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(54) **SMOKEABLE PRODUCT WITH REDUCED
CONTENT OF PATHOGENS**

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(57) **ABSTRACT**

Smokeable products, such as tobacco, substantially free of pathogens, and methods for the preparation of such products, are disclosed.

SMOKEABLE PRODUCT WITH REDUCED CONTENT OF PATHOGENS

[0001] This application claims the benefit under 35 USC §119(e) from U.S. provisional patent application Ser. No. 60/880,738, filed Jan. 17, 2007, which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The application relates to a smokeable product in a finished form ready for smoking wherein said smokeable product has been treated in the finished form so as to be substantially free of potential pathogens.

BACKGROUND OF THE INVENTION

[0003] While the consumption of tobacco products, such as the smoking of cigarettes and cigars and the consumption of smokeless tobacco products such as snuff and chewing tobacco, has been statistically associated with a variety of diseases, including several types of cancer, cardiovascular diseases, stroke, diabetes, and cataracts, precise causal relationships remain elusive in spite of extensive research. Statistical indications extend to inadvertent consumers of tobacco products such as those who inhale so called "second-hand smoke", but again the precise way in which this inadvertent consumption leads to disease is not well understood.

[0004] Tobacco is an organic product of extreme complexity and variety and much research effort has been expended in identifying constituents of tobacco and its smoke which might cause disease. Tars, carbon monoxide and nitrosoamines have each been identified as "possible", "probable", or "known" causes of disease in humans and in laboratory test animals. Filters which remove tars from cigarette smoke are now in common use throughout the world and smokers in many localities have switched to smokeless tobacco such as snuff, reducing their consumption of tars and carbon monoxide. Williams in U.S. Pat. No. 6,135,121 and Lane in U.S. Pat. No. 6,786,221 teach processes for reduction of several nitrosamines and other toxins in cured tobacco. These toxins are principally the result of microbial action on tobacco, and the above patents teach microbe control during processing of tobacco as a means of reducing the content of microbially generated toxins, including nitrosamines. As yet, little or no clear health benefit has been demonstrated by these activities, and many programs, public and private, are now underway to restrict the consumption of tobacco products, often to the consternation of tobacco consumers who continue to enjoy the flavor and other attributes of these tobacco products and to the detriment of an industry which has long supplied them.

[0005] Several of the diseases with which tobacco consumption is statistically associated are also closely associated with pathogens: Cancers have been associated with viruses which interfere with the cellular control of apoptosis. "Intracellular" bacteria, which have evolved the means to reside within certain human cells, have been associated with cardiovascular disease, cancer of the stomach and other human diseases. Cigarette smokers can be carriers of tobacco mosaic virus and can transmit this plant pathogen to tomato and potato fields.

[0006] Tobacco and tobacco products contain a myriad of microorganisms of a wide variety of types, and many, if not most, of these microorganisms are harmless to humans and

agriculture. Some are pathogens or potential pathogens of the tobacco plant itself. Others are normally resident on the tobacco leaf and in the curing sheds and contribute singly and collectively to the breakdown of the tobacco leaf during cure. Many naturally-occurring tobacco microorganisms are killed during conventional processing of some tobacco, especially processing which subjects the tobacco to heat. R. G. Warke et al. (see R. G. Warke et al., Journal of Food Protection, vol. 62, No. 6, 1999, pp. 678-681, hereafter referred to as Warke et al.) cultured a variety of fungal and bacterial microorganisms from chewing tobacco purchased in Mumbai, India, and recommended irradiation of smokeless chewing tobacco as a public health measure.

[0007] Tobacco is itself a source of anti-microbial substances and cured tobacco products are normally quite stable against decay and deterioration, and have long shelf lives under varied and often uncontrolled storage conditions. There are exceptions, and Roth et al. in U.S. Pat. No. 5,372,149 teach the sterilization of moist snuff in order to extend its shelf life by controlling over-fermentation.

[0008] Tobacco is a natural product of great variety and antiquity and its processing to suit the varied tastes of tobacco consumers around the world is also diverse. One commonality of all tobacco products, however, is that they contain viable microorganisms. Although gastric and other malaise is often experienced by first-time consumers of tobacco products, tobacco is not considered to be responsible for acute human disease. Warke et al. observed, for example, that none of 15 samples of varied chewing tobacco types purchased in Mumbai, India, and possibly prepared for market under conditions of less-than-ideal sanitation, contained either viable *Salmonella* or *Coliform* species. The burning of tobacco which occurs during smoking might be thought to kill any residual microorganisms, but this does not seem to be the case.

