bean extract, is a natural component of tobacco (0.9-1.8 ppm).[69] Vanilla bean extract may be applied directly to the tobacco as an additive, flavoring or flavoring agent, and as such, may be subject to pyrolysis-type reactions during the smoking process. Vanilla bean extract may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures.

As suggested by purge and trap studies conducted by PM USA, the vanillin in vanilla bean extract would be expected to distill at 100ºC prior to the burning cone of the tobacco.[70] At the higher temperatures used in the pyrolysis studies conducted by PM USA, the results suggested that vanilla bean extract and its constituents would not pyrolyze extensively during the smoking process and would be delivered to the smoke intact.[71]

Vanilla bean extract was part of a PM USA testing program that was designed to evaluate the potential effects of 333 ingredients added to typical commercial blended test cigarettes on selected biological and chemical endpoints.[72-75] Three pairs of test cigarettes were produced, each containing different groups of ingredients. Vanilla bean extract was added to two pairs at target levels of <1 ppm, 5 ppm, and 15 ppm. No significant effects were noted in cytotoxicity, mutagenic studies or in respiratory tract endpoints in 90-day rat inhalation studies. In addition, smoke chemistry studies from cigarettes containing a mixture of flavors including vanilla bean extract did not significantly alter the smoke chemistry profile compared to control cigarettes. Based on the results of these studies, the authors concluded that these ingredients (including vanilla bean extract) added to tobacco do not add significantly to the overall toxicity of cigarettes.

Currently, information is only available for tests utilizing vanilla bean extract in a mixture of ingredients applied to cigarette tobacco. Studies are ongoing to address the use of vanilla bean extract as a single ingredient and at higher target levels. Published studies show there is no meaningful difference in the composition or toxicity of smoke from cigarettes with added ingredients (including vanilla bean extract at a target level of 468 ppm)[80] compared to the smoke from cigarettes without added ingredients.[72-80] Based on the best available data, the ingredients used in PM USA and/or PMP SA cigarettes do not increase the overall toxicity of cigarette smoke.

## References


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