The Effects of Cigarette Additives on the Palatability of Cigarettes

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Appendices

Acknowledgments

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Executive Summary

It is estimated that since 1950 almost one million Australians have died prematurely because they smoked, almost all from smoking cigarettes. As the cumulative death toll from smoking continues to mount each year, factors that influence the palatability and attractiveness of tobacco products to children and other novice smokers, are a significant public health concern.

This literature review is part of a two-staged project examining the impact of additives and selected engineering features on the palatability of cigarettes. The review examines international and domestic research, including individual and population studies, on the role of flavours and masking agents in smoking initiation and uptake. It also examines relevant information from the tobacco company documents made available through the Minnesota litigation in the United States and the US Master Settlement Agreement.

The report considers the following seven questions and presents the findings from the literature:

- what is known about tobacco ingredients and the use of additives;
- what is known about the use of engineering features that affect palatability such as filter ventilation;
- what is the use/potential use of additives in Australia and their use in manufacturing processes;
- what impact do additives and engineering features have on smoking behaviour;
- what impact do additives and engineering features have on human health;
- what regulatory approaches have been adopted in Australia and overseas;
- what are the gaps and deficiencies in the research.

The second stage of the project is presented in a separate report and includes the results of data analysis on the ingredients in Australian tobacco products provided under the Voluntary Agreement for the Disclosure of Ingredients of Cigarettes (Voluntary Agreement) by the three largest tobacco companies in the Australian market: Philip Morris Limited (PM), British American Tobacco Australia Limited (BATA) and Imperial Tobacco Australia Limited (Imperial) in 2000. It also includes the results of data analysis from the Australian component of the International Tobacco Control Policy Evaluation Project relevant to additives and their influence on the palatability of cigarettes.

Currently in Australia there is very little regulation of the contents of tobacco products, apart from regulatory standards on reduced ignition propensity and bans on the sale of fruit or confectionary-flavoured cigarettes. Disclosure of cigarette ingredients is in accord with the Voluntary Agreement between the three largest

tobacco companies in the Australian market and the Australian Government. In contrast, a number of countries, including the United States, Canada, Thailand, Brazil and Lithuania, have introduced regulatory controls on additives.

What Additives are Contained in Australian Cigarettes?

The Australian cigarette ingredients disclosed under the Voluntary Agreement include around 200 additives, excluding those related to papers, filters, adhesives and inks. The tobacco companies disclose only the highest amount of ingredients used in their brands (that is, Quantity Not Exceeded (QNE) across all the brands and varieties they sell. Disclosures on individual varieties are only by broad type of ingredient. Therefore, it is not possible to draw conclusions about the average amount added or about the percentage of brands that contain a particular ingredient.

In several other countries, including the United States and New Zealand, around 600 additives are listed in ingredient returns. It is not clear why Australian brands list fewer additives than these countries.

Some Australian cigarette brands are listed as being nothing more than tobacco and water, while others are listed as tobacco, water and processing aids. However, as the guidelines do not specify a consistent minimum level at which disclosures must be made, it is possible that there are additives which are added at some lower level than the threshold level specified for any given set of disclosures. This suggests that some cigarettes in the Australian market may contain no or very low levels of additives As there is no regulatory requirement obliging companies to disclose sales by brand and brand variant; the proportion of the cigarette market that is additive-free or contains very low levels of additives is not known. Under current reporting arrangements, the relationship between the use of additives and the composition of tobacco cannot be determined. The current disclosures do not extend to roll-your-own tobacco, or other classes of tobacco, so nothing is known about additives in these classes of tobacco products in Australia.

There are a number of differences between the three companies. The current Australian disclosures report only four products used as processing aids (excluding water), all by Imperial Tobacco. BATA is the only company to list preservatives, with benzoic acid and potassium sorbate reported. In relation to solvents, Imperial lists glycerol and propylene glycol; BATA lists sorbitol; and Philip Morris does not list any solvents.

Humectants (excluding water) are listed by all three companies and include glycerol and propylene glycol. Humectants are moisturizing agents for tobacco, and play a role in preventing the tobacco drying out and becoming crumbly. However, tobacco company documents reveal that humectants are also used to impart sweetness and increase the mildness of the smoke.

BATA lists cellulose fibre and guar gum as binders, and Philip Morris lists guar gum and phenylacetaldehyde; there are no Imperial disclosures under this heading. BATA also lists calcium carbonate as filler.

Philip Morris lists 'carob bean and/or extract', cocoa and cocoa products, and liquorice extract as casings, the only company to use this category. The term casings refers to relatively large levels of sugars and sweeteners added early in the manufacture process. Tobacco industry documents define casings as solid/semi-solid materials added in significant weight quantities to tobacco, usually as an aqueous 'liquor' or 'sauce' during manufacture. The most common casings include sugar, liquorice extract, carob or cocoa. Casings serve both a sweetening function and regulate the overall sugar levels to control the pH of the smoke. It is notable that, these additives are just listed as flavourings by the other companies (although BATA does not list carob).

Sweeteners and other flavours added later in processing are sometimes referred to as "top dressing" flavours. Top dressing flavours are volatile, highly aromatic oils, usually applied to tobacco in very small quantities as an alcohol-based spray in the final stage of primary processing.

All the remaining additives are listed as flavours. It is apparent that the vast majority of additives are included to affect the flavour of the final product.

A number of findings from part two of this project are relevant to this literature review. Analysis of brand by brand cigarette ingredients reported over time provides evidence that, rather than having a fixed recipe for each brand variety which is adhered to each year, there is some degree of year by year variation in the additives used by manufacturers. Some of this may be to standardise characteristics of the product to maintain a constant consumer experience of use, others may reflect changes in product specifications, and some may be due to the movement of products on and off the market (and thus the disclosed list of ingredients). Currently it is impossible to differentiate these three kinds of activity.

The analysis of brand by brand disclosures between 2000 and 2012 also provide strong evidence that the manufacturers take somewhat different approaches to producing palatable cigarettes. All three manufacturers have some brands which are reported to contain sugars, humectants, flavourings commonly used as casings and 'top dressing flavours'. However, Philip Morris reported a much greater proportion of brands as containing ingredients other than tobacco and water. Given that the companies reports go down to the same low levels, we do not think this is due to differences in reporting in the brand-specific part, but cannot be certain.

All three manufacturers had brands with only tobacco and water as their disclosed ingredients. However, it is possible that they may contain additives below the lowest-reported quantitative cut off, as per item 6.3 (E) of the Voluntary Agreement.

What Do We Know about Tobacco Additives?

It is clear that cigarettes are highly engineered products. The engineering of cigarettes begins with a focus on the specific growing conditions and methods of curing the tobacco. It continues in the manufacturing process, with detailed attention given to factors such as the mix of types of tobacco (including parts of the plant) and filter systems (including filter ventilation). Additives are added at several stages of the manufacturing process. They may be added to the cured tobacco leaf, the processed tobacco, or infused into the finished product via the packaging.

According to the ingredient disclosure reports, the vast majority of additives in Australian cigarettes have a flavour function. Most of the additives listed in Australian cigarettes are added to tobacco in very small quantities, most probably as 'top dressing' flavours. However, according to tobacco company documents, even though these 'top dressing flavours' are used in very small amounts, they have a a marked influence on the palatability of cigarettes, as flavour additives can be an important factor in achieving a milder and more consumer-acceptable cigarette.

The most used additives (by weight) declared in the voluntary disclosure lists in Australia are in the form of sugars, cocoa, liquorice, humectants, and menthol. Sugars constitute a large proportion of additives in cigarettes, and the sweetness of the product is an important characteristic that increases the attractiveness of cigarettes, particularly to children and young people. Similarly, liquorice is used to decrease harshness and create a milder, sweeter smoke.

Humectants such as propylene glycol and glycerol are also listed in significant quantities and are used as moisturising agents for tobacco. However, tobacco company documents reveal that these additives are also used to impart sweetness and to increase the smoothness or mildness of the smoke.

Various spices and herbs can be used to improve the palatability of tobacco products by introducing complex flavour notes. A number of herbs and spices and botanical extracts are listed in Australian cigarette disclosures, including raisin extract, tamarind extract, apple juice concentrate, lovage extract, peppermint oil, orange oil, nutmeg oil, prune juice concentrate, chamomile flower oil and dill oil.

Flavourings such as vanillin and ethyl vanillin are added to tobacco to impart a vanilla flavour to the smoke. Vanilla and ethyl vanillin effectively sweeten tobacco smoke as they are subjectively experienced as similar to sugar.

Other additives make a more complex contribution to the taste of cigarettes than simply increasing sweetness. Menthol has a minty taste and aroma, and is added to cool the smoke or make it less harsh, which means that it makes a cigarette easier to smoke. Menthol is also an anaesthetic – it soothes or even numbs the lining of the mouth and throat, and suppresses the body's natural cough reflex. By making the

cigarette easier to smoke, menthol also potentially makes cigarettes more palatable for young or beginner smokers.

The recent report by the Tobacco Products Scientific Advisory Committee of the US Food and Drug Administration (TPSAC) found that menthol cigarettes have an adverse impact on public health in the United States. TPSAC also found the evidence is sufficient to conclude that the availability of menthol cigarettes increases experimentation and regular smoking in the US.

A range of other additives are used to facilitate the manufacture of cigarette tobacco rods or sticks, increase shelf life and control burn rates. There is also evidence from tobacco company documents that additives have been used to mask the effects of second-hand smoke.

This literature review also details the substantial evidence about the impact of filter ventilation on the palatability of cigarettes. Nearly all cigarettes in Australia are filter tipped, virtually all using cellulose acetate filters. The filter is attached to the rod of tobacco (encased in the cigarette paper). In about 90 per cent of Australian brands, the tipping paper contains perforations – known as filter vents – to dilute the smoke with fresh air when the smoker takes a puff. Filter ventilation has a major impact on the palatability and attractiveness of cigarettes in several ways: by creating a lighter and milder taste and making the smoke easier to inhale, and by reinforcing smokers' perceptions that milder tasting cigarettes are less harmful by decreasing the harshness of the flavour of the smoke and reducing irritation.

The combined effects of the filters themselves and the filter ventilation make the smoke more diluted so it tastes weaker or milder and produces less harshness and irritation. The filter ventilation facilitates compensatory smoking, both by the capacity to block vent holes and the reduction in venting that occurs when puffing is harder and greater laminar flow is achieved in the stream of smoke-filled air from the burning cone of the cigarette. This coupled with greater intakes, more or larger puffs, allow smokers to achieve their desired levels of nicotine, and thus their exposures to toxic chemicals in cigarettes end up being largely unaffected. Filter ventilation creates the illusion of reduced harm as the cigarettes taste milder, but do not deliver any commensurate reduction in exposure to the toxic chemicals in cigarettes and thus no reduction in harm.

Published Research by Tobacco Company Scientists

This literature review examined research published by tobacco company scientists in peer-reviewed journals (refer to Section 6). These studies conclude that cigarette additives do not increase the toxicity of smoke, and that therefore their use poses no additional risk to smokers. However, both the findings of industry studies of additive usage and the interpretations of these findings offered by the tobacco industry deserve close scrutiny. A recent study by Wertz et al. has challenged the

conclusions reached by industry studies based on identification of several methodological limitations.

In addition, and perhaps of greater relevance to public health, these studies focus only on issues associated with potential toxicity and do not examine the impact of additives on the palatability of tobacco, something that can both facilitate initiation and help sustain use. This literature review provides overwhelming evidence that by altering the flavour and aroma of cigarettes, and masking the harshness associated with tobacco smoke, additives and filter ventilation can make cigarettes easier to smoke. It should be noted that in this review we do not attempt to review the evidence on the effects of filters per se, although their effects on the experience of smoking are considerable. The use of additives makes cigarettes treated with them more attractive to young or beginner smokers, thus contributing to the uptake of smoking, ongoing use and tobacco-related disease.

Tobacco Company Documents

The review of tobacco industry documents undertaken as part of this literature review confirms that flavour additives have been used to influence and refine taste. There is evidence that:

- there is a long history of using additives in Australia, with the use of some flavourings dating back to the 1920s;
- increased additive use appears to have been associated with the production and marketing of low tar cigarettes with one industry document suggesting flavour application for low tar products at two to three times the level of 'full flavour' products;
- casings and top dressing flavours have been credited with playing a crucial role in the commercial success of some products;
- some Australian Virginia brands have contained casings;
- a number of cigarette design factors influence perceived irritation (for example, cigarette circumference, moisture levels, nicotine to tar ratios, position of filter ventilation zones and pH of the smoke condensate);and
- humectants (for example, glycerol and propylene glycol) are used in Australian cigarettes to reduce irritation and increase smoothness.

Existing Regulatory Approaches

A number of countries, including Canada, the United States, Thailand and Brazil, have introduced legislation to place controls on additives. It should be noted that regulatory approaches in Canada and Brazil prohibit all flavour additives except for a very limited number of additives specified in the legislation (Brazil permits eight additives/classes of additives and Canada permits 21 specific additives).

Gaps in the Research

Conclusions and Key Findings

This report examines the literature on the impact of additives on the palatability of cigarettes. There is evidence presented in this report demonstrating the extensive use of additives by the tobacco industry to influence the flavour and aroma of cigarettes; mask the unfavourable harsh characteristics of cigarettes; create milder and sweeter smoke; and reduce sensory irritation by the use of additives such as menthol.

Australian ingredient lists (based on the voluntary disclosure arrangement) indicate that almost 200 additives may be present in Australian cigarettes, with the vast majority identified as having a flavour function. There is overwhelming evidence presented in this review that the majority of additives to cigarettes (or at least those added to the tobacco), are added to improve the palatability of the product. There is also overwhelming evidence that some engineering features of cigarettes are explicitly designed to serve similar functions, most notably filter ventilation which we review in detail in the report, and filters themselves, which was beyond the scope of this report.

Appealing to younger smokers is essential for the long-term continuation of the tobacco industry. Reviews of tobacco industry documents confirm the importance of

smoothness, mildness and sweetness when designing brands to appeal to young and inexperienced smokers. Tobacco company documents also confirm that even though many flavour additives are used in small amounts, they have an important impact on cigarette products. There is evidence that tobacco companies have extensively researched the pharmacological and sensory effects of additives for many decades, both in Australia and overseas.

There is an extensive evidence base in relation to the impact of additives on the palatability and attractiveness of tobacco that is sufficient to inform policy action to prohibit or restrict the use of additives, and filter ventilation. The key findings of this review of Australian and international literature can be summarised as follows, with evidence that:

1. A large number of additives are used in Australian cigarettes to influence the flavour and aroma of cigarettes, thereby influencing the palatability of the product and making it more attractive to young people and novice smokers.

2. Tobacco companies have systematically researched and developed a range of additives to alter the sensory qualities of cigarettes in order to create a smoother and milder smoking experience. Tobacco companies have identified and extensively researched the importance of smoothness, mildness and sweetness as important flavour characteristics that would increase the appeal of cigarettes particularly to young and inexperienced smokers. By creating a smoother and milder smoking experience, and masking the negative effects of smoking, additives can contribute to the experimentation with and uptake of tobacco use.

3. Additives such as menthol have been used to mask the irritation associated with smoking; for example, by numbing the throat so the smoker doesn't feel the smoke's irritating effects. By making the cigarettes easier to smoke, menthol also makes them more attractive to young or beginner smokers.

4. Filter ventilation is used extensively in Australian cigarettes, and has a major impact on the palatability and attractiveness of cigarettes in several ways: by creating a lighter and milder taste and making the smoke easier to inhale, and by reinforcing smokers' perceptions that milder-tasting cigarettes are less harmful. There is no evidence or any plausible theoretical means by which filter ventilation could reduce the harmfulness of cigarettes, and the evidence clearly shows that it is the major factor determining the perceived strength of the cigarette and other elements of consumer acceptability.

5. A number of countries have already introduced regulatory requirements to strengthen the controls on cigarette ingredient disclosure and control the use

of additives. Articles 9 and 10 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) are likely to provide the catalyst for other countries to implement similar regulatory approaches. Elements of best practice in regulating additives identified as part of the literature review include requirements relating to:

- disclosure of ingredients;
- disclosure of cigarette engineering features such as filter ventilation;
- independent testing of the contents and emissions of tobacco products;
- prohibition on additives unless they are necessary for the manufacture of cigarettes and are specifically authorised;
- disclosure of additional information such as sales data, and research and development activities;
- strong and effective penalties for compliance breaches;
- public disclosure of ingredient and emissions information and/or making it available to interested parties such as researchers in an appropriate form;
- filter ventilation: given the evidence on the importance of filter ventilation in modifying the harshness and strength of cigarette smoke, consideration should also be given to regulating this engineering feature in any proposed regulatory scheme around additive use.

6. Australian smokers support regulation of the use of chemicals and additives in cigarettes. There is also strong public support for tobacco companies to disclose this information to the public.

7. There is sufficient evidence to determine that additives have an impact on the palatability of tobacco. Future research priorities should focus on what Australia needs to know to progress towards more effective product regulation that covers additives and engineering features. Five broad areas have been identified:

    - independent research dependent on more extensive industry disclosures;
    - research that the industry should be required to conduct and report;
    - research that can be conducted independently of industry;
    - research on public understanding and communication needs; and
    - the surveillance system required to evaluate the impacts of any policy advances.

Section 1 Background

1.1 Introduction

Tobacco causes death, disease and disability on a huge scale. One in every two long-term smokers will die prematurely because they smoked.[1] In Australia, approximately 15,000 people die every year from tobacco-related disease.[2]

The Commonwealth, state and territory governments in Australia have committed to reducing the prevalence of adult daily smoking to 10 per cent by 2018. Australia's success in driving down smoking prevalence has been achieved by a comprehensive approach that includes tobacco taxation; mass media campaigns; regulatory measures restricting tobacco advertising, sponsorship and marketing; prohibiting the sale of tobacco to minors; laws requiring smoke-free workplaces and public places and cessation support. The implementation of the world's first legislation requiring plain packaging of cigarettes, as well as requirements for new, larger graphic health warnings on tobacco packaging, are expected to be effective strategies that will contribute to reduced smoking prevalence in the future.

Nonetheless, achieving the goal of 10 per cent prevalence by 2018 and further declines in prevalence beyond 2018 will require the continuation and extension of these tobacco control strategies and in all likelihood some new and more innovative approaches.

For several decades there has been increasing concern among tobacco control experts and many government health agencies, about the use of additives in tobacco products. Concerns about the effects of additives began to emerge in the 1980s. For example, the 1981 US Surgeon General Report, The Health Consequences of Smoking – The Changing Cigarette,[3] expressed concern about the use of additives. The report raised concerns about the risks arising from changing cigarettes (into so-called low-yield cigarettes), particularly as a result of *"their design, filtering mechanisms, tobacco ingredients, or additives. The chief concern is additives."* The report also stated that *"some additives available for use are either known or suspected carcinogens or give rise to carcinogenic substances when burned. The use of these additives may result in increased or new and different disease risks."*[3] Some public health experts and government authorities also suggest that the rise in additives in tobacco products is closely linked with the strategy to reduce tar yields in cigarettes.[3] [4]

In Australia, there is very little regulation of the contents of tobacco products apart from regulatory standards on reduced ignition propensity and bans on the sale of fruit-flavoured cigarettes.

In 2009 the Preventative Health Taskforce[5] recommended regulation of tobacco design, contents, emissions and labelling and specifically called for the Australian Government to:

- Establish or nominate a body with the power to regulate the contents and performance of tobacco products and any alternative nicotine delivery devices that come onto the market in Australia, and with responsibility for specifying the exact wording of any public disclosure about contents and performance;
- Specify the form and content of reporting required for all tobacco products, and the exact wording required for disclosures to consumers;
- Consider prohibiting the use of filter ventilation in Australian cigarettes;
- Consider banning all additives that enhance palatability or addictiveness; and
- Specify any further modifications required, restrictions on additives or upper limits for emissions.

In the Australian government response to the report *Taking Preventative Action – A Response to Australia: The Healthiest Country by 2020 – The Report of the National Preventative Health Taskforce* [6] the Australian government noted that the Department of Health and Ageing had commissioned research on the value of the disclosure of tobacco ingredients and emissions of Australian tobacco products. The outcomes from this research will be considered as the legislation on plain packaging is developed. The response notes that the Commonwealth Government is not intending to establish a body specifically to regulate the contents and performance of tobacco products. The Government will engage the states and territories in preliminary discussions on the possibility of regulation of tobacco products through the National Drugs and Poisons Scheduling Committee, which currently regulates nicotine as a poison.

As a result of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC),[7] the regulation of the contents and engineering of cigarettes and product disclosure is now a global tobacco control priority. Articles 9 and 10 of the WHO FCTC include provisions for member nations relating to the regulation of the contents of tobacco products and tobacco product disclosures. However, progress on negotiating guidelines for action has proven to be slow.

A wide range of additives and chemicals are found in cigarettes and they are used by tobacco manufacturers for many purposes.[4 8 9]

Additives can be used to improve the flavour and aroma of cigarettes, and decrease the harshness of tobacco.[4 10 11 12] They are used to mask the taste and immediate discomfort of smoke, and reduce the irritation of the mucous membranes of the nose and airways, as well as the eyes.[4 8 10 13] Additives are also used to facilitate the manufacture of cigarette tobacco rods, increase shelf life and control burn rates.[13]

Modern cigarettes are engineered so that it is reasonably easy to take the smoke into the lungs. Some older forms of cigarette have more acrid smoke that is much harder to inhale. [13] We do not know the extent to which such cigarettes still exist, but think it unlikely that many are used in Australia.

We review evidence that shows there have been systematic attempts by the tobacco industry to mask signs of the inherent harmfulness of tobacco smoke. The harsh and irritating character of tobacco smoke is known to provide a significant barrier to experimentation and initial use. Tobacco industry documents and published reviews of tobacco industry documents have shown that significant effort has been put into mitigating these unfavourable characteristics through the use of a range of additives and other engineering features. [14] [15] [16] [17] [18]

As well as being used to reduce many of the unpleasant features of tobacco smoke, additives (in particular flavour additives) may also be used to increase the pleasant characteristics of tobacco smoke, including flavour and aroma. [10] [11] [12]

The use of additives to reduce unpleasant sensations and increase pleasant sensations, and the use of other aspects of cigarette engineering such as filtration and dilution that enhance the palatability of cigarette smoke, both serve to facilitate initiation and continuation of smoking behaviour, and thereby lead to subsequent smoking-related disease and disability. [9] [16]

1.2 Purpose of This Report

The purpose of this literature review is to examine the literature in Australia and internationally on the effects and importance of additives and other engineering features in increasing the palatability of tobacco products and the impact of these substances on smoking behaviours (particularly smoking initiation and uptake). It also considers their possible direct effects on health.

This report describes and analyses relevant literature and research on the following areas:

- ingredients in tobacco products;
- some engineering features of cigarettes, most notably filter ventilation;
- use, manufacturing and sourcing of tobacco products in Australia;
- impact on smoking behaviour;
- impact on human health; and
- regulatory approaches.

The report considers the following seven questions and presents the findings from the literature:

- what is known about tobacco ingredients and the use of additives;

- what is known about the use of engineering features such as filter ventilation;
- what is the use/potential use of additives in Australia and their use in manufacturing processes;
- what impact do additives and engineering features have on smoking behaviour;
- what impact do additives and engineering features have on human health;
- what regulatory approaches have been adopted in Australia and overseas; and
- what are the gaps and deficiencies in the research.

1.3 Methodology

The search for published research on additives, including peer-reviewed journal articles and reports and research by public health researchers and tobacco industry researchers, was conducted using the Google Scholar and Pub Med search engines. The original search terms used were 'cigarette additives', 'cigarette ingredients', 'additives', 'tobacco flavours/flavourings' and 'tobacco ingredients'. Subsequent searches added 'palatability', 'attractiveness' and 'acceptability' to these terms, followed by 'uptake' and 'cessation'. The next round of searches employed the names of known researchers. Searches were also conducted on 'filter venting' and 'regulation/legislation'.

The original searches revealed more than 50 relevant published papers or reports with moderate to high relevance to the question of how additives (including menthol) affect the palatability/consumer attractiveness of cigarettes and thereby increase uptake or reduce cessation. The search excluded non-scientific publications, reports and websites that did not have the communication of scientific research as their primary role. However, the search of the unpublished literature (grey literature) had a broader scope beyond these journals, and has identified a number of relevant reports including information on regulatory approaches adopted internationally from a broad range of sources.

The degree of relevance was based on whether the topic of the paper was directly concerned with additives and palatability/attractiveness, and the proportion of the paper that dealt with additives. High relevance papers dealt primarily with additives and had substantive focus on palatability/attractiveness. Medium relevance papers dealt primarily with additives but focused on another issue – such as the question of whether additives make cigarettes more toxic – or dealt with additives alongside other topics. Examples of the latter include papers giving overviews of tobacco control regulation issues or research agendas.

A snowballing search strategy was utilised in this report. The reference lists of relevant published papers were reviewed to identify other relevant articles and reports, and other relevant search terms.

In this report we have given prominence among research from overseas to that from New Zealand, as New Zealand has essentially the same set of manufacturers and range of products as Australia. The evidence is likely to be highly transferable from New Zealand to Australia. Further, the Trans-Tasman Mutual Recognition Arrangement between the two countries makes New Zealand's regulatory and policy efforts of additional relevance.

An important element of the review was a search of Tobacco Company documents made available through the Minnesota litigation in the United States and the US Master Settlement Agreement. The tobacco industry document collections contain millions of pages of previously secret industry documents in publicly searchable forms.

The document search had two objectives. The first was to gain more information about industry practices concerning the use of additives and engineering features to boost palatability or consumer attractiveness. The second was to identify relevant information on practices within the Australian tobacco industry – especially with regard to the particular additives used in Australia.

1.4 Terminology

It is important to clarify the terminology used in this report.

In this review we have used the term 'additives' to refer to 'anything that is added to tobacco or other cigarette components (paper, filter etc.)'.[19] It should be taken to include additives, processing aids, residual substances found in tobacco (following storage and processing), and substances added to other components, as well as substances that migrate from the packaging material into the product. [9]

This definition is necessary because the term 'ingredient' is used inconsistently and may have very different meanings to different groups; for example, health groups and the tobacco industry. [19] Further, it has been argued that the tobacco industry frequently makes fine distinctions between additives, ingredients, flavours, casings, processing aids and so on, which can create confusion in non-specialist readers. Researchers such as Steven Hecht [20] further classify the term ingredients by differentiating between 'flavours' and 'additives'. Under this classification, 'flavours' are elements that impart a specific taste, flavour or aroma to the product, while 'additives' are elements used for specific technological purposes; the latter include humectants, preservatives, masking agents, solvents, binders, strengtheners and fillers. In common with the definition proposed by Gray and Borland, [19] in this review the term 'additives' is used to cover both categories.

The term 'toxicant' and related words are used throughout this report to include the possibility of carcinogenicity, mutagenicity and other long-term health-related harms. Where the use of such a term is used to refer only to acute toxicity, it is so qualified.

Pesticides and fertilisers are used extensively in the growing of tobacco, and residues of these substances often remain in the tobacco leaf.[13] However as they are not additives per se we do not examine them in any detail in this report.

The term 'engineering' is used to refer to any aspect of the manufacture of cigarettes, from the choice of tobaccos through to all aspects of the finished product, including all additives.

Other relevant terms used in this report include:

Attractiveness: This term refers to factors such as taste, smell and other sensory attributes, ease of use, flexibility of the dosing system, cost, reputation or image, assumed risks and benefits, and other characteristics of a product designed to stimulate use.[21]

Casings: Tobacco industry documents define casings as solid/semi-solid materials which are added in significant weight quantities to tobacco (kg/per 100 kg), usually as an aqueous 'liquor' or 'sauce' during manufacture.[15] In general, the most common casings include sugar, liquorice extract, carob or cocoa.

Cigarette aroma: Tobacco company documents describe cigarette aromas as the aromatic sensation of the cigarette, perceived in the nose before smoking. [25]

Cigarette rod: The combined form of blended tobacco wrapped in cigarette paper (ie the stick).[22]

Filter: Any air permeable substance (e.g. paper, cotton, cork, silica gel, meerschaum, cellulose acetate, etc.) attached to the smoking end of a cigarette. Paper and cellulose acetate are in most common use today, often in conjunction with charcoal. The paper and cellulose acetate help reduce particulate matter; the charcoal absorbs portions of the gaseous phase of the smoke. Filters are made in varying densities, diameters, and designs.[23]

Harshness: A chemically induced physical effect associated with an experience of roughness or rawness, generally localised in the mouth and to a lesser degree in the upper reaches of the throat and the trachea due to inhalation of tobacco smoke. It can cause a drying, rasping, coarse, astringent sensation. [21] Tobacco company documents define harshness as a disagreeable or painful sensory reaction. [25]

Humectants: Moisturizing agents for tobacco, and play a role in preventing the tobacco drying out and becoming crumbly.[14]

Impact: Tobacco company documents define impact as the feeling while inhaling (that is, the feeling when sucking in smoke). [25]

Irritation: Tobacco company documents define irritation as a painful sensation when inhaling and/or exhaling. [25]

Mouth coating: Tobacco company documents define mouth coating as the residual flavour in the mouth; the mouthfeel factor that typically builds during smoking. [25]

Mildness: A dictionary definition of mildness is moderate in type, degree, effect, or force. [24]

Odour: A dictionary definition of odour is the property of a substance that gives it a characteristic scent or smell. [24]

Palatability: A dictionary definition of palatability is: acceptable to the taste; sufficiently agreeable in flavour to be consumed (in this case, smoked). [24]

Sweetness: Tobacco company documents define sweet as suggestive of a sweet taste (for example, sugar). [25]

Smoothness: Reduction in the harsh irritation of nicotine-containing tobacco smoke.[21] Tobacco company documents define smoothness as an absence of painful or disagreeable sensory reaction, or lack of irritation. [25]

Taste: A dictionary definition of taste is the sense which, in combination with the senses of smell and touch, receives a sensation of a substance in the mouth.[24] Tobacco company documents define taste in various ways, including as the taste sensation typical of tobacco, perceived while smoking, and the tobacco flavour/taste and strength of tobacco.[25]

Top dressing flavours: Tobacco industry documents define top dressing flavours as volatile, highly aromatic oils, usually applied to tobacco in very small quantities as an alcohol-based spray in the final stage of primary processing. [15]

1.5 Structure of This Report

Section 1 of this report provides the background to this review, including the purpose, methodology and terminology.

Section 2 outlines the relevant policy context.

Section 3 summarises what is known about the additives in cigarettes.

Section 4 summarises aspects of the use, manufacturing and sourcing of tobacco products in Australia that are relevant to additives.

Section 5 summarises characteristics of cigarette design relevant to cigarette palatability.

Section 6 summarises research published by tobacco company scientists.

Section 7 describes the impact of additives on smoking behaviour.

Section 8 describes the impact of additives on human health.

Section 9 summarises the key findings of the tobacco company document search.

Section 10 summarises consumer awareness and attitudes to additives.

Section 11 summarises relevant legislation and identifies elements of effective regulatory practice.

Section 12 identifies the gaps in the existing research.

Section 13 provides a summary of the analysis and conclusions in the report.

Section 2: Policy Context

2.1 Background

In Australia, there is very little regulation of the contents of tobacco products, apart from regulatory standards on reduced ignition propensity and bans on the sale of fruit-flavoured cigarettes.

Unlike such countries as Canada, the United States, Thailand and Brazil, which have regulated additives and disclosure arrangements, Australia has a Voluntary Disclosure Agreement in place between the Government and the three tobacco companies dominant in the Australian market.[26] This Agreement, which first came into effect in 2000, has been varied three times and requires the companies to provide annual reports to the Government regarding the ingredients of cigarettes. The data are posted unmodified on the Department of Health and Ageing's website. Several years of data are currently available.

The tobacco industry in Australia and elsewhere has generally argued that it should not be required to disclose details of additives as it would compromise trade secrets. Under the Voluntary Agreement, each tobacco company discloses the ingredients in order of descending weight by brand. Importantly, however, flavourings, processing aids and preservatives are disclosed in the composite list of tobacco ingredients. This composite list of ingredients comprises around 200 substances that can be added to tobacco, and a range of other ingredients that can be added to the papers, filters and inks.[27] However, the list of additives may not be exhaustive as the list may not contain additives used at low levels below the quantitative cut off, as per item 6.3 (E) of the Voluntary Agreement.[26] That is, tobacco companies can apply quantitative cut-points below which they do not report. Further it is unclear whether the same criteria apply to the composite disclosures of all additives used by the company and the more general listing of additives by class for individual brands and varieties.

In 2009, the Preventative Health Taskforce (PHT) recommended that the Australian Government consider banning all additives to tobacco products that enhance palatability or addictiveness.[5] The Australian Government response to the Taskforce report *Taking Preventative Action – A Response to Australia: The Healthiest Country by 2020 – The Report of the National Preventative Health Taskforce* [6] noted that the Department of Health and Ageing had commissioned research on the value of the disclosure of tobacco ingredients and emissions of Australian tobacco products and that the Government will engage the states and territories in preliminary discussions on the possibility of regulation of tobacco products.

The regulation of the contents of tobacco products and tobacco product disclosures are important components of the World Health Organization Framework Convention

on Tobacco Control (WHO FCTC). Australia has ratified and is a party to the Treaty. Article 9 of the WHO FCTC covers the regulation of the *contents* of tobacco products and Article 10 covers tobacco product *disclosures.*

2.2 The Framework Convention on Tobacco Control

The WHO FCTC aims to advance international cooperation to protect present and future generations from the preventable and devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.[7]

The WHO FCTC commits member nations to implement policies on tobacco price and tax increases; prohibiting or restricting tobacco advertising, promotion and sponsorship; introducing labelling with more prominent health warnings; reducing exposure to second-hand smoke; smoking cessation interventions; and reducing illicit trade.[7]

Articles 9 and 10 of the WHO FCTC cover the regulation of the *contents* of tobacco products and tobacco product *disclosures.*

Article 9 states:

The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.[7]

Article 10 states:

Each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.[7]

In 2010, the Conference of Parties (COP) agreed on partial guidelines to assist parties in the implementation of Articles 9 and 10 of the WHO FCTC. [9] These guidelines recommend that member countries take action to:

1. require manufacturers and importers to disclose information on ingredients used at each stage of the manufacturing process;

2. require manufacturers and importers to disclose information about design features;
3. prohibit or restrict ingredients that may be used to increase palatability, have colouring properties, create the impression that they have a health benefit or are associated with energy and vitality (such as stimulant compounds); and
4. require manufacturers and importers to report on sales to assist with effective product regulation.

The WHO FCTC Guidelines define ingredients as tobacco components (for example, paper, filter), including materials used to manufacture those components; additives; processing aids; residual substances found in tobacco (following storage and processing); and substances that migrate from the packaging material into the product. Contaminants are not part of the ingredients. [9]

The WHO Guidelines for Articles 9 and 10 express concern about the use of additives such as flavouring agents that can increase the attractiveness of tobacco products and thereby increase their use. [9]

'… tobacco products are commonly made to be attractive in order to encourage their use. From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive.' WHO FCTC Partial Guidelines Articles 9 and 10. [9]

It should be noted that current guidelines are partial and will be progressed in phases as experience from newly engaged countries becomes available, along with scientific, medical and other evidence on this issue. [9]

The Australian Government reports every two years to the COP on progress in implementing the WHO FCTC.

2.3 Legislation Prohibiting the Sale of Fruit or Confectionery-Flavoured Cigarettes in Australia

Fruit and confectionery-flavoured cigarettes project a sweet smelling, light-hearted and glamorous image that is inconsistent with the devastating health consequences of smoking. There is concern that these products can increase the appeal of cigarettes to first-time smokers, mask the harsh taste normally associated with smoking, and can be a gateway for children and young adults to become regular smokers. [28]

In response to concerns about the impact of these products on young people who may be influenced to take up smoking, the Australian Health Ministers' Conference and the Ministerial Conference on Drug Strategy agreed in 2008 that all jurisdictions

would ban the sale of fruit and confectionery-flavoured cigarettes by December 2009.[29]

All states and territories in Australia, with the exception of Queensland and Western Australia, have introduced legislative restrictions on the sale of fruit or confectionery-flavoured cigarettes.

Queensland's *Health Legislation Amendment Act 2011* received royal assent on 24 November 2011, including a provision restricting the sale of fruit or confectionery-flavoured cigarettes. However, at the time of writing, the relevant section (section 72) has not yet come into force because it is yet to be proclaimed. Western Australia included this issue in a consultation paper on the Review of the Tobacco Products Control Act 2006 but has not yet introduced any legislation to prohibit the sale of fruit and confectionery-flavoured cigarettes.

2.4 Regulatory Standards on Reduced Ignition Propensity

Over 4500 fires are caused annually by cigarettes and other materials used in smoking, such as cigarette lighters and matches, and 7 per cent of Australian bushfires are caused by discarded cigarettes.[30]

To reduce the fire risk associated with cigarettes, all cigarettes sold in Australia since 23 September 2010 have been required to comply with the mandatory standard for reduced fire risk. *Australian Standard 4830–2007, Determination of the extinction propensity of cigarettes*. This must be stated on the packaging.

These are requirements under the *Competition and Consumer Act 2010*, formerly the *Trade Practices Act 1974*, administered by the Australian Competition and Consumer Commission (ACCC). Further information is available on the ACCC Product Safety website: www.productsafety.gov.au.

2.5 Voluntary Agreement on the Disclosure of the Ingredients of Cigarettes

The Department of Health and Ageing negotiated a Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes (Voluntary Agreement) with the three major tobacco companies: Philip Morris Limited (PM), British American Tobacco Australia Limited (BATA) and Imperial Tobacco Australia Limited (Imperial). The Voluntary Agreement was signed by the tobacco companies and then Minister for Health and Aged Care, Dr Michael Wooldridge, in 2000. [26]

The Voluntary Agreement was originally for a period of three years from December 2000. Three variations have been made to the initial agreement, all extending the period of the agreement. The first two variations each extended the period of the

agreement for a further 12 months, continuing the agreement until December 2005. The third variation, in 2006, provided for the provisions of the Voluntary Agreement to continue indefinitely. [26] Under the agreement, the companies provide annual reports to the Government regarding the ingredients of cigarettes. The data has been posted unmodified on the Department of Health and Ageing's website.

Analysis of data from the Voluntary Agreement has been conducted in part two of this project and is reported in *Analysis of Australian Tobacco Companies' Voluntary Disclosures on Cigarette Ingredients 2000—11.*[31]

In 2008, qualitative research was commissioned into the public health value of the current system of voluntary disclosure in Australia. This report, The Public Health Value of Disclosed Cigarette Ingredients and Emissions Data, was prepared for the Department of Health and Ageing by Ipsos Eureka.[32] The report found that the current arrangements were ineffective and that smokers, non-smokers and tobacco control experts found the current information on emissions and ingredients incomprehensible and difficult to access.[32]

There are also a number of other limitations of the Voluntary Agreement Under the Voluntary Agreement, each tobacco company discloses the ingredients in order of descending weight by brand but does not quantify use at a brand by brand level. There is also a provision for a threshold level to be applied (quantitative cut-off), below which specific additives are not disclosed for individual brands (Clause 6.3(i)(E)).

Clause 6.3(E) states

"*all ingredients added to tobacco must be individually disclosed in the composite list of ingredients added to tobacco required under paragraph (ii) of clause 6.3. Each Manufacturer shall disclose the criteria it applied (including quantitative cut-offs) to determine which flavourings it included in the by-brand variant lists*." [2627]

Additionally, it appears that one company may be limiting by-brand variant disclosure by grouping some ingredients under "natural/artificial flavours" in their by-brand variant reports. The use of these clauses consequently limits the by-brand variant analysis that can be undertaken. Also, if these reports are read by the public, without reference to the Voluntary Agreement, they are likely to be misleading, in that some brand variants may appear to be free of additives.

However, individual flavourings, processing aids and preservatives that may not be disclosed at the brand by brand level are disclosed in the manufacturers' composite lists of tobacco ingredients. These composite lists of ingredients comprise substances that may be added to tobacco, and a range of other ingredients that may be added to the papers, filters and inks. However, the lists of disclosed additives may not be exhaustive if the manufacturers have also applied a quantitative cut off to their reporting for the composite lists. It should be noted that the Voluntary

Agreement only provides for a quantitative cut-off to be applied to the by-brand disclosures and not the composite disclosures. It is not clear whether such cut off points have been used, and if used what they are.

