Revised draft submitted to Department of Health. Does not reflect Government policy.

### Regulation Impact Statement

**Tobacco product content regulation and disclosure requirements for tobacco products**

19 March 2014

---

**Disclaimer**

The Department of Health contracted Allen and Clarke Policy and Regulatory Specialists (Allen + Clarke) to develop this regulation impact statement.

No regulatory decisions have been made by the Department of Health or the Australian Government about potential new tobacco product content regulation controls or revised disclosure requirements for tobacco products.

---

1 This RIS was substantially developed prior to the new RIS system being introduced, as described in the Government’s Best Practice Regulation Handbook (2013). As such no options-stage RIS was prepared.
Revised draft submitted to Department of Health. Does not reflect Government policy.

Contents

Executive Summary .......................................................................................................................... 3

1. Introduction .................................................................................................................................. 6
   1.1 Purpose ...................................................................................................................................... 6
   1.2 Tobacco product content regulation and disclosure ................................................................. 6
   1.3 Key terms ................................................................................................................................ 6
   1.4 The tobacco industry in Australia ............................................................................................. 8

2. Problem definition ......................................................................................................................... 9
   2.1 High level problem – health and social costs from smoking .................................................... 9
   2.2 More specific problem definition for this RIS .......................................................................... 10
   2.3 Australian Government intervention to date ............................................................................ 20
   2.4 International context .............................................................................................................. 25

3. Policy objectives .......................................................................................................................... 28
   3.1 High‐level tobacco control objectives ..................................................................................... 28
   3.2 Specific policy objectives for tobacco product content regulation ............................................ 29
   3.3 Specific policy objectives for tobacco product disclosure ....................................................... 29

4. Options ......................................................................................................................................... 31
   4.1 Options for new tobacco product content regulation requirements ........................................ 31
   4.2 Options for new tobacco product disclosure requirements ..................................................... 40

5. Impact analysis ............................................................................................................................ 51
   5.1 Qualitative assessment of the options ..................................................................................... 51
   5.2 Quantitative assessment - CBA .............................................................................................. 60

6. Consultation .................................................................................................................................... 66
   6.1 Consultation process .................................................................................................................. 67
   6.2 Summary of key themes .......................................................................................................... 68

7. Conclusion and recommended options ....................................................................................... 72

8. Implementation and review ......................................................................................................... 76

Appendix 1: Filter ventilation ......................................................................................................... 79
Appendix 2: Summary of the Voluntary Disclosure Agreement ..................................................... 91
Appendix 3: Research and Reference Materials .............................................................................. 93
Appendix 4: Cost benefit analysis report .......................................................................................... 101
Executive Summary

Tobacco product content regulation

International thinking on tobacco product content regulation has identified three broad areas of potential intervention: attractiveness (including *palatability*), toxicity, and addictiveness. To-date, international public health efforts have focused on potential new controls on additives that increase the attractiveness (including *palatability*) of tobacco products. Thinking is less advanced about controls on content or product design features that may increase the already toxic or addictive nature of tobacco products.

Tobacco product disclosure

In Australia, tobacco product disclosure is currently governed by the *Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes* (the Voluntary Agreement). The Voluntary Agreement is between the Australian Government and the three largest tobacco companies in Australia. In summary, each year, information about tobacco product ingredients is disclosed to the Department of Health.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Currently, no jurisdiction in the world bans filter ventilation in cigarettes. Additionally, Articles 9 and 10 of the WHO FCTC currently make no mention of filter ventilation.

Another key consideration is consistency with the international approach being driven by the World Health Organization. Following the Partial Guidelines for implementation of Articles 9 and 10 of the WHO FCTC would promote international consistency.

Implementation

Once the preferred approaches have been decided, a number of key planning and implementation issues will need to be further worked through. These are highlighted in Part 8 and include:

- regulatory design;
- ensuring any new legislation empowers additional controls to be introduced as the international evidence base evolves;
- confirming roles and responsibilities of various government agencies and considering capacity and capability needed to administer and enforce any reforms;
- developing the necessary administrative systems and processes needed to implement any new legislation;
- the need for ongoing research;
- cost recovery considerations;
- transition times;
- audit, testing, and compliance and enforcement approaches; and
- awareness raising and communications with the public and stakeholders.
1. Introduction

1.1 Purpose

1.2 Tobacco product content regulation and disclosure

Despite the range of past and existing tobacco control initiatives, there is still room to strengthen Australia’s tobacco control framework in order to continue to reduce smoking rates and address the harms caused by tobacco use. Australia is a signatory to the WHO Framework Convention on Tobacco control (WHO FCTC).

In recent times, as the international evidence base has grown, the wider international community has been considering expanding upon the existing platform of controls and interventions. This has included considering initiatives in the areas of tobacco product regulation and disclosure.

1.3 Key terms

It is important to clearly define some of the key terms underpinning the two areas of intervention. There are many different ingredients and constituents in tobacco products – some occur naturally and some are added to tobacco products for specific purposes. When tobacco is ignited its emissions also contain many different substances. Tobacco content regulation and disclosure requirements can be targeted to all or some of these ingredients, constituents and substances. Figure 1, below, defines some key terms for the purposes of this RIS.
Revised draft submitted to Department of Health. Does not reflect Government policy.

Figure 1 – key terms

**Tobacco Industry**
General collective term for everyone who has an interest in the production and sale of tobacco products. Primarily refers to manufacturers, wholesale distributors, and importers of tobacco products as a whole.

**Tobacco Companies**
Refers to manufacturers and importers of tobacco products.

**Tobacco Products**
Products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, snacking, chewing, or snuffing (e.g., manufactured cigarettes, pipe tobacco, roll-your-own, cigars, blintz wraps etc).

**Ingredients**
Include the tobacco leaf itself, components (e.g., filter paper) including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing) and substances that migrate from packaging material into the product. This generic term also includes non-tobacco ingredients such as paper, filters, inks and glues.

**Constituents**
Naturally-occurring compounds in whole tobacco. These are compounds that are present in the tobacco itself, rather than anything that has been added.

**Non-tobacco ingredients**
These are the non-tobacco components of a tobacco product and include things such as cigarette papers and filters.

**Additives**
Ingredients that are added to tobacco. They are often used in the manufacture or preparation of a tobacco product for a specific purpose (e.g., flavourings).

**Emissions**
Emissions are substances that are released when the tobacco product is used as intended. For example, in the case of cigarettes and other combusted products, emissions are the substances found in the smoke.

---

Where possible, the definitions used in this diagram have been drawn from those used by the World Health Organization. Sources include the definition sections of the WHO FCTC or the WHO FCTC Guidelines for Implementation, 2013 edition. The Guidelines are available at: [http://apps.who.int/iris/bitstream/10665/80510/3/9789241505185_eng.pdf](http://apps.who.int/iris/bitstream/10665/80510/3/9789241505185_eng.pdf). Some terms used are not defined in these sources (e.g., additives, constituents, and non-tobacco ingredients).
1.4 The tobacco industry in Australia

British American Tobacco Australia (BATA), Philip Morris limited, and Imperial Tobacco Australia are the three largest tobacco companies in Australia, and make up a significant proportion of the tobacco product market. These three tobacco companies had a reported turnover of approximately $2.5 billion in 2006-07, with profit of around $586 million. The three companies are wholly owned by parent companies, meaning they do not need to make information about their revenue and expenditure available locally. This reduces the amount of information available on the companies, but estimates from 2007 place their total market share at around 98 per cent (46 per cent BATA, 34 per cent Philip Morris, 17.5 per cent Imperial).

The remainder of the tobacco market is made up by a number of smaller importers. Some companies, like Scandinavian Tobacco, focus on importing cigars and pipe tobacco instead of manufactured cigarettes. The much smaller market for cigars (around two per cent of the total tobacco market) explains why, despite holding a significant market share, they only make up a small percentage of the overall tobacco market, which is dominated by manufactured cigarettes and roll-your-own tobacco products. For cigarette importers, Richland Express estimates that it is the largest of the cigarette importers outside of the big three, with a reported one per cent of the cigarette market.

The retail sale of cigarettes and other tobacco products was estimated to make up around 4.7 per cent of all retail sales in Australia in 2004, and be worth around $9.3 billion annually. Supermarkets and grocery stores accounted for over half of the total sales (51 percent), with tobacconists (19 percent) and convenience stores (13 percent) the other major points of sale.

Tobacco manufacturers in Australia pay excise duty on locally-manufactured cigarettes and tobacco products. In 2009-10, the total excise tax collected from domestically-manufactured tobacco products or tobacco produced for the domestic market was AUD$5.742 billion. The duty rate for tobacco is levied per cigarette for manufactured cigarettes, and per kilogram of tobacco for all other products. Excise was paid on 20,622,000,000 individual cigarettes and 647,686 kilograms of tobacco in other tobacco products in 2009-10. For imported products produced for the Australian domestic market, a customs duty is paid at a rate equivalent to the excise rate and this information is included in the figures above.

---

4 Richland Express, the Department of Health Tobacco Industry Interview, November 21, 2011.
6 PricewaterhouseCoopers, Sales of cigarettes and tobacco products by type of retail business: An analysis of sales of cigarettes and tobacco products to tobacco retailers in Australia. PricewaterhouseCoopers, 2005
8 Ibid.
2. Problem definition

2.1 High level problem – health and social costs from smoking

The harms from smoking are well documented. Smoking greatly increases the risk of many cancers, cardiovascular disease, chronic obstructive pulmonary disease and other respiratory diseases, peripheral vascular disease and many other serious medical conditions. Exposure to second-hand smoke also causes disease and premature death in adults and children who do not smoke. Half of all long-term smokers will die prematurely because they smoked. Smoking also imposes a heavy financial burden on the Australian community – estimated at $31.5 billion in 2004–05.

There are no safe levels of consumption of tobacco products. Tobacco is one of the most significant causes of death and disability in Australia. Around 3.3 million Australians (15.1 per cent) aged 14 years or older still smoke and around 15,000 Australians die each year of smoking-related illness. Smoking amongst Aboriginal and Torres Strait Islander people is more than double that of the general population, with 45 per cent of people over the age of 15 years smoking daily.

The National Tobacco Strategy (2012-18) further describes the size of the smoking problem by looking at smoking prevalence:

- across the general population (smoking prevalence amongst daily smokers has reduced from 24.3 per cent in 1991, to 16.6 per cent in 2007, to 15.1 per cent in 2010);
- in key population sub-groups (smoking rates among people from low socioeconomic groups, those who are unemployed, homeless or imprisoned, and those with a mental illness, or other drug or alcohol dependency are much higher than for the general population);
- across the states and territories (in 2010, ACT had the lowest daily smoking prevalence, while Northern Territory had the highest); and
- among secondary school students (the majority of smokers start smoking as teenagers).

It is clear that Australia has made significant gains in reducing smoking prevalence over many years. However, smoking rates in Australia are still too high. Through the National Health Care Agreement in 2008 (which was updated in 2012), the Council of Australian Governments committed to the following performance benchmarks:

---

11 Much of the information in this section has been taken from Australia’s National Tobacco Strategy 2012-18, available at: http://www.nationalstrategy.gov.au/internet/drugstrategy/publishing.nsf/content/national-ts_2012-2018. Where relevant, primary references cited in the Strategy have also been cited in the RIS.
12 US Department of Health and Human Services. The Health Consequences of Smoking: A Report of the Surgeon General 2004, Centers for Disease Control and Prevention, Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, GA.
13 US Department of Health and Human Services. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. 2006, Centers for Disease Control and Prevention, Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, GA.
16 Refer to part 2 of the National Tobacco Strategy, pp 3-6.
‘By 2018, reduce the national smoking rate to 10 per cent of the population, and halve the Indigenous smoking rate, over the 2009 baseline’.