[0009] Microorganisms often live in complex environments and associate with other microorganisms of the same or different species in complex ways: Living viral bacteriophages can infect bacteria, by which both bacteriophage and bacterial RNA or DNA may be transmitted to other species. Innocuous bacteria may become virulent and pathogenic when infected with viral material. Bacteria which are innocuous when present singly or at low density may become virulent and pathogenic when they are grouped together at higher density. Mixed colonies of microorganisms, sometimes including yeast or fungus species, can benefit from symbiotic association, often in complex bio-films such as those normally present in the human oral cavity. Some bacterial strains, often containing viral plasmids, which have evolved the capability of entering certain human cells and remaining there for extended periods can adhere to other species which are normally non-pathogenic and stabilize the presence of these other species in the protected intra-cellular environment.

[0010] Some tobacco products may contain pathogens or potential pathogens which may contribute to, or be causative agents of, human disease, animal disease, or plant disease. These may be passed to the primary consumers and "inadvertent" consumers of tobacco products wherein and whereon they may reside, develop and incubate for extended periods of time, eventually causing or contributing to disease. While some tobacco products may, from time-to-time, be naturally free of such unwanted pathogens, comprehensive testing to determine the presence or absence of all unwanted

species in tobacco is presently problematic, especially as many pathogens have probably not yet been identified.

[0011] Smoking tobacco and tobacco products are of particular concern because of the ability of smoke particles to carry microbes. In a cigarette, cigar, pipe, etc., only the combustion gasses near the burning ember are hot enough to kill microbes. These humid gasses cool rapidly to the 60° C. to 35° C. range and may then lift viable microbes from ambient-temperature tobacco as they pass through the cigarette, cigar, pipe, etc. Microbes may adhere to the small smoke particles and remain suspended and stable until they are deposited onto the skin, the mucous membranes of the smoker's oral cavity, the respiratory tract, etc., or carried as "second-hand smoke" to others.

[0012] While there may be benefit in the reduction in amounts of tobacco-borne chemical substances which may be harmful if consumed, there is a need for tobacco products which can be substantially free of all live pathogenic microorganisms, including any live microorganisms which may contribute indirectly to pathogenicity, at the point of consumption. Williams, Lane, and others teach that in order to reduce toxins, certain species must be killed before they are able to produce these toxins. For them, sterilization of the finished cigarette would be useless, as the microbial damage they identify—the production of toxins including nitrosamines—has already been done. In the absence of proof that tobacco-borne microbes are harmless or beneficial to humans, and with many clear indications that the smoking of such tobacco is harmful to human health, there is a need for reducing or eliminating the microbial content of cigarettes, cigars, and pipe tobacco, and any microbes including bacteria, fungi, archaea, animal parasites, viruses and plasmids which have not been clearly shown to be harmless should be considered to be potential pathogens.

[0013] Means for reduction in the content of live microorganisms are commonly used in dairy products and canned goods. Pasteurization and sterilization means, including the use of ionizing irradiation, are known for raw meat and fresh vegetables. Methods employing chemical treatment of food-stuffs with salt, spices and other chemical preservatives in order to deter the growth of microorganisms are well known, as is the preservation of dairy and other products by intentional inoculation with controlled cultures of microorganisms. Tobacco products may sometimes be subjected to processes which result in a reduction in the content of some types of live microorganisms. High-temperature fermentation of tobacco must certainly kill some species of microorganisms while favoring the proliferation of other species and leaving the content of still other species unaffected. Drying of tobacco kills some microorganisms, causes others to form resistant spores, and may cause others, especially certain bacteriophages, to proliferate. Williams (U.S. Pat. No. 6,135,121) teaches a microwave heating and drying method which may kill some microorganisms, but re-infection and re-colonization of the microwave-treated tobacco is uncontrolled during subsequent conventional processing of the subject tobacco and of tobacco products fabricated from it. Similarly, the thermal pasteurization method taught by Roth et al. as a method for extending the shelf life of snuff, controls primarily those microorganisms responsible for the over-fermentation of said snuff and the consequent generation of "off-flavors". Thermal treatment is, by the method of Roth et al., optimized for this purpose alone, regardless of a wide spectrum of live microorganisms which may remain, and re-colonization is

uncontrolled. Flavoring additives may also, coincidentally, be poisonous to some microorganisms, and ash, lime, and other stabilizers can kill some microorganisms and retard the growth of others. Warke et al. suggest the irradiation sterilization of hermetically sealed moist chewing tobacco products to kill bacteria and fungi which are otherwise directly consumed. None of these methods can be effective in assuring the tobacco consumer, and the public at large, of a smoking product, and the resulting smoke, free of live and potentially pathogenic microorganisms.