The disclosure reports provided by the tobacco companies under the Voluntary Agreement do not report on the quantitative cut off they have applied to the disclosure of ingredients, thus limiting the disclosure of cigarette ingredients.

The Voluntary Agreement does not include details of additives for each variant nor does it cover disclosure of engineering features of individual brands/varieties. This means that there is no possibility of understanding how some additives might be associated with particular types of cigarette.

Additional limitations of the Voluntary Agreement are that the Agreement is not enforceable; there is no disclosure of other classes of tobacco products; and only three companies are party to the Agreement.

Section 3 Additives in Tobacco Products

3.1 What Do We Know about the Use of Additives in Tobacco Products?

Around 200 additives are listed in tobacco companies' annual reports under the Voluntary Agreement . The three tobacco manufacturers identify that the vast majority of these additives have a flavour function. Other additives are listed as components of papers, filters adhesives and inks.

The tobacco industries in various countries (including the United States and Brazil) admit to using around 600 different additives in cigarettes.[4] [10] [13] In New Zealand there was a common list of over 350 known additives in cigarettes between 1999 and 2006.[33] It is not clear why tobacco manufacturers report the use of fewer additives in Australia.

Additives are used by the tobacco industry to influence the palatability of cigarettes in a variety of ways. Additives are used to influence the flavour and aroma of cigarettes; mask the unfavourable harsh characteristics of cigarettes; create milder and sweeter smoke; and reduce sensory irritation associated with smoking. This increases the appeal of cigarette brands to children and novice smokers.[4] [10] [11] [34] [35]

"*Additives contribute to cigarette characteristics in terms of taste and flavour, and pack aroma. The exact materials required to achieve this will depend on the style of cigarette involved and the tobaccos used."* BAT [12]

Additives are also used to facilitate the manufacture of tobacco, increase shelf life and control burn rates.[8] [13] [34] Some additives are identified as processing aids which facilitate the manufacture of cigarettes; for example, by making cured tobacco less brittle. These additives include some ammonia compounds, carbon dioxide and ethyl alcohol.[36] Under the Voluntary Agreement, 'processing aids and preservatives that are not significantly present in, and do not functionally affect, the finished product are grouped as "processing aids" and/or "preservatives"'. These are disclosed in the composite list of tobacco ingredients in the report.

Other additives may be classified as combustion aids and are used to control the smoking mechanics of cigarettes, such as the burning properties of cigarette paper. These may include ammonium, sodium phosphate, sodium and potassium citrate. [36] Philip Morris, Imperial and BATA all list ammonia citrate and potassium citrate as ingredients in cigarette paper in 2011 ingredient lists.

Additives such as cocoa, liquorice and molasses have been used since the 19th century but they have now been joined by many hundreds of other chemicals. For many of these chemicals, their purpose and pharmacological effects are largely unknown, except to the tobacco industry. [13] Most of the little that we know about the

roles of additives comes from tobacco company documents on research conducted by the tobacco industry, mainly over the past four decades.

The industry has devoted significant resources to researching the sensory qualities of tobacco and the impact of various additives. [10 13 37 38] The tobacco industry also invests heavily in purchasing these products. The US tobacco industry spent US$76 million on flavourings in 1977 and US$113 million two years later.[13] Tobacco company documents reveal that during the 1970s and 1980s there was considerable research on new aromatics for the enhancement of smoke taste and aroma, a trend reflected in patents on aroma chemicals and flavour compositions.[37] Tobacco company scientists also published a highly selective segment of some of this research. Some of these studies are summarised in Section 6 of this report.

In 1990, tobacco manufacturers in the United States added a total of 35,324 pounds (15,800 kg) of maple syrup, half a million pounds (225,000 kg) of honey and nearly nine million pounds (4.05 million kg) of liquorice to manufactured cigarettes.[13]

The most common additives reported in Australian disclosure lists are sugars, humectants, menthol, cocoa and liquorice. The literature identifies several additives that can influence the palatability of tobacco products including menthol, sugar, liquorice, eugenol, cocoa, caffeine, and various herbs and spices and botanical products. [4 8 10]

It is estimated that current US-style cigarettes generally contain about a 10 per cent level of additives according to weight, mostly in the form of sugars, humectants, ammonia compounds, cocoa, and liquorice. Most other additives are used in small amounts, less than 0.01per cent of total weight.[4 10] It has also been suggested that the percentage of additives by weight may have increased in the United States during the 1990s, especially the use of sweeteners (which many researchers believe were added to entice young people to smoke).[10]

Flavours can be segmented into casings and 'top dressing' flavours. Australian tobacco industry documents note that the border line between these two classes is not clear, and several materials overlap from one class to the other. [15]

The term casings refer to relatively large levels of sugars and sweeteners added early in the manufacture process. Tobacco industry documents define casings as solid/semi-solid materials added in significant weight quantities to tobacco (kg/per 100kg), usually as an aqueous 'liquor' or 'sauce' during manufacture. [15] The most common casings include sugar, liquorice extract, carob or cocoa. Casings serve both a sweetening function and regulate the overall sugar levels to control the pH of the smoke.

Top dressing flavours, on the other hand, are volatile, highly aromatic oils, usually applied to tobacco in very small quantities as an alcoholic spray during the final

stage of primary processing. Based on disclosures under the Voluntary Agreement, it appears that most of the flavours listed in Australian ingredient lists are added to tobacco in very small quantities. However, according to BATA documents, even though the top dressing flavours are used in very small amounts, they have an extremely significant impact on cigarette products, as flavour additives can be an important factor in achieving a milder and more consumer-acceptable cigarette.[14]

'*Despite the very small amounts of individual flavours (parts per million) used, they make a major contribution to taste and appeal which are part of the individual distinctiveness of cigarette brands*.' BATA[14]

A Philip Morris document describes the various ways in which casings and flavours can be used in product development.[38]

'In processing, casings are applied prior to cutting to moisturize and soften the tobacco and reduce breakage. It is used to subjectively improve the smoking characteristics of the cigarette, in addition to providing a cleaner tobacco taste, or eliminating, a mouth-coating effect if need be …' Philip Morris[34]

Examples of other flavouring substances include benzaldehyde, maltol and vanillin. Spices and herbs such as cinnamon, ginger, sage, mint and oil extracts from cardamom, cedar and coriander can also be used to improve the palatability of tobacco products. [13] One of the main purposes of these flavourings claimed by tobacco companies was to replace flavours lost as tobacco companies introduced low-tar brands.[4] [39]

The disclosure reports for some Australian brands only list tobacco and water, and do not include any flavouring or other additives. However, it is possible that they may contain additives below the lowest-reported quantitative cut off, as per item 6.3 (E) of the Voluntary Agreement.

Some classes of additives have been more successful than others. Proctor reports that many fruit and chocolate flavours have been tried, along with extracts to provide a bourbon or whisky flavour. Some spices were judged too sharp and hot, while perfume and floral flavours such as mimosa, frangipani, jasmine and musk were explored in relation to second-hand smoke and to intensify the smoking experience. Raspberry, peach and banana were largely judged unsuccessful by the tobacco industry, although orange, apple and cherry as well as brandy, rum and bourbon flavourings were used.[13]

As natural flavourings can be expensive or unstable, synthetics that mimicked these flavours were generally used.[13]

Other additives reduce the lingering odour of the smoke in order to improve the acceptability of smoking to people nearby (for example, acetylpyrazine, anethole, limonene, vanillin and benzaldehyde).[21]

3.2 Sugars and Sweeteners

Sugar is naturally present in the tobacco leaf in considerable amounts, and the quantities remaining in the final product depend on the curing methods. [21] As sugar in different forms is also one of the most common additives in tobacco, many tobacco products are highly sweetened and flavoured. [4] [21]

The addition of sugar is particularly important for burley tobacco, and plays a lesser role in the Virginia flue-cured cigarettes that dominate the Australian market.[21]

The European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on the Addictiveness and Attractiveness of Additives states that the presence of sugars in cigarettes is associated with a more favourable taste. The experience of the smoke is less negative and the irritability is somewhat masked. [21]

Essentially, the addition of sugars sweetens the taste of tobacco, making it easier for new smokers to experiment with smoking and continue smoking, since these tobacco products do not have the same harshness and negative experience at the first inhalations.

New Zealand analysis reveals that up to 12.7 per cent of a cigarette by weight may be added sugars and sweeteners. [8] Undoubtedly, the high sugar content affects the palatability and flavour of cigarettes. [8] In Australia, BATA returns list sugar as QNE 5.15 per cent of a cigarette by weight, Philip Morris lists a total of 7.1 per cent by weight and Imperial lists a total of 2.37 per cent.).[40] [41] [42]

It is well known that children favour sweet flavours and it can therefore be assumed that any added sweetness in tobacco smoke would be received favourably by the child experimenting with smoking.[8]

One use of saccharin, a potent artificial sweetener, was apparently to serve as a sweetening agent added to the filter matrix of cigarettes rather than to the tobacco itself, effectively sweetening the smoke upon inhalation as it passed through the filter. [8] Saccharin is not included in current Australian cigarette ingredient lists.

Acetaldehyde is formed in high concentrations when cigarette constituents, including sugars, are burned. [10] Animal research suggests that acetaldehyde (a likely human carcinogen) may act as a synergist with nicotine, though the precise mechanism has not been identified. [8] [10]

Section 6.3 of this report summarises some of the published research conducted by tobacco company scientists in relation to sugar and whether it increases the toxicity of the product. This research is limited in that it fails to consider the influence of sugars and sweeteners on the palatability of cigarettes.

3.3 Liquorice

Liquorice has a long history of use in the food industry as a sweetening enhancer, essentially serving to make foods taste sweet when the amount of actual sugar may be quite low. The constituent of liquorice, glycyrrhizin, is 50 times sweeter than sugar. [8] Apart from glycyrrhizin, liquorice also contains sugar substances, cellulose fibres and essential oils. [21]

Liquorice has been widely used in cigarettes for many years. In the 1980s, tobacco manufacturers in the United States were using 12 million pounds (5.4 million kg) of liquorice in cigarettes every year – an estimated 90 per cent of all liquorice in the country was going into tobacco products. In New Zealand, liquorice is reported to be added to cigarettes in quantities of up to 1.3 per cent by weight. [8]

Liquorice is used to decrease harshness and create a milder, sweeter smoke.[4 8 13] According to the SCENIHR report, [21] the taste and flavour of tobacco with liquorice/liquorice root added is described as sweet, woody and round, but tobacco company documents reveal that adding liquorice/liquorice root also has the objective of camouflaging the unpleasant taste of tobacco.

The use of adding liquorice/liquorice root to tobacco has a number of advantages: it reduces the harshness of tobacco smoke, and dryness in the mouth and throat, and provides a pleasant sweet undertone to the smoke. [21] Liquorice also has a bronchodilator effect, which is important given the quantities added to cigarettes. [13]

Tobacco company documents[43] confirm that liquorice '*is used in cigarettes both as a flavour and as a casing material to smooth the harsh taste of certain kinds of tobacco'.*

Liquorice and its derived products are added to cigarette tobacco as '*flavourants, and as enhancing, potentiating, and smoothing agents. They are also thought to act as surface active agents during the casing operation to help distribute flavours evenly on the blend. Liquorice is used as an adjunct to boost the sweetness of tobacco*.' [43]

Australian ingredient lists identify that liquorice is used in Australian brands as a casing in some Philip Morris brands and as a flavour by BATA and Imperial. In 2011, Philip Morris lists liquorice at QNE 0.7 per cent by weight (as a casing), BATA at 1.14156 per cent and Imperial at 0.11 per cent (as flavourings. [40 41 42]

3.4 Coffee and Cocoa

Bronchodilators have been added to cigarettes to smooth the smoke and facilitate deep inhalation. The tobacco industry has tried many different mechanisms to

achieve milder smoke that is easier to inhale. Compounds used include menthol, cocoa and many other additives. [8 13]

Theobromine, the chief alkaloid in cocoa and chocolate, is known to dilate bronchial airways and has pharmaceutical uses as a drug treatment for asthmatics.[8 13 21]

Cocoa has been added to cigarettes since the 19th century, but its pharmacological effects only began to be understood in the 1960s. [13]

In the 1970s, the National Cancer Institute's (NCI) cigarette testing program found that cocoa added to a tobacco blend increases the carcinogenicity of cigarette smoke condensate.[44 45] While the results were not statistically significant, they prompted the British Government to ban the use of cocoa in tobacco products. By 1983, however, after additional toxicological data were submitted to the British Government's Independent Scientific Committee, the cocoa ban was lifted in the United Kingdom for additions of cocoa up to 5 per cent of the tobacco weight. [45]

In 2011, BATA lists cocoa at QNE 0.82413 per cent by weight.[42] Philip Morris lists it at 0.2 per cent and Imperial at 0.48 per cent.[41 42] Philip Morris identifies cocoa as a casing.[41]

There is some debate in the literature on the impact of theobromine in cigarettes. Bates et al. [4] and Fowles [8] suggested that the bronchodilating effect of theobromine may contribute to the absorption of nicotine in connection with smoking. The SCENIHR report, [21] however, concluded that the content of theobromine per cigarette is too low to have a bronchodilating effect on the lungs and thereby increase the absorption of nicotine.

Regardless of whether it has a brochodilation effect, cocoa appears to be an important flavouring in Australian cigarettes as it is listed in fairly significant quantities compared to other flavourings identified in Australian cigarettes.

A 1978 BAT document [46] reveals that cocoa has two important effects on cigarette subjective properties:

- a smoothing effect on the mainstream smoke (possibly due to the effect of butterfat); and
- a modifying effect on the cigarette aroma due to the volatile components of cocoa.

It is quite possible that cocoa can be replaced with another chemical compound with the same effects. There is some evidence that some tobacco companies, such as Lorillard (a US company), have replaced cocoa with a substitute compound. [45]

Caffeine is usually added to cigarettes as coffee extract. Caffeine is the major alkaloid in coffee, caffeine has similar stimulant properties to theobromine, and

caffeine aerosols have been found to induce improved pulmonary function changes in asthmatics. [8]

In 2011, BATA lists coffee extract at QNE 0.00112 per cent by weight, Philip Morris lists it at 0.005 per cent. [43] [41] Coffee extract does not appear on the Imperial list.[42]

3.5 Vanilla Flavours

In New Zealand, the flavouring additives vanillin and ethyl vanillin are apparently added to tobacco in substantial quantities to impart a vanilla flavour to the smoke. Vanilla may effectively sweeten tobacco smoke. [4] [8]

In the Australian 2011 ingredient lists, BATA lists ethyl vanillin at 0.00066 per cent, vanillin at 0.00540 per cent and vanilla oleoresin at 0.00049 per cent by total weight, making an overall total of QNE 0.0065 per cent by weight.[42] Philip Morris lists vanilla extract; vanilla and ethyl vanillin at a total QNE 0.006 per cent [40] and Imperial lists QNE 0.0046 per cent. [41]

In addition to vanilla, coumarin was used as a food additive due to its vanilla-like taste for many years until it became known that it could cause liver damage and was a suspected carcinogen. The concern over coumarin in tobacco led to the UK's Independent Scientific Committee on Smoking and Health (ISCSH) placing limits on the amount of coumarin in tobacco. Tobacco industry documents reveal that while tobacco companies were required to abide by the limits set in the UK they saw no reason to amend or lower the limits of coumarin in other countries where no such regulatory restrictions existed. [45]

While coumarin is no longer used, it is possible that similar compounds or derivatives may still be used as additives. For example, in New Zealand, 3,4-dihydrocoumarin is listed as a cigarette ingredient at 0.01 per cent (100 ppm). The compound is one of the metabolites of coumarin but its contribution to the flavour of tobacco is unknown.8

3.6 Menthol

Cigarette smoke, like any smoke, is inherently irritating to the mucous membranes of the nasal and airway passages, as well as to the eyes. This irritation is a natural warning sign by the body of an ongoing harmful exposure. [8]

A number of additives in cigarettes appear to be used to temporarily decrease or mask the irritation caused by cigarette smoke and ultimately affect the attractiveness of cigarettes. [8]

Menthol is an organic compound, derived from either natural or synthetic sources, and is widely used in consumer and medicinal products. It has a minty taste and aroma, and depending on the dose it can have cooling, analgesic and irritative properties, reflecting its interactions with specific neuronal receptors that can modulate pain and communicate to areas of the brain concerned with taste and other sensations. [11]

Menthol is added to cool the smoke or make it less harsh, thereby making the cigarette easier to smoke.[13] An anaesthetic, menthol soothes or even numbs the lining of the mouth and throat, and suppresses the body's natural cough reflex.[8] [10] [13] By making it easier to smoke, the addition of menthol can also make cigarettes more attractive to young or beginner smokers.

The recent report by the US Food and Drug Administration (FDA) Tobacco Products Scientific Advisory Committee (TPSAC) review found that menthol cigarettes have an adverse impact on public health in the US. TPSAC also found the evidence is sufficient to conclude that the availability of menthol cigarettes increases experimentation and regular smoking. [11]

It should be noted that there are differences in the patterns of consumption and prevalence of use of menthol cigarettes between Australia and the United States. Menthol cigarettes function as 'starter' cigarettes for young people in the US, and are also smoked more commonly among low SES groups and African Americans.

In relation to palatability, the TPSAC also found that 'menthol's cooling and anaesthetic properties reduce the harshness of cigarette smoke for new smokers. Menthol cigarettes produce sensory cues, such as a minty taste and odour, a cooling sensation and throat irritation or impact – all of which may provide strong cigarette-associated cues that can reinforce smoking behaviour. Thus, it is biologically plausible that menthol cigarettes lead to increased experimentation and higher risk for continued regular smoking among youth.' [11]

A recent US study by Vozoris found that smokers of mentholated cigarettes have significantly increased odds of stroke compared with non-mentholated cigarette smokers. The authors suggested that increased cigarette particulate matter entering the lungs because of facilitation of reflex breath-holding through menthol-induced upper-airway cold-receptor stimulation could be a potential mechanism for mentholated cigarettes causing increased stroke over non-mentholated cigarettes.[47]

Another recent study showed that smokers retain more ultrafine particulate and fine particulate benzo(a)pyrene when smoking menthol cigarettes. There were no significant differences in the levels of urinary biomarkers for nicotine, NNK or pyrene.[48]

Menthol is present in the vast majority (almost 90 per cent) of cigarettes in the US in varying concentrations. [11] However, we are unable to determine this for Australia due to limits on disclosure under the Voluntary Agreement.

Menthol was first added to cigarettes in the 1920s, when it was regarded as a medicinal cough suppressant. Smokers were advised to switch to menthol-cooled 'spud' cigarettes when they had a cold. [13]

Those cigarettes marketed as menthol have sufficient menthol content for menthol to become a 'characterising flavour'. Estimates of the menthol levels in menthol-flavoured cigarettes vary considerably. The recent report by the TPSAC [11] reported that some tobacco companies list menthol levels of around 1000 ppm (wt/wt) of cigarette tobacco [A] or higher as providing a characterising flavour. Other tobacco companies state "… *typically characterizes a cigarette as a menthol cigarette when the cigarette's menthol level is 0.3 per cent or greater"* by weight. A literature review by Heck[49] noted that the menthol content of some cigarettes reaches 2 per cent by weight.

The TPSAC report summarises responses provided to the committee from tobacco companies in relation to menthol characteristics. Menthol is reportedly added to cigarettes both as a characterising flavour (higher levels) and for other taste reasons (lower levels). According to RJ Reynolds, these other taste reasons include brightening the flavour of tobacco blends and/or smoothing or balancing the taste of the blend. Lorillard Tobacco Company, for example, advises that the lowest detectable concentration identified by smokers as menthol characterising is about 0.12 per cent. [11]

Most cigarettes with menthol as a characterising flavour contain at least 0.30 per cent of menthol or higher. Celebucki et al.[50] (2005) found the average menthol content by weight of US menthol brands was 3.9 mg/gm tobacco, with a range from 2.35 mg to 7.76 mg. Menthol concentrations in non-menthol cigarettes averaged about 0.01 to 0.03 per cent. [11] In 2011 ingredient lists, menthol is listed in BATA returns in some brands and in the composite ingredient list as a flavour at QNE 0.70040 per cent of product weight. [42] It is also listed In Philip Morris returns in some brand variants as an ingredient and in the composite ingredient list as a filtration material QNE 0.5 per cent by weight.[40] Imperial lists it in some brands and as a flavour at QNE 0.56 per cent.[41] However, as previously noted, additional low levels of menthol and other additives may be present in various brands at levels below the reporting threshold as per item 6.3 (E) of the Voluntary Agreement. Given the limitations in the Voluntary Agreement arising from this issue it is not possible to ascertain the actual levels of menthol present in Australian brands.

[A] According to the TPSAC, 1000 ppm is equivalent to 0.1 per cent.

In addition to taste, menthol also contributes to smoke impact and to modulation of the irritation from nicotine. [11]

At low concentrations menthol has a soothing effect, but at high concentrations it is irritative. Menthol is used to add flavour while simultaneously deadening local nerve endings to reduce the feeling of irritation from inhalation of the various combustion products. [8 11]

Some cigarette manufacturers use natural menthol only, while others use a mixture of natural and synthetic menthol. Natural menthol has been reported to impart greater cooling and mintiness, and less sharpness, perhaps due to trace chemicals in the natural extract. [11 51]

Peppermint and spearmint oils may be added along with menthol to some cigarettes to modify the taste and other sensory characteristics of the smoke. [11 52]

Menthol readily vaporises during cigarette smoking and easily transfers from the cigarette smoke to the smoker, with little pyrolysis, or decomposition. In mainstream smoke, the vast majority of menthol is in the particulate phase (consisting of solids and condensed droplets in suspension) rather than the gaseous (vapour) phase.[11 B] Menthol is added to cigarettes in a number of ways:

- spraying the cut tobacco during blending;
- application to the pack foil;
- injection into the tobacco stream in the cigarette maker;
- injection into the filter on the filter maker;
- insertion of a crushable capsule in the filter;
- placement of a menthol thread in the filter; or
- a combination of the above.[11]

Over time, menthol diffuses throughout the cigarette, irrespective of where it was applied. Menthol cigarettes are typically blended using more flue-cured Virginia and less burley tobacco. [4 11] This is because some of the chemicals in burley tobaccos create an incompatible taste character with menthol.[11]

3.7 Clove Oil (Eugenol)

Eugenol has long been known to have local anaesthetic properties. [8] An organic compound found in clove oil, it was used in cigarettes in the 1970s and 1980s. Eugenol is described by Rabinoff [10] as a local anaesthetic compound of interest to

[B] The gaseous (vapour) phase of cigarette smoke consists of permanent gases and vapours, including oxygen, nitrogen, carbon monoxide, carbon dioxide, methane, ethane, butane, low boiling hydrocarbons, alcohols, esters, carbonyls, etc. The particulate phase consists of solids and condensed droplets in suspension ranging mostly in size from 0.2 to 0.4 micron, having a maximum size of 1.0-1.5 micron.[23]

scientists because of the potential central nervous system depressant effect that was possibly synergistic with barbiturates and alcohol, and because of a possible interaction with nicotine.

Pharmacologically, eugenol has been reported to exhibit antiseptic properties, analgesic action (local and general), spasmolytic and myorelaxant activities, parasympathetic effects (salivary gland secretion), and direct peripheral vasodilation.[10]

Rabinoff reports that RJ Reynolds also knew that it was present in botanical agents. Although eugenol is no longer found in the list of additives in the United States, it is still present in many of the botanical agents that are used as additives in the US, including basil, black pepper, Ceylon citronella, Ceylon cinnamon, lovage, liquorice, mace, thyme, and other botanical additives. [10] Some of these are also listed in Australian returns; for example, liquorice and lovage.

In New Zealand, the reported level of clove extract is low at 0.0001 per cent. However, the amount of eugenol and its contribution to the numbing effect of the peripheral nerves in the upper airways is unknown.[8]

Clove oil does not appear in recent cigarette ingredient lists provided under the Voluntary Agreement. However, clove oil was reported by BATA in the 2000 composite ingredient list at QNE 0.002 as a flavour. It was not listed in Philip Morris or Imperial returns from 2000.It should be noted that clove (kretek) cigarettes are not captured by the Australian Voluntary Agreement.

3.8 Spices, Herbs, Fruits and Vegetables

According to Proctor, [13] various spices and herbs such as cinnamon, ginger, sage, mint and oil extracts from cardamom, cedar and coriander can be used to improve the palatability of tobacco products by introducing complex flavour notes. The 2011 ingredient lists contain many products in this category. Examples include raisin extract and/or concentrate, tamarind extract, apple juice concentrate, lovage extract, peppermint oil, orange oil, nutmeg oil, prune juice concentrate, chamomile flower oil and dill oil.[40 41 42]

Philip Morris lists lovage extract as a flavour at QNE 0.005 per cent and BATA lists it at QNE 0.00011 per cent.[40 42]

The use of such additives to create a smoother and milder smoking experience and to mask the negative effects of smoking, can contribute to the experimentation and uptake of tobacco use.[10]

3.9 Humectants

Humectants are moisturizing agents for tobacco, and play a role in preventing the tobacco drying out and becoming crumbly. However, tobacco company documents reveal that humectants may also used to impart sweetness and increase the mildness of the smoke.

Humectants, are used in cigarette tobacco blends to assist with aerosol formation and thus make cigarette smoke 'milder'. The more the nicotine can be dissolved in the tar droplets, the less irritating the smoke is to the consumer's throat and the easier it is to inhale.[8 17]

According to Australian cigarette ingredient lists, humectants in use in Australia include glycerol and propylene glycol. BATA also lists water as a humectant.[42]

Glycerol and methylglycerol are also added to cigarettes as humectants, to decrease the sensory irritation of the inhaled smoke.[8]

Glycerol is listed in BATA composite returns for Australia at QNE 2.02 per cent of product weight, for Philip Morris at 2.1 per cent and Imperial at 1.5 per cent.[42 40 41]

Propylene glycol is commonly listed in PM ingredient lists at QNE 2.6 per cent, by Imperial as a humectant/solvent at QNE 1.4 per cent and by BATA as a humectant at QNE 2.41608 per cent. [40 42]

Philip Morris lists sugar (invert sugar and sucrose) as both flavours and humectants at QNE 4.1 per cent and 3.0 per cent respectively.

Imperial lists both glycerol and propylene glycol as a humectant/solvent.[41]

BATA lists water at QNE 14.8 per cent as a humectant.[42]

3.10 Ingredients that may Create the Impression of Health Benefits

Various ingredients have been used in tobacco products to help create the impression that such products have health benefits, or to create the impression that they present reduced health hazards. Examples include vitamins, such as vitamin C and vitamin E, fruit and vegetables (and products resulting from their processing such as fruit juices), amino acids such as cysteine and tryptophan, and essential fatty acids such as omega-3 and omega-6. [9]

There is evidence that vitamins have been used as a tobacco additive, and that tobacco companies have used various marketing strategies in some countries to claim nutritional properties. Media reports confirm that cigarettes with vitamins have been sold and marketed in countries including Germany, the United States and

Canada, with health claims appearing to have been associated with these products. However, there is no evidence that vitamins have been added to cigarettes in Australia.

A media report from Canada in 2006 stated that a Quebec company was producing a cigarette that was claimed to not stain smokers' teeth, to have less of an odour than regular brands and to contain beneficial ingredients like vitamin C.[53] Refer to Figure 1.

Figure 1: Vita-Cig, developed and marketed in Quebec, Canada, prior to the prohibition on the sale and manufacture of cigarettes containing vitamins.

The use of menthol in cigarettes is also significant when considering the use of ingredients that may create the impression of health benefits. A major selling point for menthol brands has been that they have more pleasant, 'fresher' or 'smoother' smoke than 'regular' cigarettes, suggesting relative health benefits, rather than claiming them explicitly.[54] The fresher/smoother smoke of menthol cigarettes is also widely believed to make them easier to smoke and thus attractive to adolescent experimental smokers who are struggling to overcome their aversion to certain sensations of smoking, such as harshness, throat and chest irritation, and stale after-taste.[55]

There is also evidence that smokers believe that many low-yield brands ('light and mild' cigarettes) are also less hazardous than other tobacco products, mainly as a result of the lighter and smoother taste.[56]

3.11 Additives Associated with Energy and Vitality

According to the WHO Guidelines for Articles 9 and 10, energy drinks, popular with young people in some parts of the world, are perceived to increase mental alertness and physical performance. Examples of stimulant compounds contained in such drinks include caffeine, guarana, taurine and glucuronolactone. [9]

Tobacco industry documents and patent applications show that some of these additives (caffeine and taurine) have also been considered for use in tobacco products.[9] It is not clear if any of these additives are currently added to cigarettes, or whether levels that could be ingested from smoking would have stimulant effects.

3.12 Colouring Additives and Burn Accelerants

Colouring agents are added to various components of tobacco products to make the resulting product more appealing. Attractively coloured cigarettes (for example, pink, black, denim blue) have been marketed in some countries. Examples of colouring agents include inks (for example, an imitation cork pattern on tipping paper) and pigments (such as titanium dioxide in the filter material). [9]

Australian ingredient returns list a number of chemicals used for this purpose.[40 41 42] A list is provided at Appendix 1.

Any substance that is added to cigarette papers is smoked along with the tobacco. Cigarettes usually have a brand name inked onto the rod, and therefore the ink products are also smoked by the smoker. Colourings and bleaches may also be added and are also smoked. Cigarette papers contain a number of additives, such as bleaching products to ensure that the paper is white, along with burn accelerants such as sodium or potassium citrate to keep the cigarette lit. [13] Philip Morris lists potassium citrate at QNE 0.2 per cent as an additive to cigarette papers and sodium citrate at QNE 0.05 per cent.[40] Imperial lists potassium citrate at QNE 0.22 per cent and sodium citrate at 0.08 per cent as an additive to cigarette paper.[41] BATA lists potassium citrate at QNE 0.05676 per cent and sodium citrate at QNE 0.10268 per cent.[42]

More recently, the addition of bands to the paper to help meet reduced ignition propensity requirements is very likely to have resulted in increased levels of some paper additives.

As the plain packaging regulations restrict what can be included on the cigarette stick, and the colours thereof, the range of products used for this purpose is likely to decrease markedly in the future.

3.13 Additives Used to Mask the Irritation and Odour from Sidestream Smoke

A 2009 study by Connolly et al.[57] reviewed tobacco industry documents on the research, development and use of additives to mask the irritation and odour of second-hand smoke (SHS), namely the smoke given off the end of the burning tip and also exhaled by smokers.

The review found that tobacco manufacturers employed additives and other cigarette design technologies to alter the visibility, odour, and irritating quality of SHS without necessarily reducing the overall level of smoke or its constituents, or testing for alterations in smoke toxicity. The authors suggest that this approach was used as

part of an overall campaign to counter the decline in the social acceptability of smoking.

Connolly et al. concluded that the tobacco company documents clearly indicate that cigarette additives were developed along with other product design changes to reduce or mask the aroma, visibility and irritation of sidestream smoke, and less frequently to lower actual smoke emissions. [57]

Given that the focus of this literature review is on additives and their influence on palatability, we do not explore these issues in detail.

3.14 Ammonia

Ammonia and ammonia compounds influence the pH of the tobacco and the smoke, resulting in higher amounts of uncharged nicotine that is more easily absorbed by the cells. However, due to the high buffer capacity of the lining fluid in the lungs it is uncertain if more nicotine is absorbed with higher smoke pH.[21] However, as high smoke pH results in higher impact sensation,[17] ammonia additives may be included to lower pH, and therefore influence palatability.

Ammonia does not appear in recent Australian ingredient lists, although ammonium phosphate dibasic was listed as a flavour/processing aid by BATA in 2000 at QNE 0.3 per cent. Phillip Morris listed ammonium hydroxide at QNE 0.25 per cent in 2000 as a flavour/processing aid.

Ammonia has been associated with the manufacture of reconstituted tobacco. It is not clear if reconstituted tobacco is included in Australian cigarettes, as current disclosures do not require tobacco companies to provide information on the type of tobacco used. However, if reconstituted tobacco is used in Australia, the ingredients used in its manufacture should be listed.

Given that the focus of this literature review is on additives and their influence on palatability, we do not explore these issues in detail.

3.15 Summary of Possible Pharmacological Effects of Additives

There is limited information on the pharmacological and toxicological effects of many tobacco additives. However, Rabinoff's study provides a useful summary of some of the possible pharmacological effects of selected chemical additives.[10] Refer to Table 1.

Table 1 Possible Pharmacological Effects of Selected Chemical Additives and Selected Combustion By-products

Chemical Additives	Possible Pharmacological Effects
Acetaldehyde (predominantly a combustion by-product)	Positive reinforcer that acts on the CNS, synergistic and enhanced reinforcing effects with nicotine, may contribute to addiction, carcinogen, production increased with increased use of sugars in cigarettes.
Aconitic acid	Unproven uses: treatment of neuralgia, serous skin inflammation, migraine, myalgia, rheumatism, pleurisy, mucosal diseases, pericarditis sicca, fever, as an anti-inflammatory, cardiac tonic (aconitin can trigger cardiac arrhythmia), for disinfecting and wound treatment.
Alpha-tocopherol	Antioxidant/mitigant; extensively studied by RJR for addition to cigarettes for mitigant effect.
Benzyl salicylate	Flavouring that is also anti-inflammatory, antipyretic, analgesic (partly to completely metabolized to salicylic acid).
Beta-carotene	Antioxidant/mitigant; extensively studied by RJR for addition to cigarettes for mitigant effect.
Caffeic acid (in botanical additives)	According to RJR, blocks the formation of nitrosamines in vivo, and 'results of study suggest that dietary caffeic acid and ferulic acid may play a role in the body's defense against carcinogenesis by inhibiting the formation of N-nitroso compounds'.
Chocolate	Contains theobromine, a bronchodilator; suspected to be added to entice young people to smoke.
Cocoa	Contains theobromine, a bronchodilator; suspected to be added to entice young people to smoke.
Ethyl salicylate	Flavouring, also anti-inflammatory, antipyretic, analgesic (partly to completely metabolised to salicylic acid).
Ethyl vanillin	Flavouring, subjectively experienced as similar to sugar.
Eucalyptol (1,8-cineole)	Antimicrobial, increases lung mucociliary clearance, suppresses arachidonic acid metabolism and cytokine production in human monocytes, anti-inflammatory activity in asthma patients; induction of apoptosis in human leukaemia cell lines, antinocioceptive.
Eugenol	Used in cigarettes in 1970s and 1980s; a local anaesthetic compound of interest to scientists because of potential CNS depressant effect that was possibly synergistic with barbiturates and alcohol, and because of a possible interaction of nicotine as a stimulant with eugenol as a depressant; removed after possible hepatotoxic and carcinogenic effects of the compound were discovered. An internal 1985 RJR document indicated awareness of eugenol's pharmacological properties.
Farnesol	Inhibits growth and viability of a variety of neoplastic cells.
Ferulic acid (in botanical additives)	According to RJR, blocks the formation of nitrosamines in vivo, and 'results of study suggest that dietary caffeic acid and ferulic acid may play a role in the body's defense against carcinogenesis by inhibiting the formation of N-nitroso compounds'.
Glycyrrhizin, ammoniated	Glycyrrhizin has anti-inflammatory, antiviral and anti-gastrointestinal ulcer properties; may enhance interleukin 10 production.
Isobutyl salicylate	Flavouring, also anti-inflammatory, anti-pyretic, analgesic (partly to completely metabolised to salicylic acid).
Isovaleric acid	Possible pheromone effect. Isovaleric acid is a component of the pheromones present in the vaginal secretions responsible in the female rhesus monkey for stimulating sexual behaviour in the male. It is also found to be one of the major components of the subauricular gland secretion of the male pronghorn (antelope); its odour produces a strong response from the male as indicated by

Chemical Additives	Possible Pharmacological Effects
	sniffing, licking, marking and thrashing.
Levulinic acid	Nicotine levulinate and levulinic acid enhance the binding of nicotine to nicotinic receptors in rat and mouse brains. Levulinic acid also increases peak plasma nicotine levels while enhancing perceptions of smoothness and mildness; it desensitises the upper respiratory tract, increasing the potential for cigarette smoke to be inhaled deeper into the lungs.
D-limonene (and its metabolites perillic acid, dihydroperillic acid perillyl alcohol, uroterpenol and limonene1,2-diol)	Possible anticancer properties. May inhibit tumour growth via inhibition of p21-dependent signalling and apoptosis resulting from induction of the transforming growth factor beta-signalling pathway. D-limonene metabolites also cause G1 cell cycle arrest, inhibit posttranslational modification of signal transduction proteins, and cause differential expression of cell cycle–related and apoptosis-related genes. Animal studies show activity of D-limonene against pancreatic, stomach, colon, skin, and liver cancers. Data also indicate that D-limonene slows the promotion/progression stage of carcinogen-induced tumours in rats.
Menthol	Anaesthetic action, complex interaction with nicotine, increase in P1-N2 amplitudes.
Methyl salicylate	Anti-inflammatory, antipyretic, analgesic, counterirritant (partly to completely metabolised to salicylic acid).
Mitigants	Of 127 chemicals on a list of mitigants, 12 are direct chemical additives to cigarettes (beta-carotene, ascorbic acid/vitamin C, L-histidine, cinnamaldehyde, histidine, tannic acid, lauric acid, octanoic acid, oleic acid, vanillin, essential oils) and 40 are contained within botanical additives on the University of Indiana list of additives (carotenoids, beta-carotene, ascorbic acid/vitamin C, bioflavonoids, catechin, myricetin, quercitin, isoquercitrin, quercitrin, rutin, kaemferol, naringenin, naringin, epigallocatechin gallate, caffeic acid, L-histidine, alpha-tocopherol/vitamin E, tryptophan, glutathionine, provitamin A, chlorophylls, chlorophyllin, cinnamaldehyde, curcumin, ellagic acid, eugenol, ferulic acid, gallic acid, histidine, tannic acid, chlorogenic acid, linoleic acid, linolenic acid, lauric acid, octanoic acid, oleic acid, vanillin, vitamin B2, polyphenols, essential oils).
Phenethyl salicylate	Flavouring, also anti-inflammatory, antipyretic, analgesic (partly to completely metabolised to salicylic acid).
Propylene glycol	Alters P1-N2 amplitude, an objective CNS activity measure correlated with favourable sensory characteristics of cigarettes.
Pyrazine	Alters P1-N2 amplitude, an objective CNS activity measure correlated with favourable sensory characteristics of cigarettes.
Pyridine	Has documented similar peripheral effects, but opposite CNS effects, to nicotine; has suspected synergistic CNS effects.
Salicy-acetaldehyde	Metabolised by oxidation to salicylic acid. Promotes wound healing and granulation when applied topically, and was shown in a rat study to be a less potent analgesic and anti-inflammatory agent. Equipotent with salicylic acid, methyl salicylate and aspirin in hindpaw edema assay; equipotent with aspirin in acute inflammation.
5,6,7,8-tetrahydroquinoxaline	Tetrahydroquinolines, on the basis of experimental data, have been hypothesised to act as 'false neurotransmitters' in catecholamine-containing neurons. In the 1960s, formaldehyde was shown to condense with endogenous catecholamines to form tetrahydroquinolines. That acetaldehyde is highly reactive with catecholamines was one of the reasons for DeNoble pursuing his research on the reinforcing effects of acetaldehyde. Might serve

Chemical Additives	Possible Pharmacological Effects
	as a 'false neurotransmitter' and might have an addictive effect.
Thiamine hydrochloride	Vitamin B1.
Valeric acid	Flavouring. Chemical in botanical *Valeriana officinalis*, which is also a listed additive. Valeric acid has documented direct sedative effects and interactions with neurotransmitters such as GABA.
Gamma-valerolactone	Inhibits CYP2A6, a nicotine metabolising enzyme, which could lead to higher nicotine blood levels. There are 20 known chemically related lactone compounds that are included on the University of Indiana list of additives and are known to inhibit CYP2A6. In addition, on the basis of a study noting that the level of inhibition of CYP2A6 varies by side chain substitutions, at least 14 other lactone compounds also on the University of Indiana list of additives may act as CYP2A6 inhibitors as well.
Vanillin	Flavourant. Also increases P1-N2 amplitude, an objective CNS activity measure correlated with favourable sensory characteristics of cigarettes, subjectively experienced as similar to sugar.

