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**OPTIONS FOR THE REGULATION OF  
TOBACCO PRODUCTS**

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## **2.0 EXECUTIVE SUMMARY**

The effects of tobacco use have recently been described by the Institute of Medicine (USA) as 'the most deadly epidemic of modern times' (Institute of Medicine 2001). The disastrous health effects of tobacco smoking provide the justification for national and international regulatory action to reduce the harm from tobacco use. This report reviews the evidential support for options to regulate tobacco products in order to reduce that harm.

### **Recent international developments**

There were significant international developments in tobacco product regulation in 2002 and 2003. European Council Directive 2001/37/EC, which requires member states of the European Union to take steps to regulate packaging, labelling, tar and nicotine reduction, among other actions, has been upheld by the European Court of Justice against a strong challenge from the tobacco industry. The significance of this decision is that it paves the way for the banning of product descriptors such as 'light' or 'low-tar', which are regarded as dangerously misleading, and it affirms the right of regulators to require large health warnings to be displayed on packaging.

On 13 December 2002, the Superior Court of Québec rejected the tobacco industry's challenges to the Canadian federal Tobacco Act 1997 and attendant regulations. This decision is likely to be appealed to the federal appeal courts, but is nonetheless significant to New Zealand because of the similarities between New Zealand and Canadian federal law, including rights legislation. The Superior Court's decision once again affirms the right of regulators to place restrictions and requirements on tobacco packaging, and to require product testing and disclosure.

Under the auspices of the World Health Organization (WHO), the Framework Convention on Tobacco Control was concluded on 1 March 2003. This Convention provides international support for regulatory moves of the type recently undertaken and upheld by courts in Europe and Canada and discussed in this report.

The WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) has called for a 'broad and comprehensive regulatory framework' aimed at reducing harm from tobacco use and has recently issued a series of recommendations on aspects of tobacco product regulation. This report is consistent with those recommendations.

Each of these international developments provides support for regulatory action in New Zealand. However, as this report notes, regulatory action in this country will in most cases require New Zealand-specific research and thorough examination of legal and policy risks and (most importantly) public health effects.

## **Harm reduction and tobacco product regulation**

This report proceeds on the assumption that the purpose of regulating tobacco products is to reduce the harm from such products. While complete cessation would be desirable, it is unlikely that all smokers will quit, either because they are unwilling or unable to overcome their nicotine addiction. Accordingly, harm minimisation strategies are needed to minimise the harm from smoking for smokers, potential smokers, and non-smokers exposed to environmental tobacco smoke. Harm reduction strategies include:

- prevention of the development of tobacco dependence
- cessation programmes for addicted smokers
- reduction of exposure to tobacco toxins or addictive substances in people who are unwilling or unable to completely cease their tobacco use
- protection for non-smokers.

As discussed in this report, the major difficulties in attempting harm reduction through modifications to tobacco or provision of alternative nicotine sources are that:

- current methods of measuring the constituents of tobacco smoke are inadequate
- there is little certainty about the constituents of New Zealand tobacco and tobacco smoke
- the biological effects of tobacco smoke are extremely complex, making it difficult to assess the likely effects of product modifications
- innovations that provide cleaner nicotine for smokers may discourage smokers from quitting
- cleaner nicotine sources may provide more of an incentive for non-smokers to initiate smoking.

From these difficulties will flow the likely priorities for action: development of new methods for measuring the constituents of tobacco smoke; research into the constituents of New Zealand tobacco and tobacco smoke, and its biological effects; and assessment of the likely effect of harm reduction options on smokers and potential smokers.

## **Options for tobacco product modification**

This report canvasses a number of options for reducing exposure to tobacco toxins by people who are unwilling or unable to completely cease their tobacco use if it is decided to pursue a harm reduction strategy of that sort.

### ***Regulation of ‘tar’ levels***

It appears that it is technically viable to regulate tar levels, which is an option that has been adopted to a limited degree in some jurisdictions. Europe is a notable example, where maximum tar and nicotine levels have been set. However, there are risks in adopting such a policy:

- Tar levels would have to be accurately measured using better methodologies than are currently provided for.
- There is no simple dose-response relationship between tar-yields and tar-related disease
- Unconventional nicotine-delivery devices may have tar of a completely different composition to conventional tobacco, with unknown mutagenicity or toxicity.

It might be possible to avoid some of these risks if a low-tar, medium-nicotine policy is adopted, but the viability of such an option is unknown, particularly if it involves extensive product modification.

### ***Regulation of additives in tobacco products***

Few jurisdictions regulate additives in products, although the United Kingdom has a voluntary agreement requiring tobacco companies not to use new additives unless they are approved. However, varying additives may alter the disease risks or addictiveness of tobacco products.

Given the complicated health risks of any combusted and inhaled product, it would be sensible to consider requiring full disclosure of additives used in tobacco products (discussed in a later section of the report), and prohibiting the use of new additives unless it can be conclusively shown that they have a health benefit.

### ***Manipulation of tobacco products to reduce the delivery of toxins to the smoker***

There are numerous technologies available to manipulate tobacco products to reduce the delivery of toxins to the smoker, although few have ever been the subject of regulation. Technologies range from methods used in the tobacco plantation to the manufacture of cigarettes, including processing of the tobacco, and design of papers and filters. It is also important to consider how the public’s perception of these technologies affects the way they smoke tobacco. Each of these areas could be regulated if it was determined that regulation was necessary for public health reasons. The most likely area for regulation is around filter technology.

As an initial step towards any regulation in this area, it is necessary to engage in continued research, monitoring and surveillance of tobacco products, design and marketing so that innovations by tobacco companies can be factored into the final policy decision.

### ***Reduction of smoke and smokeless tobacco products***

Snuffs and chewing tobacco are unavailable in New Zealand under current law. All smokeless tobacco products carry health risks, and there is no evidence that any of them should be used as part of a harm reduction strategy. However, literature suggests that there is some theoretical potential for Swedish-style snuff (snus) to reduce the harms from tobacco use among current smokers. Debate is ongoing, but there is some agreement that use of snus, in preference to smoking tobacco, can reduce the risk of cancers by a significant amount. However, snus has no track history of use in New Zealand, and there would be risks associated with promoting it as an alternative to smoking if that would encourage potential quitters or potential smokers to take up snus use when they would otherwise have refrained from smoking.

A number of cigarette-like products with reduced smoke have been developed and marketed overseas, but early testing shows questionable health benefits, and these products should be subject to thorough testing and review before any conclusion is drawn about their potential benefits.

### ***Reducing nicotine levels in tobacco***

This option has been highly debated in recent years. It is technically viable to reduce nicotine levels, which in theory would reduce the addictiveness and attractiveness of tobacco. However, it could also encourage compensatory smoking, and might also lead to an increase in the black-market tobacco trade and home-grown tobacco use. Some people would see these as less harmful trade-offs if the total number of smokers could be significantly reduced by lowering nicotine levels.

It is also possible that there are compounds in tobacco smoke that have nicotinic activity, but that are not measured as nicotine. The addictive properties of tobacco smoke are not fully understood.

### ***Substitution of nicotine-delivery products for cigarettes to maintain the nicotine addiction without resort to smoking***

A number of alternative cigarettes (such as clove cigarettes) and nicotine products (such as nicotine sweets) are being developed and traded around the world. These products have the major disadvantage of being attractive to potential smokers, especially young people, and may create nicotine addiction,

possibly leading to the initiation of smoking, in those who are not already addicted.

### **Discussion of options for regulation of tobacco product modification**

A policy that reduces the exposure of smokers to harmful toxins risks undermining other harm reduction policies, because, without adequate co-ordination, education programmes, and regulatory measures, the provision of cleaner sources of nicotine could make it easier for non-smokers to become nicotine-dependent and more difficult to encourage nicotine-dependent people to cease use of tobacco products.

The health effects of new or altered products are unknown. There would have to be thorough investigation before any move to liberalise access to alternative nicotine sources is adopted. Three priorities have been identified for the regulation of tobacco products:

- Revision of testing methodologies and requirements to ensure that there is full information about the content of tobacco products.
- Restriction of any future tobacco or nicotine product innovations unless they have proven health advantages over products currently on the market.
- Research into tobacco products and tobacco product regulation, including research with a New Zealand focus.

### **Tobacco product labelling and marketing**

There are international moves towards bold, pictorial tobacco warnings similar to those in Canada and Brazil. Australia is investigating whether to move towards such warnings. Recent Canadian research shows that the warnings do have an effect on the motivation of smokers to quit, and the motivation of non-smokers to initiate smoking.

There are some legal hurdles in the way of large pictorial warnings, including rights issues and international obligations. However, similar hurdles have not prevented Canada, Brazil and the European Union legislating for larger warnings. Article 11 of the FCTC mandates large warnings, and provides support for pictorial warnings.

If New Zealand should consider introducing pictorial health warnings it will be important to carry out an assessment of which future warnings would be most effective and appropriate for a New Zealand audience. In particular, messages that target at-risk groups, are culturally appropriate, that confront knowledge gaps, and that are likely to spark positive attitudinal responses among both smokers and non-smokers are the key.

## **Regulation of product descriptors**

As with larger warnings, there is a strong international move in the direction of banning misleading descriptors such as 'light', 'mild', 'low-tar' or 'low-nicotine'. These descriptors are misleading because they do not reflect the actual delivery of tar or nicotine, and give the false impression that there are fewer health risks associated with some tobacco products.

Many of the cautions that apply to the regulation of health warnings also apply to the use of product descriptors. Although the FCTC requires state parties to ban misleading descriptors, it does not specify which terms are misleading. Regulation would require New Zealand-specific research and careful product development to show whether prohibiting the descriptors is reasonable and proportionate step to protect public health. A useful first step would be to commission research into New Zealanders' beliefs and attitudes towards products marketed as light or mild.

## **Tobacco product disclosure**

More detailed disclosure of information about tobacco products is crucial in order to facilitate the development of tobacco control policies, provide full information to consumers, and conduct research into the likely health effects of using modified tobacco products. The FCTC mandates states parties to require disclosure of the contents of tobacco products, and to supply information to the public.

Options for regulation in New Zealand include requiring full disclosure of all additives and constituents in all parts of tobacco products, disclosure of tobacco industry research, and testing of tobacco products for a wider range of constituents than at present. Regulatory powers already exist that may be used for some of these purposes.

*Before implementation of any of the policy options discussed in this report, there would need to be detailed consideration of the views of consumers, the public, industry and health groups.*

### 3.0 INTRODUCTION

It is sometimes remarked upon that tobacco is the only legally available consumer product that kills people when it is entirely used as intended.<sup>1</sup> Despite the dangers of tobacco, World Health Organization statistics estimate that as many as one third of the global population over age 15 smokes (Aftab et al. 1999). In New Zealand, 25 percent of the adult population smokes and for Maori and Pacific peoples the rate is even higher at approximately 51 percent and 31 percent respectively (Ministry of Health 2002). It has been estimated that one in two New Zealand smokers will die early as a result of smoking, each losing, on average, 14 years of life (Peto, Lopez et al. 1994).

Tobacco products have a unique place in society. Despite the clear evidence of intrinsic harm, they are comparatively lightly regulated, and in New Zealand at least, there are no controls over the types or quantities of additives that may be added to them, what constituents they may contain, or what emissions are permitted to be delivered by them. Public support for stronger regulation, while building, does not appear proportional to the nature of harms, to individuals and to society as a whole, posed by the use of tobacco.

The design of tobacco products can be altered in a number of ways to suit different markets and regulatory regimes. One of the difficulties in regulating tobacco products is the extent to which they can be altered to deliver numerous different effects to the smoker while still meeting regulatory requirements. Tobacco products such as cigarettes have been described as:

highly sophisticated devices designed and engineered to provide a means for the controlled delivery of nicotine for pharmacological effects. (Robertson 2000)

This raises challenges for the regulator faced with a highly engineered and dangerous product but one for which there is still a sense of acceptability among the public.

Furthermore, when compared with other regulated products, such as foods or medicines, the level of disclosure required of tobacco manufacturers in relation to the content and emissions of products (disclosure to the Ministry of Health and to consumers) is arguably inadequate to inform policy and regulatory development or to fully inform consumers. This lack of effective disclosure has been criticised by health groups and has been a continuing concern to the Ministry of Health which has a responsibility to monitor the use of, and harms caused by, tobacco products.

Unlike many other legally available consumer products, tobacco products are required to carry statutory health warnings and some consumer information. It has been suggested by some commentators, however, that this information does

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<sup>1</sup> *The Oxford Medical Companion*. 1994.

not adequately convey the true extent of harms presented by using tobacco products. Studies also suggest that such warnings need to be regularly 'refreshed' so as to be noticeable and persuasive to smokers (as discussed in section 6 of this report).

In light of the above issues, *Allen & Clarke* has been asked by the Ministry of Health to review the international experience with, and evidence in support or opposition to, options for the regulation of tobacco product content, disclosure and the application of pictorial health warnings.

This report presents the findings of our review, and identifies policy issues for consideration by the Ministry of Health. In developing this report we have reviewed international literature and legislation, consulted with international tobacco control experts and considered existing and proposed legislative provisions in New Zealand. We have also considered the implications of the Framework Convention on Tobacco Control and the work of the World Health Organization's Scientific Advisory Committee on Tobacco (SACTob).

The four policy areas reviewed by this report are in a constant state of evolution. It is quite likely that new evidence or research relating to these areas, or entirely new alternative options or initiatives, will be identified before the ink is even dry on this report. The reader is cautioned to consider this fact when reviewing this report and to take care when deciding, as a policy maker (or advocate), what initiatives may be appropriately adopted for implementation in New Zealand.

#### 4.0 GENERAL ISSUES RELATING TO REGULATORY OPTIONS

There are two general issues that affect all regulatory choices in the field of tobacco product modification:

- *The problem of consumer acceptance*

As nicotine is highly addictive, consumers who are faced with a choice will generally choose an option that provides them with an efficient source of nicotine at a level necessary to satisfy their addiction. This means that public health strategies are not likely to be successful unless they provide nicotine addicts with options that are at least as appealing as smoking regular cigarettes.

- *The problem of measurement*

In order to weigh the likely harm or safety of tobacco products it is necessary to be able to assess accurately the toxins that are delivered to the smoker. It is also necessary to measure the addictive potential of tobacco smoke.

These two difficulties are discussed in detail in the following two sections.

#### 4.1 THE PROBLEM OF CONSUMER ACCEPTANCE

One concern commonly raised in discussions about tobacco control is that the success of a tobacco control strategy may depend on whether smokers find the strategy acceptable or appealing in comparison to cigarette smoking. This may apply particularly strongly to strategies for product modification, since:

A virtually harmless cigarette smoked by only 1 percent of the [total smoking] population will have a lesser impact on the reduction of tobacco-related diseases than a somewhat more harmful cigarette smoked by 80 percent of the total smoking population. (Wynder and Hoffmann 1979)

In other words, potential health benefits will not be realised if they are not delivered by means that are acceptable to smokers (Health Canada 1993).

The primary focus of any tobacco control policy must be a reduction in tobacco use. However, the market for tobacco products might be maintained or even expanded by any product innovations that are interpreted by consumers as creating 'safer' products. Any regulatory decisions of this nature will therefore require thorough market testing to ensure that the potential health benefits in modifying tobacco products do not reverse or stall the progress that has been, or can be, made in reducing the predominance of smoking.

Policy-makers must balance the health benefits of any policy option for tobacco control against its effects in the tobacco marketplace, but a complication for predicting policy outcomes is that cigarettes are not used in a consistent manner by smokers and dosages of tobacco smoke are highly variable. This makes it difficult to predict the effect of any policy decision that does not involve abstinence from cigarette smoking.

Another view is that consumer 'acceptance' is a misleading concept, since nicotine-dependent smokers have limited free choice in whether or not to smoke cigarettes (Slade et al 2000). Instead, some policy exponents identify nicotine addiction as the key issue in tobacco control and propose that it should be made easier for smokers to satisfy their need for nicotine through methods other than tobacco smoke (Slade et al. 2000). This possibility is discussed below in section 5.7: *Substitution of cigarettes for nicotine-delivery products to maintain the nicotine addiction without resort to smoking.*

## **4.2 THE PROBLEM OF MEASUREMENT**

One major complication in regulating the modification of tobacco products is the difficulty in measuring the toxins in them or originating from them. Accurate measurement of toxins delivered to smokers is necessary to determine the potential risks or effects of any tobacco product modification. International Standards Organisation (ISO) and US Federal Trade Commission (FTC) standard methodologies provide highly similar means of assessing standardised methods to determine relative yields of tar, nicotine and carbon monoxide in the smoke of manufactured cigarettes.

The FTC and ISO methodologies do not, however, reflect the smoking patterns of most smokers who may compensate for varying levels of nicotine in different brands of cigarettes (SACTob 2002a). Also, there are no international standards for measuring other constituents in tobacco products or tobacco smoke, although some jurisdictions (including Canada and Massachusetts) have moved to establish more comprehensive testing regimes. Furthermore, ISO standards have not been developed to date to measure tar, nicotine and carbon monoxide levels in roll-your-own tobaccos and other products: manufactured cigarettes are the only products for which countries regularly test for these constituents. There are considerable difficulties in designing a testing regime for roll-your-own tobacco (even were such methodologies reliable in other ways). These include different weights of tobacco used by smokers in rolling their own cigarettes and different compaction of tobacco leading to differing aeration and thus smoke production. There is no accepted 'standard' roll-your-own cigarette for testing purposes, although it may be possible to establish a range of values. Canada

has developed test methods for whole tobacco<sup>2</sup> but it is not clear whether these have been adopted elsewhere.

The term 'yield' refers to the amount of a substance that is able to be isolated from a tobacco product under a standardised process. 'Delivery' refers to the total substance that is obtained by a smoker from a tobacco product, which may be in excess of the measurable yield, depending on the methodology that has been used to measure the yield and the manner in which the product is smoked. 'Content' is the amount of a substance that can be isolated from the tobacco before smoking. Systems derived from the ISO and FTC methods usually measure particulate yield, rather than gas-phase yield. Moreover, they measure the yield of substances under conditions that are quite different from the usual manner of smoking.

'Tar' is the conglomerate residue of combustion that is trapped in the filter (or measuring device), minus water and nicotine. The term 'tar', therefore gives no accurate idea about the toxicity of the combusted product of cigarettes, does not measure the gaseous by-products of combustion, and has been described as 'misleading' (WHO 2001). Moreover, the amount of tar, and its composition, can be varied by smoker behaviour, since intense smoking of cigarettes produces more tar and higher combustion temperatures (which alter the by-products of combustion) (WHO 2001).

Tar may also vary widely in its composition from brand to brand or over time, depending on the recipe and processes used to manufacture the tobacco product, the growing conditions, and other variables. A 1994 report by RJ Reynolds showed significant variations in tar constituents among eight experimental cigarettes, even though the total tar content remained level (Shopland 2000).