SUMMARY

[0014] The present inventor has shown that cigarettes and cigars that have been sterilized using irradiation have a reduced content of bacteria as compared to untreated cigarettes and cigars. Accordingly, the present application provides a smokeable product in a finished form ready for smoking wherein said smokeable product has been treated in the finished form so as to be substantially free of potential pathogens.

[0015] The present application also includes a process for preparing a smokeable product that is substantially free of potential pathogens comprising:

[0016] a) providing a finished smokeable product in a form ready for smoking; and

[0017] b) treating the smokeable product with a sterilizing means under conditions to remove, kill or inactivate pathogens wherein said treatment results in a smokeable product that is substantially free of potential pathogens.

[0018] In a preferred embodiment, the smokeable product is a tobacco product. One advantage of the present application is to substantially eliminate the possibility that tobacco products, at the point of consumption, contain microorganisms which may under some conditions become human pathogens or alternatively interact with other microorganisms to affect pathogenicity. This advantage is both for the protection and reassurance of the primary consumers of the tobacco products, especially smokers, and for the protection and reassurance of inadvertent consumers of tobacco consumption by-products, such as those who inhale so-called "second-hand smoke".

[0019] Another advantage of the present application is to reduce the transmission of tobacco-borne human, animal, and plant pathogens, such as tobacco mosaic virus, by consumers of tobacco products.

[0020] Yet another advantage of the present application is to contribute to a healthier environment while minimizing any degradation of flavor or other enjoyment attributes of tobacco consumption.

[0021] Other features and advantages of the present application will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the application are given by way of illustration only, since various changes and modifications within the spirit and scope of the application will become apparent to those skilled in the art from this detailed description.

DETAILED DESCRIPTION

[0022] As mentioned previously, the present application relates to a smokeable product in a finished form ready for

smoking wherein said smokeable product has been treated in the finished form so as to be substantially free of potential pathogens.

[0023] The term "smokeable product" as used herein means any product that is ready for human consumption by smoking including, but not limited to, cigarettes and cigars of all types and sizes, loose tobacco for rolling into cigarettes by the consumer, pipe tobacco, marijuana and herbaceous tobacco additives or replacements.

[0024] In a preferred embodiment, the smokeable product is a tobacco product, such as cigarettes, cigars, pipe tobacco or rolling tobacco.

[0025] The term "potential pathogen" as used herein means any propagatable biological agent that can or may cause or contribute to disease or illness including, but not limited to, bacteria, bacteriophages, viruses, protozoa, fungi, archaea, plasmids, parasites, as well as their various life forms including viable eggs and spores.

[0026] The term "substantially free of pathogens" means that the treated smokeable product contains significantly less pathogens as compared to non-treated smokeable products.

[0027] Preferably, the pathogens are reduced by at least 90%, more preferably at least 95%, most preferably at least 99%.

[0028] The present application also includes a process for preparing a smokeable product that is substantially free of pathogens comprising:

[0029] a) providing a finished smokeable product in a form ready for smoking; and

[0030] b) treating the smokeable product with a sterilizing means under conditions to remove, kill or inactivate pathogens or potential pathogens wherein said treatment results in smokeable product that is substantially free of pathogens.

[0031] The sterilizing means can be any means that can substantially reduce the levels of pathogens including, but not limited to, electromagnetic irradiation, ionizing irradiation, heat, chemical treatment and combinations thereof.

[0032] In one embodiment, the sterilizing means comprises treating the finished tobacco product by ionizing irradiation. The dose of radiation may preferably be from 0.5 to about 50 kGy, most preferably about 2 kGy to 10 kGy.

[0033] In a preferred embodiment, the method is used on a tobacco product such as cigarettes, cigars, pipe tobacco or rolling tobacco.

[0034] In one embodiment, the method further provides a means for restricting the re-colonization of the tobacco by potential pathogens. In one embodiment, such means may comprise hermetically packaging the treated tobacco to prevent re-entry of microorganisms up until the point of consumption at which point the package is opened.

[0035] In another embodiment of the present application, such means may comprise maintaining a substantially sterile state through care in processing cleanliness and packaged to keep the treated tobacco product substantially or reasonably sterile for a sufficient shelf life.

[0036] In another embodiment, the conventionally cured tobacco is sterilized after cure, processed into tobacco products, such as cigarettes, in a clean environment, these tobacco products packaged to maintain cleanliness and sold for consumption within a shelf-life that assures negligible re-colonization by unwanted microorganisms.