Note: CNS = central nervous system; RJR = RJ Reynolds. This is not an exhaustive list of specific chemical additives with pharmacological effects; rather, it represents selected examples of additives with possible pharmacological effects.

Source: Rabinoff et al. [10] et al.

3.16 Additives in Australian Cigarettes

As noted earlier, there are around 200 additives listed in the 2011 disclosures by the three largest tobacco companies in Australia (excluding filters, papers, adhesives and inks). Under current arrangements, Australian consumers and policy makers cannot identify the amount and type of ingredients in specific brands by examining this ingredient information. Comparisons of the products are of limited utility because important information on additives is provided as a composite list of ingredients containing many different additives rather than disclosure of all ingredients per brand.

The tobacco companies disclose only the highest amount of ingredients used in their brands (QNE). Therefore, it is not possible to draw conclusions about the average amount added or about the percentage of brands that contain a particular ingredient. In addition, additives that are used in very small amounts and fall below the quantitative cut off point may not be disclosed in accordance with item 6.3 (E) of the Voluntary Agreement.

The current Australian disclosures report only four products used as processing aids (excluding water), all by Imperial. Ethanol is reported as also being a solvent. The other three products include two largely irrelevant gases (CO_2 and nitrogen) and one extremely volatile chemical, isopentane, which is likely to have evaporated unless added very close to the time of packaging.

BATA is the only company to list preservatives, with benzoic acid and potassium sorbate being reported. It may be possible that the other companies do not use any preservatives, raising the question as to why BATA needs to use these products.[42] Alternatively it may be that preservatives are included in the general category of processing aids listed by the other companies.

There also appears to be differences in the use of solvents. Imperial lists glycerol and propylene glycol as solvents. [41] BATA lists sorbitol as a solvent [42] and Philip Morris does not list any solvents. [40]

Humectants (excluding water) are listed by all three companies: glycerol and propylene glycol. Philip Morris also lists invert sugar and sucrose (sugar), which are also listed as flavourings.[40 41 42]

BATA lists cellulose fibre and guar gum as binders and Philip Morris lists guar gum and phenylacetaldehyde, with no Imperial disclosures under this heading. [40 41 42]

BATA lists calcium carbonate as a filler. [42]

Philip Morris lists 'carob bean and/or extract', cocoa and cocoa products, and liquorice extract as casings, the only firm to use this category. However, these are listed as flavourings by the other companies (although BATA does not list carob). [40 41 42]

All the remaining additives are listed as flavours. It is apparent that the vast majority of additives are included to affect the flavour of the final product.

A number of findings from part two of this project are relevant to this literature review. In the report *Analysis of Australian Tobacco Companies' Voluntary Disclosures on Cigarette Ingredients 2000—11* [31] *w*e found that the ingredient disclosures provide evidence of a substantial amount of change occurring in the use of additives by the Australian manufacturers in the period between 2000 and 2011.

The changes have not simply occurred in the direction of declining use of additives – a conclusion that is suggested, but not demonstrated, from the declining numbers of additives disclosed by all three manufacturers in the composite disclosures. It remains possible that early disclosures of large numbers of additives, include some that might be used or had been used (here or elsewhere), but which were not currently being used. [31]

While the composite disclosures show a general trend of declining numbers of additives disclosed between 2000-1 and 2010-11, new additives have been reported in most years and increases in the maximum levels used have also been reported for some additives. A major limitation impacting on this analysis was that current Australian disclosure arrangements are not comprehensive. The possibility of quantitative cut off provisions, and them possibly differing by overall lists and brand-

specific lists, mean that even brands that are reported as having no additives on the disclosure may still contain additives that are not disclosed. [31]

The brand by brand disclosures also provide evidence that, rather than having a fixed recipe for each brand variety which is adhered to each year, there is some degree of year by year variation in the reported additives used. One possibility is that there is a particular set of smoking characteristics (including flavour, aroma and smoothness) sought after by the manufacturers and changes are made in the additives used in order to achieve the standards for those brand varieties in a context of changing characteristics of the tobaccos used (ie tobacco product characteristics presumably vary by growing conditions, both climatic and related to soil type). Another possibility is that the varying availability and/or cost of particular additives may produce year by year variation in their use.[31]

The brand by brand disclosures also provide strong evidence that the manufacturers take somewhat different approaches to producing palatable cigarettes. All three manufacturers have some brand varieties which are reported to contain no ingredients apart from tobacco and water (but may contain additives below the quantitative cut off point), and all three manufacturers have some brands which are reported to contain sugars, humectants, casings and top flavours. [31]

However, PMI had a much greater proportion of brands than the other two manufacturers which were reported as containing ingredients other than tobacco and water. One possibility is that Imperial Tobacco and BATA allow a greater degree of variation in the taste, aroma and smoothness characteristics of their brands. Another possibility is that Imperial Tobacco and BATA are able to achieve a high level of standardization of these characteristics using selection of tobacco feedstock, whereas PMI is more reliant on using additives to achieve standardization.[31]

Section 4 Use, Manufacturing and Sourcing of Tobacco Products

4.1 Australian Tobacco Manufacturers

Three tobacco companies currently dominate the market in Australia: British American Tobacco Australia (BATA), Philip Morris International (Australia) (Philip Morris) and Imperial Tobacco Australia (Imperial). These companies are wholly owned subsidiaries of overseas corporations. Although per capita consumption in Australia is declining, Australian tobacco companies remain highly profitable businesses.[58]

In 2009, an estimated 21,928.5 million cigarettes were sold in Australia, the equivalent of 1669 packs of 25 cigarettes per minute (this does not include roll-your-own tobacco, which has increased in consumption in recent years).[58 59]

Only two of the companies, Philip Morris and BATA, own local manufacturing facilities. Previously, brands sold by Imperial were marketed under licence by BATA.[58] However, in 2012 Imperial Tobacco announced it would move cigarette manufacturing from Sydney to New Zealand.[60]

In addition, a small number of companies import speciality products and brands.

A total of 23,544.5 million cigarettes were produced in Australia in 2009, with 4021 million cigarettes exported (primarily to Pacific Island countries). An additional 2465 million cigarettes are imported.[58 59]

4.2 Tobacco Growing in Australia

Tobacco has been grown in Australia since the 1800s. By 1840, tobacco was under cultivation around Sydney; commercial tobacco leaf growing began in the 1860s around Myrtleford in Victoria and in southern Queensland in the 1880s.[61]

Tobacco growing reached its peak in Australia in the early 1970s, when nearly 16,000 tonnes of leaf were sold annually. By 2006, the crop was less than 4000 tonnes.[62] Prior to deregulation of the market, most Australian leaf was purchased by local manufacturers.[63] By the 1990s, however, various government support schemes and tariff protections were progressively wound back, and tobacco manufacturers increased the volume of cheaper imported tobacco leaf.[64]

Tobacco is no longer grown commercially in Australia. It is not known precisely (to those outside tobacco companies) where the tobacco used in Australian cigarettes is grown. However it appears that tobacco is imported into Australia from Brazil, China, India, the United States, Zimbabwe and Turkey.[65]

4.3 What is in a Cigarette?

The cigarette became the dominant form of tobacco use as a result of the discovery of flue curing in the mid-19th century and the invention of the cigarette-making machine in 1880. [19]

The original old-fashioned cigarette, or 'gasper', was little more than a simple tube of cut tobacco rolled in paper by a machine. For many Western nations, the First World War established smoking as a majority behaviour among men while women began to take it up in large numbers in the late 1920s. The cigarette did not appear to change significantly until after the Second World War, when filters in cigarettes were introduced. [19]

The way that tobacco leaf is grown and cured, and the way that cigarettes are designed and manufactured, have significant impacts on the delivery of nicotine to the smoker and the way the product is used. [13]

Cigarettes contain tobacco from different parts of the plant. Cut tobacco leaf (or 'lamina'), varies in flavour and nicotine content, depending on which part of the plant it has been taken from. Leaf taken from high on the plant will have higher nicotine content and will generally also have a richer flavour. [13]

Modern manufactured cigarettes are carefully designed 'nicotine delivery devices', engineered to maximise consumer satisfaction through effective delivery of nicotine. Cigarettes are also engineered to maximise consumer acceptance through improving the experience of use (for example, making the cigarette taste less harsh and creating positive expectancies of use via aroma). [4 9 19 21 66]

Modern manufactured cigarettes in Australia consist of a rod of cut tobacco and a crimped cellulose acetate filter wrapped in porous paper. At the mouth end of the cigarette there is another layer of non-porous paper, called tipping paper, which is typically around 30 mm in length. [58] This tipping paper is often pierced by sets of holes designed to let in air when the cigarette is puffed (this is known as filter ventilation). [16] As tobacco industry documents reveal:

'The cigarettes should be conceived not as a product but a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine … Think of the cigarette as the dispenser for a dose unit of nicotine … Smoke is beyond question the most optimised vehicle of nicotine and the cigarette the most optimised dispenser of smoke.' Philip Morris, 1972.[67]

From all we now understand, this 40-year-old statement is probably more true today than when it was made.

Cigarettes contain tobacco leaf as well as engineered and processed forms of tobacco such as expanded tobacco and reconstituted tobacco. Several hundred additives are also used overseas in cigarettes. These additives are used to facilitate manufacture of cigarettes, increase shelf life, improve flavour and aroma and control burn mechanics, influence nicotine delivery and mask the harshness and irritation associated with smoking.

4.3.1 Tobacco Leaf

The chemical content of the tobacco leaf can be influenced by a range of factors including genetic manipulation, agricultural practices and curing methods. For example, the nicotine content of tobacco is related to the amount of nitrate fertiliser used in cultivation. [3]

It is also possible to genetically manipulate the tobacco plant to change the content of the constituents of the leaf. [3] There is evidence that tobacco companies have experimented with genetic engineering as a way of manipulating nicotine concentration and other attributes of the tobacco leaf. [10] [68]

For example, RJ Reynolds development projects focused on incorporating the beta carotene gene, controlling nicotine levels and genetically modifying the plant in other ways.[10] Philip Morris developed specific molecules to decrease carcinogenic tobacco-specific nitrosamines, [10] while BAT began experimenting with growing genetically modified tobacco plants or 'super tobacco' in the 1970s. This 'super tobacco' was given the code name Y1 and was genetically altered to produce twice the nicotine of regular leaf.[69]

The extent to which these practices are currently used in Australia is unknown.

4.3.2 Chemical Residues from Pesticides

Most tobacco crops are treated with a wide variety of pesticides; the amount and type varies depending on where the tobacco was grown and the regulatory requirements in place. [52] While this issue is largely outside the scope of this literature review, a brief summary is included to contribute to a broader understanding of the issues involved regarding toxicity.

Chemicals are used to save time and/or human labour as well as to prevent the tobacco plant from being attacked by pathogens and insects. [13] Treatments generally involve spraying the soil, plant or stored leaf with chemicals that can end up as residues in groundwater or in the cigarettes people smoke.[13]

A wide variety of pesticides are used in tobacco growing and applications tend to be quite heavy, with some tobacco crops receiving as many as 16 treatments.[13]

A wide range of toxic metals are also found in tobacco, depending largely on the soil content where the tobacco was grown. The use of fertilisers has been linked with high concentrations of arsenic, mercury, lead, cadmium, chromium, polonium and beryllium in tobacco. [52]

Historically, lead was present in cigarettes, mainly through pesticide use. In addition, the metal was commonly used in the foil used to wrap cigarettes until the 1940s.[13] Chemical pesticides remain a significant element of tobacco-growing practices. The degree of transfer of pesticides to cigarettes through mainstream or passive smoking is largely unknown. The nature and extent of the combustion products from these compounds is also largely unknown. [52] It should be noted that the use of these chemicals is governed largely by the regulatory regime in the country where the tobacco is grown, rather than the country in which the tobacco in the form of cigarettes is ultimately sold. These arrangements vary considerably throughout the world.

4.3.3 Expanded Tobacco

Expanded tobacco is lamina or stem that has been 'puffed up' or expanded by the use of either ammonium carbonate (ACET) or carbon dioxide to increase its filling power. [66] The expansion process 'puffs' stems or lamina utilising 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 utilised to puff either stems or lamina. Both expanded stems and lamina are treated with casing sauces which have been discussed previously in this report.

The term casing refers to relatively large levels of sugars and sweeteners added early in the manufacture process. Tobacco industry documents define casings as solid/semi-solid materials added in significant weight quantities to tobacco, usually as an aqueous 'liquor' or 'sauce' during manufacture. The most common casings include sugar, liquorice extract, carob or cocoa.[15] Other additives can also be added to these forms of expanded tobacco, although it is not clear which additives are added at each stage of the process. In addition, the thermal decomposition of ACET results in the production of ammonia and carbon dioxide. Hence, ACET is one of the means by which ammonia chemistry is achieved in tobacco products without the explicit use of ammonia. [66]

Expanded tobacco is less dense, which means a cigarette can be filled with less mass. It is used to control burning properties, as well as to control the weight/firmness combination of the tobacco rod. Expanded stem, in particular, imparts firmness to tobacco rods. [13]

It appears that high levels of expanded leaf and stem were used in Australian cigarettes during the 1980s and 1990s. During this period, cigarettes were

engineered to minimise weight and thereby reduce tobacco excise payments. It appears that the expanded tobacco was used to increase the 'firmness' of the lightweight cigarettes. [13 58 70]

Expanded tobacco was also one of the means by which 'low-tar' and 'light' cigarettes were able to deliver less tar during ISO smoking tests. [13]

4.3.4 Reconstituted Tobacco

Reconstituted tobacco, or 'recon', is a cigarette ingredient made from tobacco waste by a papermaking process. Recon was used to reduce production costs (by using what is essentially a waste product from the manufacturing process) but also to fine tune the chemical composition of cigarette filler. [13] This product was known by different names by the tobacco companies; for example, inside Philip Morris it was referred to as blended leaf or BL, and elsewhere as RT or 'root technology' or tobacco sheet. RJ Reynolds referred to it and the process by which it was made as G-7. [13]

In US blended cigarettes, reconstituted tobacco comprises about 20 to 30 per cent of a cigarette's blend formulation on a weight basis. According to a report to the WHO by Jeff Wigand (the former vice president of research and development at the Brown & Williamson tobacco company), reconstituted tobacco is a chemically manipulated material using abundant additives, such as glycerol, liquorice, cocoa, honey, polyethyleneglycol (PEG), simple sugars, invert sugars and ammonia-based additives such as ammonium hydroxide, urea and diammonium hydrogen phosphate (DAP).[66]

Reconstituted tobacco also provides a mechanism for reducing standard ISO-measured tar and nicotine yields, a particularly important goal for tobacco companies, during the time when many government authorities and health groups believed there were benefits associated with low-yield cigarettes (a policy now largely discredited). [4 13 66]

However, as Australian cigarettes are predominantly Virginia style cigarettes rather than the blended cigarettes that dominate the US market, it is unlikely that reconstituted tobacco was used at the same levels as in the US. However as discussed in section 9 of this review, tobacco company documents reveal evidence of experimentation with ammonia technology in Australia.

Tobacco company documents also suggest that the use of reconstituted tobacco was phased out in Australian cigarettes in the 1980s and 1990s.[70] The most likely reason for this change is related to tobacco company efforts to manufacture

extremely low weight cigarettes to minimise tobacco excise that was levied on a weight system. [58 C]

As tobacco excise increased during the 1980s, Australian tobacco manufacturers had a strong incentive to produce low-weight cigarettes. However, it appears that the production of very low weight cigarettes created some technical challenges. In order to create low-weight cigarettes that were sufficiently firm to hold together prior to smoking and to facilitate burning, it appears that reconstituted tobacco was replaced with expanded tobacco, especially expanded stem.[58 70] The amount of reconstituted and expanded tobacco in current Australian cigarettes is uncertain. It is unclear whether the change in excise arrangements in 1998 to a per stick method has had a major influence on cigarette engineering, given there is no longer a financial reason to manufacture lightweight cigarettes.

4.3.6 Casings

The term casing refers to relatively large levels of sugars and sweeteners added early in the manufacture process. Tobacco industry documents define casings as solid/semi-solid materials added in significant weight quantities to tobacco, usually as an aqueous 'liquor' or 'sauce' during manufacture. The most common casings include sugar, liquorice extract, carob or cocoa. Casings serve both a sweetening function and regulate the overall sugar levels to control the pH of the smoke.[15] Casings are used extensively with burley tobacco (part of the American blend), but are not used as much with flue-cured or Virginia tobacco as these have a naturally higher sugar content. [21]

According to the SCENIHR report,[21]

"*casings are usually applied to tobacco strips or leaf early in the primary processing scheme to tone down or mute the strength or harshness of tobacco smoke, improve the processability of tobacco and add deep flavour notes to the smoke. These casings are added to the burley tobacco line through the means of the casing cylinder or cased leaf dryer*."

Tobacco company documents demonstrate the importance of casing and flavour formulas to the tobacco manufacturers, and their importance in increasing the palatability of cigarettes:

[C] The Australian tobacco excise system was levied on a weight basis until 1998, when it changed to a per stick basis.

'Casing or sauce materials are added to tobaccos to enhance their quality by balancing the chemical composition and to develop certain desired flavour characteristics...sugar is added to restore a chemical equilibrium between the acid forming and the base forming constituents of the smoke. This balance od sugars, acid and alkaline constituents varies by types of tobacco and must be carefully adjusted by the tobacco manufacturer to produce a mellow, full bodied smoke. Although each tobacco manufacturer carefully guards the secrets of his casing (and flavour) formulas, it is well known that casings for smoking products often contain sugar, liquorice, cocoa, or chocolate liquor and sometimes natural extracts. Of these, liquorice deserves special mention. Just as sugar is used in "casing" the tobacco to mellow and smooth the smoke, liquorice is used as an adjunct to boost the sweetness of tobacco products. The taste of liquorice to the smoker is that of a mellow sweet woody note which, at proper use levels, greatly enhances the quality of the final product.' BATA, *Tobacco Flavouring for Smoking Products*. [71]

A 1992 Brown & Williamson/BAT document by J Wigand titled Product Testing and Product Development Best Practices[12] explains the critical importance of casings and flavour to the tobacco industry.

'Casing and flavor play a very crucial role in the commercial success of a product. Their part in total product development is of growing importance.' [12]

Australian tobacco company documents described in Section 9 of this report also reveal that tobacco companies experimented with the application of casings on Virginia-blend cigarettes; for example, Project Commonwealth,[72 74] which focused on Virginia-style cigarette markets in the United Kingdom, Canada and Australia. There is also evidence from tobacco company documents that:

- casings and flavour have been credited with playing a very crucial role in the commercial success of a product; [12 15]
- low-tar brands may contain higher levels of casings and top dressings than 'full flavour' brands; [73]
- Australian Virginia brands do contain casings in some instances.[74 38]

4.4 Overview of the Manufacturing Process

Unsurprisingly, there is a lack of published data on the steps and processes involved in the manufacture of Australian and international cigarettes.

The growing and manufacturing processes for tobacco provide a number of opportunities for the addition of additives of various types. The exact type and amount of additives used in the growing, processing and manufacturing of tobacco is largely unknown except to the tobacco industry. That said, we do know that levels of additives vary greatly from brand to brand and also by variety within brand families. There are numerous tobacco industry documents that document the use of at least

some of these additives. Australian cigarette returns also include some of these additives but as they are generally reported in the composite list their presence in individual brands cannot be determined.

Harvested tobacco goes through multiple manufacturing process steps after purchasing and prior to any cigarette manufacturing. [66] The first step occurs at the green leaf threshing (GLT) processing plant, sometimes referred to as the stemmery. The GLT plant removes the mid-rib and veins from the leaf to produce de-stemmed lamina. The stems that are removed are collected, packaged by size and used later in the manufacturing process. [66]

The properties of tobacco are based primarily on curing methods, locality of growth, position on the stalk from which the leaves have originated and factors such as colour quality and ripeness at harvest. 21

Curing is the process for drying freshly harvested tobacco with partially or fully controlled temperature and moisture schedules. Freshly cured leaf is then threshed to separate stem from lamina, sometimes blended with other tobacco lamina and then re-dried to a uniform moisture level then packed into bales or hogsheads. Virginia tobacco (the predominant type in Australian cigarettes) is flue-cured by drying with artificial heat; Burley tobacco (predominantly used in US blended cigarettes) is air-cured; Oriental (Turkish) tobacco is sun-cured.21

According to Proctor,13 the development of the flue curing process for tobacco is particularly significant because it resulted in smoke that was easily inhalable. Prior to this tobacco was not generally drawn into the lungs but rather only the nose and the mouth. The smoke from flue cured tobacco is less alkaline and therefore less harsh and irritating and is more likely to be inhaled into the lung. Proctor13 argues that cigarettes made from flue cured leaf are more addictive because the lungs are more effective conduits of nicotine than the mouth. This issue warrants further investigation, in particular, research on the possible implications of setting lower limits of the pH of tobacco smoke to inhibit lung inhalation.

The controlled ageing process last for several months with the intent to enhance smoking characteristics before the material is processed into cigarettes. During the ageing process, the environmental conditions are controlled to avoid mould growth.[66]

According to BATA and Jeff Wigand's report to the WHO, the cigarette manufacturing plant is divided into two distinct operating sections: primary processing and 'fabrication' or secondary manufacturing.[66] [75]

4.4.1 Primary Processing

During the primary processing stage, tobacco leaf that has arrived in 200 kg cases is converted into batches of cut tobacco, ready to be made into cigarettes. [75]

In his report to the WHO, Jeff Wigand provides an overview of the primary processing of tobacco. This description is broadly consistent with the process identified by Australian tobacco companies on their websites. The major difference appears to be that Wigand's descriptions of the process highlight some of the steps during this processing where additives are added to tobacco and cigarettes. [66]

In primary processing, both flue-cured (Virginia) and burley tobacco are steam conditioned in a vacuum chamber. Oriental tobacco is not steam conditioned. Once the burley and flue-cured components of the blend are moisture equilibrated, casings are applied.

The most common casings include sugar, liquorice extract, carob or cocoa. Casings serve both a sweetening function and regulate the overall sugar levels to control the pH of the smoke and are contingent on blend formulas.

Burley is cased in large revolving cylinders and then goes through a re-drying process. The casing is reapplied and then dried to about 20 per cent moisture content. Burley can be re-dried as many as six times. Once the burley is cased and re-dried for the last time, the blend is reconstituted. [66]

Flue-cured tobacco (the more common type of tobacco used in Australia) requires lower applications of casings compared to burley tobacco due to its higher intrinsic sugar content and generally only goes through one phase of casing.

Like burley tobacco, it is re-dried to 20 per cent moisture content. The moisture of oriental tobacco is also adjusted to 20 per cent. [66]

The next step is tobacco blend configuration, where burley, flue-cured, oriental and reconstituted tobacco (if used) are blended, followed by cutting, reduction in moisture content (to less than 15 per cent), the addition of 'expanded tobacco' (if used) and the application of the final blend flavouring package. [66]

Blending is the selection and thorough mixing of the tobacco-based components plus any associated casings, humectants and flavouring required for a particular product or brand. The tobacco-based components may include the leaf lamina, cut and rolled stem, reconstituted sheet and expanded tobacco. [21]

According to the SCENIHR report, there are no fixed rules as to when humectants, flavours and flavourings are added to the processed tobacco. Generally, the more volatile ingredients are added as late as possible during tobacco processing to prevent losses. Those tobacco blends that contain flavours and flavourings are usually held in a bin to allow for equilibration across the blend before it is passed to the making machine as the final blend. [21]

Top flavourings are generally applied to the total tobacco blend as one of the last steps in processing. Usually carried in an alcohol base, they are used to improve quality of smoke, and impart a pleasant pack aroma and sidestream aroma. [21]

Once completed, the rag[D] is ready for transport to the fabrication or secondary processing section of the plant for cigarette making, packaging and storage in a condition warehouse for equilibration prior to market distribution. [66]

4.4.2 Secondary Processing – Making the Cigarette

There is relatively little information available on the 'fabrication' or secondary manufacturing processing of cigarettes.

According to BATA, modern high-speed machines are used to make filters, assemble cigarettes and pack them into packets, 'outers' (cartons) and 'shippers' (cardboard boxes). [75]

The company notes that cigarette filters are made from cellulose acetate and that filter machines make enough filter rods per minute to make 18,000 cigarettes. Filter rods are transferred to the cigarette-making machines by vacuum tube. [75]

According to BATA, the next process is to make a cigarette rod. In this process tobacco is formed into a continuous 'cylinder', wrapping cigarette paper around the tobacco then cutting the whole into lengths, making a cigarette rod. For the production of menthol brands, one method is for menthol to be applied to the cigarette paper; other methods are discussed in section 3.6. [75]

According to the SCENIHR report, flavours may be added to the tobacco, cigarette paper or filter, in a plastic pellet placed in the filter or the foil wrapper, in an attempt to enhance the tobacco flavour, mask unpleasant odour and deliver a pleasant cigarette-pack aroma. Internal industry documents reveal additional flavour technologies such as flavour microencapsulation in the paper, carbon beads and polymer-based flavour fibres inserted into the filter and flavoured tipping. [21]

A double filter is then inserted between pairs of cigarette rods, tipping paper is wrapped around the assembly, and the double cigarette is cut in two. [75]

Each brand is made to a recipe, including a particular tobacco blend, filter and tipping paper, designed to achieve 'consistent quality and satisfaction'. [75]BATA also notes that '*some tipping paper is perforated to allow air into the smoke stream'.* [75] The perforations in the tipping paper are known as filter vents. Filter ventilation is the most important cigarette design feature influencing flavour, strength, harshness and

[D] Rag is tobacco that has been cut into fine strips for use in cigarettes. Also known as cut rag.

irritation. Filtration and filter ventilation play a critical role in making cigarette smoke more palatable by decreasing the harshness and irritation of the cigarette.[16] [76] For over three decades, cigarette filter ventilation has also been the major design feature used by tobacco manufacturers for reducing the official machine-smoked measured standard tar, nicotine and carbon monoxide yields of cigarettes. [16] [76]

As Kozlowski and O'Connor describe:

'Filter vents are both an effective design feature for the industry and a tragedy for the smoker seeking a less hazardous smoke. The industry gets an inexpensive-to-make cigarette that beats the standard tar tests, reassures smokers with a lighter taste, and facilitates the taking of bigger, compensating puffs.' [76]

Given the importance of filter venting on influencing the palatability of cigarettes, it is discussed in detail in Section 5 of this paper.

Once the cigarettes are made, they are transported to the packing complex. First, the cigarettes are formed into groups as per the pack size, and then the foil is wrapped around to form a 'bundle'. The cigarette packet arrives in a flat cut-out form (a 'blank'). The blank is wrapped around the bundle, an inner frame is inserted at the front of the bundle underneath the lid and glue is applied to form the packet. On a separate but linked machine, the packet is wrapped with film to prevent the cigarettes from drying out and tear tape is attached. On yet another machine, the wrapped packets are packed into 'outers' (cartons) for bulk sale. [75]

It is difficult from this description provided by BATA to identify the key points at which additives are introduced into the process. It is likely that a range of additives are applied at multiple points in the manufacturing process. As Australia imports all its tobacco, additives will already have been applied to the tobacco prior to importation.

Only the tobacco companies are aware of the full range of additives and the specific processes used to apply them. For this reason, the WHO FCTC Guidelines recommend that member nations introduce legislation to:

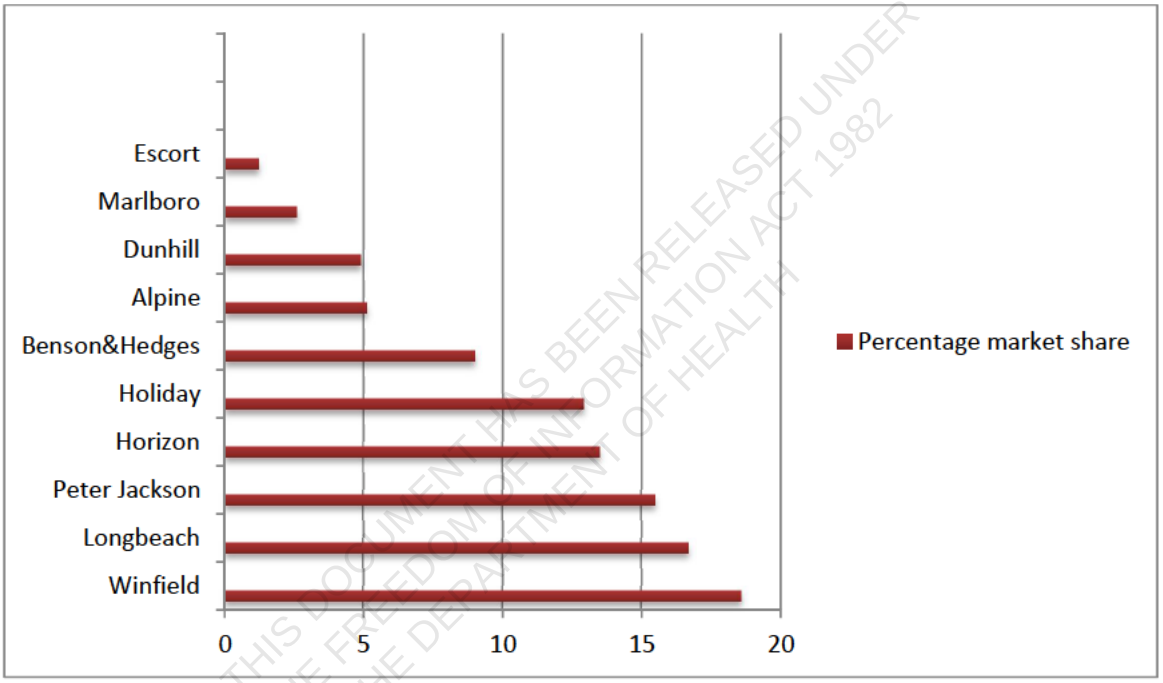
- require manufacturers and importers to disclose information on ingredients used at each stage of the manufacturing process;
- require manufacturers and importers to disclose information about design features. [9]

It should also be noted that there are products that enter cigarettes largely through chance, such as shards of metal or glass, dirt and grease from processing machines.[13]

4.5 The Composition of Australian Cigarettes

Most Australian cigarette brands are 'Virginia-only' products. [36] [77] This means that all of the tobacco used in their manufacture is Virginia or flue-cured. The other most common type of cigarette in Western countries, particularly in the United States, is the blended cigarette, which contains a mixture of several different kinds of tobacco. [77] In the Australian market, Virginia cigarettes tend to be more popular than blended ones. [58] Only a small number of brands currently sold in Australia, including Alpine and Marlboro, are blended. [58]The most popular brands smoked by Australian adults are Winfield, Longbeach, Peter Jackson, Horizon and Holiday. [58]

Among secondary school students, the most popular brands are Winfield (42 per cent), Peter Jackson (13 per cent), Longbeach (13 per cent), Horizon (5 per cent) and Benson & Hedges (7 per cent).[78]



Source: 2010 International Tobacco Control Policy Evaluation Study, n = 587, unpublished data.[58]

Virginia tobacco has a high sugar content compared to the tobacco types cured by other means. It consequently produces 'sweeter-tasting smoke' than other tobacco types, at least when nicotine levels are comparable. However, Virginia tobacco also produces more acidic smoke, because a number of acids are produced from the combustion of sugars. [58] The lower smoke pH of Virginia cigarettes means that there is generally proportionately less unprotonated or 'free' nicotine in the smoke. [34] [79] This 'free' nicotine is the more pharmacologically active form of nicotine, which appears to produce most of the rewarding sensations associated with smoking. The other form – called protonated or 'bound' nicotine – acts more slowly. However, 'free' nicotine also produces more sensations of harshness than protonated nicotine. [34]

The smoke from Virginia cigarettes also has a slightly different profile of known carcinogens and cardiovascular/respiratory toxicants than the smoke from cigarettes containing other tobacco types.[80] [81]

The tobacco industry argues that Virginia-type cigarettes, which dominate the Australian market, contain few or no flavour ingredients.

'Today millions of smokers in countries including China, the United Kingdom, South Africa, Canada and Australia smoke cigarettes that do not contain flavor ingredients (Virginia-style cigarettes).' Philip Morris [77]

However, the ingredient lists published under the Voluntary Agreement and on the industry websites acknowledges the use of a large number of additives in their tobacco products in Australia. The BATA website states:[82]

'Tobacco ingredients are added to a small number of Australian products during manufacturing, and have a specific function in the final product.' [82]

BATA states that *'Food-type ingredients and flavourings are added to balance the natural tobacco taste. This replaces sugars lost in the curing process and gives individual brands their characteristic flavour and aroma. Other ingredients have technological functions such as controlling moisture, protecting against microbial degradation, affecting burn rates and acting as binders or fillers.*' [82]

In addition, the BATA website states:

- *'In British American Tobacco's view, based on the currently available scientific evidence, the ingredients that its Group companies use, at the levels used, do not add to the harm of tobacco consumption, do not induce people to start smoking and do not affect people's ability to quit.*
- *There is no evidence that smoking cigarettes without added ingredients reduces the health risks. There is no such thing as a safe cigarette.*
- *Ingredients are not added to make cigarettes appealing to children. The ingredients in some types of cigarettes do include sugars, cocoa, and fruit extracts, they blend with tobacco, making a characteristic tobacco taste distinct from the effect these ingredients have on foods.*
- *Tobacco products are not "spiked" with nicotine.*
- *Ingredients are not added to increase the amount of nicotine in cigarette smoke, nor to increase the amount or speed of nicotine absorbed into the smoker's body.*' [82]

Imperial Tobacco Company also acknowledges the use of flavourings and other substances in their tobacco products:[83]

'*We do not add anything to our products to make it more difficult for smokers to stop smoking, to make our products attractive to children or to increase the level or*

change the chemical form of nicotine in tobacco smoke … Ingredients may be added to tobacco products during manufacture. Ingredients (for example, flavourings typically used in food) are used in very small quantities in some brands to enhance their overall flavour characteristics and aroma, giving each Imperial Tobacco brand variant its own distinctive style, in line with consumer preferences … The term "ingredient" also applies to substances in the non-tobacco materials that are used to make our products. These materials include the cigarette paper, the filter, the adhesive that seals the paper and the ink that colours the tipping.' [83]

We note that these statements are carefully worded and relate to the primary espoused aim of the additives, and not to 'incidental' or unclaimed effects they might have.

A study by Hammond and O'Connor[84] examined 21 constituents in tobacco and 41 constituents in smoke emissions from Canadian cigarettes. In common with Australia, Virginia-type cigarettes dominate the Canadian market. Data are reported for 247 brands tested in 2004. While the data appear to provide partial support to anecdotal evidence and industry assertions that Canadian 'Virginia' cigarettes contain fewer chemical 'additives' compared with US blended cigarettes, the tobacco in Canadian Virginia-style cigarettes was by no means 'additive free'. [84]

The study reported ammonia compound levels of US cigarettes were more than four times greater than Canadian cigarettes, as were other 'additives' such as triethylene glycol. However, the tobacco in Canadian cigarettes also contained numerous additives. The authors noted that the results may have been influenced by the reporting requirements, which did not require reporting of ingredients contained in a number of elements of cigarettes. For example, Canadian brands had similar levels of glycerol and detectable levels of propylene glycol, both of which serve as humectants to retain moisture and alter flavour. In addition, many additives applied to cigarette paper and the filter are exempt from Canadian reporting guidelines, including adhesive and binders, plasticisers, colours for papers and salts, all of which can leach into the tobacco after it is packaged. Other common additives, including theobromine, menthol and cocoa, were also exempt from reporting. As a result, the authors concluded that it is not possible to fully evaluate the level of additives in domestic Canadian cigarettes. [84]

There is a substantial body of evidence demonstrating a huge amount of tobacco industry activity to improve the palatability of its products. While there is debate about whether this may be less relevant to the Virginia (or flue-cured) tobacco used primarily in Australia, there is no doubt that both additives and other engineering features have been used to influence the palatability of cigarettes.

Section 5 Characteristics of Cigarette Design Relevant to Cigarette Palatability

5.1 Background

The palatability and related perceptions of cigarettes are affected by additives and a range of other factors. The following factors have been identified in the literature as important:

- the amount of tar and nicotine delivered in each puff;
- the use of filters and differences in filters;
- the use of filter ventilation;
- the composition of and kinds of tobacco used in the cigarette (for example, flue-cured, fire-cured, air-cured, fermented);
- the pH of the smoke;
- Additives, particularly flavours, but also including casings and humectants.

Other factors such as paper porosity, the density of packing the tobacco and the cut width of the tobacco strands may also affect palatability. Finally, the way the person puffs on the cigarette also has effects by influencing burn rate, and other physical parameters. There is evidence that the physical design characteristics of cigarettes, such as filter venting, interact with additives and the overall physical and chemical composition of tobacco to influence function, affecting both the delivery of nicotine to the smoker and the overall experience of smoking. [16 21 85]

5.2 The Link between Low-Tar Cigarettes, Additive Use and Changing Cigarette Design

There is evidence that tobacco companies have used both additive technology and engineering of the cigarettes to reduce machine-measured tar and nicotine yields while manipulating the levels of nicotine received by smokers to maximise the likelihood that they will continue to receive 'satisfying' doses. [16 21 76]

When concerns about the cancer risk from smoking were first raised in the 1950s, tobacco manufacturers responded by introducing filtered cigarettes and sought to reassure smokers that their brand of tobacco was safe.[86] This was often accomplished by comparing the yields of tar and nicotine in their brands to those of rival manufacturers. Manufacturers increasingly competed with one another to reassure health-conscious smokers with new, 'healthier' products. This began what came to be called the 'Tar Derby', as manufacturers increasingly developed new brands of cigarettes that were supposedly lower in tar and nicotine. [86]

As we will outline in this review, a less harmful cigarette never eventuated, although an appearance of progress was maintained by the tobacco industry for many years as progressively lower tar, nicotine and carbon monoxide yields were reported.

To date, the primary means of testing cigarette toxicity has been to use a 'smoking' machine to smoke the cigarettes according to a standard puffing regime and to measure the chemical emissions in the mainstream smoke.[87]

In 1967, the Federal Trade Commission (FTC) in the United States began a program to test cigarettes for tar and nicotine yields in cigarette smoke. In this test, a machine takes a 35 ml puff of two seconds duration once a minute until a fixed butt length is reached (23 mm or overwrap plus 3 mm). The International Organization for Standardization (ISO) adopted the same parameters in the 1980s, with slight modification. The ISO standard was adopted by Australia for reporting on the pack, but this was subsequently discontinued in 2006. [86] The ISO test has been used in many other countries.

A study by Hammond et al. demonstrated that the ISO regime 'constitutes a set of puffing parameters that systematically underestimate smoking behaviour in humans'. Tobacco manufacturers have also designed cigarette brands to perform one way under the machine smoking conditions, but to deliver much greater smoke constituents to humans. As a result, the emissions generated under the ISO smoking regime have little relationship with actual measures of human exposure, and exaggerate the differences between brands in a manner that has proved deceptive to both consumers and regulators. [87]

According to Hammond, the emissions from the ISO regime have served as more of an industry marketing tool to falsely reassure health-concerned smokers, rather than as a valid measure of cigarette toxicity. [87]

In Australia, the campaign for low tar began in 1966 when the Anti Cancer Council of Victoria (ACCV) developed a harm-reduction program for smokers who were unwilling or unable to quit following similar advice from the US Public Health Service to smokers. [86] It was anticipated that smokers could reduce their individual disease risks, and that a general reduction of tar and nicotine yields would lead to lower levels of smoking-related disease and death. [4 86]

In 1982 the Australian Government passed legislation to require the pack labelling of tar and nicotine yields. This requirement was in place until March 2006, when it was discontinued because, based on the scientific literature, the labelling was potentially misleading and confusing for smokers. Smokers erroneously believed that these light cigarettes were less hazardous than other cigarettes. The tobacco industry targeted many of these brands to smokers who were thinking of quitting, in an effort to reassure such smokers and keep them smoking cigarettes.[88] As the US National Cancer Institute states, '*the switch to low machine-measured-yield cigarettes with*

the illusion of risk reduction was, therefore, substituted for a real risk reduction that would have occurred had the smoker quit smoking altogether.' [88]

Typically, the tar, nicotine and CO levels measured from any cigarette are quite highly correlated, so it appeared that lowering the tar also lowered nicotine and carbon monoxide exposures. As a result, attempts to reduce the levels of tar also tended to lower nicotine yields. Adding filters reduced both tar and nicotine levels, actually resulting in an increase in carbon monoxide levels as the filter takes out the particulate matter and not the gases. [88]

At the time, this was thought to be a reasonable trade-off, as chemicals in the tar were of more concern than the carbon monoxide (at those levels). What was not realised was that, because nicotine levels dropped, these cigarettes were smoked harder (compensatory smoking) to obtain the desired nicotine levels. Therefore, actual exposures to tar may not have changed much at all, while exposures to the carbon monoxide were likely to have increased significantly. [16 76]

During the 1970s and 1980s, the tobacco industry introduced a multitude of cigarettes with progressively lower tar and nicotine contents. However, early low-tar cigarettes met with limited acceptance among smokers and presented a range of technical challenges to tobacco manufacturers. King and Borland [16] suggest that the limited acceptance of these early products is possibly related to:

- high-efficiency filters, which have high draw resistance (requiring greater effort to gain a standard puff of smoke);
- blandness – prior to the 1980s, smokers frequently reported that low-tar brands lacked the flavour of their high-yield counterparts; and
- low nicotine delivery.