2.2 More specific problem definition for this RIS

2.2.1 Tobacco product content regulation

International thinking on tobacco product content regulation has identified three broad areas: attractiveness (including palatability), toxicity, and addictiveness. These three areas are recognised in the World Health Organization’s (WHO’s) Guidelines for implementation of the WHO FCTC\(^\text{21}\). The Guidelines note that tobacco product regulation has the potential to contribute to reducing tobacco- attributable disease and premature death by reducing the attractiveness of tobacco products, reducing their addictiveness (or dependence liability) or reducing their overall toxicity.\(^\text{22}\)

The WHO Partial Guidelines on Articles 9 and 10 of the WHO FCTC note that tobacco products are commonly made to be attractive in order to encourage their use. From the perspective of public health, the Guidelines state that there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive.\(^\text{23}\)

“Attractiveness” is defined as including 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.\(^\text{24}\) The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also uses the concept of ‘stimulation to use’ when describing attractiveness, and notes sensory factors such as taste and smell, but also notes that external factors such as marketing and promotion, ease of use, and cost can all contribute to the attractiveness of a product.\(^\text{25}\)

\(^\text{21}\) FCTC. WHO Framework Convention on Tobacco Control: Guidelines for implementation, Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14, 2013 edition. The guidelines covering content regulation and disclosure (Articles 9 and 10 of the FCTC) have only been partially completed by the WHO. Work on additional guidelines is being undertaken by working groups established by the Conference of the Parties. This includes further work on the partial guidelines on Articles 9 and 10 of the WHO FCTC. The Guidelines are available at: http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf.
\(^\text{22}\) Ibid at p 33.
\(^\text{23}\) Ibid at p 33.
To-date, international public health efforts have primarily focused on potential new controls on additives that increase the attractiveness (including *palatability*) of tobacco products. Thinking is less advanced about controls on content or product design features that may increase the already toxic or addictive nature of tobacco products. A working group under the WHO FCTC Conference of the Parties system has been convened to further consider the areas of addictiveness and toxicity. It is expected that in time this work will lead to the Partial Guidelines on Articles 9 and 10 of the WHO FCTC being expanded to guidance on regulating content to reduce addictiveness and toxicity.

---

**Palatability**

The Department of Health recently commissioned a literature review, to examine the effect of additives and product engineering features on the palatability of tobacco cigarettes and their impact on smoking behaviour (particularly smoking initiation, uptake and cessation). The review was undertaken by Purcell Consulting. At the time of writing, the Purcell report is still in draft form.

The draft report by Purcell Consulting was used to inform the tobacco product content regulation section of the RIS. Much of this section has been drawn from Purcell’s work in the first instance, with direct reference to primary sources cited by Purcell, where necessary, and our consideration of other literature.

Purcell cites a dictionary definition of *palatability* as something that is: acceptable to the taste; sufficiently agreeable in flavour to be consumed (in this case, smoked).

The palatability of tobacco products can be influenced in a number of ways. For example, by:

---

26 Purcell Consulting. 2013. The Effect of Cigarette Additives on the Palatability of Cigarettes. Draft report provided to the Department of Health and Ageing. The review developed by group of people including Kate Purcell, Professor Ron Borland, Bill King, Professor Melanie Wakefield, and Dr Coral Gartner.

27 Ibid at p. 21.
using additives (such as flavourings or sweeteners) to alter or improve the taste of the products and their emissions;

- using additives that reduce the harshness of tobacco smoke and numb the throat to mask the irritating effects of the smoke (e.g., menthol);

- using additives that appeal to other senses such as smell (e.g., masking the irritation and odour of second-hand smoke\(^{28}\)) or sight (use of colourings or substances to make the smoke appear whiter);

- using additives that may create misleading perceptions of health benefits or incorrect associations with vitality/energy (e.g., taurine);

- using product design features (such as filters or filter vents) that mask the harshness of tobacco smoke, create a lighter and milder taste, make the smoke easier to inhale, and reinforce smokers perceptions that milder tasting products are less harmful.

Considering the preventable morbidity, mortality, and social and economic costs related to tobacco use, factors that influence the palatability and attractiveness of tobacco products to children and other novice smokers or those trying to quit, are considered to be a public health concern. In Australia there is opportunity to place greater controls on ingredients and product design features that can influence the palatability of tobacco products.

Additives in Australian cigarettes

The Purcell review found that the Australian cigarette ingredients disclosed under the current Voluntary Agreement (between the three biggest tobacco companies and the Government\(^ {29}\)) include around 200 additives, excluding those related to papers, filters, adhesives and inks.\(^ {30}\) However, because of limitations in the information that is actually disclosed, the average amount of any given additive added per brand or the percentage of brands that contain a particular ingredient cannot be determined. Additionally, some brands are described by tobacco companies as only containing tobacco and water, or tobacco water and processing aids. The authors noted that tobacco industries in other countries had well more than 200 additives (they cited evidence of 350 for New Zealand and around 600 different additives in United States and Brazil).

In terms of additives used in Australian cigarettes, Purcell found that:

- industry disclosure reports show that the majority of additives are described as having a flavour function;

- the most used additives (by weight) are sugars, cocoa, liquorice, humectants, and menthol;

- sugars can be used to impart sweetness which can increase the attractiveness of cigarettes, particularly to children and young people;

- liquorice can be used to help decrease harshness and create a milder, sweeter smoke;

- humectants are used in significant quantities (e.g., propylene glycol and glycerol) and act as moisturising agents for tobacco. They can also impart sweetness and increase the smoothness or mildness of the smoke;

- herbs, spices, fruit and other extracts can enhance the palatability of tobacco products by introducing complex flavour notes (e.g., raisin extract, tamarind extract, lovage extract, peppermint oil, orange oil, nutmeg oil, prune juice concentrate, chamomile flower oil and dill oil);

- flavourings such as vanillin and ethyl vanillin can impart a vanilla flavour to the smoke, which can sweeten smoke and be subjectively experienced as similar to sugar;

---

^{29}\) The Voluntary Agreement is described as part of section 2.3, below.

^{30}\) Purcell Consulting. 2013, at p 7.
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. Being an anaesthetic, menthol can soothe or numb the lining of the mouth and throat, and suppress the body’s natural cough reflex. By making tobacco products easier to smoke, it can potentially make cigarettes more palatable for young or beginner smokers. Purcell noted the review by the US Food and Drug Administration’s Tobacco Products Scientific Advisory Committee (TPSAC), which 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;31

- additives are also used to facilitate the manufacture of tobacco, increase shelf-life, and control burn rates.

Filter ventilation in Australia

Product design features can also influence the palatability of tobacco. In about 90 per cent of Australian brands, the tipping paper contains perforations – known as filter ventilation – to dilute the smoke with air when the smoker takes a puff.32 There is evidence that this particular form of product engineering influences the palatability of tobacco, by decreasing the harshness of the flavour of the smoke and reducing irritation. It has also been suggested that such a feature influences the toxicity and/or addictiveness of tobacco products by enabling 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 exposing smokers to higher levels of tar and carbon monoxide as well) through the processes of compensatory smoking.33

Filter ventilation is discussed further below, and some of the key issues and literature around filter ventilation is discussed at Appendix 1.

Purcell’s findings and conclusions

The Purcell review found the extensive use of additives by the tobacco industry to influence the flavour and aroma of cigarettes; mask the unfavourable harsh characteristics of tobacco; create milder and sweeter smoke; and reduce sensory irritation by the use of additives such as menthol.34 The authors argue that they found overwhelming evidence that the majority of additives to cigarettes are added to improve the palatability of the product. They further concluded that some engineering features of cigarettes are explicitly designed to serve similar functions – most notably filter ventilation.35

Purcell concludes that 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 regulatory action to prohibit

---

34 Purcell Consulting, 2013, at p. 12.
35 Purcell Consulting, 2013, at p. 12.
or restrict the use of additives and filter ventilation. A summary of some of Purcell’s key conclusions is provided below:36

- 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.

- 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.

- 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 cigarettes easier to smoke, menthol also makes them more attractive to young or beginner smokers.

- 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.

The Purcell review also considered the literature on the impact of additives and engineering features on smoking behaviour – specifically the impacts on smokers’ perceptions of cigarettes, initiation and uptake of smoking, rate/frequency/intensity of smoking, and cessation.

Unfortunately, there are limitations to conducting public health research on the impact of ingredients and product design features on such behaviours. There are a number of reasons for this – particularly the difficulty to show causality and obvious ethical issues limiting the type of experiments that can be undertaken. For example, Purcell notes, in the context of cessation, that it would be hard to demonstrate the effects of additives 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.

Purcell found that 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.

Smokers' sensory perceptions

The Purcell review emphasised that while there may be limited public health research published on the impact of additives or product design on smoking behaviour (e.g., cessation), there is a very large body of tobacco industry research, spanning decades, on the impact of additives on smokers' sensory perceptions and their influences on consumer preferences. In summary, these sorts of sensory perceptions include:

- flavour/taste;
- aroma to the smoker;
- reducing the lingering aroma to other people;
- creating milder, smoother, or sweeter smoke; and
- reducing/masking harshness, irritation, or unpleasant aftertaste.

This RIS argues that such sensory perceptions and experiences are very important factors that can influence smoking initiation and help maintain smoking. Such perceptions can be influenced by both additives and product design features (e.g., filter ventilation). Specifically, Purcell states that the tobacco industry has extensively researched smokers' perceptions of their products and that much of this research has 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.²⁷

Purcell notes that 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.²⁸

The authors conclude that 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.

³⁷ Purcell Consulting, 2013, at p 68. Purcell cites the following to support this statement:
³⁸ Purcell Consulting, 2013, at p 85. Purcell cites the following to support this assertion:
It is not just additives that can influence smokers’ sensory perceptions. Purcell’s review found that filter ventilation has a very significant impact on smokers’ perceptions as it results in a ‘lighter’ or ‘milder’ taste because the perforations in the filter dilute the smoke. Filter ventilation also produces less harshness and irritation. 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’.

These perceptions of ‘lightness’ and ‘less irritation’ 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.

Purcell found 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.

Initiation/uptake

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. After considering tobacco company documents, and various commentaries on them, Purcell concludes that 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. By masking the harshness associated with tobacco use, and modifying the flavour characteristics of cigarettes, the authors argue that additives and filter ventilation contribute to the experimentation and uptake of tobacco use.

Concern that some tobacco products (particularly flavoured little cigars) were encouraging smoking uptake by youth was a key driver behind the 2009 tobacco control legislative reforms in Canada. One initiative introduced by the reforms involved banning flavours and selected additives (but not menthol) in three classes of tobacco products – little cigars, cigarettes and blunt wraps. The reforms were implemented in response to a growing trend amongst young people trying candy and alcohol

---

39 Purcell Consulting (2013) at pp 91-92. The authors specifically cite:
- Kozlowski & O’Connor. Cigarette Filter Ventilation is a Defective Design Because of Misleading Taste, Bigger Puffs and Blocked Vents. Tobacco Control 2002:11(Suppl I):i40–i50

40 Ibid.
41 Ibid.
42 Purcell, 2013, p 92 supported by:
flavoured little cigars. These products were flavoured with fruit, chocolate and vanilla and such additives masked the harshness of the smoke and were considered as making the products more attractive to youth and novice or first time users.

Health Canada considers that the legislative amendment impacted on youth use of little cigars. For example, Health Canada’s survey data found that prevalence of 15-19 years old that have used little cigars in the preceding 30 days fell from 8 per cent in 2009 to 5 per cent in 2011. Additionally, in 2010/11, 2 percent of 6th-9th graders reported having smoked little cigars in the preceding 30 days, compared with 4 per cent in the 2008/09 year. The full nature of any impact is yet to be fully understood. For instance, Health Canada advise that youth (15-19 years) are still twice as likely to smoke little cigars than adults, 65 per cent of youth that smoke little cigars are using flavoured varieties, and sales data indicates that flavoured cigar products continue to be as popular as unflavoured varieties. Further evaluative work is being undertaken, but was not available for consideration in the development of this RIS.45

Rate, frequency, and intensity of smoking

Purcell’s review found that there is little published evidence on the impact of additives on the rate, frequency and intensity of smoking. However, the authors argue that there is strong evidence in the peer-reviewed literature regarding the significant impact of filter ventilation on the rate, frequency and intensity of smoking. Purcell notes that filter ventilation results in a lighter/milder taste, as well as promoting larger puffs. The authors cite evidence suggesting that46:

- heavy ventilation can promote behavioural blocking of vents;
- filter ventilation facilitates increased puff volumes by smokers, a key means of compensatory smoking (nicotine-addicted smokers smoke lower yield cigarettes more intensively by taking more frequent or larger puffs);
- low-tar cigarettes have been engineered to become more conducive to compensatory smoking, with tobacco companies designing cigarettes to be more ‘elastic’ – yielding more smoke to human smokers than to smoking machines;
- 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. 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.

45 Health Canada PowerPoint presentation: Regulating Tobacco additives: Canada’s Experience that was presented at a Pan American Health Organization workshop on labelling and tobacco product regulation.
46 Purcell (2013) pp 95–97. The following studies are cited in relation to these points:
- Kozlowski & O’Connor. Cigarette Filter Ventilation is a Defective Design Because of Misleading Taste, Bigger Puffs and Blocked Vents. Tobacco Control 2002;11(Suppl I):i40–i50
Cessation

Arguably the most relevant study that looks at the impact of additives on cessation is the 2011 TPSAC review of menthol cigarettes. Purcell notes that this review concluded that it is biologically plausible that menthol makes cigarette smoking more addictive. The evidence is sufficient to conclude that it 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.