[0037] Another preferred embodiment of the present application is a tobacco product intended for consumption by

smoking in which the probability of containing pathogens has been reduced significantly by sterilization of the tobacco feedstock, further processed using controls to prevent or significantly restrict re-contamination by viable microorganisms, and packaged and stored in a manner which substantially prevents re-contamination for the product's shelf life.

[0038] A preferred method for achieving the aforementioned preferred embodiment of the present application is: heating and irradiating a fully cured tobacco in bulk, before or after cutting as may suit convenience, such heating to be effected by thermal radiation, conduction, convection or microwave means, to a temperature in the range of 80° C. to 120° C. but which may be higher or lower depending on the nature of the bulk tobacco and the level of the dose of ionizing radiation, normally about 2 kGy but which may be higher or lower as well, the combined effect of heat and ionizing radiation being an effective sterilization means; further processing optionally including cutting, rolling, compressing, weighing, trimming, etc., under clean and controlled conditions which substantially prevent re-contamination, as will be understood by those familiar with the art and practice of processing pills and other pharmaceutical products; and packaging tobacco product under similarly clean and controlled conditions in treated paper, foil, plastic, metal, cloth or combinations thereof which, although not perfectly impervious to, or free of, all microorganisms, by their relative impermeability and tortuosity and in view of dry, clean, or otherwise controlled conditions of storage of the packaged product, serve to substantially prevent re-contamination for an extended period of time.

[0039] Another preferred embodiment of the present application is a tobacco product, suitable for human consumption by smoking, substantially free of all potentially pathogenic microorganisms, with additionally reduced levels of toxins, potential toxins, or other substances of microbial origin, and packaged to prevent or substantially restrict re-infection. Some substances of microbial origin which may or may not appear to be inherently toxic, carcinogenic, or otherwise harmful, may inspire microorganisms or colonies of microorganisms to altered behavior or form which behavior or form renders such microorganisms or colonies more virulent or better conditioned to survive harsh conditions or within or on the surface of the human body or within or on the surface of other hosts. Other such substances, such as nitrosoamines, are recognized to be inherently toxic.

[0040] A preferred method for achieving the aforementioned preferred embodiment of the present application is: pasteurizing green, uncured, tobacco, optionally wilted and optionally having any stems, midrib matter and other thick structures crushed or fractured, said pasteurization accomplished using heat, ionizing radiation, or a combination thereof to achieve a substantial reduction, though not necessarily complete elimination, of viable microorganisms; inoculating the pasteurized tobacco with a controlled microbial culture, or mixed culture, by dipping, wiping, spraying, fogging, or other dissemination means, said culture prepared from lines and strains of bacteria, fungi or yeasts known or determined to be harmless and beneficial; curing the tobacco by dry, moist or wet fermentation and under such conditions of temperature, aeration, etc. as befits the particular desired tobacco end-product and culture used, and under conditions of controlled cleanliness sufficient to deter the growth of wild strains of microorganisms during the fermentation period; mechanically, chemically, or thermally processing the

tobacco as is conventionally accomplished to render the tobacco suitable for human consumption and having the desired flavor and other attributes; further processing the tobacco and its resulting tobacco product in accordance with the methods of the above embodiments 1 or 2.

[0041] A preferred embodiment of the present application is a smoking tobacco product, such as cigarettes, which is substantially free of all pathogens and hermetically packaged to prevent re-entry of pathogens up until the point at which the package is opened for consumption of the smoking tobacco product.

[0042] A preferred method of the present application is: fabrication of the smoking tobacco product by conventional methods known to those versed in the art; encapsulating and sealing the tobacco product in a plastic, foil, laminate, or other packaging material capable of excluding even the smallest of pathogens; and irradiating the packaged tobacco product with a dose of ionizing radiation, normally about 10 kGy but which may be lower or higher depending on the nature of the tobacco product and subject to testing as is well understood by those versed in the art of radiation sterilization, which dose is sufficient to destroy the viability of substantially all contained microorganisms.

[0043] One of skill in the art can readily test the treated tobacco products to determine if levels of specified pathogens have been substantially reduced using techniques known in the art. Such detection methods include cell culture techniques, immunological techniques and nucleic acid based techniques. For unspecified potential pathogens, levels of specified microbes of similar types can be used as indicators of the effectiveness of treatment.