Over time, the tobacco companies successfully used additive technology [4 10] and re-engineered the filter ventilation to create low-tar cigarettes to overcome these barriers. Cigarettes were created that appeared to be low in tar, while delivering similar levels of nicotine to standard cigarettes. [16] The rise in additives in tobacco products is closely linked with the strategy to reduce tar yields in cigarettes. [3 4] Tobacco company documents reveal that the companies invested heavily in research and development in additives to replace the 'lost flavour' associated with the reduction in tar levels, and attempted to produce a more flavoursome cigarette. [4 10] There was also significant research and development in relation to filters and filter ventilation. [16]

Over the past 30 years, tar and nicotine yields in low-yield cigarettes declined considerably. It was hoped that this would result in a less hazardous cigarette and deliver reductions in tobacco-related disease. Epidemiological evidence shows that despite these lower yields there has been no associated decline in overall disease risk for all smokers or among low-tar smokers.[16] These hoped-for health gains did

not materialise and the so called 'low-tar policy approach' has been largely discredited as it offers no health benefits to smokers. [4 16]

Research reveals that the system for measuring tar and nicotine yields is seriously flawed. The yields measured by the ISO test do not relate to the smoker's exposure to tar and nicotine. [16 76 89 90] It is very likely that the tobacco companies were aware of the impact of compensatory smoking behaviour and that low-yield cigarettes did not deliver reduced levels of tar and nicotine to the smoker.

There is evidence that smokers' fears about the health risks associated with smoking were somewhat lessened by the availability and marketing of these low-yield cigarettes. Smokers generally believed that these low-yield cigarettes were less harmful than other cigarettes. [88]

In addition, many in the public health community were also misled by the standard tests to believe that tar and nicotine levels in cigarettes had actually been reduced. However, since the mid-1990s there has been increased awareness that the yields measured by the ISO test are seriously flawed and significantly underestimate the exposure of the smoker to tar, nicotine and carbon monoxide. [16]

There is now overwhelming evidence that yield figures using the standard ISO measures have little relation to the actual delivery of tar and nicotine to the smoker. [16 76 89 90] For example, Jarvis et al. in 2001 found that nicotine intake per cigarette smoked, as estimated from salivary cotinine level, did not correspond with machine-smoked yields at any level of nicotine yield. In fact, nicotine intake per cigarette was about eight times greater than machine-smoked yields at the lowest deliveries and 1.4 times greater for the highest yield cigarettes. [89]

This result is not surprising, as the amount of tobacco remains fairly constant between types of cigarettes and the amount of nicotine in the tobacco is also similar. Indeed, in some cases the tobacco in low-yield cigarettes can be higher in nicotine than standard cigarettes. This means the potential amount of nicotine and tar does not differ to any great extent; it is the filter venting and the way the cigarette is smoked that affects delivery, independent of ISO testing levels. Indeed, so powerful are aspects of the engineering that it is possible to engineer cigarettes with equivalent ISO deliveries while containing vastly different amounts of tobacco. For example, extra-long 'normal'-diameter cigarettes can deliver the same amounts of tar and nicotine as measured by a standard test as a shorter, thinner (smaller diameter) cigarette, even though the latter may have only around half as much tobacco. To the extent that the cigarettes with less tobacco can be smoked to obtain desired nicotine levels (and clearly some can), these cigarettes can be considered to be functionally equivalent to the larger cigarettes.

The concerns about the reliability of the current ISO test have led to a search for a better way to assess cigarette yields. Since the 1990s, a number of other smoking

machine test protocols have been introduced. Of particular note is the ISO Intensive Condition test (also frequently referred to as the Canadian Intensive Condition test), in which the machine takes a 55 ml puff of two seconds duration, once every 30 seconds (and with all filter ventilation taped over). [87]

A study by Hammond et al. concluded that none of the alternative smoking regimes, including the Canadian Intense method, are more 'representative' of human smoking behaviour and none provide adequate prediction of human exposure. [87]

The main reasons why tar and nicotine yields measured by a smoking machine do not correspond to actual exposure levels of the smoker are that:

1. nicotine-addicted smokers smoke lower yield cigarettes more intensively by taking more frequent or larger puffs and covering filter vents; [16 91 92] and
2. low-tar cigarettes have been engineered to become more conducive to compensation over the past three decades – the cigarettes were designed to be 'elastic', yielding more smoke to human smokers than to smoking machines. [16 76]

King and Borland [16] suggest there have been two generations of low-tar cigarettes that can be distinguished by the use of filter ventilation. Early low-tar cigarettes relied primarily on high filtration efficiency and to a lesser extent on high static burn rates to produce low yields in testing situations.

The second generation of low-tar cigarettes developed by the tobacco companies employed filter ventilation to deliver low yields in testing situations but were able to deliver higher levels of nicotine to the smoker. [16]

Filter ventilation is the primary mechanism used by tobacco manufacturers to reduce cigarette yields while satisfying the nicotine cravings of smokers. The mechanism by which filter ventilation can achieve this is outlined in more detail in Section 5.3 below.

The use by smokers of compensatory behaviours, facilitated by the use of filter venting on the product, means that tests using standard puffing parameters are severely flawed as indicators of human exposures, and thus of any potential for harm reduction by altering yields. This analysis has led some public health experts to suggest that cigarette performance should be assessed by measuring toxins per mg of nicotine. [85 87] This is based on the evidence that most smokers titrate their smoking to get a relatively fixed dose of nicotine, although the work of Benowitz [91] and others would suggest that they may use taste (mainly from the tar quotient) as their initial means of doing this. Because the tar to nicotine ratio (or more specifically the nicotine to any given toxicant ratio) can vary as a function of the puffing parameters used, there is currently no consensus on how to best measure toxicant levels per mg of nicotine.

There is also some debate among tobacco control experts regarding the impact of filters themselves with some experts arguing they are ineffective and are being used as a marketing tool by the tobacco industry and calling for them to be banned. [93] Others however, argue they have some benefit. However this issue is beyond the scope of this literature review, rather we focus on the impact of filter ventilation on the palatability of cigarettes.

5.3 The Importance of Filter Ventilation

The engineering features of a cigarette, such as filtration and filter ventilation systems, are one of the most important influences on the palatability of tobacco by decreasing the harshness of the flavour of the smoke and reducing irritation. [16]

In the vast majority of Australian cigarettes the tipping paper contains perforations – known as filter ventilation – to dilute the smoke with fresh air when the smoker takes a puff. [16] Essentially, smoke is replaced with air in the standard puff, and this also causes less smoke to be produced at the burning coal. There are also some subtler effects. The reduced draw on the burning cigarette coal also reduces the temperature of the coal, which can change the nature of the smoke. The smoke moves through the filter at a lower velocity because of ventilation. [16] [76]

Between 1970 and 1985 there was a rapid rise of vented cigarettes in the United States. In 1970, Marlboro 100 was the first Philip Morris product to use mechanical perforation in regular production, shortly followed by Alpine and Marlboro menthol 85s. In 1975 only 7 per cent of cigarettes were ventilated, rising to 20 per cent by 1977 and 88 per cent by 1982. [76]

In Australia, at least one ventilated filter cigarette was available in 1974. At that time, ventilated filter brands comprised only 0.1 per cent of the market in Australia (compared with 6 per cent in the United Kingdom and United States), rising to a 1 per cent market share in 1977. It appears that filter ventilation was introduced into Australia later than the UK and the US, and seems to have penetrated the market more slowly. [16]

It appears that the first ventilated filter cigarette in Australia was Ransom Select, which replaced Ransom in 1974 and had lower yields (5 mg tar and 0.3 mg nicotine), despite an increase to King Size. [16] King and Borland present detailed analysis of the changing construction of Australian cigarettes associated with the low-tar strategy[16].

Filter ventilation was the most important determinant of both tar and nicotine yields in Australian brands in 1994, when nearly 90 per cent of brands used filter ventilation.[16] Filter ventilation enabled tobacco manufacturers to measure reduced machine yields of tar, nicotine and carbon monoxide, while enabling nicotine-addicted smokers to

achieve their typically larger target doses of nicotine (and thus higher levels of tar and CO as well) through the processes of compensatory smoking.[16] [76]

The combined effects of increased filtration and increased ventilation make the smoke more dilute so it tastes weaker or 'milder' and produces less harshness (the immediate burning/scratching sensations in the mouth and throat) and irritation (the lingering tingling sensations in the throat and chest). [16]

This lighter 'lighter' or 'milder' taste can support the smoker's perception that these cigarettes deliver less tar and nicotine, and by tasting less harsh, stimulate beliefs about diminished dangers to health. The more air added by dilution, the milder and more air-cooled the smoke. This reduces the overall perception of 'harshness' and increases the perception of mildness. [76]

These perceptions of 'lightness' and 'less irritation' can constitute compelling (but incorrect) sensory evidence that can mislead smokers and allay their concerns about the health risks of smoking. Because vented filter cigarettes feel milder, many smokers believe they are less toxic. [76]

The second issue is that increased ventilation facilitates increased puff volumes, a key means of compensatory smoking. Kozlowski notes that when common best-selling US 'light' cigarettes are smoked, increased puff volume can achieve compensation so well that behavioural vent blocking is superfluous. [76]

The third issue is behavioural vent blocking, which is important when increased puffs will not comfortably provide ample compensation. It is well known that smokers commonly block the vent holes with their lips or fingers. [72] When these vents are blocked, cigarettes are rated as harsher and hotter than unblocked vents; however, most behavioural vent blocking is incomplete, often diminishing ventilation levels by 50 per cent or 25 per cent. [76]

Kozlowski and O'Connor argue that filter vents are a defective and misleading design feature and should be prohibited. Smokers appear to be largely unaware of the features and they have received surprisingly little attention from policy makers to date. [76]

Filter ventilation is present in the vast majority of Australian cigarettes and results in a lighter/milder taste. It promotes larger puffs and, with heavy ventilation, promotes behavioural blocking of vents.[16] [76] From a public health perspective, the influence of filter ventilation on smokers' perceptions is a major concern: it is one of the most powerful means for varying the taste strength, harshness and irritation of cigarette smoke. Filter ventilation is therefore a powerful means for influencing the beliefs of smokers about the relative harmfulness of different brands. It is also a powerful means for increasing the palatability of some brands for young people and other novice smokers, or those smokers who find 'full strength' cigarettes unpleasant.

5.4 Use of Additives to Add Flavour to Low-Tar Cigarettes

The production of low-tar cigarettes initially presented challenges for tobacco manufacturers in terms of flavour. According to the Philip Morris documents, tobacco company market research showed that nine out of 10 smokers had tried the low-tar brands but had failed to accept them as their choice of cigarette, primarily because of the reduced flavour. [37] It is uncertain whether the flavourings Philip Morris refers to in this documents related to levels of nicotine and/or the amount of tar, which tends to signal the amount of nicotine.

Philip Morris also noted the impact of high-efficiency filters and air-dilution systems that have been engineered into the low-tar cigarette, making low-delivery cigarette smoke '*less and less flavorful and less and less acceptable and enjoyable to the smoking public'*. [37]

A Philip Morris document, Breakthrough of High Taste Low Tar Cigarette – A Case History of Innovation, details the development of Merit cigarettes, a full-flavour low-tar product developed after 12 years of research. [37]

A critical aspect of tobacco companies' research and development focused on enhancing the flavour of low-tar cigarettes, and they invested heavily in developing flavourants and other additives. [4 10 37] '*Since the advent of the filter cigarette, the tobacco industry has been heavily involved in research in flavour chemistry. Flavorants are often the key to the success or failure of a new brand. Flavoring systems are a closely guarded secret among the cigarette manufacturers, but certain casing and top flavor components are widely used.*' [37]

According to Philip Morris, one method of enhancing flavouring in low-tar cigarettes was the modification of the tobacco blend to enhance flavour contributions from various blend components. The second and most significant was flavour amplification. In principle, amplification was achieved through the identification of the high-intensity flavour components in the particulate smoke and reformulation of the traditional flavour formula. [37] These approaches became increasingly sophisticated over time, as Philip Morris scientists describe:

'Instead of a hit and miss method of formulating flavors to produce a desired smoke, a precise and reproducible system of selecting out specific flavorants with known characteristics and enriching the cigarette had been developed.' [37]

As research and development efforts into low-tar cigarettes continued, combinations of additives that produced high-intensity flavour but low tar were perfected and incorporated into the ongoing product development efforts. Mixtures of these flavourings were formulated into special flavour systems which were applied to different tobacco blends. [37]

It is unclear from the tobacco industry document whether the research and development efforts were seeking alternatives to lost nicotine or other influences of flavour. However, it clearly indicates the capacity of the industry to finely tune the flavour of cigarettes to maximise consumer appeal.

Section 6 Research Published by Tobacco Company Scientists

6.1 Summary of Published Studies

A number of articles related to the use of additives have been published by tobacco company scientists.[94 95 96 97 98 99 100]

In 2004, British American Tobacco scientists Baker et al. [94] published an overview of the effects of tobacco ingredients on smoke chemistry and toxicity in the *Journal of Food and Chemical Toxicology*. This study presented an overview of a series of previous studies designed to assess the influence of 482 tobacco ingredients on cigarette smoke chemistry and toxicity.[94]The studies included:

- the effect of pyrolysis on the specified ingredients;
- the influence of the ingredients on smoke constituents believed by regulatory authorities to be relevant to smoking-related diseases;
- the influence of the ingredients on in vitro genotoxicity and cytotoxicity of smoke particulate matter;
- the influence of the ingredients on the inhalation toxicity of smoke. [94]

The ingredients tested included 462 flavours, one flavour/solvent, one solvent, seven preservatives, three humectants, five binders, one filler and two process aids (one of which is water). The ingredients were added to 19 test cigarettes '*at or above their typical maximum use levels, in various combinations'* in three experimental cigarette series. The test cigarettes were compared to the control cigarette. [94]

Baker et al. concluded that their research and that conducted by other scientists (who also worked for the tobacco industry) indicated that commonly used tobacco ingredients '*do not change the toxicity of smoke as measured in specified assays'*. They also concluded '*that the ingredients have no effect on the levels of most smoke constituents that may be relevant to smoking-related diseases'. [94]*

Baker et al. reported that from a sample of 291 single-substance ingredients, almost one-third would transfer out of the cigarette burning zone at least 99 per cent intact (that is, less than 1% pyrolysis), and almost two-thirds would transfer at least 95 per cent intact. Of the ingredients that underwent some degree of pyrolysis, a few 'Hoffmann analytes' (tobacco ingredients that may increase the toxicity of cigarettes) were detected amongst the pyrolysis products of 19 ingredients. The authors argued that taking into account maximum use levels, their maximum pyrolysis levels were generally small and often insignificant compared to the levels typically present in smoke. Possible exceptions were acetaldehyde and benzene from the pyrolysis of malic acid. [94]

Baker et al.'s study also examined the activity of smoke particulate matter by three in vitro bioassays, two for genotoxicity and one for cytotoxicity. These were the Ames test, the mammalian cell micronucleus assay, and the neutral red uptake cytotoxicity assay. The authors concluded that '*within the sensitivity and specificity of these bioassays, the specific activity of the cigarette smoke particulate matter was not changed by the addition of ingredients to the cigarette'.* [94]

In 2002, Rodgman, a senior scientist with RJ Reynolds (RJR) Tobacco Company, examined the data on the effects of tobacco ingredients on smoke chemistry and various bioassays, in particular previously unpublished information from the RJ Reynolds Tobacco Company conducted between the 1950s and 1970s. [95 100] Rodgman concluded that '*this data indicates that none of the materials used as flavorants ("top dressing") on smoking tobacco products, particularly cigarettes marketed by a US manufacturer, imparts any significant adverse chemical or biological properties to the mainstream smoke (MSS) from flavorant-treated tobacco.*' [95]

In his related study on casings and humectants, Rodgman concluded that the materials used as casing materials (sugars, liquorice, cocoa) and humectants (glycerol, propylene glycol, other glycols) on smoking tobacco products, particularly cigarettes, *'do not impart any significant adverse chemical or biological properties to the mainstream smoke (MSS)'.* [95]

In 2002, Philip Morris scientists published a series of four papers that described a study on 333 ingredients used in cigarettes, known within Philip Morris as Project MIX [96 97 98 99] This four-part study examined the effects of ingredients added to a cigarette on the chemical and biological properties of MSS, and included studies on smoke chemistry, in vitro genotoxicity and cytotoxicity, and animal sub-chronic inhalation toxicity.

These studies reported on the potential effects of 333 ingredients added to typical commercial blended test cigarettes. Three pairs of test cigarettes were produced, each containing one of three different groups of ingredients. In each pair, one of the cigarettes contained the normal approximate use level of the ingredients (low level) and the other a 1.5-3 multiple of the normal use level (high level). [96] Carmines et al. reported that the addition of the ingredients at high levels did not significantly alter the burning characteristics of the test cigarettes. [96]

'*The results of the smoke chemistry studies indicated a reduction in the majority of the smoke constituents and a few isolated instances of increases when compared to the control cigarettes. These smoke chemistry changes, while statistically significant, were not supported by any significant alteration in the biological effects of cigarette smoke normally seen with the bacterial mutagenicity assay, cytotoxicity assay or subchronic inhalation study*.' [96]

The authors concluded that based on the results of these studies, it can be concluded that these ingredients added to tobacco do not add significantly to the overall toxicity of cigarettes. [96]

In the second study of the Project MIX series, Rustemeier et al. examined the impact of the ingredients on the chemical composition of mainstream smoke, by examining 51 smoke constituents. [97] There was an increase in the yield of total particulate matter (TPM) in the range of 13 to 28 per cent relative to the control cigarette without ingredients for all test cigarettes. The authors suggest that this was presumably caused by the higher transfer rates of the added ingredients to the smoke compared to the transfer from the tobacco part of the filler. [97]

The results showed that when the yields of individual constituents were normalised to the TPM yields, there was a reduction in the majority of the constituents compared to the control. The authors noted that these results are consistent with the lack of any increased activity in the in vitro and in vivo assays in this same series of studies, and concluded that '*an overall assessment of our data suggests that these ingredients, when added to the tobacco, do not add to the toxicity of smoke, even at the elevated levels tested in this series of studies.*' [97]

In the third study by Roemer et al., [98] mainstream smoke from blended cigarettes with and without the addition of ingredients was assayed for its cytotoxicity and genotoxicity. The mutagenicity of the particulate phase of the resulting cigarette smoke was assayed in the Salmonella plate incorporation (Ames) assay. The cytotoxicity of the gas/vapour phase and the particulate phase was determined in the neutral red uptake assay. The authors concluded *that 'within the sensitivity and specificity of the test systems, the in vitro mutagenicity and cytotoxicity of the cigarette smoke were not increased by the addition of the ingredients'.* [98]

In the fourth study by Vanscheeuwijck et al., [99] mainstream smoke was assayed for inhalation toxicity. Male and female Sprague-Dawley rats were exposed nose-only either to fresh air (sham) or diluted mainstream smoke from the test, the control or the reference cigarette at a concentration of 150 mcg total particulate matter/l for 90 days, six hours per day, seven days a week. The study found there were no remarkable differences in in-life observations or gross pathology between test and control groups. The authors concluded that the addition of these 333 commonly used ingredients, added to cigarettes in three groups, did not increase the inhalation toxicity of the smoke, even at the exaggerated levels used.

6.2 Analysis and Review of these Studies

The research studies examined as part of this literature review on additives published by scientists employed by the tobacco industry reached the same conclusion; namely, that ingredients in cigarettes do not impart any significant

adverse chemical or biological properties to the mainstream smoke.[95] [100] For example:

' … ingredients have no effect on the levels of most smoke constituents that may be relevant to smoking-related diseases.' [94]

'*The statistically significant changes detected in some of the parameters measured in these studies were considered incidental, without influence on the overall biological effects normally seen with cigarette smoke exposure. There was no indication of any new effects that could be attributable to ingredients.*' [95]

Tobacco companies have used these published studies to assert the safety of individual additives. [101] However, a recent study published in 2011 by Wertz et al.[101] raises several concerns about the analysis and conclusions reached by the Project MIX studies and that of Baker.

In 2011, Wertz et al. examined tobacco company documents to investigate the origin and design of Project MIX and conducted additional analysis of the results. This assessment challenges the Philip Morris assertions made in these papers and raises concerns about the independence of the review and publication process. [101]

Wertz et al. concluded that while the procedures to collect the data themselves appear sound, the way that the data were analysed and interpreted is not . [101] The key concerns identified by Wertz related to:

- Philip Morris's decision to normalise the data by TPM rather than by cigarette weight;
- the selection of the 51 mainstream smoke constituents to be analysed;
- the omission of the ammonia results in the published reports;
- the low power of the in vivo toxicology studies;
- the use of the Ames test, which is not capable of detecting a dose response relationship. [101]

Given the similarity of the research design and the conclusions reached, many of Wertz's concerns described above may also apply to the study published by the British American Tobacco scientist Richard Baker in the *Journal of Food and Chemical Toxicology* in 2004. [101]

6.2.1 Presentation of Results: Normalising by Total Particulate Matter

Wertz et al. argue that the conclusion reached by the authors that the additives did not increase the yield of toxins in the smoke is a reflection of the way the data were

normalised by TPM. The cigarettes containing the additives produced 15–28 per cent more total particulate matter (TPM) or tar than the control tobacco-only cigarettes. [101]

As Wertz states, the fact that the additives lead to more TPM is, itself, an important indicator of increased toxicity because the TPM in cigarette smoke leads to substantial increases in risk of cardiovascular disease and disrupts physiological angiogenesis and contributes to ectopic pregnancy, spontaneous abortion, preterm delivery, sudden infant death syndrome and slower wound healing.[101] In a letter to the editor of *Food and Chemical Toxicology*, Vleeming et al.[102] also commented on the fact that normalising toxin production in smoke gave a misleading picture of the effects of the additives on smoke toxicity, and suggested that toxin levels should be normalised by the amount of tobacco in each cigarette.

If Philip Morris had presented the results normalised by tobacco weight rather than TPM, it appears that a much greater increase in the estimated effects of the toxins would have been reported. [101] In a letter to the editor of the *Journal of Food and Chemical Toxicology*, Philip Morris researchers justified their use of TPM normalisation on the grounds that 'We chose TPM as our basis of comparison to be consistent with the animal and in vitro studies presented in this series of publications', and 'Since consumers choose to smoke cigarettes according to the tar delivery and taste, we chose to normalise the data to the TPM yield to reveal the effect of ingredients which contribute to the taste'.[103]

However, Wertz et al. suggest that reporting and analysing the results normalised by TPM was not originally intended as part of the project and was only introduced after Philip Morris received results showing that the additives led to higher levels of TPM (even though there was correspondingly less tobacco in the cigarettes). [101]

Despite Philip Morris scientists arguing that smokers smoke according to tar delivery and taste, it is well established that smokers smoke to control the delivery of nicotine rather than tar. [13] If Philip Morris had normalised toxin deliveries by nicotine delivery yields, the study would have reported higher toxicity estimates. [101]

6.2.2 Selection of the Mainstream Constituents for Analysis

Project MIX reports on the analysis of 51 mainstream smoke constituents. According to Rustemeier et al., [97] this list was based on those analytes suggested for analysis in a US Consumer Product Safety Commission proposal for low-ignition cigarettes and cigarette smoke constituents identified by the International Agency for Research on Cancer as worthy of concern and characterised as carcinogens. [97]

However, combining these lists provides a total of 118 compounds rather than 51. The list of 72 constituents not measured includes 11 polycyclic aromatic hydrocarbons (PAHs). PAHs are of particular concern because they cause carcinogenic and non-carcinogenic disease in animals and in humans. [101] Project MIX also included eight chemicals that did not appear on these lists and it is not clear how these were selected.

6.2.3 Omission of Ammonia Results

There is evidence from internal tobacco company documents that Project MIX assessed ammonia levels in the smoke of the test cigarettes, yet the results were not included in the published report. [101]

Ammonia levels were significantly elevated in the smoke from ingredient group 1 (high level) and ingredient group 2 (low and high levels), and significantly decreased in ingredient group 3 (low and high levels), containing menthol, compared to control cigarette smoke. [101]

As previously reported, there is evidence that ammonia increases the pH of tobacco smoke, making it less acidic and therefore easier to smoke while increasing the bioavailability of the nicotine present in the smoke.[104] [105]

Wertz also re-analysed Rustemeier's published results to prepare a corresponding set of radar plots that present the levels of toxins per cigarette (as a fraction of control). The ratio of the levels of toxin per unit nicotine for the cigarettes containing additives compared to the control cigarettes provides a different picture to that in the published study. [101]

On a per cigarette basis, 31 of 51 chemicals increased in at least one of the three ingredient groups over control (with 17 decreased), and 37 increased (and nine decreased) on a per unit nicotine basis. Fifteen chemicals increased by 20 per cent or more above the levels observed in the control cigarettes. These chemicals include a number of human and animal carcinogens (arsenic, cadmium, 1,3-butadiene, lead, formaldehyde and PAHs), respiratory irritants (for example, acrolein) and cellular toxicants (hydrogen cyanide, carbon monoxide). [101]

6.2.4 The In Vivo Toxicology Study Design

Wertz et al highlighted several study design issues in the in vivo toxicology study by Vanscheeuwijck et al [99] that may also have influenced the results. These included:

- The studies were conducted at matched levels of TPM for the smoke from all cigarettes (to hold TPM constant); therefore, the rats breathing the smoke from the cigarettes with the additives were exposed to lower levels of toxins in

the smoke than if the exposures had been matched on another smoke variable, such as nicotine delivery.

- The studies exposed the animals to fixed levels of TPM, while the ratio of TPM to gas phase toxins changes with the different ingredient groups.
- The way the animal toxicology studies were designed with the relatively short (90 day) exposure period and follow-up after the end of the exposure (42 day) also raises concerns.

Wertz et al.'s results suggest that an adequately powered design would have revealed a large number of toxic effects on the rats. [101]

6.2.5 The Use of the Ames Test

Roemer's study on the vitro genotoxicity and cytotoxicity of ingredients added to cigarettes reported on the results of the Ames test.

The study found that all of the cigarettes, whether or not they included additives, were genotoxic and mutagenic, and concluded that 'within the sensitivity and specificity of the test systems, the in vitro mutagenicity and cytotoxicity of the cigarette smoke were not increased by the addition of the ingredients'. [98]

However, as Wertz et al. point out, these tests are screening tests and do not provide sensitive measures of dose-response. Therefore, they are not appropriate for quantifying changes in toxicity associated with the additives. Unless the additives could eliminate tobacco smoke's existing genotoxicity and mutagenicity, the failure to find increased toxicity associated with the additives does not support the conclusion reported in the study. [101]

6.2.6 Independence of the Peer Review and Publication Process

Wertz et al. also raised concerns about the independence of the review process prior to publication of these documents. [101]

The articles published by tobacco company scientists summarised in this review report were published in one of two journals – the tobacco industry journal *Beiträge zur Tabakforschung International/Contributions to Tobacco Research* or the *Journal of Food and Chemical Toxicology*. Wertz et al. argues that tobacco company documents reveal that the process of accepting some of these studies for publication may have been compromised. [101]

In a response to an email regarding the comments received by the company from peer reviewers, Edward Carmines, a Philip Morris scientist, leader of Project Mix and author of the papers, replied:

'It was an inside job. We went to a journal whose editor knew us. The comments were technical trivia. One reviewer rejected one of the papers because he felt it was unrealistic to test cigarettes the way we did. He thought we should be testing marketed brands.'[106]

As Wertz and her colleagues' detail, there were also close links between the editor and the members of the international editorial board and the tobacco industry. The then editor of the *Journal of Food and Chemical Toxicology*, Joseph Borzelleca, was a member of the US tobacco industry's Council for Tobacco Research Scientific Advisory Board and PM Scientific Advisory Board, and had a long history of doing contract research and consulting for Philip Morris. There are thousands of documents mentioning Borzelleca in the Legacy Tobacco Documents Library. [101]

The associate editor, PJ van Bladeren, was co-author of a paper at the 1991 meeting sponsored by Indoor Air International, a group managed by tobacco industry lawyers. The International Conference: Priorities for Indoor Air Research and Action served as the launch for a nominally peer-reviewed journal that could be used to publish research supporting the tobacco industry's position on second-hand smoke.[101]

Susan Barlow, one of two review editors, co-authored a Philip Morris–funded review paper that, after incorporating comments from Philip Morris, questioned the evidence linking second-hand smoke and sudden infant death syndrome. Eleven of the journal's international editorial board members had ties to the tobacco industry: three were employees; two held positions on the Scientific Advisory Board of Philip Morris; and six others had tobacco industry funding or other connections. [101]

Studies published by tobacco company scientists including Baker, Carmines, Rustemeier, Roemer, Vanscheeuwijck and Rodgman have been promoted by tobacco companies as providing 'scientific evidence' that the use of cigarette additives in modern cigarettes does not increase the toxicity of cigarettes.

However, the study published by Wertz et al. suggests that there were significant problems associated with the analysis, design and reporting of some of these studies. [101]

Wertz et al. argue that in contrast to the results of the published Philip Morris studies on project MIX, many of the toxins in cigarette smoke do increase substantially when additives are included in cigarettes, including the level of total particulate matter (TPM), and may have adverse biological consequences. [101]

Wertz et al. conclude that the failure of the Philip Morris studies to reach statistical significance was the result of underpowered studies rather than the lack of an effect. They argue that better powered studies would probably have detected a much broader range of adverse biological effects associated with the additives than those identified in the Philip Morris published papers, suggesting that the published papers

substantially underestimate the toxic potential combination of cigarette smoke and additives. [101] [107]

Wertz et al. argue that:

'this manipulation of the presentation of scientific results demonstrated by the publication of the Project MIX results is nothing new for the tobacco industry; industry researchers have a long history of doing so around a variety of issues related to secondhand smoke.' [101]

Wertz et al. caution the scientific community and regulatory authorities against taking the conclusions in tobacco industry (or industry-funded) research or research published in industry-dominated journals such as *Food and Chemical Toxicology* at face value. [101]

6.3 Research on Sugar

In 2012, Roemer et al.[108] published a review of the scientific assessment of the use of sugars as cigarette tobacco ingredients. They noted that sugars, such as sucrose or invert sugar, have been used as tobacco ingredients in American blend cigarettes to replenish the sugars lost during curing of the burley component of the blended tobacco in order to maintain a balanced flavour.

Roemer stated that chemical-analytical studies of the mainstream smoke of research cigarettes with various sugar application levels revealed that most of the smoke constituents determined did not show any sugar-related changes in yields (per mg nicotine). [108]

However, 10 constituents were found to either increase (formaldehyde, acrolein, 2-butanone, isoprene, benzene, toluene, benzo[*k*]fluoranthene) or decrease (4-aminobiphenyl, N-nitrosodimethylamine, N-nitrosonornicotine) in a statistically significant manner with increasing sugar application levels. [108]

The US FDA has developed an *Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke,* [109] which states that:

- formaldehyde is a carcinogen and a respiratory toxicant;
- acrolein is a respiratory toxicant and a cardiovascular toxicant;
- isoprene is a carcinogen;
- benzene is a carcinogen, cardiovascular toxicant and a reproductive/developmental toxicant;
- toluene is a respiratory toxicant and a respiratory/developmental toxicant.

Among the products that decreased, 4-aminobiphenyl and N-nitrosodimethylamine are listed as carcinogens.

Formaldehyde, acrolein and benzene are among the smoke constituents identified by the WHO Study Group on Tobacco Regulation as priorities for regulation, and the setting of upper limits on nine specific smoke constituents was recommended.[85]

Roemer et al. also assessed the potential impact of using sugars as tobacco ingredients by comparing published data from markets with predominantly American blend or Virginia type (no added sugars) cigarettes. They report that *no relevant difference* was found between these markets for smoking prevalence, intensity, some markers of dependence, nicotine uptake or mortality from smoking-related lung cancer and chronic obstructive pulmonary disease. [108]

Roemer et al. concluded that the data available suggests that the use of sugars as ingredients in cigarette tobacco does not increase the inherent risk and harm of cigarette smoking. [108]

Stavanja et al.[110] conducted a series of studies with cigarettes containing 3 per cent high fructose corn syrup (HFCS) as an alternate tobacco casing material to corn syrup/invert sugar. The authors concluded that the addition of up to 5 per cent HFCS to cigarettes does not alter the mainstream smoke chemistry or biological activity of mainstream smoke or mainstream smoke condensate as compared to cigarettes with 3 per cent corn syrup/invert sugar.

Once again, the focus of this research by tobacco company scientists is to explore whether the addition of sugars or other sweeteners increases the individual toxicity of the product. They do not consider the influence of sugars and sweeteners on the palatability of cigarettes. The addition of sugars sweetens the taste of tobacco, making it easier to experiment with smoking and keep on smoking.

While it is true that Virginia-style cigarettes contain more natural sugar than burley tobacco, and therefore contain less added sugar, Australian ingredient returns confirm that sugar is added in significant quantities to Australian cigarettes.

6.4 Other Recent Research

A number of recent studies have been published by tobacco company scientists focusing on the impact of various ingredients or additives on the toxicity of cigarettes.

Gaworski et al.[111] examined the impact and variability of ingredients, environmental and agricultural factors and manufacturing process on the toxicity of cigarette smoke. They concluded that the ingredients studied demonstrated little relevant influence on mainstream cigarette smoke toxicity endpoints measured compared to natural agricultural change and manufacturing control.

Baker[112] examined the generation of formaldehyde in cigarettes. He stated that studies have indicated that commonly used tobacco ingredients do not change the toxicity of smoke as measured in specified assays, and that the ingredients have

little effect on the levels of most smoke constituents that may be relevant to smoking-related diseases. One exception to this generalisation is formaldehyde, which is generated from saccharides used as tobacco ingredients.

In Baker's study, several individual saccharides commonly used as tobacco ingredients were added to cigarettes; the cigarettes were machine-smoked and the yields of formaldehyde in the resultant smoke compared to those from a control (no ingredient) cigarette. Baker reported that the results indicated that all tested sugars added to tobacco increase the yield of formaldehyde in mainstream cigarette smoke under ISO standard smoking-machine conditions. Increases up to 60 per cent were observed at maximum sugar levels used on cigarettes. [112]

Different sugars increase mainstream formaldehyde to different extents, which may be due at least partially to the presence of varying amounts of amino compounds in some of the sugars, such as honey and maple syrup. In general, the first puff of the cigarette generates abnormally high yields of formaldehyde, and this effect has been shown to persist in the presence of added sugars. In sidestream smoke, the levels of formaldehyde are not affected by the presence of sugars. [112]

Gaworski et al.[113] examined propylene glycol (PG), a humectant commonly used in cigarettes. In his study, toxicological comparisons were made of experimental cigarettes containing no added PG against otherwise similar cigarettes with three different amounts of PG added to the tobacco. The main toxicological comparison was a sub-chronic inhalation study with mainstream smoke in Sprague-Dawley rats (exposures of 150 mg/m(3) of total particulate matter, six-hour exposure per day, for 90 consecutive days). Additional studies were bacterial mutagenicity, cytotoxicity and analytical chemistry studies.

The authors concluded that the results showed that the graded inclusion of PG into experimental cigarettes resulted in increases in the smoke concentrations of propylene oxide, at very low concentrations. The authors state that the addition of PG to experimental cigarettes reduced concentrations of some smoke components (for example, nicotine), but had minimal effects on the biological responses. [113] The US FDA has identified propylene oxide as a carcinogen and respiratory toxicant. [109]

Purkis et al.[114] conducted a series of experiments on volatile and non-volatile ingredients either during cigarette smoking or under pyrolysis conditions that try to simulate cigarette smoking. In particular, the fate of a series of deuterium- and 13C-labelled volatiles was studied. Purkis et al. found that, in a similar way to unlabelled volatiles, a large proportion of each was transferred intact into mainstream smoke. The unaccounted material, which was not transferred intact, in the studies of both volatile and non-volatile ingredients was primarily transformed into products of complete combustion such as carbon monoxide or carbon dioxide, with only very minor amounts transformed into products of incomplete combustion. They concluded that the utility of pyrolysis studies lies mainly in distinguishing between those

compounds that transfer intact into mainstream smoke from those that might be liable to degrade. Pyrolysis does not provide a robust prediction of the compounds that are formed from ingredients during cigarette smoking studies.

Renne et al.[115] examined the effects of flavouring and casing ingredients on the toxicity of mainstream cigarette smoke in rats. Study 1 utilised as a reference control cigarette a typical commercial tobacco blend without flavouring ingredients, and a test cigarette containing a mixture of 165 low-use flavouring ingredients. Study 2 utilised the same reference control cigarette and a test cigarette containing eight high-use ingredients. The authors concluded that the results did not indicate any consistent differences in toxicologic effects between smoke from cigarettes containing the flavouring or casing ingredients and reference cigarettes.

Gaworski also conducted a study of the toxicity of 95 ingredients added individually to experimental cigarettes.[116] A total of 95 ingredients were tested individually through addition at different concentrations to the tobacco of experimental cigarettes. Mainstream cigarette smoke chemistry analysis, bacterial mutagenicity testing and cytotoxicity testing were conducted. Additionally, 31 of the ingredients were tested in 90-day nose-only rat inhalation studies using mainstream cigarette smoke.

Gaworski et al. reported that high levels of some ingredients can change the quantity of some smoke constituents, altering the smoke chemistry profile; however, they argued that added ingredients produced minimal changes in the overall toxicity profile of mainstream cigarette smoke. In some cases, the addition of high levels of an ingredient caused a small reduction in toxicity findings, probably due to displacement of burning tobacco. [116]

These studies conclude that various additives or ingredients do not increase the toxicity of cigarettes. The industry argues that cigarettes with or without additives are harmful. However, this argument fails to take account of the overwhelming evidence identified in this review that the tobacco companies have systematically researched and developed a range of additives to influence the flavour, taste and aroma of cigarettes to alter their sensory qualities in order to create a smoother and milder smoking experience. [4 10 11 12 38]

Additives have a significant influence on the palatability of cigarettes. By creating a smoother milder cigarette that is easier to smoke, the use of additives causes a substantial health detriment at a population level. There are strong public health reasons for limiting activities that unnecessarily encourage tobacco use.

Section 7 The Impact of Additives on Smoking Behaviour

7.1 Impact on Attractiveness and Smokers' Perceptions of Cigarettes

As stated in a report prepared for Health Canada on Cigarette Attractiveness by Wayne and Henningfield,[117] the tobacco industry has been extraordinarily effective in its employment of product designs and marketing strategies to make tobacco products attractive, despite the fact that these products often produce noxious effects upon initial use, and despite the general knowledge that they are harmful.