The TPSAC also considered whether those who smoke menthol cigarettes are less likely to successfully quit than people who smoke non-menthol cigarettes. The TPSAC concluded that while 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 more mixed.47

Further literature considered

A summary of other research considered is provided at Appendix 3.

Information asymmetry regarding the purpose/function of additives and product design features

Not only does the wider market have limited information about the nature of the content and design features of tobacco products, but there is a clear information asymmetry about the purpose or intended function of such product design features, and their ultimate effects (intended or not). This clearly favours the tobacco industry. Tobacco companies have specific knowledge of the ingredients used in their products, the levels they are used, the design features of products, and the underlying purposes/functions of such additives and design features, which the wider market (consumers, NGOs, regulators, etc) does not have equal access to.

This asymmetry is further discussed in the context of tobacco product disclosure below.

---

2.2.2 Tobacco product disclosure

The key problem in the disclosure context is that there is a clear information asymmetry in the market. The Government, regulators, researchers and, to a lesser extent, the wider public do not have adequate and sufficient information about tobacco products compared to tobacco companies.

There is wide public awareness that tobacco products are generally harmful when consumed. Many people will also be aware that tobacco products are addictive and may assume that some types of additives have been added to tobacco products, or design modifications have been made to products for various purposes. However, there is very limited information and awareness about:

- what substances (either naturally occurring or added) are contained in tobacco products or their emissions. This includes specific product information for each individual Australian tobacco product brand variant;
- the amounts of such substances in different tobacco products;
- the purpose and functions of such substances (e.g., why specific substances are added during manufacturing) or product design features (e.g., filter ventilation); and
- how such substances and design features then actually affect the smoker (regardless of their stated purpose or function) either in their own right or in combination with other substances in tobacco products.

A key issue at the heart of the information asymmetry is that it is not about obtaining a lot of very technical information, but information that can be readily interpreted and then used to inform decisions and actions. For example, the contents of existing tobacco returns provide a lot of

---

48 Note, whilst comparisons are made here between the regulation of industries, there is no safe level of tobacco consumption and all medical authorities advise against its use.

---
technical information, which has some fundamental limitations for policy-makers, regulators or researchers, and others (refer to section 2.3 and Appendix 2, describing the existing disclosure system).

2.3 Australian Government intervention to date

2.3.1 Strategic policy context for tobacco control

“Australia has been among the global leaders in tobacco control – nationally, in the states and territories, and through the work of nongovernment organisations and researchers.” 49

The National Tobacco Strategy

The National Tobacco Strategy 2012-2018 was approved by all Health Ministers at the 9 November 2012 meeting of the Standing Council on Health. It explicitly recognises that reducing tobacco-related harm in our community is a priority for all Australian governments.

The Strategy builds on previous national tobacco control strategies that have existed since 1999 and sets out the national framework to reduce tobacco-related harm in Australia. It reflects best practice in tobacco control and complements existing policy frameworks at the state and territory, national and international levels.

The Strategy describes shared goals, objectives and targets for tobacco control across government and non-government agencies for the next six years (this is further outlined in section 3.1, below).

Other key documents that have guided steps to reduce the morbidity and mortality associated with tobacco use include:

- **Australia: the Healthiest Country by 2020 – National Preventative Health Strategy (NPHS)**\(^{50}\) - this report, prepared by the National Preventative Health Taskforce, outlines a range of goals for key preventive health areas (tobacco, obesity, alcohol, and closing the gap between Indigenous and non-Indigenous Australians). For tobacco, the report recommends implementation of a range of measures, such as:

  - making tobacco products more expensive;
  - increasing use of social marketing campaigns;
  - ending all forms of advertising and promotion of tobacco products;
  - eliminating exposure to second-hand smoke in public places; and
  - regulating manufacturing and supply of tobacco products.

- **Taking Preventative Action (2010)**\(^{51}\) – the Australian Government’s response to the recommendations of the National Preventative Health Taskforce.

### 2.3.2 Australian tobacco control interventions

Successive Australian Governments have been serious about reducing the enormous harm, suffering, and loss of life that smoking causes. Australia’s comprehensive tobacco control initiatives include the following:

- a 25 per cent increase in tobacco excise in April 2010;
- investment of more than $135 million in anti-smoking social marketing campaigns;
- listing of nicotine replacement therapies on the Pharmaceutical Benefits Scheme, which subsidises access for lower-income Australians and people with a prescription from the GP, and extended listings for the smoking cessation support drugs bupropion (available in two brands) and varenicline (Champix\(^{\text{a}}\));
- funding support for Aboriginal and Torres Strait Islander communities to reduce smoking rates, including the COAG Closing the Gap in Indigenous Health Outcomes National Partnership Agreement supporting Regional Tackling Smoking and Healthy Lifestyle Teams, with national coverage across 57 regions, including the ACT;
- legislation to restrict Australian internet advertising of tobacco products, from 6 September 2012, bringing restrictions on tobacco advertising on the internet into line with other points of sale;
- legislation to mandate the plain packaging of tobacco products, with full effect from 1 December 2012;
- regulations to update and expand the graphic health warnings appearing on tobacco products, in line with plain packaging requirements;


• reduction in the duty free allowance to 50 cigarettes or 50 grams of cigars or tobacco products from 1 September 2012;
• introduction of a maximum penalty of ten years’ imprisonment for tobacco smuggling offences, from 6 November 2012;
• a four staged increase in tobacco excise and excise-equivalent customs duty on tobacco and tobacco-related products. The first increase of 12.5% commenced on 1 December 2013 and further 12.5% increases will occur on 1 September 2014, 1 September 2015 and 1 September 2016. This is in addition to changes from bi-annual indexation of tobacco excise and excise-equivalent customs duty based on the Consumer Price Index (CPI) to bi-annual indexation based on average weekly ordinary time earnings (AWOTE), effective 1 March 2014.

These initiatives have come on top of a comprehensive suite of tobacco control measures already in place in Australia, including: minimum age restrictions on purchase of tobacco products; comprehensive advertising bans under the Tobacco Advertising Prohibition Act 1992; health warnings on tobacco product packaging; retail display bans; bans on smoking in workplaces, bars, restaurants and other indoor public spaces, and increasingly in outdoor places including where children may be exposed to environmental tobacco smoke; extensive and continuing public education campaigns on the dangers of smoking; subsidies for smoking cessation supports; and Quitlines and other smoking cessation support services in each state and territory to help people quit smoking.

When combined, these initiatives support Australia’s tobacco control policy and legislative framework, and have contributed to a steady reduction in smoking rates over several decades.

2.3.4 Existing interventions regarding content regulation and disclosure

In the wider international context, the two areas of tobacco product regulation and tobacco product disclosure have also been recognised under the WHO FCTC. Article 9 (regulation of the contents of tobacco products) and Article 10 (tobacco product disclosure) collectively require Parties to the WHO FCTC to adopt and implement measures for testing, measuring and regulating the contents and emissions of tobacco products; and for disclosure of the contents, toxic emissions and constituents of tobacco products. As mentioned above, the WHO has developed partial guidelines for the implementation of Articles 9 and 10 of the WHO FCTC.

Content regulation

In Australia, there is currently no specific tobacco control focused legislation at the Commonwealth level that regulates additives and constituents along the lines that countries such as Brazil and Canada have recently introduced. There is some industrial chemical legislation that applies, however.

In Australia, chemical additives in tobacco products are regulated as “industrial chemicals” under the Industrial Chemicals (Notification and Assessment) Act 1989 (http://www.nicnas.gov.au/about-nicnas/legislation-and-regulations). This means that companies importing or manufacturing chemicals for use as additives in tobacco products must be registered under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), and the chemicals must either be listed on the Australian Inventory of Chemical Substances (some legislative exceptions apply), or the chemical must be notified to and assessed by NICNAS for that use, (again, some legislative exemptions apply). An important exception is that the NICNAS legislation grand-parented around 39,000

chemicals, that were already being used across all industries, onto the Australian Inventory of Chemical Substances.

Most states and territories in Australia (excluding Queensland and Western Australia) have existing legislative controls on the sale and/or marketing of overtly fruit or confectionery-flavoured cigarettes (on the basis of protecting young people from smoking uptake). Queensland’s Health Legislation Amendment Act 2011 included a provision restricting the sale of fruit or confectionery-flavoured cigarettes. However, this provision has not yet come into force (it requires a proclamation by the Queensland Minister of Health, which had not occurred at the time of writing). Western Australia has proposed to prohibit the sale of fruit and confectionery-flavoured cigarettes as part of its review of the Tobacco Products Control Act 2006. However, this reform has not yet been progressed.

There is no evidence of a problem with such products being on the Australian market in contravention of this legislation.

Lit cigarettes that are left unattended pose a fire risk and every year people around the world are injured or killed from fires caused by cigarettes. Cigarettes can be designed in a way that they self extinguish when not puffed or left unattended. Regulations introduced under the (then) Trade Practices Act 1974 require all cigarettes sold in Australia after 23 September 2010 to comply with the mandatory standard for reduced fire risk cigarettes: Australian Standard 4830–2007, Determination of the extinction propensity of cigarettes. This requirement still applies under the Consumer and Competition Act 2010.

The existing tobacco content regulatory framework in Australia can be starkly contrasted with the far more comprehensive regulatory requirements that exist for most other products that are consumed by humans – e.g., food regulation, alcohol laws, and medicines legislation. These regulatory systems have a comprehensive and continually evolving body of scientific evidence about the composition of such products and the types and amounts of additives and other substances that are allowed to be added to them. In the tobacco context there are considerably less regulatory restrictions to the content and composition of tobacco products – even though the harms from using such products are recognised internationally as a global public health epidemic.

Disclosure

In Australia, tobacco product disclosure is currently governed by the Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes (the Voluntary Agreement). The Voluntary Agreement is between the Australian Government and the three tobacco companies with the largest market shares in Australia: Philip Morris Limited; British American Tobacco Australia Limited; and Imperial Tobacco Australia Limited. The smaller industry companies are not covered by the agreement.

A summary of what the Voluntary Agreement covers is provided at Appendix 2. Essentially, each of the signatory tobacco companies provides an annual report on the ingredients of their cigarettes, which includes:

- a by-brand variant disclosure list, which covers product weight, tobacco weight, and ingredients added to cigarettes in descending order of weight. Manufacturers can group

---

54 National Tobacco Strategy 2012-18, p 30.
ingredients added to cigarettes that provide flavour as general groups under ‘natural flavours’ and ‘artificial flavours’. Processing aids and preservatives are grouped in the same way;

- a composite list of all ingredients added to cigarettes, including all flavouring and processing aids and preservatives, including the function of each ingredient (e.g., filler, flavour, humectant, preservative, binder, etc.). This list is not broken down to brand-variants but provides information across the whole range of cigarettes. The quantity not exceeded is reported, which indicates the highest concentration in which the ingredients can be found in any one of a company’s products; and

- a composite list of non-tobacco ingredients across all cigarette brands, which follows the same structure as the composite cigarettes ingredients list.

The Voluntary Agreement has provided some information for policy makers about the contents of cigarettes and the purposes of various additives. For example, the majority of additives disclosed have been described by tobacco companies as flavouring agents. However, a number of commentators have referred to limitations in the system.

The Ipsos-Eureka report on Public Health Value of Disclosed Cigarette Ingredients and Emissions Data concluded that the public disclosure of information under the Voluntary Agreement is unlikely to promote the health of Australians because the information was seen to be: “…incomprehensible, uninteresting, incomplete, and difficult to access.” The study found that most members of the public do not access the information and, even if they do, the information does not discourage them from smoking. As a result, the report concluded that there are unlikely to be direct health benefits from releasing information obtained through the Voluntary Agreement to the public, and benefits are more likely to be gained from using the information to inform government policy, research and regulation. This clearly contradicts a key reason the Voluntary Agreement was established and raises an important question about when, how, and what information on tobacco products should be released to the public.

Further, there is a fundamental concern around the inadequacy of the current voluntary disclosure system in determining the exact number, quantity added and purpose of many of the large number of tobacco additives used in individual Australian cigarette brands. The agreement also does not cover other importers who import cigarettes into Australia, and ignores other forms of tobacco products (roll-your-own, pipe tobacco, cigars, etc.) entirely. This lack of information is a barrier not only to robust policy decision-making and public health initiatives, but also to providing consumers with the information they need to make informed and healthy choices.

These concerns are illustrative of the fundamental problem with the existing non-regulatory disclosure approach – the Australian tobacco industry arguably does not disclose sufficient, accessible and readily usable information on the specific quantity and purpose of ingredients in tobacco products.

