

EXPERT REPORT
on TOBACCO ADDITIVES

and

VALIDITY of the DUTCH
DECREE on LISTS of TOBACCO INGREDIENTS

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This is an Expert Opinion rendered in response to a request by the law firm of Pels Rijcken & Droogleever Fortuijn, The Hague, The Netherlands. This firm represents the Dutch State in a law suit brought by the tobacco industry against the Dutch State for incorrectly transposing European Directive 2001/37 into domestic law.

Specifically, the tobacco industry asserts that because the Dutch Regulation of April 14, 2003 requires disclosure of all ingredients used, by product and brand in descending order of weight, it violates the tobacco industry's proprietary trade secrets contained in their brand formulation. In this opinion I will demonstrate why the industry's assertion is unfounded.

The basis of this expert report is more than seventeen years experience with tobacco chemistry and science. For more than four years, I was the Chief Scientific Officer and Vice President of Research and Development and Environmental Affairs for Brown and Williamson Tobacco Corporation (B&W). B&W is the US subsidiary of British American Tobacco, plc, the world's second largest tobacco concern. In my capacity as Vice President, I was senior scientific officer for the corporation and responsible for all technical aspects of cigarette design and performance, formulation, consumer testing, product development, smoking and health issues, nicotine pharmacology and chemistry and manufacturing process specifications.

In addition, I have served as an expert witness in tobacco litigation both in the US and abroad, and have provided expert technical consulting to the US Food and Drug Administration (FDA), The Centers for Disease Control and Prevention (CDC), the Office of Smoking and Health, and to numerous countries, most extensively with the Canadian government.

My expert opinion relies on extensive review of industry documents produced in litigation dealing with cigarette design, additives and smoking and health issues.

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I) Introductory Remarks

For the purpose of this expert opinion, the terms “additive”, “ingredient”, and “flavoring” are all synonymous. They are defined as “any extraneous chemical substance that is intentionally or unintentionally added to any of the following entities: tobacco, reconstituted tobacco (RECON), add-ons, filtration materials, plug wrap, cigarette tobacco column and filter papers, and monogram and packaging inks used in the manufacture of cigarettes.”

I am aware that Article 2(5) of the EU Directive gives a definition of ‘ingredients’ in which terms “additives” or “flavouring” are not used.

I have been provided with copies of the EU Directive, the Dutch Regulation and the three Philip Morris commissioned expert reports by Mr. Thomas Cravotta, Prof. F.A. de Wolff and Dr. Hubertus Klus. I have not been provided with copies of the briefs submitted by plaintiffs and defendant to the District Court of The Hague.

I have been asked to address in particular the following questions:

1. Are you of the opinion that the manufacturing of a cigarette product involves trade secrets? In case of an affirmative answer, do trade secrets necessarily and exclusively relate to the flavoring of each brand or do they emerge from the specific combination of all ingredients used, their exact quantity and the manufacturing process applied?
2. Are you of the opinion that disclosure of a full list of ingredients in descending order as provided for in Table A of the Dutch Decree will enable competitors or counterfeiters to produce a cigarette product which would not be perceived as really different from the original by most consumers?
3. Do you believe that there is, from the point of view of informing the public on the toxicological risks of tobacco products, any value in giving governmental health agencies and consumers access to the full list of flavors used in descending order as to each brand?

For a proper understanding of my answers to those questions it is necessary not only to highlight the fundamental interests involved in a policy mandating disclosure of ingredients in tobacco products but also to explain at some length the science and chemistry of cigarette design. Only US blended (USB) cigarettes will be discussed in this opinion. The vast majority of cigarettes on the (legal) EU-market are USB cigarettes. Since the manufacture of USB cigarettes utilizes substantial quantities of additives, this opinion focuses on USB cigarettes rather than on Virginia tobacco based (VTB) cigarettes. VTB cigarettes utilize significantly fewer additives in the formulation of a given brand blend. Importantly, although USB cigarettes are the focus of this report, its

findings are applicable to all pyrolyzed tobacco products such as VTB, roll-your-own, pipe tobacco, and various cigar products.

II) Background¹

The health care and societal burdens associated with the use of tobacco are pervasive. Every year in the United States, 400,000 people lose their lives due to direct tobacco use and an additional 38,000 to 67,500 non-smokers lose their lives because of exposure to second hand smoke. In addition to causing 90% of the diagnosed lung cancer cases, tobacco use also directly contributes to coronary heart disease, emphysema, and cognitive impairment and disabilities in children (either through *in utero* exposure or passive neonatal exposure to second hand smoke). Moreover, tobacco use causes numerous other fatal or debilitating diseases accounting for 25% of the annual death toll. According to the World Health Organization (WHO), the number of world-wide deaths caused by tobacco use exceeds 5.1 million per year and is expected to double by 2025 as the tobacco industry infiltrates developing countries that have low or non-existent regulatory barriers with regard to their lethal and addictive products.

Since 1998, when the seven major tobacco companies and 46 state Attorneys General signed the Master Tobacco Settlement Agreement (MSA), governments have implemented modest and proactive policies to curb the harmful effects of tobacco. These policies take the form of smoke-free environments, disclosure policies and labeling regulations designed to make the consumer more informed about tobacco products, aggressive counter-advertising, and industry regulations that make exposure to tobacco products less harmful. These policies not only mitigate the health burdens caused by tobacco use, but also change the public's perception of tobacco products, thereby 'denormalizing' these products.

Rather than perceiving smoking to be what it truly is, a lethal activity for both the person who engages in it, and for those who are proximal to the smoker, the industry has convinced many that smoking is a natural and normal activity in which we have a right to engage. Clearly, denormalizing tobacco products, i.e., changing the public's perception that these products are a normal part of everyday life, to the perception that tobacco products are just as lethal as asbestos and hexavalent chromium, is integral to diminishing the health and societal burdens caused by tobacco. If the public does not understand the true dangers of smoking and exposure to second hand smoke, they will continue to engage in harmful behavior, with no decrease in mortality and morbidity rates in sight.