The criterion for attractiveness is the stimulation to use the product. Attractiveness of additives refers to factors such as taste, smell and other sensory attributes. In addition, a number of external factors (for example, ease of use, marketing and promotion, flexibility of the dosing system, cost) contribute to the attractiveness of the product. [21]

The attractiveness of tobacco products may be increased by a number of additives that create a specific taste/flavour in order to attract certain target groups. An attractive effect may be obtained by changing the appearance of the product and the smoke, decreasing the harshness of the smoke, and inducing a pleasant experience of smoking. In order to make smoking more acceptable to other people nearby, some additives reduce lingering odour or sidestream smoke visibility. [21]

A significant amount of the effort to make tobacco products attractive is targeted at young people, but designs and marketing have also been targeted at adults and specific adult populations (for example, women and ethnic minorities), with characteristics intended to appeal to these populations. These efforts contribute to the initiation of use and, along with addiction, play a role in persistence of use as well as relapse following quitting. [117]

Carpenter et al.[118] reported on evidence that the tobacco industry conducted extensive research on female smoking patterns, needs and product preferences, and has intentionally modified product design for promotion of cigarette smoking among women. Cigarette manufacturers responded to changing female trends by focusing on social and health concerns as well as promoting dual-sex brands that also featured traditional female style characteristics.

Carpenter et al (2005) [118] reports on a range of tobacco industry documents that showed that females preferred longer, milder and menthol styles more than their male counterparts, were more responsive to cigarette taste, and desired a cigarette with "*ease of draw, smoothness and mildness*." A Brown and Williamson market research report [119] reveals that taste (i.e. flavour and mildness) and 'real smoking enjoyment' remained the most important product attributes among women.

Carpenter et al also reports that cigarette features such as after taste, odour and reduced side stream smoke were aimed specifically at female smokers. Tobacco companies used various flavours including menthol, spearmint, peppermint, chocolate, apricot, coconut and marshmallow to influence the aftertaste and aroma of cigarettes for female smokers. RJR experimented with a 'Colgate-type' (toothpaste) flavoured pellet inserted into the filter to provide a fresh/pleasant aftertaste to target women. Consumer testing by RJR showed that female smokers found spearmint and ethyl vanillin glucoside prototypes to be "*very pleasant and refreshing*".[1188]

As Carpenter et al note,

"Internal product development efforts have identified a variety of cigarette features aimed at meeting the needs and wants of female smokers. The resulting products exploit mistaken health notions about the relative safety of light cigarettes; create false perceptions of social and health effects through reduced sidestream smoke and improved aroma and aftertaste; match female taste preferences through flavored, smooth and mild-tasting cigarettes; and target physiological and inhalation differences with greater ease of draw, increased sensory pleasure and altered tar and nicotine levels."[118]

While delivery of a dose of nicotine in a rewarding form is the fundamental requirement of a satisfying cigarette, a range of other factors contribute to a cigarette that is "palatable," including pleasant flavour and aroma and the relative absence of unpleasant sensations in the form of harshness, irritation and stale aftertaste.[10 12 13 14 15 25 39 47]

There is evidence that the addictiveness of cigarettes is also influenced by a variety of sensory factors. Menthol is contained in the vast majority of cigarettes and provides an unmistakable sensory experience – the minty taste, cooling sensation and throat irritation or impact. [11]

As Gray and Borland argue, addiction is more than just chemistry. The addictiveness of a product is affected by the context of use, the experiences associated with use, and the effects of the product on the brain. [19]

Additives influence the aroma and taste of cigarettes. When taste and odour are pleasurable for smokers, they may reinforce smoking behaviour. Animal studies have shown that taste and/or smell can enhance self-administration of drugs, even when those drugs are at concentrations so low that pharmacologically reinforcing effects are not necessarily produced. [11]

Sensory factors can also contribute to smoking behaviour because they mask the undesirable properties of the cigarette. [11] Sensory experiences can also contribute to conditioned aspects of smoking behaviour. Once smoking has been established,

taste and other sensory factors can function as stimuli that can substantially enhance the strength and persistence of smoking behaviour. [11]

As the TPSAC states, taste is a complex perception, since it is the product of both flavour and other sensory attributes. Consumers are often unclear as to what they mean by taste. Smokers may be influenced by tobacco marketing or labelling, and may link it to a range of other product attributes. [11]

'… there is evidence that consumers use elements of taste to infer the healthiness and other attributes of products. This is likely a natural human tendency, with evolutionary advantages. For example, a key element of unpleasant taste is the perception of bitterness, thought likely to have evolved in animals to help them avoid eating plants and other foods containing toxins and other harmful chemicals.' US FDA TPSAC [11]

Carpenter et al (2007)[120] noted that sensory research is a priority for the tobacco industry:

"*Sensory factors contribute to smoker satisfaction and product acceptance, and play an important role in controlling puffing behavior. Cigarette manufacturers have capitalized on distinct sensory preferences across gender, age and ethnic groups by tailoring products for specific populations.*"[120]

Carpenter et al (2007) reports that the relative importance of sensory research to the tobacco industry is clearly illustrated by the significant investment in research and related product development made by the industry over many decades. [120]

A BAT document reveals the importance of initial sensory perceptions

"Any consumer is going to make judgments about a new product, probably within the first few puffs on the first cigarette . . . This judgment will reflect quality and strength of taste, as well as impact and irritation. First impressions are therefore very important. Further judgement may be made at the end of the pack, which could relate to how long the .pack lasted, and whether there is any residual taste, irritation or lack of satisfaction. The first few puffs need special attention."[121]

The tobacco industry also recognized that sensory properties were linked with smoking behaviour and puffing parameters produced by the smoker.[120120]

Industry research on gender-specific sensory preferences led to changes in targeted product development. As research identified distinct sensory preferences across gender, age and ethnic groups tobacco companies developed new products or changed existing products to appeal to these specific populations "in an effort to maximize pleasurable and minimize negative sensory stimulation." [120]

According to Carpenter et al (2007)

"*cigarette smoking combines input from multiple sensory cues including tactile product feel, visual appearance, as well as smoke aroma, taste and inhalation sensations...Internal industry findings support published studies showing that these combined sensory effects result in an overall sensory experience that significantly impacts smoker satisfaction beyond nicotine delivery and may ultimately contribute to or enhance tobacco dependence."*[120]

According to Proctor, [13] tobacco company documents highlight the importance of flavour and aroma to the smoker; for example, the importance of the 'pleasant' and familiar aroma when opening a pack of cigarettes.

There is evidence that WD & HO Wills convened a twice-weekly Taste and Flavour Panel to examine and report on their products and test products. A BATA document[122] describes some of the sensory experiences associated with smoking that were investigated and documented by the panel:

'There are many sensations involved in the total appreciation of smoking. The skin of the hands and face "feel" smoke. The eyes might water or smart. The appearance of the cigarette itself is important. The colour and visual texture of smoke can be pleasing to the smoker. The aroma of the packet or the unlit cigarette, the sidestream aroma of the smoke are all important …

'Many smokers, plain smokers particularly, draw on the cigarette before lighting it. The first sensations of active smoking are on the lips, tongue, cheeks and soft palate. Here we might experience biting, burning, cooling, tingling, astringency or the primary tastes of salt, sour, sweet, bitter or metallic.' [122]

Some factors affecting attractiveness, such as fruit- and confectionery-flavoured cigarettes, may seem obvious. [117] Other factors are more subtle, such as the use of additives to mask throat irritation, smooth the smoke, and influence the flavour and taste of cigarettes [4 10 13 117] Engineering features such as filter ventilation can make cigarettes more attractive by making the smoke taste milder and easier to inhale, and by reinforcing the deception that such cigarettes are less harmful. [16 76]

Together, these factors contribute to the attractiveness or appeal of cigarettes, and can therefore promote the initiation of use and development of addiction or dependence and associated tobacco-related disease.

There is a lack of public health research specifically exploring the impact of additives on smoking behaviour. However there is significant evidence from tobacco company research of the impact of additives on sensory perceptions of smokers and their influence on consumer preferences.

Tobacco companies extensively researched smoker's perceptions of their products. Much of this research focused on the use of additives to create milder and sweeter

smoke while reducing sensory irritation in order to mask the unfavourable harsh characteristics of cigarettes. [10 37]

One 1994 BAT document reported on the "*Reduction of Tobacco Smoke Irritation by use of Potential Ameliorants*".[123] According to this report, the least desirable sensation associated with tobacco smoke for the smoker is that of irritation.

"Excessive irritation will be perceived by the smoker as "harshness", a property generally associated with a low quality product. At the other end of the spectrum, the term "smoothness", when applied to tobacco smoke, implies low levels of spiky, lingering irritation, and such a product may be considered by the smoker to be of a higher quality than its irritating and harsh competitor." BAT 1994[123]

This document notes that a number of tastes and sensations are important when smokers are judging the strength of a product. The major sensory cue for the smoker is nicotine impact - although irritation is also an aspect of the overall perception of "inhalation strength". The maintenance of impact, while reducing irritation is therefore desirable particularly for those smokers seeking a smoother and full strength product. [123]

BAT research showed that propylene glycol was successful in reducing irritation however there was a corresponding decrease in impact sensation. The BAT report notes that the small losses of impact combined with some reduction in irritation may prove acceptable and even preferable to the consumer. The report recommended further consumer testing. [123]

A 1987 Brown and Williamson document[124] reported that the volatile aldehyde compounds such as formaldehyde, acetaldehyde, and acrolein are contributors to cigarette smoke sensory irritation. This document reported the results of research on strategies to reduce smoke irritation, including the application of citric acid.

There is also evidence that other additives such as menthol can reduce irritation[11] and that additives such as propylene glycol are used to decrease the harshness of the smoke and increase the smoothness or mildness of the smoke. [21]

Various sugars constitute a large proportion of additives in cigarettes. The sweetness of the product is an important characteristic that increases the attractiveness of cigarettes, particularly to children and young people. [8 13] High sugar content improves the palatability of tobacco products to tobacco users. These are particularly important for burley tobacco, and play a lesser role in the Virginia, flue-cured cigarettes that dominate the Australian market. [21]

Flavourings such as vanillin and ethyl vanillin are added in substantial quantities to tobacco to impart a vanilla flavour to the smoke. Vanilla may also effectively sweeten tobacco smoke. [8 10 13]

Tobacco industry documents confirm the importance of additives such as sugar and liquorice in influencing the sensory perceptions of smokers:

'Just as sugar is used in "casing" the tobacco to mellow and smooth the smoke, liquorice is used as an adjunct to boost the sweetness of tobacco products. The taste of liquorice to the smoker is that of a mellow sweet woody note which, at proper use levels, greatly enhances the quality of the final product.' BATA[125]

Liquorice has a long history of use in both the food and tobacco industries as a sweetening enhancer. [4 8 13 21] It is estimated that the constituent of liquorice, glycyrrhizin, is around 50 times sweeter than sugar.[8] Tobacco company documents[126] confirm that liquorice is used in cigarettes both as a flavour and as a casing material to decrease harshness and create a milder, sweeter smoke.

Cigarette smoke irritates the mucous membranes of the nasal and airway passages, as well as to the eyes. This irritation is a natural warning sign by the body of an ongoing harmful exposure. [8]A number of additives are also used to temporarily decrease irritation of the mucous membranes of the nose and airways, as well as the eyes. These products are used to mask the irritation caused by cigarette smoke and ultimately affect the attractiveness of cigarettes. [8 11]They include clove oil and menthol.

Eugenol, an organic compound found in clove oil, has local anaesthetic properties. [8] Menthol has a minty taste and aroma, and is added to cool the smoke or make it less harsh, which means that it makes a cigarette easier to smoke.[11 13] Menthol is an anaesthetic – it soothes or even numbs the lining of the mouth and throat, and suppresses the body's natural cough reflex. By making it easier to smoke, the addition of menthol also makes cigarettes more attractive to young or beginner smokers. [11 13]

Menthol is also added to cigarettes as a characterising flavour and for other taste reasons, including brightening the flavour of tobacco blends and/or smoothing or balancing the taste of the blend.[11] while simultaneously reducing irritation and inflammation. It has a numbing effect on sensory nerve endings in the respiratory tract, and helps to temporarily soothe sensations of discomfort in areas of inflammation and irritation. [8 52] At low concentrations, menthol has a soothing effect, but at high concentrations it has an irritating effect. [11]

As the Tobacco Products Scientific Advisory Council report on menthol states,

'The evidence is sufficient to conclude that menthol has cooling and anesthetic effects that reduce the harshness of cigarette smoke. Research indicates that menthol acts on both thermal and nociceptive receptors. This dual action results in both cooling and counter-irritant effects. Menthol desensitizes receptors by which nicotine produces irritant effects, thereby reducing the irritation from nicotine in tobacco smoke.' TPSAC on Menthol [11]

Other additives reduce the lingering odour of the smoke in order to improve the acceptability of smoking to people nearby (for example, acetylpyrazine, anethole, limonene, vanillin and benzaldehyde). [21] Industry patents describe the use of several food-derived substances for modifying sidestream odour. These included vanillin, benzaldehyde, bergamot oil, cinnamon/cinnamon extract, coffee extract and nutmeg oil as well as other additives. [57] A range of substances may also have been added to the cigarette wrapper to reduce visible sidestream smoke levels. [57]

The SCENIHR report on' *The Addictiveness and Attractiveness of Additives*' [21] concluded that the attractiveness of tobacco products may be increased by a number of additives but is also influenced by external factors such as marketing, price etc. The SCENIHR [21] also noted that factors influencing attractiveness can be broadly divided into: extrinsic factors (e.g. marketing, packaging, pricing); and intrinsic factors (e.g. taste, smell, sensory attributes, and pharmacological factors). Additives play a role mainly in the intrinsic factor category, but marketing and packaging can also reflect the presence of additives in a way to attract and maintain customers (e.g. by signalling that the tobacco product contains menthol).

Significantly, the SCENIHR [21] stated that given the subtle interactions between different factors, identifying and measuring the influence of individual additives on attractiveness of products is difficult. The SCENIHR [21] identified the important influence of tobacco marketing on the attractiveness of tobacco products, demonstrating the importance of multi faceted approaches in tobacco control targeting all factors that influence attractiveness (extrinsic and intrinsic). The evidence presented in this literature review from the published literature and from tobacco company documents confirms the significant role of additives in increasing the palatability of cigarettes.

The key findings of the SCENIHR in relation to palatability are that: [21]

- Various sugars constitute a large proportion of additives, and the sweetness of the product is an important characteristic;
- the use of fruit and candy flavoured cigarettes seems to favour smoking initiation in young people;
- menthol also attracts a number of smokers, in particular African Americans;
- Some additives decrease the harshness and increase the smoothness of the smoke;certain additives yield a full and white smoke and other additives reduce the lingering odour of the smoke in order to favour the acceptability of smoking to people nearby;
- additives considered attractive may in principle lead to brand preference or a higher consumption of tobacco products. However, it remains difficult to distinguish the direct effects of these additives from indirect effects such as the marketing towards specific groups.

It is reasonable to suppose in the context of products having different physical characteristics, including the range of additives used, that decisions to market such products to different sectors of the overall market are influenced in part by consumer responses to the sensory differences produced by the differences in the products, but it is difficult to demonstrate this without access to the actual decision-making processes and the information on user experiences available to the companies concerned.

There is evidence that additives are used extensively by tobacco companies to influence smokers' sensory perceptions and to increase the flavour and aroma of cigarettes. Additives are also used to mask the harshness of tobacco and to reduce sensory irritation. By masking the harshness associated with cigarette smoking and enhancing the flavour of cigarettes to create a smoother and milder smoking experience, cigarettes are made more palatable and attractive, particularly to young people and other novice smokers who may be deterred by the harshness and sensory irritation associated with smoking.

7.2 The Impact of Filter Ventilation on Smokers' Perceptions of Cigarettes

As detailed in Section 5 of this report, filter ventilation also has a very significant impact on a smokers' perceptions of cigarettes. Filter ventilation is present in the vast majority of Australian cigarettes and results in a 'lighter' or 'milder' taste because the perforations in the filter dilute the smoke. [16] [76]

Filter ventilation also produces less harshness (the immediate burning/scratching sensations in the mouth and throat) and irritation (the lingering tingling sensations in the throat and chest). [16]

This 'lighter' or 'milder' taste can support the smoker's perception that these cigarettes deliver less tar and nicotine, as well as diminished dangers to health. The more air added by dilution, the milder and more air-cooled the smoke. This reduces the overall perception of 'harshness' and increases the perception of mildness. [76]

These perceptions of 'lightness' and 'less irritation' can constitute compelling (but incorrect) sensory evidence that can mislead smokers and allay their concerns about the health risks of smoking. Because vented filter cigarettes feel milder, some smokers come to believe they are less toxic. [76]

From a public health perspective, the influence of filter ventilation on smokers' perceptions is a major concern. Filter ventilation is one of the most powerful means of varying the taste strength, harshness and irritation of cigarette smoke. That makes

it a powerful means for influencing the beliefs of smokers about the relative harmfulness of different brands, and also a powerful means for increasing the palatability of some brands for young people and other novice smokers or those smokers who find 'full strength' cigarettes unpleasant. [16] [76]

In 2005, following a lengthy investigation, the ACCC found that the three Australian tobacco manufacturers had represented that low yield cigarettes marketed and packaged as 'light', 'mild', 'medium', 'ultra-light', 'micro' etc had certain health benefits in comparison to those marketed as regular or higher yield cigarettes. In the ACCC's view, the claimed health benefits of low yield cigarettes compared to high yield cigarettes breached the misleading and deceptive conduct provision, and other sections, of the Trade Practices Act 1974.A court enforceable agreement between the ACCC and the tobacco manufacturers resulted in an extensive education campaign funded by the industry and removal of the misleading labels.

7.3 The Impact of Additives on Initiation and Uptake of Smoking

One of the major uses of additives is to influence the flavour and aroma of cigarettes and to mitigate the harshness of cigarette smoke, thereby making them more palatable to children and other novice smokers. [9] [10] The use of additives to reduce the irritation of the eyes, throat and lungs associated with smoking is also likely to be a significant influence in terms of minimising the negative aspects of smoking for children and other novice smokers.

Appeal to younger smokers is essential for the long-term sustainability of the tobacco industry. [35] [54] There is evidence that among high-sensation-seeking young people, the appeal of cigarette brands is enhanced through the use of flavours and associated descriptions on product packaging.[127]

Tobacco industry documents confirm the importance of smoothness, mildness and sweetness characteristics in attracting young people and novice smokers. RJ Reynolds determined that the most important physical characteristic of the 'younger adult brand' was its smoothness or mildness. [35]

As Wayne and Connolly report, a 1973 RJ Reynolds internal memo titled 'Some thoughts about a new brand of cigarettes for the youth market' identified the need to provide a cigarette 'as bland and free of obvious negatives as possible'.[35] RJ Reynolds' research of a product that would successfully appeal to the first-time smoker centred on a cigarette prototype coded XG. According to an August 1985 summary of the product development plan:

'Two key areas identified for improvement were smoothness and sweetness delivery. Smoothness is an identified opportunity area for improvement versus Marlboro, and

sweetness can impart a different delivery taste dimension which younger adult smokers may be receptive to, as evidenced by their taste wants in other product areas.' RJ Reynolds Tobacco Company [35]

The role of menthol cigarettes and 'light and mild' brands is important to consider in terms of initiation and uptake by young people.

In the United States, there has been significant debate about the role of menthol cigarettes as a 'starter cigarette' encouraging the initiation and uptake of smoking by children and teenagers. There is strong evidence for this conclusion in the US. [11] [54] A starter cigarette is generally characterised as an easier-to-smoke cigarette that attracts experimenting smokers [54]

A major selling point for menthol brands has been that they have more pleasant, 'fresher' or 'smoother' smoke than 'regular' cigarettes. The fresher/smoother smoke of menthol cigarettes is also widely believed to make them easier to smoke, and thus attractive to adolescent experimental smokers who are struggling to overcome their aversion to certain sensations of smoking, such as harshness, throat and chest irritation and stale after-taste. [54] [55] [128]

Menthol cigarettes are clearly more popular among adolescent smokers in the United States. Hersey et al. [55] found that menthol smoking was more common among both younger adolescent smokers and those who had smoked for less than a year, and concluded that they functioned as 'starter cigarettes' for teenagers. In 2006, slightly more than half (52 per cent) of middle school students and 43 per cent of high school students who smoked usually smoked menthol cigarettes. [55]

There is evidence, however, that while menthol cigarettes function as 'starter cigarettes' for a proportion of adolescents in Australia, they are no longer as widespread a 'starter product' as they appear to be in the United States. Menthol would appear to be just one of a range of methods for making cigarettes taste mild enough to appeal to novice smokers. [54]

The Australian menthol market is split between several 'stand-alone' menthol brands and menthol 'line extensions' within 'brand families' where the original or 'parent' brand is non-menthol. One 'stand-alone' menthol brand, Philip Morris' Alpine, has long been the most well recognised menthol brand. [54] It is clear that Alpine did play a role as a 'starter' cigarette in Australia but that role has decreased markedly since the 1980s. In contrast to the US data, only a small proportion of Australian adolescents smoked menthol cigarettes at any point in the past two decades. Alpine and other menthol brands are now primarily "older women's cigarettes", who are most likely a cohort who started on this brand when it was more popular. The trends in declining popularity among younger smokers suggest that targeted marketing by the tobacco industry is an important influence on the maintenance of menthol brand market share. [54]

King et al. have suggested that within the Australian context, 'light/mild' (that is, low-tar brands) may have taken over the role of 'starter cigarettes' or easier-to-smoke cigarettes for children and other novice smokers. [54]

As previously discussed in Section 4, Australian cigarettes are predominantly Virginia cigarettes, which are typically less harsh and irritating than US blended cigarettes. Also, the Australian cigarette market went further down the 'low-tar' track than any other market in the world during the period in which we found menthol smoking dramatically decreased among Australian adolescents and younger adult smokers. [16 54]

By 1994, mild and ultra-mild brands dominated the market, with more than 90 per cent market share in Australia. The mean sales-weighted tar yield of Australian brands had dropped to 6.8 mg, compared to 12.6 mg in the United States. The importance of filter ventilation and additive use in achieving low-tar cigarettes is discussed in Section 5 of this report. Filter ventilation was used extensively by tobacco manufacturers to achieve decreasing tar, nicotine and carbon monoxide yields in ISO tests while maintaining actual nicotine delivery to smokers. [16 76]

By the mid-1990s, the vast majority of Australian cigarettes were characterised by a smoother and milder flavour, and would have been less harsh and irritating than they had been in the 1980s. King et al. suggest that these products may have filled the 'demand niche previously occupied by menthol brands'. [54] In addition, as flue-cured tobacco is naturally less harsh than the American blend, use of filter venting and other strategies may be less necessary in a Virginia cigarette market.

As Wayne and Connolly identified, the tobacco industry prototypes were developed to appeal to the 'young adult smoker' by identifying product design elements that addressed the issues of smoothness, harshness and mildness while maintaining nicotine delivery. [35]

According to Wayne and Connolly, an RJ Reynolds' brainstorming session identified solvents, leaf/blends, tobacco processing and cigarette construction as key design issues, including such possible areas of investigation as perforation type and placement, cigarette paper and filter materials, and modifications of burn characteristics and blend components. [35]

Wayne and Connolly described one RJ Reynolds flavourings developed to increase smoothness perceptions: a combination top dressing consisting of chocolate, vanillin, liquorice and 'toba**c**co enhancer' flavour. A personal memo from 22 November to the developer of the flavourings notes:

'*I would like to express my sincere appreciation for the exciting flavoring work you have done on Project XG. The chocolate/vanillin/licorice/ tobacco enhancer is undoubtedly one of the most exciting and promising flavorants that has been developed during the last several years … As you know, this flavorant appears to*

have significant appeal among the 18–24-year-old smoker group and this is obviously the group that we desperately are after.'[129]

The use of additives to modify the taste and flavour of cigarettes and mask the harshness and sensory irritation associated with smoking is likely to increase the attractiveness of cigarettes to young people and other novice users. Tobacco industry documents have documented the importance of smoothness and sweetness when designing brands to appeal to young and inexperienced smokers. [35] [129]

By masking the harshness associated with tobacco use, and modifying the flavour characteristics of cigarettes, additives and filter ventilation contribute to the experimentation and uptake of tobacco use.

7.4 The Impact of Additives and Filter Ventilation on the Rate, Frequency and Intensity of Smoking

There is little published evidence on the impact of additives on the rate, frequency and intensity of smoking. However, there is strong evidence in the peer-reviewed literature regarding the significant impact of filter ventilation on the rate, frequency and intensity of smoking.

Cocoa beans are an additive to tobacco and contain theobromine, which is a bronchodilator. [8] [21]Theobromine has also been shown to act as a cough suppressant in guinea pigs and humans.[130] While some authors argue that the bronchodilating effect of theobromine may contribute to the absorption of nicotine in connection with smoking, [4] [8] others, such as the SCENIHR, [21] have concluded that the content of theobromine per cigarette will be too low to have a bronchodilating effect on the lungs and thereby increase the absorption of nicotine.

A pilot study by O'Connor et al evaluated differences in puff topography and cigarette ratings among 20 college student smokers smoking Camel Light and Camel Exotic Blend cigarettes. The study found that participants took smaller puffs on the Exotic Blend versus Camel Light but there was no reliable difference in total smoke volume or CO boost. Exotic Blend cigarettes were rated as more different from the participant's usual brand, but otherwise the taste ratings did not differ. Overall, the authors concluded that the preliminary data suggest that adding flavours to cigarettes may not significantly impact how they are smoked by current smokers.[131]

The TPSAC found there is some evidence from one large study that while daily exposure is not different, the intake of nicotine per cigarette is higher for menthol compared to non-menthol smokers. They concluded that there are insufficient data to

know if smoking menthol cigarettes is associated with greater smoke intake or exposure to higher levels of nicotine and other tobacco toxins. [11]

Filter ventilation is present in the vast majority of Australian cigarettes and results in a lighter/milder taste, as well as promoting larger puffs. With heavy ventilation, it can promote behavioural blocking of vents. [16 76] There is evidence that filter ventilation facilitates increased puff volumes by smokers, a key means of compensatory smoking. It is well established that nicotine-addicted smokers smoke lower yield cigarettes more intensively by taking more frequent or larger puffs.[16 76 91 92]

There is also evidence that low-tar cigarettes have been engineered to become more conducive to this compensatory smoking over the past three decades, with tobacco companies designing cigarettes to be more 'elastic' – yielding more smoke to human smokers than to smoking machines. [16 76]

Filter ventilation was used by tobacco manufacturers to reduce the yields of tar, nicotine and carbon monoxide measured by smoking-machine tests while enabling nicotine-addicted smokers to achieve their target doses through the processes of compensatory smoking. [16 76] The ISO test used to measure the tar, nicotine and carbon monoxide yields is seriously flawed and there is strong evidence that the yields measured by this method do not relate to the smoker's exposure to tar and nicotine. [16 76 91 92]

Smoking behaviour in humans is primarily driven by nicotine. People smoke to achieve a particular nicotine dose and will adjust their smoking behaviour to maintain this dose across products. Therefore, smokers increase the number and intensity of their puffs when switching to a brand that generates a lower nicotine emission under the ISO machine-smoking conditions. [87]

However, this process does not necessarily happen automatically. Smokers given denicotinised cigarettes will smoke in a fairly typical manner for some time. However, over time, these smokers either abandon such products, given the choice, or quit. When smoking different variants, they tend to compensate over time to preferred nicotine intakes, again probably aided by the immediate experience of the puffing, which is more a function of tar levels. Where this information does not provide a good indication of changing nicotine levels (for example, in denicotinised cigarettes), compensation tends not to occur, but over time satisfaction with the cigarettes decreases. [91]

7.6 The Impact of Additives on Cessation

There is little research published specifically on the impact of additives on cessation of tobacco use. Indeed, it would be hard to demonstrate these effects directly as there are so many other factors affecting quitting success. It would also be difficult to

isolate the effects of additives because the likely magnitude is small for most plausible additive effects. Complicating matters further is the number of additives, which are used in different amounts, making the task of identifying effects virtually impossible.

A further complication is the fact that taste preferences differ between individuals. A taste that might attract and maintain some smokers might do nothing for those who did not like that particular taste. If there is to be further research in this area, it needs to focus on the effects of additives in total, rather than on specific effects of specific additives. The exception might be such additives as menthol, which very much characterise the overall flavour of some products.

In the United States, the report of the TPSAC on menthol cigarettes and public health concluded that the evidence is sufficient to conclude that it is biologically plausible that menthol makes cigarette smoking more addictive. The evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes increases the likelihood of addiction and the degree of addiction in youth smokers. However, there is insufficient evidence to conclude that menthol cigarettes increase the likelihood of addiction and the severity of addiction in adults.[11]

The TPSAC also examined the evidence on whether smokers of menthol cigarettes are less likely to quit successfully than smokers of non-menthol cigarettes. The report concluded that although the number of studies that are considered to be of adequate quality is limited, there is sufficient evidence based on national surveys in the United States to show that the non-white smokers, particularly African American, of menthol cigarettes compared to non-menthol cigarettes experience more difficulty with cessation. The data in white populations is mixed. [11]

The report also noted that the literature suggests that menthol cigarette smoking leads to less responsiveness to medications. [11] The TPSAC report found that menthol is present in many cigarettes, not just those characterised as menthol brands. It is likely that menthol is also present in many Australian cigarettes, not just brands characterised by menthol, therefore these issues may extend beyond menthol brand cigarettes.

Additives are used to influence the sensory characteristics of cigarettes, particularly to modify their flavour, taste and aroma. Filter ventilation is used to dilute the smoke and provide a smoother and lighter taste to the smoker. There is evidence that smokers believe that because the cigarettes taste ‘lighter’ and ‘smoother’, the product is less harmful. [16] From a public health perspective, this belief is likely to influence their motivation to quit.

There is evidence that smokers use their experience of smoking to refine their judgements about product harmfulness – the less harsh and irritating the experience, the less harmful the products are perceived to be.[132]

There is evidence that some smokers have made choices to move to what they perceive as a less harmful brand rather than try to quit, but the extent of this pattern is not clear, nor the extent to which it has resulted in more smokers failing to quit.

While there is no direct evidence available in the published literature, it may be that some smokers are more influenced by the actions of additives than others. For example, additives may have less effect on quit rates among more addicted smokers (especially where those additives do not affect nicotine uptake), while those who are less addicted may be more sensitive to factors that influence the overall experience of smoking created by additives or filter venting.

Similarly, smokers who are highly motivated to quit smoking may find the withdrawal of an additive to be the 'straw that breaks the camel's back' in further reducing their enjoyment or satisfaction with smoking, enabling them to quit for good, while those less motivated may simply perceive it as a minor inconvenience.

Section 8 The Impact of Additives on Human Health

8.1 The Physiological Effects of Additives

There is considerable scientific uncertainty regarding the specific impact of additives on human health.

To date, most attention on the use of cigarette additives has focused on the toxicity of cigarette additives and whether they pose additional health risks for the smoker, thereby making smoking a more hazardous activity. [3] For example, the 1981 US Surgeon General Report, The Health Consequences of Smoking – The Changing Cigarette,[3] expressed concern about the use of cigarette additives and the potential for these additives to give rise to carcinogenic substances when burned, resulting in increased or new smoking-related disease. [3]

Tobacco company scientists have published a number of studies which are summarised in Section 6 of this review. The studies all reached the same conclusion: that cigarette additives do not increase the toxicity of smoke, and that therefore their use poses no additional risk to smokers.

Over time, the tobacco industry has changed its public stance on the harm associated with tobacco use. After many decades of denying that cigarettes were addictive and did not cause smoking-related disease, Australian tobacco companies now argue that:

'With or without ingredients, all tobacco products cause serious diseases and are addictive … The data, including our internal testing and the data in the marketplace, show that the ingredients we use do not increase the harmful effects of smoking … There is no basis to believe that cigarettes sold without ingredients are less harmful or less addictive than cigarettes sold with ingredients.' Philip Morris[133]

The British American Tobacco (Australia) website also contains a number of statements about their position in regard to cigarette additives. They argue that '*based on the currently available scientific evidence, the ingredients that its Group companies use, at the levels used, do not add to the harm of tobacco consumption, do not induce people to start smoking and do not affect people's ability to quit'.* [82]

Philip Morris argues that the prevalence of smoking, cessation rates and rates of smoking-related diseases are generally the same in countries where most consumers smoke cigarettes with flavour ingredients as in countries where most consumers smoke cigarettes without flavour ingredients.

Based on our analysis of the research to date, there are large areas of scientific uncertainty in relation to the toxicity of cigarette additives because the information available at this time is limited.

As Fowles notes, the assessment of the safety of cigarette additives using conventional toxicological methods is difficult because there is insufficient information on the combustion chemistry of the additives to evaluate their relative contribution to the various toxicants or other biologically active compounds in cigarette smoke.[6]

Research published by tobacco company scientists [93 94 95 96 97 98 99 100] detail some increases in specific toxicants but claim their research shows no overall increase in carcinogenicity. However, Wertz [101] argues that the failure of the tobacco company studies to reach statistical significance was the result of underpowered studies rather than the lack of an effect, and that better powered studies would probably have detected a much broader range of adverse biological effects associated with the additives. Wertz suggests that the tobacco company research studies substantially underestimate the toxic potential combination of cigarette smoke and additives [101 106]

The specific type and amount of additives in each brand of cigarettes, the chemical composition and physiological and pathological effects of most additives are unknown except to the tobacco industry. It is not clear whether sufficient amounts of pharmacologically active chemicals derived from these additives remain after pyrolysis; limited information is available on the effects of combustion of these compounds in cigarettes at the concentrations used. [10]

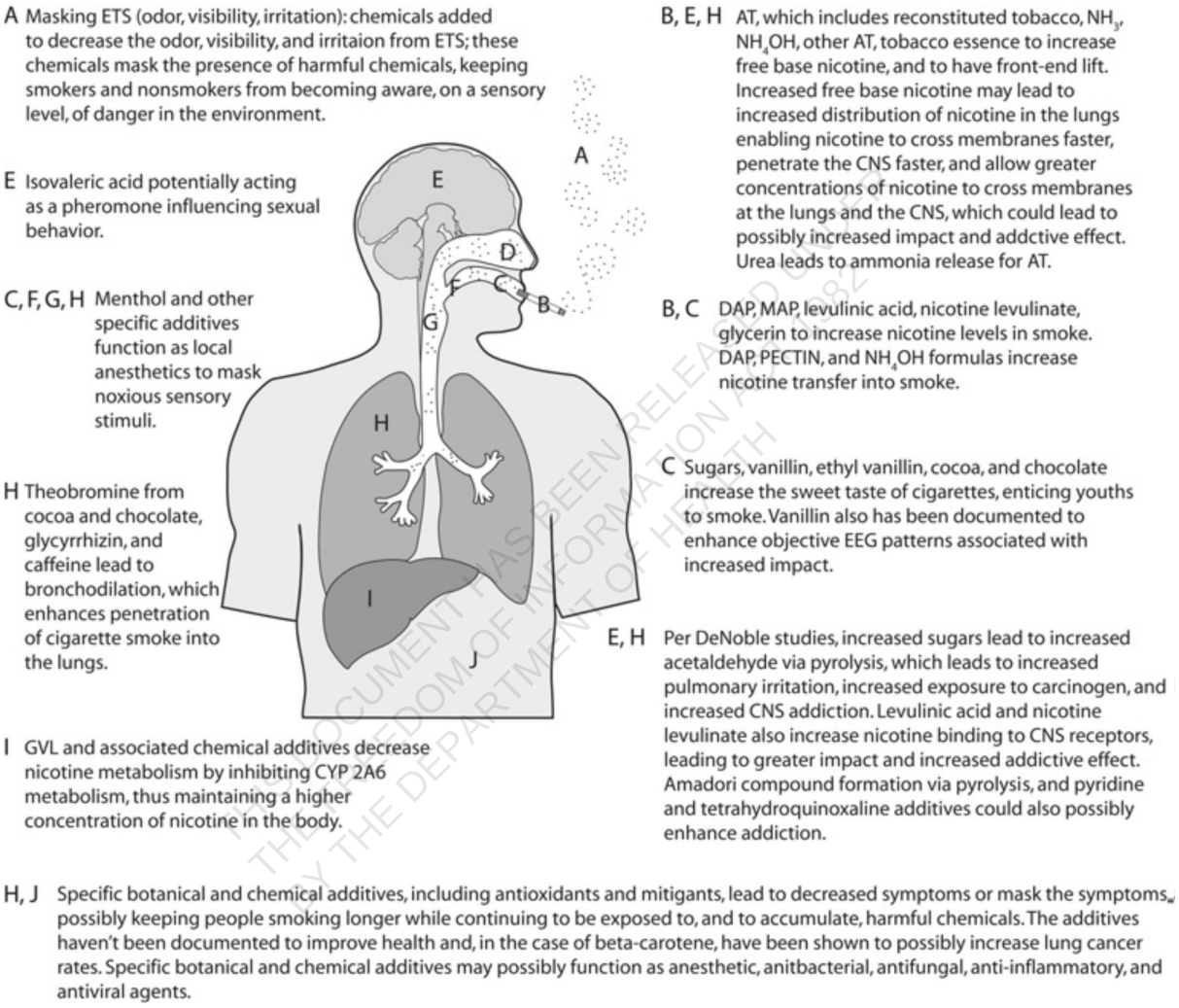
Gray and Borland argue that addictiveness is also affected by a number of substances which facilitate the effect of nicotine. [19] These include acetaldehyde, which is dependent on the amount of sugars which produce it on combustion. Other nicotine facilitators include levulinic acid, which enhances the binding of nicotine in the brain, and bronchodilators such as cocoa and liquorice, which allow deeper inhalation.[19]

However, in a product as toxic and dangerous as cigarettes, the most relevant public health issue is not the individual toxicity of each additive and whether the use of additives increases the toxicity of cigarettes. Rather, the more relevant question is: *Do these additives make cigarettes more palatable and appealing to smokers, thereby increasing initiation and maintenance of smoking behaviour?* In our view, the answer is yes.

There is evidence detailed in Section 7 and elsewhere in this report that the use of additives and cigarette engineering features such as filter ventilation make cigarettes more attractive to smokers and could increase the risk for dependence by encouraging uptake and repeated use. [85] A consequence of features modulating cigarettes' attractiveness (and frequently manipulated by the tobacco industry) have

the effect of increasing the risk and frequency of pharmacologic exposure and addictive effects of nicotine. This, then, increases the prevalence and persistence of tobacco product use, along with the prevalence of disease and premature mortality. [113]

Figure 3: Summary of pharmacological and chemical effects of cigarette additives



Note: ETS = environmental tobacco smoke; GVL = gamma-valerolactone; AT = ammonia technology; NH_3 = ammonia; NH_4OH = ammonia hydroxide; CNS = central nervous system; DAP = diammonium phosphate; MAP = monoammonium phosphate.
Source: Rabinoff et al. [10]

The tobacco industry has consistently argued that it only uses 'approved' food additives or GRAS, generally regarded as safe. [13] [134] However, the major difference between food additives and cigarette additives is the combustion of the cigarette. As Proctor states:

'A fruit salad eaten is quite different from a fruit salad burned and inhaled. Almost any complex organic mixture will be toxic when pyrolysed and drawn into the lungs …' [13]

In addition, while the exposure to additives from any one cigarette may be small, the aggregate over a lifetime can add up. There is also scientific uncertainty regarding the effects of combinations of these additives. More than 100 of the 599 cigarette additives documented in the US cigarette additive list have pharmacological actions.[10]

Rabinoff argues that the inclusion of additives could reduce, mask or prevent smokers' awareness of the adverse symptoms caused by smoking, and therefore smokers might continue to smoke even when they are ill, preventing reductions in cigarette consumption and sales revenues. [10]

Rabinoff argues that RJ Reynolds' addition of beta-carotene to cigarettes, which was subsequently linked to an increased risk of lung cancer in smokers, suggests that adverse health effects can occur even when a seemingly benign additive is used. [10] Although the actions of beta-carotene and other additives may have decreased the carcinogenicity of cigarettes, they may have unintentionally increased the risk for and rate of lung cancer in smokers. [10]

8.3 Population Health Impacts

There are three main areas of concern relating to the use of additives from a population health perspective:

- **Toxicity**: the toxicity of the additives themselves and their potential to increase the toxicity or carcinogenicity of cigarettes or tobacco smoke;
- **Addictiveness**: the potential for additives to increase the addictiveness of cigarettes or influence the pattern of smoking behaviours;
- **Palatability**: that additives might increase the palatability of these deadly products, influencing the uptake of smoking.