There are also other areas of information that the Government, independent researchers and public health bodies would find useful for policy development and public education purposes. This includes sales volume information, and information on the emissions from smoked tobacco products (i.e. what is actually in the smoke that consumers inhale). None of this information is currently provided to the Government under the Voluntary Agreement, although there is scope for the Government to request certain emission information from tobacco companies.

57 Ipsos-Eureka Social Research Institute, Public Health Value of Disclosed Cigarette Ingredients and Emissions Data, p 2.
58 Ibid.
A stronger new disclosure model could improve the quality of information available on additives and constituents contained in individual Australian tobacco product brands and on product design features, and the nature and type of emissions in the smoke of cigarettes.

2.4 International context

2.4.1 The WHO Framework Convention on Tobacco Control (WHO FCTC)

The WHO FCTC was the first international treaty negotiated under the auspices of the WHO. It was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. Australia ratified the WHO FCTC in 2004, meaning that the Government is obligated to take steps to implement its requirements. It sets out a range of evidence-based tobacco control interventions that Parties to the WHO FCTC are in some cases required, and in other cases encouraged, to implement. The core objective of the WHO FCTC is to protect present and future generations from the...

... devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

Tobacco product regulation and tobacco product disclosure are specifically recognised under the WHO FCTC. Articles 9 (regulation of the contents of tobacco products) and 10 (tobacco product disclosure) collectively require Parties to the FCTC to adopt and implement measures for testing, measuring and regulating the contents and emissions of tobacco products, and for disclosure of the contents, toxic emissions and constituents of tobacco products.

The WHO’s Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC recommend that Parties should take a number of measures. A summary of some of the key recommendations is provided below.

- In regard to content regulation the Partial Guidelines recommend that Parties should:
  - prohibit or restrict ingredients that may be used to increase palatability (e.g., sweeteners, flavourings, and substances that mask the harshness of the smoke);
  - prohibit or restrict ingredients that have colouring properties, which could make the product more appealing;
  - prohibit ingredients that may create the impression that they have a health benefit (e.g., vitamins or fruit and vegetable extracts, etc);
  - prohibit ingredients associated with energy and vitality (such as stimulant compounds).

- In regard to disclosure the Partial Guidelines recommend that Parties should:
  - require manufacturers and importers to disclose to government authorities information on:
    - the ingredients used at each stage of the manufacturing process (and any changes to such ingredients);
    - the purpose of ingredients added;

---

60 World Health Organization, WHO Framework Convention on Tobacco Control, Article 3.
61 Refer pages 38-44 of the WHO FCTC’s: Guidelines for implementation, Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14, 2013 edition. Available at: http://apps.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf.
Revised draft submitted to Department of Health. Does not reflect Government policy.

- the characteristics of the tobacco leaves used;
- tobacco product design features (and any changes to such design features);
- sales to assist with effective product regulation;
  - consider making information about constituents and emissions and other disclosed information publicly accessible in a meaningful way.

2.4.2 WHO Global Action Plan for the Prevention and Control of NCDs

At the 66th World Health Assembly in Geneva in May 2013 delegates approved a resolution which endorsed the WHO Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020 (A66/8). This plan contains a suite of actions to help achieve globally agreed targets for NCDs. One of the key policy areas under the tobacco control component of the action plan is to regulate the contents and emissions of tobacco products and require manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products, consistent with Articles 9 (Regulation of the contents of tobacco products) and 10 (Regulation of tobacco product disclosures) of the WHO FCTC.

2.4.3 SACTob and TobReg

In 2000, the WHO established the Scientific Advisory Committee on Tobacco Product Regulation (SACTob). This committee was charged with guiding international policy making in the area of regulating tobacco products and facilitating access to scientific information to inform this process. SACTob prepared a number of technical reports that commented on tobacco product contents and emissions, including about the International Organization for Standardization (ISO) and Federal Trade Commission machine-testing methods, regulating nicotine in tobacco products, evaluating new tobacco products, and smokeless tobacco products.

In 2003, WHO formalised the status of the former SACTob as a study group: the WHO Study Group on Tobacco Product Regulation (TobReg). The main objectives of this body are the same as the original objectives of SACTob, but it is specifically mandated to promote principles to guide the development of laboratory capacity to assist with the implementation of Articles 9, 10 and 11 of the WHO FCTC. TobReg has developed a range of reports on the scientific basis of tobacco product regulation and best practices in tobacco control. TobReg membership is drawn from scientists in the fields of product regulation and laboratory analysis of tobacco contents, emissions, and design features.

TobReg sees disclosure to the public as a consumer right, but states that regulatory bodies have an obligation to ensure that the public is not misled by the information, particularly by thinking that lower levels of certain constituents mean lower risk. It notes that regulators should ensure that information about the levels of carcinogens in smokeless tobacco products should not be given to consumers in any way that may be used to rank products or lead them to believe that certain products are less harmful than others. This recommendation is equally true of any tobacco product, and TobReg notes that displaying information about tar, nicotine and carbon monoxide on packaging is harmful to the public partly for this reason.

---

63 Further information about TobReg is available at: http://www.who.int/tobacco/global_interaction/tobreg/en/.
TobReg’s main focus is on developing guidance on the implementation of product regulation, particularly regulating the mainstream smoke from manufactured cigarettes. It makes a number of recommendations about limiting additives, setting biomarkers of tobacco smoke-induced health effects, and setting maximum limits on toxic constituents in cigarette smoke.67

When discussing the regulation of toxicants in cigarette smoke, TobReg states that regulatory strategies for nicotine, tar and carbon monoxide, based on international standards, are causing harm because they mislead consumers into thinking that lower yields equate to lower risk.68

TobReg promotes a precautionary approach to the reduction of toxicants, similar to the approach taken to reduce contaminants in food, where there is often an absence of clear evidence that reducing the level of contaminants reduces the risk of disease but levels are regulated regardless.69 It cautions that this approach is a strategy for regulating products rather than reducing harm because of the lack of definitive evidence that reducing the level of a single toxicant would reduce the risk, but concludes that reducing the level of toxicants is a worthwhile public health exercise. TobReg further recommends that limits be placed on any additives that could contribute to “dependence, initiation, or increase in second-hand smoke exposure, or that discourages cessation.”70

3. Policy objectives

3.1 High-level tobacco control objectives

The core goal of the National Tobacco Strategy 2012-2018 is:

“To improve the health of all Australians by reducing the prevalence of smoking and its associated health, social and economic costs, and the inequalities it causes.”

The targets outlined in the Strategy are to, by 2018:

- reduce the national adult daily smoking rate to 10 per cent of the population; and
- halve the Aboriginal and Torres Strait Islander adult daily smoking rate.

Specific objectives of the Strategy are to:

- prevent uptake of smoking;
- encourage and assist as many smokers as possible to quit as soon as possible, and prevent relapse;
- reduce smoking among Aboriginal and Torres Strait Islander people, groups at higher risk from smoking, and other populations with a high prevalence of smoking;
- eliminate harmful exposure to tobacco smoke among non smokers;
- reduce harm associated with continuing use of tobacco and nicotine products;
- ensure that tobacco control in Australia is supported by focused research and evaluation;
- ensure that all of the above contribute to the continued denormalisation of smoking.

It also identifies nine priority areas and associated key actions to be implemented to reduce tobacco-related harm. Priority area 7 specifically relates to this RIS:

“Consider further regulation of the contents, product disclosure and supply of tobacco products and...”

These statements explicitly signal that the Government has previously intervened, and is willing to continue to intervene, in an established market, and work with stakeholders to reduce peoples’ participation in that market – i.e., reducing the prevalence of smoking with a view to reducing the costs and harms caused by tobacco products.

It is not the intention of this RIS, however, to look at all of the potential tobacco control measures and select the exact mix that is needed to achieve the goals of the NTS. Australia’s comprehensive tobacco control program recognises that a range of initiatives are needed. This RIS does not seek to provide a comparative analysis of the value/merits of interventions in these two areas of tobacco control against the full range of other established or potential new tobacco control interventions that make up (or could be added to) Australia’s current framework (e.g. tax, health promotion, plain packaging requirements, graphic health warnings, advertising/sponsorship restrictions, display restrictions, second hand smoke intervention, smoking cessation, enforcement activity, etc.).
3.2 Specific policy objectives for tobacco product content regulation

3.3 Specific policy objectives for tobacco product disclosure
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

4. Options

4.1 Options for new tobacco product content regulation requirements
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Component</th>
<th>Summary of coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

33
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Component</th>
<th>Summary of coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Component</th>
<th>Summary of coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FOI 111-1617

DOCUMENT 1
Page 36 of 101
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
4.2 Options for new tobacco product disclosure requirements

In 2011-12, the Department of Health commissioned a study to assess the scientific, technical, practical feasibility and public health value of regulating disclosure of tobacco product ingredients and emissions data in Australia.81

The study was to help inform consideration of options in the area of tobacco product disclosure. It considered potential approaches to tobacco product disclosure that are being used internationally, and identified a number of potential disclosure scheme “packages” that could be implemented in Australia. Some of the packages provided for more comprehensive and specific information to be disclosed by tobacco companies to the Australian Government, but would cost more to implement (to both industry and Government). Other packages would impose less stringent disclosure requirements and provide proportionately less detailed information, but would impose fewer costs.

Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 3</th>
<th>Column 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 5</th>
<th>Column 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 7</th>
<th>Column 8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 9</th>
<th>Column 10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 11</th>
<th>Column 12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 13</th>
<th>Column 14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 15</th>
<th>Column 16</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 17</th>
<th>Column 18</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 19</th>
<th>Column 20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
5. Impact analysis

5.1 Qualitative assessment of the options
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
5.2 Quantitative assessment - CBA
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

6. Consultation
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

FOI 111-1617
Revised draft submitted to Department of Health. Does not reflect Government policy.

7. Conclusion
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.

8. Implementation and review
Revised draft submitted to Department of Health. Does not reflect Government policy.
Revised draft submitted to Department of Health. Does not reflect Government policy.
Appendix 1: Filter ventilation

NB: The intent of this paper is to provide background information on filter ventilation to inform further policy consideration. It does not answer all questions/issues raised.

This information on filter ventilation is drawn from a number of sources. The primary source is Purcell Consulting’s literature review commissioned by the Department of Health. This literature review was drawn on to inform the product content regulation parts of the RIS. Other sources include peer-reviewed research papers and submissions and further information provided during the development of the RIS.

Introduction of filter ventilation

Filter ventilation is a common term used to describe tipping paper perforations which are used to dilute the smoke with fresh air when the smoker takes a puff. Essentially, some smoke is replaced with air in the standard puff, causing less smoke to be produced at the burning cone. There are also some subtler effects. The reduced draw on the burning cigarette cone also reduces the temperature at the cone, which can change the nature of the smoke. The smoke moves through the filter at a lower velocity because of ventilation.

Some commentators argue that filter ventilation was introduced 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 process of compensatory smoking. Purcell’s literature review found that the International Organisation for Standardization (ISO) test used to measure 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. Kozlowski et al. argue that “ultimately, filter ventilation became a virtually required way to make very low tar cigarettes (i.e. less than 10 mg tar)”. Purcell found that filter ventilation is an important cigarette design feature which influences flavour, strength, harshness and irritation. Smoking behaviour is primarily driven by demand for nicotine.

100 Purcell cites the following to support this assertion:
102 Purcell, 2013.
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.103

Of the manufacturing changes to cigarettes that have contributed to the development of lower tar and nicotine cigarettes, filter ventilation has been the major innovation behind the modern low-yield cigarette.104 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.’105 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.

Kozlowski and O’Connor described it as follows:

“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.” 106

Three key issues identified by Purcell with this form of product modification are noted below.107

1. The combined effects of increased filtration and increased ventilation make the smoke more diluted 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).

This lighter or milder taste can support the smoker’s perception that filter vented 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. 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.

2. Increased ventilation can facilitate increased puff volumes (i.e. puff duration and inhalation depth), a key means of compensatory smoking. Kozlowski notes that when common best-selling American ‘light’ cigarettes are smoked, increased puff volume can achieve compensation so well that behavioural vent blocking is superfluous. This can lead to additional health problems caused by deeper inhalation. A potential link between deep inhalation and cancer was suggested in recent research by Thun et al (a summary of this paper is provided below).108

107 Purcell, 2013, p. 69.
3. Behavioural vent blocking can play a role when increased puffs do not comfortably provide ample compensation. It is well known that smokers commonly block the vent holes with their lips or fingers. When these vents are blocked, cigarettes are rated as harsh as and hotter than unblocked vents; however, most behavioural vent blocking is incomplete, often diminishing ventilation levels by 50 per cent or 25 per cent.

