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EXECUTIVE SUMMARY

Influence of Additives on Cigarette Related Health Risks*

[H. Klus, G. Scherer and L. Müller; Beitr. Tabakforsch. Int. 25 (2012) 411–493]

by

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Additives are substances, used in small amounts in the process of manufacturing, for achieving the desired quality or improving definite properties of a finished product. Additives may affect the production, processing, storage, appearance, attractiveness and performance of a product.
There is common use of additives in the manufacturing of tobacco products, including cigarettes. In a legal product this is legitimate provided certain conditions are being met, of which consumer safety is clearly the most important.
Cigarettes are known to pose serious health risks to consumers. It is mandatory to explore and determine whether the health risks of smoking are increased by any additive present in cigarettes. Sound scientific data and studies, and their learned interpretation, are relied on for responsible assessment. Frequently, however, serious impediments counteract this approach, such as the unawareness of the full scope of available knowledge, the arbitrary selection of published or otherwise accessible sources or - particularly obvious in tobacco related discourses - the distorting impact of partiality and ideology.
Fortunately, a wealth of good scientific information is available today for assessing the safety of tobacco additives. A considerable number of studies were performed by tobacco companies from the 1960s on, though with very limited impact on the scientific community due to the restrictive publication policy that prevailed at that time. The situation changed markedly in the 1990s, when large-scale research on additives was planned, executed and eventually published by both the tobacco industry and academic institutions. As the sense of corporate responsibility grew and regulatory pressure mounted, systematic research approaches were developed and pertinent studies performed along the following lines of thought:

Over 95 % of the tobacco additives currently in use are approved as food additives. Starting with the chemical, biological and toxicological data compiled for each substance, it is examined carefully whether, and if so to which extent, a tobacco additive is subjected to the specific conditions of smoking, i.e. pyrolysis and combustion. Pyrolysis studies executed under realistic conditions have shown that of the flavor additives, which represent by far the largest fraction of additives in use and are generally rather volatile and applied in very small amounts, about two thirds are expected to escape the burning zone of a cigarette more than 95 % intact. This definitely reduces the likelihood of decomposition products having significant effects on cigarette mainstream smoke composition and toxicity. When done with additives of higher molecular weight mostly used in casing mixtures, which are characterized by low (or no) volatility and relatively high inclusion levels, appropriate pyrolysis studies indicate the kind and quantities of degradation products, which are to be expected in mainstream smoke and require further analysis.
Consequentially, the effects of additives, present in cigarettes, on the composition of mainstream smoke needed to be investigated. Experimentally, additives may be added as single substances, allowing direct attribution of impact, or in reasonably composed mixtures, which may reveal possible interactions.
Toxicity testing is required for assessing possible biological effects of tobacco additives. An internationally recognized and standardized in vitro test battery, adapted to cigarette smoke and its fractions, is generally used to determine cytotoxicity (effects on cell viability and growth rates) and genotoxicity (DNA damage). The most widely employed experimental models for in vivo toxicity testing are rodent

inhalation studies with whole cigarette smoke and mouse skin painting assays with smoke condensate.

It was found that the composition and toxicity of cigarette mainstream smoke are generally not influenced by the application of flavor additives at their typically very low inclusion levels. With casing additives at higher use levels two effects were often seen: an increase in the total particulate matter of smoke and a decrease in its biological activity, presumably due to the replacement of tobacco in the filler and the dilution of the smoke by the additives. Significant reductions of biologically active compounds in smoke were occasionally observed, and increases were noted in very rare cases with specific additives. Remarkably, such changes were hardly reflected in in vitro toxicity assays and never detected in the outcomes of in vivo studies.

In a recent review [H. Klus, G. Scherer and L. Müller: Influence of Additives on Cigarette Related Health Risks; Beitr. Tabakforsch. Int. 25 (2012) 411-493] the effects of a number of important tobacco additives on cigarette mainstream smoke composition and toxicity were assessed in detail by compiling, collating and - to some degree - evaluating the wealth of pertinent scientific information available from the published literature and other special sources. The additives under consideration include menthol, glycerol, 1,2-propylene glycol, sorbitol, sugars, cocoa, licorice, citric acid, triacetin, and ammonium compounds.

Allegations that additives may have certain detrimental effects linger on (mainly for ideological reasons) in spite of the fact that they are not supported by reason or scientific evidence. It is claimed that ammonium compounds added to tobacco increase nicotine availability to the smoker. However, unrestrained speculations of this kind are completely invalidated by chemical measurements and the reality of pulmonary physiology, which demonstrate that ammonium compounds are not able to significantly affect nicotine uptake from cigarette smoke. Further, the claim that sugars added to tobacco increase the addictiveness of nicotine (via acetaldehyde formation) does not hold up in view of the fact that acetaldehyde in smoke is not the result of sugar degradation and is, under the conditions of smoking, downright unlikely to exert an effect on a consumer's central nervous system.

In fact, an independent international scientific body (SCENIHR) stated recently that "no tobacco additives which are addictive by themselves have so far been identified".

For assessing the potential influence of additives in cigarettes on smoking related health risks, two questions were addressed in several studies: human smoking behavior (smoking topography) and health outcome indices, such as mortality rates.

Immediate insight into the effects of additives on human smoking behavior was gained by the measurement of biomarkers in smokers of different kinds of cigarettes, specifically those with and without additives. Biomarkers are highly specific indicators of the uptake of smoke constituents (innocuous or harmful) and reflect a smoker's individual smoking habits (number of cigarettes; puff number, volume and duration). No significant differences were observed when additive containing cigarettes (of the American blend type, preferred in the U.S. and continental Europe) were compared to additive free cigarettes (of the Virginia style, dominating, for instance, the U.K. and Canadian markets).

Conclusive evidence on the health risks due to the use of tobacco additives in cigarettes was obtained by the evaluation of properly designed and well conducted epidemiological studies. In a multi-country approach, smoking related mortality rates (for lung cancer and chronic obstructive pulmonary disease) were compared for smokers of American blend cigarettes (with additives) and Virginia cigarettes (without additives). No significant differences were found.

In practice, it is not possible to examine individual additives in epidemiological studies. This, however, is different for one additive, menthol. Because of its common use in certain markets (like the U.S.) data of sufficient quality and volume are available for conducting meaningful epidemiological assessments. In their entirety, more than a dozen studies (some of them with impressive numbers of participants) support the conclusion that smokers of mentholated cigarettes face no different risk of tobacco caused diseases (specifically lung cancer) than smokers of non-menthol cigarettes.

In summary, the results of a large amount of scientific work show that tobacco additives have only occasional and limited effects on cigarette mainstream smoke composition, which are almost never reflected in toxicological in vitro assays or in vivo studies, and do not confirm the assumption that the additives used in cigarette manufacturing increase the risk of smokers for any cancers, chronic obstructive lung disease or cardiovascular diseases. It is unproven that nicotine availability or nicotine addictiveness is enhanced and that additives seduce adolescents to smoke or reduce the effectiveness of smoking cessation measures.

As a matter of fact, the use of additives is important for technological reasons and - in certain cigarette styles - for competing successfully in the marketplace.

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