Some additives are relatively volatile and are transferred directly to mainstream smoke. Other additives combust to a significant degree, forming new chemicals, which may also be toxic or pharmacologically active. [4] Indeed, a number of additives have been identified as toxic when partially combusted. [4 10 135] Examples include acetaldehyde, an identified carcinogen that is produced by the partial combustion of sugars (something identified as likely to potentiate the effects of nicotine, so there are other reasons for trying to minimise it in tobacco smoke); similarly, the cilia toxicant acrolein is produced by the burning cigarette paper.

It is difficult to quantify the specific contribution of tobacco additives to tobacco related harm at a population level. It should be noted that limitations of the current disclosure system have limited researcher's ability to further investigate this issue.

However, the use of additives to enhance the taste of tobacco smoke to make the product more desirable to smokers is of particular concern from a public health perspective. [9] However, until recently this issue has received little attention from policy makers. For products as harmful and addictive as cigarettes, a powerful case can be made that it is not acceptable to modify the product in ways that mask some of the unpleasant side effects, such as the natural harshness of nicotine, as these could be a disincentive to experimentation and uptake of smoking.

Tobacco industry documents and published research have shown that the industry has put significant effort into mitigating these unfavourable characteristics of smoking (irritation and harshness) through the use of a range of additives. [4] [10] [11] [13] [38] [73] As well as being used to reduce many of the unpleasant features of tobacco smoke (such as sensations of irritation in the throat and chest, and a stale after-taste), additives (in particular flavour additives) may also be used to increase the pleasant characteristics of tobacco smoke, including flavour and aroma.

Although many of the frequently used additives such as sugar, honey, liquorice and cocoa seem rather innocuous at first glance, the addition of these flavourings is of significant concern because they are likely to make cigarettes more palatable to children and other novice smokers. [4] In addition, additives such as menthol numb the throat, so the smoker cannot feel the smoke's irritating effects. [11]

Section 9 What Tobacco Company Documents Reveal about the Use of Additives

9.1 Methodology

A search was conducted of the tobacco company documents made available through the Minnesota litigation in the United States and the US Master Settlement Agreement. The document search had two objectives. The first was to gain more information about industry practices concerning the use of additives and engineering features to boost palatability or consumer-attractiveness. The second was to identify relevant information on practices within the Australian tobacco industry – especially with regard to the particular additives used in Australia.

The tobacco industry document collections contain millions of pages of previously secret industry documents in publicly searchable forms. For this study the following tobacco document websites were used: www.legacy.library.ucsf.edu, www.pmdocs.com and www.tobaccodocuments.org.

The initial search terms were 'Australia'/'Australian' paired with 'additives', 'cigarette additives', 'additives', 'palatability', 'humectants', 'casings', 'flavours'/'flavors' and similar terms involving specific additives. These initial searches yielded thousands of documents that the search engines deemed relevant.

In practice, relevance generally declined steadily as results lists progressed, so it is more likely that a comprehensive collection of relevant documents would number in the hundreds rather than thousands. The documents turned up by the searches were then scanned for relevance, with those that appeared useful saved for closer analysis.

The initial searches also turned up other search terms, such as relevant staff names and code names, which were used in subsequent searches. Robin Shiffman and Richard Ruff were identified as important technical staff at Philip Morris, and Tasman Wilson was identified as a particularly important technical staff member at Wills.

We reviewed a sample of 68 relevant tobacco company documents. However, because of time constraints, this review by no means constitutes an exhaustive review of the available materials. A number of additional documents were identified through a snowballing strategy, where reference lists from relevant published articles were reviewed to identify further relevant sources.

9.2 The Use of Flavours and Additives in Australian Cigarette Brands

Two of the main issues regarding Australian cigarette brands and the additives used in them concern the extent to which Australian brands use flavour additives, humectants and sugars. Tobacco companies have claimed that Virginia-only brands generally do not use flavour additives and generally do not have sugars or humectants added.[136] As nearly all Australian brands are Virginia-only products, those claims might be expected to apply to most Australian brands.

Research by Hammond [84] previously described in this paper studied Virginia-style cigarettes from the Canadian domestic market and found that while they contained fewer additives compared with US-style blended cigarettes, they were by no means additive free.

Tobacco company documents also confirm that the industry has a long history of using additives in Australia, with the use of some flavourings dating back to the 1920s.[137]

There are many documents that summarise the purpose and use of additives internationally and in Australia. A BATA document, Additive Chemicals, [1] notes that the use of additive chemicals has a long tradition of use in the tobacco industry, and that the use of additives varies considerably from country to country. The purpose of this document is not stated but it appears to set out the public position of BATA in regard to additives. In the document, BATA acknowledges that additives contribute to cigarette characteristics in terms of taste and flavour, as well as in pack aroma, and notes the differences between Virginia cigarettes which contain natural sugar and American blended cigarettes which have negligible natural sugar. [14]

The role of humectants, or moisturisers, such as glycerol or propylene glycol, is described as preventing tobacco in cigarettes from drying out. [14] Another industry document notes the use of humectants in Australian WD & HO Wills' brands to reduce irritation and increase smoothness.[17] It was suggested that humectants may ameliorate irritation when applied to products incorporating high levels of expanded tobacco (ET) such as those in Australia.[17] The use of processing aids, such as water and carbon dioxide, is also described, including their use for a variety of purposes, such as '*volume modification, in order to meet the particular design specifications of individual brands*'[17]

Importantly, BATA acknowledge in the Additive Chemicals document that while the top dressing flavours are used in very small amounts, they have an extremely significant impact on cigarette products, and that flavour additives can be an important factor in achieving a milder cigarette. [14]

'*Despite the very small amounts of individual flavours (parts per million) used, they make a major contribution to taste and appeal which are part of the individual distinctiveness of cigarette brands*.' BATA [14]

The document claims that Virginia cigarettes in Australia contain minimal amounts of additives. It is interesting to note that this document states that menthol (the best known additive) is put on the inner packaging – not in the cigarette; it then subtly impregnates the tobacco, so any regulation would also need to include guidelines on adding flavour to the packaging itself instead of directly in the cigarette.[14]

Another important BAT document describes the use of casings and flavours or 'top dressing' flavours. [15] The document notes that the border line between these two classes is not a clear one, and several materials overlap from one class to the other. Broadly, however, 'casings' are solid/semi-solid materials which are added in significant weight quantities to tobacco (kg/per 100 kg), usually as an aqueous 'liquor' or 'sauce' during manufacture. Top dressing 'flavours' are volatile, highly aromatic oils, usually applied to tobacco in very small quantities as an alcoholic spray at the final stage of primary processing. According to this document, casings affect the chemical composition of the smoke very significantly because they form a significant proportion by weight of the final product, while top dressings add very small amounts of additional material to the smoke without fundamentally altering the chemical composition. [15]

The casings and flavours document goes on to describe the various groups of casings, and other common additives to tobacco and the purposes they serve. These groups are:

- sugars;
- flavouring casings;
- humectants;
- ameliorants;
- combustion agents;
- preservatives;
- dyestuffs; and
- binding agents. [15]

Significantly, BAT notes that '*All of the above types of material can be used to create dramatic changes in final smoking characteristics. Their uses can be varied and although much of the chemistry of the effects is known, more is unknown.'* [15]

The document contains detailed information on the use of additives. This information has been incorporated into Section 3 of this report where relevant.

A 1992 Brown & Williamson/BAT document by J Wigand titled Product Testing and Product Development Best Practices [12]explains the critical importance of casings and flavour to the tobacco industry.

'Casing and flavor play a very crucial role in the commercial success of a product. Their part in total product development is of growing importance.' [12]

The document notes casing and flavour can contribute in the following aspects:

- correcting blend chemistry deficits;
- protecting against negative processing influences;
- suppressing negative taste effects (blend, design, packaging);
- upgrading tobacco and tobacco by-products;
- enhancing specific tobacco notes;
- introducing root technology (liquid recon);
- achieving product identity. [12]

The document also explains that Australia is a Virginia market where casing and flavours 'remain subtle'. [12] The document later refers to commercial casings specifically available for flue-cured tobacco. [12]

A Philip Morris document describes the various ways in which casings and flavours can be used in product development: [38]

'In processing, casings are applied prior to cutting to moisturize and soften the tobacco and reduce breakage. It is used to subjectively improve the smoking characteristics of the cigarette, in addition to providing a cleaner tobacco taste, or eliminating, a mouth-coating effect if need be. Care must be taken not to detract from the tobacco-like aroma emitted from the pack and side stream. There are casings that reduce the negative smoking qualities of stems or reconstituted tobacco, and flavors that can reinforce the key flavor ingredients of tobacco smoke, particularly in low-delivery cigarettes.' Philip Morris [38]

A Philip Morris document from the 1970s confirms that some Australian brands (for example, Marlboro) contained casings.[138] In a comparison of international brands, the memo states:

'The Australian brand significantly beat that from the UK. The conclusion, therefore, is clearly that a cased Marlboro is preferable to an uncased variety. The cased products did particularly well on the dimensions of mildness and being "less harsh".' Philip Morris[138]

A WD & HO Wills document mentions ordering/seeking various flavours and also mentions that work has been undertaken on the absorption and distribution of casings. [74] This document also reveals that some Australian brands contain burley tobacco. The document notes that:

'… the Australian market is basically a Virginian market with our first menthol being Kool. Consequently menthol smokers have grown used to menthol products being based on cased burley blends. While with later brands we have modified both casings and blends we still largely follow the lead set by Kool. You should also be aware that the leading menthol brand on the Australian market is Alpine which we believe to be a cased burley blend.' [74]

Several Philip Morris documents describe Project Commonwealth, [38] [139] [140] the objective of which was to develop a superior flue-cured cigarette to compete successfully in three markets: Australia, Canada, and the United Kingdom. [38]

'*Casings and flavorings, compatible with Virginia cigarettes, will be used whenever possible to develop a superior product.'* Philip Morris[38]

'In my opinion the casings and flavours to be developed' for this project should increase the sweetness and fulfill the taste in the mouth. It will be worth seeing, some Virginia grades, maybe with some waste, treated in Burley line with special casings and flavours.' [139]

The 1981 Project Commonwealth document also confirms the importance of price to consumers and that many popular Australian Virginia-style cigarettes contain no casings. The document states that Rothman's Winfield brand, the market leader with 25.4 per cent market share: [38]

'… was the first brand to move to the 25's pack and thereby discount the price. It has no casings, no flavours, and competes in price as a straight Virginia product with BENSON & HEDGES (Wills).' Philip Morris [38]

A further update on Project Commonwealth in 1983 notes that Philip Morris recently stopped drying Virginia cigarettes and notes an important side benefit, in that this removes the single biggest obstacle to the use of Virginia flavours. [130] The document goes on to note that with the relaxation of the rules on Australian leaf content, Philip Morris intended to prepare their best approximation of US-blend Marlboro and that US Marlboro casings and top flavour had been ordered. [140]

Other tobacco documents identified in the search reveal the use or likely use of specific flavour additives. The search identified several Wills/BAT documents, concentrated in the 1990s. These documents show that WD & HO Wills Tobacco Company was using a wide range of commercially produced flavours, which were referred to in the documents by various code names.

An RJ Reynolds document[141] outlines the use of the flavour enhancer Talin in tobacco products. It notes that Talin is permitted by the National Health and Medical Research Council (NHMRC) as an intense sweetener and flavour enhancer in all foods in Australia where flavours are used, except baby foods. The document notes that Talin has dual properties, flavour enhancement and/or sweetness, and that both

of these attributes are useful in cigarettes and tobacco. Talin also acts as a flavour enhancer for additives such as menthol, cinnamon, peppermint and glycyrrhizin, increasing their aroma and allowing lower concentrations of these flavours to be used. [141]

A Brown & Williamson/BAT document lists the following additives as prohibited in Australia: coumarin, safrole, dehydrosafrole, isosafrole, sassafras oil.[142]

A Philip Morris document describes the use of various preservatives on roll-your-own tobacco in Australia and New Zealand.[143]

A 1994 Wills NZ memo to the BAT office in Southampton, in the United Kingdom, explains different scenarios for reporting additive/ingredient usage in New Zealand. It describes varying interpretations of additive, ingredient, flavour, casing etc., and how 'used in manufacturing' should be interpreted.[144] Importantly, the document also notes the use of 'LTR reconstituted sheet tobacco' in New Zealand in 1995.

It is clear that the use of flavours and casings was commercially sensitive, given the competition between tobacco companies and the ongoing research activities and analysis of competitors' brands. A BAT 1994 document found during this search explains the use of code names for flavour additives and the procedures for ensuring the secrecy of brand recipes. Code names for flavours were controlled by the Flavour Department at the BAT Technical Centre in Southampton.[145] Each code name is uniquely associated with a specific tobacco additive or formulation; any change of a formulation, however slight, requires the issue of a new code name. Further, a BAT policy prohibits the disclosure of both code names and transcriptions within the same document for all company correspondence and documents. [145]

A 1994 document notes that Wills did not know the identity of all flavour ingredients used in its brands – seven ingredients were known to BATCO but not Wills, and the flavour ingredients used in Kent were known to Brown &Williamson.[146] The document also suggests that local management of Philip Morris may not have known all of the flavour ingredients and would need to rely on the US additive list, which has toxicological endorsement. Wills, however, could not use the disclosed US additive list because they used ingredients that were not on the list.

This document also notes in relation to a pending senate inquiry: 'Our initial approach would be to demonstrate that additives are not a significant issue in Australia because of the Virginia tobacco market for cigarettes. However, they are used in RYO [roll-your-own] and Wills is the only local manufacturer.' [146]

A number of documents concerning the use of specific flavours and compounds occurring in flavours were identified. Some of these documents question whether the limits for use of certain toxicologically active compounds would be exceeded by using these flavour additives at proposed rates of application. Some also noted that

certain flavours conform to regulations in some jurisdictions but not others.[147] [148] [149] [150] [151] One document questions whether proprietary flavours from Keith Harris and Co, a chemical manufacturer focused on the production of flavours and colours for the Australian food and tobacco industry, contained coumarin.[152]

There is also evidence that Australian tobacco companies sought advice and technical support to enhance the flavour and reduce irritation of existing Australian brands and new test products in 1990 as part of Project Bendigo.[153] The advice received recommends significant modification to the test products, including blend and construction changes to reduce irritation and enhance flavour, and seeks additional information that may be available from a test panel or consumer views in Australia. [153]

'*Meanwhile, I will continue experimenting with various additives NOT only flavours, but I am including trials with tobacco extracts from "good" VA tobacco, different flavour modifiers such as extracts from Tea and Carob bean which might give more tobacco taste and hopefully ameliorate the irritation, which I personally find very high in all the cigarettes you sent*.' BAT [153]

The document suggests that there may be value in exploring the '"*INT concept" (Irritation reduction – neutralisation of tobacco cellulosic taste – Targeting tobacco flavour) which has been developed by QUEST INTERNATIONAL, where they would "fingerprint" your present product, using all the analytical facilities they have at their disposal and compare this with a "fingerprint" of what you would consider the "ideal" blend for your market. On the basis of these results they would develop flavours and/or casings which when added to your present blend would bring it closer to your "ideal" blend.'* [153]

Other documents report on research related to impact (that is, the effects of nicotine) and irritation.A BAT document describes a meeting that was held in 1993 to discuss current thinking on the mechanisms of impact and irritation, and to recommend potential methods of reducing irritation without producing reductions in impact and other desirable sensations such as mouthfeel and flavour amplitude. [17]

The document notes that it was agreed that previous studies on impact sensation had been successful, and that the *'magnitude of impact is clearly related to the amounts of free nicotine delivered to the impact sensing region i.e. the throat'.* [17]

The document notes that there is no universal approach for modifying the sensation of irritation, which is believed to be a very complex sensation and is likely to be influenced by many factors. The meeting recommended the conduct of carefully controlled studies on cigarette design factors that are believed to influence perceived irritation; for example,

- cigarette circumference;,

- moisture levels;,
- nicotine to tar ratios;
- position of filter ventilation zones; and
- condensate pH manipulations. [17]

'*Many of these design factors are believed to influence perceived irritation but may also influence other factors such as impact and mouthfeel. Our ultimate goal would be to determine those design factors which could be used to reduce perceived irritation without concomitant reductions in impact etc.'* [17]

The document notes that Canadian research suggested that the addition of diammonium phosphate (DAP) to cigarette filters reduces irritation. It is not clear whether the reduction in irritation is accompanied by a concomitant reduction in impact. The company agreed that DAP should be added to filters, and that work should then be undertaken to determine its effect on impact and irritation. [17] The document suggests that the research on the effectiveness of humectants such as glycerol and propylene glycol in reducing irritation and improving mouthfeel had been mixed. However, it notes the extensive use of humectants to reduce irritation in Australian WD & HO Wills brands: [17]

'One of the main advocates of using humectants to reduce irritation is Chris Murray from Wills in Australia. Chris claims that Rothmans low delivery Virginia products incorporate humectants and are perceived as being smoother and higher in mouthfeel than equivalent delivery Wills products. As Australian products tend to incorporate high amounts of expanded tobacco, and ET is believed to introduce additional irritation, it is possible that humectants may ameliorate irritation when applied to products incorporating high levels of ET.' [17]

A letter from Brown & Williamson Tobacco Company to Doug Bickhoff at WD & HO Wills in 1990 highlights problems associated with low-tar Australian brands and provides advice on strategies to improve Australian low-tar cigarettes. [73]

The deficiencies of the 1mg tar cigarette are described as:

1) little if any tobacco taste;
2) very low overall sensory perception; and
3) an 'airy draw', making it difficult and uncomfortable to smoke. [73]

Of particular relevance to this review are the recommendations on casings and flavour provided to WD & HO Wills Australia:

- use a 'light' level of sugar casing on flue-cured tobacco, and a 'light' level of sugar casing on non-redried bu rley tobacco;
- use a cigarette paper with low porosity and high burn additive;

- use cocoa powder on redried burley at a level of 2–31. This helps give a better mouthfeel to smoke. Use licorice on non-redried burley at a level of 0.5–1.0%. This also gives mouthfeel and sweetness;
- must use two to three times normal levels of flavour (that is, relative to full taste product flavour levels);
- if tobacco taste is deficient, use tobacco-type flavours;
- may need to use flavour additives which add 'body and mouthfeel' to smoke.[73]

Specific flavour examples were not offered due to chemical regulatory use positions of different countries. [73]

These documents confirm the extensive use of flavour technology in Australian cigarettes, and suggest that casings may also have been used in some Australian cigarettes.

9.3 Influencing the Delivery and Impact of Nicotine

The tobacco company document search identified limited information relating to the use of ammonia technology in Australia. The extent to which this technology was used in Australia remains unclear.

A BAT document on Project Brownie examined the use of root technology (RT) and Philip Morris flue-cured products in Australia in 1993.[154]

The Project Brownie document reports that the use of root technology by Philip Morris in US blended products such as Marlboro was investigated in detail through projects such as Ship and World Wide Best. As a consequence, much is known about the different incorporation routes for this technology and the sensory effects produced in US blended products. However, the document reports that relatively little is known about the applicability of this technology to flue-cured products in markets such as Canada and Australia. [154]

As part of Project Brownie, a set of Philip Morris and BAT brands from these markets were analysed in detail. The document reports that BAT found no evidence of the use of RT by Philip Morris in flue-cured products in Canada and Australia. [154]

'*This does not mean that RT cannot be used in flue cured products if an appropriate form can be developed, but the results do suggest that PM who have a long history of use of RT have either:*

a) not found a route;

b) consider the technology inappropriate in principle; or perhaps less likely

c) have simply not sought to apply the technology.' [154]

A 1981 Philip Morris document reveals that Wills and Rothmans brands contain 12 to 15 per cent expanded tobacco (ET) and that WD & HO Wills has *'phased out reconstituted sheet while Rothmans uses none, and both use "improved" stems*.' [74]

However, a BAT New Zealand document acknowledges the use of reconstituted sheet tobacco in New Zealand in 1995. [144]

There is evidence that tobacco companies experimented with ammonia technology to manipulate the levels of nicotine available to smokers in Australia. For example, in January 1988 JSC Wong from WD & HO Wills in Australia reported on his company's efforts to use ammonia to develop a 'low alkaloid smoking product without adversely affecting smoking properties.'[155]

Wong reported that the nicotine content in a tobacco blend had been reduced by water extraction, and noted that subsequent exposure to ammonia 'restored impact and irritation levels to a similar order of magnitude as those for the unextracted tobacco'. Wong also remarked on the smoother smoke produced by ammoniation. [155]

Significantly, the report reaches the following conclusion:

'*A method was developed for reducing nicotine in tobacco. Further processing restored sugar and TVB levels and to a large extent the smoking properties of the tobacco. This procedure will be held as a contingent plan for possible use should the Australian Government introduce nicotine labelling of tobacco as has been suggested.'* BAT [155]

There is evidence of experimentation with ammonia technology in Australia, as noted above, and there is evidence that ammonia technology was used extensively in the United States and many other countries. The extent to which ammonia technology was implemented in Australia is unclear. Cigarette disclosure lists from BATA in 2000 list ammonium phosphate dibasic compounds as a flavour/processing aid. Philip Morris listed ammonium hydroxide. However, ammonia has not appeared in lists since that time.

9.6 Flavour Research

A BAT document reported on flavour research undertaken by the company in 1984, which had the following objective: to identify blending and flavouring components which augment the sensory characteristics of cigarette smoke.[156]

The document identified that the following broad areas of research had been undertaken:

(1) Leaf and Smoke Studies: provision of scientific insight into the sources of tobacco components which contribute to smoke sensory character.

(2) Chemoreception Research: elucidation of the effects of chemical additives upon the chemosensory system and upon sensory properties relevant to tobacco;

(3) Blending and Flavouring Methods: examination of new 'mapping' and chemical techniques for the incorporation of blend constituents and volatile flavourings into the product, respectively;

(4) Processes, Constituents and Formulations: production and performance testing of novel blends, blend components and additives. [156]

Examples of research related to blending and flavouring methods included spraying tobacco with menthol-containing microcapsules. The resulting cigarettes demonstrated a high menthol transfer efficiency. The document stated that further analyses will establish whether this particular type of encapsulation can lock volatiles in place and offer product design opportunities. [156]

The document notes that an approach to the bioencapsulation of additives (for example, nicotine and menthol) was examined. The adopted method involves utilising transpiration in whole or macerated green leaf to introduce the additive via the vascular tissue. The nicotine concentration in the leaf may be doubled by this method. As well as allowing nicotine/tar ratio adjustment, the technique may increase the free-base nicotine in mainstream smoke as a result of the type of nicotine bonding in the cells. [156]

Examples of research relevant to processes, constituents and formulations included a collaborative research effort with a chemical company developing and producing various flavours. This project focused on tobacco sulphur chemistry to achieve an array of new flavours for assessment. The document also mentions research related to reconstituted tobacco and nicotine. [156]

The extent to which these individual processes were used in Australia is not clear, however these documents demonstrate some of the approaches to flavour research that BAT was investing in and no doubt applying across multiple markets.

9.7 Filter Ventilation

A 1981 Philip Morris document reveals that Winfield Extra Mild used filter perforations (that is, filter ventilation) rather than filter dilution to achieve 12.5 mg tar. [38]

Another Philip Morris document states that 'filtration and dilution are powerful tools for the reduction of smoke component delivery'. [157]

'*Because of interactions between dilution, filtration and combustion, vented cigarettes deliver more or less of many smoke components than might be expected from the dilution levels. By an appropriate combination of these physical techniques, it is possible to design cigarettes with almost any level of delivery of tar, nicotine and gaseous components.'* Philip Morris [157]

This document also confirms that Philip Morris were aware that filter ventilation allowed cigarettes to measure low levels of tar and carbon monoxide, while nicotine delivery was essentially unchanged. [157]

'This ability to control both the rate of burn and the degree of dilution is important in that it allows greater than expected reductions in the delivery of some smoke components. This is illustrated in data reported by Owens (1978) who showed that increasing dilution by means of inherently porous paper gave reduced puff counts and sizeable reductions in tar, nicotine, carbon monoxide and nitric oxide. Conversely, when perforated paper was used to achieve similar dilutions, increased puff counts were observed along with large reductions in CO and NO. Tar was also reduced, but to a lesser degree than previously and nicotine delivery was essentially unchanged until high dilutions were achieved.' Philip Morris [157]

9.8 Tactics – Dealing with the Threat of Product Regulation

The regulation of additives, including product disclosure and prohibitions and/or restrictions on their use, poses a serious threat to the tobacco industry. This threat has been identified by both the tobacco industry and the public health community. [7] [158]

A Philip Morris document from 2000 [158] identifies product regulation as one of five issues that have a significant impact on its business, and recommends the development of a comprehensive, consistent and integrated approach for Philip Morris International in the new millennium.

The Philip Morris Task Force determined that part of their response should include non-conventional and so-called 'reduced risk' products. [158]

The document identifies a number of guiding principles that Philip Morris should consistently argue in relation to the threats associated with product regulation. Of relevance are the following points:

- Regulations must be based on scientifically valid methods and disclosure requirements should protect companies' 'brand recipes'.
- Regulations should ensure that cigarettes are made in accordance with good manufacturing practices, and that ingredients added by the manufacturers do not present additional risks to consumers. **This does not mean that**

governments should be able to impose product design restrictions including the use of ingredients, based on the desire to make cigarettes less palatable.

- Regulations should require governments to work with the public health community and the tobacco industry to define tobacco products that have the potential for offering reduced risk to consumers.
- Regulatory regimes should not be utilised as mechanisms to ban products that don't qualify as 'reduced risk', or to impose prohibition by stealth, such as by the imposition of increasingly lower ceilings on tar and nicotine yields. [158]

The document specifically mentions the need to accelerate the process of compiling information on current ingredients to allow the company to go to governments voluntarily with a form of ingredients disclosure. In addition, the document identifies the need to complete the Australian model for review and submission to the Government. This suggests that the approach may have been seen as a global model. [158]

Philip Morris also indicates that in the event that governments require by-brand disclosure of all ingredients, Philip Morris will seek complete and secure protection of the information. [158]

The document reveals that Philip Morris was concerned about regulation of additives in relation to palatability, and provides some insight into their approaches.

'Governments should have the power to ban any ingredient that is shown on the basis of valid scientific data to increase the inherent risks of smoking but must weigh any potential hazardous effects of the ingredient in question against the effects of tobacco itself. Under this standard, a regulator may not prohibit ingredients on the basis that they contribute to the palatability of the tobacco product. Governments should not be able to ban ingredients if their goal is to make cigarettes taste bad.' [158]

Also of interest is the approach to identify countries where only one brand is sold, and the need consider introducing other brands immediately in each of those markets to permit disclosure without disclosing specific formulae. The document notes that this is underway in Ireland and Iceland. [158]

A 1996, BAT document on Future Business Environment[159] also mentions product regulation as a strategic issue and their concern about brand-by-brand disclosure arrangements. It notes that:

'A number of countries (e.g., the U.S., Canada and Thailand) are considering the limitation of what they call potentially "hazardous" additives used in the manufacture of cigarettes. Linked with this issue is the question of brand-by-brand ingredients disclosure. Given the anti-smoking movement is aware that a brand-by-brand

disclosure of ingredients would be threatening because of the competitive formula issue, they will continue to lobby for this very hard with governments.' BAT [159]

An RJ Reynolds document from 1989 prepared by their attorneys details sample questions and answers on cigarette ingredients. [134] Many of the sample answers to questions include some of the same statements currently made by tobacco companies. These include the arguments that additives have been used for a long time; in general, they are natural-type substances that are generally regarded as safe for use in food; and that there is no evidence in the scientific literature to indicate that ingredients present a measurable health risk to the smoker. The document does note the importance of additives in relation to low-tar cigarettes, and states:

'This decrease could not have been achieved without the use of non-tobacco ingredients. Without the use of ingredients to enhance taste, it is highly unlikely that consumers would have been willing to smoke modern "low-tar" cigarettes.' [134]

There is evidence that the tobacco industry is concerned about the potential domino effect of tobacco product regulation.[160] A Philip Morris document provides an insight into the level of concern the company had in regard to ingredient disclosure legislation in Thailand:

'My information is that they will be requiring specific percentages as well as a list of substances ingested after combustion. Their goal seems to be the creation of a situation similar to that of Coca-Cola in India: the requirement, for alleged health reasons, of proprietary information. Please let me know what information you have on this matter. If my information is correct, this will constitute a very dangerous precedent which could affect us in other markets as well as in Thailand itself.'[161]

There is evidence that tobacco companies have identified the use of trade agreements as important mechanisms to challenge tobacco control legislation, and used the World Trade Organization (WTO) to challenge proposed legislation in Thailand:

'We feel sure that the enforcement of [Thailand legislation] Article 11 violates International trading agreements, as well as setting ingredients disclosure precedents that could eventually impact on many other industries. I would like to express these views to the British Ambassador to Thailand. Before contacting him, I would be interested to hear your views on the issue and how else we might convince the Thailand government that ingredients disclosure by brand will deny BAT market access.' [162]

Recently, Indonesia, the world's top producer of clove cigarettes, brought a World Trade Organization case in April 2010 against the United States. They argued that the provision of the Family Smoking Prevention Tobacco Control Act of 2009 that

bans clove cigarettes was inconsistent with various trade agreements. The WTO appellate body ruled that the ban on clove cigarettes was discriminatory because a similar product, menthol cigarettes, can still be sold in the United States. Media reports indicate that the US Trade Representative's Office was examining its options for complying with the ruling. [163] [164]

9.9 Summary and Conclusions

The search of tobacco industry documents has highlighted a number of important findings. Some of this evidence appears to challenge assumptions that have been previously made and contradicts some of the public statements made by tobacco companies.

There is evidence that:

- there is a long history of using additives in Australia, with the use of some flavourings dating back to the 1920s; [12] [74] [134]
- increased additive use appears to have been associated with the production and marketing of low tar cigarettes with one industry document suggesting flavour application for low tar products at two to three times the level of 'full flavour' products;[73]
- casings and top dressing flavours have been credited with playing a crucial role in the commercial success of some products; [12] [15]
- some Australian Virginia brands have contained casings; [74]
- a number of cigarette design factors influence perceived irritation (for example, cigarette circumference, moisture levels, nicotine to tar ratios, position of filter ventilation zones and pH of the smoke condensate); [17]
- humectants (for example, glycerol and propylene glycol) are used in Australian cigarettes to reduce irritation and increase smoothness. [17]

The tobacco company search also reveals that regulation of additives to reduce palatability of cigarettes has been identified as a significant threat by tobacco companies. [158] [159] The search also provided some insights into the tactics adopted by the tobacco industry to resist the threat of product regulation; for example, the use of world trade agreements to challenge tobacco control legislation. [162]

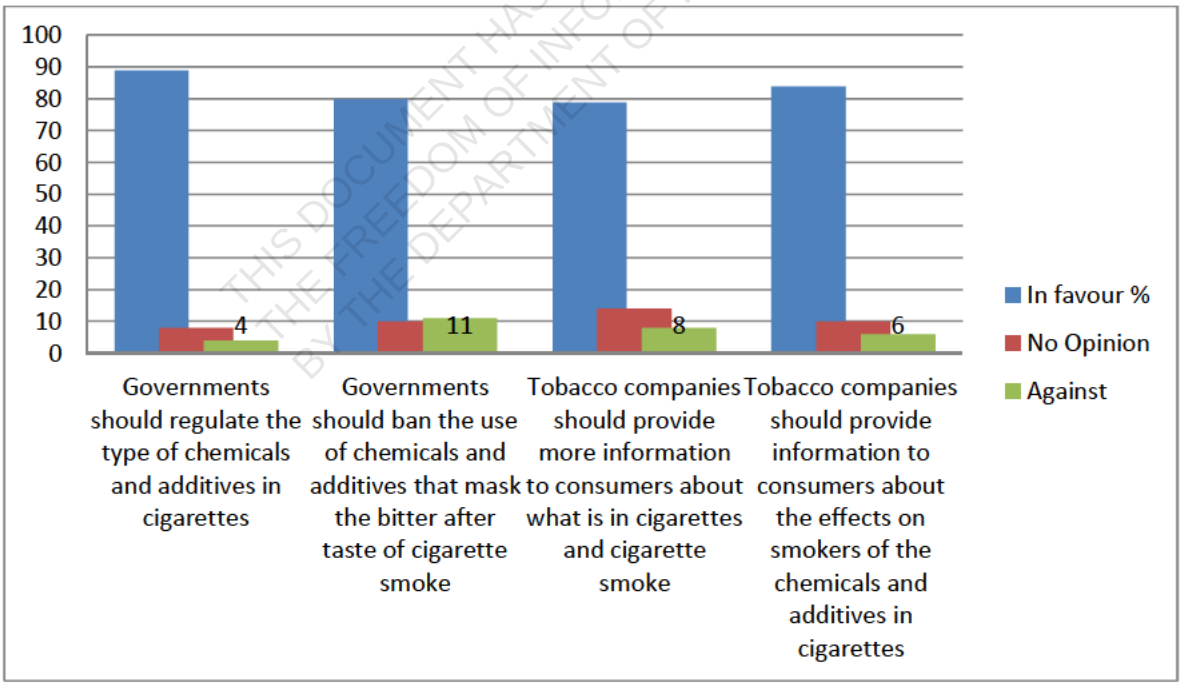
Section 10 Awareness and Attitudes to Additives

10.1 Awareness among Smokers

In 2011, Heydon et al. published an article demonstrating that smokers in Western Australia strongly support the regulation of the use of chemicals and additives in cigarettes.[165] In 2009, Cancer Council WA conducted a mass media campaign focused on cigarette ingredients. The *Sugar Sugar* campaign was broadcast across WA in 2009, including television and print advertisements. The advertising highlighted that while ingredients such as sugar and honey can mask the bitter taste of tobacco, the damage smoking can do cannot be hidden.

A post-campaign evaluation survey was conducted with a sample of 200 Western Australian adult smokers and recent quitters aged 25 to 54 years. The vast majority of smokers surveyed were in favour of government regulation of the type of chemicals and additives used in the manufacture of cigarettes (89 per cent), and 80 per cent were in favour of banning the use of chemicals and additives that mask the bitter taste of cigarette smoke.

Figure 4: Smokers' attitudes towards the use and disclosure of chemicals and additives in cigarettes



Source: Adapted from Heydon N J, Kennington K, Jalleh G. Western Australian smokers strongly support regulations on the use of chemicals and additives in cigarettes. Tobacco Control. Published 14 December 2011; e-pub ahead of print journal.

There was strong support for tobacco companies providing information about the contents in cigarettes and cigarette smoke (79 per cent), and the effects the chemicals and additives in cigarettes and cigarette smoke have on smokers (84 per cent). Only 11 per cent of smokers or less were opposed to each of these four statements. [165]

A qualitative research study published in 2006 examined smokers' views and attitudes to a range of regulatory policies on tobacco.[166] According to Carter et al., when smokers were informed that ingredients such as cocoa, coffee, peppermint, sugars and other sweeteners are added to most manufactured cigarettes, and not just 'niche' flavoured varieties, many smokers expressed amusement and surprise, or became shocked and angered. [166]

Most groups of smokers said chemicals were added to cigarettes to increase addiction, harm and/or consumption. 'Chemicals' were a potent touchstone for condemnation of tobacco corporations. Participants argued that flavours made it easier for children to smoke, were a form of marketing to children, or made it easier to smoke too much. [166]Others countered that they enjoyed their cigarettes the way they were and did not want them to taste bad; or conversely, that no matter how bad cigarettes tasted, children and smokers would still smoke them. Some smokers supported unflavoured cigarettes because they should logically be cheaper (the additives must cost money) or less harmful or addictive. Most smokers were strongly in favour of disclosure, preferably on or in the pack. No-one knew that ingredient information was available on a government website, suggesting that this is a highly ineffective means of communicating with smokers. [166]

Surveys conducted by the Cancer Institute NSW between 2005 and 2008[167] found that more than four-fifths of smokers (85 per cent) agreed with the erroneous statement that 'it's the additives put in cigarettes that make natural tobacco so dangerous to health'. Agreement with this statement increased compared between 2005 and 2007 (79 per cent to 85 per cent), most likely because of mass media campaign activity by the Commonwealth, which emphasised the chemicals in cigarettes. [167]

A number of findings from part two of this project are relevant. The report on '*Smokers' Beliefs about Cigarette Palatability and Attitudes Towards the Regulation of Cigarette Additives*'[168] uses data from the International Tobacco Control Policy Evaluation Survey, Four Nations Study, to analyse Australian smokers' attitudes toward the regulation of cigarette additives, as well as analysing Australian smokers' beliefs about the relationship between smoking sensations and perceived harmfulness which are potentially relevant to the issue of tighter regulation of additives. These are compared with the attitudes and beliefs of respondents from Canada, the UK and the US.

There are some limitations of the ITC survey that need to be considered. The ITC is a recurrent survey and, as such, results at later waves suggesting changed beliefs or attitudes among the entire population of smokers may actually be artefacts of repeated testing on the particular cohort.[168]

At Wave 1(2002), Australian respondents to the ITC Four Nations Survey were the most likely among those of the four nations studied to support tighter regulation of tobacco products, with 70 per cent responding positively. By Wave 8 (2009) the proportion of Australian respondents responding positively to this item had fallen to 48 per cent and similar declines in levels of agreement with the particular survey item were found in Canada, the UK and the US. [168]

The results of the analysis of this project on first glance may suggest an apparent decline in support among smokers for more tightly regulating tobacco products. However, the fact that apparently declining support for regulation occurred in all four countries of the survey at the same wave and was not found when following only the replenishment cohort is consistent with methodological artefacts, rather than a real decline in support for regulation at a population level, and in particular shows no differential effect of the stronger regulatory environment in Australia compared with say the US over the period of the surveys. The reasons for this difference are not clear. [168]

In Waves 7 and 8, there was an item concerning support for a law that banned additives or flavourings that make cigarettes seem less harsh. Support was highest in Australia at both waves, with 68 per cent of Australian respondents supporting such a law in Wave 8, compared to a 4-country average of 58 per cent. Support increased from 62 per cent in Wave 7.[168]

Another item included in Wave 8 only, and was asked immediately after the above question, which was not specific about effects of additives but simply asked if respondents would support banning *all* additives from cigarettes was more strongly supported in all four countries than the aforementioned item. It was supported by 83 per cent of respondents in Australia, compared to a 4-country average of 75 per cent. This is a surprising result, as typically support is greater for less restrictive rather than more restrictive rules. It is possible that those who did not support removing additives for taste approve of removing them for other reasons, rather than simply agreeing with something stronger than what they previously disagreed about. It is also possible, although we think less likely, that some who "changed" opposed limited restrictions because they support complete bans, so saw the first proposal as too weak. In the absence of more information, we urge caution in interpreting specific levels. That said, it is clear that most smokers are generally supportive of the idea of banning additives, at least in the abstract.[168]

The ITC items concerning smokers' beliefs about the sensory characteristics of smoke and their possible influence over beliefs about harmfulness are consistent

with additives which make cigarette smoke more palatable interfering with the sensory processes by which smokers can be made aware that they are engaged in a harmful activity. The relatively low percentage of Australian respondents agreeing with the statement that lighter taste means less tar is consistent with the public education efforts that have gone into informing smokers that “low tar”/ “light and mild” cigarettes are not less harmful. However, that levels are similar across countreis is inconsistent with a role for the legislative ban on the terms, which had not occurred in the US during the period of surveying and which occurred in Australia during surveying (see also Yong et al, 2011. [168]

The relevant belief questions in the ITC survey are consistent with a significant proportion of Australian smokers retaining beliefs that lighter/ smoother/ less harsh tasting cigarettes are less harmful. The lowest levels of respondent endorsement came for the item stating that “lighter taste means less tar” with 17 per cent of Australian smokers agreeing at Wave 8, compared with a 4-country average of 22 per cent . A higher percentage of respondents supported the statement that menthol cigarettes are smoother on the throat and chest than regular cigarettes, with 29 per cent of Australian smokers agreeing at Wave 8, compared with a 4-country average of 28 per cent. [168]

The substantially higher level of agreement that cigarettes that feel more harsh to the throat and chest are more harmful (by logical extension, implying agreement to the statement that less harsh cigarettes are less harmful) suggests that the cigarettes previously labelled as “low tar” under the smoke constituents labelling system that ended in 2006 continue to influence smokers’ beliefs about relative harm, insofar as smokers continue to experience that brands with larger filters and higher levels of filter ventilation are indeed less harsh on the throat and chest. Insofar as harshness is also reduced by added flavours, humectants, sugars, and so on, smokers can also be expected to have their beliefs influenced by the experience of smoking brands that contain any of the aforementioned harshness reducing additives. [168]

The demographic and behavioural variables which were found to relate significantly to the attitudes and beliefs investigated in the ITC Four Nations survey suggest that past experience of smoking and anticipated future experience are likely to be the most important moderators of support for regulation of cigarette additives. Non-experiential knowledge (such as knowledge about what is added to cigarettes and why) appears to be a less important moderator, at least in so far as we can assume that smokers with higher levels of education are more likely to have accurate knowledge of what additives are used in cigarettes and for what purposes. [168]

Lower levels of support for regulation were found among younger smokers and those not currently considering quitting. Given that younger smokers are less likely to be currently experiencing the negative effects of smoking and more likely to want to continue enjoying smoking into the foreseeable future, it is understandable that they

would be somewhat less supportive of new regulations which could impact on their enjoyment of smoking. Thus concerns that bans on additives would make cigarettes significantly less palatable might incline those intending to continue smoking to be less supportive of such bans. However, one might also expect those wishing to continue smoking to be supportive of bans on additives that they believe would make cigarettes less harmful. [168]

Lower levels of support for regulation among heavier smokers may have a related explanation. Heavy smokers may be more concerned that regulation of additives could make their regular brand less satisfying or even see it removed from the market. If they are also not interested in making a quit attempt, they could anticipate that future regulation would be likely to impact on their smoking, whereas those anticipating quitting sooner could anticipate that regulation would either not occur until after they had quit or, if it occurred before they quit, would assist them in the quitting process. [168]

In summary, the evidence that can be gained from the ITC Four Nations Survey is consistent with a high level of support among Australian smokers for regulation of cigarette additives. However, it is possible that there is a lack of accurate understanding about additives that are used in Australian cigarettes and for what purposes. It is possible that a public education process about the possible regulation of additives would lead to increased support for regulation. [168]

Section 11 Summary of Relevant Legislation

The regulation of the tobacco product itself has received less regulatory attention than many other tobacco control areas. This is expected to change as member countries progressively implement Articles 9 and 10 of the WHO FCTC.