**WHO FCTC Partial Guidelines for Articles 9 & 10**

The WHO FCTC Partial Guidelines also advise on “design features” (meaning a characteristic of the design of a tobacco product that has an immediate causal link with the testing and measuring of its contents and emissions). It is noted, for example, that ventilation holes around cigarette filters decrease machine-measured yields of nicotine by diluting mainstream smoke. Filter ventilation is only discussed in the Partial Guidelines in the context of disclosure.

**WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob); Study Group on Tobacco Product Regulation (TobReg); and Working Group(s) Guidelines/Research**

The WHO SACTob; TobReg; and Working Group(s) recognise that product modification is an area of tobacco control that requires further scientific enquiry and should be considered during tobacco control policy and regulation. There is no clear direction or guidance on how regulation in this area could/should be developed.

A paper by SACTob developed in 2001 on a “Statement of Principle Guiding the Evaluation of New or Modified Tobacco Products”, argues that increasingly new tobacco products on the market claim reduced exposure, reduced toxicity and reduced health risks due to modification of product design, and that Member States face the need to make decisions and formulate policies with regard to these modified products as they come to market. It sets out three general categories of products for which claims are being made:

1. Products that resemble conventional cigarettes but which claim to reduce toxicity or addiction potential of the smoke generated by altering the tobacco used or the filter characteristics, or by adding new substances;
2. Products in which the principal means of delivering nicotine is heating rather than burning the tobacco (reducing the carcinogenic constituents of smoke); and
3. Oral tobacco products - as generally less hazardous than cigarettes.110

Conclusions include that:

- Existing scientific evidence is not sufficient to assess the differences in health risk potential between newly engineered tobacco products and existing products for composition, exposure, toxicity, or harm;
- Regulatory oversight of cigarette and cigarette-like products should include examination of at least five separate aspects of the new products: physical chemical characteristics of the tobacco and tobacco smoke, uptake of toxicants, toxicity, addiction potential, and disease risk;
- Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim; and
- Each type of claim requires a substantive body of evidence; an independent regulatory body capable of examining the claims should determine whether the claims are valid.111

---

Aside from this study, there is very little other guidance on the regulation of modified products, particularly on toxicity as the scientific evidence remains unavailable.

More specifically on filter ventilation, most of the WHO literature uncovered is focused on one of two areas of concern. Firstly, on the marketing potential of selling filtered cigarettes as “lighter brands”, due to the lower yields of tar, nicotine and carbon monoxide estimated on testing machines. Secondly, on the validity of these tests, given the more intense smoking experiences smokers can have when cigarette filter vents are blocked. Recommendations within these two areas of concern are clear:

- a ban should apply to packaging, brand names, advertising and other promotional activities with the terms light, ultra-light, mild, and low tar; and
- new methods of testing for tar, nicotine and carbon monoxide yields need to be developed by the international community.

In the area of regulation for filter vents for palatability reasons there were no clear directives uncovered.

**Machine testing approaches for tar and nicotine yields**

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 35ml puff of two seconds duration once a minute until a fixed butt length (23 mm) is reached. The FTC method has its origin in the early efforts of tobacco industry researchers to compare cigarettes of the day. Kozlowski argues that it ‘would be wrong to assume that the numbers [achieved through the FTC testing regime] have any bearing on smoker exposure to tar and nicotine’. Limitations of this method for accurately testing human intakes of tar, nicotine and other chemicals while smoking cigarettes with filter ventilation has long been recognised.

Despite these limitations the ISO adopted the same parameters as the FTC regime in the 1980s, with a slight modification. Among other differences, the ISO method uses different conditions for smoking, such as temperature, different drafts on the smoking machine, and different cigarette butt length. The ISO standard was adopted by Australia for reporting on cigarette packets, but this was subsequently discontinued in 2006. The ISO test has been used in many other countries. The limitations are recognised by the tobacco industry as well, with the BAT website informing readers that:

> While [the ISO] standard method gives a consistent way of ranking tar, nicotine and carbon monoxide yields among different types of cigarettes, the machines do not measure what tar yield levels individual smokers actually get from cigarettes. A person may take more puffs, puff more strongly or smoke more of the cigarette than the smoking machines using the standard ISO method, all of which would result in the smoker taking more tar than indicated by the standard ISO method.

---

111 Ibid.
115 Purcell Consulting, 2013, p. 64.
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 tests 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 55ml puff over two seconds, once every 30 seconds (and with all filter ventilation taped over). However, the tobacco industry has argued that the Canadian Intensive regime ‘creates more problems than it solves’ and provides the following evidence to support their claim:117

- Blocking of 100 percent of ventilation holes does not occur in human smoking (Pickworth et al., 2005)
- Ventilation is proven to be a viable design tool since it leads to lower levels of biomarker of exposures for most smokers (Roep, 2009)
- Strong relationship between yields and the difference between smouldering and smoking time, with filter ventilation open or blocked under a wide range of smoking regimes (Colard et al., 2012) and so the Canadian Intensive method does not provide better product characterisation than the ISO regime.

A study by Hammond et al. concluded that none of the alternative smoking regimes, including the Canadian Intensive method, are more ‘representative’ of human smoking behaviour and none provide adequate prediction of human exposure. The 2010 Surgeon General’s report states that ‘there is no available cigarette machine-smoking method that can be used to accurately predict doses of the chemical constituents of tobacco smoke received when using tobacco products’.119

Arguments for banning filter ventilation

A tobacco control researcher asserts that there is ‘no empirical evidence or any compelling theoretical reason that filter ventilation might have any positive effects on the health consequences of smoking’.120 Additionally, there is evidence that it is the major factor determining the perceived strength of a cigarette and other elements of consumer acceptability. They go on to argue that:

\[
\text{It is likely that a ban on filter venting would do more to reduce the palatability of cigarettes than prohibitions on additives. However, it is not an either/or situation; prohibition of both filter venting and palatability/inhalability-related additives would be optimal.}\]

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 reduced harm but does not deliver any corresponding reduction in exposure to the toxic chemicals in cigarettes. Filter ventilation creates the illusion of reduced harm as the cigarettes taste milder. Filter ventilation is used extensively by

118 Imperial Tobacco, Cigarette Filter Ventilation – Background and rationale, paper submitted as part of their submission on: Discussion Paper on potential new tobacco control initiatives; options to introduce new tobacco product content controls and new disclosure requirements for tobacco products.
120 Submission by Ron Borland on: Discussion Paper on potential new tobacco control initiatives; options to introduce new tobacco product content controls and new disclosure requirements for tobacco products.
121 Ibid.
tobacco manufacturers to achieve decreasing tar, nicotine and carbon monoxide yields in ISO tests while maintaining actual nicotine delivery to smokers.\textsuperscript{122}

Purcell found a number of peer-reviewed articles regarding the significant impact of filter ventilation on the rate, frequency and intensity of smoking. Purcell concluded that there is ‘strong evidence in the peer-reviewed literature regarding the significant impact of filter ventilation on the rate, frequency and intensity of smoking’.\textsuperscript{123} Purcell also notes that there is evidence that filter ventilation facilitates increased puff volumes by smokers, a key means of compensatory smoking. Purcell states that it is well established that nicotine-addicted smokers smoke lower yield cigarettes more intensively by taking more frequent or larger puffs.\textsuperscript{124}

As the following quote from Philip Morris demonstrates, the tobacco companies were aware that filter ventilation allowed cigarettes to measure low levels of tar and carbon monoxide, while nicotine delivery was essentially unchanged:

\begin{quote}
The 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 [carbon monoxide and nitric oxide]. Tar was also reduced, but to a lesser degree than previously and nicotine delivery was essentially unchanged until high dilutions were achieved.\textsuperscript{125}
\end{quote}

Purcell found that there is evidence that filter ventilation zones are one of a number of cigarette design factors that influence perceived irritation.\textsuperscript{126} 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 harm at the population level by promoting smoking uptake and discouraging cessation.\textsuperscript{127}

Table 1, below, taken from the fourth edition of \textit{Tobacco in Australia: Facts and Issues}, compares Australian brands in the six ‘tar bands’ in 1994.\textsuperscript{128} The table shows that average filter ventilation and average filter weight increase steadily as nominal tar yield decreases. Percent nicotine, estimated total available nicotine and tobacco weight did not illustrate extensive difference across the six tar bands. Rather, as illustrated below, mean percent nicotine contents were highest in the ‘1mg or less’

\begin{itemize}
\item Dixon M. Notes on Meeting Held on 13/10/93 to Discuss Approaches to Modify Impact: Irritation Ratios. Available from http://legacy.library.ucsf.edu/tid/ctv53a99/pdf.
\item SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks). Addictiveness and Attractiveness of Additives, 12 November 2010.
\end{itemize}
Revised draft submitted to Department of Health. Does not reflect Government policy.

and '2mg or less' tar bands. So while reducing nicotine levels in unburned tobacco could potentially reduce nicotine levels, this does not actually occur.

**Table 1: Comparison of Australian brands in the six nominal yield 'tar bands' from 1994, mean performance and construction figures**

<table>
<thead>
<tr>
<th>Nominal tar yield</th>
<th>1mg</th>
<th>2mg</th>
<th>4mg</th>
<th>8mg</th>
<th>12mg</th>
<th>16mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tar yield (CPM), mg</td>
<td>1.29</td>
<td>2.36</td>
<td>3.41</td>
<td>6.4</td>
<td>8.91</td>
<td>10.87</td>
</tr>
<tr>
<td>Nicotine yield, mg</td>
<td>0.19</td>
<td>0.30</td>
<td>0.40</td>
<td>0.68</td>
<td>0.91</td>
<td>1.00</td>
</tr>
<tr>
<td>Carbon monoxide yield, mg</td>
<td>1.81</td>
<td>2.79</td>
<td>3.6</td>
<td>6.2</td>
<td>8.18</td>
<td>9.88</td>
</tr>
<tr>
<td>Filter weight, mg</td>
<td>141</td>
<td>123</td>
<td>119</td>
<td>103</td>
<td>97</td>
<td>92</td>
</tr>
<tr>
<td>Ventilation %</td>
<td>77</td>
<td>69</td>
<td>62</td>
<td>36</td>
<td>21</td>
<td>4</td>
</tr>
<tr>
<td>Nicotine %</td>
<td>2.5</td>
<td>2.5</td>
<td>2.3</td>
<td>2.3</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Tobacco weight, mg</td>
<td>523</td>
<td>496</td>
<td>543</td>
<td>549</td>
<td>559</td>
<td>564</td>
</tr>
<tr>
<td>Available nicotine, mg</td>
<td>11.3</td>
<td>10.6</td>
<td>10.7</td>
<td>11.1</td>
<td>11.5</td>
<td>11.6</td>
</tr>
</tbody>
</table>

**International studies on tobacco product design**

The Journal of Tobacco Control documents a number of papers/studies in the area of product modification, with a focus on filter ventilation rather than other forms of modification/engineering. We also looked more closely at key reports that were heavily referenced in these articles to identify their key findings. A selection of literature considered during the development of the RIS is noted below.

Kozlowski et al: Maximum yields might improve public health – if filter vents were banned: a lesson from the history of vented filters

Kozlowski et al propose that the banning of filter vents, coupled with low maximum standard tar, nicotine, and carbon monoxide yields, would contribute to making cigarettes much less palatable and foster smoking cessation or the use of clearly less hazardous nicotine delivery systems.

The reasons behind this proposed ban are a combination of palatability and toxicity reasons. Kozlowski et al cite a 1999 study where UK Action on Smoking and Health (ASH) and The Observer commissioned tests that looked at the effects of blocking all vents on ISO tar and nicotine yields. Unblocked, the ISO yields for Silk Cut Ultra were 0.16mg nicotine and 1.4 mg tar; fully blocked, the nicotine was 1.21 mg and 12.3 mg tar. Silk Cut Ultra was approximately 84 percent filter vented.

Kozlowski et al also argue that if companies were forced to meet yields without reliance on filter ventilation, it is likely that they would need to use less tobacco per cigarette as well as improved filtration and would need to emphasise decreased burn-time. Further, many smokers would find them difficult and unpleasant to smoke which might facilitate them cutting back or quitting.


The 2004 United States Surgeon General’s Report into The Health Consequences of Smoking included a range of findings about the use of perforation of the filter tips (filter ventilation).

---


The report recognised the limitations of the Federal Trade Commission (FTC) protocol for measuring average tar and nicotine yields of cigarettes, including the fact that ‘tar and nicotine yields are lowered by perforation of the filter with small holes to increase dilution during machine smoking in the FTC protocol; unlike the machines, smokers tend to cover these holes with their fingers, thereby increasing the yield beyond that measured by the machine.

