

DISCUSSION DOCUMENT **and** POLICY/LITERATURE REVIEW

Tobacco Product Regulation and Policy Frameworks



PREPARED BY

Michael Blewden

Gravitas Research and Strategy Limited

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ASH NZ, PO Box 99 126, Newmarket, Auckland, New Zealand
ashnz@ash.org.nz

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EXECUTIVE SUMMARY

Introduction

A review of the national and international literature on tobacco product regulation and consultations with experts and stakeholders in the field were undertaken to examine models or frameworks of regulation that could minimise harm in New Zealand from tobacco and nicotine products. The research examined models or frameworks of regulation that could be feasible and sustainable in New Zealand, and different options for regulation and the organisational type/nature that would be required to implement a regulation framework. The role of Potential Reduced Exposure Products (PREPs) within a tobacco product regulation framework was also explored.

The research presents a wide range of views and perspectives on tobacco product regulation. A lack of empirical evidence in many areas makes it difficult to provide absolute conclusions about future direction; however, a number of key premises and principles that should guide future decisions are identified. Decisions about the future direction of tobacco product regulation in New Zealand will also require further consideration of the information presented in the research and further development of an evidence base, as well as further discussion about the desired goals for tobacco product regulation in New Zealand.

Tobacco Product Regulation

There is consensus amongst experts/stakeholders and the relevant literature that further tobacco product regulation is required. Despite acknowledged and immense harms caused by tobacco, it is widely considered that tobacco products are comparatively under-regulated compared to other consumer products and drugs and that significant deficiencies exist within existing regulatory regimes. Many experts/stakeholders see continuation of the status quo as inexcusable and highly irresponsible. While the literature and experts/stakeholders are cognisant of the challenges to effective regulation, not least the strategies of the tobacco industry, calls are made for more decisive regulatory action, resulting in tighter controls over all aspects of tobacco manufacture and supply.

New Zealand has achieved much in tobacco product regulation and it is now timely to consider future directions. During a time in which the tobacco control community is grappling with complex regulatory issues, there is a common opinion amongst experts/stakeholders that all regulatory options should be seriously examined and considered. Given the stakes, there is a view that the tobacco control community needs to be open-minded about different options for regulation.

What works and is appropriate in one context will not necessarily work and be appropriate in another and decisions about appropriate direction in New Zealand need to be based on careful assessment at both the micro and macro level. This would include assessment of existing regulations and smoking prevalence rates and how these are likely to influence policy outcomes. Need and impact should also be assessed at the ethnic group level, rather than just at the total smoker population level. Analysis at the total population level risks ignoring different smoking histories, realities and behaviour and how such factors may impact on the appropriateness and effectiveness of different regulatory options. For example, macro level approaches risk failing to meet Treaty of Waitangi obligations in terms of Maori access to appropriate health services and the protection of Maori health. What works in the mainstream may also not be appropriate or achieve results in Pacific communities.

The current debate about the possible introduction of snus (an oral, moist smokeless tobacco product) to New Zealand is an example of how this move could impact differently for Maori and non-Maori. Due to the differences in smoking prevalence rates, smoking behaviour, and progress in de-normalising tobacco use amongst both Maori and non-Maori, how snus is received and used in different communities will vary. For example introducing snus into a community where tobacco use continues to be widespread and normalised may simply add to the range of tobacco products available and act to further normalise, rather than de-normalise, tobacco use.

A significant feature of the current regulatory environment is a relative lack of empirical evidence to categorically inform decisions about tobacco product regulation. Decision-making needs to be evidence based and a focused programme of research will be important to advance this. Core questions remain, however, as to how much evidence and how much certainty is required before decisions can be made. Overall, it seems that decisions will be guided by historical lessons; current and emerging new science; and a substantial level of common sense.

While tobacco control experts/stakeholders recognise the need for global co-operation and consistency in tobacco product regulation, there is a feeling that individual countries also need to push ahead with regulatory innovation. This provides the opportunity for advancing understanding about what works, for models of best practice to be established and for other countries to learn from the experience of others.

There is a common view amongst experts/stakeholders that New Zealand provides particular potential as a world leader in tobacco product regulation. A single house of Parliament and ability to implement regulation nationally, a relatively favourable political environment for increased tobacco control and geographical factors limiting the potential for tobacco black markets, are all seen as favourable attributes. Ironically, however, it may be the relative success of the Smoke-free Environment Act (SFE Act), a progressive piece of legislation by world standards, which may constitute a key barrier to further tobacco product regulation. There is a view that given the success of the SFE Act, it may now be difficult to persuade the public and politicians that further regulation of tobacco is required and that a marketing strategy will be required to help build support for such development.

Regulatory Framework

There are calls that any tobacco product regulator and regulatory framework should reflect the uniqueness of tobacco products, particularly the immensity of harms caused when the product is used as intended. A comprehensive regulatory framework, covering all nicotine delivery systems, is commonly advocated. An emerging view advocates that the regulatory framework should recognise and treat combustible and non-combustible tobacco products differently, based on identified differences in resultant harms. Related is the view that the regulation of combustible products should focus on reducing addictiveness and palatability rather than harmfulness. Another view is that regulation should address tobacco-related mortality and nicotine addiction separately. Advocates of this view contend that attention should first be focused on reducing tobacco-related morbidity and mortality, with nicotine addiction addressed subsequently.

This review also identifies a number of core principles to guide decisions about tobacco product regulation in New Zealand. Regulation must:

- exist within the context of a comprehensive tobacco control programme and give priority to public health goals;
- not exist to serve the purposes of the tobacco industry;
- not result in a weakening or diversion of core focus on preventing initiation and providing affordable, accessible and effective cessation services;
- not undermine attempts to de-normalise tobacco use and to increase the cognitive dissonance around smoking through supply side strategies which reduce the accessibility, palatability and affordability of tobacco products.

While it can be tempting to consider that the SFE Act has addressed the advertising of tobacco in New Zealand, it must be remembered that product marketing comprises more than product advertising. There is a common opinion amongst New Zealand key informants that regulation must continue to focus on regulating the 4 P's of the tobacco marketing mix; The 4 P's are product, place, promotion and price. Supply side regulatory strategies such as restricting the way, place and structures through which tobacco is made available are seen as important by some tobacco control leaders. This includes more restricted access to tobacco products, further reductions in point-of-sale display (although this is a move which may be contradictory to current moves to graphic warnings) and examination of the possibility of a tobacco control authority.

However, there is also a view that a product and content lead approach to tobacco regulation, introduced incrementally, will not achieve the scale and speed of reform required for significant public health gains. While an incremental approach is likely to achieve some further reduction in smoking prevalence, there is a view that these approaches alone will not stop people smoking and that they will potentially tie up scarce tobacco control resources and divert attention from other strategies which may enable faster progress towards the end goal. There is also a view that tobacco companies are likely to be more comfortable with a product and content lead approach, particularly as it potentially offers them the chance to stay 'ahead of the game'. This approach may also extend the total timeframe to eventual tobacco elimination. Some New

Zealand experts/stakeholders feel that the country may be quite close to a 'tipping point' in terms of tobacco control and that the feasibility of tobacco control strategies which explicitly seek to eliminate smoked tobacco should not be discounted.

Proponents of structural regulation assert that fundamental changes to core market forces and the systems underpinning the tobacco industry are required if significant public health gains are to be achieved. Suggested strategies include removing the tobacco product marketing function from the tobacco industry or purchasing and operating the tobacco industry to reduce harm to health, with the ultimate goal of putting the industry out of business. These strategies fundamentally assert that as long as tobacco companies are dictated by the profit motive, they will always be motivated to obstruct regulation designed to reduce tobacco-related harm.

While some experts/stakeholders involved in the current research support and agree with the foundation principles driving the ideas of structural regulation, there is less certainty that such reform is feasible, necessary or even likely to be effective in reducing harm.

While this document has discussed product and content regulation and structural regulation separately, an appropriate way forward may be found in an integrated framework which concurrently develops regulation at both levels. An incremental, issue by issue, approach may best allow for the precise identification of need, clear specification of regulatory requirements and the specific monitoring of progress and outcomes. It may also be that it is only through the incremental introduction of ever-increasing controls at the product and content level that sufficient public and political support will be built to enable more substantial structural regulation in the future. Further de-normalisation of tobacco and further reductions in smoking prevalence may also be required before substantial structural reform becomes feasible.

Harm-reduction Approach

The issue of harm-reduction looms large in the tobacco control landscape and must be considered in any decision about future tobacco product regulation. In its broadest context, tobacco harm-reduction refers to the overall goal of minimising tobacco-related disease and death and therefore includes the core strategies of cessation, the prevention of smoking initiation and protection from environmental tobacco smoke. More recently, tobacco harm-reduction refers to the minimisation of the harms and decreasing total morbidity and mortality from tobacco use without completely eliminating tobacco and nicotine use.

Support for tobacco harm-reduction is commonly based on the view that if tobacco products were less toxic, fewer people would die from using them. A failure to provide less toxic alternatives is seen as unethical, particularly if it is assumed that even the most effective treatment or prevention programmes will not reach or be successful for all smokers. With increasing interest in and pressure to develop alternative forms of nicotine delivery, there is a view that a new era of harm-reduction needs to be faced up to whether the tobacco control community likes it or not. Proponents assert that what is critical is

appropriate regulatory control of harm-reduction approaches and that with this there are grounds for cautious optimism that new approaches to harm-reduction might truly reduce harm.

Scepticism and caution about harm-reduction has its roots in the failures of early harm-reduction approaches such as the filter cigarette and 'light and mild' cigarettes. Mistakenly promoted as reducing smokers' health risks, evidence now suggests these products have contributed to far greater harms than would have eventuated in their absence. This concern about tobacco harm-reduction continues today; it will undermine cessation and prevention imperatives. Further, it will play into the hands of the tobacco industry, eager to promote alternative nicotine delivery systems that include tobacco. Another view is that a harm-reduction approach is not required; rather, governments need to fully fund comprehensive tobacco strategies which provide the optimum level of intervention known to be effective in preventing uptake and assisting current smokers to stop.

Potential Role and Place of Potential Reduced-Exposure Products (PREPS)

A harm-reduction approach perhaps has most risks if it is undertaken within a context of accepting smoked tobacco and a long term future for the cigarette. Many doubts are now raised about the efficacy and value of regulating the conventional cigarette content, particularly for reduced-toxicity. Similar doubts are also raised about any PREPs which involve the combustion of tobacco. Tobacco control experts/stakeholders clearly see more potential in focusing product and content level regulation on reducing the addictiveness of cigarettes and to potentiate quitting. Regulation to reduce nicotine content and increased controls over additives are two such strategies currently being debated. While merit can be seen in both strategies, neither is without potential problems and both require further examination and consideration in the New Zealand context.

Any harm-reduction approach which accepts the ongoing use of tobacco and nicotine products will inevitably require regulation, particularly to protect the public health and to ensure that the previous failures of harm-reduction approaches are not repeated. Decisions about whether harm-reduction includes conventional product modification strategies and combustible PREPs or just non-combustible PREPs, will ultimately affect the nature and extent of regulatory control and infrastructure required. It will be critical therefore, that a debate occurs about the future goals and objectives for tobacco regulation and that all tobacco control experts/stakeholders are clear about the vision and overall goal. For example, a highly regulated and advanced regulatory system will be required to manage the many risks associated with conventional product modification strategies and combustible PREPs. This requirement contributes to a view that harm-reduction has a less useful or appropriate application to combustible products. In comparison, a strategy which explicitly seeks to eliminate the use of smoked tobacco may require substantially less regulatory infrastructure.

Numerous concerns about PREPs and a nicotine maintenance approach generally, are identified in the literature and by some tobacco control leaders. The potential for this approach to increase rather than reduce tobacco-related harms is a core concern. Any further examination of the potential role and fit of PREPs within a regulatory framework will need to be undertaken with an understanding of the key debates and concerns.

A key concern is that PREPs are fundamentally based on a false premise; that is, they are required because existing tobacco control strategies are unlikely to alone solve the tobacco problem. PREPs' opponents believe that existing strategies are effective and what is needed is an appropriate level of funding and full commitment to comprehensive tobacco control programmes. Proponents of PREPs believe that this outcome is unlikely and that there will always remain a core of smokers who will not be reached through existing, conventional tobacco control strategies.

The development of PREPs will inevitably require a level of relationship and co-operation between regulators and the tobacco industry. Based on past history, there is a view within public health that such a relationship is not possible. It is also felt that the end goal for the industry will never be consistent with public health goals and that there is a real risk that PREPs will ultimately act to serve the needs and interests of the tobacco industry. However, there is also a view that the tobacco control community risks losing credibility if it fails to be open to approaches that may genuinely reduce harm and lead to real public health gains.

Some consider that PREPs are unproven and that the science required to prove their efficacy and safety is not currently, and may never be available. There are concerns that the science, research and regulatory infrastructure required to evaluate, control and monitor PREPs will be substantial, extremely costly and difficult to achieve as well as cost ineffective in relation to likely public health outcomes. Proponents consider that, guided by best evidence, new research methods and understanding, strict regulatory controls and post-market surveillance, current uncertainty should not inhibit development.

There are concerns that the introduction of PREPs will give mixed messages, undermining fundamental tobacco control objectives such as prevention and cessation. Proponents recognise these risks and recommend that PREPs be introduced only with carefully developed controls and conditions designed to mitigate these.

PREPs may divert resources away from higher priority tobacco control policies and programmes. Proponents emphasise that PREPs must be delivered as part of a comprehensive tobacco control strategy and, in many areas, identify the need for increased funding of conventional strategies such as cessation to complement their introduction.

There is a view that PREPs will perpetuate the continued delivery of nicotine, a known toxin which is addictive. Proponents consider that nicotine per se should not be considered the initial issue of concern; rather, it is the elimination of dirty forms of nicotine delivery that must first be achieved. It is accepted

that effective and competitive alternative forms of nicotine delivery are essential to achieving the first goal. Once mortality and morbidity are effectively reduced, nicotine addiction can then be addressed.

Nicotine Replacement Therapy (NRT), snus and, potentially, pure forms of nicotine, all emerge from the research findings as offering some potential as non-combustible nicotine replacement tools for harm-reduction. These products find favour amongst some experts/stakeholders interviewed; however, this support is by no means absolute nor is endorsement without cautions and concerns. In the New Zealand context, concern about the possible negative impact of snus on Maori is particularly expressed.

This document has not necessarily resolved or drawn conclusions in respect to current debates on PREPs. In most cases, definitive conclusions are difficult, as empirical evidence is lacking. It is clear, however, that there is no alternative but to approach any introduction of PREPs in a highly regulated and controlled way. Allowing an unregulated or market-based approach to this would be potentially disastrous. Insufficient control could lead to the creation of new tobacco markets and demand for new tobacco products with implications for new public health problems.

If PREPs are accepted as a harm-reduction strategy, the potential contradictions between this approach and existing tobacco control goals will need to be carefully managed. A number of key principles are identified as a means to guide this management. In general, PREPs must not undermine comprehensive tobacco control programmes. This would include ensuring that this approach is not interpreted as a signal that the tobacco problem is solved. PREPs should not undermine baseline messages that all tobacco products are unsafe. They should be presented in the context of 'not starting to smoke or quitting smoking, is the best way to protect health'. An ongoing focus on de-normalising tobacco use is essential within any comprehensive strategy and this focus should not be compromised. A harm-reduction approach must not weaken or divert resources from a core focus on preventing smoking initiation and on providing affordable, accessible and effective cessation services. There is a view that any PREP must not increase youth uptake, increase young adult prevalence, decrease quit attempts, lead to increased relapse of former smokers, or lead to wide misuse. There is also a view that PREPs should not be marketed to the general public and should only be made available to existing smokers.

The onus, accountability and cost to demonstrate and then monitor (over the short and long term) the safety and impact of any PREP should, as much as possible, lie with the manufacturer. Any regulatory system will require defined standards of performance, derived through best possible scientific evidence, with these standards needing to be met as a condition of any product introduction.

1. INTRODUCTION

1.1 Background

Action on Smoking and Health (ASH) and the Smokefree Coalition (the ‘sponsors’) contracted Gravitas Research and Strategy Ltd to undertake a discussion document and policy/literature review of tobacco product regulation. The research will provide options for possible frameworks for tobacco product and industry regulation in New Zealand and will enable the sponsors to take an informed position on potential harm-reduction policies and products. It will also assist in identifying future tobacco control legislation.

1.2 Research Aims and Objectives

The key aim of the research is to assist the sponsoring organisations to form an evidence-based position on tobacco product regulation in New Zealand.

Within this overall aim, two key research questions have shaped the focus of the research. These are:

1. What models/frameworks would most effectively minimise harm in New Zealand from tobacco and nicotine products?
2. What models/frameworks are most likely to be feasible and sustainable in New Zealand?

To address the questions above, the research pursued the following key areas of investigation:

1. Existing or proposed models/frameworks for tobacco product regulation (including as appropriate, description of organisational type/nature required for implementation and monitoring).
2. Options for regulation, including strength of evidence and challenges to implementation.
3. The role of potentially harm-reducing products within a tobacco product regulation framework.

1.3 Research Method

The data was collected through two research methods: a review of national and international literature on tobacco product regulation; and key informant interviews with national and international experts and/or stakeholders in tobacco product regulation. Both methods are described in detail below.

1.3.1 Literature Review

A review of the national and international literature on tobacco product regulation was conducted in order to identify recent developments and thinking in the field.

The parameters defining the scope and extent of the review were established as outlined below.

- A primary focus on material published or made available in the last 5 years.
- An international focus primarily on the United Kingdom (UK), Canada, Australia, Sweden, and the United States of America (USA).
- Published articles sourced primarily from three key tobacco journals with these being: *Addiction*; *Tobacco Control*; and *Nicotine and Tobacco Research*. Limited articles were also sourced from *Drug and Alcohol Review*, *The New Zealand Medical Journal* and *Food and Drug Law Supplement*.
- Recognition that relevant material would also be drawn from sources other than academic journals (e.g. Government-commissioned reports, NGO reports and websites, Google scholar).
- Agreed budget to enable approximately 30 articles to be fully reviewed and included in the final report.

The literature search was conducted primarily through databases available through the University of Auckland's Library Electronic Academic Resources Network (LEARN) system. Databases searched included:

- Index New Zealand/ Te Puna
- Expanded Academic
- JSTOR
- MEDLINE
- ProQuest
- PsycINFO
- Social Sciences Index (SSCI).

A series of search terms were constructed to guide the literature search. The search included single and multiple terms or phrase searching of the following key words:

- Tobacco
- Product Regulation
- [Control] Framework/s
- Harm/Harm-reduction/Harm-reduction Approach/es
- Cigarette/s
- Smoke/Smoking/Smoking Behaviour
- Snus/Snuff/PREPs.

A total of 72 articles and reports were identified through the completed search. Material for full review and inclusion in the final review was then selected using a framework developed with reference to the research aims and agreed search parameters. Full abstracts of all literature search results were reviewed with reference to research questions. Selected material was then reviewed and reported using an analytical framework designed to ensure address of the key research questions and to ensure that an evaluative and interpretative analysis of the material reviewed was undertaken.

1.3.2 Key Informant Consultation

A total of 17 interviews were undertaken with national and international experts and stakeholders in the area of tobacco product regulation. Participants were selected from a list of key informants provided to the researchers by the research sponsors. While all originally identified key informants agreed to participate, interviews were unable to be finalised with two of them. A number of further informants were then identified by the research sponsors as possible informants; the final group of participants is listed below.

New Zealand

- Murray Laugesen, *Public Health Physician*
- Ashley Bloomfield, *Ministry of Health*
- Marewa Glover, *University of Auckland*
- George Thomson, *Wellington School of Medicine*
- Alistair Woodward, *University of Auckland*
- Iain Potter, *Health Sponsorship Council (HSC)*
- Debbie Ryan, *Ministry of Health*
- Helen Glasgow, *Quit Group*

International

- Michael Cummings, *Tobacco Control Researcher, USA*
- Matthew Myers, *President, Campaign for Tobacco-Free Kids, USA*
- Denis Choiniere, Murray Kaiserman and Byron Rodgers, *Health Canada*
- Cynthia Callard and Neil Collishaw, *Physicians for a Smoke-free Canada, Canada*
- Karl Fagerstrom, *Tobacco Control Researcher, Sweden*
- Deborah Arnott, *Director, Action on Smoking and Health, UK*
- Luk Joossens, *European Cancer Leagues, Belgium*
- Ron Borland, *Tobacco Control Researcher, Australia*
- Jonathan Liberman, *Tobacco Control Researcher and Legal Advisor, Australia*

All participants were initially sent a letter of introduction about the research from the research sponsor. This was followed up by a letter from the research team (See Appendix One), providing further information about the research and inviting participation in an interview. All interested and consenting key informants were then further followed up by email and telephone to determine an appropriate time for the interview.

Interviewing took place between 4 April and 7 June, 2006. All interviews were conducted using a semi-structured interview guide (See Appendix Two). Two interviews were conducted face-to-face with all other interviews conducted by telephone. Interviews took on average one to one-and-a-half hours and each was audio-taped to assist later data analysis and reporting.

Key findings, including selected verbatim quotes, were written up for each interview using a pre-determined analysis framework. Each participant was emailed a copy of their key finding report and asked to review and approve the document. Participants were also asked to approve identified verbatim quotes

for possible use in the report and consent to be identified in the final report as a participant in the research. All edits and other feedback received were integrated back into the key finding reports before this material was incorporated into final reporting.

1.4 Report Overview

The report begins with an introduction to tobacco product regulation and considers current thinking in relation to the need for further regulatory control of tobacco products and the tobacco industry. Current New Zealand tobacco regulation is described to provide context for the research findings.

Foundation principles for the development of tobacco product regulation are then discussed, including macro level considerations for the development of a tobacco regulatory framework.

Regulatory options at the tobacco product level are then considered in detail, with this discussion focusing on three key areas of current debate: regulation to reduce toxicity; regulation of additives; and regulation to reduce nicotine content.

The next section defines Potential Reduced-Exposure Products (PREPs) and considers their potential role and place within an overall tobacco regulatory framework. Two PREPs, Swedish snus and Nicotine Replacement Therapy (NRT) are examined in depth and consideration given to possible direction and options for PREPs in the New Zealand context.