Policy makers rightly understand that they have the power and the responsibility to educate and protect the public with respect to tobacco products. Tobacco control policies have been proven to denormalize these products and subsequently mitigate the health burdens that they cause. Government's primary charge is to design policies that protect those fundamental interests that are necessary for an autonomous life. Among these interests, of course, is the interest to be free from undue harm. If individuals can

¹ Much of this section is taken from Jeffrey Wigand and Hope May (2005), *The Right To Choose: Why Governments Should Compel the Tobacco Industry to Disclose Its Ingredients*, Essays in Philosophy, vol. 6, no. 2, June 2005.

freely inflict harm on others without consequence, autonomy would be impossible. Also crucial to autonomy is the interest to be informed so that one can make a rational choice from a number of competing alternatives. Tobacco control policies are necessary to protect both interests. Some tobacco control policies protect citizens' interest to be free from harm; others protect the interest to be informed. For example, policies mandating 'smoke-free' environments protect the citizens' interest to be free from harm, whereas a policy that mandates the disclosure of ingredients in tobacco products protects the citizens' interest to be informed. The EU Directive clearly fits into the latter policy objective.

In what follows, I will explain the science and chemistry of cigarette design in order to illustrate how additives are used to affect the delivery of nicotine to the smokers' brain. As I will show, additives/ingredients/flavorings are only part of the overall cigarette design. Moreover, additives/ingredients/flavorings are only part of the brand's identity.

III) How Additives are used to affect the Addictive Properties of Nicotine

In the Annex to this Report, a comprehensive description is given of the chemistry of cigarette design. In this section, I will highlight a number of key elements of that description and indicate briefly the effects of some of the additives used in the manufacture of cigarettes. Only the full version contained in the Annex has a scientific claim. Obviously, the Annex is an integral part of this opinion.

a. Blend Formulation and Cigarette Components

The use of Reconstituted Tobacco ('RECON') is the principal method of introducing ammonia chemistry and other additives into the USB non-menthol cigarette blend. Ammonia chemistry is utilized for several reasons; 1) to scavenge nicotine from each blend component; 2) to equalize the concentration of nicotine in the tobacco column rod; and 3) to modify pH such that nicotine becomes a free base.

RECON is important because it introduces a significant amount of additives into the cigarette blend. These additives accomplish two distinct purposes: 1) they increase the addictive capacity of the cigarette, and 2) they facilitate the ease of smoking by ameliorating the effects of inhaling smoke.

RECON tobacco is a chemically manipulated material using abundant additives, such as glycerol, licorice, cocoa, honey, polyethyleneglycol (PEG), simple sugars, invert sugars and ammonia based additives such as ammonium hydroxide, urea and diammonium hydrogen phosphate (DAP). The ammonia based additives in RECON play a key role in the manipulation of nicotine.

For further explanations I refer to the Annex.

b) Additives

1. The Industry's GRAS/FEMA Argument

The US Food and Drug Cosmetic Act of 1936, and in particular CFR 21, provides for extraneously added chemicals that have been demonstrated as safe over an extended period of time in foods and cosmetics. These substances are granted a FDA designation as "**Generally Recognized As Safe**" or "**GRAS**" listed. In order to earn a place on the **GRAS** list, a chemical must meet two absolute requirements: 1) it must be found with reasonable scientific certainty to pose no harm, and 2) there must be a body of common knowledge with general availability that demonstrates acceptance of the chemical. Both of these requirements must be met in order for a chemical to earn a **GRAS** designation. In commenting on proving reasonable certainty of harm, the FDA claims:

"Safety requires proof of a reasonable certainty that no harm will result from the proposed use...if it does not and cannot-require proof beyond any possible doubt that no harm will result under any conceivable circumstance."

The toxicological proof burden is explicit and an obligatory mandate. To meet this burden, the following questions must be satisfactorily answered:

- 1) What kinds of chemical changes can occur?
- 2) In what amounts?
- 3) Are the products of these changes likely to be toxic in the amounts used?

Once a substance has scientifically achieved this standard, it then can be considered GRAS positive listing approved.

The tobacco industry claims that all of the additives used in the manufacture of cigarettes and other tobacco products are approved for use by either by the FDA GRAS list or the Flavor and Extract Manufacturers Association (FEMA) list.² These claims are faulty and misleading.

First, although an additive may be approved for use in foods or toiletries, when pyrolyzed, a benign additive can be transformed into a carcinogenic substance. Importantly, neither the GRAS nor the FEMA lists cover the use of the positive listing for use in any form of tobacco. Nor have any of the GRAS and FEMA positive listings been

² FEMA was formed in 1909 to ensure a substantial supply of safe flavor materials to the consumer. The key element of their mission is safe and wholesome flavors to enhance the appeal of foods, beverages and drugs. All are used expressly for ingested items and FEMA makes no claim for tobacco use(s). The FEMA Table and the GRAS Table are almost identical. Flavors not meeting the GRAS/FEMA positive list must be labeled "artificially flavored."

tested in tobacco, in a pyrolyzed state, or in conjunction with other pyrolyzed additives or tobacco. The industry has not tested any of its additives in any formal scientific manner consistent with due diligence or duty of care. The additives used in by the tobacco industry have not been tested neat, or in conjunction with other additives or in conjunction with tobacco in any scientifically accepted standardized toxicity protocols. Without this type of testing it is impossible to determine the toxicological effect of the single additive or the reaction product(s) on humans or provide adequate advice to the consumer.

Second, foods and cosmetics are “filtered” by the body’s detoxification systems, whereas the lungs lack any detoxification system. Therefore, a chemical may be “safe” if applied or ingested because the body’s detoxification systems disarm the potential harm that it may cause. But the very same chemical may be dangerous if inhaled through the lungs, since the lungs lack the capacity to disarm the potential of this chemical to do harm. The ingredients on the GRAS/FEMA lists have NEVER been approved for use in products that are inhaled directly into the body with unlimited access to virtually any organ system.