Some jurisdictions have instituted testing for a wider range of constituents in order to provide data about the composition of tar and the gas-phase constituents of tobacco smoke. Three jurisdictions (Australia, Canada, and Massachusetts) have conducted 'benchmarking' exercises so that they have data against which they can monitor alterations in the composition of tobacco smoke over time.

A further problem in the measurement of toxins is that raw measurements of toxic constituents do not indicate the effective toxicity of smoke, which is in large part determined by the interaction between constituents delivered to the smoker. In order to reliably assess the toxicity of tobacco smoke, it would be necessary to measure the bioavailability and metabolism of toxins in concert.

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<sup>2</sup> CAN/CGSB-176.1-92 - Preparation of Cigarettes from Cigarette Tobacco for Testing. National Standard of Canada. Canadian General Standards Board, December 1992; and Health Canada Test Method T-401 – Preparation of cigarettes from packaged leaf tobacco for testing, 1999-12-31.

Bialous and Yach found that tobacco companies influenced the development of international standards and measures for tobacco products through an industry research organisation called CORESTA, the Cooperation Centre for Scientific Research Relative to Tobacco. They concluded that ISO's standards are not adequate to guide regulatory policy, and that no health claims can be based on ISO's standards (Bialous and Yach 2001). Other studies have shown that the tobacco industry knew of the flaws of the FTC method since the 1960s, and were able to 'cheat' the machines and the resulting reports (WHO 2001). Since 1998, the FTC has acknowledged the weakness of its methodology, and has designed a public education campaign alerting consumers against relying on FTC tar and nicotine ratings for health benefits (Bates et al 1999). A Canadian Expert Committee has concluded that ISO- and FTC-measured nicotine levels have no relevance to what amount of nicotine individual smokers obtain from their cigarettes (Bates et al 1999).

### **International moves to develop new measures**

The existing FTC method was developed by the United States' Federal Trade Commission in 1967. The method involves a 35 ml puff of two seconds' duration every 60 seconds, with none of the filter vents blocked. The ISO method is closely based on the FTC method. There are now strong moves at the Federal level in the USA to replace the FTC method with methods that reflect actual smoking behaviour (Wilkenfield 2001).

Following the lead of British Columbia, Canada now requires cigarettes to be tested according to ISO standard tests under normal and 'intense' smoking conditions. The modified ISO (or 'intense' smoking) test involves 55 ml puffs of two-second duration every 30 seconds with all of the ventilation holes blocked.<sup>3</sup> In addition, Canada requires that both sidestream and mainstream smoke be analysed for the presence of 44 chemicals, pH levels, and filter efficiency.

Similar modifications to the ISO and FTC methods are required in Massachusetts regulations. The Massachusetts method (developed in 1997) involves 45 ml puffs of 2-second duration every 30 seconds with 50 percent of the filter holes blocked.

The European Union is moving towards new measurement methods: European Council Directive 2001/37/EC requires the Commission to 'adapt [the ISO measurement methods] to scientific and technical progress'. In the meantime, without better testing, the European Union's new maxima for tar, nicotine and carbon monoxide have been criticised as 'illusory', 'largely cosmetic' and 'certainly misleading' because of the methods used to assess the maxima. Instead, critics have proposed other measures of toxicity (Bates et al 1999).

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<sup>3</sup> <http://www.moh.hnet.bc.ca/ttdr/regs.html#testing>

### Machine testing methods

Method	Puff vol.	Puff duration	Puff frequency	Vent holes blocked	Constituents tested
FTC/ ISO	35 ml	2 secs	60 secs	nil	Tar, nicotine. Optional CO.
Massachusetts	45 ml	2 secs	30 secs	50 %	Nic. Testing is proposed for 44 other constituents.
British Columbia/ Canada	55 ml	2 secs	30 secs	100 %	Tar, nic, CO, pH, 44 other constituents.

### Current New Zealand testing requirements

Section 33 of the Smoke-free Environments Act 1990 currently provides for regulations to be made to identify classes of tobacco products for which annual tests must be undertaken on the constituents of those tobacco products and their respective quantities (and under section 35 reported to the Director-General). The regulations may also determine the method of testing. The current method prescribed in regulations is the ISO method. The regulations require that tobacco smoke be tested for tar, nicotine and carbon monoxide.

Section 34 enables the Director-General of Health to require a manufacturer or importer to undertake a further test of any brand's constituents. These tests must be carried out at a laboratory nominated by the Director-General, at the expense of the manufacturer or importer. The Director-General of Health cannot require tests in respect of more than ten percent of tobacco products sold by the manufacturer or importer. To date, section 34 has not been activated.

Legislation currently before the House (the Smoke-free Environments (Enhanced Protection) Amendment Bill – as reported by the Health Committee) would provide regulation-making powers to require annual testing of constituents in the product or in the smoke of tobacco or herbal products.

### Discussion

A limitation of the current testing regime prescribed in New Zealand regulations is that it only measures tar, nicotine and carbon monoxide. Since the emissions of these substances may be altered by product modification, the constituents of tar might, as a consequence, be varied without the consumer's or the regulator's knowledge. As a result of such variation, the toxicity or addictiveness of tobacco products could be altered significantly, and any advances in product regulation or tobacco control could be stalled or reversed.

It is essential for regulators to be provided with accurate measures of a range of the most important constituents of tobacco smoke in order to:

- monitor tobacco product innovations made by the manufacturer
- make accurate comparisons with tobacco products in other jurisdictions
- assess policy options based on sound information
- monitor the effects of any policy initiatives
- provide consumers with accurate information about the potential health effects of the products they use.

One option is to measure a range of constituents of cigarette smoke, similar to the system adopted in Canada, which measures 44 constituents and Ph. The constituents are those listed in Appendix A. In order to meet industry concerns about the costs involved in testing all tobacco products for this many constituents, Health Canada negotiated with industry to develop a benchmark cigarette, against which a selection of cigarette brands will be tested periodically. The benchmark will be useful for monitoring any variations in tobacco constituents. In addition, the tar level is used to estimate the level of various constituents in tobacco smoke. Similar benchmarking projects have been undertaken in Australia and Massachusetts. The worth of a benchmarking project will vary depending on the consistency of manufacturing processes and ingredients (including the types of tobaccos) used in tobacco products that come within the project.

If the benchmarking option is chosen, it would be desirable to review the list of substances periodically to identify whether other constituents, not on the list, were being consumed by smokers in quantities significant enough to have an effect on toxicity or addictiveness of the tobacco products. The Eclipse cigarette, for example, has a very high tar:nicotine ratio, but most of the weight of the tar is comprised of glycerin, and the mutagenicity/toxicity of Eclipse tar is therefore thought to be lower than for the tar from conventional cigarettes.

Some commentators have suggested that a measure of total toxicity should be used instead of a measure of individual constituents (Bates et al 1999), although an appropriate method for doing this would have to be determined, and would undoubtedly prove to be a complicated undertaking. One of the greatest challenges for measuring total toxicity is the inclusion of gas-phase constituents in any bioassay. The New Zealand Institute for Environmental and Scientific Research (ESR) has attempted to rate and rank the most harmful constituents in cigarette smoke, which could provide the basis for selecting constituents for routine monitoring (Fowles and Bates 2000b).

Any option for assessing the toxicity of cigarette smoke will depend on a method for accurately generating and measuring smoke from the tobacco product. A limitation of methods derived from the ISO/FTC method is that they attempt to

measure smoke yields per cigarette, but smoking patterns vary, and different smokers will derive different amounts of smoke from each cigarette. The Canadian and Massachusetts methods attempt to overcome this limitation by testing cigarettes under 'intense' smoking conditions, meaning that the smoke yields represent closer to an upper limit.

Another option is to use a 'yields per litre' (ypl) measure, which measures the amount of toxins in a given amount of smoke. This:

- would emphasise that yields refer to smoke, not tobacco
- would approximately reflect the upper limit of smoke inhaled by smokers from one cigarette
- would more accurately reflect the delivery of toxins to a smoker
- could be used to illustrate a range of yields depending on variations in smoker behaviour. (Rickert 2000)

Since nicotine availability varies depending on whether it is delivered to the smoker in 'ionised' or 'neutral' form (depending on the alkalinity of the tobacco), it may be necessary to develop a system of measuring these two forms of nicotine separately in order to give a more accurate picture of the addictiveness of cigarettes. Furthermore, the form of nicotine delivered may vary as a cigarette burns down, and it has been suggested that cigarettes should be tested to give a puff-by-puff profile of alkalinity in order to reveal whether they are engineered to give a front-end nicotine kick or rush to the smoker, which could potentially increase the addictiveness of the cigarette (Bates et al 1999).

A separate alternative for measuring the toxicity and addictiveness of tobacco products is to identify and test for biomarkers that show how tobacco products have acted on a smoker's body. ESR has been conducting independently funded research on biochemical events relevant to nicotine addiction, i.e. how tobacco smoke acts on a smoker's body. It is hoped that ESR's *in vitro* research will provide a way to assess the influence of product modifications on nicotinic activity in the central and peripheral nervous system.<sup>4</sup>

Further issues are whether any test data supplied by tobacco companies should be relied upon without independent verification, and who should meet the expense of expanded testing. New Zealand legislation provides for the Director-General of Health to require testing of tobacco products in independent laboratories at the expense of manufacturers.<sup>5</sup> A Health Legal opinion has suggested that the power contained in s34 of the Act would allow the Director-General to require further testing for any constituents, whether or not they are the constituents (currently tar, nicotine and carbon monoxide), for which testing is already required by regulations made under s33 of the Act.

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<sup>4</sup> Dr Jeff Fowles, ESR, personal communication.

<sup>5</sup> Section 34, Smoke-free Environments Act 1990.

It would appear, therefore, that tobacco companies could be required under the Act to present two sets of test results: results for all brands of tests for constituents under s33 (which are currently limited to tar, nicotine and carbon monoxide, but could extend to other constituents); and results for up to ten percent of the brands for a more extensive range of constituents under the power contained in s34. The latter test would be conducted at the expense of tobacco companies in independent laboratories. This would provide independent verification of the tobacco companies' test results.

Accurate measurement and reporting of tobacco constituents is integral to any regulation of product disclosure or labelling, and is also essential for any regulation of product modification. As discussed in the next section, it is impossible to embark on any harm reduction strategy without first having in place a regime to provide for accurate and comprehensive testing of toxin delivery from tobacco smoke. For these reasons, it is recommended that the Ministry give priority to reviewing tobacco testing methods in New Zealand.

## 5.0 TOBACCO PRODUCT MODIFICATION

### 5.1 INTRODUCTION

#### Harm minimisation strategies in tobacco control

Harm reduction has been defined generally as:

... the philosophical and practical development of strategies so that the outcomes of drug use are as safe as is situationally possible. It involves the provision of factual information, resources, education, skills and the development of attitude change, in order that the consequences of drug use for the users, the community and the culture have minimal negative impact. (Watson 1991)

The approach of applying harm minimisation, or harm reduction, strategies in tobacco control efforts assumes that it is impossible to wean all smokers off nicotine use. It involves strategies to minimise the harm from smoking for those people who are unable or unwilling to overcome their nicotine dependence.

Harm minimisation strategies are usually adopted in tandem with other strategies for the prevention of drug use. In terms of its application to tobacco use, harm minimisation would constitute only one aspect of a four-pronged approach to tobacco control, which together would consist of:<sup>6</sup>

- prevention of the development of tobacco dependence
- cessation programmes for addicted smokers
- reduction of exposure to tobacco toxins in people who are unwilling or unable to completely cease their tobacco use
- Protection for non-smokers.

Some possible harm minimisation strategies involve reducing nicotine exposure to below addictive levels, while others involve reducing tar: providing cleaner nicotine that has fewer harmful substances associated with it (Borland 1997; Single 2000). Other strategies involve the substitution of cigarettes for different, less harmful products. Harm minimisation for tobacco use may therefore involve one or more of the following strategies:

1. Regulation of maximum tar levels.
2. Regulation of additives in tobacco products.
3. Manipulation of tobacco products to reduce the delivery of toxins to the smoker.
4. Reduction of smoke and regulation of smokeless tobacco products.
5. Reducing nicotine levels.

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<sup>6</sup> Adapted from: Henningfield and Fant, 'Nicotine Delivery Systems: Implications for Abuse Potential, Medications Development, and Public Health,' in Ferrence, et al. *Nicotine and Public Health*, APHA, Washington DC, 2000, 229-247.

6. Substitution of cigarettes for nicotine-delivery products to maintain the nicotine addiction without resort to smoking.
7. Regulation of alternative tobacco products.
8. Regulation of the tar:nicotine ratio.

Each of these is discussed in subsequent sections of this report. First, though, it is useful to discuss some cross-cutting issues relating to regulation in this area.

### **Potential Limits to Harm Minimisation**

Unlike some other consumer products (such as alcohol or fatty foods, for example), there is no safe level of tobacco use. After prolonged exposure, even low levels of tobacco smoke may cause serious health problems to smokers and people exposed to passive smoke. The greater predictor of morbidity and mortality from tobacco use is length of use, rather than amount of smoke inhaled. Therefore, there is a need for caution when adopting harm minimisation strategies that envisage long-term, low-level tobacco use.<sup>7</sup>

Less harmful products may be more acceptable to the public, and may therefore lead to an increase in tobacco consumption and prevalence. Novel tobacco products may also open up new markets of tobacco consumers and expose non-smokers to nicotine addiction (Borland 1997). As an example, the tobacco industry's development of 'low-tar' and 'mild' cigarettes in the 1970s may have encouraged people, who otherwise would have quit, to continue smoking in the mistaken belief that these cigarettes were safer (see section 7 of this report: *Regulation of product descriptors*).

Caution must therefore be adopted for any harm minimisation strategy that involves product innovation or alteration. Without comprehensive research into the biological effects of new or altered products, it is impossible to know whether the modified product is any less dangerous than the unmodified product. Any policy that encourages the use of one tobacco product as an alternative to another runs the risk of complicity in exposing consumers to unknown harms.

As it is not as simple to predict the outcomes of harm minimisation strategies as it is to predict the outcome of abstinence, the explicit goal of most tobacco control strategies is elimination of tobacco use, even though most of those people working in the area doubt that elimination is achievable (Borland 1997). Harm minimisation is therefore generally advocated as a medium-term option en route to more comprehensive regulation.

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<sup>7</sup> See, for example, Single, in Ferrence, et al. *Nicotine and Public Health*, APHA, Washington DC, 2000, 57-59; and Borland, 'Minimizing the Harm from Nicotine Addiction,' *Health Promotion Journal of Australia*, 1997;7(2):138-141.

## 5.2 REGULATION OF 'TAR' LEVELS

During the 1960s, the US Public Health Service encouraged the development and adoption of 'low-tar' cigarettes in the belief that lowering the tar and nicotine content of the smoke would reduce the risk of lung cancer (Shopland 2001). However, as discussed above, there are widespread concerns about the accuracy of the methods used to measure tar and nicotine, which means that cigarettes that test as low in tar may contain or deliver no less tar than regular cigarettes. There is also uncertainty about whether changes in cigarette design to reduce tar levels have resulted in any important health benefits.

### Current New Zealand legislation

Section 31 of the Smoke-free Environments Act 1990 states that no manufacturer or importer may sell or offer for sale, or export, any tobacco product that contains within it, or in its smoke, a harmful constituent prohibited by regulation, or harmful constituents in excess of limits set by regulation. It is an offence to sell a product in breach of section 31. A maximum fine of \$10,000 applies.

Currently there are no harmful constituents prescribed by regulations for the purposes of section 31, and no maxima are set.

### International moves to regulate tar levels

Internationally, regulation of maximum tar yields in cigarettes is more common than regulation of nicotine yields. In most countries where there is regulation, it is of fairly recent origin (Bates 1998).

In the European Union, a 1990 Directive required the gradual reduction of tar yield in cigarettes to a target of 12 mg by the end of 1997. More recently, European Council Directive 2001/37/EC sets maximum tar, nicotine and CO levels for cigarettes marketed, manufactured, or distributed in the Member States of:

- 10 mg per cigarette for tar
- 1 mg per cigarette for nicotine
- 10 mg per cigarette for carbon monoxide.

The maxima will apply from 1 January 2004 in most Member States. European States have begun to introduce regulations to enforce the EU Directive: for example, the Netherlands Government issued a decree on 21 January 2002 setting maxima.<sup>8</sup>

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<sup>8</sup> Staatsblad van het Koninkrijk der Nederlanden 2002, 83 & 84.

In Australia, a voluntary agreement had seen maximum tar levels reduce to 14 mg by 1988. In 1994, Federal regulations superseded the voluntary agreement, setting maximum tar levels at 16 mg, and maximum CO levels at 20 mg per cigarette.<sup>9</sup>

In Canada, the 1987 Tobacco Products Control Act (TPCA) required reporting on tar, nicotine and CO levels, but did not set maxima. The Tobacco Act 1997 replaced the TPCA, and contains regulation-making powers to set maxima, although none have been set.

Switzerland introduced regulations in 1995 setting the maximum tar yield at 15 mg per cigarette (Bates 1998).

In the UK, a series of voluntary agreements with industry since 1973 lowered reported tar levels. Low tar cigarettes were introduced, and consumers were encouraged to switch to them. The reported yields of higher tar cigarettes were progressively lowered. Average tar-yield targets were set, and limits were placed on the tar yield of new brands. The sales-weighted tar yield average fell from 20.8 mg in 1972 to 11 mg in 1993. However, this was undermined, to some extent, by increasing popularity of hand-rolled cigarettes (Bates 1998).

In the USA, no maximum tar yields have been set. The American Medical Association has focussed on nicotine reduction for policy action.

The International Union Against Cancer (UICC) has recommended a progressive eradication of higher tar brands from the market (Bates 1998).

### **Complications surrounding tar reduction**

The perception of a simplistic relationship between tar yield and lung cancer risk drives much tobacco control policy. This is problematic in light of evidence from a number of studies from the 1980s to the present that a reduction in tar is associated with far more complex effects than previously believed (Rickert 2000; Gray 2000a).

Since the 1950s, most studies of cigarette tar yields have reached the conclusion that a reduction in tar yield from cigarettes is accompanied by a quantitative reduction in the risk of lung cancer (Rickert 2000; SCOTH 1998). However, according to some epidemiological studies, there may be an attenuated risk of lung cancer among smokers of 'reduced yield' cigarettes compared to smokers of unfiltered, high yield products. These studies probably do not account appropriately for compensatory smoking or for other differences between high- and low-yield cigarettes. Declining lung cancer death rates in young adults in some countries may be attributable to 'reduced yield' cigarettes, but the extent to which this is so is unclear (Thun and Burns 2001).

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<sup>9</sup> <http://www.quit.org.au/quit/FandI/fandi/c05s4.htm>

A review of epidemiological studies undertaken for the Ministry of Health in 1998 indicated that there was some reduction in adverse health effects including cancer, respiratory, and cardiovascular disease among smokers of lower tar and nicotine yield cigarettes. However, the reduction in risk was not as great as would be expected if there was a simple relationship between tar yield and health risk (Blakely and Bates 1997; Fowles and Bates 2000b). It has been hypothesised that low-tar cigarettes may even increase the risk of adenocarcinomas (as opposed to squamous cell carcinomas) in the lung (Health Canada 1993).