The potential of structural regulation, which aims to achieve greater control over the systems and structures which underpin the tobacco industry, is then considered.

The final section of the report considers the organisational type that may be required to implement an overall tobacco regulatory framework. This includes discussion of the research, monitoring and evaluation systems identified as being required to support an effective regulatory framework.

Each section integrates the literature findings with relevant findings from the key informant consultation. Key issues in the New Zealand context are also considered in each section where possible. Direct quotes from the key informant interviews are used throughout the report to illustrate and provide depth to key points made.

2. TOBACCO PRODUCT REGULATION

2.1 The Need for Tobacco Product Regulation

Historically, tobacco control has used regulatory measures to try and reduce the harm associated with the use of tobacco products. Restrictions of tobacco promotion, health warnings, bans on sales to children and smoke-free environment policies can all be seen as examples of regulatory control (Lieberman, 2003). There is, however, increasing awareness that current regulations are severely deficient, that the tobacco industry should not be afforded any special regulatory concessions, and that tobacco products should come under the same type of regulatory control as faced by other drugs and consumer products (Borland, 2003; Liberman, 2003; Royal College of Physicians of London, 2002; WHO, 2001; Siem, 2000; Bates et al, 1999; Slade & Henningfield, 1998). National and international tobacco control experts and stakeholders interviewed in this study (hereafter referred to as 'key informants') agree that current regulatory approaches to tobacco control are inadequate for achieving effective regulation to reduce harm. They also agree that further regulatory development is necessary to address the errors of history, to ensure the tobacco industry no longer evades effective regulation and to ensure a level of regulatory control appropriate to the harms caused by tobacco.

Lieberman (2003) points out the extreme irony that the tobacco industry currently operates under conditions where (subject to some regulatory restrictions), increased sales result not only in higher levels of addiction and death but in increased profitability. He strongly advocates for more extensive regulatory control of tobacco, particularly that which focuses on the industry as a whole and within areas such as product composition, manufacture, promotion and distribution. The World Health Organization (2001) describes cigarettes as highly addictive and toxic nicotine delivery devices, which warrant a level of regulation more consistent with their health effects. WHO considers that more effective product regulation in the past may have reduced the extent of negative health impacts from tobacco use and that current public health efforts to reduce tobacco-related harm are impeded by deficiencies in existing regulatory approaches.

2.1.1 Regulatory Imbalance

Many authors note a situation of regulatory imbalance of tobacco products. While causing significant morbidity and mortality, tobacco products enjoy greater regulatory advantage over alternative and less harmful products such as nicotine replacement therapies (Royal College of Physicians of London, 2002; WHO, 2001; Swenor, 2000; Bates et al, 1999). WHO (2001) notes that alternative nicotine products often face significant barriers to entering the market, due to high regulatory standards; a situation which can impede rather than encourage the development of innovative treatment responses. Swenor (2000) also

notes that the most hazardous and lethal way of supplying nicotine remains virtually unregulated while alternative nicotine-containing products that can reduce harm can be required to meet safety and efficacy standards that are unattainable, not economically viable, or severely constrained by marketing limitations. This situation of regulatory imbalance is further evidenced through many current areas of deficiency in tobacco product regulation. Evidence shows that cigarettes have been allowed to be designed to lead consumers to higher levels of toxin exposure than they are led to believe or from that indicated through product labelling (WHO, 2001). Cigarette additives and ingredients that become toxic when burnt, yet are not proven by manufacturers to be necessary for the use of the product, are currently permitted (Slade & Henningfield, 1998). With rapid development in the quest to develop less harmful tobacco products, there is increasing risk that manufacturers will make reduced harm claims without reliable evidence and testing against agreed and proven standards.

2.1.2 Tobacco as a Regulatory Abnormality

There are a number of reasons why tobacco products have for so long largely escaped meaningful regulation.

Sweanor (2000) observes that the early, widespread use of tobacco predated the development of consumer and drug regulation laws. He notes that when such regulation was being developed, the tobacco industry argued that tobacco would effectively be banned if required standards had to be met. Slade & Henningfield (1998) note that awareness of the dangers of smoking only became apparent after smoking was firmly entrenched throughout the world. They also note that meaningful regulation has been constrained in the past because of the relative scarcity of knowledge about tobacco products outside the tobacco industry itself. A number of authors also note that the tobacco industry has been particularly successful in their tactics to prevent and obstruct meaningful regulation (Lieberman, 2003; Borland, 2003).

2.2 The Challenge of Regulation

In recent times, increasing tobacco industry attention to developing less harmful tobacco products has highlighted the need for the more rapid development of regulatory control over tobacco, particularly as the industry is expected to use 'reduced harm' claims to market and sell new products. This pressure has stimulated renewed attention to the issue of regulatory control, the need for which is widely accepted (Borland, 2004; Lieberman, 2003; Royal College of Physicians of London, 2002; WHO 2001; Sweanor, 2000). However, this attention has also, in turn, highlighted the many challenges and difficulties inherent in developing effective tobacco product regulation.

By definition, regulation requires co-operation between regulators and the tobacco industry. However, based on past history, there is strong doubt within public health that such relationship with the tobacco industry can ever be effectively realised (Slade & Henningfield, 1998).

Citing current experience in the US, key informants also warn that regulation can be seen by tobacco companies as an important strategy enabling them to continue in the business of manufacturing and

selling cigarettes. Regulation provides future certainty for business planning and will likely involve long timeframes, due to inevitable legal delays and other stalling tactics. Overall, this may result in less significant impacts on reducing cigarette consumption and the enabling of manufacturers to still be in business in the future.

However, it may also be the perception by some key stakeholders that tobacco control is 'finished business' that could constitute a key barrier to regulatory progress. Liberman (2003) reports that such attitudes can exist within politicians, bureaucrats and public health professionals and that tobacco control can consequently be seen as a lower priority than other issues. In New Zealand, key informants recognise the risk that the relative success of the Smoke-free Environments Act (SFE Act) and recent amendments to the Act, may support the attitude or belief that there is no need for further regulation of tobacco. It is observed that one outcome of the SFE Act may be the public perception that smoking is now largely an issue of individual choice; the belief maybe that it is up to the individual to choose to smoke in the face of widespread warnings and smoking can be accepted as long as people smoke in a way and in places that do not negatively impact on others. While 'harm to others' has been used as major leverage for regulation in respect to smoke-free environments, this positioning may in itself now work against public perceptions of the need and importance for further regulatory reform, particularly at a structural level.

Getting the need for further regulation back on the public agenda in New Zealand is seen as a key challenge and one central to the future success of any regulatory framework. Opportunity is seen for publicly communicating public opinion survey research results which show the high level of support for increased regulation and control over the tobacco industry.

"We need to articulate [that further regulation]... is not radical, it is achievable, realistic, and workable and it will produce a phenomenal result... paint the picture as achievable and desirable and move towards it... at the moment we are a long way away from that..." (New Zealand key informant)

Available knowledge about tobacco product design and opportunities for product improvement are currently limited outside of the tobacco industry itself and this will also continue to be a key challenge in developing effective regulation. The potential for ad hoc, uninformed and reactive development of regulation, which results in harms rather than gains to public health, is real.

Historically, the tobacco industry has also used a range of strategies to prevent meaningful regulation of tobacco products (Thomson, Wilson, & Crane, 2005; WHO, 2001; Slade & Henningfield, 1998). Documented strategies used have included:

- lobbying, the use of third parties, using scientists with unproven ideas;
 - the destruction of documents;
 - arguing that regulation could interfere with trade secrets and intellectual property rights, and could create discrimination against international manufacturers;
 - questioning the science and raising public doubt about health and addiction effects;
-

- warning governments about the cost of regulation;
- dissemination and repackaging of legislative/regulatory problems from other countries;
- ‘divide and conquer’ tactics;
- using the courts to challenge, delay and sometimes prevent regulatory action;
- using the media to attack regulatory agencies;
- using voluntary agreements with governments and scientists to ensure that regulation that does exist favours their interests.

As a result, introducing new regulation can take a significant period of time to accomplish. International key informants involved in the implementation of tobacco product regulation report near constant litigation with tobacco companies. This presents challenges, not only in terms of getting regulation implemented, but also in terms of maintaining support at both public and political levels. As a result of the constant threat of litigation, regulators are increasingly premising regulatory action on extensive and comprehensive research and investigations in order to increase their chances of being successful in court (Wilkenfeld, 2000 cited in WHO, 2001).

2.3 New Zealand Tobacco Regulation

The following section provides an overview of current New Zealand tobacco regulation.

Regulatory control of tobacco in New Zealand is currently provided through the Smoke-free Environments Act 1990 (SFE Act). The SFE Act 1990 defines tobacco products 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. (MOH, 2004)

Under this definition, any nicotine product that is not smoked, inhaled or masticated is not covered by the SFE Act 1990 or the Medicines Act (unless a therapeutic claim is made about the product). Such a product would likely be regulated by the New Zealand Food Safety Authority under the Food Act 1981. Therapeutic products containing nicotine (e.g. Nicotine Replacement Therapy) are regulated by Medsafe and other products (except for smokeable tobacco, chewing tobacco and snuff) are regulated by the New Zealand Food Safety Authority (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

2.3.1 Control of Harmful Constituents

Section 31 of the SFE 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. A maximum fine of \$10,000 applies for any breach of Section 31. No harmful constituents are currently prescribed and no maximum limits are currently set.

Section 39 also provides for regulations to be made specifying and/or prohibiting 'harmful constituents of tobacco products.' This provides the ability to control specific additives and other content. This section also provides for regulations to determine methods of testing for tobacco product constituents and their smoke.

2.3.2 Testing

Section 33 of the SFE Act 1990 provides for regulations to be made to identify classes of tobacco products for which annual tests must be undertaken on tobacco product constituents and their respective quantities. The regulation also provides for the method of testing to be determined. The International Standards Organisation (ISO) testing method is currently prescribed and tobacco smoke is required to be tested for tar, nicotine and carbon monoxide.

Section 34 also enables the Director-General of Health to require a manufacturer or importer to undertake a further test of any brand's constituent. To date, this requirement has not been activated and enforced.

2.3.3 Snus

Section 29 of the Act 1990 bans the importation for 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. While this effectively bans the sale of smokeless tobacco in New Zealand, current regulations do permit importation for personal use.

2.3.4 Health Warnings

Section 32 of the SFE Act 1990 describes required health warnings and information for tobacco products. The regulations currently 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);
- all information to be provided in black writing in a white box with a black border;
- a health message in te reo Maori;
- the free phone number of the Quitline.

Regulatory power requiring a leaflet inside tobacco products on the health effects of tobacco regulations has to date not been activated (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

The Smoke-free Environments (Enhanced Protection) Amendment Bill proposes a range of additional provisions in respect to health warnings and information (see Allen & Clarke Policy and Regulatory Specialists Limited, 2003 for detail).

2.3.5 Content Disclosure

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

- weight of tobacco and 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 (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

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 and under Section 35(2) the Director-General of Health is permitted to publish any report provided.

Allen & Clarke (2003) report there has been considerable debate whether section 35(1)(b) requires disclosure of additives by brand. A current agreement exists whereby additives are reported by class of tobacco product and the maximum amount of each additive present in any brand of each class. More recently, Philip Morris has provided more product-specific information, listing all additives in each product in descending order of quantity.

Proposals under the Smoke-free Environments (Enhanced Protection) Amendment Bill would provide regulatory power to require product information listing the amount of tobacco, and the amount of each additive used in the manufacture of either:

- each class of tobacco products; or
 - each brand of each product class; or
 - each brand or brand variant (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).
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3. FOUNDATION PRINCIPLES FOR REGULATION

A number of foundation principles for the development of tobacco product regulation are identified in the literature and from consultation with key informants.

3.1 Clarity of Purpose

Key informants stress the importance of having a clear vision and overall goal for tobacco regulation. Clarity of purpose is seen as important for gaining political and public support and for maintaining unity within the tobacco control community, even when ideas may differ on the means to achieve stated goals.

Establishing timeframes for achieving goals is also stressed as important; there is general consensus that more needs to be done sooner and faster to reduce harm now. There is, however, a warning that regulation that is rushed, poorly conceived and implemented runs the risk of doing more harm than good.

Goals are usually long-term and not necessarily achievable within a short timeframe; however, goals are critical for focusing resources and decisions on appropriate direction. There is a view that the ultimate and long term-goal of regulation should be zero (or near zero) harm to health caused by tobacco. Another view is that near zero use of tobacco products should be the goal.

Some key informants believe the complete elimination of nicotine use is not attainable; it is felt that societies will need to accept some level of ongoing nicotine use (albeit not necessarily involving smoked tobacco).

“...I think it is a little like coffee and caffeine, we like to drink coffee but how many of us would like to take a pill with caffeine. I think without tobacco and without smoking and the very fast influx of nicotine into the body... I think pure nicotine may not necessarily be very addictive, and if it is less addictive than alcohol and on the same level as caffeine and some people say ‘it actually helps me a little bit in my life to cope with things’... why not then, let it be...” (International key informant)

A New Zealand key informant observes that to date, the aim of tobacco regulatory intervention in New Zealand has been consistent with the aims of the broader tobacco control programme; that is, focused on the reduction of the consumption of smoked tobacco. However, with recent debates about harm-reduction in tobacco control (see later discussion) a need is seen to re-examine what is meant by ‘smoke-free’ in the overall tobacco control programme. For example, is the term ‘smoke-free’ now being more literally interpreted as meaning totally free of tobacco?

Another New Zealand informant supports the view that the long term vision should be for New Zealand to be totally smoke-free. A recent poll showing 52 percent public support for a total ban on tobacco is read as indicating the feasibility and potential to make the smoke-free vision a reality. A key objective would be to phase out and ultimately ban the sale of tobacco (with a ban on the growth, use, and import of tobacco for personal use possibly implemented as part of a longer-term strategy). The vision would be framed in the context of making New Zealand a safe, smoke-free place for new generations.

3.2 Comprehensive Tobacco Control Strategy

WHO advocates that tobacco product regulation is conceptualised within a context of existing public health strategies targeted on reducing tobacco consumption. Therefore, rather than replacing existing, proven strategies (e.g. taxation, prevention and cessation programmes), regulation should be regarded as a complementary measure, occurring within an overall tobacco control strategy (WHO, 2001).

Key informants agree that tobacco product regulation is an integral part of an overall tobacco control strategy to reduce harm caused by tobacco. In serving the interests of the overall tobacco control strategy, regulation is recognised as providing the context in which tobacco industries and products are manufactured, marketed, made available and consumed. A New Zealand informant considers regulation as the key lever for shaping the environment in which tobacco use occurs (e.g. how it is sold etc) and that this is critical for the success of other tobacco control strategies. For example, recent New Zealand evidence showing continued reduced use of tobacco amongst 4th Form students is seen as reflecting changing attitudes about smoking which have been influenced by regulatory controls in key areas such as tobacco availability and exposure. Some informants consider regulation the most important and potentially most effective tobacco control intervention and one which can be considered to drive all other components of overall tobacco control strategy. Others consider regulation as an important part of the overall strategy and reinforce the need to also remain focused on other core strategies known to be effective.

3.2.1 Public Health Imperative

It is commonly advocated that tobacco product regulation should give priority to the goals of public health, harm-reduction and social wellbeing (Borland, 2004; WHO, 2001). A key challenge is to ensure that regulation does not result in alternative tobacco or nicotine products which claim harm-reduction properties, when in fact they offer little or no benefit to health. It is recognised that regulation must be designed to protect public health rather than provide regulatory protection for the tobacco industry (Borland, 2004).

3.3 Place of Prohibition

Some authors believe that a prohibitionist approach to regulatory effort to eliminate tobacco use is problematic (Borland, 2003; Liberman, 2003). Some consider the phasing out of tobacco use a more appropriate strategy (Callard, Thompson, & Collishaw, 2005). A number of key informants also comment on the issue of prohibition.

Borland (2003) predicts there is likely to be continuing demand for tobacco products and that a prohibitionist approach will not eliminate use. He warns of the potential for significant social harm if prohibition criminalises smokers and deems otherwise good citizens as lawbreakers. In the context of nicotine addiction and acceptance that smokers are victims of addiction, Liberman (2003) has moral difficulties with prohibition and making tobacco a law-and-order issue. Given the addictiveness of tobacco and the prevalence of use, he warns of additional harms through prohibition such as illicit use and the development of black markets. If users and suppliers became outside the law, he also predicts increased difficulties in working openly with tobacco users, for example, in encouraging cessation and discouraging initiation.

Callard, Thompson, & Collishaw (2005) also point out the risks involved in making smoking illegal, without first eliminating the demand for cigarettes or other tobacco products. They see the use of criminal law to address a problematic behaviour as potentially adding to the victimisation of smokers and those needing help. They advocate working to eventually phase tobacco out rather than simply seeking to ban possession or consumption.

Liberman (2003) considers a key challenge to be the development of a regulatory framework under which tobacco products continue to be made available to those addicted (and who cannot quit) and those wishing to use them, but at the same time marshalling all forces and influences as far as possible towards the minimisation of harm.

A New Zealand key informant feels that while prohibition may be possible in the long term (e.g. 20 years), significant risks are seen in the approach when a significant number of people still smoke. The potential for prohibition to punish or further victimise smokers is again recognised, along with the potential for black markets to develop. Another New Zealand informant feels that prohibition within tobacco control generally only becomes more acceptable when alternatives are available. For example, banning smoking in enclosed, indoor spaces becomes feasible and acceptable as smokers still have the option of smoking outside. Therefore, it is only when a true nicotine alternative product becomes available that prohibition could be considered.

In recognising the inherent risks and ethical issues in prohibiting smoking, other informants see the banning of tobacco sales (rather than smoking) as more appropriate. Such a move would not ban the growth, use or importation of tobacco for personal use and would accept some residual level of ongoing tobacco use within society.

Reflecting the previous discussion on nicotine alternatives and prohibition, a New Zealand advocate of introducing snus to New Zealand considers the supply of this alternative product as essential within a transition period to banning the sale of smoked tobacco (see later discussion).

3.4 Regulatory Framework

3.4.1 Unique Framework

Some authors feel that tobacco cannot be treated as an ordinary consumer product and that a different regulator and regulatory framework is required for tobacco compared to those applied to other drugs and products (Lieberman, 2003; Royal College of Physicians of London, 2002; Swenor, 2000). Borland (2004) sees a regulatory framework needing to allow for the stable, yet flexible, control of all aspects of tobacco products and their manufacture, promotion, and distribution.

Swenor (2000) argues that any product that kills when it is used as intended, has no safe level of consumption and is addictive, cannot be covered under existing legislation. Lieberman (2003) identifies differences between the regulation of therapeutic goods, food and drugs and the type of regulation appropriate for tobacco. He notes that the former regulation is designed to ensure the safety of products which, if properly regulated, are beneficial for consumers. The former regulation also aims to ensure the quality, safety, efficacy and timely availability of goods and products, acting to ensure goods are safe and effective for their intended use. For products offering net benefits and/or therapy, regulation also acts to ensure these products are manufactured, distributed and promoted to deliver on these aims (Lieberman, 2003). He argues that such conventional regulatory aims cannot be applied to tobacco, as tobacco products are inherently harmful and addictive, have no identified therapeutic benefit, and no safe level of ongoing use. He argues that in this context, a regulator cannot ensure the safety for such products nor that they are used voluntarily. At best, the regulations can only seek to minimise the harm caused by tobacco products. Lieberman (2003) further argues that in this context, regulation may also justifiably be used to shape the tobacco product market, including attempts to reduce the market or shift market demand to less harmful forms of use.

Such thinking leads the way for other commentators on potential broader roles for regulation; particularly those advocating the use of regulation to achieve structural reform of the tobacco industry (see later discussion).

3.4.2 Common Framework

Bates et al (1999) see the need for a common regulatory framework for all nicotine delivery systems, achieved by either extending pharmaceutical regulation to include nicotine-containing products or by introducing new legislation to develop a new nicotine regulatory authority. The framework would control all aspects of the product and provide an initial focus on addressing the current regulatory imbalance that favours the dirtiest nicotine delivery over cleaner forms. The authors note that while a common framework may not necessarily require identical standards, it could establish common approaches to testing whether new product developments are in the public interest and in encouraging the production and marketing of less harmful forms of nicotine delivery. The authors recognise that such a framework would require substantial investment in developing a necessary knowledge and skill base in areas such as tobacco content, toxicology and product modification (see later discussion).

Bates et al (1999) recommend that a comprehensive tobacco product regulatory framework should address a range of areas including product modification¹, measurement and disclosure², labelling, product information and claims³ and monitoring and surveillance⁴.

More recently, Liberman (2003) sees a comprehensive regulatory framework addressing:

- product characteristics including ingredients and manufacturing processes;
- consumer communication including the provision of content and health and cessation information;
- product modification and the development and distribution of less harmful and/or less addictive tobacco products;
- the use of pricing strategies to discourage use and/or shift use to less harmful products;
- control over the circumstances in which users can access tobacco products;
- extensive monitoring and access to information which provides understanding about the impact and effect of the regulatory framework.

Thomson, Wilson, & Crane (2005) support the need for a comprehensive regulatory framework within New Zealand which enables much greater control over the tobacco industry. They observe a tendency for tobacco product regulation to be developed through narrowly focusing on particular tobacco control interventions with less attention paid to the overall policy, regulatory, and organisational framework in which interventions occur. The authors see need for a strong, independent and effective regulatory framework given the size and nature of the tobacco companies, the effectiveness of their marketing, the addictiveness of the product and the danger of tobacco smoke to smokers and others. They also see a framework needing to achieve structural change and the provision of long-term foundations for effective tobacco control.

3.4.3 Importance of Co-regulation

It is recognised that current regulatory controls over tobacco products are extremely deficient when compared to those applied to alternative tobacco and nicotine products and other pharmaceutical and consumer products (Royal College of Physicians of London, 2002; WHO, 2001; Sweanor, 2000; Bates et al, 1999).

It is for this reason that co-regulation is seen by some authors as critical within an overall tobacco regulatory framework. Co-regulation seeks to ensure that the deadliest nicotine delivery products are not given greater market advantage over those products providing cleaner and safer delivery of nicotine.