A number of countries, including Canada, the United States, Thailand, Lithuania and Brazil, have already regulated additives and disclosure arrangements to some extent.

11.1 Brazil

On 13 March 2012, Brazil's National Health Surveillance Agency (Anvisa) announced the introduction of a regulation to ban all flavours and additives in tobacco products to reduce smoking by young people. The new law requires the banning of all flavours, such as menthol, honey, cherry, tutti-frutti and chocolate, plus additives like ammonia, sweeteners, colours, vitamins and essential fatty acids.[169 170]

The board of Anvisa believes that the additives act as a means of luring young people into starting and maintaining use of tobacco products. Until now, flavoured cigarettes have represented 22 per cent of cigarette sales in Brazil. [169 170]

Manufacturers have 18 months to adapt their products to meet the requirements of the new law, but will have an additional six months to allow for withdrawal of flavoured products from the market. The ban extends to imported products, which can only enter Brazil if they comply with the new regulation. [169 170]

There are some exceptions to the ban permitted, both for sweeteners – to replace sugars lost during the curing process – and colours, including bleaching agents for paper, in order to indicate a brand or logo on the cigarette or to imitate a cork filter tip. [169 170]

According to an Anvisa survey, there are currently about 600 additives used in the production of cigarettes. Under the new rule, only eight additives/ classes of additives are still permitted: adhesives, binding agents, combustion agents, supporting technology (or process aids) other than for flavouring and flavouring t, pigments, glycerol and propylene glycol, and potassium sorbate. The eighth permitted additive is sugar (exclusively for restoration of the content sugar originally present in the tobacco sheet before the process of drying). [169 170]

The regulation includes the following definitions:

- additive: any substance or compound which is not tobacco or water used in processing tobacco leaves and reconstituted tobacco, in the manufacture and

packaging of a product derived from tobacco smoke, including sugars, sweeteners, flavourings and ameliorants;

- sugars: monosaccharide and disaccharide, including sucrose obtained from the juice of sugar cane (*Saccharum officinarum* L.) or sugar beet (*Beta alba* L.), which can be presented in various textures and forms of presentation;sweetener: productcomprised of artificial sweetner(s) that may contain other ingredient(s) which confer(s) a sweet taste to the product derived from tobacco smoke;
- ameliorant: substance that reduces the irritating aspects of the smoke of tobacco products;
- flavouring agents: a natural or synthetic substance or mixture of substances that imparts, modifies, enhances or intensifies the flavor of tobacco products; and
- packaging: housing, container or any form of packaging for containing the smoking product derived from tobacco.[169] [171]

Chapter II of the Regulation establishes the maximum levels of tar, nicotine and carbon monoxide that are permitted in cigarettes. Article 4 states that in the cigarettes sold in Brazil, the maximum permitted levels of tar, nicotine and carbon monoxide in mainstream smoke are:

- tar: 10 mg/cigarette (10 mg per cigarette);
- nicotine: 1 mg/cigarette (mg per cigarette);
- CO: 10 mg/cigarette (10 mg per cigarette). [169]

Chapter IV of the Regulation prohibits the use of additives. Article 6 prohibits the importation and marketing of tobacco products that contain any of the following additives:

1. natural and synthetic substances, in any form of presentation (pure substances, extracts, oils, absolutes, balsams, among others), with properties flavouring or flavourings may confer, enhance, modify or enhance the flavour or aroma product, including additives identified as flavouring agents or flavours:

   a) by the Joint FAO/WHO Expert Committee on Food Additives – JECFA (Joint Committee of the United Nations for Food and Agriculture Organization (FAO)/World Health Organization Health Organization (WHO) Expert Committee on Food Additives), or

   b) by the Flavour and Extract Manufacturers Association – FEMA (Manufacturers Association of Flavours and Extracts);

2. supporting technology (or process aids) for flavouring;

3. additives with nutritional properties, including:

   a) amino acids;

   b) vitamins;

   c) essential fatty acids;

   d) minerals, except those essential to prove the manufacture of tobacco products;

4. additives associated with alleged stimulant or invigorating properties, including taurine, guarana, caffeine and glucuronolactone;

5. pigment (or dyes);

6. fruits, vegetables or any product originating from processing fruit and vegetables, except activated carbon and starch;

7. sweeteners, honey, molasses or any other substance that can impart odour or taste sweet, except sugars;

8. spices, herbs and spices or any substance that can impart odour or flavour of spices, herbs and spices;

9. ameliorants;

10. all ammonia compounds and their derivatives. [169]

Article 7 sets out the exceptions to the ban on additives. It is permissible to use the following eight additives/ classes of additives:

1. sugars, exclusively for restoration of the content sugar originally present in the tobacco sheet before the process of drying;

2. adhesives;

3. binders;

4. agents of combustion;

5. supporting technology (or process aids) other than for flavouring and flavouring;

6. pigments (or dyes) used in the bleaching paper or filter to mimic the pattern of the cork wrapper tip and those used to print logos or trademarks;

7. glycerol and propylene glycol;

8. potassium sorbate. [169]

The addition of sugars under clause I is subject to statements to be presented by companies in the act of petitioning for a change in registration or renewal of tobacco products. [169]The Anvisa Board may approve the use of other additives, after considering justifications made by tobacco companies about the need for continued use of a product which does not alter the flavour or aroma of tobacco. [169]

It should be noted that this Regulation has been challenged by several countries objecting to the measure as an unjustifiable restriction on trade at meetings of the WTO Committee on Technical Barriers to Trade in 2011. Brazil has defended its proposed ban on additives and maximum levels of tar and carbon monoxide in tobacco products, arguing that this is necessary to address significant public health concerns.

11.2 Canada

The most relevant legislation in Canada is the Federal legislation *An Act to Amend the Tobacco Act,* Statutes of Canada 2009, c.27. There is also relevant legislation in place in Ontario, New Brunswick and Saskatchewan provinces.

On 8 October 2009, the Canadian Parliament passed an *Act to Amend the Tobacco Act.*

According to Health Canada, the amendments aim to protect children and youth from tobacco industry marketing practices that encourage them to use tobacco products.[172] These marketing practices include:

- the use of additives, such as flavourings, that contribute to making cigarettes, little cigars and blunt wraps (sheets or tubes of tobacco) more appealing to children and youth (excluding menthol);
- the availability of little cigars and blunt wraps as singles, or in small-quantity 'kiddy-packs';
- tobacco advertising in publications that may be viewed by children and youth.

A transition period was provided for retailers and manufacturers to adjust to some of the changes to the *Tobacco Act*. [172]

The Act contains the following definitions:

- 'additive' means an ingredient other than tobacco leaves;
- 'blunt wrap' means a sheet, including one that is rolled, that is composed of natural or reconstituted tobacco and that is ready to be filled;
- 'ingredient' means tobacco leaves and any substance used in the manufacture of a tobacco product or its components, including any substance used in the manufacture of that substance;
- 'little cigar' means a roll or tubular construction that:

(*a*) is intended for smoking;

(*b*) contains a filler composed of natural or reconstituted tobacco;

(*c*) has a wrapper, or a binder and a wrapper, composed of natural or reconstituted tobacco;

(*d*) has a cigarette filter or weighs no more than 1.4 g, excluding the weight of any mouthpiece or tip.

It includes any tobacco product that is prescribed to be a little cigar. [173]

Section 5 of the Act prohibits the *manufacture* and *sale* of cigarettes, little cigars and blunt wraps that contain the additives set out in a schedule to that Act. The Act does not prohibit the use of a colouring agent to depict a trademark on a tobacco product or to display a marking required under this or any other Act of Parliament or of the legislature of a province or for any other prescribed purpose. [173]

Section 6 of the Act requires manufacturers to submit information to the Minister, in the prescribed manner and within the prescribed time, that is required by the regulations about tobacco products, their emissions and any research and development related to tobacco products and their emissions, whether the tobacco products are for sale or not. The Minister may also request supplementary information. [173]

The manufacture and sale of tobacco products is prohibited unless all of the required information about their composition is submitted to the Minister. [158] Tobacco products manufactured in Canada solely for the export market are still permitted to contain these additives. [173]

Section 23 of the Act prohibits the packaging and sale of cigarettes, little cigars and blunt wraps in a manner that suggests that they contain a prohibited additive (such as a picture or a graphic). [173]

Section 7 of the Act allows the Governor in Council to make regulations for the purpose of:

(*a*) establishing standards for tobacco products, including prescribing the amounts of substances that may be contained in the product or its emissions;

(*b*) respecting test methods, including methods to assess conformity with the standards;

(*c*) prescribing information that manufacturers must submit to the Minister about tobacco products and their emissions, including sales data and information on market research, product composition, ingredients, health effects, hazardous properties and brand elements;

(*c.1*) prescribing information that manufacturers must submit to the Minister about research and development related to tobacco products and their emissions, including information on market research, product composition, ingredients, health effects, hazardous properties and brand elements;

(*c.2*) respecting requests for supplementary information under subsection 6(2);

(*c.3*) respecting the prohibition under section 6.1, including providing for the suspension of the manufacture or sale of a tobacco product;

(*d*) prescribing the means, including electronic means, by which the information referred to in paragraphs (*c*) to (*c.2*) may be submitted to the Minister;

(*d.1*) prescribing anything that by this Part is to be prescribed. [173]

Section 7(1) of the Act also provides flexibility to address future concerns through a Governor in Council authority to amend the schedule and ban other appealing additives or include other product categories in the flavour ban at any time in the future if evidence indicates that these are serving as inducements to youth. [173]

Penalties for manufacturers who are found guilty of an offence against the ban on additives in section 5 and the ban on packaging of tobacco products in section 23 include a fine of up to $300,000 Canadian dollars or imprisonment for up to two years, or both. [173]

Penalties for retailers who sell tobacco products containing the prohibited additives or breach section 23 packaging requirements may be fined up to C$50,000. [173]

Table 2 provides the information contained in the schedule from the Act that sets out the prohibited additives.

Table 2: Schedule (Section *5.1, 5.2, 7.1 and 23.1)* Prohibited Additives

Item	Additive	Tobacco Product
1	Additives that have flavouring properties or that enhance flavour, including: – additives identified as flavouring agents by the Joint FAO/WHO Expert Committee on Food Additives in the Committee's evaluations, as published from time to time in the WHO Technical Report Series; – additives identified as flavouring substances by the Flavour and Extract Manufacturers Association (FEMA) Expert Panel in its lists of GRAS (Generally Recognised as Safe) flavouring substances referred to as GRAS 3 to GRAS 24 and subsequent GRAS lists, as published from time to time, if any.	Cigarettes, little cigars and blunt wraps

Item	Additive	Tobacco Product
	The following additives are excluded: – benzoic acid (CAS 65-85-0) and its salts – butylated hydroxytoluene (CAS 128-37-0) – carboxy methyl cellulose (CAS 9000-11-7) – citric acid (CAS 77-92-9) and its salts – ethanol (CAS 64-17-5) – ethoxylated sorbitan monolaurate (CAS 9005-64-5) – fumaric acid (CAS 110-17-8) – glycerol (CAS 56-81-5) – guar gum (CAS 9000-30-0) – menthol (CAS 89-78-1) – *l*-menthol (CAS 2216-51-5) – *l*-menthone (CAS 14073-97-3) – n-propyl acetate (CAS 109-60-4) – paraffin wax (CAS 8002-74-2) – propylene glycol (CAS 57-55-6) – rosin glycerol ester (CAS 8050-31-5) – sodium acetate anhydrous (CAS 127-09-3) – sodium alginate (CAS 9005-38-3) – sorbic acid (CAS 110-44-1) and its salts – triacetin (CAS 102-76-1) – tributyl acetylcitrate (CAS 77-90-7)	
2.	Amino acids	Cigarettes, little cigars and blunt wraps
3	Caffeine	Cigarettes, little cigars and blunt wraps
4	Colouring agents, excluding those used to whiten paper or the filter or to imitate a cork pattern on tipping paper	Cigarettes
4.1	Colouring agents, excluding those used to whiten plug wrap paper, to render tipping paper brown or bronze, or to imitate a cork pattern on tipping paper	Little cigars
4.2	Colouring agents	Blunt wraps
5	Essential fatty acids	Cigarettes, little cigars and blunt wraps

Item	Additive	Tobacco Product
6	Fruits, vegetables or any product obtained from the processing of a fruit or vegetable, excluding activated charcoal and starch	Cigarettes, little cigars and blunt wraps
7	Glucuronolactone	Cigarettes, little cigars and blunt wraps
8	Probiotics	Cigarettes, little cigars and blunt wraps
9	Spices, seasonings and herbs	Cigarettes, little cigars and blunt wraps
10	Sugars and sweeteners, excluding starch	Cigarettes, little cigars and blunt wraps
11	Taurine	Cigarettes, little cigars and blunt wraps
12	Vitamins	Cigarettes, little cigars and blunt wraps
13	Mineral nutrients, excluding those necessary to manufacture the product	Cigarettes, little cigars and blunt wraps

Source: Canadian Parliament: *An Act to Amend the Tobacco Act,* Statutes of Canada 2009, c.27. [173]

The Canadian legislation has also been challenged in the WTO.

11.3 The United States

11.3.1 Federal Legislation

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law on 22 June 2009. It gives the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution and marketing of tobacco products to protect public health.[174]

The Act gives FDA authority over, among other things:

1. Registration and inspection of tobacco companies (Sec. 905) – Requires owners and operators of tobacco companies to register annually and be subject to inspection every two years by FDA.

2. Standards for tobacco products (Sec. 907) – Allows FDA to require standards for tobacco products (for example, tar and nicotine levels) as appropriate to protect public health. Also bans cigarettes with characterising flavours (except menthol and tobacco).

3. 'Premarket Review' of new tobacco products (Sec. 910 and 905) – Requires manufacturers who wish to market a new tobacco product to obtain a marketing order from FDA prior to marketing that new product.

4. 'Modified risk' products (Sec. 911) – Requires manufacturers who wish to market a tobacco product with a claim of reduced harm to obtain a marketing order from FDA. [174]

Of particular relevance to this review is Section 907 of the Act dealing with Tobacco Product Standards. Section 907 states:

(1)(A) Special rule for cigarettes. – Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, liquorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) Additional special rule. – Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.[175]

Therefore, from 22 September 2009, cigarettes and their component parts that contain characterising flavours (other than tobacco or menthol) or a herb or spice are illegal in the United States. The FDA has announced they will use a range of enforcement and regulatory tools to address violations of the ban by, among others, manufacturers, importers, distributors and retailers.[176]

Section 904 of the Act requires the tobacco industry to disclose research on the health, toxicological, behavioural or physiologic effects of tobacco use; disclose

information on ingredients and constituents in tobacco products; and notify FDA of any changes. [175]

From 22 June 2012, manufacturers of tobacco products and importers of such products or their agents must submit a list of the potentially harmful constituents in those products and in the smoke they produce – and report it by the quantity found in each brand. The FDA has created the list of harmful and potentially harmful constituents plus draft guidance to help those who must report. The Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke was open for comment until 4 June 2012.[109]

For the purpose of establishing a list of harmful and potentially harmful constituents in tobacco products, the FDA believes that the phrase 'harmful and potentially harmful constituent' includes any chemical or chemical compound in a tobacco product or in tobacco smoke:

a) that is or potentially is inhaled, ingested or absorbed into the body;

b) that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products. [175]

Examples of constituents that have the 'potential to cause direct harm' to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds.

Examples of constituents that have the 'potential to cause indirect harm' to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by:

1) potentially facilitating initiation of the use of tobacco products;

2) potentially impeding cessation of the use of tobacco products;

3) potentially increasing the intensity of tobacco product use (for example, frequency of use, amount consumed, depth of inhalation).

Another example of a constituent that has the 'potential to cause indirect harm' is a constituent that may enhance the harmful effects of a tobacco product constituent.[177]

The established list of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke currently includes 93 substances, listed in Appendix 1.

The Act also places a number of limits on FDA's authority. The FDA cannot:

- ban certain specified classes of tobacco products – Sec. 907 of the FDCA;
- require the reduction of nicotine yields to zero – Sec. 907 of the FDCA;
- require prescriptions to purchase tobacco products – Sec. 906 of the FDCA;

- ban face-to-face tobacco sales in any particular category of retail outlet – Sec. 906 of the FDCA.

The Tobacco Control Act also preserves the authority of state, local and tribal governments to regulate tobacco products in certain specific respects. It also prohibits, with certain exceptions, state and local requirements that are different from, or in addition to, requirements under the provisions of the FDCA relating to specified areas. [173]

11.3.2 State and Local Laws in the United States

A number of US states and cities have also passed relevant legislation. These include the following jurisdictions:

The US state of Maine introduced legislation prohibiting the sale of flavoured cigarettes in 2007. Maine (state): Public Law, ch 467 1556 (2007).

New Jersey introduced state legislation in 2008 to prohibit the sale of certain flavoured cigarettes. *An Act Banning the Sale of Certain Flavored Cigarettes*, P.L. 2008, c. 91, codified at N.J.S.A. 2A: 170-51.5.

New York City has introduced local laws to regulate flavoured cigarettes. These include:

- New York City: *Local Law to amend the New York city charter and the administrative code of the city of New York, in relation to the regulation of tobacco products*, Local Laws of the City of New York for the year 2009, No. 69, enacted October 28, 2009.
- Restriction on the Sale of Certain Flavoured Tobacco Products, chapter 28, Rules of the City of New York, Section 1, Title 24.

Santa Clara County (California) has introduced a relevant local ordinance, *An Ordinance of the Board of Supervisors of the County of Santa Clara Adding Chapter XXIII of Division A18 to the County of Santa Clara Ordinance Code Relating to Tobacco Retailer Permits*, Ordinance No.NS-300.832, adopted November 23, 2010.

A number of state Attorney Generals reached agreement on the sale of flavoured cigarettes as part of the Master Settlement Agreement with tobacco companies.

11.4 Thailand

Thailand passed the Tobacco Product Control Act (TPCA) in March 1992, and the law became effective from 5 June 1992. [160]

Section 11 of the Act states that *'tobacco products to be sold shall have the composition in accordance with the standards prescribed in the Ministerial Rules. In*

case where the composition of any product does not comply with the standards prescribed in paragraph one, the Minister shall have the power to order the prohibition of sale or import of such tobacco product.' [160]

The subsequent development of a Ministerial regulation specifying the standards proved problematic. This regulation was not approved until 1995, with a further two-year wait before it was signed into law. Ingredients information was finally supplied by transnational tobacco companies to the Thai Ministry of Public Health in 1998, with the crucial qualification that it remain confidential. [160]

Section 29 of the Act sets out the penalties for violations of section 11. [150] Section 29 states that *'Any manufacturer or importer failing to inform the particulars or informing incomplete particulars or informing false particulars or selling or importing the tobacco products in violation of Section 11 shall be subject to an imprisonment not exceeding six months or a fine not exceeding one hundred thousand baht or both*'. At the time of law enactment, 100,000 Baht was equivalent to US$4000. [160]

11.5 New Zealand

Annual Tobacco Returns are filed by manufacturers and importers pursuant to section 35 of the *Smoke Free Environments Act 1990*. Regulation 36 of the Smoke Free Environments Regulations 1999 provides guidance on the form for returns and reports.[178]

Section 33 of the Act requires every manufacturer and every importer of a product to conduct:

- a test for the constituents of each brand of the product sold by the manufacturer or importer, and the respective quantities of those constituents;
- if the product is intended to be smoked, a test for the constituents of the smoke of each brand of the product sold by the manufacturer or importer, and the respective quantities of those constituents;
- If the regulations require it, each variant of the brand must be tested separately;
- product means anything that is:
  (a) a tobacco product of any kind; or
  (b) herbal smoking products generally; or
  (c) herbal smoking products of any kind.[179]

Section 35 of the Act requires every manufacturer and every importer of tobacco product to file with the Director-General, in the prescribed manner:

(1) (a) a return showing:
  (i) by class of tobacco product, or brand of tobacco product of any class, or variant of a brand of tobacco product of any class (as the regulations may require) the weight of tobacco and of each additive

used in the manufacture of the tobacco products sold by the manufacturer or importer during the previous year; and

(ii) the quantity of each brand, and of each variant of a brand, of tobacco product sold by the manufacturer or importer during the previous year; and

(iii) the recommended price of each brand, and of each variant of a brand, of tobacco product sold by the manufacturer or importer during the previous year; and

(b) a report of the results of all tests that the manufacturer or importer conducted during the previous year for the purposes of section 33 or 34.

(2) The Director-General:

- (a) must take all practicable steps to ensure that all returns and reports received under subsection (1) are publicly available on a website under the Director-General's control; and
- (b) may publish or make publicly available in any other way all or any part of any such return or report. [179]

11.6 France

The relevant legislation is Decree No. 2009-1764 of 30 December 2009 concerning the composition of flavoured cigarettes. Section IV of the Public Health Code sets out the maximum level of ingredients giving a sweet and/or tangy flavour to cigarettes as follows:

- vanillin 0.05% of the mass of tobacco;
- ethyl vanillin 0.05% of the mass of tobacco:
- sweetener applied on the cuff of the cigarette-analytical detection limit. [180]

11.7 Lithuania

The relevant legislation is the Hygiene Norm HN 38:2009 'Maximum Amount of Hazardous Substances permitted in Tobacco Products' approved by the Order No. V-736 of the Minister of Health on 11 September 2009.[181]

Tobacco product manufacturers and/or importers were required to submit an annual report about the ingredients used in the manufacture of tobacco products in an approved format to the Government. The report must contain information about the ingredients present in tobacco products by brand name, trademark and type, the quantity, category and function of such ingredients, the reasons for including them in tobacco products, the toxicological data available and the testing methods, and the effects of such ingredients on human health, including any addictive effects.

The legislation sets out the maximum permissible concentrations of pesticide residues in tobacco products as well as a list of forbidden substances.[181] These

include:

Table 2. List of Forbidden Substances

Name (English)	Name (Latin)
Agaric Acid	*Acidum agaracinium*
Birch Tar Oil	*Oleum betulae empyreumaticum*
Tansy Herb	*Herba tanaceti*
Yellow Melilot	*Melilotus officinalis*
Juniper Tar Oil	*Oleum juniperi empyreumaticum*
Camphor	*Camphora*
Camphor Oil	*Oleum camphorae*
Camphorwood	*Lignum camphorae*
Bitter Almond Oil	*Oleum amygdalorum amarum*
Woody Nightshade Stems	*Stipites dulcamarae*
Areca Nut Palm	*Areca catechu*
Coumarin	*Coumarinum*
Vanilla plant	*Liatris odoratissima*
Sweet Woodruff	*Asperula odorata*
Cloves	*Syzygium aromaticum*
Soap Bark	*Cortex quillaiae*
Quassia Wood	*Lignum quassia*
Rue Herb	*Herba rutae*
Indian Tobacco	*Lobelia inflata*
Safrole	*Safrolum*
Oil of Sassafras	*Oleum sassafras*
Sassafras Leaves	*Folia sassafras*
Sassafras Wood	*Lignum sassafras*
Sassafras Root Bark	*Cortex sassafras*
Polypody Rootstock	*Rhizoma polypodii, Rhizoma filicis dulcis*
Pennyroyal herb	*Herba menthae pulegii*
Tonka Beans	*Dipteryx odorata*
Thujone	*Thujonum*

Source: Lithuanian Hygiene Norm HN 38:2009 On Maximum Permissible Amounts of Harmful Substances in Tobacco Products.[182]

11.8 United Kingdom

Of relevance is the Voluntary Agreement on the Approval and use of New Additives in Tobacco Products in the United Kingdom. The Voluntary Agreement lists almost 600 ingredients permitted for use as additives in tobacco products in the UK.[183]

The list includes additives recorded in Appendix VII of the Second Report of the Independent Scientific Committee on Smoking and Health, Appendix 1 of the Committee's Fourth Report and in the Department of Health list of Permitted Additives to Tobacco Products in the United Kingdom together with any additional permitted but previously unpublished additives arising from the Voluntary Agreement on Additives to Tobacco Products. These may be applied either at a stage in the manufacture of, or directly to, the final tobacco blend or paper. [183]

Certain additives are permitted only for use in the course of manufacture of tobacco sheet or cigarette paper (as specified), providing that no free residue remains. 'Paper' is defined as sheet manufactured from cellulose derived from wood, flax, hemp, jute, esparto, ramie and other vegetable fibres. [183]

Additives are listed alphabetically under their more commonly used names, with some alternatives in the adjoining column. Percentage inclusion limits are calculated on a dry weight tobacco basis, except for cigarettes where the weight of cigarette paper and associated adhesive are included. Maximum aggregate limits for permitted additives are designated below, depending upon whether they are assigned the label List 1 or List 2. [183]

The UK Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002, which transposes the EU Tobacco Products Directive (2001/37/EC), requires manufacturers to submit information on all ingredients used in the manufacture of their products. This legislation was implemented in 2002.[184]

Provision of further product information

12.—(1) A producer of tobacco products shall, before 1st October in each year, provide to the Secretary of State for each tobacco product he produces by brand name—

(a) a list of all the ingredients of that product which shall—

(i) include the quantities of those ingredients, and

(ii) be drawn up in descending order of the weight of those ingredients;

(b) a statement of the reasons for the inclusion of those ingredients which shall indicate for each ingredient—

(i) its function,

(ii) its category;

(c) all toxicological data available to him concerning the ingredients of that tobacco product—

(i) in the case of products intended to be burnt, and unburnt,

(ii) in the case of products not intended to be burnt, unburnt

which shall for each ingredient—

(iii) refer in particular to their effects on health,

(iv) include any effects produced in combination with any of the other ingredients of that product that are not produced by that ingredient alone, and

(v) take into account any addictive effects.

(d) information concerning the renaming or discontinuation of any brand produced by him within the 12 months preceding that 1st October.

The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 are available online at: www.legislation.gov.uk/uksi/2002/3041/contents/made

11.9 Findings from the Literature on Regulatory Arrangements

There are a number of recommendations contained within the published literature in regard to the regulation of tobacco products and tobacco product disclosure arrangements.

The recommendations contained in Articles 9 and 10 of the WHO FCTC and the associated Guidelines are detailed in Section 2 of this report. In summary, they commit countries to:

- *developing guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions;*
- *require manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products and implement effective measures for public disclosure of information.*[9]

In addition, the Guidelines recommend that member countries take action to:

- require manufacturers and importers to disclose information on ingredients used at each stage of the manufacturing process;
- require manufacturers and importers to disclose information about design features;
- prohibit or restrict ingredients that may be used to increase palatability, have colouring properties, create the impression that they have a health benefit or are associated with energy and vitality (such as stimulant compounds);
- require manufacturers and importers to report on sales to assist with effective product regulation.

Bates et al. [4] recommends the development of a regulatory framework primarily focussed on reducing toxicity, where the manufacturer is obliged to demonstrate that no additional harm arises from tobacco product design decisions such as the use of an additive. This approach is also relevant to a regulatory framework focussed on palatability. Bates et al argue such a framework should include the impact of additives on smoking behaviour, passive smoking and fire risks. They argue that it is impossible to make safe cigarettes; however, it is perfectly reasonable to prevent the manufacturers doing things that lead to an increase in the harm caused by tobacco. They identify the following elements:

1. Disclosure: manufacturers and importers should be required to disclose all additives used in tobacco products, by brand, to a regulator.

2. Public information: such information should not be confidential, but made available to the public through publications, the internet or on request from the regulator.
3. Packaging: there may be some additives that should be listed as ingredients on tobacco product packaging. The right approach will depend on assessment of the direct value of such information to consumers.
4. Disclosure of purpose: tobacco companies should be required to disclose the purpose of an additive and any secondary consequences, whether intentional or unintended.
5. Conduct and disclosure of research: tobacco companies should be required to undertake extensive toxicology and pharmacological testing of all additives.
6. Regulatory challenges: regulators should have the power to challenge any of the existing additives currently allowed and to have them removed until the manufacturer is able to show that no extra harm to the public arises as a direct or indirect result of the additive. If it is impossible to supply evidence, for example because of restrictions on animal testing, then under a precautionary approach the additive should be banned.
7. Focus on pharmacologically active additives: there should be an automatic challenge to any additive thought to have a direct or indirect pharmacological influence. New additives should be permitted only if the manufacturer can show that no extra harm or other net negative consequences arise from use of the additive.
8. Permit essential additives: any regulatory framework should permit additives necessary for the manufacture and storage of tobacco products providing these are safe, but should challenge all additives that may influence smoking behaviour. [4]

Gray and Borland [19] identify three major regulatory options:

- **Regulating carcinogens and toxins:** numerous components of tobacco smoke are either carcinogenic or toxic, or both, and the prime objective of regulation is to reduce this. Some of these chemicals come from the tobacco itself, and are common to smokeless forms, but most come from the smoke. This is why smoking is inherently more harmful than smokeless tobacco use. A regulatory approach could set upper limits on individual carcinogens and toxins, and be used to reduce potential harmfulness.

- **Regulating nicotine (addictiveness):** tobacco products are addictive, and addictiveness is positively related to consumer appeal. Cigarettes have the highest abuse liability of tobacco products, with more than 85 per cent of users smoking daily. Efforts to regulate the reduction of the addictiveness of

tobacco would therefore focus on regulating nicotine, as nicotine is the drug that is central to tobacco use. Options include eliminating nicotine, reducing levels of nicotine and by regulating the forms of delivery systems.

- **Regulating additives and engineering features**: for products as harmful and addictive as cigarettes, a powerful case can be made that it is not acceptable to modify the product in ways that mask some of the unpleasant side effects, such as the natural harshness of nicotine, as these would be a disincentive to initiate the use of tobacco. Therefore, additives and engineering features that mask harshness of tobacco smoke should be prohibited as a means of reducing use.

In regard to regulating carcinogens and toxins, the WHO Study Group on Tobacco Regulation [85] recommended the setting of upper limits on nine specific smoke constituents. The Conference of the Parties (COP) Working Group identified the same nine constituents as priorities for which methods of testing should be validated. The nine substances recommended for regulation are:

- N-nitrosonornicotine (NNN)
- 4-(N-nitrosomethylamino)-1-(3-pyridil)-1 butanone (NNK)
- acetaldehyde
- acrolein
- benzene
- 13-butadiene
- benzopyrene
- carbon monoxide
- formaldehyde.

A number of other substances were identified as priorities for reporting (disclosure) arrangements:

- acrylonitrile
- 4-aminobiphenyl
- cadmium
- catechol
- crotonaldehyde
- hydrogen cyanide
- hydroquinone
- 2-naphthylamine
- nitrogen oxides.

Gray and Borland [19] suggest that measures of carcinogens/toxins should be reported per mg of nicotine delivered. The rationale for using exposures per mg of nicotine is that smokers tend to titrate their nicotine intake. There are other advantages of

testing per mg of nicotine as it is a standard that can be applied to just about any tobacco product, including such categories as large cigars, which are designed to provide multiple doses of nicotine.

Kozlowski et al. call for filter ventilation to be banned as it is the major influence on the mildness of the smoke, an important characteristic that influences uptake. [76] Gray and Borland argue that even parts of the tobacco industry claim to support some limited forms of regulation. For example, the Annual Report of the Philip Morris Company (14;14) for 2010 (page 26) states that the European Commission and some countries are considering regulating 'cigarette ingredients' with the stated objective of reducing 'attractiveness' and 'palatability'. Philip Morris '… **opposes** regulations that ban ingredients to reduce palatability' but **supports** a ban on ingredients '… that are based on sound scientific test methods and data to significantly increase the inherent toxicity and/or addictiveness of smoke'. [19]

However, Gray and Borland caution against adopting such a narrow perspective, and state that: '*Reducing the attractiveness of toxic products could potentially do more to reduce harm than reductions in their toxicity*'. [19]

As this literature review reveals, there is a clear discrepancy between the tobacco industry's public stances on whether ingredients make cigarettes more palatable and the industry's real understanding of the actions of additives studied for many decades and detailed in tobacco industry documents.

Any effort to regulate tobacco products also needs to be cognisant of the potential for consumers to misconstrue regulation of tobacco products as meaning that the regulation has resulted in greatly reducing the harms (when at most, it will only reduce them a small amount), and thus counteracting the public health message to avoid tobacco use altogether. [7 19]

Product regulation needs to occur within a framework that does not seriously interfere with societal efforts to reduce tobacco use. [7 19]

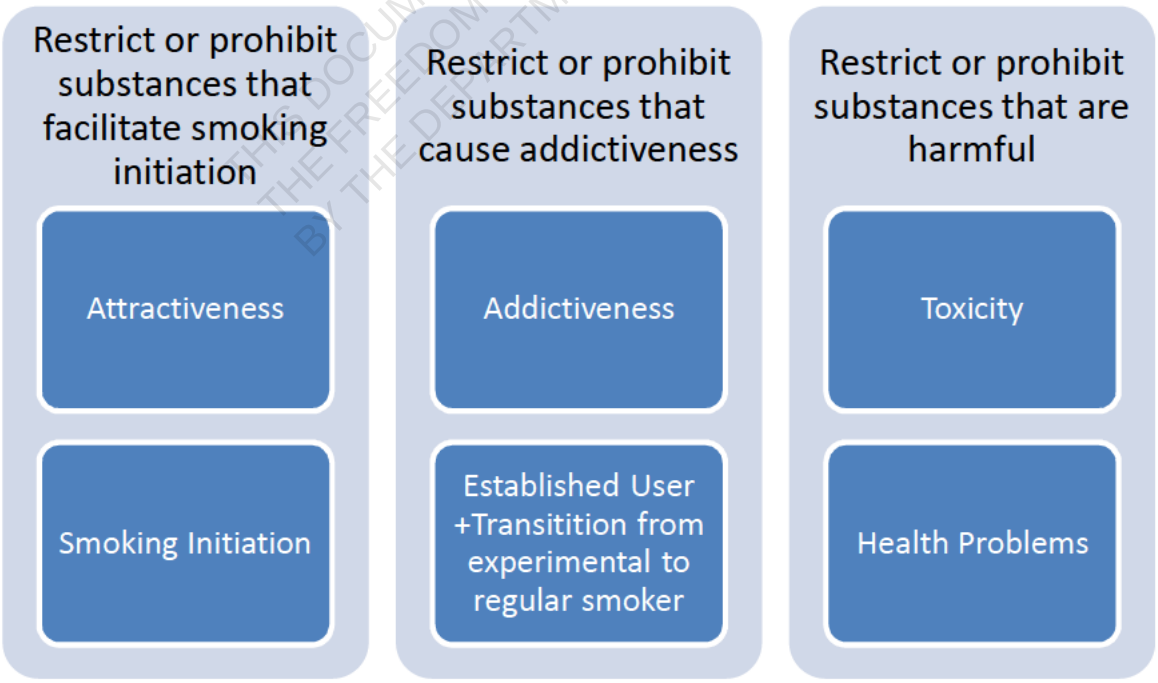
11.10 Effective Tobacco Product Regulation

Based on our review of the literature and analysis of existing regulatory models, we believe there are three major options for product regulation:

1. regulate factors that influence palatability/attractiveness of cigarettes;
2. regulate factors that influence addictiveness of cigarettes;
3. regulate factors that influence toxicity. [17]

Regulatory Option	Approach	Desired Outcome	Target Group
Regulate factors that influence palatability/ attractiveness of cigarettes	Restrict or prohibit substances or engineering features that facilitate smoking initiation	Reduce uptake	Young people and other novice smokers
Regulate factors that influence addictiveness of cigarettes	Restrict or prohibit substances that cause addictiveness	Reduce addictiveness of tobacco	Established smokers; and young people transitioning from experimental to regular smoking
Regulate factors that influence toxicity	Restrict or prohibit substances that are harmful	Reduce toxicity of tobacco products/health benefits	All smokers

Figure 5: Approaches to tobacco product regulation



Source: Adapted from Health Canada.[185]

In our view, this literature review demonstrates there is strong evidence that the use of additives influences the palatability of tobacco products and has an impact on smoking behaviour especially among young people and other novice smokers. This review also demonstrates that there is sufficient evidence of effective approaches to prohibit or restrict the use of additives in tobacco that could be introduced immediately.

Section 12 Identification of Gaps in the Research

There is considerable scientific uncertainty regarding the specific impact of additives on human health.

To date, most attention on the harms related to cigarette additives has focused on the toxicity of the additives and whether they pose direct additional health risks for the smoker, thereby making smoking a more hazardous activity.

The complexity arises because little is known outside the tobacco industry about the technologies and formulae involved in making individual products.[186] The chemical composition and the physiological and pathological effects of the majority of additives are largely unknown to the public health community. What is established is that *'cigarettes are highly engineered and sophisticated products designed to give fingertip control of nicotine intake while masking unpleasant tastes and aromas … are widely used and highly addictive'.* [186]

As Fowles asserts, these uncertainties can be identified and subjected to various avenues of scientific inquiry, however, they should not become hurdles to regulatory action and the Precautionary Principle should prevail. [8]

The research priorities focus on what Australia needs to know to progress towards more effective product regulation that covers additives and engineering features associated with palatability. The central question we will address in this section is not what is unknown (a huge topic that could consume researchers for decades), but what needs to be known to advance public policy to reduce tobacco-related harms (that is, fulfil Australia's obligations under WHO FCTC and to its people). The problem with taking this approach is that specifying the research that is needed is partly dependent on the policy options that are being considered.

In the following analysis, we assume that one policy option, that of requiring proof of potential harm before regulating any additive is not realistic, and thus we do not focus on the research needed to pursue it. This is because the vast numbers of additives used by the tobacco industry preclude the possibility of government agencies investigating the physiological impact of each and every ingredient. [8] Rather, as Gray and Borland have argued, governments should put the onus on the industry to provide detailed information on cigarette additives. [19]

The research needs are divided into five broad subsections:

1. independent research dependent on more extensive industry disclosures;
2. research that the industry should be required to conduct and report on;
3. independent research that can be conducted independently of industry;
4. research on public understanding and communication needs;

5. the surveillance system required to evaluate the impacts of any policy advances.