2. How Additives Change During Pyrolysis

There are several pertinent examples of how additives change during the pyrolysis process.

a. Sugars make up a major portion of additives contained in cigarettes. Simple sugars when pyrolyzed are converted into organic acids and subsequently to a variety of aldehydes. Of particular interest is the acetaldehyde, an aldehyde which intensifies the effect of nicotine on the brain and hence its addictive properties. Acetaldehyde-nicotine studies in animals demonstrate that animals tripled their self administration of nicotine in the presence of acetaldehyde. Even though acetaldehyde is not currently classified as a carcinogen, there is an abundance of animal and *in vitro* data supporting a classification of carcinogenicity. In addition, sugars are not listed anywhere in the FDA GRAS list. Caramel and invert sugars produce catechol. When heated, catechol produces a major known co-carcinogen in tobacco smoke. The Maillard reaction is responsible for the formation of caramel in the presence of amino acids or amines that can be derived from ammonia based additives or from complex mixtures of fruit extracts.

b. When pyrolyzed, Glycerol is converted to acrolein, a probable human carcinogen (Group C) and a ciliostatic agent in the lungs. Acrolein is a potent irritant, intensely chemically reactive and has acute toxicity.

c. Cocoa contains at least 10 psychoactive compounds that may affect the bioavailability of nicotine by acting on the respiratory system or increasing the permeability through the lung epithelium or increasing the smoke pH. In addition the combustion products of some of these compounds have MAO-I properties and may thereby together with the flavor enhancing effect contribute to the addiction of cigarette smoking.

3. Biotoxification Systems: The Body vs. The Lungs

The fact that the additives/ingredients/flavorings that appear on the GRAS/FEMA Tables are designated to be used in foods and cosmetics/toiletries is important because ingredients that are ingested have a unique and different effect on the body than ingredients that are pyrolyzed and then inhaled. The biochemical digestion process of the approved additives has multiple opportunities to be detoxified in the body's biochemical systems through biotransformation and biotransformation. The body's digestive enzymes hydrolyze compounds such as esters, acetals, lactones, and glycosides. In the lungs, on the other hand, these same chemical reactions do not occur. This is because unlike the lungs, the body, through its biochemical systems, is able to distinguish different types of toxic substances based on their "functional groups" (i.e., the complex molecular structure that is characteristic of each chemical). For example, the body will metabolize a molecular structure known as an "aliphatic chain" more efficiently than it will metabolize a more complex structure known as an "aromatic ring." This is because the former structure comprises a straight chain of saturated chemical bonds, whereas the latter structure is a cyclical chain of unsaturated chemical bonds. The lungs, however, not only lack the discriminatory capacity possessed by the body's detoxification system, even worse, the lungs lack *any* capacity to identify the molecular structure of a toxic substance. Whereas the body has a variety of detoxification processes which correspond to the various molecular structures found in toxic substances, the lungs have none. When introduced into the body, a toxic substance will meet with biochemical defenses, but when introduced into the lungs, a toxic substance will inevitably inflict damage, since the lungs have no defenses at all. The lungs are a "chink" in the body's "armor" and once a toxic substance gets through this chink, it wreaks maximum damage by going directly into the bloodstream, and ultimately to the heart and the brain. Therefore, pyrolyzed additives or intact transferred additives are not biotransformed or biotransformed in the same manner as with the process of ingestion and subsequent digestion. Biotransformation systems make substances less toxic to the body and less likely to cause human biotoxicity. Unfortunately, the lungs lack biotransformation systems.

Because tobacco additives are not rendered less toxic by the normal biochemical processes of the body, the industry's insistence that their ingredients should not be disclosed, and their argument that the ingredients in tobacco products are safe because they appear on the GRAS or the FEMA lists, jointly contribute to the public's misunderstanding about tobacco products. In addition, the industry's assertion that ingredients in their products are safe because they are either GRAS or FEMA approved, does not account for any of the pyrosynthetic reactions of the additive or their pyrolytic breakdown products. It is also noteworthy that cigarette smoke contains numerous free radicals that are highly reactive chemical species. Free radicals can react with other additives, pyrolytic products or living cells.

Since the industry does not provide precisely what levels of additives are used in its cigarettes it is impossible for anyone, whether it be governmental health agency or the public, to evaluate judiciously the exposure levels of what might pass into a smoker's lungs. In addition, the asserted inferred health claim is not substantiated by any

reasonable bio-toxicity studies that support the claim of human safety when inhaled with other additives and tobacco smoke. Lastly, the industry has not fulfilled its regulatory duty to obtain approval for the additives it uses in the production of its tobacco products. Some of the key elements of this approval are: data and information establishing "safety", intended technical effect, conditions of proposed use, identity, toxicological considerations, chemical composition, and literature search.

IV) Critical Analysis of Tobacco Industry Expert Reports

1. Cravotta Expert Report

The point this report is trying to make is that the ingredient system disclosure requested in Table A of the Dutch Decree provides third parties with information otherwise not available.

I do not think the Cravotta report is convincing. Overall, it gives an over simplification of the cigarette manufacturing process and is technically inaccurate in its scope and understanding of contemporary analytical techniques and instrumentation.

The information on tobacco processing and flavoring (section 2) starts from the premise that there exists a separate and identifiable category of "flavorings". In so doing, the industry aims at excluding certain ingredients from disclosure to the public. The most likely reason for the desired exclusion is that the ingredients in question have chemical properties which would not be in the industry's interest to reveal. In reality, a separate category of aromatic ingredients does not really exist. All ingredients used and all manufacturing processes described in the Annex to this report jointly make up for the final result. It is a combination of all the components of a cigarette, all ingredients and the manufacturing process, that gives a particular brand its character. It is my firm view that the fact that the industry claims that "flavorings" comprise a separate category is further evidence that they seek to confuse and mislead the consumer. We should respond to this accordingly, by protecting the consumer's sovereignty, and by mandating full disclosure of ingredients.

In sections 3, 4 and 5, the Cravotta report understates the existing technical possibilities to reconstruct the exact composition of a cigarette product. Reverse engineering is readily achievable in today's analytical laboratory through the use of sophisticated analytical systems linked to organoleptic sensory testing. For example, reverse engineering has defined every component of the Marlboro cigarette, its blend of tobaccos, flavor packages, etc. Thus, at B&W we were able to separate each of the blend components and fully analyze the chemical makeup of the component. The specificity of our analytical efforts was such that we were able to define the exact type of licorice that was used in the additive package of a Marlboro, the physical structure of the cigarette as well their use of ammonia based additives in casings and RECON. The "reversed engineered Marlboro" was tested against actual Philip Morris produced Marlboros and to the consumer at 95% confidence level, and was found to be identical

to the Philip Morris produced Marlboro. The ability to reverse engineer any specific brand is therefore well within the domain of a state-of-the-art laboratory.