¹ e.g. the establishment of upper limits and progressive reductions for concentrations of known carcinogens and toxins

² e.g. new measures of total toxicity and the ratio of specific carcinogens and other toxins to nicotine; control of tobacco product additives, including requirement for full disclosure of ingredients, additives, and smoke constituents by brand; requirements to disclose the purpose of additives and any secondary consequences; power to challenge and withdraw any additive until the manufacturer can prove no additional harm as a result of its use

³ e.g. removal of all misleading terms such as 'low tar' or 'lights' branding; provision of comprehensive and accurate consumer information on packets; prohibition of all health benefit claims unless the manufacturer can provide evidence-based health benefits consistent with the claim; removal of misleading tar yield numbers and strengthen warnings

⁴ e.g. monitoring of societal nicotine dependence and the impact of new products on consumer behaviour

Liberman (2003) believes that regulation aiming to minimise tobacco-related harm cannot be genuinely achieved if it is not integrated with regulation of the product's alternatives and competitors. Sweanor (2000) suggests a system where conventional tobacco products and alternative products are regulated separately but with the regulation of each taking into account the impact of the regulation on the other category of products.

3.4.4 Need for Regulation at Different Levels

Some key informants stress that regulatory controls on the conventional product or content should not be singularly pursued at the expense of other regulation such as structural reform. It is felt that product or content level regulation risks continually being in catch-up mode to an ever-resourceful and inventive tobacco industry focused on remaining one step ahead of regulatory efforts. Potential is seen for product/content level regulation to require significant timeframes and levels of resource and attention while questions are raised about efficacy (particularly if product or content level and regulation is delivered in isolation and not concurrently as part of a significant suite of major tobacco control initiatives).

3.4.5 Separate Regulatory Frameworks for Combustible and Non-Combustible Products

Some key informants note that not all tobacco is the same, a view shared by Husten (2005) in respect to PREPs. In recognising that it is not necessarily nicotine that is problematic, but rather the nicotine delivery system, a distinction is made between the dirty delivery systems from combustible products and the relatively cleaner delivery systems possible through non-combustible alternative products. It is felt that regulatory controls should acknowledge a gradient of harm, particularly by treating combustible and non-combustible products as different products.

"...You don't need a complicated bill...take the nicotine down to non-addictive levels... ban vents, no modifications, no new products unless we say so. Combustion is very different to non-combustion, even on the non-combustion level I think there is enough known at this point about what kinds of smoke-free product might fit... may be incentives ought to be there for smoke-free manufacturers to come forward and test their products as cessation aids, or [tobacco] substitutes..." (International key informant)

"...if we can come up with a way to stop people dying from tobacco use, I don't care who makes it... or if it is addictive. I drink several cups of coffee a day. If we could turn today's tobacco into tomorrow's coffee, it would be the greatest public health achievement in the history of mankind." (International key informant)

Reflecting the above, there is also a key informant view that harm-reduction is not as relevant or applicable to combustible tobacco products. It is recognised that a harm-reduction approach to such products would require a highly regulated and advanced regulatory system to adequately control the activities and operation of the industry. There is also a view that it is more appropriate to regulate combustible products for addictiveness and palatability rather than harmfulness. This position reflects doubt that consumers can truly make informed choices about reduced harm products, necessitating highly regulated control of

products claims. Difficulty is seen in predicting how consumers will interpret and react to claims and information provided and it may be best to avoid this pathway completely.

“...throws different light on reduced harm [issue] if [cigarettes] weren’t addictive... if addictiveness and palatability had been regulated and people were more capable of exercising choice, then maybe there is a stronger argument for reducing harmfulness of the product, but not while most use is addicted use.” (International key informant)

Calls for separate regulatory systems for combustible and non-combustible tobacco products also reflect a perceived need to:

- position smokeless tobacco products as quitting aids;
- make smokeless products more available relative to smoked products;
- market and position smokeless tobacco as being different and more desirable to smoked products.

3.4.6 Need to Address Mortality and Addiction Issues Separately

Some informants feel that tobacco regulation cannot effectively address the health and the addiction issues of tobacco concurrently; attempts to do this are seen as leading to a ‘quit or die’ approach. One informant suggests a two-step regulatory process is required to achieve desired public health goals.

1. The first goal is to reduce tobacco-related harm (through harm-reduction approaches, PREPs etc).
2. Then regulate nicotine content with the eventual goal of removing all nicotine content.

3.5 Practicality and Feasibility

Siem (2000) emphasises that to be effective, tobacco product regulation needs to be both practical and feasible (cited in WHO, 2001). Clear definitions are required as to what is allowed and not allowed and regulators need the necessary basis and authority to regulate the product and the industry. Regulatory measures also need to be acceptable to public and smokers in order to avoid unintended effects such as black market trading, smuggling, and consumer resistance.

3.6 International Collaboration

WHO (2001) has stated the importance of tobacco control efforts being trans-national. In relation to tobacco product regulation, WHO advocates for the establishment of an international expert group on tobacco and nicotine delivery devices. Core roles are seen in guiding international policy development on tobacco product regulation and in facilitating access to required scientific information⁵.

⁵ WHO has appointed a global team of experts to facilitate access to scientific information and to guide international policy developments in tobacco product regulation (Scientific Advisory Committee on Tobacco Product Regulation-SACTob). The body has roles in recommending action, cataloguing existing information and understanding and identifying the most effective regulatory frameworks for tobacco products. Early work has focused on testing methods, concerns around product labelling and moves to develop a common regulatory framework of tobacco products (WHO, 2001).

WHO (2001) also supports the development of a common international strategy on tobacco product modification. Bates et al (1999) supports this development and see it being achieved through a three stage process. Firstly, the authors advocate for regulation requiring comprehensive disclosure of smoke constituents and additives, improved consumer information, and the removal of misleading branding and labelling. The second stage would involve the regulation of toxic smoke constituents and additives (based on data disclosed in stage 1) and the third stage, the regulation of all nicotine delivery products within a common framework.

3.6.1 Framework Convention on Tobacco Control

The importance of strong, consistent, global level tobacco control measures has been recognised through the Framework Convention on Tobacco Control, a WHO-initiated international treaty aimed at curbing tobacco-related death and disease. The Treaty aims to provide and facilitate global tobacco control action to complement action at the national level.

A set of provisions contained in Articles, 9, 10, and 11 currently provide the Framework's core focus on tobacco product regulation, specifically, the manufacture and distribution of tobacco products. Article 9 requires periodic testing of tobacco product contents and emissions. Article 10 requires periodic disclosure to specific format, test results of per mg of tar and nicotine and all other characteristics of tobacco products. Article 11 requires large, clear, rotating health warnings and information messages, without misleading health claims (WHO, 2005).

The scientific basis for the principles guiding the implementation of Articles 9 and 10 establishes the rationale for the principles guiding the implementation of Article 11. For this reason and in order to achieve synergy between the provisions, WHO, advises that all three articles should be treated as a single set of interrelated and mutually reinforcing regulations. WHO (2005) advises that the regulatory authority for tobacco products and the regulatory duties established under the Framework should be delegated to a specialised agency within a ministry or department of government.

3.6.2 New Zealand Considerations

There is some recognition of the inter-relationships between New Zealand and other Pacific countries in relation to smoking and tobacco control and there is a view that regulatory developments in New Zealand need to at least be undertaken with reference to the Pacific region, including Australia and the Pacific Islands. This may involve efforts to develop consistency in the regulatory environment within each country and in particular to ensure that New Zealand plays its role in helping Pacific islands to address the tobacco problem.

3.7 In Summary

In summary, it can be concluded from the research that a regulatory framework for tobacco product regulation should:

- have a clear set of public health goals and strict controls and mechanism to ensure that regulation does not undermine these;
 - have agreement and clarity about how different goals relate and are to be addressed;
 - be developed as part of a comprehensive tobacco control strategy;
 - explicitly recognise the uniqueness of tobacco products;
 - be based on scientific evidence;
 - be practical, feasible and acceptable to all the public and smokers;
 - provide controls at many levels, including demand and supply side controls, those at the product and content level and those at structural level;
 - acknowledge the rights of smokers as victims of addiction within the context of the greater public good;
 - further consider the potential for a prohibitionist approach, with an eventual ban on the sale of smoked tobacco perhaps the most feasible option to explore further;
 - potentially cover all nicotine and tobacco products (conventional and alternative) yet also provide for necessary distinctions between different product types and harms;
 - be conceived consistent with the WHO Framework Convention on Tobacco Control.
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4. PRODUCT/CONTENT LEVEL REGULATORY OPTIONS

This section considers regulatory options at the product and content level in more detail.

4.1 Introduction

Regulation at the product and content level is concerned with regulating specific aspects of tobacco design, content, production, packaging, distribution, sales and marketing. Product and content regulation includes product modification initiatives as well as development and regulation of Potential Reduced-Exposure Products (PREPs). See Section 5 for detailed discussion of PREPs.

4.1.1 Focus of Product Level Discussion

It is beyond the scope of this research to discuss all possible aspects of tobacco regulation at the product and content level. Furthermore, because in some areas there is greater consensus about appropriate direction, these areas are of less immediate concern to the research sponsors. For example, strict regulatory control over tobacco advertising is widely accepted in New Zealand and generally considered an essential component of comprehensive tobacco regulation. There is also widespread agreement that it is misleading to permit product labelling terms such as 'light' or 'mild' that imply reduced harm attributable to low tar or nicotine measurements⁶. Regulation to influence the size, strength and nature of health warnings is also not considered in the current research.

For a recent review of regulatory options at the product and content level, the reader is referred to a comprehensive work by Allen & Clarke (2003).

This research is limited to examining three core areas of product and content level regulation, specifically regulation to reduce toxicity, regulation of additives, and regulation to reduce nicotine content. This focus reflects Borland's (2003) view that product and content regulation has a key role to play in making tobacco products less toxic and addictive as well as less palatable. These areas of regulation are also of particular interest within current debates about appropriate direction for tobacco regulation.

⁶ Cigarettes advertised as 'light' or 'low tar and nicotine' have been shown not to provide the health benefits implied by the claims (WHO, 2001) and it is widely recognised that such claims are misleading and inaccurate. A key reason for this has been deficiencies in the current USA Federal Trade Commission (FTC) and the International Organisation for Standardization (ISO) methods for cigarette contents (WHO, 2001). It is known that the actual levels of tar, nicotine, and other substances consumers are exposed to by smoking cigarettes bear little relation to the levels recorded through current testing and subsequently shown in product labelling. There is widespread acceptance of the need to revise current testing methods (with this happening in some countries) and in the meantime, removal from cigarette packs the tar and nicotine ratings based on the existing FTC/ISO measurements

4.2 Reduced-toxicity

Tobacco companies and others have been exploring and developing the potential for the manufacture of reduced-toxicity cigarettes for some time (Allen & Clarke Policy and Regulatory Specialists Limited, 2003). Historically, however, a number of factors have constrained development of this potential, particularly that development requires acknowledgment that existing tobacco products are dangerous and that profiting from such development requires the ability to market the products as safer. Further suspicion of this approach has been caused through the past experience of low-tar tobacco products being misleadingly marketed as safer and the current lack of reliable testing methods (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

Gray & Henningfield (2004) do, however, argue that it is technically and commercially feasible to manufacture conventional cigarettes with substantially lower levels of toxins than typical in current cigarettes. They find it difficult to see any reason for allowing unnecessarily high yields of toxicants and believe there is little justification for allowing toxicant levels to be anything other than as low as possible.

The authors identify a range of possible reduced-toxicity product modification interventions including:

- using activated charcoal filters to reduce the levels of vapour-phase toxins;
- setting maximum permissible yields of tobacco-specific nitrosamines;
- improving combustion efficiency by increasing the porosity of cigarette paper and by reducing packing density of the cigarette rod;
- examining aerosol size distribution under various filtration systems and degrees of humectant loading to see if the proportion of respirable particles can be reduced;
- examining the extent to which ventilation affects nicotine delivery and other characteristics, including pH;
- reducing or eliminating tobacco-specific nitrosamines from smokeless tobacco products;
- preventing blockage of ventilation holes;
- making cigarettes more fire-safe by reducing the extent they can cause combustion of other materials.

Gray & Henningfield (2004) also see regulation to reduce toxicity as a strategy which can negatively impact the tobacco industry generally. It is felt that setting low maximum levels of toxins could substantially impact the tobacco industry by shrinkage in the number of brands on the market; and by enforcing significant changes within the global tobacco-growing industry, and the cigarette-manufacturing industry.

Reduced-toxicity cigarettes are generally considered by key informants as a low priority for regulation. Reasons for this view include:

- doubt as to whether reduced-toxicity cigarettes can ever be developed and if they were, whether the knowledge, infrastructure and methods required to effectively test, monitor and evaluate these products will ever be achievable. There is risk that the time and expense of developing the required
-

infrastructure is excessive in relation to the potential health gains and simply provides a resource-intensive diversion from other more effective tobacco control strategies. In this respect there is concern that this direction potentially plays into the hands of the tobacco industry, particularly in the absence of extremely rigorous regulatory control;

- the difficulty of effectively controlling industry claims (explicit or implicit) about reduced-toxicity;
- the potential that developing reduced-toxicity cigarettes damages and confuses current messages and communication to smokers about smoking (e.g. undermine cessation and prevention efforts, lead smokers who have quit or who might otherwise quit to resume using tobacco products).

“...I think it is extraordinarily dangerous to be going down a product modification track in the absence of a really meaningful regulatory framework and I think that history teaches us if we do that we are simply playing into the tobacco industry hands... in the absence of a sound, broad comprehensive science base, if we sit down with a bunch of simplistic rules, the industry will create products that meet them, that probably don't reduce risk of disease but which will serve to keep people smoking. I think this is the single greatest mistake we can make in the current environment.” (International key informant)

4.2.1 Reduced Tar Strategies

While once considered a promising reduced-toxicity strategy, the efficacy of specifically reducing cigarette tar is now questioned (WHO, 2001; Rickert, 2000; Bates, et al, 1999). Increasingly, the evidence suggests that lower-tar cigarettes are not less harmful than higher-yield cigarettes. (Withey et al, 1992, Frost et al, 1995 cited in WHO, 2001). There is growing speculation that lower-tar cigarettes are linked to the increasing incidence of adenocarcinoma of the lung due to rise in tobacco-specific nitrosamine (TSNA) levels and compensatory smoking involving deeper inhalation and more intense puff volumes and frequencies (WHO, 2001). It is further speculated that consumers may have considered lower-tar cigarettes as an alternative to quitting, so these products may have in fact resulted in higher numbers of smoking-attributable deaths than had they not been introduced (WHO, 2001).

The failure of the US Federal Trade Commission and International Standards Organisation methods to accurately test tar content has also contributed to doubts over the value of lower-tar strategies as has recognition that the concept of ‘tar’ is misleading. For example, under the traditional testing regimes, Bates et al (1999) argue that reduced maximum tar yield could be achieved by manufacturers simply increasing the number of holes in cigarette filters, thus drawing more air into the testing machine and reducing the measured tar yield. An appearance of action, with minimal or no health gain, would potentially result, while also lending unjustified credibility to the FTC/ISO measurement methodology.

Bates et al (1999) note that ‘tar’ is a collective name for thousands of chemicals that form the residue of tobacco smoke. Tar has different compositions which are likely to cause different degrees of harm and tar composition varies greatly between products, countries and potentially over time. WHO (2001) further highlights these difficulties by acknowledging the many challenges in accurately studying outcomes from lower-tar strategies (e.g. self-selection of lighter smokers to these brands with lower risk of smoking-attributable disease, qualitative changes over time in the carcinogenicity of tar).

In response to the difficulties discussed WHO (2001) urges governments not to further pursue harm-reduction strategies seeking lower nominal yield measures and based on current interpretations of tar yield measurements. Bates et al (1999) see benefit in pursuing strategies to reduce specified toxic/carcinogenic substances in relation to nicotine yield, including reductions in carbon monoxide/nicotine ratios. Slade & Henningfield (1998) see value in focusing on specific emissions of compounds of interest, in both vapour and particulate phases, and suggest an alternative to tar being an index of relative toxicity in the non-water, non-nicotine emissions from tobacco products.

4.2.2 Reasons to Further Doubt Reduced-toxicity Strategy

A recent paper by Laugesen & Fowles (2005) casts further doubt on the feasibility and value of pursuing reduced-toxicity regulatory strategies. In this study, the authors set out to examine the scope of regulatory approaches to reduce the toxicity of manufactured cigarettes sold in New Zealand. The cigarette smoke emissions of 13 toxicants were examined for 20 British Columbian, 15 Australian, and one NZ brand of cigarette, Holiday Extra-mild (HEM). Using the ratio of toxicant to nicotine yield, the study estimated the relative overall smoke toxicity per disease group and per brand.

The study showed that the smoke emissions of all the cigarette brands examined contained the same leading carcinogenic, cardiovascular, and respiratory toxicants in their smoke. Under intensive smoking conditions, the study showed that low nicotine brands tended to have higher toxicant emissions than medium nicotine brands, as judged by toxicant/nicotine ratios. This result is seen by the authors as likely explained by compensatory over-smoking in low yield brands leading to an adjustment of the toxicant to nicotine ratio.

The study found little evidence that HEM (a so called 'light' cigarette) provided any reduced harm effect. In fact, the study concluded that HEM was the most toxic of the 37 brands examined based on toxicant/nicotine ratios. For three of the most powerful toxicants in cigarette smoke emissions (acrolein, butadiene, and hydrogen cyanide), HEM had the highest toxicant/nicotine ratios among all the brands examined. Under intense smoking conditions, HEM tar was 33 mg per cigarette, HEM nicotine 1.8 mg; and the tar/nicotine ratio 18, the highest for any of the brands examined. In addition, the lead level in HEM smoke was second highest of the 37 brands examined at 40 nanograms per cigarette and the highest for lead/nicotine. Compared with HEM, a Canadian brand, Export A Full Flavor, actually carried a 37 percent lower cancer risk, largely explained by differences in nicotine yield and a lower toxicant/nicotine ratio.

The study highlighted the numerous complexities and difficulties in pursuing a toxicity-regulated cigarette, least of which being whether such a strategy will lead to any significant and positive public health outcome. The authors recognised that current information gaps (e.g. in cigarette engineering areas such as filter ventilation, filter efficiency, and paper porosity) make it extremely difficult to fully understand brand to brand differences in smoke emissions. The authors note that it is unclear how unidentified or unmeasured toxicants in smoke such as free radicals may or may not reduce in parallel to any toxin reductions achieved through regulation. They also acknowledge that the amount of time

required for effective switching to reduced-toxicant brands is unclear. They further note that undue claims about reduced-toxicity are unhelpful, particularly if addicted smokers use such information to justify their continued smoking. Laugesen comments that the regulatory effort and resources required to regulate reduced-toxicity cigarettes would be extensive and would potentially overwhelm the current regulatory capacity of the Ministry of Health (www.smokeless.org.nz). He further comments that cigarette regulation and the required testing risks legitimizing and perpetuating cigarette smoking, and that this approach potentially does little to reduce the numbers of cigarettes sold or the numbers of people smoking them.

4.3 Regulation of Additives

Recommended regulatory control over additives commonly focuses on two key strategies:

1. Regulation to remove additives that contribute to toxicity, addictiveness, palatability and attractiveness (WHO, 2001; Slade & Henningfield, 1998);
2. Regulation requiring the use of additives that reduce toxicity and addictiveness (Gray & Henningfield, 2004).

Calls for greater regulatory control over cigarette additives stem from concerns about the relatively unfettered freedoms tobacco companies enjoy in manipulating and using additives to enhance tobacco product appeal and addictiveness (Slade & Henningfield, 1998). An example is the use of additives to increase the levels of 'free nicotine' available, thereby heightening the addictive kick of the nicotine. Another example is the use of additives such as menthol and eugenol to make tobacco smoke more palatable and less irritable. Some key informants support the removal of additives which serve these aims, particularly palatability, and it is also noted that regulation should prohibit the addition of new additives for any purpose.

Slade & Henningfield (1998) believe that a fundamental prerequisite for any tobacco product regulation system should be the ability to predict exposure levels to specific materials when a particular tobacco product is used. However, little is known about the potential harmful effects of many additives when burned with tobacco or in conjunction with other additives (Bates et al, 1999). Slade & Henningfield (1998) note that while the use of additives has increased as cigarettes have been designed to produce lower machine-measured tar deliveries, there has been little concurrent regulatory control requiring additive disclosure or to mandate that additives be proven safe.

WHO (2001) advocates that the burden of proof be placed on the tobacco companies to make the case for the continued use of additives. Bates et al (1999) concurs with this direction, concluding that regulation should require that the purpose, use, and overall public health impact of existing and new additives be fully explained and justified by cigarette manufacturers, should they wish to continue using them. The authors propose that regulation should require full disclosure by brand and additives should only be permitted where they can be proved by the manufacturer as not to be adding to the health consequences of tobacco or causing any other damage. They warn against regulating additives only according to toxicity, as relatively benign additives can have other undesirable functions (e.g. additives that make smoke more

palatable to the teenage palate and burn enhancers that keep cigarettes smouldering). Existing regulatory controls over additives to pharmaceutical products are seen as a useful starting point for developing a more robust regulatory framework for additives. In the pharmaceutical context they note that manufacturers are required to prove that additives do not interfere with the efficacy or safety of the product, do not increase the abuse potential of the product and do not encourage a different pattern of use (indication) for the product.

Prior to banning non-justifiable additives, (Gray, 2000 cited in Allen & Clarke Policy and Regulatory Specialists Limited, 2003) suggests that manufacturers be given a one-year period to provide the necessary evidence to demonstrate that any additives they wish to use are free from toxic effects and have a public health benefit.

While key informants agree that additives should be controlled, many consider this a lower priority for tobacco product regulation. Overall, there is concern that the energy and resources needed to implement the strategy could take the focus off other more productive and effective areas of tobacco control.

