Evaluation of the Potential Effects of Flavor Ingredients Added to Cigarettes
Part II. Chemical Composition of Mainstream Smoke

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Abstract - Cigarette mainstream smoke from American-blend research cigarettes with and without the addition of flavor ingredients was analyzed for its chemical composition. In total, 333 flavor ingredients commonly used in cigarette manufacturing were assigned to three different flavor ingredient mixtures. Each flavor mixture was introduced at a low and a high level to the test cigarettes. The list of the 51 smoke constituents determined is based on those analytes suggested for analysis in a U.S. Consumer Product Safety Commission proposal and those cigarette smoke constituents identified by the International Agency for Research on Cancer as worthy of concern and characterized as carcinogens.

An increase in the yield of total particulate matter in the range of 13 to 28 % relative to the unflavored control was observed for all test cigarettes. This was presumably caused by the higher transfer rates of the added ingredients compared to the transfer from the tobacco filler. When the yields of individual constituents were related to these TPM yields, a reduction in the majority of these constituents compared to the control was observed. For one of the mixtures this reduction was especially high: for phenols a maximum of 70 %, for polycyclic aromatic hydrocarbons 50 %, and for N-nitrosamines 45 %. An increase in the amount relative to TPM was observed for only a few smoke constituents: hydrogen cyanide (one mixture),formaldehyde and resorcinol (one mixture), and cadmium (all three mixtures). Data obtained in in vitro and in vivo assays in this same series of studies (Roemer *et al.*, 2000; Vanscheeuwijk *et al.*, 2000) indicated no change in activity. An overall assessment of all the data suggests that these flavor ingredients, when added to the filler, do not add to the toxicity of smoke, even at the exaggerated levels tested in the present series of studies.

Abbreviations: ADI = acceptable daily intake, BSTFA = N,O-*bis*(trimethylsilyl)trifluoroacetamide, CPSC = US Consumer Product Safety Commission, FTC = Federal Trade Commission, GRAS = generally recognized as safe, IARC = International Agency for Cancer Research, ICH = International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ISO = International Organization for Standardization, NAB = N'-nitrosoanabasine, NAT = N'-nitrosoanatabine, NDMA = N-nitrosodimethylamine, NDELA = N-nitrosodiethanolamine, NNK = 4-(N-methyl-N-nitrosamino)-1-(3-pyridyl)-1-butanone, NNN = N'-nitrosonornicotine, PAH = polycyclic aromatic hydrocarbons, PEL = permissible exposure level, SPE = solid phase extraction, TLV = threshold limit value, TPM = total particulate matter

Keywords: flavor; ingredient; cigarette mainstream smoke; chemical analysis

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