Some large scale studies in the USA and UK show that the risk of lung cancer continued to increase from the 1950s to the 1980s, despite the widespread introduction of low-yield cigarettes and filter tips (Thun and Burns 2001). The American Cancer Society has conducted two large scale prospective studies of lung cancer rates. One (CPS-1) ran from 1959 to 1972, and the other (CPS-2) began in 1982. Although [FTC-measured] tar yields from cigarettes were significantly lower in the second study, which examined rates of lung cancer for long term smokers who smoked more than 20 cigarettes a day, it was found that death rates from lung cancer were higher for subjects in the second study (Health Canada 1993). The reasons for the increase are not clear, but may include changes in smoker behaviour, tobacco additives, tumour type, tobacco blends, or cigarette manufacturing methods.

General acceptance of a simplistic dose-response relationship between tar and lung cancer has been a factor in the popularity of 'low-tar' cigarettes (Henningfield and Fant 2000). Cigarettes labelled as 'low-tar', 'light', and similar, were targeted at those smokers who were thinking of quitting, in order to keep them smoking (National Cancer Institute (USA) 2001).

### **Low-Tar, Medium-Nicotine approaches**

In the 1970s, it was realised that smokers compensate for low or high nicotine levels in their cigarettes by regulating their intake of smoke. The idea of a low-tar medium-nicotine (LTMN) approach was developed to provide smokers with sufficient nicotine that they do not need to compensate for nicotine levels, while tar levels are reduced in order to minimise exposure to toxins. The success of an LTMN approach would depend on delivering the sensory effects required by smokers in such a way that they do not over-smoke (Russell 2000).

The United Kingdom Independent Scientific Committee on Smoking and Health cautiously supported the LTMN approach, recommending that some cigarettes be available with low tar yields but proportionately higher nicotine levels (Froggatt 1983). More recently, the 1998 Report of the Scientific Committee on Tobacco and Health (UK) was equivocal, identifying no clear advantages or disadvantages of varying the tar:nicotine ratio, and cautiously preferring that tar and nicotine

yields be reduced in line with one another (SCOTH 1998). Variations of the types of toxicants or tar levels between brands of cigarette may defeat the LTMN approach. The approach would also depend for its success on the possibility of reducing toxins significantly. Russell has commented that:

... a cigarette that burns tobacco is such a 'dirty' delivery system that it seems more realistic to hope that cigarettes will one day be replaced by pure nicotine products. (Russell 2000)

The LTMN approach is largely complicated by compensatory smoking and the problems of measurement. One study found that the tar:nicotine ratio could be increased by 50 percent or more by intense smoking (Rickert et al 1999). A further complication is that nicotine is found in tobacco smoke in 'free' and 'ionised' forms that have qualitatively different pharmacology on smokers. Moreover, the concept of 'tar' is so heterogeneous that it would be possible to vary wildly the relative proportions of toxins found in cigarette smoke while maintaining a fixed tar:nicotine ratio (Bates et al 1999). To overcome these complications, it would be necessary to develop new methods of measuring tar and nicotine before an LTMN approach could be seriously contemplated.

Related to the LTMN approach is the use made of high nicotine tobacco (such as 'Y-1') or technologies that increase the absorption of nicotine without increasing the total nicotine yield (such as the ammonia technology developed by Marlboro to increase the alkalinity of tobacco). These developments may plausibly have public health benefits if an LTMN approach is accepted (Bates et al 1999). However, any move that has the potential to increase or maintain the addictiveness of cigarettes should be adopted with caution, and only after extensive consideration of all the medical, ethical and public health issues involved. It should be noted that Y-1 tobacco is no longer grown in the United States after tobacco companies were criminally prosecuted and sued in civil court for secretly using the high-nicotine tobacco in cigarettes and exporting Y-1 seeds from the United States after the tobacco was banned there.<sup>10</sup>

### **Tobacco weight**

The maximum delivery of any cigarette depends on the amount of material that is burned. There are several ways to reduce the amount of material that is burned, including reducing the diameter of the cigarette, increasing the proportion of the filter or the overwrap, using less tobacco, or using more filler tobacco (Health Canada 1993). However, any potential for compensatory smoking has to be taken into account when weighing up these options.

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<sup>10</sup> See: <http://www.netlink.de/gen/Zeitung/1998/980205.htm>; see also: [http://www.csuchico.edu/~shockley/syllabi/high\\_nicotine.html](http://www.csuchico.edu/~shockley/syllabi/high_nicotine.html).

## 5.3 REGULATION OF ADDITIVES IN TOBACCO PRODUCTS

### Current New Zealand legislation

Additives are regulated in the same way as tar, as discussed above: section 31 of the Smoke-free Environments Act 1990 states that no manufacturer or importer may sell or offer for sale, or export, any tobacco product that contains within it, or in its smoke, a harmful constituent prohibited by regulation, or harmful constituents in excess of limits set by regulation. It is an offence to sell a product in breach of s31, and a maximum fine of \$10,000 applies, but there are no harmful constituents currently defined for the purposes of s31, and no maxima set for any constituents.

### International moves

In the UK, tobacco additives have been subject to a Voluntary Agreement on the Approval and Use of New Additives in Tobacco Products since 1984. In 1997, the agreement was replaced by new Voluntary Agreement and 'Guidelines for Testing and Use of New Additives in Tobacco Products in the UK'. The Voluntary Agreement provides for the approval and use of new additives, but does not provide for the prohibition of additives found to be harmful. The term 'additive' refers to 'any substance added by the tobacco manufacturer in the course of manufacture of a smoking product and intended to be burnt.' It includes chemicals added to cigarette papers (including adhesives), and tobacco processing agents. All tobacco additives in the UK (approximately 600 of them) are subject to limits on the quantities that may be added to tobacco, and a maximum is set for the aggregate quantity of additives (SCOTH 1998).

There is a Swiss ordinance (regulation) permitting an extensive list of ingredients in tobacco products up to a maximum of 25 percent of the dry weight of the final product. Some products have separate maxima.<sup>11</sup>

The Czech Republic has legislated against the used of two dozen aromatics in tobacco products. The law also permits the use of many other additives.<sup>12</sup>

### Discussion of policy options

Few additives were used in tobacco prior to the 1970s. Until 1986, most 'adulterants' were banned from tobacco products manufactured in New Zealand.<sup>13</sup> There is now a long list of additives in New Zealand tobacco products, including high levels of sugars. There are over 600 additives commonly used in tobacco products, most of which have unknown biological actions when combusted and inhaled in combination with each other. Though

<sup>11</sup> Ordonnance sur le tabac et les produits du tabac, 1 March 1995, RS 817.06.

<sup>12</sup> Czech Republic Law on Foodstuff and Tobacco Products No 110/1997, Publication 325/1997, Annex 3.

<sup>13</sup> Customs and Excise Act 1966, s 191: 'Adulterants—(1) No person being a manufacturer of tobacco or a dealer therein shall cut, colour, manufacture, or prepare, or have in his possession, any leaves, wood, herb, vegetable, or other material, or any harmful thing, to imitate or to be mixed with tobacco.'

some biological actions of a few of these chemicals are now becoming understood, there has been no comprehensive study of the biological actions of tobacco additives or the products of their combustion. Products with a safe history of use in foods may produce unknown or toxic effects when combusted and inhaled. Furthermore, some of the additives burned in cigarettes may be used to make the initiation of smoking easier, and to maintain smoking addiction (Fowles and Bates 2000b).

The rationale for allowing an increased use of additives from the 1970s was to make lower tar yield cigarettes more acceptable to consumers in order to facilitate the putative health benefits of 'low-tar' cigarettes. However, there is little or no evidence of any health benefit from 'low-tar' cigarettes, there is no evidence that additives are used only or primarily in 'low-tar' cigarettes, and it is widely acknowledged that smoker compensation can negate the difference in tar yield between so-called 'low-tar' and regular cigarettes (Bates, Jarvis and Connolly nd).

Bates and others raise a number of concerns about how additives are used in tobacco products, including the following:

- Additives, including ammonium compounds, are used to increase the levels of 'free' nicotine, for example by raising the alkalinity of smoke. This increases the addictive kick of the nicotine.
- Additives are used to make tobacco smoke more palatable.
- Sweeteners and chocolate may make smoke more attractive to children, young people and novice smokers.
- Menthol and eugenol numb the throat to disguise irritation.
- Additives like cocoa may be used to dilate the airways, allowing easier passage of smoke into the lungs. (Bates, Jarvis and Connolly nd)

Combusted forms of additives may have toxic or pharmacological effects on their own or in combination. Acetaldehyde, from burnt sugars, for example, has biochemical effects that are relevant to addiction (Fowles 2001a). Other additives may be addictive and may produce withdrawal symptoms in their own right. ESR has produced a report for the Ministry of Health assessing risks of many tobacco constituents, including the risks of some additives. However, for most of the substances added to tobacco, little is known of their combustion chemistry (Fowles and Bates 2000b).

Some additives may have increased the danger of environmental tobacco smoke, both by disguising its warning smell and by adding compounds with unknown pharmacological effects to tobacco (Connolly et al 2000a). One study found that tobacco companies had been adding chemicals to tobacco in order to disguise the smell of environmental tobacco smoke without reducing its toxicity or the amount of smoke (Connolly et al 2000a).

A number of policy options are available to regulate some, if not all, of these additives. These policy options depend, foremost, on full and accurate disclosure of additives used in cigarettes by brand (see section 8 of this report on tobacco product disclosure). The options include:

- development of a regulatory regime based on the pre-1984 regime (prohibition of adulterants, except those that are approved for use)
- prohibition of any new additives and conduct research into the health effects of existing ones
- restriction on the use of specific additives that, when combusted, have pharmacological effects, deaden peripheral nerves, influence absorption of nicotine, or disguise environmental tobacco smoke (Fowles 2001a)
- quantification of, and reporting on or restriction of the use of, the most toxic additives (Laugesen 2002).

It may be possible to achieve some of these options by way of regulations made under section 39 of the Smoke-free Environments Act 1990, which provides for regulations to be made specifying and/or prohibiting 'harmful constituents of tobacco products.' The section also provides for regulations determining methods of testing for the constituents of tobacco products and their smoke.

With respect to a ban on all additives, it has been suggested that consideration be given to such a ban with one year's notice, giving the manufacturers an opportunity to provide evidence that any additives they wish to use are free from toxic effects in burnt or unburnt form, and have a public health benefit (Gray 2000b). It has also been suggested that the toxicity of the product should not be the only category for regulation; if the intended purpose of the additive is to increase the addictiveness or attractiveness of tobacco products, 'it hardly matters whether the additive itself is toxic or benign.'<sup>14</sup> Gray has pointed out that such requirements would not be seen as draconian for most other products: the pharmaceutical industry is required to provide evidence of product safety for additives such as mint in nicotine chewing gum (Bates et al 1999).

Any option that involves a process of approval of a tobacco product, additive or constituent for consumption would entail risks unless the regulator could be entirely certain that the product, additive or constituent produced no harmful or addictive effects on its own or in combination with other substances in unburned, burned, particulate or gaseous form. Such a low threshold for risk would necessitate an extremely high threshold for approval of an additive, which might amount to an effective ban on additives.

#### **5.4 MANIPULATION OF TOBACCO PRODUCTS TO REDUCE THE DELIVERY OF TOXINS TO THE SMOKER**

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<sup>14</sup> Bates, et al., 'The future of tobacco product regulation and labelling in Europe: implications for the forthcoming European Union directive.' *Tobacco Control* 1999;8:225-235.

Tobacco companies and others have obtained numerous patents for technologies and processes that have the potential to reduce the toxicity of cigarette smoke without necessarily reducing the tar. These patents include the addition of catalysts to cigarette tobacco, manufacturing processes that would inhibit the localisation of nitrosamines in smokers' lungs, and chemical filters that would remove toxins from smoke.<sup>15</sup>

However, few of these patented technologies and processes have ever been used in commercial production. There are several factors discouraging tobacco companies from using these technologies and processes:

- Development of 'safer' products involves the acknowledgement of the dangers of the existing product.
- Tobacco companies would be unlikely to invest in new technologies if they were not able to profit from them by marketing products as 'safer'.
- There is no regulatory requirement to use the best or safest technology.
- Standard tobacco product tests do not adequately assess the harmful characteristics of tobacco products.
- Low-tar tobacco products have already been misleadingly marketed as safer.

Russell summarises the purpose of reducing toxins thus:

Since people smoke for nicotine, but die mainly from the tar and harmful gases, the obvious strategy is to identify those constituents of the smoke that are harmful, and then to eliminate them as far as possible without seriously impairing acceptability or causing appreciable compensatory self-regulation. (Russell 2000)

In addition, a policy of regulating cleaner cigarettes would also have to ensure that the public was not led into believing that cigarettes were safer, as this might discourage smokers from quitting or make it easier for non-smokers to initiate smoking. A public perception that cigarettes are dirty is a useful tool in any campaign against tobacco use. The challenge for policy-makers would be to reduce the dirtiness of cigarettes to the extent that is possible, while at the same time increasing the public's knowledge about the health risks of tobacco use.

### **Manufacturing processes**

Changes in the types of tobacco used since the mid-twentieth century may have had an effect on the chemicals released into the body. Blends used in some markets contain a higher proportion of burley tobacco, which contains more tobacco-specific nitrosamines (TSNAs), and lower proportions of benzo(a)pyrene

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<sup>15</sup> 'The safer cigarette: what the tobacco industry could do . . . and why it hasn't done it.' ASH and Imperial Cancer Research Fund, 3 March 1999.

and other carcinogenic polynuclear aromatic hydrocarbons (Health Canada 1993). A study of cigarettes purchased in 29 countries found wide variations (within the same brands) in the levels of two carcinogenic tobacco-specific nitrosamines: 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and N-nitrosornicotin (NNN). The study concluded that 'a three- to ninefold variation in carcinogen dose can be given to the smoker, without any warning, in products that are trademarked and globally advertised.' The study also suggests that lower nitrosamine cigarettes can be, and are, produced (Gray et al 2000).

The Canadian Expert Committee on Cigarette Modification reported that toxic and tumorigenic agents in smoke can be significantly reduced by using a tobacco blend containing 25 to 35 percent of low nitrate reconstituted tobacco, and by adding expanded tobacco with high filling power. The risk of bladder cancer may be reduced by limiting the nitrate content of tobaccos, since aromatic amines such as 4-aminobiphenyl are linked to that sort of cancer (Health Canada 1993).

Fowles and Bates have suggested that nitrosamines account for between four and 17 percent of the cancer risk associated with tobacco (Fowles and Bates 2000a). RJ Reynolds has indicated that it is developing low- or no-nitrate cigarettes from flue-cured tobacco (Fowles 2001b). Tobacco growers in Canada have been planning to introduce low-nitrosamine tobacco. In order to monitor the effect that this has on the delivery of other toxins to smokers, Health Canada has benchmarked a range of toxins currently found in Canadian cigarettes.

On the other hand, although TSNAs are carcinogens, there may be, on balance, a health benefit in preferring nitrate rich tobacco (with higher proportions of TSNAs) over tobaccos containing more polynuclear aromatic hydrocarbons (SCOTH 1998). The Scientific Committee on Tobacco and Health (UK) recommended that consideration be given to whether there could be health benefits in moving towards higher burley blends in the UK (SCOTH 1998). It is not clear what blends are used in New Zealand cigarettes, and more research would be advisable in this area before any policy decisions are taken.

Vector Tobacco claims to be able to prevent TSNAs from developing in the tobacco plant through a patented technology: the company has genetically modified plants in order to lower nicotine and nitrosamine levels.<sup>16</sup> Vector Tobacco has developed a cigarette called 'Quest' that reputedly contains only trace levels of nicotine and low levels of nitrosamine. The company also markets a cigarette called Omni, which contains a palladium catalyst intended to break down and remove carcinogens.

Vector's own test data for Omni show reductions in most toxins when compared with 'the leading competitive brand'. However, some of these reductions (such as for benzo[a]pyrene and catechol) are insignificant when compared with the Kentucky reference cigarette IR4F. Furthermore, marked increases in Omni

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<sup>16</sup> *Tobacco Reporter*, March 2001; available at: <http://www.prn2.usm.my/mainsite/tobacco/2001/news7.html>.

cigarettes of formaldehyde, some nitrosamines (NAB, NAT) and nitric oxide need explanation, particularly given nitric oxide's known interactions with nicotine and a role in regulating delivery of gases to the blood system.<sup>17</sup> Fowles suggests that an assay of mutagenic activity would be useful to evaluate the smoke from Omni (Fowles 2001b), as with any product innovation that alters the constitution of cigarettes.

## Filters

When health concerns about smoking were first raised in the 1950s, tobacco companies promoted filtration as a way to reduce the harms of cigarette smoking. A large proportion of the tobacco sold in New Zealand is pouch tobacco, which may or may not be sold with filters. This tobacco presents additional health concerns, especially in relation to populations which are high users of roll-your-own tobacco (for example, those on lower incomes).

Activated carbon filters have been gaining in popularity in some countries. These filters adsorb compounds, physically attracting them to the surface of the carbon. Various types of carbon can be used, but carbon manufactured from coconut shells is the most microporous and therefore the best suited for trapping gaseous compounds.<sup>18</sup> Star Scientific, Inc. and Brown and Wilkinson market a brand of cigarette (Advance) that reputedly yields reduced nitrosamines and other constituents. Advance has a charcoal activated filter and may have other technologies that reduce nitrosamines (Fowles 2001b).

BioFilter, a cigarette sold in Europe by Greek tobacco manufacturer Sekap, has a filter containing activated carbon impregnated with haemoglobin. The manufacturer claims that the filter acts as second lung, reacting with and filtering out toxic gases and solids.<sup>19</sup>

Vector Tobacco has recently begun to add palladium, a combustible metal, to cigarettes. Palladium catalyst technology has been known since the 1970s, when it was developed by Liggett, but the technology was never commercially used. Palladium added to tobacco may react to remove certain toxicants from the smoke stream. However, the health effects of combusted palladium are not known. Some scientists are concerned about the addition of palladium to cigarette smoke without proper testing to assess its biological effects.<sup>20</sup>

Another aspect of filter design has recently raised concerns. There have been news reports of novelty filters being marketed in Taiwan. These heart-shaped filters appear to be aimed at the youth market: they are marketed as '520', which

<sup>17</sup> [www.omnicigs.com/chartISO.asp](http://www.omnicigs.com/chartISO.asp).

<sup>18</sup> [http://www.tobaccoreporter.com/backissues/Oct2000/Oct2000\\_feature2.asp](http://www.tobaccoreporter.com/backissues/Oct2000/Oct2000_feature2.asp).