However, without the infrastructure of marketing and promotional financial assets to support the brand recognition and manufacturing capacity, the reversed engineered product has little or no potential to usurp the recognized brand. To simply assert that a competitor can gain market share just by reproducing a leading brand is naive and lacks an understanding of the marketing effort needed to establish a brand image. It is *not* just taste that makes a brand. In order for a brand to be successful, i.e., have 5-10% market share, millions of dollars must be expended continually to establish and maintain brand image.

In Section 6 of the Cravotta report it is suggested that disclosure of the information in the format of Table A of the Dutch Decree would allow third parties to copy specific brands of cigarettes and hence would increase the risk of copying. I disagree.

Sophisticated laboratories are already able to reverse engineer specific brands of cigarettes (see above). Counterfeiters too may have access to such laboratories.

Moreover, public disclosure of the information contained in Table A does not facilitate reverse engineering carried out with a view to developing a new cigarette brand having a taste that comes as closely as possible to that of the original brand. What the Cravotta report fails to recognize is that a cigarette brand is more than the aggregate sum of all its ingredients; the manufacturing *process* is equally relevant. It would also be rather pointless to expend resources in order to reverse engineer a brand, if it is unlikely that the 'new' brand will sell in any significant numbers (see above).

Nor does public disclosure of the information contained in Table A does not help counterfeiters who may wish to copy a particular tobacco product *and* its packaging with a view to selling it as if it were an original product. On this particular issue, the Cravotta report appears to be based on an erroneous reading of the Dutch Decree. As I understand it, Table A requires ingredients to be disclosed, not the flavor system 'formula,' as the author suggests. Furthermore, Table A does not require the industry to produce any information regarding the manufacturing process. Finally, Table A only requires tobacco companies to list ingredients in *rank order*. The information thus requested is definitely not sufficiently precise to allow counterfeiting.

I must admit that the counterfeiting issue somehow strikes me as a smoke screen. Counterfeiting is a criminal offense, in the US and in the EU. The claim that disclosure of ingredient information following the format of Table A increases the risk that criminal offenses be perpetrated is difficult to sustain. In all likelihood, the tobacco industry uses the alleged risk of counterfeiting as a deterrent argument to stop government measures aimed at protecting public health or informing consumers of toxicological and other health risks, just as it has frequently claimed that an increase of tobacco excise duties exacerbates the risks of cigarette smuggling. Again, such arguments are used for no other reason than to discourage the government from enacting measures that the

industry sees as contrary to their commercial interests.

2. De Wolff Expert Report

This author holds that in comparison to the three list model applied by the tobacco industry, the information to be produced under the Dutch Decree does not have any real added value, neither for the purpose of making a toxicological assessment nor for the purpose of informing the consumer. The apparent implication is that the Decree is excessive in its requirements.

I disagree with the toxicological assessment made by this author.

In order to make a determination on the bio-risk one not only needs the exact chemical entity, and the quantity of the chemical entity. One also needs the chemical entity's reaction, neat and in combination with the other chemicals produced in a pyrolytic system that burns from 300 degree C to 900 degree C. It is not a paper exercise to evaluate the fate and risks associated with any of the over 599 intentional additives. In addition, the asserted inferred health claim is not substantiated by any reasonable bio-toxicity studies that support the claim of human safety when inhaled with other additives and tobacco smoke.

As long as the industry does not disclose precisely what levels of additives are used in its cigarettes, it is impossible for anyone, whether it be governmental health agency or the public, to evaluate judiciously the exposure levels of what might pass into a smoker's lungs; and it is equally impossible to determine the toxicological effect of the single additive or the reaction product(s) on humans or to provide adequate advice to the consumer. The three-list model is therefore neither a proper basis for carrying out any well-informed toxicological assessment nor an adequate means of informing the consumer.

The three list model does not give the consumer exact information about all ingredients processed in a specific brand and type of tobacco product. With regard to some ingredients, the consumer will only know that these ingredients *might be* present in his or her brand. Exact information on all ingredients used is missing. Such limitation shall not be justified by the false argument of trade secrets. Besides, such limitation is a blatant denial of the inalienable right of consumers to optimum information about the product they consume. In addition, the trade secret argument violates the Doctrine of Consumer Sovereignty. According to this doctrine, misrepresenting or withholding material information is prohibited, since a consumer can exercise a free, rational choice to consume a product, only when fully and accurately informed.

I would even go further and say that the information on Table A, even though it goes beyond the level of detail of the three list model, nevertheless comes nowhere near the information required to make an evaluation of the exposure levels that meets the requisite scientific standards. For such purposes it would be necessary at the very least

to know the exact quantities of all ingredients used, as mentioned in Table B of the Dutch Decree, and not just the quantities in rank order.

3. *Klus Expert Report*

The Klus report claims that tobacco products are essentially the sum of two different “ingredients:” 1) the manufacturing process, and 2) the flavorings. Whereas the former consists of ingredients and processes that are common knowledge, the latter does not.

Basically, I have the same comments as above. There are many simplifications in this report that are inaccurate, e.g. RECON is neutral filler and does not contribute to the character of a given brand. This is in direct contradiction to the industry's own documents as to how RECON enhances nicotine delivery and sensory attributes.

As already stated in reaction to the Cravotta report, a separate and well-defined category of ingredients referred to as ‘flavoring’ simply does not exist. A large number of the ca. 599 additives, many of which Dr Klus rightly considers as being generally known or easily identifiable, account directly or indirectly for the flavor of the cigarette brand.

Overall, the Klus testimony fails to make clear what ingredients would not be identifiable and why. Interestingly, the author implicitly admits that any trade secrets only relate to the manufacturing *process* (at par 3.2.4).

V. Questions to be addressed

1) *Are you of the opinion that the manufacturing of a cigarette product involves trade secrets? In case of an affirmative answer, do trade secrets necessarily and exclusively relate to the flavoring of each brand or do they emerge from the specific combination of all ingredients used, their exact quantity and the manufacturing process applied?*

a) There is very little trade secret information in the production of a given cigarette brand and if there is, only the methods of combining all the design features of a cigarette brand (the manufacturing/product specifications) are the true proprietary secrets. The additives are just one component of the total design characteristics.

b) There is no trade secret information contained in a mere list of ingredients in rank order by brand.

c) There is no sustainable basis for distinguishing certain types of ingredients as flavoring, merely for the purpose of excluding them from public disclosure.