The report referred to findings from the 1981 Surgeon General’s report which had focused on the ‘changing cigarette’, including the following major conclusions: 131

1. There is no safe cigarette and no safe level of consumption.
2. Smoking cigarettes with lower yields of ‘tar’ and nicotine reduces the risk of lung cancer and, to some extent, improves the smoker’s chance for longer life, provided there is no compensatory increase in the amount smoked. However, the benefits are minimal in comparison with giving up cigarettes entirely.
3. Smokers may increase the number of cigarettes they smoke and inhale more deeply when they switch to lower yield cigarettes. Compensatory behaviour may negate any advantage of the lower yield product or even increase the health risk.
4. The ‘tar’ and nicotine yields obtained by present testing methods do not correlate to the dosages that the individual smokers receive: in some cases they may seriously underestimate these dosages.
5. A final question is unresolved; whether the new cigarettes being produced today introduce new risks through their design, filtering mechanisms, tobacco ingredients or additives.

The 2004 Surgeon General’s report goes on to analyse a range of epidemiological studies into cancers and other health risks and their relationship to cigarette smoking, with a particular focus on lung cancer. A synthesis of the evidence found:

- The risk of lung cancer varies strongly with duration of smoking and with the number of cigarettes smoked.
- By comparison, the characteristics of the cigarettes smoked, primarily indicated by the presence or absence of a filter and machine-measured tar and nicotine yields, have at most a small effect on risk. 132

The Surgeon General goes on to argue that the net consequences of products with lower yields may be a detriment to public health, if their availability affects decisions to start or stop smoking.

Amongst other points, the report concluded that although characteristics of cigarettes have changed during the last 50 years, and yields of tar and nicotine have declined substantially as assessed by the FTC protocol, the risk of lung cancer has not declined.

The overriding implication of the Surgeon General’s report is that changes in the design of cigarettes intended to reduce tar and nicotine yields have had no significant beneficial consequences [our emphasis] for lung cancer risks in smokers.

More recently, the 2010 Surgeon General’s report concludes ‘The evidence indicates that changing cigarette designs over the last five decades, including filtered, low-tar, and “light” variations, have not reduced overall disease risk among smokers and may have hindered prevention and cessation efforts.’ 133

131 Ibid, pp. 49-51. This list includes the key points that relate to filter ventilation from the 1981 report as outlined by the Surgeon General in 2004. The bolded text represents our emphasis.
132 Ibid. p. 61. The bolded text represents our emphasis.
Kozlowski, O’Connor & Sweeney, Smoking and Tobacco Control Monograph 13, Chapter 2: Cigarette Design

This report concludes that the observed decreases in standardised yields of tar and nicotine that have occurred since 1968 do not seem to translate into reduced exposure for smokers. Smokers can consciously or unconsciously compensate for lower standard yields in a number of easy and effective ways. Two of the more common ones, which are recognised by the tobacco industry, are increasing the number and volume of puffs.

The report discusses how smokers are not limited in the number of puffs they may take from a cigarette. Smokers can counteract yield reduction methods simply by taking more puffs per cigarette. If smokers receive less tar and nicotine per puff from lower yield products (including those with filter ventilation) then they can easily compensate by taking more puffs or smoking more cigarettes per day.

Another easy way for the smoker to increase smoke intake, suggests the report, is to increase the volume of each puff. Total puff volume per cigarette is a function of puff number and volume per puff. In terms of overall exposure, total volume per cigarette is a better index and gives insight into how much ‘work’ the smoker performs in smoking the cigarette. Published studies confirm that smokers will change their puff size (volume) in response to the type of cigarette they smoke, including those with increased filter ventilation.

Another technique smokers can use to increase smoke concentration is the blocking of filter vents. Research has shown that the majority of smokers are unaware of the presence of vents in general or even in their own brands. Kozlowski et al. argue that the ‘ease with which smokers can unknowingly compensate for low standard yields by interfering with this important design has long been known within the cigarette industry’.

Conclusions of this report included that “increasing puff volume and frequency, covering the ventilation holes with fingers or lips, and other changes in smoking behaviour known to occur with use of low machine-measured-tar cigarettes can dramatically increase the tar and nicotine delivery of low and ultralow yield brands”.

Other articles

A recent journal article also suggested a potential link between historical product design changes in cigarettes and the evolving trends in smoking-related harm. Thun et al. (2013) measured temporal trends in mortality across three time periods (1959-65, 1982-88, and 2000-10) and presented a 50 year perspective on the evolution of smoking-related risks in United States’ smokers.

One of the authors’ key findings was that the rate of death from chronic obstructive pulmonary disease (COPD) continues to increase among both male and female smokers over time in contrast to a significant decrease in risk among men who never smoked. After ruling out some explanations the authors suggested that a plausible explanation for the continuing increase in deaths from COPD among male smokers is that cigarettes marketed since the late 1950s have undergone design changes that promote deeper inhalation. For example, the introduction of blended tobacco and


87
Revised draft submitted to Department of Health. Does not reflect Government policy.

Genetic selection of tobacco plants lowered the pH of smoke so that inhalation was easier and deeper inhalation was needed for the absorption of protonated nicotine.

Thun et al. also noted design changes such as the use of more porous wrapping paper and perforated filters, also have helped dilute tobacco smoke. The authors argue that deeper inhalation of more dilute smoke increases exposure of the lung parenchyma. Such design features may also have contributed to the shift, in the histologic and topographic features of lung cancers in male smokers, which began to emerge in the 1970s. This involved an increase in the incidence of peripheral adenocarcinomas that largely offset the decrease in squamous-cell small cell cancers of the central airways. The likely net effect of deeper inhalation on COPD could be wholly detrimental, since COPD results from injury to the lung parenchyma.

Arguments against product design controls (i.e. banning filter ventilation) raised by industry during consultation

During the consultation period, three tobacco companies and one tobacco importer opposed product design controls.

The tobacco companies had three clear reasons for this opposition including:

- general misunderstanding of the purpose of filter vents;
- the myths around filter vents and potential unintended consequences of regulation; and
- lack of scientific evidence behind the need for regulation.

The tobacco companies argued that the purpose of filter vents is generally misunderstood, and controls are not necessary and/or relevant to achieving public health objectives. Arguments against banning filter ventilation included:

- that the main purpose of a cigarette filter is to reduce the particulate smoke yield, which is achieved by mechanical filtration of aerosol particles,
- apparent misunderstanding of the purpose of the filter ventilation technology, which it is argued is used to ensure compliance with other obligations to deliver consistent tar, nicotine and carbon dioxide yields (as well as reducing the fire risk).

All of the tobacco companies asserted that because filter vents have an important effect on cigarette smoke yields, banning them could result in consumers being exposed to increase levels of smoke toxicants (most notably to gas phase constituents, such as carbon monoxide). One company referred to a research paper by Benowitz et al. as evidence to support the drawbacks of the removal of ventilation. The key argument for the tobacco company from this paper was that 'nicotine and tobacco toxin exposure was substantially reduced while smoking 0.1mg nicotine cigarettes'.
One tobacco company suggested that:

> Smokers in Australia prefer cigarettes with ISO tar yields at or below 12mg. These cigarettes use filter ventilation to achieve the specific tar yields. Banning filter ventilation would lead to an increase in the ISO tar, nicotine and carbon monoxide yields of Australian cigarettes.144

The tobacco companies were not only concerned about a perceived lack of understanding about the purpose of filter vents, but also what they see as the myths surrounding the technology. One submitter argued that filter ventilation does not increase the palatability of the cigarette and nor does it “cheat” machine yields through compensatory smoking. Rather, the submission argued that the palatability of the cigarette is diminished as the smoke, the taste, and the sensory satisfaction is diluted. While the submission acknowledged that an amount of constituents can be affected by the intensity of smoking, considerable reductions of vapour phase components are still achievable, even with 50 percent vent blocking during machine-smoking.

Another submitter argued that it would be premature to impose restrictions on product design features of cigarettes without an adequate understanding of the potential public health effects and any adverse consequences. They suggested that care has to be undertaken to ensure that regulatory measures do not cut across harm reduction initiatives or prevent future development of similar mechanisms.

Finally, the tobacco companies all argued that there is a lack of scientific evidence that controls around product design features would lead to a decrease in smoking prevalence, youth smoking, addiction or toxicity.

**Conclusion**

Filter ventilation is arguably a powerful means for influencing the beliefs of smokers about the relative harmfulness of different brands. It is also considered 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.

There is clear support for banning filter ventilation in cigarettes from some Australian and international public health commentators. The 2004 Surgeon General’s report found that the introduction of low tar and nicotine yield cigarettes, often achieved through filter ventilation, ‘have had no significant beneficial consequences for lung cancer risks in smokers’.145 More recently, as noted above, the 2010 Surgeon General’s report concluded that changing cigarette designs over time (including filtered, low-tar, and “light” variations) have not reduced overall disease risk among smokers and may have hindered prevention and cessation efforts.146

Any moves to prohibit filter ventilation will be strongly opposed by Industry using arguments such as those noted above.

Cigarette filter ventilation has not been prohibited by any country. There is a lack of stated international consensus over filter ventilation and other approaches to product engineering.

---

144 Philip Morris Limited submission.
Additionally, if the Government decides to ban filter ventilation, it may need to consider the implications of industry potentially adopting other product designs that have a similar effect.

Any options that consider the banning of filter ventilation would need to be supported by extensive awareness-raising to explain the actual effects of filter ventilation and that prohibiting this design feature is intended to make cigarettes less palatable and is unlikely to affect the toxicity of cigarettes. It is likely the tobacco industry would run a parallel campaign arguing that government is banning one of the few options they have available to make cigarettes less harmful.
Appendix 2: Summary of the Voluntary Disclosure Agreement

<table>
<thead>
<tr>
<th>Disclosure element</th>
<th>Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose (Why is the information disclosed? What is it used for?)</td>
<td>The preamble to the Voluntary Agreement states that the information is collected to provide information to consumers on the ingredients of tobacco products.</td>
</tr>
<tr>
<td>Coverage (Who is covered?)</td>
<td>The Voluntary Agreement only covers the three tobacco manufacturers (and largest importers) in the country: Philip Morris Limited, British American Tobacco Australia Limited and Imperial Tobacco Australia Limited. Smaller companies are not covered.</td>
</tr>
<tr>
<td>History of arrangement</td>
<td>The agreement was signed on 20 December 2000.</td>
</tr>
<tr>
<td>Key documents and legislation</td>
<td><em>Voluntary Agreement for the Disclosure of Ingredients of Cigarettes.</em> The agreement is voluntary and not covered by legislation or regulation.</td>
</tr>
<tr>
<td>Ingredients (What information is disclosed?)</td>
<td>Each manufacturer provides an annual report that covers three aspects of their products:</td>
</tr>
<tr>
<td></td>
<td>• A by-brand variant disclosure list, which covers product weight, tobacco weight, and ingredients added to tobacco in descending order of weight. Manufacturers group ingredients added to tobacco that provides flavour as general groups under ‘natural flavours’ and ‘artificial flavours’. Processing aids and preservatives are grouped in the same way.</td>
</tr>
<tr>
<td></td>
<td>• A composite list of all ingredients added to tobacco, including all flavouring and processing aids and preservatives, including the function of each ingredient (e.g., filler, flavour, humectant, preservative, binder, etc.). This list is not broken down to brand-variants but provides information across the whole range of cigarettes. The quantity not exceeded is reported, which indicates the highest concentration that the ingredients can be found in, in any one of a company’s products.</td>
</tr>
<tr>
<td></td>
<td>• A composite list of non-tobacco ingredients across all cigarette brands, which follows the same structure as the composite tobacco ingredients list.</td>
</tr>
<tr>
<td>Constituents (What information is disclosed?)</td>
<td>No requirements.</td>
</tr>
<tr>
<td>Emissions (What information is disclosed?)</td>
<td>Emissions information was provided once in 2001 and has not been sought since. Information on 40 separate emissions was provided.</td>
</tr>
<tr>
<td>Product characteristics</td>
<td>No requirements beyond non-tobacco ingredients.</td>
</tr>
<tr>
<td>Testing (What are the requirements for disclosed information?)</td>
<td>No testing requirements as such, but each report must include an attestation that states the information in the report is true and complete to the best of the knowledge and belief of the person responsible for providing the report.</td>
</tr>
<tr>
<td>Sales (What information is disclosed?)</td>
<td>No information relating to sales is collected under the Voluntary Agreement. Outside of the agreement, sales information is collected by the Australian Taxation Office (total excise tax paid on all products) and Customs (amount of product imported into Australia).</td>
</tr>
</tbody>
</table>
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Disclosure element</th>
<th>Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry research (What information is disclosed?)</td>
<td>No requirements.</td>
</tr>
<tr>
<td>Reporting and collection format (How is the information disclosed? How is accuracy and completeness of data ensured?)</td>
<td>The information is provided in both electronic and hard copy formats. The information must be provided in the format described in Schedule A to the Voluntary Agreement. Government authorities check that the information provided is complete, but rely on the tobacco companies to provide accurate information.</td>
</tr>
<tr>
<td>Compliance costs (for tobacco companies)</td>
<td>Actual compliance costs are unclear; however, one tobacco company estimated that completing information for the report took around two weeks work (i.e., 10 days FTE) between the company's technical staff in Europe and corporate staff in Australia.</td>
</tr>
<tr>
<td>Resource requirements for government (staffing and costs)</td>
<td>The Government is involved in ensuring the information is provided on time and that it complies with the requirements of the Voluntary Agreement. The core activity is ensuring the Information is placed on the Department’s website for public consumption. Some analysis of the data, such as comparing brands between years, has been undertaken most years.</td>
</tr>
<tr>
<td>Public disclosure (What is provided to the public? How often? (How) are trade secrets protected?)</td>
<td>The reports are made available for public download on the Department of Health’s website. The Voluntary Agreement allows companies to apply a quantitative cut off whereby ingredients used at low levels are reported by-brand variant and flavours can be grouped under the category natural/artificial flavours.</td>
</tr>
</tbody>
</table>
Appendix 3: Research and Reference Materials

For several decades there has been increasing concern amongst tobacco control experts and health agencies about the use of ingredients to increase palatability of cigarettes; the methods of testing these additives; and the disclosure of these ingredients.