Informants raise questions of effectiveness and the ability of an additive strategy to have a real impact on improving health outcomes. For example, additive-free or additive-controlled cigarettes will still be addictive and harmful to health. Simply removing some additives may also not achieve desired reduced palatability. Informants recognise the possibility that removing additives may change smoker behaviour and/or disease characteristics, therefore limiting beneficial health outcomes and potentially resulting in new harms or new patterns of harm. The effects of removing additives, some or all, is at present unknown. One informant also notes the intent to control additives to reduce palatability is not currently supported by scientific evidence, i.e. there are other ways of making the product less harsh (different leaves, blends etc), and the tobacco industry may simply respond with new strategies to maintain palatability in an additive-controlled environment.

While key informants agree that disclosure of additives and their use should occur as a matter of course, it is noted that there is currently limited value in this as the tobacco control lacks the ability to interpret the information. There is a view that the information will be more useful once this knowledge is developed. Until this time, it is considered more of an issue of integrity that information be disclosed.

Informants caution about bringing additives into the public forum through increased regulation and/or disclosure of additive content. The possibility of confusing and undermining the 'harm to health' message is considered high. For example, attention to additives may distract from the message that combustible tobacco is the primary constituent of harm. This may lead to an assumption amongst the public that once additives are controlled or removed, that harm is reduced to an acceptable level of safety. This perception may in turn act to endorse use of additive-modified tobacco products and undermine fundamental prevention and cessation messages.

The potential for the tobacco industry to contribute to public confusion surrounding additive removal or control is also considered a significant risk by some informants. As with 'light' and 'mild' marketing

methods that confuse the public health message, it is felt that the ability to market additive-controlled or additive-free cigarettes is an avenue that the tobacco industry will seek to exploit in efforts to retain an increasingly health-concerned market of smokers.

4.4 Regulation to Reduce Nicotine

Greater regulatory authority to reduce tobacco-delivered nicotine has long been considered within tobacco product regulation. In theory, cigarettes could be made less addictive by reducing nicotine levels to values so low that addiction cannot be created or sustained. Calls to pursue this strategy typically stem from the belief that regulation has a role to play in reducing the addictiveness and therefore the use of tobacco products. In the face of evidence that the tobacco industry has long sought to maximise the addictiveness of cigarettes, some authors see little reason to believe that the tobacco industry will themselves voluntarily reduce the addictiveness of their products (Henningfield et al, 2004).

4.4.1 Cautions about Reduced-nicotine Strategy

While seemingly a 'good idea', cautions are expressed in both the literature and by key informants about pursuing a reduced-nicotine strategy. Key informants conclude that if implemented as an isolated strategy, not supported by effective regulation, reducing nicotine content is problematic and a strategy which may not result in significant public health outcomes.

Questions are asked whether a reduced-nicotine strategy would deliver desired public health outcomes (Slade & Henningfield, 1998) and whether a strategy of reduction or total elimination of nicotine should be pursued (WHO, 2001). Bates et al (1999) urge caution anticipating the possibility of compensatory smoking⁷. Hatsukami et al (2002) also see a risk that compensatory smoking could potentially negate any beneficial effects of low-nicotine-containing cigarettes. They also suggest that high-nicotine but low-tar cigarettes (while not focused on the prevention of initiation or on cessation) may in fact help to reduce harm if adequate nicotine can be achieved with fewer cigarettes. Key informants also raise questions as to the impact of such a strategy on smoking behaviour and posit smokers may compensate for less nicotine by smoking more, inhaling more deeply or by taking other measures to ensure their addiction needs are met. This may result in nil health benefit from the strategy or even an increase in harm.

The risk that lower nicotine levels may drive smokers to other tobacco products is also noted (Slade & Henningfield, 1998; Henningfield et al, 2004) as is the potential for the strategy to encourage a black market in high-nicotine cigarettes (Slade & Henningfield, 1998).

Henningfield et al (2004) note that there is a need to actually verify that there is a threshold nicotine dose per cigarette and per day which is required to sustain addiction. They also recognise that further work is required to establish whether it is technically feasible to manufacture cigarettes with a nicotine content which falls below the addiction threshold.

⁷ Where smokers adjust their smoking (e.g. smoking more cigarettes, smoking each cigarette more intensely) to maintain blood nicotine levels

Henningfield et al (2004) suggest it may be more feasible to only reduce nicotine to a level that would sustain addiction in existing users. This approach is seen as reducing the gap between tobacco products and available addiction treatment products with respect to acceptability and appeal. They note the importance of continuing strong product warnings and effective regulation so that reducing nicotine does not undermine prevention or cessation efforts. The importance of post-market surveillance is also noted to understand and enable a response to any unintended effects.

4.4.2 Need for Further Information and Understanding

In recognition of the pros and cons of regulating nicotine yields, there are common calls for further examination of this approach, before strategy decisions are made (Hatsukami et al, 2002; WHO, 2001; Slade & Henningfield, 1998).

Hatsukami et al (2002) identify the need for further research to inform development of any reduced-nicotine regulatory strategy. For example:

- better understanding of smoker ‘titration’ – the process of smokers adjusting their smoking behaviour to attain a certain level of nicotine;
- better understanding of the extent smokers try to maintain certain levels of nicotine, variability of levels across smokers, the factors contributing to variation and whether and how these levels could be altered;
- determining the level of nicotine exposure which will no longer be reinforcing to the majority of the population;
- examination of whether smokers can adapt to lower nicotine intake levels over time and whether lowering the nicotine to this level will reduce initiation of smoking and facilitate quitting.

The implication of Hatsukami et al (2002) identifying these and many other nicotine-related research questions, is that in the absence of such understanding there will exist some uncertainty about likely efficacy and outcomes from pursuing a reduced-nicotine strategy.

Key informants raise similar questions about the effectiveness of a reduced-nicotine strategy, in the context of current gaps in knowledge; in particular, lack of scientific evidence as to what level nicotine would need to be reduced in order to break addiction.

4.4.3 Reduced Nicotine as Part of a Broader Strategy

Informants raise doubts about the value of implementing a reduced-nicotine strategy as a standalone strategy for a number of reasons:

- Singularly reducing nicotine to reduce addictiveness risks failing to attend to the other ways used to enhance delivery/reception of nicotine. Tobacco industries will take other measures in the context of reduced-nicotine controls to ensure addictive levels are maintained (e.g. different tobacco leaves, blends).
-

“...when tobacco companies lowered tar and nicotine levels beyond the changes that were visible to the naked eye, we didn't know what else they did to the tobacco products and that was among our fatal flaws... in the absence of a broad regulatory scheme, I think we are kidding ourselves if we think we are helping ourselves...”
(International key informant)

- Reducing nicotine may not have broad-reaching impact in reducing addiction. Other factors contribute significantly to addiction (e.g. emotional, social and environmental factors).

There is, however, some support for reduced levels or the removal of nicotine as part of a broader regulatory strategy to potentiate quitting. One key informant defines a ‘safer cigarette’ as one which encourages quitting and therefore provides the consumer with choice. This informant sees quitting potentially encouraged through:

- removing the nicotine content;
- removing filter vent holes, making it harder to draw cigarette smoke – smoke would be harsher, less enjoyable;
- removing additives that increase nicotine bioavailability and make the smoke less harsh;
- low ignition cigarettes (to reduce fire risk).

This informant recognises that nicotine-free combustible cigarettes would potentially give consumers a real choice about whether to continue smoking or not (i.e. in the absence of physical addiction to nicotine a true decision on this is more likely).

“If it is nicotine that keeps you going back to combustible tobacco and it is so dangerous, it seems to me, just take the nicotine out to non-addictive levels so that people have a choice and then when you get into non-combustible tobacco products, then I think you can have a discussion on whether nicotine is really that evil. Is nicotine addiction the problem? I would say, no. The problem is the exposure to the toxins in tobacco smoke.”
(International key informant)

Other identified examples of how a reduced-nicotine strategy could be implemented in conjunction with other regulatory strategies include reducing nicotine content in cigarettes in conjunction with

- promotion of alternative products to promote continued use of these products and to potentiate quitting, or to simply aid in quitting. For example, reducing nicotine in cigarettes supported by increased promotion of NRT could encourage smokers to shift from cigarettes to NRT and eventually quit. Alternatively, reducing nicotine in cigarettes could be used to promote alternative products such as snus, if these are considered a more acceptable alternative in terms of reduced harm;
 - the supply of pure nicotine or a smokeless tobacco product such as snus;
 - appropriate promotion of accessible NRT.
-

4.5 New Zealand Considerations

4.5.1 Reduced-toxicity

Allen & Clarke (2003) identify a range of possible reduced-toxicity regulatory strategies. These include prohibiting or regulating the use of certain tobaccos, additives or processes and requiring pouch tobaccos to be sold with filters. However, they also note a number of risks in pursuing reduced-toxicity regulatory policy, a key risk being the potential for quitting being discouraged or smoking initiation actually encouraged through any initiative which leads to the perception that cigarettes are safer. They acknowledge that current perceptions of cigarettes as dirty and dangerous is useful in any campaign aimed at reducing tobacco use. The authors also recognise that reduced-toxicity conventional cigarettes could lead to an increase in consumers switching to roll-your-own tobacco products; tobacco smuggling could also become a problem.

If a reduced-toxicity strategy was to be pursued, Allen & Clarke reinforce the importance of concurrent policy development aimed at reducing the likelihood of undesirable, unintended effects. They also acknowledge a challenge would lie in being able to reduce cigarettes' toxicity while also increasing the public's knowledge and acceptance of the health risks of continued tobacco use.

4.5.2 Reduced Nicotine

Allen & Clarke (2003) also identify policy options to regulate tobacco product additives. They note, however, that the feasibility of the options depends on the ability to enforce full and accurate disclosure of additives used in cigarettes by brand.

Policy options identified include:

- development of a regulatory regime based on the pre-1984 regime (prohibition of adulterants, except those that are approved for use);
- a ban on any new additives and implementation of research to assess the health effects of existing ones;
- restriction on the use of specific additives that act to enhance toxicity, addictiveness and palatability;
- restrictions on the use of the most toxic additives.

Some of the options may be possible under existing regulations under section 39 of the Smoke-free Environments Act 1990 (Allen & Clarke Policy and Regulatory Specialists Limited, 2003). The authors note that any option requiring approval of a tobacco product, additive or constituent entails risk unless the regulator is entirely certain that no harmful or addictive effect is likely to result from use of the product, additive or constituent. They see a low threshold for risk as likely necessitating an extremely high threshold for approval, a situation which might effectively result in a ban on additives.

4.6 Other Product Level Regulation

In addition to product regulation, some key informants consider it essential that regulation continues to focus on the remaining P's of the tobacco marketing mix: placement, promotion and price. It is noted that it is a mistake to consider that tobacco advertising singularly constitutes tobacco marketing and, given the ban of tobacco advertising in New Zealand, that the marketing of tobacco in New Zealand has been addressed.

Identified areas for further regulatory control in placement, promotion and price are briefly discussed below.

4.6.1 Placement

There is a view that the availability and accessibility of tobacco products in New Zealand needs to be further reduced. There is some support for the concept of licensed outlets, similar to liquor sale licenses. Licences would require compliance with certain regulations and infringements (e.g. sales to minors) would result in greater sanctions than exist currently, for example, licence removal. One informant suggests that regulation could prevent access by children by only permitting tobacco products to be sold at venues that are only able to be accessed by persons aged 18 years and older (e.g. licensed premises). This would remove tobacco products from dairies, supermarkets and petrol stations. Restricting access to tobacco products through prescription only is seen by some as an appropriate longer-term goal.

*"I like the idea that has been suggested, of a future in which tobacco products are available on prescription to those who have a proven dependency. Removing it from the area of a recreational good, into the therapeutics."
(New Zealand key informant)*

However, there is also a view that making tobacco harder to access may in fact strengthen resolve to smoke. It is felt this could be a particular issue for youth if they are drawn to smoke in order to rebel or to 'be cool'.

4.6.2 Promotion

There is support from some key informants to increase the promotion and awareness of less harmful alternatives to combustible tobacco, predominantly NRT, but also snus if this is deemed appropriate for introduction to the New Zealand market. There is a view that such promotion may work best in conjunction with increased restrictions on the promotion, placement and availability of combustible tobacco. Promotion may include the positioning of alternative products directly alongside tobacco products, advertising and education campaigns to encourage smokers to switch to alternatives, and improvements in the packaging and marketing of alternative products to increase appeal.

Informants are positive about the current moves towards graphic warnings on cigarette packs. These are seen as important not only in destroying the attractiveness of packaging and educating people about health risks associated with smoking but also necessary in destroying tobacco brand equity. International informants recommend focus on using graphic warnings with the central aim of increasing awareness of harm. They also note the need for fresh and updated warnings to avoid 'wear-out'.

Full disclosure of cigarette content, marketing and business activities is seen as valuable in terms of guiding regulatory needs and responses at both the product and industry level. Disclosure of cigarette ingredients to the public (e.g. through display on cigarette packs) is considered valuable in dispelling 'myths' by exposing all the harmful chemical components of cigarettes. However, informants also caution that this can cause consumer confusion, necessitating careful consideration of what information is displayed on packs.

There is also support for further reducing the visibility of cigarette packs at point-of-sale. Moves in this area are seen as a feasible first step towards restricting one of the last bastions of tobacco product promotion. The complete removal of all displays is seen as preferable by some.

Continuing the drive to inform people about smoking-related harm and to de-normalise smoking is seen as important. These measures are in turn recognised as important in building public support for increased regulation and compliance with regulation.

*"You can't do everything through law; you have to move the population along, in terms of a gradual changing of social attitudes – which takes sometimes generations. You can't expect law to stop everything in its track."
(International key informant)*

There is a view that social marketing needs to be used to build further public support for tobacco product regulation. One New Zealand informant believes the issue of regulation needs to be positioned on the public agenda at a level similar to the nuclear-free debate. Informants express confidence that there is increasing public support for regulation in New Zealand and that evidence of this support (e.g. public survey results) should be directly communicated back to the public and politicians. Getting the public to recognise the feasibility of a country free of tobacco and building public support for this vision is seen as important.

There is a view that the promotion of smoking in films requires further regulatory control. Film is reported to have significant impact in terms of normalising smoking activity, particularly among youth. Suggestions for dealing with this issue include requiring the provision of smoking-related information before and after screenings of films containing smoking behaviour (e.g. through screened advertisements) or raising the age restrictions on films containing smoking behaviour so that no persons under 18 years are exposed to these images.

4.6.3 Price and Taxation Policy

Key informants, both national and international, note the ongoing importance of price increases as a further means to reduce access to tobacco products. Some New Zealand informants consider that substantial price increases are still required.

5. ROLE AND PLACE OF PREPS

The following section defines Potential Reduced Exposure Products (PREPs) and considers the arguments for and against their use in a tobacco product regulatory framework. Two PREPs considered to provide particular potential, Swedish snus and Nicotine Replacement Therapy (NRT), are examined in depth. The basis upon which the role and place of PREPs within an overall tobacco regulatory framework may be determined is examined and, finally, comment made on possible direction and options in the New Zealand context.

Examination of PREPs within a regulatory framework must first consider the issue of harm-reduction in the context of tobacco control.

5.1 Harm-reduction

A harm-reduction approach within tobacco control is controversial (Pierce, 2002); however, determining the role and place of harm-reduction within a regulatory framework is increasingly important, particularly given the emergent need for regulatory control of PREPs and other harm-reduction strategies.

In its broadest context, tobacco harm-reduction refers to the overall goal of minimising tobacco-related disease and death (Warner, 2002). Similarly, Stratton, Shetty, Wallace, & Bondurant (2001) see tobacco harm-reduction referring to the goal of reducing harm to health from tobacco use, including environmental smoke. Key informants recognise that as long as tobacco is made available, every action taken to reduce the harms caused by tobacco in essence represents a harm-reduction approach.

Traditionally, harm-reduction has consisted of the core strategies of cessation and the prevention of smoking initiation and, more recently, the protection from environmental tobacco smoke. Slade & Henningfield (1998) see abstinence from tobacco continuing to be the primary public health strategy for avoiding tobacco-related death and illness. Gray & Henningfield (2004) see no valid reason for not fully pursuing prevention and cessation as neither have any consequential downsides associated with their implementation.

Warner (2002) notes that a fourth tobacco harm-reduction objective has recently emerged, this being the minimisation of the net damage to health for consumers of tobacco products. In this context, harm-reduction refers to minimising the harms and decreasing total morbidity and mortality from tobacco use without completely eliminating tobacco and nicotine use (Stratton, Shetty, Wallace, & Bondurant, 2001). Stratton et al (2001) therefore define a product as harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants.

Warner (2002) sees contemporary understanding and use of tobacco harm-reduction now primarily referring to this fourth objective. Under this objective, Fox & Cohen (2002) recognise two broad approaches to harm-reduction, these being the:

1. Substitution by users of conventional tobacco products for alternative products (e.g. NRT, PREPs).
2. Continued use of conventional tobacco products in a manner that reduces exposure to toxic substances, primarily by reducing consumption.

Oliva (cited in Robins 2005) in his outline of the California State Department of Health Services, Tobacco Control Section's (TCS) position on harm-reduction and tobacco regulation, considers 'harm-reduction' to be a strategy that encourages tobacco users who cannot or will not quit to switch to an alternative nicotine-delivery product that is potentially less harmful than their regular product. Recognising that this approach still involves at least nicotine and potentially, tobacco-containing products, TCS prefer an alternative definition of the approach; this being 'nicotine maintenance' strategy.

Allen & Clarke (2003) recognise that product modification strategies constitute a further form of harm-reduction, with these including regulatory measures to reduce the toxicity of tobacco products (e.g. reduced tar and the tar nicotine ratio) as well as their palatability and addictiveness (e.g. removal and control of tobacco-product additives, reduction of nicotine content levels).

5.1.1 Support for Harm-reduction

A core rationale for harm-reduction is that if tobacco products were less toxic, fewer people would die from using these products (Gray & Henningfield, 2004). Warner (2002) accepts that condemning smokers who cannot or will not quit to a premature death is harsh, particularly if viable harm-reduction alternatives to cessation exist. Harm-reduction is also advocated by those who feel that current efforts alone to prevent and treat tobacco use will not solve the smoking problem. This view accepts the position that despite current strategies, there will remain a significant core of individuals unable to quit and that even the most effective treatments or prevention programmes will not reach all smokers. Fox & Cohen (2002) for example, argue that there will be a core group of smokers (often poorer, less educated, with co-morbidity such as mental illness) that would disproportionately benefit from safer products.

Key informants supporting a harm-reduction approach typically base their support on a number of assertions. The assertions include those that follow.

- If tobacco control ultimately aims to reduce death and disease from tobacco products and there continues to be a significant number of people using tobacco, an approach which reduces death and disease without necessarily eliminating tobacco can be viewed as acceptable.
 - If technology exists to reduce harm from tobacco use through harm-reduction initiatives, if evidence exists to prove a positive impact and if harm-reduction strategies can create a true net public health gain, then harm-reduction approaches are acceptable.
 - If harm-reduction strategies can be implemented without undermining the likelihood that someone will quit or start using tobacco, then harm-reduction approaches are acceptable.
-

Key informants supportive of further consideration to harm-reduction justify this position because:

- at the societal level, harm-reduction is unavoidable – all public policy decisions are based on a risk/benefit analysis and the need to achieve a balance between the potential costs and benefits of any decision;
- tobacco industries are pursuing a harm-reduction approach, at least in rhetoric, regardless of tobacco control efforts as this is the only available path to maintaining a strong presence in a market that is increasingly wary of the safety of tobacco products;
- that a ‘quit or die’ approach will not achieve desired outcomes in the desired timeframe;
- that tobacco control strategies must recognise the current and longer term reality of addiction; in this context, an ethical imperative is seen in supporting a harm-reduction approach (e.g. addicted individuals have a right to know about valid harm-reduction options).

“At the level of the individual, for a product for which there is no known safe level of use, no sensible strategy would have as its primary goal to get people to use a less harmful version of the product... rather than trying to get them to stop already. However, as a secondary strategy for those people who can’t stop altogether or who choose not to, minimising the potential risk is a legitimate part of the agenda... conceptually... if you produce a product that is less harmful, you reduce the incentives to stop using it but if that is a rational choice, then it seems to me that this is the best choice you should be allowing people to make. If it is based in part on its dependence properties... and then the cost of quitting because of the dependence makes what would otherwise be a choice you would make into one you don’t make, then you have a problem...” (International key informant)

“[Harm-reduction] is the right way to go for individuals themselves and those around them, it’s more realistic and it is more relevant than the ‘quit or die’ approach – we have gone as far as we can with that approach. We have already started with a harm-reduction approach, NRT, and it’s just a logical extension of that approach” (International key informant)

5.1.2 Reasons for Caution

Scepticism about the value of harm-reduction in tobacco control can be traced back to the failures of early harm-reduction approaches, such as the filter cigarette, the ‘light and mild’ experience and misleading cigarette testing regimes (Gray & Henningfield, 2004). The light cigarette experience has been particularly damaging, with available evidence now indicating that lower-tar and nicotine cigarettes only minimally reduce smokers’ health risks (Slade & Henningfield, 1998). Evidence also shows that such products are likely to have contributed to different forms of cancer (WHO, 2001). The belief by consumers that such products were safer than conventional cigarettes may have also prevented cessation, encouraged initiation and actually led to increased number of smoking-attributable deaths (Slade & Henningfield, 1998).

Key informants identify a potential tension between population and individual level impacts of a harm-reduction approach. Collective harm may be reduced at the population level, while gains may not be substantial or may in fact be negative at the individual level. Alternatively, individual level benefits could be significant, while there could be negative outcomes on a population-wide basis (e.g. greater overall prevalence of tobacco product use).

Fox & Cohen (2002) contend that the claim that tobacco harm-reduction strategies are 'inevitable' invites contention, particularly that this view simply abdicates responsibility for exploring whether a harm-reduction approach is desirable. Pierce (2002) believes that the tobacco industry would like the public health tobacco control movement to adopt a harm-reduction strategy so that the industry could use it to promote its alternate nicotine delivery systems that include tobacco. Olivia (2005) expresses similar concern that harm-reduction creates a 'safe harbour' for tobacco companies and protects their ill-made profits.

For key informants who see the overall goal of tobacco control being an environment free of tobacco products, harm-reduction is considered problematic in that use of tobacco is considered a means to reduce harm. It is felt that under harm-reduction, both tobacco and harm will still exist, even if the tobacco product is different and the harm is reduced.