2) *Are you of the opinion that disclosure of a full list of ingredients in descending order as provided for in Table A of the Dutch Decree will enable competitors or counterfeiters to produce a cigarette product which would not be perceived as really different from the original by most consumers?*

Table A is not adequate to duplicate a brand. On the one hand, it does not add ingredient information that could not also be identified by a state-of-the-art laboratory by reverse engineering. On the other hand, further and more detailed information, about both the ingredients used and the manufacturing process followed, would be needed to duplicate a brand.

3) *Do you believe that there is, from the point of view of informing the public on the toxicological risks of tobacco products, any value in giving consumers access to the full list of flavors used in descending order as to each brand?*

a) It is the government as well as the scientific community that will find the comprehensive list of additives valuable. These scientific entities can understand and interpret the toxicological implications of a specific additive or combinations of additives in a pyrolytic system. These understandings could lead to a list of approved additives or banned additives based on their toxicological implications on the human system. In combination with information on the manufacturing process and the pyrolytic system applied, Table B of the Dutch Decree constitutes a suitable basis for making a toxicological assessment in accordance with the requisite scientific standards.

b) The public is entitled to full knowledge as to what is in the product they are using in order to make an informed and responsible decision. In my opinion, public disclosure of the information on Table A is an adequate and appropriate means to inform the consumer.

VI) Final Statement³

A public disclosure of the complete ingredient list for each tobacco product is necessary to adequately protect public health. Such a list is consonant with a government's fundamental charge to protect the interests of citizen-consumers. The fact is, no tobacco company uses due diligent laboratory testing on their intentional additives either neat or in combination with other additives to assess any increased biotoxicity. The industry practice is to have lawyers construct "white papers" for each additive without any valid laboratory testing of either the additive's toxicity when burned in isolation, or when burned in conjunction with other additives or components of the product. Each and every additive or ingredient used in the manufacture of a tobacco product should be tested in the manner in which it is used, i.e., being burned with other chemicals.

Given that the industry does not adequately test the additives that it uses in its products, then at the very least, the ingredients in these products should be disclosed so

³ Much of this section is taken from Jeffrey Wigand and Hope May (2005), *The Right To Choose: Why Governments Should Compel the Tobacco Industry to Disclose Its Ingredients*, Essays in Philosophy, vol. 6, no. 2, June 2005.

that public interest groups, conscientious scientists and policy makers can conduct the research that is necessary to adequately inform the public. It is interesting to note that some tobacco companies promote some of their products as "additive free," implying that the absence of additives is a healthier alternative to products laden with additives.

With a proper understanding of the science and chemistry of tobacco products, both policy makers and judges should see that disclosure policies are necessary to protect the public interest, whilst posing minimal burdens on the tobacco industry.

Jeffrey S. Wigand
Mt. Pleasant, Michigan
19 May 2005,

ANNEX

The Chemistry and Science of Cigarette Design

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a. Blend Formulation and Cigarette Components

a.1. TOBACCO TYPES

There are three specific types of tobacco that are used in the manufacture of a US Blended cigarette (USB):

1) *Flue cured or sometimes referred to as fire cured, Virginia or bright tobacco.* This type of tobacco is aged by using heat in the post harvest senescence period. This tobacco cultivar is characteristically moderate in nicotine and relatively high in natural sugar content.

2) *Burley or air cured.* This type of tobacco is ambient air cured in the post harvest senescence period. It is characteristically high in nicotine and low in sugar content.

3) *Oriental tobacco* grown in countries in the Mediterranean area such as, Yugoslavia, Greece, and Turkey. This tobacco is characteristically low in both nicotine and sugars but relatively high in volatile aromatic compounds.

In the USB cigarette there is an equal ratio on a weight-weight basis (w/w) of flue cured and burley but can be skewed in favor of either tobacco type. This mixture accounts for ca. 50% of the total mass of the cigarette tobacco column rod.

Oriental tobacco makes up less than 5% w/w of the tobacco column rod.

a.2. RECONSTITUTED TOBACCO (RECON)

The use of RECON is the principal method of introducing ammonia chemistry and other additives into the USB non-menthol cigarette blend. Ammonia chemistry is utilized for several reasons; 1) to scavenge nicotine from each blend component; 2) to equalize the concentration of nicotine in the tobacco column rod; and 3) to modify pH such that nicotine becomes a free base. *Free nicotine*, which is controlled by smoke pH, is a more potent form of nicotine that is in the gas phase rather than bound nicotine that is in the particulate phase. The extensive use of ammonia chemistry in RECON converts the salt linked or protonated nicotine into "free" nicotine that has a higher potency than its salt/protonated form. Free nicotine it is not detected by the smoking machine analysis of tar and nicotine since it is in the gaseous state not in the particulate state of matter.

The primary importance of RECON is neither the utilization of manufacturing waste nor the enhancement of economy of manufacture. Rather, RECON is important because it introduces a significant amount of additives/ingredients/flavorings into the cigarette blend. These additives/ingredients/flavorings accomplish two distinct purposes: 1) they increase the addictive capacity of the cigarette and 2) they facilitate the ease of

smoking by ameliorating the effects of inhaling smoke.