<sup>19</sup> <http://www.greekembassy.org/press/newsflash/1997/January/nflash0123c.html>. See also: [http://www.tob-business.com/eng/info/scripts/show\\_news.asp?file\\_url=%5CENG%5CINFO%5CCONTENTS%5CINFO%5Ce\\_info3.htm](http://www.tob-business.com/eng/info/scripts/show_news.asp?file_url=%5CENG%5CINFO%5CCONTENTS%5CINFO%5Ce_info3.htm).

<sup>20</sup> 'Vector Tobacco develops nicotine-free cigarettes,' *Tobacco Reporter*, March 2001.

is a synonym for 'I love you' in Chinese, and are impregnated with fragrances aimed at women and teenagers.<sup>21</sup>

## **Ventilation**

Filter vents were introduced into some cigarettes (particularly 'light' and 'mild') from the 1970s. These are small holes in the paper around the filter that allow air to mix with the smoke upon inhalation which have the purpose of diluting the smoke inhaled. A concern about filter ventilation is that the vents are easily blocked by smokers, negating the effect of the vents and rendering inaccurate the nicotine and tar ratings of the cigarettes as established by FTC and ISO tests.

A recent study has shown that smokers of vented cigarettes are provided with the false assurance that they are smoking low-tar or low-nicotine cigarettes: 'Smokers can take comfort from a lighter taste and a consoling name (such-and-such Ultra Light or Light) and their smoking is sustained by satisfaction from bigger puffs on the majority of low tar cigarettes and from blocking filter vents on the relatively rare 'Ultra Ultra' Lights (>65 percent air diluted, 1-2 mg standard tar)' (Kozlowski and O'Connor 2002). The study concluded that filter ventilation is dangerous and should be abandoned. Cigarettes should be tested in a way that reflects compensatory smoking, and vented filter tests should be 'counter-marketed'.

## **Policy options**

There are a number of options for reducing the toxicity of tobacco products. However, as noted above, any policy action will have to take into account the effect on the marketplace, including:

- Likelihood of smuggling.
- Likelihood of increased use of home-grown or alternative tobaccos or tobacco products.
- Smoker compensation.
- Potential effect on the way that the public perceives tobacco products.
- Effect on potential quitters or potential smokers.

Any policy action should be staged in conjunction with a public education campaign to ensure that there are no unintended effects of the policy on public perceptions. A public education campaign could also be used to raise public awareness of the toxic constituents of tobacco. If such a campaign were conducted in association with comprehensive testing and targeted labelling of cigarette products, market forces might be brought to bear on tobacco companies to reduce the levels of the targeted toxins.

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<sup>21</sup> 'Heart-shaped filter', *Bangkok Post*, May 14th, 1999, pg4.

In the case of filter technology, policy-makers will also have to take into account the prevalence of roll-your-own or pouch tobaccos in New Zealand, and bear in mind the possibility that consumers might switch to roll-your-owns if they found modified products unacceptable.

Policy options therefore include:

- licensing of manufacturers and importers to ensure compliance with minimum standards
- testing for a wider range of toxic constituents
- educating the public about the most toxic constituents of tobacco smoke
- labelling tobacco products with toxic constituents
- requiring or prohibiting the use of certain tobaccos, additives or processes
- requiring pouch tobaccos to be sold with filters
- prohibiting the sale of unfiltered cigarette tobacco.

Filter vents are misleading, and therefore potentially dangerous, because smokers have a low-knowledge of their existence and purpose, and because their purpose can easily (and unknowingly) be circumvented. Options for regulating filter vents include:

- prohibition of filter ventilation
- product testing that takes into account their occlusion or obstruction
- product redesign so that filter vents cannot easily be occluded.

Consideration could also be given to regulating the design of filters. Such consideration could extend to regulating the texts, images, shapes and colours used in the design of cigarettes and their components.

## 5.5 REDUCTION OF SMOKE AND SMOKELESS TOBACCO PRODUCTS

### Cigarettes with reduced smoke

Tobacco smoke contains a complex mixture of potentially toxic and carcinogenic compounds. The complexity of the mixture can be reduced by eliminating the amount of smoke. One means for this is to heat, rather than burn, tobacco. A number of products are on the market or in development that would achieve this. However, to reduce harm, the product must be acceptable to consumers, and must be thoroughly tested for its safety (Health Canada 1993).

Premier, a product that heated rather than burned tobacco was marketed by RJ Reynolds in 1988, but withdrawn because of poor sales (Fowles 2001b). Eclipse, also developed by RJ Reynolds, is currently being marketed (in some countries as 'Hi-Q' or 'Inside'). Eclipse generates a nicotine-containing aerosol from burning only 25mg or less of tobacco. Deliveries of most toxins are greatly reduced, although concentrations of furfural, CO, and nicotine are at or above the deliveries of conventional cigarettes. An RJ Reynolds study has suggested that Eclipse smoke is much less genotoxic than conventional smoke. It would be expected that Eclipse smoke would produce fewer cancers, although it may not reduce the risk of cardiovascular disease, and is not likely to be any less addictive than conventional smoke (Fowles 2001b).

Some studies have noted a disparity between the blood nicotine or cotinine levels in Eclipse smokers, and the measured nicotine yield of Eclipse cigarettes. This may be because machine-testing methods cannot replicate the way smokers use Eclipse, or because they do not account for the way Eclipse is designed (with, for example, higher nicotine tobacco concentrated towards the mouth end of the cigarette) (Fowles 2001b).

Fowles has suggested that there needs to be more research done into the formation of dioxins from the incomplete combustion of tobacco in Eclipse cigarettes. However, he has hypothesised a significant reduction in cancer risk (but not other health risks) using Eclipse (Fowles 2001b).

Philip Morris has been test-marketing a product called 'Accord' in Richmond Virginia since 1998. It also sells the product in Japan under the name 'Oasis'. Accord electronically lights tobacco only when the smoker inhales, thus reducing environmental tobacco smoke. Smoke constituent yields for Accord are not available, but there has been speculation that the exposures and risks from Accord are less than for Eclipse (Fowles 2001b). Another product claiming to reduce exposure to tobacco smoke toxins is 'Advance'. A recent study found that Advance produces 'similar withdrawal suppression and heart rate increase, lower CO boost, and higher plasma nicotine concentrations' than smokers' usual brands, suggesting that it is unclear whether Advance has any health advantages over other brands and more research is needed (Breland et al 2002).

In some respects, these products raise similar concerns to so-called 'light' and 'mild' cigarettes:

- There is insufficient evidence to conclude that these products are less toxic than conventional cigarettes.
- In the absence of firm evidence that these products are less dangerous than conventional cigarettes, smokers may be misled into believing that these products provide health benefits over conventional cigarettes.
- Even if these products do provide some health benefits for smokers who are unable to quit, there may be disadvantages if they are used to provide an alternative to quitting, or if they provide a smooth route for the initiation into smoking of new smokers or the return to smoking by people who have previously quit.

## **Snuff**

Snuff is a form of tobacco that is used either nasally, or orally. Unlike chewing tobacco, snuff is not chewed, but is placed between the gum and the lip or cheek for about half an hour. In the western world, snuff is used mainly in Sweden (where it is known as 'snus') and the United States of America. There are significant differences in the types of snuff available, depending on the curing process or tobaccos used. As Swedish snus is not fermented, it contains much lower rates of nitrosamines, and therefore is less likely to be genotoxic (Institute of Medicine 2001).

Section 29 of the Smoke-free Environments Act 1990 bans the importation for sale, sale, packing, advertising or distribution of any tobacco product labelled or otherwise described as suitable for chewing or for any other oral use other than smoking. This effectively prevents oral forms of tobacco being sold on the New Zealand market. Annual tobacco returns supplied by tobacco companies, and Customs entries, do not indicate that any snuff is currently sold in New Zealand, although these returns are not completely reliable, and the author understands from the Ministry of Health that there are anecdotes of snuff being obtained in New Zealand.

Oral snuff use may provide a safer alternative to smoking for existing tobacco users because it does not involve combustion of tobacco or inhalation of smoke. According to a report from the Institute of Environmental Medicine at the University of Stockholm, snuff use does not conclusively increase the risk for cancer over non-tobacco users. Despite high rates of snuff use in Sweden, oral cancer rates are lower than international averages (Ramstrom 2000). However, there is continuing debate about whether there is sufficient evidence to make conclusions about the cancer risks of snuff use. The World Health Organization and the Surgeon-General (USA) have stated that snuff is a cause of mouth

cancer among humans (Connolly 2000b). Article 8 of the European Council Directive 2001/37/EC requires most Member States to ‘prohibit the placing on the market of tobacco for oral use.’ However, there is some expectation in Sweden that the European prohibition (which does not extend to Sweden) will be lifted.<sup>22</sup>

It has been suggested that the high rate of snuff use in Sweden has kept smoking rates low, both by reducing initiation and by increasing cessation (Ramstrom 2000).<sup>23</sup> On the other hand, particular marketing strategies used in the United States have used snuff to target and hook young people on tobacco use. Strategies included the use of graduated pH levels and flavours, and instructions about use. US Smokeless Tobacco has been criticised for violating a 1998 legal settlement by advertising in magazines with large youth readership.<sup>24</sup> Data from the United States show that boys tend to graduate from snuff to smoking when they start dating (Connolly 2000b).

Among its recent recommendations, SACTob has made the following statements relating to smokeless tobacco products:

- Current evidence does not indicate that use of any smokeless tobacco is free of health risks.
- There is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy. (SACTob 2003a)

A full list of SACTob recommendations is included as Appendix F.

Another option is to explore the possibility of legalising the trade in snuff as a harm reduction alternative to smoking tobacco. There are a number of considerations to be taken into account if this option is developed further:

- Research into the effects of snuff use, and debate about its harm reduction use, is ongoing, and there is no clear position on the effectiveness of snuff as a harm reduction alternative to smoking tobacco.
- Any harm reduction benefits of snuff use would require numbers of smokers to switch to snuff, which has no recent history of use in New Zealand.
- Harm reduction would be defeated if people who would otherwise not have become tobacco users are attracted to snuff use. This risk may be heightened if snuff is shown to be, or believed or implied to be, significantly less harmful than tobacco smoking.
- It would be necessary to ensure that the form of snuff used was as harmless as possible and manufactured to the highest standard.

<sup>22</sup> <http://www.tobaccoreporter.com/current/story3.asp>.

<sup>23</sup> Ramström, ‘Snuff—An Alternative Nicotine Delivery System,’ in Ferrence, et al. *Nicotine and Public Health*, APHA, Washington DC, 2000, 170-171.

<sup>24</sup> ‘Smokeless Tobacco Accused of Advertising to Children’, Nancy Zuckerbrod, Associated Press, 6 April 2002.

## 5.6 REDUCING NICOTINE LEVELS IN TOBACCO

Nicotine reduction strategies would gradually reduce the amounts of nicotine available from tobacco, over up to ten years, to the point where smokers were unable to obtain sufficient nicotine from cigarettes to sustain a smoking habit. This strategy was originally advocated by Benowitz and Henningfield, and is sometimes called the 'Benningfield' or 'nicotine weaning' approach. Gray has proposed a global reduction in levels of nicotine and tar to 1.0 mg and 12 mg respectively per cigarette in order to reduce the addictiveness of cigarettes (Gray 1996). It has been suggested that the strategy would work well with a tobacco substitution programme that allowed nicotine addicts easier access to low-risk nicotine products such as patches and gums (as is the case in New Zealand).

There is vocal opposition to the Benningfield approach on the grounds that it would provoke a revolt among smokers, would provoke smuggling, or could stimulate dangerous levels of compensatory smoking.<sup>25</sup> While the Benningfield approach has never been attempted, some jurisdictions have legislated smaller reductions in nicotine levels.

SACTob has recently recommended that, 'With respect to nicotine, it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine per unit (e.g., cigarette) and further study of this issue is required' (SACTob 2003b).

The assumptions informing a nicotine reduction strategy are that:

- there is a threshold nicotine exposure level that is necessary to sustain addiction
- it is possible to accurately measure nicotine *delivery* and the biological effects of delivered nicotine
- it is technically feasible to manufacture cigarettes with nicotine levels that fall below the threshold level
- smokers would not adopt ways of defeating the nicotine reduction strategy.

There is ongoing research into biomarkers that could provide accurate measures of the delivery of nicotine. As noted above, ESR is making some progress in this direction, and recently published research suggests that hair nicotine could be used as a biomarker for exposure to tobacco smoke (Al-Delaimy 2002).

### Threshold nicotine addiction level

It appears that the nicotine dosing characteristics of a cigarette type must fall within a relatively narrow range to sustain broad commercial use, and a nicotine reduction strategy could in theory gradually reduce nicotine levels to below that range in order to reduce tobacco use (Henningfield 1998).

<sup>25</sup> See Letters from Shatenstein, and Jarvis and Bates, *Tobacco Control* 1999;8:106-107.

Benowitz and Henningfield proposed that the amount of nicotine allowable in cigarettes be reduced so that even allowing for compensatory smoking of over 30 cigarettes a day, most new smokers would not receive enough nicotine to develop or maintain addiction.

Nicotine produces psychoactive and rewarding effects at doses possibly as low as 0.2 mg in nicotine tolerant persons. A cigarette with a total nicotine content of 0.5 mg would produce a bioavailability of 0.1 mg to 0.2 mg. However, even lower doses of nicotine may be sufficient to reinforce a pre-existent smoking habit (Henningfield et al 1998). It has been suggested that 0.17 mg/cigarette should be considered as a maximum nicotine level for cigarettes, and that there should probably be a lower maximum set to minimise the possibility that young and nicotine-intolerant people would experience nicotine effects that might lead to habituation (Henningfield et al 1998).

### **Relevance of other factors to addiction**

Several factors other than nicotine may influence the maintenance of a smoking habit (Health Canada 1993). These may include taste, smell, other addictive substances in tobacco smoke, habituation, social factors, etc. Clearly, factors other than nicotine influence the initiation of tobacco smoking and it is likely that some of these factors help sustain the smoking habit after initiation.

The efficiency of cigarettes is also a complicating factor in addictiveness. Cigarettes deliver the drug rapidly and cheaply. These considerations, along with the variation in natural tolerance to nicotine, complicate attempts to estimate an accurate nicotine-addiction threshold level, leading the tobacco industry to argue that a threshold level cannot be determined (Henningfield et al 1998).

It is also possible for tobacco companies to vary the availability of nicotine from cigarettes by adding ammonia compounds into the tobacco. This alters the pH level of the smoke and converts the nicotine from a bound chemical state to a more potent free chemical state in order to increase the transfer of nicotine from cigarette to smoker (Zeller 2000). Nitric oxide can play a similar role in altering the body's metabolism of nicotine (Vleeming et al 2002).

### **Altering nicotine levels through manufacture**

Over the past five decades, the [machine-measured] smoke and nicotine yields of commercial cigarettes in developed countries have been reduced significantly (Health Canada 1993). It is possible for the tobacco industry to vary the yield of nicotine from approximately 0.1 to 4.0 mg/cigarette by means of various aspects of cigarette design, agricultural processes, plant genetics, and commercial processes (Spears 1975; Henningfield et al 1998; Zeller 2000).

Tobacco companies have produced denicotinised cigarettes, containing trace levels of nicotine. These cigarettes (Next, Merit De-Nic, Benson & Hedges De-Nic, Quest) have not been well received in the market, which may suggest that without nicotine, the consumption of cigarettes would be significantly reduced, or they would be possibly ignored for black-market products containing higher nicotine levels. On the other hand, the denicotinised cigarettes were sufficiently similar in attributes to regular cigarettes that researchers were able to use them as placebo cigarettes (Henningfield et al 1998).

As noted above, Vector Group, an American tobacco company, claims to have developed a 'virtually nicotine-free' tobacco from genetically modified tobacco plants. Fowles cautions that this tobacco would need to be carefully tested for biological effects similar to nicotine. It would also be necessary to examine whether this tobacco would meet the acceptance of ERMA (Fowles 2001b). American tobacco growers are reportedly concerned that the presence of genetically modified tobacco might damage their exports to Europe. The North Carolina State Legislature has considered a bill that would require a \$US1 million bond from people dealing with the genetically modified tobacco.<sup>26</sup>

At the other end of the scale, the tobacco industry has developed a high nicotine tobacco, known as Y-1, which could potentially provide a higher dose of nicotine, requiring less tobacco to be smoked for the same effect, thus reducing toxins. As noted above, Y-1 has been banned from production in the United States.

### **Compensation & over-smoking**

In theory, a reduction in nicotine should reduce the addictiveness of cigarettes and lead to a decline in smoking. However, cigarettes allow smokers to vary delivery of nicotine, and smokers can increase their nicotine intake by taking more intense puffs or more frequent puffs (known as 'over-smoking'), or blocking the ventilation holes in manufactured cigarettes (Borland 1997). Smokers might also change brands, or switch to unfiltered, hand-rolled cigarettes if they felt that they were not receiving sufficient nicotine to satisfy their addiction.

There are concerns that compensatory over-smoking could expose smokers to greater levels of toxins and carcinogens (Jarvis and Bates 1999). Responding to lower nicotine yields, a smoker will take more frequent and deeper puffs, more greatly exposing the lung, especially the peripheral lung. The result, when combined with low-tar blends of tobacco that are higher in nitrates, is an increased exposure of the lung to carcinogens that could be associated with a proportionally greater increase of adenocarcinoma (primarily in the peripheral lung) than of squamous cell carcinoma in the bronchi (Health Canada 1993).

However, over-smoking tends to be only partial, and does not fully compensate for the reduction in nicotine. Studies have shown that levels of nicotine and its

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<sup>26</sup> <http://www.prn2.usm.my/mainsite/tobacco/2001/news7.html>.

metabolite cotinine can be reduced by approximately one third over three to twelve weeks (Henningfield et al 1998). Most studies show that over-smoking declines over time and smokers adapt to the lower levels of nicotine in low nicotine products (Guyatt et al 1989). On the other hand, the two largest, long-duration studies of 'switching' (which monitor smokers who have switched to low-nicotine brands), found complete or near-complete nicotine compensation over six months (Withey et al 1992; Frost et al 1995). One way to avoid compensatory over-smoking would be to make nicotine more available through patches, gums, and other smokeless sources of nicotine (Henningfield et al 1998).

The greatest benefits from nicotine reduction are not likely to come from long-term adaptation to low-nicotine products, since the main determinant of harm from smoking is duration of use and number of cigarettes smoked per day (Borland 1997). Greater benefits of low nicotine cigarettes would be delivered if nicotine levels were reduced to a point where smokers' habits could not be sustained by cigarettes (Henningfield et al 1998). However, the lower the nicotine level, the greater the likelihood that smokers would seek other sources of nicotine.

### **Tobacco black markets**

Borland suggests that if nicotine levels are regulated down to a level that is not acceptable to nicotine addicts, that might encourage the development of a black market in higher nicotine tobacco (Borland 1997). While New Zealand has been largely insulated from the tobacco smuggling that occurs in some continental markets, that might not remain the case if maximum nicotine levels were significantly reduced by regulation. In addition to the risk of smuggling, there would likely be an increase in the use of, or trade in, home-grown tobacco. Tobacco cultivation kits are already available in some stores.