This has led to the development of a body of international evidence, including several studies undertaken in Australia, in the areas of tobacco product content regulation and tobacco product disclosure.

During the consultation period, stakeholders provided or referred to various research papers to support their submissions. This was dealt with in three ways:

- Technical / published papers provided to Allen & Clarke were reviewed, and information was inputted into the submissions database and briefly summarised in the summary of submissions. The source is identified.
- Any international research papers forwarded to Allen & Clarke by stakeholders, or any international research papers that stakeholders have specifically recommended in their submissions for inclusion in our analysis, have been noted and summarised in the summary of submissions.
- Any published papers that are merely referenced in submissions, as a means of supporting various arguments presented in that submission, are noted by the project team within the summary of submissions.

The table below highlights the key documents on the palatability of tobacco products from this body of research and commentary. Literature relating to toxicity and/or addictiveness has been omitted from this table as it is out of scope of the RIS (see discussion in section 4.1)

**Tobacco Product Regulation**

Some key studies and commentaries include (see Appendix 1 for further information related to filter ventilation):

<table>
<thead>
<tr>
<th>Publication</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purcell Consulting. The Effect of Cigarette Additives on the Palatability of Cigarette. Draft report provided to the Department of Health and Ageing, 26 March 2013.</td>
<td>The Department of Health contracted this review to help inform the content regulation part of the RIS. The review considered the effect of additives and product engineering features on the palatability of tobacco products. It considered international and Australian research, tobacco company documents, published research by tobacco company scientists and international regulatory approaches in other countries. The key findings from Purcell report are included in section 2.2 of the RIS and, in relation to filter ventilation, in Appendix 1.</td>
</tr>
<tr>
<td>Purcell Consulting. Analysis of Tobacco Companies’ Voluntary Disclosures on Cigarette Ingredients (2000-2011). Draft Report provided to the Department of Health and Ageing, January 2013.</td>
<td>This report was part of a wider project looking at the impact of tobacco additives on the palatability of cigarettes (the first stage was the literature review referred to in the row above). The report analysed voluntary disclosures on cigarette ingredients and focused on: (i) the composite disclosures of ingredients added to the tobacco used in cigarettes, and (ii) the brand by brand disclosures of ingredients added. It also describes the results of tobacco company document searches. The review found considerable change occurring in the use of additives by the Australian manufacturers in the period between 2000 and 2012. This included a suggested (but, the authors argue, “not demonstrated”) general trend of decline in numbers of additives disclosed between 2000-1 and 2010-11. New additives have been reported in most years</td>
</tr>
</tbody>
</table>
and increases in the maximum levels used have also been reported for some additives. The authors note a major limitation on their findings being shortcomings in the current voluntary disclosure agreement (such as quantitative cut off provisions meaning that an additive below a certain amount may not be being disclosed).

The brand by brand disclosures provided evidence that, rather than having a fixed recipe for each brand variety which is adhered to each year, there appears to be some degree of year by year variation in the reported additives used.

The authors also report that brand by brand disclosures also provide strong evidence that the three big tobacco companies take somewhat different approaches to produce 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 BAT 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.

The searching of tobacco company documents highlighted the extensive use of tobacco additives as ameliorants in Australian cigarettes. Ameliorants are used to reduce the harshness and irritation associated with smoking and as a result they can improve the palatability of cigarettes. Tobacco company documents also confirmed that many tobacco additives have multiple functions – for example sugar used as a casing may act as an ameliorant; influence the character or flavour of the tobacco, assist in moisture retention and/or retard the burn rate. A number of acids are included in Australian ingredient reports that are reported as flavours but are likely to also act as ameliorants. It is also possible that humectants such as propylene glycol and glycerol may serve a similar function.

Purcell Consulting, ‘Smokers’ Beliefs about Cigarette Palatability and Attitudes Toward the Regulation of Cigarette Additives. Draft report provided to the Department of Health and Ageing, January 2013.

The review was undertaken as a companion paper to review tobacco company disclosures noted above. The report analysed Australian smokers’ attitudes toward the regulation of cigarette additives, as well as smokers’ beliefs about the relationship between smoking sensations and perceived harmfulness.

It found an apparent decline in smokers’ support (over a ten year period) for tighter regulation of tobacco products. The authors argue that this finding may, in part, reflect a methodological artefact and noted that such a decline was not observed when looking solely at responses from a replenishment cohort of subjects that were brought in when some existing subjects dropped out of the research.

In later waves of the research more specific questions have begun to be asked. Waves 7 and 8 included a question about smokers’ support for a law that, “banned additives or flavourings that make cigarettes seem less harsh.” 62 and 68 per cent of Australian respondents supported such a law in research waves 7 and 8 respectively (compared to an average of 52 and 58 per cent when Australian results were combined with three other countries: Canada, UK, and USA).

In wave 8 another question was added: would smokers support banning off additives from cigarettes? This was more strongly supported in all four countries than the aforementioned question. It was supported by 83 per cent of respondents in Australia, compared to a 4-country average of 75 per cent. The authors suggest that the greater support to ban “all additives” might reflect some confusion about what the term ‘additive’ actually covers and means in practice. For example, some could think it would lead would lead to significant...
reductions in carcinogenic and toxic smoke constituents and it is also plausible that many smokers believe that a ban on additives would lead to cigarettes becoming significantly less addictive. Such potential outcomes may be more highly valued by smokers than the potential outcome of a ban on additives making cigarettes less palatable, even if they appear far less likely from an expert standpoint (carcinogenic and toxic smoke constituents are the result of the combustion of tobacco and the addictive properties of cigarette smoke are from the rapid delivery of nicotine to the central nervous system, and additives mostly affect secondary reinforcement).

<table>
<thead>
<tr>
<th>Publication</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Council of the European Union (EU), Proposal of a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (First reading), 2012/0366 (COD), Brussels, 24 June 2013</td>
<td>The EU recently released a proposal for a new Directive relating to member states' tobacco control laws. Part of the proposals related to content control and disclosure requirements on tobacco products sold in the EU. The proposals are seeking to harmonise the approach of Member States to ingredients regulation, to ensure Member States have the necessary information to exercise their legal regulatory function on tobacco products, and to fulfil to the EU's commitment under Article 9 and 10 of the WHO FCTC. The proposals prohibit tobacco products with characterising flavours. It is also proposed to prohibit products containing the following: vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards; caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality; additives having colouring properties for emissions; and additives that facilitate inhalation or nicotine uptake (relevant only for tobacco for smoking). It is proposed that Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products (i.e. sugar to replace sugar lost during the curing process), as long as the additives do not result in a product with a characterising flavour and do not increase in a significant or measurable manner the addictiveness of a product. It is proposed that Member States shall prohibit tobacco products containing flavourings in their components, such as filters, papers, packages, capsules, or any technical features allowing modification of smell, or taste or smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine. Tobacco products other than cigarettes and roll-your-own tobacco are proposed to be exempted from any prohibition. Under the Directive, the yields of cigarettes placed on the market, or manufactured in the Member States, shall not be greater than: 10mg per cigarette for tar; 1mg per cigarette for nicotine; and 10mg per cigarette for carbon monoxide. It is also proposed that Member States shall also require manufacturers and importers of tobacco products to disclose a list of all ingredients (including quantities) used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers and/or importers shall also inform authorities of the concerned Member State if the composition of a product is modified (information of this nature shall be submitted prior to placing on the market a new or modified tobacco product). It is proposed that the list of ingredients needs to be accompanied by a statement setting out the reasons for the inclusion of ingredients in the tobacco products, as well as the relevant toxicological data regarding these ingredients in burnt or unburnt form.</td>
</tr>
</tbody>
</table>
## Publication | Summary
--- | ---
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): European Union, Addictiveness and Attractiveness of Tobacco Additives, 2010. | Evaluates the role of tobacco additives in the addictiveness and attractiveness of tobacco products. The report concluded that the addictiveness of tobacco products may be increased by a number of additives but is also influenced by external factors such as marketing, price, etc. It noted that factors influencing addictiveness can be broadly divided into: extrinsic factors (e.g., marketing, packaging, pricing); and intrinsic factors (e.g., taste, smell, sensory attributes, and pharmacological factors). SCENIHR argues that additives play a role mainly in the first 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).

Purcell summarises the findings of the SCENIHR in relation to palatability as follows:
- 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.

German Cancer Research Center (DKFZ) [written in the context of the EU project Public Information Tobacco Control (PITOC), Report: Additives in Tobacco Products: Contribution of Carob Bean Extract, Cellulose Fibre, Guar Gum, Liquorice, Menthol, Prune Juice Concentrate and Vanillin to Attractiveness, Addictiveness and Toxicity of Tobacco Smoking, 2012. | Describes facts on the attractive, addictive, and hazardous health effects associated with seven tobacco additives used by the tobacco industry most often and in highest quantities: carob bean, cellulose fibre, guar gum, liquorice, prune juice extract, menthol and vanillin. The report argues that all of these additives have a role in making tobacco products more attractive/palatable (even if some additives also have other functions).

Argues that tobacco additives may increase the consumption rate of tobacco products by making the product more palatable and attractive to consumers, or by enhancing the addictiveness of the products. Additives may make individual brands taste more appealing and mask the taste and immediate discomfort of smoke. As such, additives may indirectly enhance tobacco-related harm by increasing the consumption of tobacco products.

Argues that additives are intentionally added to cigarettes by industry to modify flavour, regulate combustion, moisturise the smoke, preserve the cigarettes, and to act as solvents for other additives. Cites SCENIHR's conclusion that the addictiveness of tobacco products can be increased by additives but can also be influenced by external factors such as marketing, price, etc.

Gray, N. & Borland, R., Research Required for the Effective Implementation of the Framework Convention on Tobacco Control Articles 9 and 10, Nicotine Tob Res. 2013 Apr; 15(4): 777-88., 2013. | This paper is part of a series of articles which discusses the scientific challenges involved in successfully implementing Articles 9 and 10 of the FCTC, which focuses on regulating carcinogens and toxins in tobacco and tobacco smoke, the degree to which people can become addicted to tobacco products, and the additives and engineering features in tobacco products that make tobacco products appealing to future consumers.

The research issues focussed on are those required to support the early stages of regulation.

Gray & Borland argue that 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.