[0044] The following non-limiting examples are illustrative of the present application:

EXAMPLE 1

[0045] Finished cigarettes purchased at retail (Player's Navy Cut Plain, John Player & Sons, Montreal Canada) were sealed in a polypropylene jar and subjected to 5 kGy of ionizing radiation from a Cobalt 60 source. Tobacco was taken from several of the irradiated cigarettes and shaken with distilled water. No culture could be grown at 25° C.±5° C. from samples of this water, neither under aerobic nor anaerobic conditions. Further, drops of this water had no killing effect on multi-species cultures which resulted from using non-irradiated cigarette tobacco as an inoculant. Untreated tobacco from an identical package of cigarettes, cultured identically, was used as a positive control, while pure distilled water was used as a negative control. The positive control resulted in irregular multi-culture growths with occasional clear plaque spots; the negative control remained clear.

EXAMPLE 2

[0046] Finished cigars purchased at retail (Century Sam) were sealed in a polypropylene jar and subjected to 5 kGy of ionizing radiation from a Cobalt 60 source. Tobacco, including wrapper tobacco leaves and cut filler tobacco, was taken from one of the irradiated cigars and shaken with distilled water. No culture could be grown at 25° C.±5° C. from samples of this water, neither under aerobic nor anaerobic conditions. Further, drops of this water had no killing effect on multi-species cultures which resulted from using non-irradiated cigar tobacco as an inoculant. Untreated tobacco from a cigar of the same brand, purchased at the same time

and cultured identically, was used as a positive control. The positive control resulted in irregular multi-culture growths; the negative control remained clear.

[0047] It is clear that the radiation treatment had the effect of very greatly reducing the content of living species, and the polypropylene jar was clearly effective in preventing re-contamination. Other means of sealing, known to those skilled in the art, more acceptable for shipping and retailing, could have been equally effective in preventing re-contamination. Likewise, other methods for testing of the irradiated product are known to those skilled in the art, and might have resulted in detection of living species that remained unkilld. Thus, improved sealing, detecting and sterilization methods could be expected to result in improved processes within the scope of the present application.

[0048] The irradiated tobacco products of Examples 1 and 2 appeared unchanged when compared with the originally purchased cigarettes and cigars and could be expected to be equally acceptable to consumers of products of these types, and perhaps more acceptable because of the knowledge that the irradiated product contained reduced content of potential pathogens.

[0049] It is understood that the above preferred embodiments are exemplary and that combinations, variations and parameters may be optimized to the many varied particulars of a diversity of tobacco products, all within the scope of the present application.

[0050] While the present application has been described with reference to what are presently considered to be the preferred examples, it is to be understood that the application is not limited to the disclosed examples. To the contrary, the application is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

[0051] All publications, patents and patent applications are herein incorporated by reference in their entirety to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference in its entirety.

1. A smokeable product in a finished form ready for smoking wherein said smokeable product has been treated in the finished form so as to be substantially free of potential pathogens.

2. The finished smokeable product of claim 1 selected from the group consisting of cigarettes, cigars, and pipe tobacco.

3. The smokeable product of claim 1 wherein said treatment comprises subjecting the smokeable to sterilizing means.

4. The smokeable product of claim 3 wherein said sterilizing means comprises radiation, heat, chemical treatment, or a combination thereof.

5. The smokeable product of claim 1 wherein the smokeable product is sealed in packaging impervious to pathogens either before treatment or under aseptic conditions after treatment.

6. The smokeable product of claim 1 wherein the smokeable product is treated with an antimicrobial preservative.

7. The smokeable product of claim 1 wherein the treated smokeable product is inoculated with a controlled culture of microorganisms which contains viable microorganisms which are known to be beneficial or harmless.

8. The smokeable product of claim 1 which is a cigarette.
9. A process for preparing a smokeable product that is substantially free of potential pathogens comprising:
- providing a finished smokeable product in a form ready for smoking; and
 - treating the smokeable product with a sterilizing means under conditions to remove, kill or inactivate pathogens wherein said treatment results in a smokeable product that is substantially free of potential pathogens.
10. The process of claim 9 wherein the finished smokeable product is selected from the group consisting of cigarettes, cigars and pipe tobacco.
11. The process of claim 9 wherein the sterilizing means comprises radiation, heat, chemical treatment, or a combination thereof.

12. The process of claim 9 further comprising the step of treating the smokeable product with an antimicrobial preservative.

13. The process of claim 9 further comprising the step of inoculating the treated smokeable with a controlled culture of microorganisms which contains viable microorganisms which are known to be beneficial or harmless.

14. The process of claim 9 further comprising the step of sealing the treated smokeable product in packaging impervious to pathogens under aseptic conditions.

15. The process of claim 9 further comprising an initial step of sealing the finished smokeable product in packaging impervious to pathogens.

16. The process of claim 9 wherein the smokeable product is a cigarette.

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