Similarly, Allen & Clarke (2003) recognise that harm-reduction is problematic when applied to smoking as there is no safe level of tobacco use. These authors also note that it is the length of time tobacco is used, rather than the amount of smoke inhaled, that is the greater predictor of morbidity and mortality from smoking. They are therefore cautious about harm-reduction strategies that envisage long-term, low-level use of smoked tobacco. These authors recognise that abstinence has clear and definite health benefit outcomes, while such outcomes from harm-reduction are uncertain. They advocate that harm-reduction be considered a medium-term option en route to more comprehensive tobacco regulation and that most tobacco control strategies should ultimately seek to eliminate tobacco use (even though total elimination may not ever be possible). Foulds (2005) supports this view of a harm-reduction approach as a strategy, rather than the desired outcome.

A major concern expressed about harm-reduction is its potential impact on undermining tobacco de-normalisation strategies (Oliva 2005). Key informants also note that a harm-reduction approach risks confusing the public about the harms and risks associated with tobacco use. There is concern that a harm-reduction approach potentially dilutes the harm message and may undermine cessation and prevention efforts because of perceived lower or acceptable levels of harm. Hatsukami (2005) states that it is important that harm-reduction and/or the introduction of PREPs does not undermine strategies to change social norms around smoking and that such an approach should not normalise tobacco and nicotine use.

5.1.3 Effective Tools Already Exist

Some authors feel a harm-reduction approach is not justified, believing that appropriate and effective tools for reducing tobacco harm already exist (Fiore et al, 2000 cited in Fox & Cohen, 2002). The problem is re-positioned as not a lack of effective tools, but rather as a failure to apply existing tools sufficiently, particularly cessation and prevention programmes. Fox & Cohen (2002) see this view supported by evidence that adult tobacco cessation treatment is among the most effective, cost-effective, yet under-utilised prevention intervention (Coffield et al, 2001 cited in Fox & Cohen, 2002). These authors are particularly concerned that harm-reduction strategies are not delivered at the expense of delivering cessation and prevention programmes already known to be effective. In this regard, Fox & Cohen (2002) question whether it is ethical to invest time, energy, and resources to harm-reduction.

Husten (2005) also raises the possibility that the case for harm-reduction may be based on a false premise; this being that all proven alternatives to tobacco control have been fully exploited. She argues it is debatable as to whether the public health community has done everything it can with current initiatives which focus on cessation support and preventing uptake. Until these proven methods are effectively funded and implemented on a national scale, so as to fully exploit these methods, Husten argues that a harm-reduction approach should not be implemented. While this view is shared by some key informants, another view is that while it can be accepted that sufficient resources have not been invested into cessation and prevention, it is important to ask whether these measures will ever achieve zero use of tobacco. This view contends that if this is unlikely, then harm-reduction approaches can be justified in this context.

The California tobacco control model provides an example of a well-funded de-normalisation strategy that achieves results. The strategy focuses on adults rather than youth on the premise that through changing this group you can impact on youth as they will not grow up in an environment that accepts tobacco and nicotine use as normal (Oliva 2005). Supporters of the California approach contend that if appropriate and effective de-normalisation strategies were to be adopted and fully funded in other localities, then the need for a harm-reduction approach would be drastically reduced.

5.1.4 A New Era of Harm-reduction

With the rapid development of PREPs and the need for regulatory control over such products, Warner (2002) contends that until such products are banned outright or until manufacturers give up on developing alternative products, a new era of tobacco harm-reduction must be accepted. While the failures of previous harm-reduction strategies provide reason for caution, Warner does not accept this as reason to do nothing; particularly while significant numbers of people remain addicted to cigarette smoking and exposed to resulting harms. Foulds (2005) also supports this view.

Borland (2003) points out that the previous failures of harm-reduction occurred without appropriate regulation and that a continued failure to regulate effectively is the surest way to repeat the past mistakes. He sees even the possibility of less harmful products as a key reason for needing a comprehensive regulatory framework.

Warner (2002) believes there are grounds for cautious optimism that new approaches to harm-reduction might actually deliver real reductions in harm. He provides NRT as an example of an alternative product that is safe and has low risk of excess use. He sees an ideal harm-reduction approach providing a range of products such that every smoker who cannot or will not quit smoking would be able to switch to the least hazardous product that meets their needs. Further, any smoker who is able and willing to quit would do so, rather than use a PREP. There is some support amongst key informants of this view, as well as the view that a harm-reduction approach should only be targeted at smokers who cannot or will not stop smoking despite full efforts and funding of cessation programmes.

5.1.5 Harm-reduction and the Importance of a Regulatory Framework

There is wide agreement amongst key informants that an appropriate regulatory framework is first required before harm-reduction strategies are considered. Any regulatory authority that permits harm-reduction claims must also have the authority and ability to monitor the impact of these approaches (e.g. who is using the products, what impact on cessation, what long-term impacts on behaviour etc). Harm-reduction is considered problematic if unregulated commercial interests or imperatives are allowed into the market.

There is a view that any regulatory change to accept harm-reduction approaches will require very careful consideration and policy development. Introduction of products such as snus before such time, potentially introduces many additional problems (as was evidenced in the 'light and mild' experience). Moving towards eliminating smoked tobacco is also considered potentially risky without appropriate regulation and controls in place.

5.1.6 New Zealand Considerations

Key informants acknowledge the need for further debate about the appropriateness of a harm-reduction approach within New Zealand tobacco control. Whether harm-reduction is considered an end point or a strategy to reach desired goals requires discussion, as does agreement on terms and definitions. Establishing overall goals for tobacco control in New Zealand is seen as critical in the overall debate.

"... [to date] we have called our programme Smoke-free New Zealand but actually what we have been aiming for is tobacco free... and actually it is incongruous because... tobacco [was included] in the past in our previous national drug policy and it is in the current one...which is firmly about harm-reduction... and yet we haven't thought about what harm-reduction might like look in terms of tobacco and we now have to confront that issue and find a constructive way forward..." (New Zealand key informant)

Key informants also acknowledge the importance of decisions about harm-reduction being based on evidence rather than fear or myth about potential positive or negative impacts. Development of such an evidence base is considered by some to be critical in moving forward on the issue.

The potential for harm-reduction to undermine de-normalisation strategies is a key issue in the New Zealand context. Key informants particularly recognise that much still needs to be done to de-normalise tobacco use in both Maori and Pacific communities. In both communities, where smoking prevalence is particularly high, real risks are seen in harm-reduction resulting in further acceptance and use of tobacco products rather than further reductions.

5.2 Potential Reduced-Exposure Products (PREPs)

5.2.1 Introduction

For this study PREPs are defined to include modified combustible tobacco products (e.g. reduced combustion or 'heated' cigarettes, low nitrosamine cigarettes, low polyaromatic hydrocarbon content cigarettes), non-combustible tobacco products (e.g. snus) and nicotine pharmaceuticals (e.g. NRT). Other novel tobacco products (e.g. kreteks, bidis, cigarettes, and nicotine water) can also be considered as PREPs; however, these are not directly discussed.

The term PREP reflects acceptance that with the current knowledge base, it is impossible to categorically say that any existing PREP is harm-reducing. The term acknowledges that ascertainment of exposure reduction is likely to be the greatest level of certainty that will be achieved for the foreseeable future. Giovino (2005) draws an important distinction between risk and exposure. Reduced exposure to tobacco smoke does not ensure reduced risk or necessarily reduced harm to the population. He therefore asserts that PREPs may reduce exposures to toxins without reducing overall disease risk.

Not all PREPs are considered equal and Hatsukami (2005) describes a continuum of potential harm from PREPs. Hatsukami sees modified cigarettes and cigarette-like nicotine delivery products as extremely hazardous and unlikely to lead to any substantial reduction in harm. Smokeless tobacco products, because they do not have any combustion associated with them, are seen as likely to be less hazardous than cigarettes while medicinal nicotine, with its single constituent, is seen as likely to produce the least harm.

Key informants also recognise that different PREPs are likely to provide different levels of reduced exposure and risk. It is agreed that PREPs, particularly modified cigarette-like products involving combustion, are unlikely to significantly reduce harm to an acceptable level. For example, it is recognised that there is a lack of scientific evidence to show that removing or changing cigarette components will reduce harm and that it is almost impossible to understand how and why modifications may or may not have certain outcomes.

"We may fiddle with the cigarette to potentially reduce one ingredient, but it is such a soup of potentially toxic substances so intimate to the body, delivered so effectively to such a large part of the body, it is just very difficult to see how you would quickly and confidently identify a safe product". (New Zealand key informant)

5.3 Caution about PREPs

5.3.1 Historical Failure

The past failures of early products marketed as harm-reducing (e.g. light cigarettes) and increasing evidence that these products have added to rather than reduced tobacco-related harms, is a common justification to be cautious about PREPs (Slade & Henningfield, 1998; Gray & Henningfield, 2004).

There is concern that the introduction of PREPs will invariably mislead the public in the same way as 'light' and 'mild' cigarettes (e.g. reduced exposure will be interpreted to mean reduced risk). Giovino (2005) argues that PREPs should not be allowed to enter the market unless they demonstrably reduce overall disease risk (see later discussion).

5.3.2 Tobacco Industry Involvement

That the development and regulation of PREPs will inevitably involve some form of relationship and collaboration between the public health community and the tobacco industry is of concern for some authors (Fox & Cohen, 2002) as well as some key informants. Slade & Henningfield (1998) see the past actions and denials of the tobacco industry as creating a difficult environment from within which to conduct any productive discussion with the industry.

Concerns about collaboration can reflect a belief that tobacco company motives for developing PREPs will likely conflict with public health goals and motives. For example, Fox & Cohen (2002) see core drivers for industry involvement likely to include the desire to improve public relations, to avoid future litigation, and to achieve market advantage over competitors through manufacturing and claiming safer products. The authors believe that any collaboration, complicity, or acquiescence with the industry risks increasing the industry's credibility which in turn may make it harder to oppose industry efforts in the future. Fox & Cohen voice similar concerns about the involvement of the pharmaceutical industry in providing alternative nicotine products, seeing potential for the profit motive and business ethic to conflict with a public health ethic (e.g. products may be developed that reduce harm but do not promote cessation).

Borland (2003) recognises that tobacco companies are forced, rather than necessarily wanting, to search for less harmful products. He notes that tobacco companies receive little benefit from killing half their long-term customers and that without less harmful products face the dilemma that to keep making money, they have to continue to cause harm. Pierce (2002) also warns that tobacco industry interest in harm-reduction is likely to be driven by a desire to maintain profits. He cautions that there is currently little scientific basis for concluding that the new 'harm-reduction' products will reduce risk for disease compared to conventional tobacco products.

Despite their concerns and suspicions, Fox & Cohen (2002) recognise that a view of the tobacco industry as beyond redemption may be faulty and a risky assumption. If the industry does change and the tobacco control community is not prepared to deal with this, they feel the tobacco control community risks losing credibility. It is also recognised that censorship of the industry could marginalise the tobacco control community and further erode credibility.

5.3.3 Resultant Excess Use

There is concern about the potential of PREPs to result in excess use; that is the use of PREPs by people who otherwise would have been tobacco product and PREP free. A key concern is that PREPs have the potential to create new beliefs about reduced harms or risks from smoking (Warner, 2002; Slade and Henningfield, 1998).

Related concerns include that PREPs may:

- diminish the pool of smokers who will eventually quit nicotine entirely (i.e. smokers may switch to a PREP instead of quitting);
- keep consumers in the nicotine market longer than otherwise (i.e. would have quit in the absence of PREPs);
- encourage former smokers to resume using a PREP;
- encourage new consumers of PREPs who otherwise would not have become addicted (e.g. through believing health-related risks have been significantly reduced);
- initiate new generations of nicotine dependency;
- introduce unforeseen hazards in the form of new toxic exposures.

5.3.4 Difficulty Meeting Consumer Demand

Warner (2002) recognises potential difficulties in PREPs meeting consumer demand. He contends that the less similar the delivery of chemicals by PREPs is to conventional cigarettes, the less likely the PREP will be satisfying to consumers. Stapleton et al (cited in Phillips 2001) notes failed uptake of Premier, a reduced combustion cigarette, due to unpleasant taste and low nicotine levels. Therefore a modified conventional cigarette, providing only modest harm-reduction may be the only acceptable alternative (while risking excess use), while a high-dose nicotine inhaler may provide substantial harm-reduction benefits, yet may fail to encourage sufficient numbers of users in order to significantly reduce harm.

Key informants also question consumer acceptability and whether levels of uptake will be sufficient to lead to significant reduction in harm. There is a view that smokers would rather quit smoking altogether than switch to a safer tobacco product that maintains addiction. In this context, the introduction of PREPs can be considered of limited value.

“...what all this [the failure of Eclipse and Accord in the US] tells me... [is that] there actually isn't huge consumer demand for reduced risk nicotine products, or even in circumstances where people are perfectly free to create such demand, no demand has arisen, no one has been successful in doing it.” (International key informant)

5.3.5 Education Difficulties

Warner (2002) sees significant challenges in educating health professionals and the general public about PREPs so that they will respond appropriately to these products. He observes that even in relatively uncomplicated situations, health professionals often given poor advice, or no advice at all (e.g. as in the case of doctors who fail to counsel their smoking patients to quit). New Zealand key informants see similar issues in New Zealand and feel that more could be done to encourage and support smoking cessation, particularly at the primary health care level.

Educating the public about PREPs could constitute even more significant difficulties in this context. Evidence suggests that many smokers still only have limited appreciation of the dangers of smoking,

underestimate their smoking-related mortality risk and are unaware of the multiple disease risks from smoking beyond lung and heart disease (Stratton et al, 2001; Warner, 2002). Warner sees addressing such knowledge gaps as challenging enough, let alone educating about complicated harm-reduction in an environment likely to be made even more complex by the marketing and promotion strategies (regulated or not) of PREP manufacturers.

There is also a view amongst key informants that there is risk that PREPs re-educate the public to believe that there exist tobacco products which offer acceptable levels of risk and that this undermines public health messages to prevent initiation and encourage smoking cessation.

5.4 Nicotine Replacement Therapy

There is considerable support in the literature for the place of Nicotine Replacement Therapy (NRT) within a tobacco product regulatory framework. Using regulation to expand the use and accessibility of NRT is supported; however, some concerns and cautions about the efficacy and value of NRT are expressed.

5.4.1 Support for NRT

NRT delivers no smoke or tobacco toxins except nicotine to the user and the case for NRT recognises that not all PREPs are equal in terms of their harm-reducing potential. Some PREPs such as NRT are widely considered to be demonstrably less hazardous to health when used strictly instead of smoking.

Evidence of Reduced Harm

While accepting that further research is needed, Kozlowski, (2002) believes the toxicology and epidemiology of NRT are currently well enough understood to be confident that NRT is substantially less dangerous than cigarettes. On current evidence, NRT appears to reduce risk in comparison with cigarettes by close to 100 percent (Kozlowski, Strasser, Giovino et al, 2001 cited in Kozlowski, 2002). NRT has been demonstrated to carry little excess cardiovascular risk (Kimmel et al, 2001; Benowitz, & Gourlay, 1997 cited in Kozlowski, 2002), even in heart patients (Rennard, Daughton, & Windle, 1998 cited in Kozlowski, 2002) and no risks of oral cancer, lung cancer, or respiratory disease (Greenland et al., 1998 cited in Kozlowski, 2002). Longitudinal studies have shown longer term use to be unrelated to cardiovascular disease or other serious health impacts (Murray & Daniels, 1998 cited in Kozlowski, 2002). Warner (2002) also notes that even when used longer-term, NRT is likely to pose relatively little risk, except during pregnancy.

Some questions remain about the risk potential of NRT from substantive long-term use and particularly in regard to cardiovascular disease (Kozlowski, 2002; West, 2000). While nicotine is a neurotoxin, both Kozlowski (2002) and West (2000) see NRT providing a vastly safer way of delivering nicotine compared to cigarettes and feel that any risks would never come close to the dangers of cigarettes.

Using risk-use equilibrium analysis, Kozlowski et al (2001) show that NRT offers a huge reduction in risk compared to smoking cigarettes, while posing little risk of uptake amongst otherwise tobacco-free people. Indeed, the low abuse liability and dependence potential of NRT is commonly recognised as an important benefit and reason to increase its accessibility and acceptability (Shiffman, Gitchell, Pinney, Burton, Kemper, & Lara, 1997 cited in West, 2000).

Kozlowski (2002) argues that smokers should be clearly informed of the reduced risk of NRT, and that using NRT is preferable to continued smoking. However, he also stresses that smokers should concurrently be informed that:

- never starting smoking and completely quitting smoking as soon as possible are the best choices to promote health;
- NRT should be used as a complete substitute rather than mixing it with continued smoking.

Role in Assisting Cessation

West (2000) notes that the health benefits associated with smoking cessation are well established and therefore, a key way to reduce overall tobacco-related harm is to increase cessation. Citing evidence that NRT approximately doubles successful smoking cessation rates compared to willpower alone (Silagy, Mant, Fowler & Lancaster, 1997 cited in West, 2000), West argues that there is sufficient evidence to encourage and support as many smokers as possible to use NRT during their cessation attempts.

West (2000) acknowledges concerns that increased access to NRT may risk reducing motivation to quit, particularly if NRT is promoted as enabling reduced consumption and that smokers believe this brings risks to within acceptable limits. However, he cites evidence (Fagerstrom, Tejding, Westin & Lunell, 1997 cited in West, 2000) which show an increase rather than decrease in motivation to quit as a result of decreased consumption (i.e. NRT helps to reduce consumption with this outcome in turn leading to increased confidence that quitting is possible).

Potential Long-Term Use

Longer-term use of NRT post-cessation is another direction considered by some key informants to be worthy of further exploration. Informants working in cessation report that for smokers who find it most difficult to quit, long-term NRT may be the best alternative in terms of getting them to stop smoking as soon as possible. In order to develop longer-term use of NRT as a viable alternative to smoking, some modifications (not only in terms of marketing and positioning) to the product itself may be required.

“The current NRT products aren’t really made for people who need something longer term – they are made for [short-term] cessation, yet there are people out there, using them long term. There is a market out there for long-term nicotine products. We need to accept the fact that not everyone can give up short term”. (International key informant)

“I think [products like NRT and smokeless] can do less good if we reserve them only for cessation. If we could instead use these products to compete with smoked tobacco and then venture into this much bigger market, they would do more to reduce tobacco-related harm to the society, but for this to happen, smokers would need to see improved products...” (International key informant)

“One of things about existing NRT products is that they are fit for purpose, in other words, they are there as nicotine replacements to assist cessation, as opposed to being another means by which you can get a nicotine hit... so they would be different products and it would be a very different purpose for those products and again you would be thinking, ‘what is the role of making a nicotine hit available... not as a way primarily of assisting people to give up smoking... but as a way of making people shift their nicotine delivery device, from one which is very harmful to one which is probably of a very low level of harm’. So it is a philosophical shift and a fundamental change in the purpose of those products...” (New Zealand key informant)

New NRT Products

NRT products that meet the distinct physiological needs of each sub-group of smokers may also need to be considered and developed to ensure effective uptake, particularly among Maori and Pacific populations in New Zealand.

New, faster acting, stronger NRT products may also be required. There is a view amongst key informants that NRT may have inherent limitations in the absence of tobacco from the product. For example, evidence is cited that the interaction of nicotine with tobacco may be more addictive than solely nicotine. In such instances, smokeless tobacco such as snus may prove to be more attractive to smokers as an alternative (see later discussion).

Education

Key informants identify a need to improve public and in particular, smokers’ understanding of NRT. Misconceptions about nicotine are perceived to be common, for example, that it is the nicotine in cigarettes that causes harm, rather than tobacco.

Taxation and Pricing

There is a view that regulation should be used to reduce the retail price of NRT such that tobacco products lose their competitive advantage, and that smokers have a price incentive to switch to NRT.

5.4.2 Cautions about NRT

NRT Evidence Not Certain

Pierce (2002) considers that the evidence for NRT is not fully convincing. Consumer acceptance and uptake is considered problematic, with some studies showing limited use of NRT by smokers attempting to quit (Gilpin et al., 2001 cited in Pierce, 2002). He reports little evidence that NRT increases long-term

effectiveness of quitting, nor that smokers continue to use NRT after relapse as a way of reducing consumption. Shu-Hong Zhu (2005) also argues that NRT helps only a minority of smokers quit, and that most smokers will quit without NRT.

Hatsukami et al (2002) also note the need for further research to definitively determine the feasibility and safety of long-term medicinal nicotine use.

The low use of NRT by smokers is attributed by some to deficiencies in how the product is targeted and marketed. Cummings (2005) argues that there is disconnection between the marketing focus and methods of the tobacco industry and that of the public health community. He argues that the current public health approach to marketing creates a 'catch 22 of harm-reduction' whereby health and marketing campaigns appeal to those who are least likely to benefit from switching (older, health-concerned smokers). Instead, public health campaigns should directly target those of priority to the tobacco industry: younger, heavy smokers who are not thinking about quitting. Cummings (2005) sees the need to make NRT more attractive than cigarettes through targeted marketing and product development. He suggests increased, more appropriate marketing, free samples through the Quitline, and improved products to make NRT 'less medicine and more fun' (e.g. tastier gum, designer patches).

Other reasons seen by Cummings (2005) for low use of NRT by smokers include:

- limited access (too expensive and less available than cigarettes);
- misconceptions about nicotine (especially with regards to safety);
- lack of knowledge about how to use NRT and how it works.

Nature of Addiction Uncertain

While nicotine is generally accepted as the main tobacco constituent associated with addiction, questions are increasingly being asked about how many other constituents also play a role (Stratton et al, 2001). It is also recognised that the development of strong psychological and environmental associations with stimuli coincident with smoking behaviour and the development of expectancies regarding the use and effects of tobacco, can also contribute to addiction (Pierce, 2002; Shu-Hong Zhu 2005). Pierce (2002) sees this providing reason for caution and warns that we should not simply assume that smokers will be willing and able to substitute NRT or other nicotine replacement products for smoking.