RECON tobacco comprises about 20-30% of a USB cigarette's blend formulation on a w/w basis. It is a chemically manipulated material using abundant additives, such as glycerol, licorice, cocoa, honey, polyethyleneglycol (PEG), simple sugars, invert sugars and ammonia based additives such as ammonium hydroxide, urea and diammonium hydrogen phosphate (DAP). The ammonia based additives in RECON play a key role in the manipulation of nicotine. The finished product is a highly energized chemical matrix which forms the basis of many of the chemical reactions occurring in the tobacco rod column, such as nicotine scavenging, generation of free nicotine, smoke pH manipulation, and formation of some flavor reaction products.

a. Raw material components and composition of RECON

RECON is produced utilizing by numerous by-products of the cigarette manufacturing process. There are three (3) distinct RECON types; Paper I, Paper II and band cast. The raw material used to make RECON contains the following components:

- 1) *Offal or the tobacco dust* generated in either the Green Leaf Trashing (GLT) plant or in the Primary manufacturing process. The GLT Plant strips and removes the veins of the tobacco leaf into large strips of lamina and produces a by-product called stems. Stems can be utilized either as a cigarette blend component or as one of the sources of raw material for RECON.
- 2) The primary portion of the manufacturing plant produces the fines and winnowers when tobacco, a moisture sensitive biomaterial is moved rapidly through the manufacturing process, either pneumatically or via high-speed conveyor belts. This aspect of the manufacturing process causes dehydration and brittleness of the tobacco material, and therewith the formation of tobacco fines and dust (offal).
- 3) *Stems* produced at the GLT Plant
- 4) *Tobacco fines or winnowers*
- 5) *Product Reclaim*. Finished product that is collected from the distribution channel is returned to the manufacturing plant for reprocessing. This includes the finished goods that, due to moisture content loss, are deemed unsuitable for smoking due to increased irritation, harshness and the fact that they pose a fire hazard.

When they leave the manufacturing plant, cigarettes are at ca. 14-14.5% moisture content (MC). This MC decreases at the rate of 0.5% per month until the MC reaches 10-11 % at which time they are collected and returned to the manufacturing plant for reutilization. Essentially, a finished product leaving the manufacturing plant has 6-8 months of shelf life contingent on ambient conditions. Large variations in temperature, humidity and storage conditions

can greatly affect the rate of moisture loss.

The filter and tobacco rod column paper are then mechanically removed and the original manufactured tobacco with all its additives are reclaimed. Non-menthol and menthol cigarette brands are processed separately.

- 6) *Unique tobacco cultivars* are used either to augment nicotine content or to flavor attributes of the final RECON product.
- 7) *Cellulosic* material from wood pulp added for fiber content

b. How is Paper RECON Made?

There are two distinct types of paper RECON; Paper I and Paper II. The paper RECON is manufactured using the Schweitzer process and it is the same manufacturing process utilized in the manufacture of ordinary paper. The differentiating factor of the final RECON product depends on where in the EU the RECON will be used, and the specific country regulations on the types of additives that can be used in the manufacture of cigarettes. The main difference between Paper I and Paper II is the use of diammonium hydrogen phosphate (DAP). In some countries e.g. Germany, the use of DAP as an additive is prohibited.

1. Type I

Paper RECON is made by taking tobacco by-product materials and putting them through a process of repetitive hot water extraction until the residual material is white cellulosic pulp/fiber suspended in an aqueous medium. The extracted solubles are collected in a thermally controlled reaction vessel/vat where additives are combined and chemically reacted. This extracted solution is referred to as the "Mother Liquor" and it can be concentrated or diluted as required or specified in the manufacturing process.

The cellulosic pulp is poured onto a moving stainless steel (S/S) perforated belt which has a vacuum applied to the underside of this belt. The application of the vacuum facilitates the removal of the water and the formation of the paper sheet. Both the rate at which the cellulosic pulp is applied to the belt and the rate of dehydration control the basis weight of the formed sheet, i.e. the thickness.

The chemically reacted "Mother Liquor" is then reapplied to the partially dehydrated paper sheet at the terminus of the sheet formation process. The rate of application is also a controllable parameter in the final product. The two main controllable variables in this process are 1) the basis weight and 2) the chemically reacted "Mother Liquor" application rate. Both factors can determine the final chemical characteristics of the final product, such as nicotine or additive content.

The product is dried and cut into irregular pieces and placed into plastic lined container.

2. Type II

The only difference in paper RECON Type II product is that there is NO DAP added to the "Mother Liquor" in the reaction vessel/vat. Albeit, the same ammonia chemistry for which DAP is responsible is achieved through other means, i.e. by using ammonia and salts of organic acids.

3. Band cast reconstituted tobacco (DARK RECON)

Band cast uses the same starting raw materials but differs fundamentally from the paper making RECON process. Unlike the paper process, band cast is made by adding the stock raw tobacco materials (see list above) and prescribed chemical additives into one reaction vessel. The tobacco material is then pulverized with the additives forming a thermally and chemically reacted slurry mixture. The sheet is made by pouring the slurry into a "doctor blade" which regulates the amount of slurry that is applied to a moving S/S non-perforated belt. The basis weight can be controlled at this point.

The slurry mixture then goes through three separate heating zones where the water content is reduced forming a solid sheet. This solid sheet is then cut into irregular pieces and boxed in a similar manner to the paper RECON.

a.3. ADD-ONS

a. Expanded Tobacco (ET)

ET is produced by use of either the ammonium carbonate (ACET) or the pressurized carbon dioxide expansion process. The expansion process "puffs" either stems or lamina utilizing the different states of matter of carbon dioxide at different temperatures and pressures. In the case of ACET, however, the thermal decomposition of ACET into carbon dioxide and ammonia is utilized to puff either stems or lamina. Both expanded stems and lamina are treated with casing sauces. Additives are also added to these forms of ET.

b. Stems

There are two basic types of stems that are added to the blend, water treated stems (WTS) or shredded dry stems (SDS).

c. Shorts

These are small tobacco fragments added to the blend that originated when the longer strands (tobacco rag) break down during the manufacturing process. The amounts and sizes of shorts are closely controlled since the pressure drop, resistance to draw (RTD) and combustion mechanics are affected by the dimension of the shorts.

a.4 SUMMARY

Composition of a typical USB non-menthol cigarette:

Burley/Flue Cured Tobacco	45-50%
Oriental	<5%
RECON	
Paper	10-15%
Band	15-20%
ET	5-10%
Shorts	<5%
Stems	<5%

b) ADDITIVES/INGREDIENTS/FLAVORS

There are ca. 599 additives that are used in cigarette manufacturing and account for 10% by weight of the cigarette and mostly in the form of sugars, flavorants, and humectants, excluding water. Additives are used to ameliorate the effects of inhaling smoke and to enhance the delivery of addictive nicotine.