Beyond the scope of this report, there is also a need for more research on the balance of benefits of filters themselves and on the possible implications of setting lower limits of the pH of tobacco smoke to inhibit lung inhalation as suggested by Robert Proctor in his recent book The Golden Holocaust.[13]

12.1 What More Can We Learn from Current Industry Disclosures?

Given the shortcomings of the current Voluntary Agreement there is a limited amount to be learned from current industry disclosures. However in part two of this project we conducted analysis to identify whether any new additives had been included and any old additives were no longer reported on the disclosure lists. We also conducted analysis to determine whether there had been any changes in the reported maximum levels of additives that were disclosed. These analyses are reported in the *Analysis of Australian Tobacco Companies' Voluntary Disclosures on Cigarette Ingredients*. (A report prepared for the Department of Health and Ageing by King et al. 2012).[31]

The most general conclusion that can be drawn from these analyses is that the ingredient disclosures provide evidence of a substantial amount of change occurring in the use of additives by the Australian manufacturers in the period between 2000 and 2012. The changes have not simply occurred in the direction of declining use of additives – a conclusion that is suggested, but not demonstrated, from the declining numbers of additives disclosed by all three manufacturers in the composite disclosures. It remains possible that early disclosures of large numbers of additives, include some that might be used or had been used (here or elsewhere), but which were not currently being used in Australia. [31]

While the composite disclosures show a general trend of declining numbers of additives disclosed between 2000-1 and 2010-11, new additives have been reported in most years and increases in the maximum levels used have also been reported for some additives. A major limitation impacting on the by-brand analysis was that current Australian disclosure arrangements are not comprehensive. The possibility of quantitative cut off provisions, and this possibly differing by overall lists and brand-specific lists, mean that even brands that are reported as having no additives on the disclosure may still contain additives that are not disclosed. This is only a problem for the by-brand disclosure data, where it is unclear if a cut-off has been applied and if so, what that the cut-off might be. [31]

The brand by brand disclosures also provide evidence that, rather than having a fixed recipe for each brand variety which is adhered to each year, there is some degree of year by year variation in the reported additives used. One possibility is that there is a particular set of smoking characteristics (including flavour, aroma and

smoothness) sought after by the manufacturers and changes are made in the additives used in order to achieve the standards for those brand varieties in a context of changing characteristics of the tobaccos used (ie tobacco product characteristics presumably vary by growing conditions, both climatic and related to soil type). Another possibility is that the varying availability and/or cost of particular additives may produce year by year variation in their use. No information is available on additives that fall below the quantitative cut off point, if one has been applied. [31]

The brand by brand disclosures also provide strong evidence that the manufacturers take somewhat different approaches to producing palatable cigarettes. All three manufacturers have some brand varieties which are reported to contain no ingredients apart from tobacco and water (but may contain additives below a quantitative cut off point, if one has been applied), and all three manufacturers have some brands which are reported to contain sugars, humectants, casings and top flavours. However, PMI had a much greater proportion of brands than the other two manufacturers which were reported as containing ingredients other than tobacco and water. One possibility is that Imperial Tobacco and BATA allow a greater degree of variation in the taste, aroma and smoothness characteristics of their brands. Another possibility is that Imperial Tobacco and BATA are able to achieve a high level of standardization of these characteristics using selection of tobacco feedstock, whereas PMI is more reliant on using additives to achieve standardization. [31]

12.2 Research Requiring More Extensive Industry Disclosures

Clearly, what can be done is a function of what is disclosed. Section 2.5 of this report contains a summary of the Voluntary Agreement and a brief critique of the current approach.

Several countries have introduced legislation to require manufacturers to disclose important and detailed information on the use, pharmacological effects and toxicity of additives. Requiring the tobacco companies to disclose all ingredients and additives and their purpose by brand, and at each step of the manufacturing process, represents the most effective first step for addressing this knowledge gap.

The disclosure arrangements that have been put in place in countries such as Thailand, New Zealand, the United States and Canada will strengthen the

knowledge base on the use of additives by tobacco companies in general. The regulatory frameworks that have been introduced in the United States and Canada offer particular opportunities to increase the evidence base around cigarette additives, as they have the technical capacity and resources to undertake comprehensive regulation.[186] In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the FDA the authority to regulate the manufacture, distribution and marketing of tobacco products to protect public health, and this has already led to a number of actions being taken. [175]

Disclosure arrangements in line with those recommended in the Guidelines for WHO FCTC Articles 9 and 10 could ensure that more useful information is available to governments on the use of additives on a per brand basis in the manufacturing process steps, as well as the characteristics of the tobacco leaves used, and information on the use of reconstituted and expanded tobacco in Australian brands.

We consider what could be disclosed at two levels. The first level is information that is likely to be already available to the tobacco companies, so where disclosure could be achieved rapidly, with potential for historical disclosures as well.

The first and perhaps most important disclosure is of total sales by brand variant. This is critical for a range of surveillance issues, and should be provided on a regular basis, at least monthly.

Beyond this, the other disclosures relate to the characteristics of each product. Disclosures should be made on an annual basis, or where the company changes its specifications for a variety, and also at the time of the change.

These disclosures include the provision of information on product-specific engineering: weight is currently provided, but measures of standard deviation or some other index of tolerance would be useful; indeed, measures of variability are needed for the vast majority of components.

We do not provide an exhaustive list here; suggested lists have been provided previously and are listed in previous reports to Government. However, the disclosures should include details of filter size and some filter characteristics (for example the thickness and characteristics of the cellulose acetate), along with details of the mix of tobaccos used (including proportions and varieties of expanded or reconstituted tobacco), levels of filter venting and positioning of vent holes, paper porosity and nicotine content of the tobacco. Detail should be also provided of instances where additives are added to part of the tobacco mix, and what parts, plus total percentage additives per variant, by the reported types of additive. This information would allow researchers to work out more clearly the relationship between additives and other engineering features; for example, to determine whether highly filter-ventilated cigarettes actually do have greater percentages of additives.

This is particularly important given that the Australian market, unlike many other countries such as the United States, is dominated by Virginia-style cigarettes. Tobacco company documents reveal the extent to which products are re-engineered and adapted to meet the requirements of the individual market in each country. Addressing this knowledge gap requires regulatory arrangements to establish consistent and comprehensive disclosure of information about Australian brands that can be monitored over time.

Another issue is cigarette types that use additive types other than flavourings. In addition to disclosure on cigarettes, disclosures need to be made on roll-your-own tobacco, as this is widely used, and perhaps also of other less used tobacco products. This will allow us to answer such questions as: are the levels of additives in roll-your-own tobacco different from that in factory-made cigarettes, and what variability is there between roll-your-own varieties and brands on the Australian market?

Flavourings in tobacco products are included to increase the appeal of particular products to sub-sections of the existing and potential cigarette market. We do not know which mixes of flavours appeal more to each target market, except for some limited information on menthol, which is by far the most distinctive flavouring used commonly in the Australian market. In our view, it is not necessary to identify target markets to justify action, although it might be true that this could aid the advocacy task in gaining support for the removal of specific flavourings (for example, if it could be shown that some flavourings were particularly important for attracting novice smokers, such as children and young people).

Consideration does need to be given to the value of requiring detailed by-variant disclosures of complete brand recipes, including all flavourings, but as such information will be extensive, consideration will also be needed to finding the capacity to analyse it. The ITC data may provide a useful data source on brand use if more comprehensive disclosure arrangements are introduced in the future.

12.3 Research that should be Required of the Industry

In many cases, the tobacco industry is in a better position to conduct research than independent researchers, as it controls product manufacture and currently can manipulate its products at will. The main constraint is possible adverse consumer reactions. Given the history of duplicity, one should be careful about recommending a role for tobacco company research as part of tobacco control efforts, but there are areas where it may be appropriate.

12.5 Communicating with the Public

There is a need to establish a protocol to test different ways of communicating why additives are being removed and to explain how this reduces one of the outcomes (attractiveness; addictiveness; toxicity), while at the same time not discounting the risks of smoking tobacco itself.

How can governments and regulators best publicly communicate their efforts to reduce tobacco-related harm in ways that do not lead to unrealistic expectations about reduced harm? Governments will also need to manage the reality that regulation will show some tobacco products to be far lower in carcinogens/toxins than others. This is an issue that will vary depending on policy decisions about the desirability of substitution of more for less harmful alternatives.

12.6 Surveillance and Evaluation

The main level of evaluation of the effects of product regulation is likely to be its summative effects on patterns of tobacco use. As noted earlier, evaluation studies should include research on initiatives in other jurisdictions.

Surveillance needs to include the regular provision of brand and variant-specific data, including sales data. It is also important to have good survey data of tobacco users.

Australia needs to ensure that it has ongoing surveillance of tobacco use by brand and variant used, both for adolescents and adults. Currently, brand data is collected for adolescents, but not variant, and while both are collected in the ITC (Australia) survey, there is no guarantee that this survey will continue into the future (being funded from research project grants).

To evaluate the impacts of product regulation on tobacco use, both cross-sectional and longitudinal data are required; the latter to explore patterns of brand/variant shifting, the former to assess overall market shares and relate this to particular types of smoker.

There is also a need to develop more sensitive methods of tracking illicit tobacco use, to assess any effects of regulatory changes on the demand for illicit products (presumably those not meeting new standards).

Section 13 Analysis and Conclusions

The focus of this report is on the contribution of additives, and to a lesser extent other aspects of cigarette engineering (notably filter ventilation), on the palatability of tobacco and their impact on smoking behaviours and human health. This report also reviews the literature to identify and describe regulatory approaches to controlling the use of additives and identifies gaps in the existing evidence base.

There is evidence of the use of a large number of additives in tobacco. The most common additives declared in the voluntary disclosure lists are in the form of sugars, humectants, menthol, cocoa and liquorice. A large number of other flavourings are used in Australian cigarettes. Around 200 additives, excluding those related to papers, filters, adhesives and inks, are reported in the voluntary disclosure lists, and the vast majority are identified by the tobacco manufacturers as flavours.

It is clear that most of the flavours listed in Australia are added to tobacco in very small quantities and are 'top dressing' flavours. Despite the small quantities used, tobacco company documents confirm their importance in terms of flavour and aroma, and achieving a milder and more palatable cigarette. Philip Morris also reports the use of liquorice extract, carob bean and/or extract and cocoa and cocoa products as casings. BATA and Imperial also use these additives, and report them as flavours.

The use of cigarette engineering features, in particular filter ventilation, also has a very significant impact on a smoker's perception of cigarettes and their smoking behaviour. Filter ventilation is present in the vast majority of Australian cigarettes, and results in a 'lighter' or 'milder' taste because the perforations in the filter dilute the smoke. [16 76]

Tobacco company documents reveal that during the 1970s and 1980s there was considerable research done on new aromatics for the enhancement of smoke taste and aroma, a trend reflected in patents on aroma chemicals and flavour compositions. [37 73 150]

There is increasing international consensus among tobacco control experts that the use of additives should be regulated. Articles 9 and 10 of the WHO FCTC recommend member countries regulate tobacco ingredients and disclosure arrangements. The Partial Guidelines provide useful guidance for the development of comprehensive regulatory approaches. [7 9]

There is evidence that increasing the palatability of cigarettes provides an indirect mechanism by which additives and engineering features such as filter ventilation may increase the harm at a population level by promoting smoking uptake and discouraging cessation. [21] As the European Commissions Scientific Committee on Emerging and Newly Identified Health Risks describes it:

'In other words, additives and engineering features such as filter ventilation may function to increase the number of smokers within the population and also to increase the duration of their smoking "careers", relative to what would be likely if the tobacco industry did not have those means available to it.' [21]

There are three critical issues in relation to the use of additives and filter ventilation:

- Do they increase the toxicity of cigarettes?
- Do they increase the addictiveness of cigarettes?
- Do they increase the palatability and attractiveness of cigarettes?

Until recently, most debate and concern in the public health community has focused on the issue of increased toxicity of cigarettes associated with additive use, and whether they directly increase the harms caused by smoking through increasing smokers' exposures to carcinogens and cardiovascular/respiratory toxins on a per cigarette basis. Certainly, tobacco company scientists have published research that claims to demonstrate there is no increase in toxicity of cigarettes associated with the use of additives. However, as pointed out by other researchers, the research designs were weak and unlikely to find any but extremely large increases.

There are a number of gaps in the evidence base regarding the toxicity and pharmacological effects of individual additives. It is likely that this knowledge is known only to tobacco companies, although the introduction of cigarette ingredient disclosure laws in countries such as the United States and Canada are expected to increase the knowledge base in this area. The applicability of this information to Australian brands, however, is less certain, particularly given the differences between the US market and Australian Virginia-style cigarettes.

The situation with regard to the impact of additives in relation to the addictiveness of cigarettes is more complex. There is evidence to show that attempts have been made by tobacco companies to alter the addictiveness of tobacco products, or at least the capacity of cigarettes to deliver nicotine effectively to the brain. It is less clear how much of this knowledge has been applied to cigarettes currently available on the Australian market.

There is, however, a substantial body of evidence demonstrating a significant amount of tobacco industry activity to improve the palatability of its products. [4 8 10 18 38 73] Tobacco company documents confirm that although many flavour additives are used in small amounts, they have an extremely significant impact on cigarette products. [14] Tobacco companies also extensively researched flavour characteristics that would appeal most strongly to young people. Tobacco industry documents confirm the importance of smoothness, mildness and sweetness characteristics in attracting young people and novice smokers. [35]

There is also substantial evidence about the impact of filter ventilation on the palatability of cigarettes. Filter ventilation is the most important cigarette design feature influencing flavour, strength, harshness and irritation [16 76] The 'lighter' or 'milder' taste can support the smoker's perception that these cigarettes deliver less tar and nicotine, as well as diminished dangers to health. [16 76]

Several countries, including the United States, Canada, Thailand and Brazil, have introduced legislation to prohibit or restrict the use of flavourings and additives. A number of elements of effective regulatory practice have been identified from the literature and analysis of existing regulatory models.

To our knowledge, despite the strong evidence of the important influence of filter ventilation on palatability and attractiveness, no country has regulated this aspect of cigarette engineering to date.

In conclusion, this report provides strong evidence that by altering the flavour and aroma of cigarettes, and masking the harshness associated with tobacco smoke, additives and filter ventilation can make cigarettes easier to smoke, and therefore more attractive to young or beginner smokers, contributing to the uptake of smoking, ongoing use and tobacco-related disease. [4 8 10 11 13]

Regulating the use of additives and aspects of cigarette engineering such as filter ventilation would be consistent with Articles 9 and 10 of the WHO FCTC. Most importantly, however, regulating these aspects of cigarettes would provide a significant opportunity to reduce the uptake and prevalence of smoking, and reduce future tobacco-related harm in Australia.

Appendix 1- Colouring Agents Listed in 2011 Australian Cigarette Ingredient Returns

Monogram ink/Die print ink	
Pigment sunset yellow Pigment allura red AC Pigment brilliant blue FCF Pigment indigotine Pigment red lithol BK 0.0001 Pigment tartrazine 0.0001	Philip Morris
Acid blue 9 aluminium lake Allura red lake Blue (Patent V) Brilliant blue FCF Iron oxides (black, red and yellow) Orange yellow S Pentaerythritol Pigment green 7 Pigment red 172 Pigment red 53.1 Pigment yellow 100 Pigment yellow 104 Pigment yellow 174 Tall oil rosin Tartrazine yellow	Imperial
Allura red lake Brilliant blue FCF Brilliant blue FCF aluminium lake Erythrosine lake Indigotine lake Iron oxide black	BATA

Pigment green 7 Pigment red 57 Rosin resin Sunset yellow lake Tartrazine Tartrazine lake	
Filter paper inks/Tipping papers/Tipping inks	
Gold bronze Pigment iron oxide black Pigment iron oxide red Pigment silver Pigment brilliant blue FCF Pigment sunset yellow Pigment tartrazine Rosin Pigment quinoline yellow Pigment red lithol BK Pigment silver and/or gold Pigment blue 15:3 Pigment yellow 13	Philip Morris
Pigment iron oxide yellow Gold bronze Pigment iron oxide black Pigment iron oxide red Pigment silver Pigment brilliant blue FCF Pigment sunset yellow Pigment tartrazine Rosin	Imperial

Pigment quinoline yellow Pigment red lithol BK Pigment silver and/or gold	
Iron oxide yellow Pigment white 26 Iron oxide red Iron oxide black Rosin size Indigotine lake Erythrosine lake Brilliant blue FCF aluminium lake Quinoline yellow Bronze powder Pigment metal 1 Pigment metal 2 Amaranth colour Brilliant blue FCF Pigment blue 15.3 Pigment green 7 Pigment red 57	BATA

Appendix 2- Established List of the Chemicals and Chemical Compounds Identified by US Food and Drug Administration (FDA) as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke

Table 1: Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke

Constituent	Carcinogen (CA), Respiratory Toxicant (RT), Cardiovascular Toxicant (CT), Reproductive or Developmental Toxicant (RDT), Addictive (AD)
Acetaldehyde	CA, RT, AD
Acetamide	CA
Acetone	RT
Acrolein	RT, CT
Acrylamide	CA
Acrylonitrile	CA, RT
Aflatoxin B1	CA
4-Aminobiphenyl	CA
1-Aminonaphthalene	CA
2-Aminonaphthalene	CA
Ammonia	RT
Anabasine	AD
o-Anisidine	CA
Arsenic	CA, CT, RDT
A-α-C (2-Amino-9H-pyrido[2,3-b]indole)	CA
Benz[a]anthracene	CA, CT
Benz[j]aceanthrylene	CA
Benzene	CA, CT, RDT
Benzo[b]fluoranthene	CA, CT
Benzo[k]fluoranthene	CA, CT
Benzo[b]furan	CA

Table 1: Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke	
Benzo[a]pyrene	CA
Benzo[c]phenanthrene	CA
Beryllium	CA
1,3-Butadiene	CA, RT, RDT
Cadmium	CA, RT, RDT
Caffeic acid	CA
Carbon monoxide	RDT
Catechol	CA
Chlorinated dioxins/furans	CA, RDT
Chromium	CA, RT, RDT
Chrysene	CA, CT
Cobalt	CA, CT
Coumarin	Banned in food
Cresols (o-, m-, and p-cresol)	CA, RT
Crotonaldehyde	CA
Cyclopenta[c,d]pyrene	CA
Dibenz[a,h]anthracene	CA
Dibenzo[a,e]pyrene	CA
Dibenzo[a,h]pyrene	CA
Dibenzo[a,i]pyrene	CA
Dibenzo[a,l]pyrene	CA
2,6-Dimethylaniline	CA
Ethyl carbamate (urethane)	CA, RDT
Ethylbenzene	CA
Ethylene oxide	CA, RT, RDT

Table 1: Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke	
Formaldehyde	CA, RT
Furan	CA
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)	CA
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole)	CA
Hydrazine	CA, RT
Hydrogen cyanide	RT, CT
Indeno[1,2,3-cd]pyrene	CA
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	CA
Isoprene	CA
Lead	CA, CT, RDT
MeA-α-C (2-Amino-3-methyl)-9H-pyrido[2,3-b]indole)	CA
Mercury	CA, RDT
Methyl ethyl ketone	RT
5-Methylchrysene	CA
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	CA
Naphthalene	CA, RT
Nickel	CA, RT
Nicotine	RDT, AD
Nitrobenzene	CA, RT, RDT
Nitromethane	CA
2-Nitropropane	CA
N-Nitrosodiethanolamine (NDELA)	CA
N-Nitrosodiethylamine	CA
N-Nitrosodimethylamine (NDMA)	CA
N-Nitrosomethylethylamine	CA

Table 1: Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke	
N-Nitrosomorpholine (NMOR)	CA
N-Nitrosonornicotine (NNN)	CA
N-Nitrosopiperidine (NPIP)	CA
N-Nitrosopyrrolidine (NPYR)	CA
N-Nitrososarcosine (NSAR)	CA
Nornicotine	AD
Phenol	RT, CT
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine)	CA
Polonium-210	CA
Propionaldehyde	RT, CT
Propylene oxide	CA, RT
Quinoline	CA
Selenium	RT
Styrene	CA
o-Toluidine	CA
Toluene	RT, RDT
Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole)	CA
Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole)	CA
Uranium-235	CA, RT
Uranium-238	CA, RT
Vinyl acetate	CA, RT
Vinyl chloride	CA

Appendix 3-Summary Table of Additives and Engineering Features Identified in the Literature with Strong Relevance to the Palatability of Cigarettes

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
CATEGORY A: ADDITIVES IDENTIFIED AS HAVING A FLAVOUR FUNCTION IN AUSTRALIAN TOBACCO INGREDIENT LISTS				
Additives that have flavouring properties or that enhance flavour, including those identified in the Voluntary Agreement disclosure lists 2000–2012 as having a flavour function.	In 2011, the three tobacco companies listed around 200 separate flavour additives in the composite list of tobacco ingredients under the voluntary disclosure agreement. The tobacco companies disclose only the highest amount of ingredients used in their brands (i.e. Quantity Not Exceeded (QNE)). Therefore, it is not possible to draw conclusions about the average amount added or about the percentage of brands that contain a particular ingredient. It should also be noted that some brands are listed as not containing any additives – only	In Australia in 2011, around 200 additives were identified by the tobacco manufacturers as having a flavour function in Australian cigarettes. Thus there is an admission by the Australian tobacco companies using them that they are there to influence the flavour and aroma and overall palatability and attractiveness of cigarettes. Tobacco companies have systematically researched and developed a range of additives to influence the flavour, taste and aroma of cigarettes to alter the sensory qualities of cigarettes in order to create a smoother and milder smoking experience. [4 8 10 11 73 38] Flavours can be segmented into casings and 'top dressing' flavours. The border line between these two classes is not a clear one, and several materials overlap from one class to the other. Broadly, 'casings' are described as solid/semi-solid materials which are added in significant weight quantities to tobacco (kg/per 100 kg) usually as an aqueous 'liquor' or 'sauce' during manufacture. Top dressing 'flavours', on the other hand, are volatile, highly aromatic oils, usually applied to tobacco in very small quantities as an alcohol-based spray at the final stage of primary processing. [15] Most of the flavours listed are added to tobacco in very small quantities; however, they can be an important factor in achieving a milder cigarette and have a	Tobacco industry documents confirm the importance of smoothness, mildness and sweetness characteristics in attracting young people and novice smokers. [35] '*Despite the very small amounts of individual flavours (parts per million) used, they make a major contribution to taste and appeal which are part of the individual distinctiveness of cigarette brands*.' BATA [14] A Philip Morris document describes the various ways in which casings and flavours can be used in product development: [38] *'In processing, casings are applied prior to cutting to moisturize and soften the tobacco and reduce breakage. It is used to*	Canada prohibits all additives that have flavouring properties or that enhance flavour except for 21 specified substances. The US prohibits a *'cigarette or any of its component parts (including the tobacco, filter, or paper) from containing as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or a herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, liquorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor*

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	tobacco and water. Others are listed as containing tobacco, water and processing aids.	significant influence on palatability. [14] The literature identifies several additives that can influence the palatability of tobacco products, including menthol, sugar, liquorice, eugenol, cocoa, caffeine, and various herbs and spices and botanical products.	*subjectively improve the smoking characteristics of the cigarette, in addition to providing a cleaner tobacco taste, or eliminating, a mouth-coating effect if need be …'* Philip Morris[38] Tobacco company documents confirm that some Australian brands (e.g. Marlboro) did contain casings and Philip Morris continued to list casings in ingredient returns in 2011.	*of the tobacco product or tobacco smoke'.* Brazil has prohibited all additives except for eight specified additives/classes of additives. The eight additives are: adhesives, binding agents, combustion agents, technology auxiliaries, pigments, glycerol and propylene glycol, and potassium sorbate and sugar. [169 170]
Sugars and sweeteners	In 2011 ingredient lists, BATA lists sugar (brown, invert and white) as QNE 6.15 per cent of a cigarette by weight, Philip Morris lists a total of 7.1 per cent by weight (invert sugar and sucrose) and Imperial lists a total of 2.37 per cent (sucrose and invert).	Various sugars constitute a significant proportion of additives in cigarettes, and the sweetness of the product is an important characteristic that increases the attractiveness of cigarettes, particularly to children and young people. [8 21] The harsh and irritating character of tobacco smoke provides a significant barrier to children and other novice smokers experimenting with cigarettes.[9] The addition of sugars sweetens the taste of tobacco, making it easier to experiment with smoking and keep on smoking. The addition of sugar is particularly important for burley tobacco, and plays a lesser role in the Virginia, flue-cured cigarettes that dominate the Australian market.	Tobacco industry documents confirm the importance of additives such as sugar and liquorice in influencing the sensory perceptions of smoker. Connolly et al. describes RJ Reynolds' research of a product that would successfully appeal to the first time smoker: '*Two key areas identified for improvement were*	Canada has prohibited sugars and sweeteners excluding starch. Canada is a predominantly Virginia-style tobacco market similar to Australia. Brazil has prohibited all additives except for eight specified additives. Sugar is one of them.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	BATA also lists sorbitol.	Appealing to younger smokers is essential for the long-term continuation of the tobacco industry. Peer-reviewed studies of tobacco industry documents confirm that the industry identified the importance of smoothness, mildness and sweetness characteristics in designing brands to attract young people and novice smokers. [35] The European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on the Addictiveness and Attractiveness of Additives states that the presence of sugars in cigarettes is associated with a more favourable taste. The experience of the smoke is less negative and the irritability is somewhat masked. [21] The tobacco producers have used additives that create sweetness and taste in the smoke to make it easier for new smokers to start smoking, since these tobacco products do not have the same harshness and bad experience at the first inhalations.	*smoothness and sweetness delivery. Smoothness is an identified opportunity area for improvement versus Marlboro, and sweetness can impart a different delivery taste dimension which younger adult smokers may be receptive to, as evidenced by their taste wants in other product areas.*'	However, it is specified that the permitted sugars are exclusively for restoration of the content sugar originally present in the tobacco sheet before the process of drying. It is likely that sugar has been permitted because a high proportion of tobacco used in cigarettes in Brazil is burley tobacco, rather than Virginia-style cigarettes popular in Australia and Canada.
Vanillin/ethyl vanillin/vanilla	In 2011 ingredient lists, BATA lists ethyl vanillin at QNE 0.00066 per cent, vanillin at 0.00540 per cent and vanilla oleoresin at 0.00049 per cent, a total of QNE 0.0065 per cent by weight. Philip Morris lists vanilla extract; vanilla and	The flavouring additives vanillin and ethyl vanillin are added to tobacco to impart a vanilla flavour to the smoke. Vanilla may effectively sweeten tobacco smoke. [8 10 13]		Prohibited in Canada and Brazil.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	ethyl vanillin at a total QNE 0.006 per cent, and Imperial lists QNE 0.0046 per cent.			
Liquorice	In 2011 ingredient lists, Philip Morris lists liquorice at QNE 0.7 per cent by weight (as a casing), BAT at 1.04156 per cent (flavouring) and Imperial lists it at 0.11 per cent (as flavourings).	Liquorice has been widely used in cigarettes for many years. Ingredient lists identify that liquorice is used in Australian brands as a casing in some Philip Morris brands and as a flavour by BATA and Imperial. Liquorice is used to decrease harshness and create a milder, sweeter smoke. [4 8 13 21] According to the SCENIHR report, the taste and flavour of tobacco with liquorice/liquorice root added are described as sweet, woody and round, but tobacco company documents reveal that adding liquorice/liquorice root also has the objective of camouflaging the unpleasant taste of tobacco. [21] The use of adding liquorice/liquorice root to tobacco has a number of advantages: it reduces the harshness of tobacco smoke and dryness in the mouth and throat, and provides a pleasant sweet undertone to the smoke.[21] Tobacco company documents confirm that liquorice '*is used in cigarettes both as a flavour and as a casing material to smooth the harsh taste of certain kinds of tobacco*'[43]	Liquorice and its derived products are added to cigarette tobacco as '*flavourings, and as enhancing, potentiating, and smoothing agents. They are also thought to act as surface active agents during the casing operation to help distribute flavours evenly on the blend. Liquorice is used as an adjunct to boost the sweetness of tobacco*.' [43]	Prohibited in Canada and Brazil.
Cocoa	In 2011 Ingredient lists, BATA lists cocoa at quantity not exceeding (QNE)	Theobromine is a bronchodilator and has been used in the treatment of asthma.[21] It is found in cocoa beans and coca is a tobacco additive.		Prohibited in Canada and Brazil.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	0.82413 per cent by weight.Philip Morris lists it at 0.2 per cent and Imperial at 0.48 per cent.	There is some debate in the literature on the impact of theobromine in cigarettes. Bates et al.[4] and Fowles[8] suggested that the bronchodilating effect of theobromine may contribute to the absorption of nicotine in connection with smoking. The SCENIHR report concluded that the content of theobromine per cigarette will be too low to have a bronchodilating effect on the lungs and thereby increase the absorption of nicotine. [21] Regardless of whether it has a brochodilation effect, cocoa appears to be an important flavouring in Australian cigarettes as it is listed in fairly significant quantities compared to other flavourings identified in Australian cigarettes. Philip Morris also identifies cocoa as a casing.		
Caffeine/coffee extract	In 2011 ingredient lists, BATA lists coffee extract at QNE 0.00112 per cent by weight, Philip Morris lists it 0.005 per cent.It does not appear on the Imperial list.	Caffeine is usually added to cigarettes as coffee extract. Caffeine is found in coffee and has similar stimulant properties to theobromine. Caffeine aerosols have been found to induce improved pulmonary function changes in asthmatics. [8] It is not known whether the doses of caffeine per cigarette are at sufficient levels to exert a bronchodilating effect on the lung, thereby increasing the absorption of nicotine.		Prohibited in Canada and Brazil. Brazil prohibits all additives associated with alleged stimulant or invigorating properties, including caffeine.
Menthol	In 2011 Ingredient lists, menthol is listed in BATA returns in some brands and in the composite ingredient list as a flavour at QNE	Menthol is found in many cigarettes, not just those brands generally identified as 'menthol brands' Menthol has a minty taste and aroma and is added to cool the smoke or make it less harsh, which means that it makes a cigarette easier to smoke.[11] [13] Menthol is also an anaesthetic – it soothes or even numbs the lining of the mouth and throat, and suppresses the body's natural	Over time, menthol diffuses throughout the cigarette, irrespective of where it was applied. Menthol cigarettes are typically blended using	US FDA is considering the report of TPSAC. Canada and the United States currently exclude

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	0.70040 per cent of product weight. It is also listed In Philip Morris returns in some brand variants as an ingredient and in the composite ingredient list as a filtration material QNE 0.5 per cent by weight. Imperial lists it in some brands and as a flavour at QNE 0.56 per cent.	cough reflex. By making it easier to smoke, menthol also potentially makes cigarettes more attractive to young or beginner smokers. [11 13 21] The recent report by the FDA's TPSAC review found that menthol cigarettes have an adverse impact on public health in the United States. TPSAC also found that the evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes increases experimentation and regular smoking.[11] It should be noted that there are differences in the patterns of consumption and prevalence of use of menthol cigarettes between Australia and the United States. Menthol cigarettes function as 'starter' cigarettes smoked by young people. Menthol is also smoked more commonly among low SES groups and African Americans. [54]	more flue-cured and less burley tobacco. This is because some of the chemicals in burley tobaccos create an incompatible taste character with menthol. [21] Tobacco company documents reveal menthol is often put on the inner packaging, not in the cigarette; it then subtly impregnates the tobacco. Any future regulatory approaches should include guidelines/regulations on adding flavour to the packaging itself instead of directly in the cigarette.	menthol from the ban on tobacco additive/flavourings.
Eugenol/clove oil	Clove oil does not appear in recent cigarette ingredient lists provided under the Voluntary Agreement. However, clove oil was reported by BATA in the 2000 composite ingredient list at QNE 0.002 as a flavour. It was not	Eugenol, a compound found in clove oil, has local anaesthetic properties which reduce smokers' ability to perceive harshness and irritation. Additives such as eugenol and menthol have been used to mask the irritation associated with smoking; e.g. by numbing the throat so the smoker cannot feel the smoke's irritating effects. [4 8 13] By making it easier to smoke, it also makes cigarettes more attractive to young or beginner smokers. Rabinoff[10] reports that although eugenol is no longer found in the list of additives in the United States, it is still present in many of the botanical agents that are used as		Prohibited in Canada and Brazil.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	listed in Philip Morris or Imperial returns from 2000.	additives in the US, including basil, black pepper, Ceylon citronella, Ceylon cinnamon, lovage, liquorice, mace, thyme and other botanical additives. [10] Some of these are listed in Australian returns; e.g. liquorice and lovage. PM lists lovage extract as a flavour at QNE 0.005 per cent and BATA lists it at QNE 0.00011 per cent.		
Spices/herbs/ botanical extracts/ fruits and vegetables	The 2011 voluntary disclosures list many products in this category. Examples include raisin extract and/or concentrate, tamarind extract, apple juice concentrate, lovage extract, peppermint oil, orange oil, nutmeg oil, prune juice concentrate, chamomile flower oil and dill oil.	According to Proctor, [13] various spices and herbs such as cinnamon, ginger, sage, mint and oil extracts from cardamom, cedar and coriander can also be used to improve the palatability of tobacco products by introducing complex flavour notes. The use of additives to create a smoother and milder smoking experience and to mask the negative effects of smoking can contribute to experimentation and uptake of tobacco use. [8 9 10]		Prohibited in Canada and Brazil. Refer to previous information.
Humectants – propylene glycol and glycerol	Glycerol is listed in BAT composite returns for Australia at QNE 2.02% of product weight, for Philip Morris at 2.1% and Imperial at 1.5%. Propylene glycol is commonly listed in Philip Morris	Humectants are moisturizing agents for tobacco, and play a role in preventing the tobacco drying out and becoming crumbly. However, tobacco company documents reveal that humectants may also used to impart sweetness and increase the mildness of the smoke. Humectants, are used in cigarette tobacco blends to assist with aerosol formation and thus make cigarette smoke 'milder'. The more the nicotine can be dissolved	An Australian tobacco company document notes the use of humectants in Australian WD & HO Wills' brands to reduce irritation and increase smoothness. [17] It notes the extensive use of humectants to reduce irritation in Australian WD	Use is permitted in Canada, the United States and Brazil.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
	ingredient lists at QNE 2.6%, by Imperial as a humectant/solvent at QNE 1.4% and by BATA as a humectant at QNE 2.41608%. Philip Morris lists sugar (invert sugar and sucrose) as both flavours and humectants at QNE 4.1% and 3.0% respectively. Imperial lists both glycerol and propylene glycol as a humectants/solvent. BATA also lists water at QNE 14.8% as a humectant.	in the tar droplets, the less irritating the smoke is to the consumer's throat and the easier it is to inhale.[8 17] According to Australian cigarette ingredient lists, humectants in use in Australia include glycerol and propylene glycol. BATA also lists water as a humectant.[42] Glycerol and methylglycerol are also added to cigarettes as humectants, to decrease the sensory irritation of the inhaled smoke.[8]	& HO Wills brands. [17]	
CATEGORY B: CIGARETTE ENGINEERING FEATURES WITH A SIGNIFICANT IMPACT ON PALATABILITY				
Filter ventilation		In about 90 per cent of Australian brands, the tipping paper contains perforations – known as filter ventilation – to dilute the smoke with fresh air when the smoker takes a puff. [16] Essentially, smoke is replaced with air in the standard puff, and this also causes less smoke to be produced at the burning coal. [16 76] Filter ventilation has a major impact on the palatability and attractiveness of cigarettes in several ways: by		To our knowledge, no country has regulated filter ventilation in cigarettes.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
		creating a lighter and milder taste and making the smoke easier to inhale, and by reinforcing smokers' perceptions that milder tasting cigarettes are less harmful by decreasing the harshness of the flavour of the smoke and reducing irritation.[16] The combined effects of increased filtration and increased ventilation make the smoke more dilute so it tastes weaker or 'milder' and produces less harshness (the immediate burning/scratching sensations in the mouth and throat) and irritation (the lingering tingling sensations in the throat and chest).[16] Increased ventilation also facilitates increased puff volumes, a key means of compensatory smoking. Filter ventilation is one of the most powerful means for varying the taste strength, harshness and irritation of cigarette smoke.		
Other engineering features		Many aspects of cigarette engineering potentially have effects on palatability. These include packing density, paper porosity and characteristics of the filter. Their potential to affect palatability is via their potential impact on burn temperature and burn rate, which affects the mix of chemicals in the smoke, and filtration which selectively reduces some chemicals in the mixture more than others, and thus is bound to affect taste, but perhaps not in ways that have any marked effect on overall palatability.		To our knowledge, no country has regulated engineering features of cigarettes identified in this list.

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
CATEGORY C: ADDITIVES THAT DO NOT APPEAR IN AUSTRALIAN INGREDIENT LISTS BUT HAVE BEEN IDENTIFIED BY OTHER COUNTRIES AS RELEVANT TO PALATABILITY AND WARRANTED A POLICY RESPONSE				
Ammonia	Does not appear in 2011 ingredient lists. AmmoniumPhosphate Dibasic is listed in BATA 2000 Cigarette Ingredient returns at QNE 0.3%.	Ammonia does not appear in recent Australian ingredient lists. Ammonia has been associated with the manufacture of reconstituted tobacco. It is not clear if reconstituted tobacco is included in Australian cigarettes as current disclosures do not require tobacco companies to provide information on the type of tobacco used. However, if reconstituted tobacco was used in Australia, the ingredients used in its manufacture should be listed.		To our knowledge, no country regulates ammonia in cigarettes.
Ingredients that may create the impression of health benefits: -amino acids; -vitamins; -probiotics; -essential fatty acids; -minerals (except those essential to the manufacture of tobacco products)	Not listed in 2011 Australian ingredient returns. No evidence to date that tobacco with probiotics, vitamins or stimulants are being sold in Australia and no evidence of marketing activity associated this type of product.	Various ingredients have been used in tobacco products to help create the impression that such products have health benefits, or to create the impression that they present reduced health hazards. Examples include vitamins such as vitamin C and vitamin E, fruit and vegetables (and products resulting from their processing such as fruit juices), amino acids such as cysteine and tryptophan, and essential fatty acids such as omega-3 and omega-6.[9] There is evidence that vitamins have been used as a tobacco additive and tobacco companies have used various marketing strategies to claim nutritional properties used in some countries. Media reports suggest that cigarettes with vitamins have been sold and marketed in some countries (including Germany, the United States and Canada).		Prohibited in Canada and Brazil.
Additives Associated with Energy and Vitality (e.g.	Not listed in 2011 Australian ingredient returns except for coffee extract	Glucuronolactone is a stimulant found in stimulant drinks. According to the WHO Guidelines for Articles 9 and10,		Prohibited in Canada and Brazil. Brazil prohibits additives associated with

Additive name/description	Australian disclosure details	Evidence summary – link to palatability	Tobacco company document evidence	Summary of existing regulatory approaches
Glucuronolactone; Taurine; Guarana; Caffeine)	(contains caffeine)	energy drinks, popular with young people in some parts of the world, are perceived to increase mental alertness and physical performance. [9] Examples of stimulant compounds contained in such drinks include caffeine, guarana, taurine and glucuronolactone. It is not clear if any are currently added to cigarettes, or if they are, whether levels that could be ingested from smoking would have stimulant effects.		alleged stimulant or invigorating properties, including taurine, guarana, caffeine and glucuronolactone.
CATEGORY D: ADDITIVES USED AS COLOURING AGENTS				
Colouring agents: monogram ink/die print ink	In 2011 ingredient lists, many additives were listed as colouring agents for monogram ink/die print ink and filter paper inks/tipping papers/tipping inks.	No direct link to palatability. Colouring agents are added to various components of tobacco products to make the resulting product more appealing. Attractively coloured cigarettes (e.g. pink, black, denim blue) have been marketed in some countries. Examples of colouring agents include inks (e.g. imitation cork pattern on tipping paper) and pigments (e.g. titanium dioxide in filter material). [9] Australian ingredient returns list a number of chemicals used for this purpose. As the plain packaging regulations restrict what can be included on the cigarette stick, and the colours thereof, the range of products used for this purpose is likely to decrease markedly.		Colouring agents are prohibited in Canada, except for those used to whiten paper or the filter or to imitate a cork pattern on tipping paper in cigarettes. (Slightly different requirements apply to little cigars.)

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