It has been suggested that a black market in high-nicotine tobacco could not occur without some level of complicity by tobacco producers or marketers (as was found to occur in Canada). It is also considered by some commentators that a degree of smuggling would be tolerable if it was outweighed by the reduction in death and disease caused by tobacco products (Henningfield et al 1998).

### **Nicotine withdrawal and other health consequences**

Although nicotine withdrawal can precipitate symptoms that are disruptive, behaviourally, emotionally, cognitively, and physiologically, there is no evidence that the gradual reduction of nicotine would produce health problems not manageable through behavioural intervention strategies (Henningfield et al 1998). Sudden nicotine withdrawal, or acute nicotine deprivation may exacerbate or precipitate symptoms of psychiatric disorders. However, this area has not

been widely studied, and it has been argued that problems are easily treated (Henningfield et al 1998).

If nicotine reduction is chosen as an option, there would need to be a programme of education for the general public and the medical profession. Education would cover the diagnosis and treatment of conditions precipitated by nicotine withdrawal. It would also cover strategies and options for the promotion of nicotine replacement and smoking cessation (Henningfield et al 1998).

### **Other forms of nicotine dependence**

It is possible that some nicotine-dependent smokers could become dependent on other sources of nicotine. Nicotine itself has some detrimental effects, particularly during pregnancy, and possibly in the presence of cardiovascular disease. However, sources of nicotine other than tobacco are not associated with a high level of other toxins and carcinogens. Nicotine is more likely to produce toxic effects when administered by cigarette smoke than other sources because cigarette smoke produces high peak levels and more intense physiological effects (Henningfield et al 1998).

Due to the low risks from nicotine when provided through non-tobacco sources, some commentators suggest that a strategy of nicotine substitution and maintenance could be viably adopted. This option is discussed in section 5.7 below.

### **Analysis of the de-nicotinisation option**

The potential health gains of de-nicotinisation of cigarettes would be likely to be a reduction in smoking addiction and initiation. These benefits, if they eventuated, could arguably outweigh any costs, such as smuggling, black markets and (the greatest likely cost) compensatory smoking.

The Scientific Committee on Tobacco and Health (UK) thought it was difficult to reconcile two conflicting issues related to nicotine reduction: compensatory smoking of low-nicotine cigarettes, and addictiveness of high-nicotine cigarettes (SCOTH 1998). Making clean alternative nicotine sources readily available could reduce the likelihood of compensatory smoking, if nicotine levels are significantly reduced. Bates and others have urged caution in the regulation of nicotine on the grounds that it could encourage compensatory smoking or smuggling (Bates et al 1999).

A recent New Zealand Masters thesis has examined the prospect of de-nicotinisation of cigarettes. Based on surveys of people with an interest in tobacco control (including people involved in policy, advocacy, smokers and ex-smokers) the research found that there is 'not enough consensus and scientific evidence to support the introduction of a de-nicotinisation of tobacco policy, nor

would there be enough political and public support,' despite the significant potential health gains (Fraser 2002). The major risks to the introduction of a policy of de-nicotinisation would be political and social opposition. However, if there were an international consensus or lead, or if there were stronger scientific evidence for the policy, it might be possible to overcome that opposition (Fraser 2002). A summary of the findings of the thesis follows:

- A de-nicotinisation of tobacco policy would have some support amongst the public but there could be a major backlash from smokers. The barriers could be insurmountable in the current political environment but may be overcome in the future. The government would probably also need to reduce the harmful constituents in cigarettes, simultaneously with the nicotine, for the cigarettes to be acceptable.
- Shifting smokers from nicotine to non-addictive cigarettes with the option of access to [alternative nicotine delivery systems] would require a combination of consultation and education with the public. De-nicotinisation could be introduced in stages. There could also be a policy which provides for a choice of nicotine and nicotine-free cigarettes using differential taxation on nicotine. Strict regulations would be required.
- Policy makers would need to ensure they could manage the possible short term negative health impact on current smokers, while significantly improving future health. There could be social problems with some smokers turning to other drugs. The tobacco industry would be opposed to de-nicotinisation and fight the implementation of the policy.
- The major advantage of de-nicotinisation of tobacco is reducing population harm caused by smoking but a disadvantage could be that the total harm could be increased if smokers compensated in their smoking behaviour to access more nicotine. Smokers would find it easier to quit smoking and young people who experimented with smoking would not become addicted to smoking.

One commentator has suggested a variation of the de-nicotinisation proposal that would allow for the sale of no-nicotine cigarettes through the usual outlets, and normal-nicotine cigarettes through regulated schemes for addicted smokers. It has been suggested that this could reduce the potential for smuggling and some of the other harms that might arise from the proposal.<sup>27</sup>

A more modest reduction in nicotine rates might receive greater political and social acceptance than de-nicotinisation. The European Union has required gradual reductions in nicotine levels to 1 mg per cigarette. However, gradual or partial de-nicotinisation carries health risks in that it may encourage compensatory smoking.

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<sup>27</sup> Comments provided anonymously by a New Zealand health advocate.

Other considerations for a mass-weaning policy through nicotine reduction would include:<sup>28</sup>

- educating consumers and health professionals about the goals and realistic expectations of, and alternative strategies to, a nicotine reduction policy before and during implementation
- regulating the labelling of tobacco products to provide meaningful information about nicotine levels and the effects of tobacco
- further developing a treatment infrastructure
- providing alternative nicotine-delivery mechanisms for addicted smokers
- funding research into the effects of policies, nicotine dependence, treatment and prevention research, and regulation
- consistent regulation of all nicotine-delivering products
- commitment to enforcement
- international collaboration.

## **5.7 SUBSTITUTION OF CIGARETTES FOR NICOTINE-DELIVERY PRODUCTS TO MAINTAIN THE NICOTINE ADDICTION WITHOUT RESORT TO SMOKING.**

This policy option involves the active promotion of alternative delivery vehicles for nicotine as a replacement for tobacco. Products containing nicotine are already available as medicines and other consumer products (for example, nicotine-based sweets – see below). This approach can be either a short-term strategy for the purposes of weaning smokers off tobacco or a long-term strategy for those who wish to use nicotine recreationally.

The active promotion of alternative nicotine products as a way of enabling people wishing to experience the effects of nicotine use in a way that, while risking addiction, avoids the associated risks with obtaining nicotine through a dirty device (ie: tobacco) has been raised in informal discussions among the tobacco control community.<sup>29</sup> There are significant ethical issues should such a policy be adopted by government regulators. Not least of all is the question over the appropriateness of a Government encouraging or permitting the development of an industry that promotes addictive products. Secondly, while nicotine based products can be developed that are safer than tobacco-based nicotine delivery devices, they may still represent a risk in terms of the hazards from nicotine, particularly for pregnant women or people with cardio-vascular disease. Thirdly, there is a potential argument that the promotion of nicotine usage in whatever form could lead to or legitimise tobacco use.

### **Regulation of alternative tobacco products**

<sup>28</sup> Adapted from Henningfield et al., (American Medical Association) 'Reducing the addictiveness of cigarettes,' *Tobacco Control* 1998;7:281-293.

<sup>29</sup> Matthew Allen, personal comment: December 2002.

Recently a number of non-smokable tobacco products and nicotine-based products have started to be marketed internationally and some importers have indicated an interest in bringing these products to New Zealand. Concerns over these products relate primarily to the addictive nature of nicotine-based products and the ill-advisability of promoting the use of nicotine-based products as a recreational pastime.

Currently, section 29 of the Smoke-free Environments Act prohibits the importation for sale, sale, packaging, or distribution of any tobacco product not intended for smoking that is labelled or otherwise described as suitable for oral use. Tobacco product is defined in section 2 as:

... any product manufactured from tobacco and intended for use by smoking, inhalation, or mastication; and includes nasal and oral snuff; but does not include any medicine (being a medicine in respect of which there is in force a consent or provisional consent given under section 20 or section 23 of the Medicines Act 1981) that is sold or supplied wholly or principally for use as an aid in giving up smoking.

This means that nicotine products designed for drinking, or consumption by a method other than smoking, inhalation or mastication, would escape regulation under the Medicines or Smoke-free Environments Acts (unless therapeutic claims were made about the product). However, it is likely that such products would be regulated by the New Zealand Food Safety Authority under the Food Act 1981.

The Royal College of Physicians in the United Kingdom has recently called for a government body to be set up to regulate nicotine and products containing nicotine.<sup>30</sup> This option could be explored in New Zealand, as has been suggested by Health New Zealand<sup>31</sup>, or it could be possible to bring nicotine under the administration of a single existing regulatory body. Currently, therapeutic products containing nicotine are regulated by Medsafe, and other products (except for smokeable tobacco, chewing tobacco and snuff) are regulated by the New Zealand Food Safety Authority. An alternative to a stand-alone body would be to formalise links between the agencies so as to avoid duplication of resources and assist the development of a consistent policy towards the regulation of nicotine products.

The challenge in any move to greater regulation of nicotine is that there would be immense pressure to exclude smokeable tobacco products such as cigarettes from regulation by virtue of the fact that they have largely escaped regulation in the past. However, the WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) has recently arrived at the conclusion that:

The present situation in which the most toxic form of nicotine delivery is the least regulated, is unacceptable from a public health perspective.<sup>32</sup>

<sup>30</sup> NZ Smokefree e-News, 25 November 2002; 6: 44.

<sup>31</sup> Ibid.

<sup>32</sup> 'SACTob Recommendation on Nicotine and the Regulation in Tobacco and non-Tobacco Products', WHO, 2002.

The fact that cigarettes are largely unregulated is not a persuasive reason for letting other potentially harmful nicotine products go unregulated.

Alternative nicotine products include the following:

*Alternative cigarettes and cigars*

- Clove cigarettes or kreteks: cigarettes typically containing 40 percent cloves and 60 percent tobacco. The cloves contribute eugenol, which numbs the air passages. The cigarettes are densely packed and do not continue to burn when unattended. There is no evidence that these cigarettes are less harmful than conventional cigarettes (Fowles 2001b). In fact, there is some evidence that these products are more harmful (Reynolds 1999).
- Bidis: tobacco wrapped in a tendu or temburni leaf. In machine-smoking tests, these products yield more nicotine, tar and CO than conventional cigarettes, largely because of product design (Fowles 2001b).

*Other nicotine products*

- Cigalettes: a mint sweet containing approximately 60 percent crushed tobacco, and sold under the trade names such as 'Ariva', 'Nicostop' or 'Licatine'. Unlike nicotine replacement therapies (NRTs) that release nicotine slowly, this product apparently releases nicotine rapidly, in a manner similar to a cigarette (Fowles 2001b). In the USA, they are manufactured and sold by independent pharmacists in flavours like 'Very Berry' and 'Lemon Lime' (Gorman 2002).
- Nicotine Water: bottled water containing approximately two cigarettes' worth of nicotine per two litres of water. This product is available in the USA.
- Nicotine inhalers: products that mimic the nicotine exposures and hand gestures of cigarette smoking.
- Snuff: options for the regulation of snuff have been discussed above in section 5.5.

In addition, there are a number of products, such as herbal cigarettes, and Bravo, the cigarette-substitute made from lettuce leaves<sup>33</sup>, that do not contain nicotine but have associations with the smoking habit. Some of these products, such as marijuana, may be regularly mixed with tobacco, which can lead to, or reinforce, nicotine addiction. In pursuing a regulatory option, it would be advisable to consider how these smokeable non-tobacco products should be regulated.

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<sup>33</sup> <http://www.bravosmokes.com>.

Candies and chocolates that mimic tobacco products could also be targeted for greater regulation. Brazil has recently banned the manufacture, import, advertising and sale of foodstuffs in the form of cigarettes, cigars, or any other tobacco products from 8 May 2003.<sup>34</sup>

## Discussion

The marketing or promotion of alternative sources of nicotine raises significant ethical issues, not least of all for the Government that allows or encourages a nicotine market to develop. Such a move would need considerable public debate before it could proceed.

The Health Select Committee has recently recommended amends to the Smoke-free Environments Act to regulate the import, advertising, labelling, distribution or sale of any products containing nicotine that are not regulated as medicines. This would seem a prudent approach until such time as regulatory options can be considered, products assessed for risk, and appropriate controls put in place.

While some have argued that there might be benefits in considering the establishment of a joint agency for regulating all products containing nicotine, whether used for medicinal, food, or recreational purposes, or that are tobacco-based, this question falls outside the brief of this report. Such a proposal would raise significant and complex issues relating to legislative powers, existing obligations of a number of government agencies, competing priorities for regulation, trans-Tasman harmonisation concerns (in respect of the proposed establishment of a trans-Tasman regulator of therapeutic products), as well as resourcing issues.

## 5.8 CONCLUSION

A number of commentators have recommended the development of a comprehensive international strategy on the future of product modification (Bates et al 1999). New Zealand should consider taking policy initiatives that are compatible with the future direction of world action on tobacco product regulation to ensure that the initiatives are viable within the global tobacco market. SACTob provides an indication of the future direction of tobacco product regulation. It has recently made the following four recommendations, which are based on the weight of existing scientific authority:<sup>35</sup>

1. The present situation in which the most toxic form of nicotine delivery is the least regulated, is unacceptable from a public health perspective.
2. Because nicotine appears to be responsible for a small proportion of tobacco-caused diseases relative to other tobacco constituents and emissions, there is considerable scope for developments that reduce the risks experienced by

<sup>34</sup> <http://www.nietrokers.nl/e2/n05112.html>.

<sup>35</sup> 'SACTob Recommendation on Nicotine and the Regulation in Tobacco and non-Tobacco Products', WHO, 2002.

- users of tobacco, but without undermining efforts to prevent initiation to tobacco use and promote cessation among established users.
3. In the absence of firm contrary data, those responsible for public policy decisions are justified in using the conservative assumptions that smokers' preferences for a nicotine dose are persistent over time and are not influenced by changes in the product used and that smokers will compensate for reductions in yield to maintain a relatively consistent dose of nicotine.
  4. A broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in ways that minimise the risks.

These recommendations, and the brief report that accompanies them, provide cautious support for harm reduction policies that allow consumers to obtain cleaner nicotine sources as substitutes for smoking tobacco, while working to also prevent the initiation of nicotine addiction, and encourage established users to quit. The recommendations therefore provide a degree of international endorsement of a harm reduction approach involving:

- prevention of the development of tobacco dependence
- cessation programmes for addicted smokers
- reduction of exposure to tobacco toxins in people who are unwilling or unable to completely cease their tobacco use
- protection for non-smokers.

The main difficulty in adopting a policy that provides smokers with cleaner sources of nicotine is that it risks undermining the first two planks of the harm reduction approach described above, because, without adequate co-ordination, education programmes, and regulatory measures, the provision of cleaner sources of nicotine could make it easier for non-smokers to become nicotine-dependent and more difficult to encourage nicotine-dependent people to cease use of nicotine products.

It is clear that tobacco smoke is the dirtiest of the nicotine-delivery methods available. It is therefore widely accepted that priority should be given to reducing the perceived benefits and increasing the immediate perceived costs of tobacco smoking in order to prevent initiation and encourage cessation. This could be achieved through methods other than, or in addition to, product modification. At the same time, priority could also be given to modifying smokeable tobacco products in order to reduce the long-term health costs from smoking without making smoking more attractive.

In addition, many people see it as necessary to provide alternative nicotine sources for nicotine-dependent people. This notion creates heated debate, as there are public health risks in allowing novel or alternative tobacco products in the marketplace, not least because the public may consider that any novel product has received sanction from regulatory authorities, which may encourage

people to commence using the products. There are unknown health effects of new or altered products, which would require thorough investigation before any move to liberalise access to alternative nicotine products.

Article 9 of the Framework Convention on Tobacco Control envisages the development of international guidelines for testing, measuring and regulating the contents and emissions of tobacco products:

**Article 9**  
*Regulation of the contents of tobacco*

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

On balance, the author can only recommend that caution be taken not to embrace any strategy without careful consideration of the implications of that strategy. It is clear that the science is 'not in' with respect to product modification. While there is some evidence supporting nicotine and tar reduction, in particular, as a potential harm reduction strategy, difficulties with measuring the impact of such a measure, the ease of product modification, and a lack of knowledge about the content of New Zealand tobacco products limits the ability to take immediate action.

The potential for the Framework Convention on Tobacco Control to encourage international collaboration in this area, and in particular for SACTob to deliver agreed best practice advice on product regulation, provides some hope that in time there will be a clear way forward. In the meantime it is recommended that New Zealand actively engages with partners (for example, the Australian government and the WHO) to further investigate regulatory options. New Zealand should also consider implementing steps to provide for more effective disclosure of the content, and emissions, of New Zealand tobacco products (see section 8 of this report): this will help to inform potential product modification options.

Finally, when analysing options for the regulation of the content of tobacco products, it is first necessary to balance regulatory action against the following considerations:

- Whether the proposed regulatory action is required, given other tobacco control strategies.

- Whether there is public acceptance of the need to regulate and, if not, what steps are required to raise the level of acceptance should effective and appropriate regulatory mechanisms be identified.
- Whether there are reliable methods for measuring the constituents of tobacco products to enable the regulator to monitor the nature, extent and effects of product modifications.
- Whether there are any other political, consumer or practical and technical barriers to the regulatory mechanism identified.

Taking these considerations into account, it is possible to identify three priorities for preliminary action in the area of tobacco product control.

Arguably, the most important requirement underpinning any further regulatory move is revision of testing methodologies and requirements to ensure that there is full information about the content of tobacco products. Without this information, it is impossible to assess the likely health consequences of any policy initiative.

Given the uncertainties that surround any tobacco or nicotine product innovations, it would be advisable to take a conservative approach to the regulation of new products, restricting any future tobacco or nicotine product innovations unless they have proven health advantages over products currently on the market.

To provide regulators with the necessary information to make sound regulatory decisions in the best interests of public health, it would be advisable to support research into tobacco products and tobacco product regulation. This includes research with a New Zealand focus, including research into the products available in New Zealand and research into the New Zealand marketplace.

## 6.0 TOBACCO PRODUCT LABELLING AND MARKETING

### 6.1 INTRODUCTION

#### Marketing of tobacco products

Advertising has long played a dominant role in determining cigarette sales, despite the difficulties of promoting a product that has limited, if any, positive attributes. As early as 1975, a marketing research company admitted in a study conducted for Brown & Williamson that:

Most advertising for other products presents real, or at least accepted, benefits, values, attributes, end-results, etc., of the product it 'pushes,' sells. Cigarette advertising can not do the same. There are not any real, absolute, positive qualities and attributes in a cigarette. (Pollay, Lopez et al 1994)

Lacking a positive product to promote, tobacco advertising has largely relied on the creation of images (of everything from manliness to funky individuality) and illusions (including current descriptors such as 'mild' and 'light', which give the illusion of a healthier smoke) to promote its products.