There are four (4) main groups of tobacco additives:

- 1) Processing aides
- 2) Casing sauces
- 3) Flavorants, and
- 4) Combustion modifiers

b.1 INTENTIONAL ADDITIVES

1. The Industry's GRAS/FEMA Argument

The US Food and Drug Cosmetic Act of 1936, and in particular CFR 21, provides for extraneously added chemicals that have been demonstrated as safe over an extended period of time in foods and cosmetics. These substances are granted a designation as "**Generally Recognized As Safe**" or "GRAS" listed. In order to earn a place on the GRAS list, a chemical must meet two absolute requirements: 1) it must be found with reasonable scientific certainty to pose no harm, and 2) there must be a body of common knowledge with general availability that demonstrates acceptance of the chemical. Both these requirements **MUST** be met to have a GRAS designation. In commenting on proving reasonable certainty of harm, the FDA claims:

"Safety requires proof of a reasonable certainty that no harm will result from the proposed use...if it does not and cannot-require proof beyond any possible doubt that no harm will result under any conceivable circumstance."

The toxicological proof burden is explicit and an obligatory mandate. To meet this burden, the following questions must be satisfactorily answered:

- 1) What kinds of chemical changes can occur?

- 2) In what amounts?
- 3) Are the products of these changes likely to be toxic in the amounts used?

Once a substance has scientifically achieved this standard, it then can be considered GRAS positive listing approved.

The tobacco industry claims that all of the additives used in the manufacture of cigarettes are approved for use by either by the GRAS list or the Flavor and Extract Manufacturers Association (FEMA) list.⁴ These claims are faulty and misleading.

First, although an additive may be approved for use in foods or toiletries, when pyrolyzed, a benign additive can be transformed into a carcinogenic substance. Importantly, neither the GRAS nor the FEMA lists cover the use of the positive listing for use in any form of tobacco. Nor have any of the GRAS and FEMA positive listings been tested in tobacco, in a pyrolyzed state, or in conjunction with other pyrolyzed additives or tobacco. The industry has not tested any of its additives in any formal scientific manner consistent with due diligence or duty of care. The additives have not been tested neat, or in conjunction with other additives or in conjunction with tobacco in any standardized toxicity protocols, such as the tiered program of the NTP. Without this type of testing it is impossible to determine the toxicological effect of the single additive or the reaction product(s) on humans or provide adequate advice to the consumer.

Second, foods and cosmetics are “filtered” by the body’s detoxification systems, whereas the lungs lack any detoxification system. Therefore, a chemical may be “safe” if applied or ingested because the body’s detoxification systems disarm the potential harm that it may cause. But the very same chemical may be dangerous if inhaled through the lungs, since the lungs lack the capacity to disarm the potential of this chemical to do harm. The ingredients on the GRAS/FEMA lists have NEVER been approved for use in products that are inhaled directly into the body with unlimited access to virtually any organ system.

2. How Additives Change During Pyrolysis

There are several pertinent examples of how additives change during the pyrolysis process.

a. Sugars make up a major portion of additives contained in cigarettes. Simple sugars when pyrolyzed are converted into organic acids and subsequently to a variety of aldehydes. Of particular interest is the acetaldehyde, an aldehyde which intensifies the effect of nicotine on the brain and hence its addictive properties. Acetaldehyde-nicotine studies in animals demonstrated that animals tripled their self administration of nicotine in the presence of acetaldehyde. Even though acetaldehyde is not currently classified as

⁴ FEMA was formed in 1909 to ensure a substantial supply of safe flavor materials to the consumer. The key element of their mission is safe and wholesome flavors to enhance the appeal of foods, beverages and drugs. All are used expressly for ingested items and FEMA makes no claim for tobacco use(s). The FEMA Table and the GRAS Table are almost identical. Flavors not meeting the GRAS/FEMA positive list must be labeled “artificially flavored.”

a carcinogen, there is an abundance of animal and *in vitro* data supporting a classification of carcinogenicity. In addition, sugars are not listed anywhere in the FDA GRAS list. Caramel and invert sugars produce catechol. When heated, catechol produces a major known co-carcinogen in tobacco smoke. The Maillard reaction is responsible for the formation of caramel in the presence of amino acids or amines that can be derived from ammonia based additives or from complex mixtures of fruit extracts.

b. When pyrolyzed, Glycerol is converted to acrolein, a probable human carcinogen (Group C) and a ciliostatic agent in the lungs. Acrolein is a potent irritant, intensely chemically reactive and has acute toxicity.

c. Cocoa contains at least 10 psychoactive compounds that may affect the bioavailability of nicotine by acting on the respiratory system or increasing the permeability through the lung epithelium or increasing the smoke pH. In addition the combustion products of some of these compounds have MAO-I properties and may thereby together with the flavor enhancing effect contribute to the addiction of cigarette smoking.

3. Biotoxification Systems: The Body vs. The Lungs

The fact that the additives/ingredients/ flavorings that appear on the GRAS/FEMA Tables are designated to be used in foods and cosmetics/toiletries is important because Ingredients that are ingested have a unique and different effect on the body than ingredients that are pyrolyzed and then inhaled. The biochemical digestion process of the approved additives has multiple opportunities to be detoxified in the body's biochemical systems through biotransformation and biotransformation. The body's digestive enzymes hydrolyze compounds such as esters, acetals, lactones, and glycosides. In the lungs, on the other hand, these same chemical reactions do not occur. This is because unlike the lungs, the body, through its biochemical systems, is able to distinguish different types of toxic substances based on their "functional groups" (i.e., the complex molecular structure that is characteristic of each chemical). For example, the body will metabolize a molecular structure known as an "aliphatic chain" more efficiently than it will metabolize a more complex structure known as an "aromatic ring." This is because the former structure comprises a straight chain of saturated chemical bonds, whereas the latter structure is a cyclical chain of unsaturated chemical bonds. The lungs, however, not only lack the discriminatory capacity possessed by the body's detoxification system, even worse, the lungs lack *any* capacity to identify the molecular structure of a toxic substance. Whereas the body has a variety of detoxification processes which correspond to the various molecular structures found in toxic substances, the lungs have none. When introduced into the body, a toxic substance will meet with biochemical defenses, but when introduced into the lungs, a toxic substance will inevitably inflict damage, since the lungs have no defenses at all. The lungs are a "chink" in the body's "armor" and once a toxic substance gets through this chink, it wreaks maximum damage by going directly into the bloodstream, and ultimately to the heart and the brain. Therefore, pyrolyzed additives or intact transferred additives are not biotransformed or biotransformed in the same manner as with the process of ingestion and subsequent digestion. Biotransformation systems make

substances less toxic to the body and less likely to cause human biotoxicity. Unfortunately, the lungs lack biotransformation systems.