Cautions against Increased Promotion

Pierce (2005), cautions against the over-promotion of NRT, seeing this as potentially increasing smoking by leading consumers to believe that quitting is easy. He also stresses the importance of regulating NRT product claims in terms of effectiveness so that consumers have a realistic view of what can be achieved using NRT. It is perceived that NRT product claims can mislead the consumer about the ease of quitting, thereby setting the smoker up for failure. For example, an over reliance on NRT may reduce smokers' acceptance of other supports, will power and motivation required to successfully quit.

Shu-Hong Zhu (2005) also argues that the effectiveness of NRT was drastically reduced once it was made available over the counter in California. She argues that when use is less monitored, consumers start to use the product incorrectly or less effectively (e.g. patches are applied incorrectly, cut in half or not worn long enough). She argues therefore that the effectiveness of NRT rests, at least in part, on the support and guidance provided to consumers about its use and that this should preferably be provided through primary health care providers.

Key informants recognise that greater access to NRT may potentially lead to some unintended or possibly negative outcomes (e.g. potential to lead to addiction, uptake by populations not currently using nicotine products, possible function as a gateway drug, other negative health impacts). There is a view, however, that such outcomes are likely to be minimal and are acceptable in terms of reducing overall harm to health.

5.4.3 Regulatory Frameworks for NRT

Key informants acknowledge that current regulatory constraints surrounding NRT are important for preventing potential abuse of the product and ensuring safety. However, it is also recognised that in the context of unregulated smoked tobacco, the current regulatory imbalance dilutes the purpose and effectiveness of NRT as a tool for reducing harm to health caused by tobacco.

As such, whilst informants agree that NRT should continue to be regulated, there is a view that regulations should be modified so that NRT is not disadvantaged against smoked tobacco.

There is a view among key informants that regulation should be used to encourage greater access to and acceptability of NRT. The availability of NRT at supermarkets and over the counter is considered positive and it is noted that NRT is more available in New Zealand than in many other countries. There is, however, recognition that the uptake and use of NRT remains lower than desired around the world.

There is support for using regulation to increase uptake and use of NRT:

- as a quitting tool, with short-term use leading to complete cessation;
- in addition to tobacco, as a tool that may be used by smokers to cut back on cigarettes;
- as a long-term replacement for smoked tobacco.

The positioning of NRT as a medicine to assist cessation rather than as a direct, preferred alternative to tobacco is considered problematic by some, particularly in regard to encouraging greater access and uptake.

“NRT is not as readily available as tobacco. You can get hold of tobacco 24/7 because it’s available at garages, but you can’t get hold of NRT in the same way. NRT needs to be positioned as an alternative to smoking, sold and available alongside smoking and not aligned with medicines”. (International key informant)

“...we have a very medicalised view of NRT... you are selling pleasure when you are selling cigarettes and you sell medicine when you sell NRT... you are at a competitive disadvantage there...” (International key informant)

West (2000) observes a lack of uniformity between countries as to how NRT is regulated and sees a need to convince regulators that access to NRT should be widened. Sweanor (2000) supports further education of regulatory authorities about the role and place of NRT, including that tobacco products should be seen as part of the nicotine market and that NRT is replacing an existing product.

Other identified roles for regulation in achieving increased availability and access to NRT include:

- regulatory systems that approve NRT products more rapidly (e.g. (Sweanor, 2000));
- greater consistency between countries in relation to regulation and approval processes (Sweanor, 2000);
- greater over-the-counter/general sales access to NRT through pharmacists, supermarkets and other outlets (West, 2000);
- increasing the range of approved indications for NRT supply to include control of withdrawal symptoms during enforced abstinence (symptom relief) and as an aid to smoking reduction (primary or secondary prevention) (West, 2000).

5.5 Snus

Snus (also known as snuff) is an oral, moist smokeless tobacco product that is manufactured and mainly consumed in Sweden and Norway. Whilst not widely used outside of these areas, snus is available in the USA and Canada. Snus is used by placing it under the upper lip and keeping it there for a time varying from a few minutes to several hours, according to taste (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

There are two main types of snus currently available in those markets where it is permitted.

- Original snus or lössnus is a loose, moist powder which can be portioned and rolled into a cylindrical shape with the fingertips, or using a prismaster tool. The end result is often referred to as a pris (pinch) or prilla or prell (slang for pris).
- Portionssnus is pre-packaged powder in small bags made from the same material as teabags. It comes in smaller quantities than the loose powder but is considered easier to handle (and expectorate) than the loose powder (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

At the present time, the sale and importation of snus is prohibited in New Zealand. Section 29 of the Smoke-free Environments Act 1990 bans the importation for 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. Allen & Clarke (2003) report that annual tobacco company returns and customs entries indicate that no snus is currently sold in New Zealand.

5.5.1 Support for Snus

Lung cancer and respiratory disease are reported to account for around half of all deaths from combustible tobacco (English et al, 1995, cited in Kozlowski, 2002; Peto, et al, 1994, cited in Kozlowski, 2002). Snus therefore may provide a safer alternative to smoking for existing tobacco users because it does not involve combustion of tobacco or inhalation of smoke. In addition, snus is lower than other moist snuffs in known toxins (N-nitrosamines and polynuclear aromatic hydrocarbons) (Ramström, 2000 cited in Kozlowski, 2002).

Snus and smokeless tobacco products have been shown to dramatically reduce tobacco-related harm at both the individual and population level when compared with combustible tobacco products (Ramström, 2000; Henningfield & Fagerström, 2001 cited in Kozlowski, 2002). Kozlowski (2002) notes that as about half of cigarette deaths arise from lung cancer and respiratory disease and “since smokeless products are not otherwise more dangerous than cigarettes, smokefree tobacco products can be estimated to reduce mortality by at least half because they do not cause lung cancer or respiratory disease” (pg 56).

While acknowledging that findings are mixed as to whether snus contributes to cardiovascular disease and recognising that further research is needed, Kozlowski (2002) believes that the toxicology and epidemiology of snus is well enough understood at present to be confident that snus is substantially less dangerous than cigarettes. Kozlowski argues that smokers should be informed that snus would be preferable to continued smoking, while also fully informing smokers that never starting and quitting as soon as possible are ultimately the best choices to promote health. Smokers should also be informed that complete substitution of snus is preferable over mixing it with continued smoking.

Based on the premise of right to information and using snus (Swedish moist snuff) and medicinal nicotine as examples, Kozlowski (2002) argues that based on the present evidence these products offer significant reductions in health risk to individual smokers and, in the absence of clear evidence about public health harm, suspending advice about reduced individual risk from these products is unjustified.

There is acceptance amongst key informants that on the face of current medical evidence, snus is significantly less harmful than smoked tobacco; for both the user and those around the user. There is a view that snus provides an option for tobacco control that should be considered and further explored. It is also noted that snus may be a more attractive product to consumers than NRT through addressing limitations inherent in NRT. For example, it is recognised that cigarette addiction is caused by tobacco substances and processes above and beyond nicotine and that snus contains other tobacco contents known to contribute to addiction.

“It’s not just about the risk to the smoker either – smokeless tobacco reduces the risks of SHS. The biggest passive smoking risk is in the home – that is the one place that we have not been able to get to in terms of regulation, you can do social marketing, but you could change the source of nicotine and protect children – this is a major health gain” (International key informant).

“If it was the case that you could say that the harms associated with long-term smokeless tobacco use were freely chosen, then you could say that exposing say 30% of the population to small harm compared to 20% of the

population to a huge harm, in population health that's a no-brainer, but because you have got more people exposed and in a sense dependent upon it and... its not a completely free choice they are making, then there is a legitimate dilemma there... so you would want to be discouraging any use of smokeless tobacco while it has any identifiable harm. All the evidence I have seen is that smokeless tobacco is no harder to quit than smoked tobacco and what theory exists would all point to it being easier to quit, not easy, but easier than smoked. If it were harder to quit and locked you in much more tightly, that would be a problem..."(International key informant).

However, there is also a view amongst key informants that we should be cautious about seeking 'magic bullet' cures in tobacco control. The apparent simplicity of arguments supporting snus is seen as an example of simplistic thinking and as potentially ignoring the complexities of tobacco control.

5.5.2 Cautions about Snus

Health Risks

The use of snus is not considered to be completely risk free and some harm to health, albeit marginal when compared to the harm caused by combustible products, is possible. Evidence as to the nature of this cost is limited and the literature presents mixed views on this account.

There is continuing debate about whether there is sufficient evidence to make conclusions about the cancer risks of snus use. Allen & Clarke Policy and Regulatory Specialists (2003) report that the World Health Organization and Surgeon-General (USA) have stated that snus is a cause of mouth cancer amongst users. Among its recent recommendations, WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) 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 cited in Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

Foulds (2005) identifies snus as having the following health effects:

- causes and maintains nicotine addiction;
- causes oral lesions/gum recession (only some of which is reversible); but does not cause oral, gastric, or head/neck cancer;
- may increase cardiovascular risks (but less than cigarettes);
- is harmful to the fetus, but less than cigarettes;
- does not cause respiratory disease or lung cancer.

According to a report from the Institute of Environmental Medicine at the University of Stockholm, snus use does not conclusively increase the risk for cancer over non-tobacco users. Despite high rates of snus use

in Sweden, oral cancer rates are lower than international averages (Ramström 2000). Kozłowski (2002) also cites evidence that the use of snus in Sweden has generally not been associated with oral cavity cancer or increased risk for squamous cancer of the head and neck.

There is a view amongst key informants that snus is still a tobacco product, is produced predominantly by tobacco companies and still causes some harm to health and remains addictive. In line with this view, a European key informant reports that it is likely that the European Union will continue to support a ban on snus because:

- it is a tobacco product, produced by tobacco companies and is a product which creates dependence;
- it is not completely harmless;
- it is unclear how consumers in other countries will respond to or use snus and what impact it would have on smoking prevalence and consumption.

The Swedish Experience

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 (Ramström, 2000 cited in Kozłowski, 2002). However, Tomar (2005) suggests there is little evidence from Sweden to support snus as a cessation aide. He attributes increased uptake of snus to youth (particularly young males) and not smokers giving up cigarettes. Uptake of snus is also reported to be concentrated among youth in the USA. However, it is known that marketing strategies in the USA have used snuff to successfully target and hook young people on tobacco use (Tomar 2005). 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. Data from the USA show that boys tend to graduate from snuff to smoking when they start dating (Connolly 2000b cited in Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

It is also noted by an International key informant that there remains a significant proportion of smoked tobacco users in Sweden. This situation is seen as likely partially explained by Sweden never having promoted snus as less harmful than smoked tobacco or never having implemented a set of policies aimed at encouraging a switch from smoked tobacco. This situation is seen as leaving unanswered questions about introducing snus into other markets and some doubt about its potential.

“...and in the absence of [a higher level of transfer to snus in Sweden] it is speculative as to what extent you would be able to achieve that and whether the levers you would need to do that are acceptable or whether they would create such ill will and such a significant black market in cigarettes that it wouldn't really be worth the fight...” (International key informant)

Low uptake of snus among females (resulting in an unequal distribution of reduced harm) in Sweden is also noted and seen as a further reason for caution.

Questions over Acceptability

The use of snus is considered to have deep historic roots in Swedish culture. Other countries such as the US and Canada, where there has been no historical association with the product have had lower uptake.

It is noted that the experience of smoking a cigarette is vastly different from using snus and in this way snus may be unacceptable to smokers. Some key informants stress that those with ambitions to reduce harm through use of snus need to be aware of the possibility that this product may be unacceptable to smokers.

“...in parts of the world where snus is allowed outside Sweden, smokers aren’t transferring... if you put it on the market I think you discover it neither meets the fears or the hopes of people, it just kind of sits there, more junk at the counter. Some percentage of people actually use it but the actual reduction of harm done to a population isn’t measurable.” (International key informant)

“...we are talking about deeply cultural things here... so I think one shouldn’t expect things to be very, very different within a 5- to 10-year period. This is like changing eating habits, it doesn’t come overnight, but nevertheless, New Zealand is an interesting prospect here...” (International key informant)

Addressing Addiction

Some informants are concerned that the introduction of snus will not initially address nicotine addiction and in fact may contribute to increasing levels of addiction. There is concern that addiction is a particular consideration and issue for ‘at risk’ populations. Others contend that accepting snus requires accepting that snus first needs to be considered as a tool for addressing smoking-related mortality and that addiction issues can be addressed later.

Increased Access to Tobacco Products

Introducing another tobacco product, albeit a safer product, introduces the potential of making tobacco more readily available. This is problematic for those who consider a key goal of tobacco control being to reduce the overall accessibility of tobacco products.

Potential Diversion of Focus

There is concern that the provision of snus potentially diverts attention from existing efforts to prevent initiation and encourage cessation as well as addressing the de-normalisation of smoking, especially among ‘at risk’ smoking populations.

5.5.3 Regulatory Control of Snus

Key informants are unanimous that any introduction of snus should occur only after strict regulatory controls are in place to manage, shape and if necessary modify (e.g. as appropriate evidence becomes

available) its use in the market. The need for rigorous clinical trials to determine the impact and effects of snus is commonly identified prior to any introduction.

Position in the Market

There is some support for erring on the side of caution and introducing snus only as a medicine, similar to NRT (e.g. as a quitting tool only). Such positioning is viewed as potentially less damaging to existing tobacco harm messages and less likely to lead to use based on perceptions of acceptable levels of harm (e.g. less likely to result in uptake by people who would not have otherwise used tobacco products, less likely to encourage past smokers from using again).

“...need reasonably rigorous stands for safety and reasonably rigorous standards for demonstrating that it can be marketed in such a way so that it will be used either as a path for quitting or as a substitute for people who truly want to quit but who are unable to do so. If snus leads more people to start using tobacco or fewer people who want to quit, the product may reduce the risk of disease to the particular user and may increase the risk of disease to the population... I don't think I should make the sort of determination... that sort of determination should be made by a rigorous scientific agency...” (International key informant)

There is alternative support for positioning snus alongside combustible tobacco products and marketing it as a safer, more desirable alternative to smoking (rather than simply a cessation aid). This is considered an important strategy for encouraging appropriate levels of consumer uptake, particularly if the goal is to get people off smoked tobacco as quickly as possible. This view rests on the proposition that the more attractive the nicotine replacement product is to consumers, the more likely smokers will switch and the more quickly they will do so.

There is a view that snus will likely require additional marketing to increase consumer awareness and preference so that there is sufficient uptake to result in harm-reduction. However, the need for strict controls over marketing is recognised. One suggestion is that promotion should only be targeted to current smokers (although this may be particularly difficult to achieve if the product is not positioned as a cessation aid).

To encourage consumer transfer, some informants also see the need for regulatory control to provide incentives for snus and disincentives for smoked tobacco. Use of pricing policy and continued restrictions on the accessibility and availability of smoked tobacco are suggested.

Other regulatory controls suggested include:

- regulation to control the nature of the product – it is recognised that not all snus is the same (e.g. some forms of snus in the US market are reported to have been modified to bring the product closer to existing, more dangerous smokeless products in order to appeal to US tastes);
 - control of marketing to prevent it becoming a gateway product;
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- Ongoing post market surveillance to ensure that any adverse impacts are identified promptly and can be addressed;
- the need to consider the requirements for price subsidies to ensure that on price, snus competes favourably and doesn't contribute to further social inequity in terms of who can afford to use the product.

5.5.4 New Zealand Considerations

Key informants raise many questions (see below) which would need to be investigated and/or debated prior to further steps to introduce snus to New Zealand. It is suggested by informants that these questions provide a starting point for debate on whether or not snus provides an appropriate and desirable option.

There is also a New Zealand view that the issue of snus can only be considered in the context of wider discussion and policy development on the potential of harm-reduction within the New Zealand context. This would include further consideration of the potential of snus as well as other forms of nicotine delivery within an overall harm-reduction approach.

There is a further New Zealand view that a very clear and purposeful research agenda is required for snus with the objective of answering key questions associated with its possible introduction and requisite policy development.

Questions raised by informants for discussion and consideration include:

- What are the likely population impacts and harms of introducing snus? What is the potential for people who would not otherwise have smoked taking up snus? What level of such uptake is acceptable in New Zealand?
- How will Maori and particularly Maori females, respond to and use snus? (see later discussion)
- What message will snus send about tobacco products in general?
- Who in New Zealand will use snus? How will they use it? Will it be used to satisfy addiction when smoking inside is not possible (as a result of SFE Act)? Is long term and continued use of snus acceptable?
- Will smokers completely replace cigarettes with snus or will smokers use both snus and smoked tobacco?
- What impact will snus have on youth uptake and youth smoking? Will it act as a gateway to smoking?

Allen & Clarke (2003) have previously recognised the possibility of legalising snus as a harm-reduction alternative to smoked tobacco in New Zealand. However, they also raise a number of issues needing further consideration should this option be developed further. These include that:

- any harm-reduction benefits of snus use would require substantial numbers of smokers to switch to snus, which has no recent history of use in New Zealand;
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- harm-reduction would be defeated if people who would otherwise not have become tobacco users are attracted to use snus. This risk may be heightened if snus is shown to be, believed or implied to be, significantly less harmful than tobacco smoking;
- it would be necessary to ensure that the form of snus used is as harmless as possible and manufactured to the highest standard (Allen & Clarke Policy and Regulatory Specialists Limited, 2003).

Concerns for Maori

The potential for dual use of snus and smoked tobacco is recognised by informants and a New Zealand informant sees this as a particular risk for Maori. During the process of phasing out tobacco, it is recognised that both snus and smoked tobacco would need to be available as the community would not initially accept the complete removal of cigarettes. In this environment it is felt that Maori may be more likely to use both products and that this risks more Maori becoming addicted to nicotine. It is also recognised that dual use could be used to maintain nicotine addiction in the face of smoking restrictions under the SFE Act and that the legislation could in itself encourage people to use snus.

In response to these concerns, there is an alternative view that society may need to initially accept some level of dual use if the end result is an overall reduction in harm.

There is also a view that snus or other PREPs risk diverting attention from providing Maori with accessible, affordable and effective nicotine treatments to help them quit smoking. A New Zealand key informant reports that much focus and effort is still required to ensure that cessation services are being delivered as planned and as proven to be effective for Maori. It is also recognised that much is still needed to be done to de-normalise tobacco consumption within Maori communities and that adding a new tobacco product within this context particularly risks undermining the de-normalisation imperative.

It is also noted that bringing snus in as a controlled cessation product assumes that there will be political support for the product and Pharmac subsidies on the product. Subsidies would be required if the product is to be equitably available and would not lead to more inequity between Maori and non-Maori.

5.5.5 Introducing Snus into New Zealand

Laugesen proposes a strategy for introducing snus into New Zealand and as a means to largely eliminate the use of smoked tobacco (see www.smokeless.org.nz for full detail).

Laugesen's approach is based on a number of key points. These are:

- That tobacco control policy should concentrate on eliminating smoked tobacco altogether, rather than continuing to pursue reduced-toxicity or reduced-harm cigarettes. Laugesen doubts whether cigarette toxicity can be reduced sufficiently or with any reliable effect to make regulation of cigarettes an effective way to reduce smoking mortality. He also notes the enormously complex
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and expensive regulatory framework that would be required should a product modification and harm-reduction approach to regulation be adopted. He doubts whether such regulatory capacity is achievable in New Zealand and questions why society should agree to continue to permit the toxicity of cigarettes under the guise of regulation.

- That snus should only be introduced to New Zealand on the decision and basis to eliminate the sale of smoked tobacco.
- In the short to immediate term, if society is not prepared to ban all tobacco products, then smokers have a right to less dangerous forms of nicotine delivery such as snus and additive pure nicotine. There is a need to provide smokers with effective and accessible nicotine alternatives if they cannot stop using nicotine through quitting smoked tobacco.
- That other product and content regulatory measures are unlikely to effect significant and sustained reductions in smoking prevalence in the future. Even if best practice in conventional tobacco control policy was followed and assuming as a result, a one percentage point reduction in smoking prevalence per year, it will still take a long time to reduce smoking down to near zero (given existing rates of smoking in New Zealand, particularly for Maori and Pacific people).
- The importance of continuing with cessation and other components of a comprehensive tobacco control strategy. Laugesen sees an increase in funding to cessation as an important component of the overall strategy; however, he also believes that stopping smoking requires a societal approach and must include strategies beyond that which consider smokers as patients in need of treatment.

Laugesen describes a transition process (at least 10 years) during which smokers would be encouraged to transfer from smoked tobacco to addictive nicotine or snus. He suggests that snus would be made available on general sale (as a non-medicinal fast-moving consumer good) alongside existing tobacco products. The existing SFE legislation would prohibit sales to anyone under 18 years of age. During the transition period, smokers would be provided with a choice between the respective smoked and smokeless products. Nicotine content in smoked tobacco would, however, be reduced annually and nicotine products taxed on the basis of their relative harms. Smoked tobacco would therefore become progressively less addictive and less harmful smokeless alternatives would be cheaper than smoked tobacco. Both strategies are seen as important mechanisms to encourage the transfer from smoked to smokeless tobacco.

Laugesen is cautious about allowing even a temporary uplifting of the advertising ban for snus as a further mechanism to encourage transfer to the product. He suggests that the level of public discussion and debate about the policy may in itself provide sufficient advertising of the availability of snus.

Laugesen proposes that a date would be set for the eventual ban on the sale of smoked tobacco in New Zealand. Possession, growing and smoking tobacco for personal use would not be banned as Laugesen is clear that the policy is about getting rid of smoked tobacco and not about prohibiting nicotine and nicotine addiction. He notes that the sale of addictive pure nicotine or snus would need to continue for some time after cigarette sales were phased out in order to control any black market in cigarettes (however,

the right to review and eventually withdraw both products from the market would also be retained under the policy). He also suggests that non-nicotine cigarettes may need to continue to be made available for a period of time to further assist withdrawal from smoked tobacco.

Laugesen acknowledges New Zealand as one of a few countries where there is existing tobacco product legislation and sees the SFE Act as potentially providing the regulatory framework and control needed to introduce snus in New Zealand. He notes that some small-print additions would be required to cover specific issues related to snus. He suggests, for example, that Section 31 could be used to define nicotine as a harmful constituent and to develop nicotine regulations including a reduction in nicotine content and the regulation of non-medicinal nicotine products. Potential is also seen in Section 31 being used to regulate the constituents of snus to ensure appropriate control over the type and purity of product introduced.