Tobacco Products Scientific Advisory Committee: A Report to the US FDA, Menthol Cigarettes and Public Health: Review of the | This report is in response to the Family Smoking Prevention and Tobacco Control Act, which addresses the issue of the impact of the use of menthol in cigarettes on public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities. In the period 2010-2050, an estimated 9 million people in the USA will initiate smoking because of the availability of menthol cigarettes.
<table>
<thead>
<tr>
<th>Publication</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Evidence and Recommendations, FDA's Tobacco Products Scientific Advisory Committee (TPSAC) 48, Heck, 2010, Food and Chemical Toxicology 48, S1 - S38, 2011.</td>
<td>The report suggests that menthol is more than a flavouring additive, as it reduces the harshness of smoke and the irritation from nicotine and may increase the likelihood of nicotine addiction in adolescents and young adults who experiment with smoking. It points out that the TPSAC has found that the availability of menthol cigarettes has an adverse impact on public health by increasing the numbers of smokers, resulting in premature death and avoidable morbidity. Further, TPSAC found evidence that the availability of menthol cigarettes increases initiation and there is concerning Information showing that there is an increase in menthol cigarette smoking among 12-17 year olds, even as smoking of non-menthol cigarettes declines. As such, TPSAC concluded that cessation is less likely to be successful among smokers of menthol cigarettes, and the early use of menthol cigarettes by between one-half to one-third of youth smokers most likely contributes to nicotine dependence in at least the 30 per cent of adult smokers who use menthol cigarettes. This report also suggests that additives influence the aroma and taste of cigarettes. When taste and odour are pleasurable for smokers, they may reinforce smoking behaviour. Sensory factors can also contribute to smoking behaviour because they mask the undesirable properties of the cigarette, and these sensory experiences can 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.</td>
</tr>
<tr>
<td>World Health Organization (WHO): WHO Technical Report Series 945, The Scientific Basis of Tobacco Product Regulation, WHO Technical Report, Series 945, 2007.</td>
<td>The report explores four themes including: the contents and design features of tobacco products; candy-flavoured tobacco products; research needs and regulatory recommendations; biomarkers of tobacco exposure and of tobacco smoke-induced health effects; and setting maximum limits for toxic constituents in cigarette smoke. It recommends that tobacco products are evaluated based on dependence potential, and restrictions be put on designs and ingredients that enhance such potential and appeal. It also advises that candy-like flavouring agents affect the sensory perceptions and inhalation, including changes to smoke irritation, smoothness, aroma and smoking topography. Further, preliminary research on patterns of flavoured cigarette use shows that younger smokers are much more likely than older smokers to try flavoured cigarettes.</td>
</tr>
<tr>
<td>U.S. Department of Health and Human Services Food and Drug Administration Centre for Tobacco Products, Modified Risk Tobacco Product Applications, Draft guidance for industry, March 2012.</td>
<td>This guidance is intended to assist persons submitting applications for a modified risk tobacco product. A modified risk tobacco product must demonstrate, through a series of rigorous criteria, that it does in fact reduce the risk of tobacco-related diseases or reduces exposure to harmful substances before it can be marketed as modified risk. The guidance includes detailed advice as to who may submit a modified risk tobacco product, when and how to do this and what scientific studies and analysis is required when submitting an application.</td>
</tr>
<tr>
<td>King, B, et al., The Decline of Menthol Cigarette Smoking in Australia, 1980-2008, Nicotine and Tobacco Research 2012, March 13.</td>
<td>This report analysed trends in the market share of menthol brands in Australia in order to provide insight into the determinants of menthol cigarette smoking. The article used the Australian Secondary Students Alcohol and Drug Survey (1984-2008), The Smoking and Health Survey (1980-1998), and the International Tobacco Control Four Nations Survey (2002-2008) to estimate market share of brands as part of its methodology. The article argued that menthol smoking was much more popular among female smokers of all age groups in the early 1980s. During the 1980s and 1990s, use declined markedly in the 18-29 age groups, while remaining relatively stable among older smokers. Use of Alpine declined markedly among adolescents in the 1980s and 1990s. However, during this period, Alpine remained more popular among experimenting than regular smokers. It concluded that menthol brands are now primarily 'older women's cigarettes' in Australia. The trends in declining popularity among younger smokers suggest that targeted marketing</td>
</tr>
</tbody>
</table>
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>European Commission, Reporting on Tobacco Product Ingredients: Practical Guide, Health and Consumer Protection Directorate-General, 2007.</strong></td>
<td>Article 6 of the Tobacco Products Directive 2001/68/EC requires that manufacturers and importers of tobacco products submit a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. It specifies the content of this list and requires that the list be accompanied by the toxicological data available to the manufacturer and importer. This practical guide has been developed to harmonise data collection methods, to ensure all methods are based on a common EU format. Two sets of formats were developed: one with the full ingredient information for national regulators, and one with fewer requirements for the information to the public. While not legally binding, the practical guide represents the views of the European Commission. The Member States, manufacturers and importers are expected to use the common reporting formats as soon as they are published. Electronic submission of data would be the desirable form.</td>
</tr>
<tr>
<td><strong>World Health Organization, Tobacco: deadly in any form or disguise, 2006.</strong></td>
<td>This report seeks to emphasise the harm associated with the use of any tobacco product (including arguing that when people smoke they can inhale up to 4000 different chemicals), outlining the different types of tobacco products (i.e. rolls of tobacco, pipes, and oral preparations), the role of the tobacco industry in failing to disclose the truth about products (i.e. around filters and “light” and “mild” cigarettes) and calls for stronger regulation of tobacco products. The report states that the WHO Framework Convention regulations should be followed (as stated in the summary above). Article 9 (regulation of the contents and emissions of tobacco products), Article 10 (regulation of tobacco product disclosures), and Article 11 (packaging and labelling of tobacco products) are emphasised.</td>
</tr>
<tr>
<td><strong>TBT Concerns against Canada C.32, Brazil and Thailand, World Trade Organisation, G/TBT/N/51, 1 October 2010 (10-5023) Committee on Technical Barriers to Trade, Minutes of the Meeting of 23-24 June 2010.</strong></td>
<td>These minutes discuss concerns with Canada’s Bill C.32 amending the Tobacco Act; which would ban a comprehensive list of additives. A number of representatives of the European Union, Africa and South America requested from Canada the scientific evidence establishing the link between the prohibited additives and attractiveness to young people. Canada argued that there was sound evidence that certain additives, including flavours, did increase tobacco product attractiveness. The tobacco industries’ own documents, made public as a result of litigation, had shown that the use of additives helped to make tobacco products more appealing to young people. In addition, Canada had prepared a list of references of the numerous publicly available studies that had examined the use of additives that increased the appeal of tobacco products.</td>
</tr>
<tr>
<td><strong>Brazil - Draft Resolution No. 112, 29 November 2010. Maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibited use of additives (G/TBT/N/BR/407).</strong></td>
<td>A number of countries have raised concerns at the WTO over Brazil’s draft resolution which would define permitted levels of tar, nicotine and carbon monoxide in cigarette smoke and prohibit the use of a comprehensive list of additives. The representative of Brazil reiterated that the objectives of this measure were to protect public health by reducing the attractiveness of certain tobacco products particularly to children and youth. The Brazilian representative argued that tobacco addiction usually begins at a young age, when individuals were more vulnerable to tobacco products’ appeal; flavourings could increase their appeal. A previously cited study conducted by the National Institute on Cancer in Brazil showed that 45 per cent of smokers in Brazil between 13 and 15 years of age consumed tobacco products with flavour. In addition, the WHO, through its partial guidelines linked to the implementations of Articles 9 and 10 of the FCTC, had recognized that from the perspective of public health there was no justification for permitting the use of ingredients such as flavouring agents, which help make tobacco products attractive.</td>
</tr>
</tbody>
</table>
Revised draft submitted to Department of Health. Does not reflect Government policy.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dixon M, Lambing K and Seeman J. On the Transfer of Nicotine from Tobacco to the Smoker: A Brief Review of Ammonia and &quot;pH&quot; Factors, <em>Contributions to Tobacco Research</em>, 2000, 19: 103-113.</td>
<td>It should be noted that this article was written by tobacco industry researchers, and published in the journal, <em>Contributions to Tobacco Research</em>, which was founded by the German Cigarette Manufacturers' Association ([<a href="http://www.beitreu.de/nxt/gateway.dll?fn=template&amp;fl=default.html&amp;vsn=btf:f">http://www.beitreu.de/nxt/gateway.dll?fn=template&amp;fl=default.html&amp;vsn=btf:f</a>]), and this review presents the findings of scientific literature on the effects of ammonia compounds used as tobacco additives, on the chemistry of nicotine. The review found that while ammonia compounds do contribute to the flavour properties of cigarette smoke, it does not increase the amount of nicotine absorbed by the smoker or the rate or efficiency of nicotine transferred from tobacco to mainstream smoke. This study further found that cigarettes with comparable &quot;tar&quot; yields had approximately equal amounts of ammonia in mainstream smoke while differing in their ammonia content in tobacco by a factor of three. This suggests that ammonia deliveries are affected more by cigarette design characteristics and reflect total smoke delivery than by tobacco additives.</td>
</tr>
<tr>
<td>Cancer Council Victoria, <em>Australian secondary school students' use of tobacco, alcohol, and over-the-counter and illicit substances in 2011</em>, prepared for the Australian Government Department of Health and Ageing, December 2012.</td>
<td>The 2011 Australian Secondary Students' Alcohol and Drug survey was conducted during the academic school year of 2011. This was the tenth survey in a series that commenced in 1984 assessing use of tobacco and alcohol, and the sixth to include questions on the use of over-the-counter and illicit substances. Just under 25,000 secondary students aged between 12 and 17 years participated in the survey, in which they were asked about their lifetime and current use of tobacco, alcohol, analgesics, tranquilisers and illicit substances and related behaviour. In relation to tobacco, around 77 percent of all secondary students across Australia had no experience with smoking. It was found that 42 percent of 17 year-olds had experience with smoking, with cigarettes most commonly being obtained through friends, while 18 percent of all students who had smoked in the past seven days brought their last cigarette themselves (despite it being illegal for retailers to sell cigarettes to those aged under 18 years in all Australian states and territories). It also found that 13 per cent of 16 to 17 year-olds were current smokers (no increase or decrease from 2008 survey), and four percent of 12 to 15 year-olds were current smokers. There was little difference in the prevalence of smoking among male and female students at each age. The exception to this was among 12- and 14-year-olds who had never smoked, where significantly fewer males than females had never smoked. Additionally, among all students, significantly more males than females indicated they had smoked more than 100 cigarettes in their life. In 2011, Winfield was the most popular cigarette brand smoked among current smokers (37 percent). Peter Jackson (12 percent) and Longbeach (12 percent) were the next most commonly smoked brands. In 2011, Winfield, Peter Jackson and Longbeach were all sold in packets of 20s and 25s.</td>
</tr>
</tbody>
</table>
Tobacco Product Content Disclosure

There are two recent reviews that canvassed options around tobacco product disclosure schemes for Australia. The most recent is the draft Allen + Clarke report: Potential Approaches to Tobacco Product Disclosure in Australia\(^{147}\); and the other is Ipsos-Eureka: Public Health Value of Disclosed Cigarette Ingredients and Emissions Data.\(^{148}\)

The Allen + Clarke report explores the scientific, technical, practical feasibility and public health value of regulating the disclosure of tobacco product ingredients and emissions data in Australia. It also explores the current Australian Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes (the Voluntary Agreement), and the concerns expressed by the public health sector around the usefulness and public health value of the information.

The report argues that on its own, the ability of a disclosure scheme to directly influence the behaviour of smokers, potential smokers, or tobacco companies is limited without a wider tobacco control strategy in place. The Allen + Clarke report found that disclosed information can have a key role in public health through allowing regulators to analyse trends, and in providing information to inform future product regulation (in the context of international guidance in this area) and other tobacco control policy.

While some of this information is already received through the Voluntary Agreement, and supported by industry (i.e. allowing some information to reach consumers while protecting trade secrets), the report outlines a number of weaknesses with the Voluntary Agreement. This includes the level of information provided, which is not comprehensive enough to fully understand not only ingredients in, and emissions from, all tobacco products, but the quantity used or present, or emitted. Allen + Clarke suggest a number of potential disclosure scheme “packages” that attempt to address these issues.

The Ipsos-Eureka report, Public Health Value of Disclosed Cigarette Ingredients and Emission Data, assessed the effectiveness of the current voluntary disclosure of cigarette ingredients and emission data by determining the public health value of disclosing this type of information.

The Ipsos-Eureka study found that most members of the public do not access the information and, even if they do, the information does not discourage them from smoking. The study also found that public disclosure of information collected under the Voluntary Agreement is unlikely to have a significant public health benefit, due to the information being incomplete, incomprehensible and difficult to access. The report concluded that tobacco product disclosure information should be used primarily to inform government policy, research and regulation.

Future disclosure should, according to Ipsos-Eureka, recognise the disclosure of tobacco product information as a consumer right, as per other consumer products; and seek to promote and protect the health of Australians.

\(^{147}\) Allen + Clarke Policy and Regulatory Specialists Limited, “Potential Approaches to Tobacco Product Disclosure in Australia”, 2013 (Draft).

Appendix 4: Cost benefit analysis report

[Attached in separate document]