Because tobacco additives are not rendered less toxic by the normal biochemical processes of the body, the industry's insistence that their ingredients should not be disclosed, and their argument that the ingredients in tobacco products are safe because they appear on the GRAS or the FEMA lists, jointly contribute to the public's misunderstanding about tobacco products. In addition, the industry's assertion that ingredients in their products are safe because they are either GRAS or FEMA approved, does not account for any of the pyrosynthetic reactions of the additive or their pyrolytic breakdown products. It is also noteworthy that cigarette smoke contains numerous free radicals that are highly reactive chemical species, reaction with other additives, pyrolytic products or living cells.

Since the industry does not provide precisely what levels of additives are used in its cigarettes it is impossible for anyone, whether it be governmental health agency or the public, to evaluate judiciously the exposure levels of what might pass into a smoker's lungs. In addition, the asserted inferred health claim is not substantiated by any reasonable bio-toxicity studies that support the claim of human safety when inhaled with other additives and tobacco smoke. Lastly, has the industry fulfilled its regulatory duty to obtain approval for the additives it uses in the production of its tobacco products. Some of the key elements of this approval are: data and information establishing "safety", intended technical effect, conditions of proposed use, identity, toxicological considerations, chemical composition, and literature search.

c. Processing Aides

Processing aides are generally used in the physical construction of the cigarette to adhere the plugwrap paper to the filter rod. These processing aides include:

- 1) Sideseam paper adhesive for securing the cigarette paper around the tobacco rod section (vinyl acetate & ethylene copolymer);
- 2) Filter and tipping adhesive (triacetin);
- 3) Monogram ink and filter tipping paper for logo and/or brand identification;
- 4) Whitening agents (titanium dioxide/talc);
- 5) Burn control chemicals (potassium/sodium citrate); and
- 6) Lip release silicones that are added to the filter tipping to prevent the filter paper from sticking to the smoker's lips.

Monogram Inks are particularly interesting since many of the brand identification packaging inks are from organic solvent based systems. The inks have the capacity to migrate from the packaging materials into the filter and tobacco rod during storage, particularly when a barrier film has been applied to the individual cigarette pack and carton and when favorable mass transfer is present due to ratio of the mass of the packaging to the mass of the cigarettes. For instance, ultra slim cigarettes have a high package weight relative to the tobacco content, and therefore the inks tend to migrate to the filter and tobacco rod of this product. Some of the additives used in monogramming inks include linseed varnish, mineral oil, color pigments, phenolic resins, and antioxidant solvents.

d. Casings/sauces

Casings are an aqueous solution of additives. These additives include:

- 1) sugars;
- 2) DAP;
- 3) urea;
- 4) licorice;
- 5) cocoa;
- 6) chocolate;
- 7) butter fat;
- 8) furfural acetate;
- 9) maltol;
- 10) honey;
- 11) PEG;
- 12) glycerol

- 13) levulinic acid
- 14) salts of organic acids;
- 15) pyridine;
- 16) extracts of carob bean; and
- 17) coffee

These additives are applied in the primary section of the cigarette manufacturing plant. The casings are applied to burley and flue cured tobacco, stems and ET. They are applied on the tobacco and then the tobacco is re-dried either in a heated tunnel or via a cold drying system. There are multiple applications of casings. First, casings are applied to the burley side of the blend to facilitate nicotine equilibration, nicotine migration, nicotine scavenging and changing the smoke pH. Second, casings are used to ameliorate the harshness of smoking. In short, casings are applied to the blend in order to facilitate the delivery of nicotine to the smoker's brain, with minimal harshness.

Top dressings are alcohol soluble chemicals that are applied at the final stages of the primary manufacturing process. Menthol is one type of flavorant. The primary part of the manufacturing plant treats tobacco with casings and flavorants before it is cut into what is referred to as a "rag." The completed blend is squeezed, and reduced into an open tunnel to what is referred to as a "cheese" and cut at 22 to 28 cuts per inch. Once the blend is cut into "rag" it is pneumatically transferred to the fabrication side of the manufacturing plant where it is made into tobacco column rods. A filter is then added and the final product is packaged in packs and cartons. The rate of modern cigarette manufacture is 20,000-30,000 cigarettes per minute. Once they have been packaged, cigarettes are held in conditioned storage for at least two weeks to allow for the chemical reaction aging process to finish. This is particularly important with non-menthol cigarettes utilizing ammonia chemistry.

b.2 Unintentional additives

Tobacco carries with it all the non-intentional additives derived from the agronomic process, such as pesticides, herbicides, suckering agents and the normal bacteriological flora unique to the soil. Such organisms as *Bacillus subtilis*, *Aspergillus niger* and other microbiological organisms (molds, bacteria, fungi) are included in the tobacco final product as inactive spores. Many of these organisms are activated with moisture ca. 20% and can ferment the additives into potent toxins, called aflatoxins. In addition, there are insects and foreign materials included in finished cigarette product.

a. Pesticides

The ethyldithiocarbamate pesticides when pyrolyzed become ethylthiourea (ETU), a potent carcinogen. Maleic hydrazide (MH-30), dichloram, dieldrin, endrin, DDT and organochlorine residues are found in the final product at levels in excess of maximum permissible levels or tolerance levels.

b. Foreign Materials

The inclusion of polyurethane in the final product is also an unintentional additive from the insulation in curing barns as well as rubber parts from the manufacturing conveyor belts, as well as wood and metal fragments.

c. Extraneous hazardous chemicals

Dioxin is incorporated into "value for money" (lower cost products) cigarettes as a result of using recycled paper to produce the cigarette tobacco rod paper. It is a carry over from the recycling process particularly when organic based inks are used in the paper printing process. Dioxin has been listed in the 10th ROC as "having no safe dose or threshold below which Dioxin will NOT cause cancer." Premium priced cigarettes utilize virgin flax as the source of cigarette rod paper.

In addition, Benzene, Toluene as well as other organic solvents that are used in the printing process of cigarette packaging carry over and migrate into the cigarettes contained in the cellophane encased package.

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19 May 2005