Laugesen sees snus offering the potential to reduce inequality between Maori and non-Maori in relation to smoking mortality, but not necessarily in relation to nicotine addiction. He feels that if reducing mortality can first be achieved, then the issue of nicotine addiction can be addressed later. Noting the Swedish experience which suggests that the use of snus reduces the risk of becoming a smoker, he accepts that while there would potentially be more people using nicotine if snus was introduced, he predicts that fewer people overall would be using smoked tobacco. While he also accepts that introducing snus risks resulting in users who would prefer not to be addicted to the product, he contends that at least these users will be facing substantially reduced risk of future mortality and that their addiction can be addressed at a later time.

5.6 Pure Nicotine

There is some support amongst key informants for pure nicotine as alternative nicotine delivery product. Pure nicotine is fast acting and delivers a nicotine hit and dose like a cigarette and is favoured over NRT for this reason. While it is accepted that there are likely to be issues with pure nicotine (e.g. its potential to lead to addiction, possible function as a gateway drug, negative health impacts), it can be preferred over snus for reduced harm potential. Pure nicotine is also preferred on the basis that it is a product further away from being a conventional tobacco product. This is seen as reducing the incentive for tobacco companies to get involved in this market. The product would be competing against the pharmaceutical industry and is seen as potentially easier to regulate and control.

6. REGULATION OF PREPS

6.1 Introduction

While questions remain as to whether and how best to proceed with PREPs, tobacco control leaders concur that independent regulatory control and review of PREPs is essential should they be permitted (Stratton et al, 2001; Myers, 2000; World Health Organization, 2000 cited in Warner, 2002).

The following section examines core issues when considering the possible role and place of PREPs within a tobacco regulatory framework.

6.2 Research, Monitoring and Evaluation

An effective regulatory framework which includes product modification and product level harm-reduction strategies will require the regulator to have access to extensive market and product information about both conventional tobacco products and PREPs. Authors agree that it is critical that appropriate information systems are in place to prevent potential new harm-reduction s'low tar' cigarettes 30 years ago (Zeller, 2000 cited in WHO, 2001).

WHO (2001) recognises the need for access to relevant, accurate and current scientific information about the toxicity of tobacco products and tobacco smoke. This includes the regulator having the authority to access core product and market information from the tobacco industry, as required (WHO, 2001; Bates, et al, 1999). Borland (2003) states that to be effective, regulators will require ongoing access to information such as the composition and engineering of tobacco products, exposures when used, indicators of harm, patterns of use, effects of price, consumer beliefs, and effects of communication about the product. Zeller (2000) notes that agreement will be required on what scientific evidence is needed to then evaluate what should be asked of tobacco manufacturers (cited in WHO, 2001).

Slade & Henningfield (1998) advocate an orderly, step-by-step approach for regulating PREPs, including establishment of appropriate monitoring and evaluation systems. As a bottom line, these authors state that any regulatory framework that permits PREPs and harm-reduction claims must be able to evaluate these claims. Therefore they believe that a regulatory framework must establish standards for tobacco conventional products and consistent methods for testing which enable comparisons between conventional products and PREPs and the testing of claims. Under such a system, PREPs would be regulated with an approved claim against the performance standard for conventional products and the products it will most likely compete with. Claims (with appropriate qualifiers) would only be approved if evidence indicates that PREPs have a sufficient likelihood of providing a substantial public health benefit. Slade & Henningfield (1998) also feel

that any regulatory framework should require PREP manufacturers to submit a plan to address the potential for continued, maintenance use of the PREP compared to the continued use of medicinal forms of nicotine and abstinence, as well as a plan to provide long-term evidence of the reduced harm benefit.

Hatsukami et al (2002) describe the need for comprehensive, multidisciplinary and collaborative research and monitoring infrastructure to address the range of questions and research needs associated with PREPs. The infrastructure would enable rapid response capabilities and would provide a comprehensive surveillance system that would monitor PREP marketing, penetration, uptake, and consequences over the short and longer term (e.g. prevalence of use of PREPs and conventional tobacco products). Key functions would include:

- toxicological assays;
- immediate surveillance capabilities;
- a testing programme from basic PREP characterization through to preclinical testing, human clinical testing and policy development;
- a central point for collating tobacco industry information.

The Institute of Medicine (IOM) in the USA recently completed a comprehensive examination of the scientific methods and standards against which PREPS could be assessed (Stratton, Shetty, Wallace & Bondurant, 2001). The IOM committee formed to undertake this work recognised that PREPS could act to either increase or decrease tobacco-related disease in the population (Stratton et al, 2001). The committee also advocates the need for extensive surveillance and research systems which have national authority over PREPs, to ensure that the impact is positive. It is recommended that a surveillance system collect information on a broad range of elements necessary to understand the population impact of tobacco products and PREPs. This would include attitudes, beliefs, product characteristics, product distribution and usage patterns, marketing messages such as harm-reduction claims and advertising, the incidence of initiation and quitting, and non-tobacco risk factors for tobacco-related conditions. There should be surveillance of major smoking-related-diseases, as well as construction of aggregate population health measures of the net impact of conventional products and PREPs.

Warner (2002) notes that significant capacity-building, budget and genuine political support will be required to develop the level of technical knowledge and practice that would be required. He notes enormous technical challenges in areas such as assessing exposure to toxicants, evaluating claims and ensuring effective post-marketing surveillance.

6.3 Key Information Requirements

It is beyond the scope of this research to provide extensive detail on the range of market and product understanding that would be required under a conventional product modification and harm-reduction regulatory strategy. However, the following summarises core areas of need identified in the literature, primarily to illustrate the implications and needs of such policy direction⁸.

⁸ Zeller (2000 cited in WHO, 2001) notes that the Food and Drug Administration (FDA) has funded a new expert committee convened by the Institute of Medicine in the USA to examine the types of questions and issues described in this section. The committee is tasked with making recommendations to the FDA about an appropriate scientific and regulatory framework to address the complex questions related to appropriate regulation

6.3.1 Initial Questions

Authors identify a range of initial questions which must first be addressed or at least considered when contemplating the introduction and regulation of PREPs (Husten, 2005; Hatsukami et al, 2002; Warner, 2002; Slade & Henningfield, 1998). Many questions relate to the individual and population responses to PREPs. Important questions identified include those listed here.

Market and Administrative Response

- How will both smokers and non-smokers respond to the availability of a new PREP?
- Will PREPs contribute to the perception that the tobacco use problem is ‘solved’? Will this lead to officials and policy makers feeling a decreased sense of urgency to take on policy initiatives that address tobacco-related problems?
- Will the need to research PREPs divert attention and funding away from proven interventions to reduce tobacco use?

Impact on Initiation and Product Use

- To what extent will PREPs interest people who have never tried tobacco in any form?
- What types of PREPs will attract children to initiate nicotine use and to what effect?
- Will the use of PREPs among people who otherwise would never have used tobacco lead to eventual conversion to more dangerous tobacco products?
- To what extent will PREPs be chosen instead of conventional tobacco products among new users who would have used tobacco anyway?
- How many former smokers will adopt the PREP instead of remaining abstinent?

Impact on Quitting

- To what extent will current smokers view PREPs as an alternative to quitting?
 - What factors influence switching to PREPs instead of quitting?
 - To what extent will the availability of PREPs interest former smokers to use them? Conversely, will PREPs facilitate quitting for some smokers?
 - Will current smokers see PREPs as an alternative to quitting, and as a result how many will adopt the PREP instead of quitting? If this was the case, would the individual’s disease risk decline, remain roughly the same, or increase?
-

Longer-term Use

- Will users of PREPs continue to use the new devices over time, or will many (or some) switch from the PREPs back to cigarettes?
- What are the implications for long term use of NRT?

Approval Standards and Reduced Risk Claims

- What claims can responsibly be made and what qualification of claims is necessary?
- What limits on and monitoring of marketing for these products should there be once they are approved?
- If initial approval for marketing introduction is conditional, what criteria would be required for full approval?
- If standards for PREPs become more stringent over time, what would be the time frames for subsequent reviews?

Surveillance

- What post-market surveillance is required?

Warner (2002) contends that due to the many current unknowns about PREPs, fully determining the answers to questions such as those listed above, may be virtually impossible.

6.3.2 Conventional Tobacco Products

Hatsukami et al (2002) identify the need for further understanding of tobacco products, specifically the chemical constituents of tobacco and tobacco smoke, as well as structural materials such as fibres or fibre fragments. These authors note the limitations of current cigarette testing methods and the need for testing methods which actually measure the important chemical and toxic exposures consumers experience in using various products⁹. Allen & Clarke (2003) also recognise that regulatory systems require accurate and comprehensive testing of toxin delivery from tobacco smoke. Slade and Henningfield (1998) concur with this point, noting that tests must be reasonably predictive of human exposure and toxicity.

6.3.3 Establishing Measurement Foundations

Hatsukami et al (2002) see the need for further work in establishing product specifications and toxicological and epidemiologic yardsticks that would inform the regulatory systems assessment and monitoring of PREPs and other harm-reduction strategies. Core work would include determining:

⁹ Canada requires cigarettes to be tested according to ISO standard tests under normal and 'intense' (modified ISO) smoking conditions. The 'intense' test involves 55 ml puffs of two-second duration every 30 seconds with all the ventilation holes blocked (Allen & Clarke, 2003).

- which toxins were most useful to monitor;
- how dosing would be gauged;
- the extent of reduction in tobacco toxin exposure that would lead to reduced harm in health;
- which disease outcomes should be considered;
- what mix of trials and epidemiology would be required;
- measures of incidence and prevalence of tobacco use and morbidity and mortality to be used.

Zeller (2000 cited in WHO, 2001) identifies the need to agree on how reductions in exposure will be measured and how will it be known when a meaningful reduction in harm has been achieved. This will require agreement on the studies necessary to help establish the critical linkage between a reduction in exposure and a concomitant reduction in harm.

6.3.4 Dose and Disease Response

Many questions exist in respect to the relationship between product dose and disease responses (Hatsukami et al, 2002). Core areas for further understanding are identified to include:

- further assessment of the relationship between cigarette consumption/smoke exposure and disease risk;
- understanding of how changes in tobacco product exposure affect disease risk and which disease processes are altered as a result of reduced tobacco exposure;
- understanding how much reduction in tobacco smoke exposure is necessary for a meaningful reduction in disease risk and for long how is reduced exposure needed to reduce risk;
- the relative toxicity of other tobacco products compared to combustible tobacco and the effect of these products on biomarkers and disease risk;
- the need for understanding as to how behaviour and product characteristics interact to affect dose reduction and disease risk (e.g. as in compensatory smoking responses).

6.3.5 Nicotine Addiction

The further development of effective alternative nicotine products is seen as requiring better understanding of nicotine addiction (Hatsukami et al, 2002). This would include better understanding of the biological, behavioural, learning, sensory, environmental and socio-cultural basis for nicotine addiction or sustained tobacco use as well as nicotine addiction and toxicity as a function of the route and rate of dosing.

6.3.6 Identify and Validate Indirect Measures

Most tobacco-related diseases develop after many years of smoking and therefore for most tobacco-related diseases, it is impossible to conduct clinical trials of adequate duration to determine how new products

would affect disease risk (Hatsukami et al, 2002). Therefore indirect measures of disease risk are required with these including biomarkers of tobacco toxin exposure and early indicators of tobacco-caused tissue injury that predict later risk for disease (Stratton et al, 2001). Determination of valid biomarkers and predictors of reduced toxin exposure would be undertaken in vitro, in animals and humans, taking into account the number of toxin constituents and their interaction. Indirect measures of toxicity would also be required at both an individual and population level. The Institute of Medicine in the US (IOM) committee warns that biomarkers must be validated as robust predictors of disease occurrence and should be able to predict the range of important and common conditions associated with conventional tobacco products (Stratton et al, 2001). The committee also notes that the efficacy of PREPs will likely depend on user population characteristics (e.g. those defined by gender, genetic susceptibility, ethnicity, tobacco history, and medical history).

6.3.7 Modified Combustible Products

While acknowledging doubt that modified combusted tobacco products will have any significant positive impact on public health, Hatsukami et al (2002) recognise that any regulatory framework permitting modified products will require a science base to evaluate the toxin exposure from such products. The need for standards for procedures and methods of measurement for the constituents and extent of exposure (as well as for disclosure) is recognised.

6.3.8 Surveillance

Many authors note the importance of developing pre-market approval, and post-marketing surveillance systems so that the population effects of PREPs can be tracked and appropriate corrective actions quickly taken to minimise any undesirable effects (Gray & Henningfield, 2004; Hatsukami et al, 2002; Kozłowski, 2002; WHO, 2001).

Surveillance systems, using appropriate epidemiology and public health methodology, would ideally provide timely information on who is using what products, where, when, how, for how long, and to what effect. For example:

- the prevalence of use of tobacco products and PREPs;
- factors influencing use patterns;
- incidence, prevalence, and mortality from tobacco-related diseases and the impact of PREPs on this (Stratton et al, 2001).

The importance of tracking and understanding the impacts of associated communications about PREPs is emphasised. Previous harm-reduction failures (e.g. 'light and mild' cigarettes) have vividly shown the risks of releasing into the market tobacco products communicated to be 'safer' than conventional products (Hatsukami et al, 2002). As previously discussed, in relation to prohibiting or allowing harm-reduction

claims, further debate is required as to whether and to what extent communications and marketing about PREPs should be permitted.

Hatsukami et al (2002) identify a number of areas where they feel that further understanding will inform the development of communication that will lead to the greatest net public health benefit. The authors see the need for better understanding of:

- knowledge, attitudes, and behaviours regarding conventional tobacco products and PREPs and how messages affect this within relevant target groups;
- the cognitive and affective nature of communications and how individuals process these components;
- how different variables (e.g. tobacco use status, ethnicity, age, sex, and socioeconomic status) impact on the effects of communication;
- how PREPs can be made more attractive than more dangerous products, without crossing over the risk/use equilibrium and while retaining the primary messages of prevention and cessation.

6.4 Monitoring and Evaluation Challenges

The immense difficulties in effectively evaluating, monitoring and regulating PREPs are widely recognised. For some authors, doubt over the public health community's ability to do this is reason for further caution about PREPs (Warner, 2002; Fox & Cohen, 2002; Slade & Henningfield, 1998).

Husten (2005) advocates that any consideration of PREPs must be against a population, policy and programme perspective. She notes that reduced exposure does not necessarily lead to reduced risk, with this applying at the individual and population level. She states therefore that to show that a product has achieved harm-reduction, it must be shown that the reduced exposure reduced individual and population risk and that PREPs did not cause greater harm or different kinds of harm than at present. She states that to say that reduced population risk has occurred, it must be shown that measured exposure translates into actual exposure, that reduced exposure translates into reduced individual risk and reduced individual risk translates into reduced population risk.

Both short-and long-term surveillance has been recommended as a means of monitoring excess use of PREPs (Stratton et al., 2001). However, without the ability to run controlled trials, Warner (2002) doubts that short-term surveillance could meaningfully assess whether PREP users represent the intended target or excess users or whether current adult smokers switching to a given PREP would have otherwise quit. He questions the utility of information from longer-term surveillance, particularly whether epidemiology could establish net population health effects within meaningful timeframes. He also notes that even if a PREP was identified as problematic, its withdrawal from the market would leave excess users still in the market for nicotine-delivery products, including cigarettes and other PREPs.

Warner (2002) believes that the net effect of PREPs is likely to be strongly determined by the extent and nature of excess use which results from perceptions that PREPs offer a less harmful alternative to smoking. He sees a number of factors and variables influencing this, for example:

- whether excess users were current smokers who would have otherwise quit or were children who never would have started using tobacco;
- the proportion of PREP users who move back to cigarette smoking and who would have otherwise become abstinent from all tobacco products;
- the proportion of PREP users who migrate to other more or less dangerous forms of PREP.

Warner (2002) suggests that such uncertainty may lead regulatory authorities to insist on very high thresholds of likely exposure or risk-reduction to label any PREP as potentially harm-reducing (or exposure-reducing).

6.5 Proceeding with Uncertainty?

The term PREP reflects acceptance that with the current knowledge base it is impossible to categorically say that any existing PREP is harm-reducing. Warner (2002) observes that it may even be impossible to make this determination for any PREP in the future; a key reason being incomplete understanding about the relationship between chemical exposures in tobacco product use and disease outcomes and the complex manner in which thousands of chemicals interact during product consumption. The term PREP acknowledges that ascertainment of exposure reduction is likely to be the greatest level of certainty that will be achieved for the foreseeable future. However, even this is likely to be difficult; for example, because of the complexity of the products of combustion and because of the potential for PREPs to introduce new exposures not currently experienced by cigarette smokers (Warner, 2002).

A key question raised from this discussion is whether the introduction of PREPs needs to be totally contingent on absolute scientific certainty (Warner, 2002). The difficulty of producing a definitive assessment of harm-reduction potential may not be sufficient reason to halt all promising harm-reduction strategies. Acknowledged is the potential that an overly cautious stance may discourage the development of new products that are potentially effective in reducing at least some of the risks of smoking.

Fox & Cohen (2002) recognise a primary difficulty in assessing effectiveness is the time required for scientific discovery and that net epidemiologic effects of new products cannot be known for years. While acknowledging that proposed tobacco harm-reduction strategies must result in more good than harm (and not simply substitute harms), these authors suggest that where evidence shows strong potential for reduced-harm benefits, implementation should not be withheld in favour of scientific certainty, but rather should be coupled with specific research questions able to provide long-term analysis and evaluation of the strategy.

Warner (2002) suggests that scientific methods should be used to develop methods to translate findings about exposures and biomarker data into predictions of the most likely net health implications of PREPs. Such evaluations then could be used to inform regulatory developments and communications with the public.

Kozlowski (2002) argues that in relation to snus and medicinal nicotine, it is wrong to assume that we lack the practical scientific bases for estimating that there will be harm-reduction to individual smokers from these products. He sees it being more important to ensure that the regulatory and evaluation systems are in place to unequivocally judge the degree of harm-reduction afforded by these products rather than wait until all scientific research has been completed.

Slade and Henningfield (1998) acknowledge that PREPs must be substantially less hazardous compared to conventional products and should also be acceptably safe compared to abstinence (accepting that some use will occur instead of quitting). They do not believe, however, that preliminary approvals for PREPs should hinge on all possible investigations being completed and all questions being answered. They suggest approval processes should prioritise essential knowledge and certainty while also having a plan for addressing other questions and concerns by some future time. This would include the requirement for long-term studies of approved PREPs to determine whether products actually meet their harm-reduction claim; that is, that they are substantially less dangerous than competing conventional products and are not substantially more dangerous for the public health than either competing pharmaceutical products or abstinence (Slade & Henningfield, 1998).

6.6 Risk-use Trade-Off

Kozlowski (2002) recognises that while reducing toxicity to individual users, some PREPs may actually increase public health harm because of an increase in the overall numbers of users. He sees three questions being posed in relation to this possibility:

- Would there be a net benefit to society if PREPs reduced individual risk but increased overall use?
- What are the potential immediate and long-term health effects at the population level from PREPs?
- Do PREPs end up reducing harm for the population as a whole?

Kozlowski (2002) discusses the concept of ‘risk-use trade-off’ as a means to answer the questions posed. The framework contends that when individual risk from a PREP are relatively small, the level of excess or increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high. For example, if individual risk from medicinal nicotine is less than 0.1 percent (1 per 1000), then use of this product would have to increase over 1000 times to cause an equal public health problem. Similarly, if the risk from snus was 1 percent that of cigarettes, use of snus would have to increase 100 times to equal the harm or problems by cigarettes.

Alternatively, Kozlowski et al (2001) show that if a PREP offers only modest individual risk reduction compared to cigarettes, then only a small increase in excess use in response to introducing a PREP negates the potential public health value.

Warner (2002) also recognises that a PREP offering significant risk reduction but little likelihood of substantial excess use constitutes a high-probability public health success story. Further to this, he contends that any PREP involving combustion probably constitutes a poor risk-use trade-off. Such products

are likely to reduce risk modestly while, due to their similarity to conventional smoking, more likely to encourage excess use, discouraging cessation and encouraging relapse and new initiation.

6.7 Individual and Public Health Rights

Assessment of respective individual and societal harms and benefits from PREPs is a central consideration in PREP evaluation. It is generally accepted that public health interests should prevail when there is low cost to the individual and high benefit to society. In public health therefore, benefit to the many can override the rights of the individual. However, in reversing this concept, Kozlowski (2002) argues that for the individual smoker who will not or can not give up nicotine use, there could be significant individual benefits from some PREPs (and possibly to society), while the costs to society are far from clear and convincing.

Kozlowski notes that two principles, proportionality and probability, are typically emphasised when determining whether public health interests should take precedence over individual health interests. He sees these principles establishing that the limitation of rights must be proportional to the public health interest and its objective and that the risks to the public must be probable, rather than speculative or remote. In the case of snus and medical nicotine, Kozlowski believes that there is a lack of clear and convincing evidence that, under the principles of proportionality and probability, would require public health to be favoured over individual health. For example, there is little evidence to indicate that snus or medical nicotine would lead to increased initiation, result in smokers who would otherwise quit using PREPs instead or encourage initiation due to perceptions that PREPs are safe.

6.8 Ethical Considerations

Fox & Cohen (2002) provide an ethical framework for evaluating the role and place of PREPs within tobacco control. They see four key principles making up this framework, these being:

- beneficence – the principle of doing good;
- non-maleficence – the principle of not doing harm;
- self-determination – the principle of allowing individuals to make their own decisions;
- justice – the principle of fairness.

Beneficence requires products to be evaluated against their probable real world benefits, efficacy and effectiveness. Evaluation of benefits requires assessment of the likely or actual penetration of the PREP into the market. Fox & Cohen (2002) note that a strategy could be deemed to fail if a PREP is rejected by consumers and not used or is used incorrectly.

Fox & Cohen (2002) view the principle of non-maleficence and the evaluation of possible harm requiring consideration of the possibility that a PREP risks replacing one risk with another. This includes the need to consider the secondary consequences from a PREP; for example, reducing the incentive to quit smoking or

encouraging uptake and use because of perceptions of a safer product. Warner (2002) also notes that any PREP must not distract from the two key goals of preventing uptake and cessation.