In the face of growing knowledge of the serious health risks posed by cigarette smoking, many countries have instituted restrictions or bans on cigarette advertisements on television, bill-boards, in magazines, etc. As these advertising restrictions have increased, the cigarette pack itself has become the primary marketing medium for the industry, which spends an enormous amount of money on research and testing of package design. Tobacco companies regularly introduce innovative design strategies to boost sales. Examples include British American Tobacco's series of four Lucky Strike packs with 'retro' artwork sold in 1996, RJ Reynolds' four series of Camel 'collector's packs' sold between 1994 and 1996, holograms placed on packs of Parliament by Philip Morris in 1996 as part of sweepstakes promotion, and the 'microsmoke' (a low-production, high-quality parallel to the micro-brewery products) introduced by several tobacco companies (Slade 1997). See Appendix E for recent examples of tobacco companies using cigarette packs for marketing in Hong Kong.

Cigarette packs are more influential compared with most other product packaging for two additional reasons:

- Unlike most products, where packaging is discarded after opening, a cigarette pack is usually retained until its contents are used up, and is frequently taken out, opened, and placed on display near the person.
- Cigarettes brands have the highest level of brand loyalty of all consumer products, and most smokers remain with the first brand smoked (a choice

based on the image aspirations of the smoker rather than the cigarette itself, an image created in great part through packaging). (Wakefield et al 2002)

Anti-tobacco lobbyists and legislators have identified the cigarette pack as one of the most effective places to educate people about the health risks of cigarettes, and an increasing number of countries have introduced legislation to regulate cigarette labelling.

One recent study examining industry documents confirmed that package design played a predominant role in the total marketing strategy of cigarettes, and that tobacco companies intentionally use package design to influence consumer perceptions of health risks. The study concluded that:

If packs are effectively acting as advertisements for cigarettes, if their design characteristics make them more attractive to teenage smokers, communicate information about cigarettes that may be misleading (such as implying they are less strong or milder in some way), or minimise the salience of health warnings and contents information, then pack design ought to be subject to regulation. (Wakefield et al 2002)

Package design is most commonly subject to regulation through the mandating of health warnings. Some jurisdictions are now also targeting product descriptors (words such as 'low-tar' and 'light' that may mislead the public about the safety of the enclosed product), and even some tobacco companies are now voluntarily educating their customers about the unreliability of product labelling. Overall package design (colours, labels, etc.) is also being considered as an object of regulation in some jurisdictions.

Some of the legal issues involved in these areas of regulation are very different. Canada has therefore dealt with warnings and prohibition of descriptors under separate legislation to avoid confusion of the legal issues.

### **Justifications and goals for product warning labels**

The tobacco industry has often argued that warning labels do not in fact reduce the number of people who smoke. In response, advocates point out that warning labels have never been presented as the only strategy for reducing the number of smokers (other strategies include comprehensive legislation, taxation, and health education initiatives), and that their primary goal is to educate the consumer in the interest of 'informed choice.' However, studies have also shown that the labels do have a direct impact on smoking behaviours.

In 1998, the Ministry of Health concluded, following consultation with the New Zealand tobacco industry, that there was sufficient evidence, despite industry opposition and criticism, that strengthening health warnings and consumer information on tobacco packaging would better inform and educate people about the health hazards associated with smoking. It was also concluded that stronger

warning and health information would also be likely to influence people's attitudes and beliefs about smoking (the first steps towards behavioural change).<sup>36</sup>

The Ministry also concluded that,

- significant public health benefits would arise and outweigh the likely compliance costs to industry (estimated at that time as \$5.7 million)
- the requirements did not constitute expropriation of industry trademarks—just an encumbrance on their use, not significant enough to warrant compensation
- the impact of the regulations on the company's freedom of expression would be limited (as they were simply being asked to inform consumers of the health effects of consuming their products).<sup>37</sup>

The warnings were introduced in the 1999 regulations, coming into force from January 2000.

The Framework Convention on Tobacco Control now provides support for the introduction of graphic product warning labels of 50 percent or more of the principal display areas (see below for further discussion).

## 6.2 INTERNATIONAL MOVES

### *Canada*

From 1997 the Tobacco Act granted the Federal Government the right to:

- ban most tobacco advertising and promotion
- mandate effective warnings
- regulate the manufacturing of tobacco products
- require the industry to report to government on key aspects of its business.<sup>38</sup>

In 2000 the requirements for health warnings were changed. The previous law (passed in 1994) had required 35 percent of the surface display of cigarette packs to display print warnings. The new laws require the following:<sup>39</sup>

<sup>36</sup> Personal recollection (Matthew Allen)

<sup>37</sup> Personal recollection (Matthew Allen)

<sup>38</sup> 'Canada's New Tobacco Warnings,' a July 2000 update on the cover article in *Tobacco Control* Winter 1999, Vol 8, No

4.

<sup>39</sup> Information release from Health Canada, June 2000.

### *Health warning messages*

- Fifty percent of the principal display surface of smokeable tobacco products (except for cigars and bidis) must contain colour warnings with graphic illustrations and text.
- For most products there is a range of 16 health warning messages.
- For pipe tobacco and cigars, there are four health warning messages.
- In the case of chewing tobacco, snuff and bidis, manufacturers and importers are required to display four equally distributed text-only health warning messages.

### *Health information messages*

- Every manufacturer or importer must also display, equally among brands, 16 additional health information messages. These messages give detail about the health effects of tobacco, and are displayed on various parts of the pack, or on cards inserted into the packs.

### *Toxic Emissions/Constituents*

- Information about the toxic chemicals found in tobacco smoke (tar, nicotine, carbon monoxide, benzene, hydrogen cyanide and formaldehyde) must be displayed on the side of the packages of smokeable tobacco products.
- Information about nicotine, lead, and nitrosamines must be displayed on the bottom of the packages of smokeless tobacco products.

### *Cessation messages*

- The regulations also call for nine rotating cessation messages with cessation tips and a web-site address for further information.<sup>40</sup>

The Canadian regulations have been challenged by the tobacco industry in the Superior Court of Canada on the grounds that they are *ultra vires*, constitute an illegal expropriation of the cigarette package, and infringe on freedom of expression.<sup>41</sup> A judgement delivered on 13 December 2002 confirmed the regulations.<sup>41</sup> It is likely that the tobacco industry will appeal against the judgement.

A copy of the Canadian health warnings is attached in Appendix B.

<sup>40</sup> 'Canada's New Tobacco Warnings,' a July 2000 update on the cover article in *Tobacco Control* Winter 1999, Vol 8, No 4.

<sup>41</sup> <http://www.jugements.qc.ca/tabac-en.doc>.

## **Australia**

Current Australian health warnings (upon which New Zealand's are modelled) were introduced in 1994 in the Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 1994, made under the Trade Practices Act 1974. From January 1995, tobacco products were required to display:

- one of six rotating health warnings printed in black on a white background occupying the top 25 percent of the front of the pack
- detailed health information explaining and clarifying the warning on the front of the pack printed in black on a white background occupying the top 33 percent of the back of the pack
- information about the tar, nicotine and carbon monoxide content of cigarettes (specifically the average yield of these substances and an explanation of their health effects) printed in black on a white background and occupying one side of the pack. (Testing methods for determining these contents are specified in the regulations)
- a national information line number providing recorded information about the health effects of tobacco consumption to be printed on the back of the pack.

Australia is currently reviewing its existing health warnings. A discussion paper has been released, canvassing various options for new warnings, including pictorial warnings based on the European and Canadian experience.<sup>42</sup> The discussion paper drew on research findings that the current health warnings needed updating to include more information on the health effects of tobacco. The deadline for comments on the discussion paper was 6 July 2002.

## **European Union**

Under Council Directive 2001/37/EC, Member States of the European Union were obliged to adopt the following requirements for health warnings by 30 September 2002:

- Each pack must have two health warnings (as at present): a general warning and one from a list of additional warnings which must be used in rotation
- The size of the warnings will increase from four to six percent (as at present) to 30 percent for the general warning and 40 percent for the additional warning with an added 3 to 4mm border
- Colours for text and background, text font and size are specified to prevent the warning from fading into the package background
- Tar, nicotine and CO yields must be printed on one side of the packet, taking up 10 percent of the surface area.

<sup>42</sup> <http://www.health.gov.au/pubhlth/publicat/document/tobacco.pdf>.

The European Commission is required to adopt rules for the use of colour graphics by 31 December 2002.

On 10 September 2002, EC Advocate General Geelhoed issued an opinion stating that EU authorities were within their rights to set new limits on toxic ingredients and to oblige manufacturers to place larger and more graphic health warnings on all tobacco packages.<sup>43</sup> More recently, on 11 December 2002 the European Court of Justice upheld this opinion.<sup>44</sup> The Court concluded that the EC directive implementing new tobacco labelling requirements were proportionate, and did not intolerably interfere with the use of trademarks. The Court commented:

As regards Article 5 of the Directive, the obligation to show information on cigarette packets as to the tar, nicotine and carbon monoxide levels and to print on the unit packets of tobacco products warnings concerning the risks to health posed by those products are appropriate measures for attaining a high level of health protection when the barriers raised by national laws on labelling are removed. Those obligations in fact constitute a recognised means of encouraging consumers to reduce their consumption of tobacco products or of guiding them towards such of those products as pose less risk to health ... Accordingly, by requiring in Article 5 of the Directive an increase in the percentage of the surface area on certain sides of the unit packet of tobacco products to be given over to those indications and warnings, in a proportion which leaves sufficient space for the manufacturers of those products to be able to affix other material, in particular concerning their trade marks, the Community legislature has not overstepped the bounds of the discretion which it enjoys in this area.<sup>45</sup>

The Court also decided that it was not appropriate for the Court to consider the validity of the Directive in light of Article 20 of the TRIPs Agreement.<sup>46</sup>

### **Belgium**

Following EU directive 2001/37/EC, a Royal Decree published on 31 May 2002, stipulated that cigarette warnings in Belgium (a country with three official languages) should take up 35 percent of one side and 50 percent of the other side. The warnings must be surrounded by a black border of 3mm, which increases the size of the warnings to 46 percent of the surface on one side and 62 percent on the other. (In Sweden, Philip Morris filed a formal complaint against these regulations, arguing that the black border should be placed within the space allocated for the warnings. Belgium's decision to placed the border

<sup>43</sup> Press release of the Advocate General, No 70/02, 'Opinion of Advocate General Geelhoed in Case C-491/01, *R v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco*, 10 September 2002.

<sup>44</sup> Judgement of the European Court of Justice: Court Case C-491/01. Available at: [http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=\(\)](http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=())

<sup>45</sup> Judgement of the European Court of Justice: Court Case C-491/01. p20. Available at: [http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=\(\)](http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=())

<sup>46</sup> Judgement of the European Court of Justice: Court Case C-491/01. p23. Available at: [http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=\(\)](http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79978789C19010491&doc=T&ouvert=T&seance=ARRET&where=())

outside the 35 percent and 50 percent space is in conformity with guidelines of the EU Commission and legal advice of the Belgian 'Conseil d'Etat'.)

### ***Netherlands***

The Netherlands introduced health warnings in accordance with the EU Directive 2001/37/EC on 1 May 2002.

### ***Brazil***

On February 1, 2002, new legislation came into effect in Brazil requiring large warning messages. There are nine mandated health messages. The must take up one full side of the package, on a rotating basis. The messages include graphic colour photos illustrating the message and a toll free number that smokers can call for help to quit smoking (PAHO 2002). A copy of these warnings is attached as Appendix C.

### ***Bangladesh***

*Work for Bangladesh*, a non-government organisation, is currently advocating for pictorial health warnings. A pamphlet outlining their proposals is attached in Appendix C.

### ***Poland***

In November 1995, the Polish Parliament passed the *Law on the Protection of Public Health Against the Effects of Tobacco Use*. Article 9 of that legislation stipulates that cigarette packages must have two different warnings covering at least 30 percent of each of the largest sides, and information about the levels of tar and nicotine of cigarettes. Article 10 stipulates that the Ministry of Health and Social Welfare will issue ordinances determining the content, design and ways of placing health messages, as well as permissible levels of harmful substances in tobacco products, and the testing methods to be used in determining these levels.

### ***Singapore***

It has recently been reported that Singapore is to introduce large pictorial health warnings, and will require minimum pack sizes of 20 sticks.<sup>47</sup>

## **Framework Convention on Tobacco Control**

In March 2003, negotiations were concluded on the Framework Convention on Tobacco Control. New Zealand, along with a number of other countries, has

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<sup>47</sup> <http://straitstimes.asia1.com.sg/opinion/story/0,1870,141422,00.html>.

already become a signatory to the Convention. The Convention contains the following requirements relating to product health warnings (in summary):

- All tobacco products would need to carry health warnings describing the harmful effects of tobacco use and other appropriate messages.
- The warnings will be rotating.
- The warnings will be approved by the national competent authority.
- Warnings must take up not less than 30 percent, and should take up 50 percent or more of the principal display areas.
- Warnings may be in the form of or include pictures or pictograms.
- Warnings must be in the principal language or languages of the State party.

### **Regulation of stickers or covers**

After the introduction of strong or graphic health warnings on cigarette packs, some countries have experienced a trade in packaging products designed to replace or alter the cigarette pack. These products include stickers that fit over health warnings, but carry messages unrelated to the health risks of tobacco use. Other products include covers that can be slid over a package of cigarettes to hide health warnings, and which carry messages or images aimed at the youth market instead.<sup>48</sup>

## **6.3 CURRENT NEW ZEALAND SITUATION**

Section 32 of the Smoke-free Environments Act 1990 states that no manufacturer, importer, distributor or retailer may sell or offer for sale any tobacco product that does not carry required health warnings and information. These are detailed in the Smoke-free Environments Regulations 1999. The current regulations require:

- A health warning taking up 25 percent of the front of tobacco packets
- A health message taking up 33 percent of the rear of the packet
- Information on harmful constituents taking up one side of packet (manufactured cigarettes only).<sup>49</sup>

All information must be in black writing in a white box with a black border. A health message in te reo Maori must also be displayed, as must the free phone number of the Quitline.

There are also regulation-making powers for requiring tobacco companies to include a leaflet on the health effects of tobacco products inside the tobacco packet. No such regulations have been made to date.

<sup>48</sup> "Shocking' cigarette package covers make smoking cool to youngsters say critics,' Camille Bains, Canadian Press article, 13 August 2002.

<sup>49</sup> Note: the Smoke-free Environments Regulations 1999 have identified tar, nicotine and carbon monoxide as being 'harmful constituents' for the purposes of s32.

The Smoke-free Environments (Enhanced Protection) Amendment Bill (as reported back from the Health Committee) would add the following provisions:

- Clarification of the power for regulations to be made requiring tobacco products to carry pictorial health warnings relating to health effects of their use.
- An ability for regulations to be made to require leaflets to be included inside tobacco packets, not just containing information on the health effects of the product on health, but also:
  - a list of harmful constituents and their respective quantities present in the product
  - a list of additives and their respective quantities present in the product
  - a list of the harmful constituents and their respective quantities, present in the smoke.

The Bill also states that in relation to leaflets on health effects, these can be based on the health effects of the tobacco class the product belongs to (for example, manufactured cigarettes, roll-your-own tobacco, cigars, etc); the brand; or the brand variant – depending on what is required by regulations.

The Bill provides for regulations to be made requiring a similar range of health warnings and consumer information to be displayed on the packaging of herbal smoking products, and for leaflets inside products, as required for tobacco products.

Breach of section 32 of the Act carries a maximum fine of \$10,000 for a manufacturer, importer or distributor, or \$4,000 for a retailer. The same maximum penalties would apply with respect to a breach of new section 32AA.

## **6.4 EVALUATION OF HEALTH WARNINGS**

A 1999 study in Canada examined the impact of the 1994 text only warnings on encouraging teen and adult smokers to stop smoking, and on encouraging non-smoking teens not to start smoking. The study produced the following results:

- Larger warning messages were more encouraging to stop/not start smoking for almost all sample groups
- Messages with strong emotional appeal were more encouraging to stop/not start smoking than messages of a factual or unemotional nature
- Warning messages that included pictures were on average 60 times more encouraging to stop/not start smoking than messages without pictures
- For 95 percent of smokers and 80 percent of non-smokers, the ability to quickly recognize brands would not be affected by increasing the warning message to 60 percent of the surface display of the package. (Liefeld 1999)

These results were confirmed by subsequent Health Canada research, which found that that graphic warnings were more noticeable and that the larger the health warning message, the more effective it is at encouraging smokers to stop smoking. Most smokers who expressed an increased interest in quitting smoking agreed that warning messages have contributed to this desire, and about half of those smokers who had attempted to quit or reduce smoking felt that cigarette package warning had contributed to these behaviours.<sup>50</sup>

Health Canada commissioned a series of surveys in late 2000 to establish baseline data in relation to the new pictorial warnings before they began appearing in the market.<sup>51</sup> In September/October 2001, an evaluation measured the effect of the new health warnings against the baseline. The evaluation showed that the new warnings.<sup>52</sup>

- Increased the motivation of 44 percent of smokers to quit
- Increased knowledge about the health effects of smoking by 35 percent
- Made smokers and non-smokers think more about the health effects of smoking (58 and 47 percent, respectively)
- Encouraged people to smoke less, particularly indoors
- Had an effect on rates of smokers attempting to quit
- Made non-smokers feel better about being non-smokers.

It has been suggested that people have been slower to take up knowledge about the warnings because there are 16 of them in total. A smaller number could prove less confusing and have a more immediate effect on knowledge about the health effects of smoking.<sup>53</sup>

### **Benefit/cost analysis for new Canadian warnings**

In June 2000, Hara Associates conducted a 'regulatory impact analysis report' of the proposed new warnings.<sup>54</sup> The study estimated that the proposed stronger health warnings would reduce tobacco use by 3.4 percent within a ten year period.

Benefits of the new health warnings examined included:

- premature deaths avoided
- reduced cost to the health care system
- improved employee productivity.

<sup>50</sup> 'Testing New Health Warning Messages for Cigarette Packages: A Summary of Three Phases of Focus Group Research'

<sup>51</sup> 'Baseline Surveys: The Health Effects of Tobacco and Health Warning Messages on Cigarette Package' (Final Report). Environics. February 2001.

<sup>52</sup> 'Evaluation of New Warnings on Cigarette Packages—Highlights' Canadian Cancer Society, January 9, 2002.

<sup>53</sup> Murray Kaiserman (Health Canada), presentation to Ministry of Health, 2 December 2002.

<sup>54</sup> 'Benefit/Cost Analysis of Proposed Tobacco Products Information Regulations'. Prepared by Hara Associates, Inc., June 2000.

Costs of the new health warnings examined included:

- compliance costs imposed on the industry
- government administrative costs.

The best estimate of the net present value of the proposed regulations was very high at \$33 billion (CAN\$33,341 million for benefits, vs CAN\$310 million for costs). The study concluded that ‘the assurance is very high that the proposed Tobacco Products Information Regulations are of positive and significant value to Canada.’<sup>55</sup>

### ***Evaluation of 1995 Australian tobacco health warnings***

Early studies (1995) showed that the new Australian text-based health warnings were more effective than the previous ones at stimulating both thoughts about the negative effects of smoking, and the consequent action of not smoking the cigarette. One study concluded that the new warnings were an important improvement over previous ones because they had increased people’s knowledge about the health risks associated with smoking. The study confirmed high levels of awareness and recall of the new warnings; the increased size of the warnings was the most prominent element mentioned, and the messages ‘Smoking in Pregnancy Harms Your Baby’ and ‘Smoking Kills’ were the most frequently recalled messages. However, the study showed that many smokers still lacked even a basic understanding of the major constituents of tobacco smoke and their health implications, despite having increased information on the packages (Borland and Hill 1997).

A 1996 evaluation of the health warning messages on tobacco products and the tobacco information line showed the following:

- 60 percent of smokers believed that the health warnings and health information on tobacco packs had improved their knowledge of the health effects of tobacco consumption
- over 50 percent of smokers thought that the health warnings had raised their concerns about smoking
- 78 percent believed that the warnings had some effect on their behaviour
- 33 percent of smokers believed that the warnings had helped them smoke less
- 45 percent of recent ex-smokers believed that the warnings had helped them give up smoking
- 33 percent of smokers felt that the health messages had made them think about the health effects when they bought cigarettes.<sup>56</sup>

<sup>55</sup> ‘Benefit/Cost Analysis of Proposed Tobacco Products Information Regulations’. Prepared by Hara Associates, Inc., June 2000.

<sup>56</sup> ‘Review of Health Warnings on Tobacco Products in Australia’. Discussion Paper. April 2001, 11.

A subsequent (2000) assessment of the Australian warnings found the following:

- The rating of the importance of health warnings was slightly higher in 2000 (71 percent) than that reported in 1996 (67 percent)
- There was no significant change in the general awareness of health information on the front, back and side panels; or in the claimed reading levels of the information; or in the general recall of warning messages
- There was a substantive improvement in awareness of the tar, nicotine, and carbon monoxide content of cigarettes, and in the potentially damaging effects to health of these ingredients.<sup>57</sup>

Despite a high level of general awareness of the warnings, there was 'virtually universal agreement' in the discussion groups that the labels have become less noticeable with the passage of time, and that the information they carry is now taken for granted. They also expressed the belief that pack design innovations have successfully competed with health warnings for consumer attention.<sup>58</sup>

### ***Evaluation of new Dutch tobacco health warnings***

The Netherlands was the first EU country to introduce large health warnings in accordance with EU requirements. Since introducing the warnings, there have been two Dutch studies into the warnings. Early reports about the studies indicate the following findings:

- There is a strong suggestion that smokers who intend to quit smoking somewhere in the future are very much affected by the new messages, and are more motivated to quit because of the warnings
- Few adolescents think the new warnings are 'cool'.

The reports are not yet translated into English.<sup>59</sup>

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<sup>57</sup> 'Evaluation of the Health Warnings and Explanatory Health Messages on Tobacco Products': Executive Summary. October 2000, p. 9.

<sup>58</sup> 'Evaluation of the Health Warnings and Explanatory Health Messages on Tobacco Products': Executive Summary. October 2000, p. 6.

<sup>59</sup> See <http://www.stivoro.nl>.

## 6.5 DISCUSSION OF POLICY OPTIONS

There is a considerable groundswell of international opinion supporting bold, graphic tobacco warnings modelled on the Canadian and Brazilian warnings. Australia is investigating whether to move towards such warnings. Recent Canadian research shows that the warnings do have an effect on the motivation of smokers to quit, and the motivation of non-smokers to initiate smoking.

Article 11 of the Framework Convention on Tobacco Control now provides clear international support for the introduction of large pictorial health warnings on packets of tobacco products. Once New Zealand ratifies the Convention, it would be expected to introduce requirements that comply with the Convention within three years of entry into force of the Convention.

If policy-makers decide to pursue this option further, it will be necessary to bear in mind the Government's obligations under various international agreements and the New Zealand Bill of Rights Act 1990. These obligations generally require the Government to refrain from regulatory activity that restricts a right unless the Government can show that the restriction is necessary to achieve a justified policy goal. Under the Framework Convention, there is broad scope for the size, nature and wording of warnings on packages of tobacco products, which means that regulation requirements that are greater than the minimum will need to be clearly justified.

However, it is noteworthy that other governments have considered these issues prior to the Framework Convention and resolved that according to their domestic constitutions and international obligations, and based on demonstrable need and assessment of evidence, that large pictorial warnings are justified. Canadian precedents will be most helpful in this regard because of the similarities between the Canadian Charter of Rights of Freedoms and the New Zealand Bill of Rights Act 1990. Research in Canada showed that after a period of time, text only health warnings became less effective. In addition, the early results of ongoing Canadian research are beginning to show public health benefits from the new graphic warnings. Most recently, the European Union Court of Justice decision discussed in section 6.2 of this report found that European move to bring in strong warnings was justified.

Significant work was undertaken by the Ministry before the current warnings were implemented in 1999 regulations. In order to meet requirements under GATT, TRIPS and the New Zealand Bill of Rights Act 1990, the Ministry undertook extensive consultation with the public and the tobacco industry. Research was also commissioned to ensure that there was a strong evidentiary foundation for regulatory activity.

A further option worthy of consideration is whether warnings that are not only about the physiological effects of tobacco smoke might also be effective in

persuading smokers to quit or people to not start smoking. Examples of warnings could include messages of a social nature – for example, a message based on the recent ‘It’s about whanau’ campaign, or messages about the economic toll of smoking on smokers.

If New Zealand should consider introducing pictorial health warnings it will be important to carry out an assessment of which future warnings would be most effective and appropriate for a New Zealand audience. In particular, messages that target at-risk groups, are culturally appropriate, that confront knowledge gaps, and that are likely to spark positive attitudinal responses among both smokers and non-smokers are the key.

## 7.0 REGULATION OF PRODUCT DESCRIPTORS

Previously confidential tobacco industry documents show that ‘light’ and ‘ultra light’ cigarettes were introduced to the market in the 1950s and 1960s to provide an alternative to cessation for smokers who were concerned about their health (Kozlowski and Pillitteri 2001). However, there is no conclusive evidence of any important health benefit from smoking ‘low-yield’ cigarettes. In fact, early attempts to market cigarettes as ‘low-tar’ in the United States were stopped by the FTC because the terminology could mislead consumers into believing that one type of cigarette was less harmful than another. The FTC required cigarette companies wishing to use product descriptors such as ‘low-tar’ to show scientific proof of a difference in nicotine and tar levels. As a result, the industry adopted a wide range of testing methodologies, adapted to its own ends, and embarked on a notorious ‘tar derby’, making claims about cigarettes based on the inconsistent methodologies. In the late 1950s, the US House of Representative and the FTC both investigated product descriptors, and the FTC moved to ban all references to tar and nicotine on the grounds that, without a uniform testing methodology, they represented misleading health claims.<sup>60</sup>

A uniform methodology was developed in the mid-1960s, when the FTC decided to allow tar and nicotine levels on cigarettes in order to inform consumers about the health consequences of smoking. The FTC developed a methodology involving machine-measuring of nicotine and tar that does not reflect the actual behaviour of smokers. Descriptors such as ‘low-tar’ are today based on the results of tests under this methodology.

The descriptors ‘light’ and ‘ultra-light’ appear to have a minimal relation to the nicotine content of tobacco, and instead may describe the amount of filter ventilation in a cigarette. The Massachusetts Department of Public Health has found that there is an extremely high correlation between percent of filter ventilation and type of cigarette. Full-flavour brands have minimal ventilation, while ultra-light brands have ventilation of more than 50 percent. Furthermore, when 50 percent of the ventilation holes are blocked, ‘light’ and ‘ultra-light’ cigarettes all tested for moderate or high levels of nicotine, and further tests revealed no significant differences in the total nicotine content of whole tobacco in full flavour, light and ultra light cigarettes. This suggests that the descriptors ‘light’ and ‘ultra-light’ are determined by the amount of filter ventilation rather than the nicotine content of the tobacco.<sup>61</sup>

Filter vents are commonly blocked by smokers, who may also take stronger and more frequent puffs than provided for in the standard FTC/ISO methodologies in order to obtain higher levels of nicotine. As this smoker compensation may negate any reduction in tar and nicotine in ‘low-yield’ cigarettes, terms such as ‘light’ or ‘mild’ are widely considered to be misleading, and there are concerns

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<sup>60</sup> Statement of undisputed fact, *Miles v Philip Morris*, <http://pdfserver.amlaw.com/nli/factappendix.pdf>.

<sup>61</sup> 1997 Cigarette Nicotine Disclosure Report, Massachusetts Department of Public Health. Available at [www.cancer.org](http://www.cancer.org).

that the use of these terms may have delayed the cessation of potential quitters, or even encouraged non-smokers to initiate smoking. A survey of smokers in the USA revealed that many smokers of 'light' and 'ultra light' cigarettes believed that they were receiving health benefits because they thought their cigarettes were less harsh, and believed they delivered less tar, than regular cigarettes (Shiffman, Pillitteri et al 2001). A number of prospective, cross-sectional and retrospective studies have shown that smokers of 'low-yield' cigarettes are less likely to attempt cessation than smokers of regular cigarettes. There have been questions about whether this is because 'low-yield' smokers are more complacent about the harms of smoking, or because they have chosen to smoke 'low-yield' cigarettes because they think their chances of quitting are small. However, recent experimental studies have shown that more 'low-yield' smokers are likely to quit if they are aware that 'low-yield' cigarettes carry no health benefits (Hughes 2001).

## 7.1 INTERNATIONAL DEVELOPMENTS

Some jurisdictions have moved to ban or limit the use of descriptors such as 'light' or 'mild', as described below.

### European Union Directive

Article 7 of the European Council Directive 2001/37/EC will ban from the packaging of tobacco products, any 'texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others'. This restriction comes into force on 30 September 2003.

Two tobacco companies challenged the intention or obligation of the United Kingdom to transpose the Directive into national law. The UK High Court sought a ruling from the European Court of Justice on the validity of the Directive. The Advocate General of the European Community has recently found that a ban on product descriptors is justified, because it 'applies to a limited number of common designations which may cause confusion among consumers, particularly in regard to the harmfulness of the product.' The Advocate General attached relevance to the serious doubt as to whether a change to 'low-yield' cigarettes would be beneficial in health terms.<sup>62</sup>

More recently, the European Court of Justice has found similarly. The Court commented, with respect to the issue of misleading descriptors that:

As the Advocate General has pointed out ... those descriptors are liable to mislead consumers. In the first place, they might, like the word 'mild', for example, indicate a sensation of taste, without any connection with the product's level of noxious

<sup>62</sup> Press release of the Advocate General, No 70/02, 'Opinion of Advocate General Geelhoed in Case C-491/01, *R v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco*, 10 September 2002.

substances. In the second place, terms such as 'low-tar', 'light', 'ultra-light', do not, in the absence of rules governing the use of those terms, refer to specific quantitative limits. In the third place, even if the product in question is lower in tar, nicotine and carbon monoxide than other products, the fact remains that the amount of those substances actually inhaled by consumers depends on their manner of smoking and that the product may contain other harmful substances. In the fourth place, the use of descriptions which suggest that consumption of a certain tobacco product is beneficial to health, compared with other tobacco products, is liable to encourage smoking ... Furthermore, it was possible for the Community legislature to take the view, without going beyond the bounds of the discretion which it enjoys in this area, that the prohibition laid down ... was necessary in order to ensure that consumers be given objective information concerning the toxicity of tobacco products and that, specifically, there was no alternative measure which could have attained that objective as efficiently while being less restrictive of the rights of the manufacturers of tobacco products ... It follows from the preceding considerations ... that the Directive is not invalid by reason of infringement of the principle of proportionality.

### **Canadian developments**

At the request of the Health Minister, the Canadian Ministerial Advisory Council on Tobacco Control (MAC) convened a panel of experts in August 2001 for a two-day conference on product descriptors. The expert panel reported that:<sup>63</sup>

- There is no convincing evidence of a meaningful health benefit resulting from cigarettes marked as 'light' or 'mild'
- Terms such as 'light' and 'mild' are both false and misleading
- It is specious to equate the usage of these terms on tobacco products with their usage on food, because tobacco products and their use are fundamentally different from food products.

The panel recommended a complete prohibition on descriptors such as 'light' and 'mild', along with a restriction on the usage of other words, colours or devices in package design that result in a false perception of a reduction in health risk or tar/nicotine delivery. The panel also recommended that an education component be included in regulations to correct the persistent misperception caused by these descriptors and associated package designs.

Health Canada is currently considering regulations to prohibit manufacturers and importers from selling a tobacco product in a package displaying the terms 'light' and 'mild.'<sup>64</sup>

Recent Health Canada research indicates that in the absence of product descriptors, consumers are more likely to read information on the pack, such as the list of constituents.<sup>65</sup>

<sup>63</sup> 'Putting an End to Deception: Proceedings of the International Expert Panel on Cigarette Descriptors.' January 2002, I-II.

<sup>64</sup> <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/legislation/index.html>.

## Brazil

On 1 February 2002, new legislation came into effect in Brazil prohibiting descriptors such as 'light,' 'ultra-light' and 'suave', which mislead smokers into believing these products are better for their health.

Reports indicate that in the 12 months between passage of the legislation and implementation, tobacco companies took the opportunity to create different colours on their packaging to differentiate between regular, light and ultra-light cigarettes. They also included an information card in the packs explaining the relationship between pack colour and cigarette (Bialous 2002).

## France

A committee of the French National Assembly has recently passed a law to implement the EU directive and prohibit the use of 'light' or 'légère' on packets of cigarettes, from 30 September 2003. The law will prohibit wording of words, markings or symbols indicating that one tobacco product is less harmful than any other.<sup>66</sup>

## Framework Convention and SACTob

The Framework Convention on Tobacco Control now requires that state parties implement controls on tobacco packaging to ensure that it does not promote a tobacco product by false, misleading or deceptive means. The Convention includes terms such as 'low tar', 'light', 'ultra-light', or 'mild' as examples of terms that *may* create the false impression that some cigarette products are safer than others. SACTob has concluded from the scientific evidence that these terms *should* be banned (SACTob 2002b).

## 7.2 OPTIONS FOR REGULATION OF DESCRIPTORS

There are several policy options for regulating descriptors on 'low-yield' cigarettes:

- Prohibit the use of product descriptors and any other markings that suggest that a tobacco product is less harmful than any other;
- Require inclusion of product warnings specific to 'low-yield' products; or
- Require the use of a more accurate methodology to assess tar and nicotine delivery, and limit use of descriptors to those products that meet certain criteria.

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<sup>65</sup> M. Kaiserman (Health Canada), presentation – Ministry of Health, 2 December 2002.

<sup>66</sup> <http://fr.news.yahoo.com/012028/5/2tnu3.html>.

## **Prohibition of the use of product descriptors**

There are strong public health arguments for prohibiting the use of terminology such as 'light' or 'mild'. There is substantial evidence that the terminology is misleading. Due to both product design and smoker compensation, it is likely that smokers of 'low-yield' cigarettes inhale similar amounts of toxins as smokers of regular cigarettes. Tobacco company documents suggest that terminology such as 'light' or 'mild' has been used with the intention to mislead potential quitters into continuing to smoke (Jarvis and Bates 1999). Studies have shown that smokers are under misapprehensions about the amounts of tar and nicotine obtained from smoking 'low-yield' cigarettes, and many smokers of 'light' and 'ultra light' products have chosen to smoke 'low-yield' cigarettes for perceived health benefits (Kozlowski and Pillitteri 2001).

Tobacco companies give the following reasons for opposing a prohibition on the use of descriptors:<sup>67</sup>

- The terms describe brand styles, taste characteristics, and reported tar and nicotine yields;
- The terms are part of registered trademarks, and a ban on their use would strip trademark holders of their property rights;
- A less restrictive alternative to a ban exists (for example, a communication to consumers explaining that 'low-yield' cigarettes have not been established to be safer than other tobacco products); and
- A ban would constitute a technical barrier to trade, and a breach of international trade obligations.

## **Warnings about the health risks of 'low-yield' products**

Overseas, Phillip Morris has recently begun including inserts in packets of its cigarettes stating that 'low-yield cigarettes are not proven to be safer than full-flavoured cigarettes, and do not make quitting smoking easier.'<sup>68</sup> This move may make it more difficult for regulators to prove that it is necessary to ban the use of descriptors in order to dispel confusion or misunderstandings among smokers.

Research suggests that counter-marketing may dispel beliefs about the health benefits of 'low-yield' cigarettes if the counter-marketing acknowledges that 'low-yield' cigarettes taste lighter than regular cigarettes. There is some research suggesting that counter-marketing that focuses on sensory misperceptions about 'low-yield' cigarettes may encourage smokers of 'low-yield' cigarettes to quit smoking (Kozlowski and Pillitteri 2001; Shiffman, Pillitteri et al 2001).

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<sup>67</sup> Submission by Philip Morris International Inc., in response to The National Center for Standards and Certification Information Foreign Trade Notification No G/TBT/N/CAN/22, January 2002. (Proposed Canadian regulations prohibiting the display of descriptors on cigarette packages.)

<sup>68</sup> <http://www.TobaccoReporter.com>, 20 November 2002.

It would be possible to require the inclusion of product warnings on packets of 'low-yield' cigarettes. However, there would need to be:

- A comprehensive presentation of technical evidence to demonstrate that 'low-yield' products are no less harmful than ordinary tobacco products;
- Demonstration that the New Zealand smoker is misled or confused by such labelling; and
- Redesign of the methodology used to determine yields of toxins to better reflect actual smoker behaviour, so that there is an accurate basis for any mandatory product warnings.

### **Require more accurate methodology**

If it is decided not to pursue the option of prohibiting the use of descriptors such as 'low-tar' or 'low-nicotine', then it would be advisable to ensure that the descriptors are used accurately, by developing a new testing methodology that accounts for compensatory smoking.

Where cigarette brands contain a range of tar and nicotine levels, tobacco companies may seek to differentiate between the brands using labelling such as 'low-tar' or 'low-nicotine' (as distinct from the descriptors 'light' and 'mild', which do not precisely refer to the aspects of cigarettes that they purportedly describe – that is, the nicotine and tar levels). Differentiation would, for example, allow smokers who are attempting to wean themselves off nicotine the option of moving to a low-nicotine brand.

However, the purpose of differential labelling would be defeated if the descriptor did not accurately reflect the tar or nicotine delivery of cigarettes. If descriptors are not prohibited, it would be advisable to require testing of cigarettes according to a methodology that accurately measures the delivery of nicotine and other constituents to the smoker. It would also be advisable to review the use of the term 'tar' in this context, given its vagueness and potential to mislead smokers.

The terms 'light' and 'mild' also refer to sensory perceptions of taste. Research needs to be conducted to assess how these terms are interpreted by smokers. If they are understood as referring to nicotine or tar levels, then there are stronger reasons for regulating them.

## **7.3 CONCLUSIONS**

Many of the cautions that apply to the regulation of health warnings also apply to the use of product descriptors. Moves towards regulation would require New Zealand specific research into tobacco products and public perceptions. There would also have to be thorough policy development to ensure that any regulatory moves were supported by the strongest possible arguments. In particular, given

the fact that regulation of product descriptors would be argued to interfere with property rights in trade marks, any policy intervention would need to be justifiable as both a reasonable and proportionate intervention introduced in order to achieve a necessary public health goal.

The industry's use of voluntary warnings and disclaimers may present challenges for any move towards regulation, because they may tend to undermine the argument of necessity. However, the Framework Convention and the recent SACTob recommendations provide strong international support for the banning of misleading terminology.

## **8.0 TOBACCO PRODUCT DISCLOSURE**

### **8.1 INTRODUCTION**

The term 'tobacco product disclosure' is used to refer to measures taken to provide for the disclosure, to the public and/or the regulator, of the contents of tobacco products (ie: the constituents of tobacco products or the additives added, or both) and the emissions from burning of tobacco.

The rationale for regulators to require such disclosure is two-fold:

- To obtain information that can be used by the regulator to monitor the risks associated with tobacco use and to inform future policy development to reduce hazards experienced by smokers; and
- To provide information that can be shared with the public, directly (via the tobacco packet) or indirectly (via the use in media campaigns, for example) with consumers and the public generally as a way of:
  - Informing consumers of the risk of using tobacco products
  - Encouraging people not to smoke
  - Discouraging people from taking up smoking
  - Meeting accepted obligations to provide factual information to consumers of what is in the products they choose to smoke.

### **8.2 CURRENT NEW ZEALAND SITUATION**

Section 35(1)(a) of the Smoke-free Environments Act 1990 requires manufacturers and importers of tobacco products to file a return with the Director-General of Health on 31 January each year on the:

- Weight of tobacco and of all additives used in the manufacture of each product sold during the previous year;
- Quantity of each brand or brand variant sold during the previous year; and
- Recommended price of each brand and brand variants sold during the previous year.

Section 35(1)(b) requires manufacturers and importers to provide a report of all tests undertaken during the previous year under sections 33 or 34.

Section 35(2) states that any report provided under section 35(1)(b) can be published as the Director-General of Health sees fit. Note: all returns and reports can still be considered for release under the Official Information Act 1982.

Ever since regulations were first made under the power set out in the Smoke-free Environments Act 1990, there has been considerable debate over whether the regulations require disclosure of the additives in each brand of tobacco product. After several years

of discussions with tobacco companies, the Ministry of Health came to an agreement with tobacco companies that they disclose all additives by class of tobacco product (i.e. by cigarettes, cigars, pouch tobacco, etc.), and the maximum amount of each additive present in any brand of each class. The list does not identify brands or tobacco companies, but is an industry-wide list collated from information provided to lawyers in England.

More recently, Philip Morris has provided a return that is more product-specific, listing all additives in each product in descending order of quantity. Some products, such as 'Natural and Artificial Flavours' are grouped generically. This is similar to information provided to Australia under its voluntary agreement with tobacco companies negotiated in December 2000. However, recently obtained documents indicate that Rothmans New Zealand knew in 1993 that their interpretation of the regulatory requirements was untenable and that they could be required under the Smoke-free Environments Regulations 1990 to provide brand-specific disclosure of additives actually present.<sup>69</sup>

A regulation-making power contained in proposed new section 35 of the Smokefree Environments (Enhanced Protection) Amendment Bill, would enable regulations to be made, requiring returns to be supplied by manufacturers or importers of tobacco products that listed the amount of tobacco, and the amount of each additive, used in the manufacture of either:

- Each class of tobacco product; or
- Each brand of each product class; or
- Each brand or brand variant.

The Bill would also amend section 35 to clarify that the Director-General must take all practicable steps to ensure that all returns and reports are publicly available.

Breach of section 35 carries a maximum fine of \$10,000 for manufacturers or importers of tobacco products.

It is unclear whether the current requirements require companies to disclose additives in the filters or paper of manufactured. The Ministry of Health has sought clarification from tobacco companies as to whether their returns include this information, but has not received a response to date except from Philip Morris.

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<sup>69</sup> Fax from PV Lorrigan, Director of Legal 7 Industry Affairs, Rothmans of Pall Mall (NZ) Ltd to Dr D Cooper Rees, RJ Reynolds Tobacco Company, dated 18 November 1993.

## 8.3 INTERNATIONAL MOVES

### Europe

The European Union has issued an important tobacco control measure in the form of Council Directive 2001/37/EC, which regulates tar, nicotine and CO yields of cigarettes, health warnings, ingredients and product descriptors. Article 6 of the Directive obliges Member States to require tobacco manufacturers and importers to submit lists of all ingredients, with their quantities, by brand name and type. The list is to be accompanied by:

- Reasons for the inclusion of the ingredients in the products;
- An indication of the function and category of the ingredients; and
- Available toxicological data of ingredients in burnt or unburnt form, referring in particular to their effects on health, and taking into account, inter alia, any addictive effects.

Information provided by tobacco companies is to be publicly disseminated, with due regard for trade secrecy. The deadline for the first ingredients disclosure is 31 December 2002.<sup>70</sup>

### Canada

In British Columbia, tobacco companies are prohibited from selling new brands of cigarettes unless they have provided the Minister of Health with a report listing the names and quantities of all additives in the cigarettes. Most of the details are published, but there is provision in the regulations for trade secrets to be protected.<sup>71</sup>

Canadian federal regulations made in the past two years implement a range of reporting requirements. The Tobacco Reporting Regulations 2000 require reporting on a wide range of chemical compounds in whole tobacco (unburned), mainstream smoke, and sidestream smoke. There are also requirements to report on papers, tubes and filters. In addition, manufacturers are also required to report on the toxicity and health effects of tobacco products, providing lists of research into product modification and development, ingredients, and taste and flavour of tobacco products. There is no dispensation for low-volume importers and manufacturers.

The regulations were challenged by the tobacco industry in the Superior Court of Quebec. In a judgement delivered on 13 December 2002, the Court dismissed the plaintiffs case.<sup>72</sup> It is likely, however, that the industry will appeal.

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<sup>70</sup> EU Council Directive 2001/37/EC.

<sup>71</sup> Tobacco Testing and Disclosure Regulation (B.C. Reg 282/98)

<sup>72</sup> <http://www.jugements.qc.ca/tabac-en.doc>.

## United States of America

Massachusetts also requires the disclosure of additives in tobacco products ranked in descending order of weight or measure. However, the regulations have been challenged in Federal Court, and are currently enjoined.<sup>73</sup>

## Asia

Thailand has had national reporting requirements for tobacco additives since 1998. The tobacco industry reports to the Thai Ministry of Public Health, but the information is not made public (Fowles and Bates 2000b).

## Australia

In December 2000 the Australian Government negotiated a Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes with BAT, Philip Morris, and Imperial Tobacco. The agreement provides for the disclosure of brand-specific additives, except for:

- Flavourings that give each brand variant its unique characteristics; and
- Processing aids and preservatives that are not significantly present in and do not functionally affect the finished product.

These additives must be disclosed in a composite list of all components added to the tobacco. The tobacco companies also agreed to provide composite lists of all ingredients added to the non-tobacco parts of cigarettes (papers, filters, inks, etc.). The agreement is due to expire in December 2003.<sup>74</sup>

## Framework Convention on Tobacco Control

Article 10 of the Framework Convention provides international support for the requirement to disclose tobacco product ingredients and emissions:

### Article 10

#### Regulation of tobacco product disclosures

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

SACTob has recommended that the emphasis of such requirements should be on testing and disclosure of emissions rather than ingredients (SACTob 2003b)

<sup>73</sup> <http://www.state.ma.us/dph/mtcp/prodreg.htm>.

<sup>74</sup> <http://www.health.gov.au/pubhlth/strateg/drugs/tobacco/agreement.pdf>.

## 8.4 DISCUSSION OF POLICY OPTIONS

Fowles has emphasised the importance of publishing data received from tobacco companies about additives in tobacco products, as such information would advance knowledge about the public health risks of tobacco use. Fowles suggests that the information, especially if published on cigarette and tobacco packs, would inform the choice of consumers and allow for market forces to act on additives (Fowles 2000b). However, given the addictive nature of tobacco, and the high brand loyalty of smokers, it is unclear what effect such information would have on market forces.

Gray casts doubt on the effectiveness of reporting requirements without taking further regulatory action. Sugars may be listed on cigarette packs, but when burned they give rise to carcinogens and nicotine facilitators (Gray 2000).

The following regulatory options have been identified:

- Quantify and report additives that increase addictiveness (specific additives that are known or suspected to increase the bioavailability of nicotine and its related alkaloids, or additives that are addictive in their own right) (Fowles 2001a)
- Quantify and report additives that increase the attractiveness of tobacco smoke (e.g. total sugar and sweetener content, including licorice and sorbitol for each brand) (Fowles 2001a)
- Regular reporting (for each brand) of all additives and ingredients of tobacco, filter and wrappings (Fowles and Bates 2000b; Bates et al 1999)
- Testing and reporting for additives with greatest toxicological risk (Fowles and Bates 2000b)
- Listing of a range of additives on cigarette packs.
- Publication of information about tobacco additives (Fowles 2000b).

Legislation currently before the House (the Smoke-free Environments (Enhanced Protection) Amendment Bill) would clarify regulation-making powers for disclosure and arguably extend those powers beyond what is currently provided for in the 1990 Act. The question is then to what disclosure is necessary and justifiable within (or beyond) the requirements of the Framework Convention on Tobacco Control. Such a question can only be answered after extensive public debate that considers the following issues:

- What does the regulator need to:
  - monitor tobacco consumption, tobacco contents and emissions, additives, health hazards and relative risks of various products, and brands of product;
  - inform policy development, for example, options around product modification, tobacco labelling, and the use of descriptors; and

- Inform and support strategies and initiatives to discourage tobacco smoking by existing and future smokers;
- What does the consumer / the public require in order that they are fully informed about the risks of smoking or using tobacco;
- What issues need to be considered before a government can legitimately take steps to impose requirements on industry to disclose information that they may not wish to disclose. These issues would include the implications of the New Zealand Bill of Rights Act, compliance costs for industry, intellectual property issues, commercial sensitivity (for example relating to brand recipes).

## 9.0 CONCLUSION

Before deciding which strategies discussed in this report should be advanced, it is important that steps first be taken to consider what the Government wishes to achieve in tobacco control over the next ten years. While many of the initiatives discussed in this report have merit, many would be extremely resource intensive to provide the necessary level of justification to resist tobacco industry challenge. Accordingly, they may impact on the ability of government to deliver in other areas of tobacco control that are just as, or even potentially more, important.

It is the view of the author that the Ministry should consider prioritising the options in this report, and discuss this prioritisation with interested parties, including Government, health groups and industry.

It is clear that while there is considerable evidence in support of the introduction of pictorial health warnings, a ban on misleading descriptors and the introduction of a more extensive disclosure regime, the evidence in respect of product modification is often contradictory and lacks the scientific consensus and certainty that is essential if such steps are to be considered. The risks of 'getting it wrong' and legislating for product modification options that ultimately, for whatever reasons, deliver no health gain or even result in greater harm are too high.

Accordingly, the author recommends that the Ministry uses this report as a basis of advice to government and to inform the development of a discussion document to initiate debate over policy options.

It is also recommended that the Ministry actively participate in future international discussions and research on options for product modification. While the risks from unregulated tobacco product modification are great, so too are the potential benefits that could accrue if scientific uncertainty can be reduced. Any steps towards product modification must include active consideration of policy options for limiting the risks of promoting safer products to the extent that quitting smoking is no longer seen as an imperative among smokers, and potential smokers are persuaded that risks have been reduced to a satisfactory level.

## Appendix A

### Tobacco and smoke constituents for which testing is required under Canadian regulations

Ammonia  
1- aminonaphthalene  
2- aminonaphthalene  
3- aminobiphenyl and  
4- aminobiphenyl  
Benzo[a]pyrene  
Formaldehyde  
Acetaldehyde  
Acetone  
Acrolein  
Propionaldehyde  
Crotonaldehyde  
Butyraldehyde  
Hydrogen cyanide  
Mercury  
Lead  
Cadmium  
NO  
NOx  
N-nitrosornicotine  
4-(N-nitrosomethylamino)-1 -(3-pyridyl)-1-butanone  
N-nitrosoanatabine  
N-nitrosoanabasine  
Pyridine  
Quinoline  
Hydroquinone  
Resorcinol  
Cathecol  
Phenol  
m+p - Cresol  
o-Cresol  
Tar  
Nicotine  
1,3 Butadiene  
Isoprene  
Acrylonitrile  
Benzene  
Toluene  
Styrene  
Carbon Monoxide

**Appendix B****Health Canada pictorial warnings**

Not provided for intellectual property ownership reasons – please refer to Health Canada website.

**Appendix C****Brazilian pictorial tobacco warnings**

Not provided for intellectual property ownership reasons.

**Appendix D****Proposed Bangladeshi pictorial warnings**

Not provided for intellectual property ownership reasons.

**Appendix E**

**Novel tobacco packaging in Hong Kong**

Not provided for intellectual property ownership reasons.

## Appendix F

### Recommendations from SACTob, 2002-03

The Scientific Advisory Committee on Tobacco Product Regulation (SACTob) was established by the World Health Organization in 2000. The committee is composed of national and international scientific experts on product regulation, smoking cessation and laboratory analysis. The following recommendations are taken from the publications of SACTob during 2002 and the first half of 2003.

#### *Recommendation on Nicotine and its Regulation in Tobacco and Non-Tobacco Products (2002a)*

1. The present situation in which the most toxic form of nicotine delivery is the least regulated is unacceptable from a public health perspective.
2. Because nicotine appears to be responsible for a small proportion of tobacco-caused diseases relative to other tobacco constituents and emissions, there is considerable scope for developments that reduce the risks experienced by users of tobacco, but without undermining efforts to prevent initiation to tobacco use and promote cessation among established users.
3. In the absence of firm contrary data, those responsible for public policy decisions are justified in using the conservative assumptions that smokers' preferences for a nicotine dose are persistent over time and are not influenced by changes in the product used and that smokers will compensate for reductions in yield to maintain a relatively consistent dose of nicotine.
4. A broad and comprehensive regulatory framework is required to enable policy options for controlling nicotine to move forward in ways that minimise the risks.

#### *Recommendation on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield (2002b)*

1. Tar, nicotine, and CO numerical ratings based upon current ISO/FTC methods and presented on cigarette packages and in advertising as single numerical values are misleading and should not be displayed.
2. All misleading health and exposure claims should be banned.
3. The ban should apply to packaging, brand names, advertising, and other promotional activities.
4. Banned terms should include light, ultra-light, mild and low tar, and may be extended to other misleading terms. The ban should include not only

misleading terms and claims but also names, trademarks, imagery and other means to conveying the impression that the product provides a health benefit.

*Recommendation on Smokeless Tobacco Products (2003a)*

1. Current evidence does not indicate that use of any smokeless tobacco is free of health risks. Therefore, any such health claim is presently untenable and should not be permitted.
2. There is no evidence to recommend that any smokeless tobacco product should be used as part of a harm reduction strategy. Marketing of smokeless tobacco products with harm reduction claims should not be permitted unless validated by an independent regulatory authority on review of evidence to be submitted by the manufacturer.
3. It is recognised that the currently marketed tobacco products have not been subjected to adequate regulatory review prior to introduction. New smokeless tobacco products should be subjected to review based on procedures applicable to other consumer products intended for human consumption.
4. In countries where there is no established use of smokeless tobacco products, the introduction of such products should only be permitted if the manufacturer satisfied the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).
5. In countries where some smokeless tobacco products are in established use, new smokeless tobacco product categories should only be permitted if the manufacturer satisfied the regulatory requirements for the product category under which the smokeless tobacco is sought to be registered (for example, as a food, food supplement, drug, or toiletry and cosmetic).
6. The incorporation of non-tobacco ingredients into smokeless tobacco products may increase the a) appeal of the product by changing the taste, flavour, and ease of use, b) addictiveness, or c) potential for harm independently or by interaction with tobacco. Therefore, such ingredients also need to be regulated.
7. Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim. Each type of claim requires a substantive body of evidence and an independent regulatory body capable of examining the claims to determine whether the claims are valid.

8. Information on potential adverse health effects should be communicated to consumers. For example, health warnings and labelling should reflect the known adverse health effects of the smokeless tobacco product.
9. More research should be undertaken to evaluate nicotine and toxin exposures and health hazards and risks to individuals from use of smokeless tobacco products, as well as to identify population health effects of changing patterns of smokeless tobacco and other tobacco use.

*Recommendation on Tobacco Product Ingredients and Emissions (2003b)*

1. Regulations in terms of setting upper ingredients and emissions limits for toxicants need to be developed for all tobacco products whether they are intended for smoking or non smoking methods of consumption. Variation in the ways in which tobacco products are used needs to be considered in establishing performance standards.
2. For tobacco products intended to be smoked, the manufactured product needs to be differentiated from the product actually intended for consumption which is its emission (“smoke”), and the critical focus of regulation must be on the emissions.
3. Ongoing surveillance and research must be instituted to assess the consequences of regulation on initiation, cessation and health effects in order to modify the regulatory process on a regular basis.
4. With respect to nicotine, it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine per unit (e.g., cigarette) and further study of this issue is required.
5. No health claims can be permitted based on the level of ingredients or emissions or whether the products meet regulatory standards for ingredients and emissions.

*Statement of Principles Guiding the Evaluation of New or Modified Tobacco Products (2003c)*

1. 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.
2. 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 (both by smokers and by non-smokers), toxicity, addiction potential, and disease risk.

3. Regulatory oversight of smokeless tobacco products should also include examination of at least five separate aspects of the new products: physical chemical characteristics of the product uptake of toxicants, toxicity, addiction potential, and disease risk.
4. Claims of reduced exposure or reduced harm should be supported by adequate scientific data provided by the manufacturer who intends to make the claim.
5. 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.
6. No claim should be permitted for any tobacco product unless found to be valid by an independent regulatory body on the basis of adequate scientific data submitted by the manufacturer.
7. Regulatory oversight, including post-market surveillance, is necessary to assess and monitor changes in newly modified tobacco products.
8. Demonstration of reductions in smoke emissions or reduced uptake of toxicants alone is not sufficient to support claims or implications of reduced toxicity or harm.
9. Claims of reductions in smoke emissions or reduced uptake of toxicants need to be examined in post market surveillance to determine what smokers and non smokers actually understand from those messages.
10. Evidence supporting a reduction in carcinogenicity must be interpreted in light of the potential effects of the changes in the product on the other major diseases caused by cigarette smoking.

## Appendix G

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