The principle of fairness is seen as requiring evaluation in terms of social justice outcomes. For example, a truly harm-reducing product could be expensive and not readily available to all that could benefit from it. In such a situation, Fox & Cohen (2002) stress the need to consider the types of mechanism that would be needed to make a product accessible to all who might need it (e.g. public subsidies).

6.9 Prohibiting Harm-reduction Claims

As previously discussed, it is felt that no manufacturer or company should be permitted to make reduced harm or exposure claims (explicit or implicit) without providing sufficient scientific evidence to convince the regulatory authority of the validity of such claims (Warner, 2002). Control over claims can therefore be seen as a key issue when determining regulatory control over PREPs.

There is support for permitting harm-reducing claims when these are backed by sufficient data. Slade and Henningfield (1998) advocate that prior to any PREP marketing, data should be required from the manufacturer or company which supports the conclusion that the products have a substantial chance of substantially reducing risk of illness and death compared to the tobacco products that it would compete against. They also advocate that manufacturers should be required to eventually demonstrate that products are safe and effective, and describe a process where initial marketing approval is given subject to later confirmation of safety and effectiveness, after sufficient studies and market experience.

Other authors voice concerns about permitting reduced harm claims at all (Hatsukami, 2005; Gray & Henningfield, 2004; Borland, 2003). Gray & Henningfield (2004) recognise the potential for claims to undermine cessation and encourage initiation and in general note the complexity of actually determining reduced harm. They recognise, for example, that the health effects of a product can be determined just as much by how the product is used rather than on how the product is made; therefore simply reducing toxicant emission of a product will not in itself be a sufficient basis for reduced harm claims.

Borland (2004) accepts that it may be possible to allow marketing of PREPs without adding to demand; however, he contends that it is likely to be difficult to do this in a way that minimises the risk of attracting new users or over-reassuring existing users. He concludes therefore that regulatory mechanisms would be required to prevent over-promotion and to ensure that innovations deliver real public health benefits (e.g. regulation to control product composition and product claims).

Borland (2003) questions whether users of tobacco products have the capacity to properly assess harm-reduction claims and suggests a process to eliminate potentially misleading claims. While acknowledging the importance of tobacco product regulation providing adequate consumer information, he sees tobacco product users' dependence on the product limiting their capacity to assess long-term consequences of use, as well as reduced-harm claims. Within this context, Borland feels the best strategy to deal with toxicity is

to continually upgrade standards of exposure (or harm) for products so that the dirtier forms of nicotine delivery are eventually phased out. The change process is therefore brought under the control of health agencies, does not require harm-reduction claims to be made and therefore does not rely on consumers making assessments of claims. He suggests that once a PREP is assessed to have a good probability of reducing disease risk, the regulatory authority might require its adoption, with licensing fees paid to the innovation's developer. For example, the authority could require all cigarette manufacturers to remove tobacco-specific nitrosamines. The result could be universal adoption of a potentially important risk reduction with minimal risk of substantial off setting excess use.

Warner (2002) suggests that the theoretical ideal approach from a public health point of view might be for regulation to establish minimum manufacturing and performance standards without permitting manufacturers to advertise them and to compete on the basis of reduced harm or exposure reduction. Borland (2004) supports this approach, seeing it as potentially overcoming the problem of messages about reduced risk being interpreted by consumers as safe enough when risks of harm still exist. He accepts, however, that this approach may be hard to achieve for products where differences in composition can be used for claiming benefits. He also doubts whether companies who have designed their products to be less dangerous and who are motivated to sell more, can be trusted to communicate in a way that discourages use.

Those advocating that reduced-harm claims not be permitted recognise that such a policy would raise important ethical and practical questions about consumers' right to know.

6.10 Regulation Principles

The IOM's recent examination of PREPs represents a significant attempt to address the many issues raised about PREPs and to determine an appropriate way forward on the issue.

The IOM working committee positioned their examination within four core operating precepts, these being that:

- tobacco use causes serious harm to human health;
- nicotine is addictive;
- the best means to protect individual and public health from tobacco harms are to achieve abstinence, prevent initiation and relapse, and eliminate environmental tobacco smoke exposure;
- a comprehensive and authoritative national tobacco control programme, with harm-reduction as one component, is necessary to minimise adverse effects of tobacco.

These precepts are important as they establish the wider context within which all consideration of PREPs should be placed.

Key conclusions drawn by the IOM committee in relation to PREPs include:

- That for many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible (while acknowledging that complete abstinence provides the greater protection against disease risk).
- That the public health impact of PREPs is unknown and that while potentially beneficial, the net impact on population health could, in fact, be negative. It is recognised that the net effect on public health will depend on a variety of factors including any biological harms caused as well as individual and community perceptions and behaviours with respect to use.
- That regulation of all tobacco products, including PREPs and conventional products is a necessary precondition for assuring a scientific basis for evaluating PREPs and assuring health protection. Regulation would determine what research is required, what information the public requires to make informed decisions about PREPs and would ensure that any product claims do not mislead, do not lead to product misuse and that all claims are supported and verified by scientifically sound evidence.

While concluding that harm-reduction is a feasible and justifiable public health policy¹⁰, the IOM committee saw this contingent upon harm-reduction being implemented to achieve a number of core objectives (Stratton et al, 2001). These include that:

- Manufacturers have the necessary incentive to develop products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease.
- Consumers are fully and accurately informed of all the known, likely and potential consequences of using PREPs.
- Promotion, advertising and labelling of PREPS are regulated to prevent false or misleading claims, explicit or implicit.
- The health and behavioural effects of using PREPs are monitored on a continuing basis.
- Basic, clinical, and epidemiological research is conducted to establish PREPs' potential for harm-reduction for individuals and populations.
- A harm-reduction approach is adopted as a component of a comprehensive national tobacco control programme that emphasises abstinence-oriented prevention and treatment.

In drawing together their core findings, the IOM committee identified 11 principles they felt that any science-based regulatory framework for implementing tobacco harm-reduction should conform to (Stratton et al, 2001).

¹⁰ Giovino (cited in Robins, 2005) reports the Californian Department of Health Services Tobacco Control Section (TCS) being concerned about the conclusions found in the IOM report for a number of reasons, including that:

1. harm reduction through PREPs has not been convincingly demonstrated
 2. the net impact of risk reduction at the population level may be negative
 3. there does not currently exist a panel of valid biomarkers to evaluate the health effects of PREPs
 4. the current knowledge base is inadequate to formally assess the risk of PREPs
-

The principles are:

1. Manufacturers of conventional or modified tobacco products should be required to obtain and disclose to the regulator, quantitative analytical data on the ingredients of their products.
2. All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption. When necessary to support claims, human exposure to various constituents of tobacco smoke should be assessed using appropriate biomarkers. Consumers should receive understandable information (which is not misleading) on yield range and human exposure.
3. To support any health-related claims associated with any PREP, manufacturers should be required to conduct toxicological testing in preclinical laboratory and animal models and appropriate clinical testing in humans. The results of such testing should be reported to the regulator.
4. Exposure reduction or risk reduction claims about PREPs should only be permitted with regulator approval based on scientific evidence:
 - (a) that the product substantially¹¹ reduces exposure to one or more tobacco toxicants;
 - (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, compared with an identified benchmark product.
5. All labelling, advertising, and promotion of PREPs with exposure reduction or risk reduction claims must be regulated under a 'not false or misleading' standard. The burden of proof for any claim should reside with the manufacturer not the government. The regulatory authority should have the authority and resources to conduct surveys of consumer perceptions relating to claims.
6. The regulatory agency should be able to require manufacturers of all PREPs with exposure reduction or risk reduction claims to conduct appropriate and necessary post marketing surveillance and epidemiological studies to determine the short-term behavioural and long-term health consequences of using the PREP.
7. In the absence of reduced exposure or reduced risk claims, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory authority. However, they must provide information on the composition of the product and must certify that the product could not reasonably be expected to increase health risks or lead to other adverse effects, compared to similar conventional tobacco products (based on the most current toxicological and epidemiological information).
8. All added ingredients in tobacco products should be reported to the authority and be subject to a comprehensive toxicological review.
9. The regulatory authority should be able to set performance standards for all conventional or modified tobacco products and classes of products.
10. The regulatory authority should have enforcement powers commensurate with its public health mission.

¹¹ a 'substantial reduction' in exposure should be sufficiently large that independent experts would anticipate measurable reductions in morbidity and/or mortality in subsequent clinical or epidemiological studies

11. Exposure reduction and risk reduction claims for drugs and devices that are supported by appropriate scientific and clinical evidence should be permitted.

Giovino (2005) reports that the TCS considers the IOM principles to be 'too permissive' on the basis of a lack of control over manufacturing, distribution and marketing. The TCS interprets the IOM principles as essentially allowing PREPs go to market as the means to determine what happens to public health. It is also noted that the report was positively viewed by the tobacco industry, seen in itself as an indicator of fundamental flaws.

Giovino also reports TCS concern over pharmaceutical industry involvement, especially if regulatory burdens are removed or lessened. The TCS strongly advocates the need to maintain strict standards, not only to ensure the safety and benefits of pharmaceutical products but also to maintain the integrity of the industry, particularly in the eyes of the public, and relative to the tobacco industry.

The TCS consider that if PREPs are given regulatory approval, they should only be marketed or made available to identified tobacco users and not the general public. It is also recommended that regulatory approval of PREPs be conditional on the demonstration that products do not:

- increase youth uptake;
- increase young adult prevalence;
- decrease quit attempts;
- increase relapse of former smokers;
- lead to wide misuse;
- lead to marketing to the general public;
- undermine comprehensive tobacco control programmes;
- undermine tobacco policy advances.

The TCS also propose a series of standards for the regulation and provision of medicinal nicotine products. These include:

- Medicinal nicotine products would be available under prescription only and not advertised to the general public.
- The manufacturer would be responsible for paying for and communicating the findings of post-market testing for up to 10 years.
- Revoking the over-the-counter availability of current approved cessation products.

Husten (2005) identifies a number of further conditions and requirements seen as vital to safeguard against unintended consequences from PREPs. These include:

- That the introduction of PREPs is not interpreted as a signal that the tobacco problem is solved. PREPs need to be introduced and promoted as another step in tobacco control, not an endpoint.
-

- That PREPs should not undermine the baseline message that all tobacco products are unsafe.
- That PREPs should not undermine core strategy and efforts to de-normalise smoking. PREPs must not lead to an increase in acceptability of tobacco use.
- That the PREPs debate should not be used to enable proponents to portray tobacco control advocates as uncaring extremists, offering smokers the choice to 'quit or die'.

6.11 Case Study – FDA Tobacco Regulation Bill

The issues inherent in regulating PREPs and introducing tobacco product regulation generally can be seen in debates about a comprehensive tobacco regulatory framework recently considered in the USA.

In May 2004, legislation was introduced to the US Congress which would grant the US Food and Drug Administration (FDA) sweeping regulatory authority over both new and existing tobacco products and their marketing (Myers, 2004; Shatenstein, 2004). Provisions in the Bill reflected many of the regulatory initiatives advocated by public health professionals as being required should regulation be effectively used to reduce tobacco-related harm.

Provisions included:

- Prohibition of many marketing practices that impact youth and children.
 - Authority to further restrict tobacco marketing including regulation of the “time, place and manner” of cigarette advertising.
 - FDA authority to require new, larger pack warnings labels.
 - Requirement for disclosure of what is in each tobacco product (including all ingredients, constituents, and smoke constituents) by quantity in each brand and sub-brand. Requirement that the FDA publish, three years after enactment, an annual list indicating 'harmful and potentially harmful constituents to health' in each brand.
 - Requirement for prompt reporting of any changes to tobacco products.
 - Authority to set toxicant exposure standards and require changes in both current and future products to protect the public health.
 - Authority to demand the reduction or removal of any harmful ingredients or naturally occurring constituents. Also provides authority to reduce nicotine to non-addictive levels.
 - Authority to stop manufacturers from publicising that they meet new standards so that consumers do not perceive products as safe or safer.
 - Bans on certain flavourings that make tobacco products more appealing to non-smokers and gives authority to ban others.
 - Prohibition of misleading terms 'light', 'mild' or 'low' and provision for improved health warnings.
-

- Prohibition of reduced-risk claims until the FDA first determines both that the product: (1) as actually used will significantly reduce the risk of disease to individual consumers; and (2) as marketed will benefit the population as a whole taking into account its impact on initiation, quitting, and relapse.
- Prevents tobacco companies from using reduced exposure claims to indirectly communicate health claims. Reduced exposure claims are only permitted when the best available science is inadequate to meet standards required for a health claim and only when: (1) best available science demonstrates that a measurable and substantial reduction in risk is anticipated; and (2) the manufacturer can prove that consumers will not be misled into believing that the product has been proven less hazardous.
- Provides authority to determine how reduced-risk products can be marketed and requires post-market surveillance of actual use.
- Empowers the FDA to combat the existence of counterfeit, contraband, and other illicit tobacco products.
- Forbids the FDA from banning tobacco sales to adults age 18 and over or from requiring that nicotine yields be reduced to zero (Myers, 2004; Shatenstein, 2004).

Siegel (2004) provides a critique of the proposed Bill, seeing it having a range of negative effects on public health. In general, he sees the Bill diverting resources to areas where it is not politically feasible to achieve success and thereby detracting from existing tobacco control proven to be effective.

Siegel sees the Bill framing tobacco as a problem insofar that tobacco companies introduce new products, make misleading health claims and fail to comply with FDA performance standards. This positioning is seen as potentially eroding public perceptions of the harms of cigarettes, resulting in consumers seeing cigarettes as having a stamp of approval from FDA and leading to the public perceiving that tobacco has been taken care of.

He sees the Bill leading to pressure to cut the future allocation of funding to existing tobacco control strategies known to be effective. He also suggests the Bill will undermine the chance of future litigation, as tobacco companies will be able to argue that they are already regulated and that therefore there is no need for any further substantial punitive damages or injunctive relief.

Siegel considers authority to require intensive disclosure of cigarette constituents and authority to issue performance standards as unlikely to save lives. He notes that regulators simply don't know which carcinogens and which toxins in tobacco smoke are responsible for what diseases, what quantities of these chemicals produce what effect, and what the effect of removing these chemical will be. Also unknown is what combination of chemicals removed will affect disease risk, if at all, and what new chemical and harms may be created through the processes used to alter the chemicals makeup of cigarette smoke. The end result is seen as likely to be a diversion of resources away from effective tobacco control initiatives.

Siegel believes that the Bill will improve the public image and goodwill of tobacco companies because they will be able to use the fact of being regulated by FDA to achieve improved public opinion. Improved public image is seen as translating into an improved bottom line, increased cigarette sales and increased cigarette consumption.

It is noted that the Bill allows reduced exposure products to enter the market so long as the manufacturer states that it expects the product to reduce health risks. It is believed that the public will perceive that a reduced exposure product will reduce health risk and that therefore the Bill essentially allows the company to market products as reducing health risks without any substantiation.

In conclusion, Siegel (2004) sees the Bill having one positive effect; that of increasing adult smoking cessation slightly through stronger warning labels and six negative effects, these latter being:

- eroding the public perception of the inherent harms by cigarettes;
- creating the public perception that the tobacco problem is taken care of and reducing the allocation of funding to effective tobacco control strategies;
- ending any serious threat to tobacco companies of damage from litigation;
- improving the public image of tobacco companies;
- ending the incentive for the development of truly reduced-risk tobacco products; and
- institutionalising the problem of unsubstantiated health-risk claims by cigarette marketers (Siegel, 2004).

In response, Myers (2004) argues that not to bring in the additional powers under the Bill is to accept the status quo. The Bill is seen as addressing long-standing issues in tobacco control in ways long endorsed by public health experts. He contends that the Bill clearly states that regulation does not modify the liability of tobacco companies. He asserts that adoption of regulatory authority over the tobacco industry will not create the impression that the tobacco problem is resolved. He recognises that regulation must only be seen as an additional tool and not a panacea to tobacco control. He does not accept that the regulation will add any further to perceptions that already exist about the acceptability of tobacco products. Regulation is, however, seen as an important mechanism for reining in tobacco company behaviour.

7. OPTIONS FOR STRUCTURAL REGULATION

Some authors see tobacco regulation as a way to achieve fundamental structural reform of the tobacco industry as well as a means to achieve control and change at the product level. The following section considers options for using regulation to achieve such reform.

7.1 Introduction

Structural regulation is concerned with regulating and having more control over the systems and structures which underpin the overall tobacco industry. Structural regulation includes options for reforming core market forces and pressures which are seen as impacting on the success of conventional, product level regulatory approaches.

Structural regulation can be seen as a 'supply side' strategy. Compared to 'demand side' strategies, which focus on individual behaviour change and changing the consumer, supply side strategies focus on reducing the availability of cigarettes. Structural regulation approaches seek to achieve this by altering the fundamental business and economic principles under which tobacco companies currently operate.

Demand side regulatory strategies are seen by supply side advocates as having a role and place within a regulatory framework. However, in the absence of greater control over the tobacco industry, these strategies are seen as vulnerable to being undermined by tobacco companies acting rationally to maximise profits (Callard, Thompson, & Collishaw, 2005; Borland, 2004). Proponents of structural regulation see demand side regulation as likely to be easier, more effective, possibly quicker to implement and more cost-effective if the overall context within which these strategies are pursued is altered and if greater overall control of the industry is achieved (Callard et al, 2005; Borland, 2004; Liberman, 2003; Liberman & Clough, 2002). Key informant proponents of this approach see this different context providing a more favourable environment for undertaking and maximising the benefits of regulatory control. For example, structural regulation may provide greater ability to capture tobacco industry knowledge and innovation which in turn may potentiate development of reduced harm products. Such benefits are seen as potentially enabling a much faster pace of change than that which could be achieved by primarily focusing on demand side, product or content level strategies.

Key informant proponents suggest that the possibility of structural reform requires the tobacco control community to fundamentally re-think desired directions for regulatory control. A choice is seen in continuing with more conventional regulation, perceived as possibly easier than other options, yet ultimately less effective in dealing with the tobacco system as it currently exists.

7.2 Removal of Profit Incentive

A central concept in structural regulation is the belief that effective regulatory control will always be difficult if the fundamental profit maximisation driver of the tobacco industry is not changed (Borland, 2004; Liberman, 2003). In seeking to attract more smokers (and make more money), tobacco companies are simply seen as striving to meet their legal responsibility to act in the best interests of shareholders. Tobacco industry tactics to counter public health attempts to reduce smoking, are also seen as rational, logical and calculated when operating within a profit-maximizing framework (Liberman, 2003).

Liberman (2003) and Borland (2004) both question how the tobacco industry can ever be adequately regulated while tobacco manufacturers continue to operate under the profit motive. The profit motive in the context of tobacco is considered perverse in that the more tobacco products sold, the more profit made and the more death and disease that results. Liberman (2003) considers that real solutions must lie in addressing the nexus between profit and the causing of harm and in structuring a regulatory system under which the incentive is to reduce rather than increase harm. He suggests that the removal of the profit incentive would incorporate a total ban on promotion, tight control over tobacco product distribution and the use of sales revenues only to underwrite manufacturing and distribution costs with the remainder used to pay liability and contribute to efforts to reduce smoking.

Some key informant proponents of structural reform see the approach 'liberating' harm-reduction and product modification innovation. Removing or intervening at the profit motive level is seen as enabling harm-reduction and product modification to be used to meet public health goals regardless of economic, marketable and profit imperatives. It is observed that under current market models, a harm-reduction idea has to be both marketable and profitable in order to be feasible and therefore seriously pursued by manufacturers.

7.3 Removal of Marketing Relationship with Consumers

Borland (2004) questions whether there is any social value in continuing to allow tobacco companies to market their products directly to consumers. He argues that when a product is net harmful, regulation should not enable the distribution system for the product to act in a way which grows demand for the product. In the case of tobacco therefore, he argues that regulation needs to impose more than just controls over promotion and communication as these can be easily bi-passed by tobacco company tactics.

Borland (2004) identifies a range of constraints on effective regulation if regulatory approaches are adopted within the existing market status quo. These include:

- Constraints on competition to develop less harmful products because consumers have poor capacity to delineate between products.
 - That market forces provide incentives for tobacco companies to increase rather than reduce the addictiveness of their products.
-

- Working from outside the industry, regulators will always be disadvantaged and in 'catch-up' mode through a lack of relative knowledge compared to tobacco manufactures.
- Tobacco companies focus communication on the positive features of their products and provide information on harms only when required to do so. If direct means of communication are restricted, companies have incentives to adopt indirect means which can be difficult to control while products are branded by manufacturers.

Borland (2004) see these and other constraints meaning that regulators and tobacco manufacturers and distributors are continually in an antagonistic relationship because they do not share common goals. In response, he proposes a regulated market model (RMM) which would remove control of the marketing function from companies. In doing so, he sees a role of regulation in re-shaping the incentives on tobacco companies to be consistent with the goal of harm-reduction.

The RMM is proposed as a government monopolisation of the marketing of tobacco products. While free enterprise companies would retain the right to manufacture, a monopsonistic agency would be set up to market tobacco products (Tobacco Products Agency-TPA). The TPA would be tasked with servicing the existing market while also minimising the market and tobacco-related harm by making tobacco as unattractive as possible.

The TPA is seen as offering a more dynamic and trusting relationship with manufacturers because it would be in a customer-supplier relationship, rather than imposing regulatory control from outside the relationship between marketers and consumers. Working within the customer-supplier relationship is seen as making regulatory work easier as it removes the antagonistic relationship common between a regulator and manufacturers and marketers.

All marketing would be conducted through the TPA which would purchase stock made to specifications from multiple private-public manufacturers and then sold as generic products. The market would initially consist of most of the products currently available, plus, once the TPA had the capacity to assess new products, a range of potential reduced-exposure smoked and smokeless products, plus any nicotine replacement products marketed for non-cessation purposes. Where there was capacity to judge harm-reduction potential, the agency would mandate minimum standards and provide incentives to create less harmful products.

Removing the relationship between manufacturer and consumer is seen as effectively eliminating the incentive and benefits to manufacturers from marketing to consumers, therefore eliminating incentives to undermine regulatory controls. This system is also seen as making it easier to ensure drab packaging and to specify health warnings and other product information.

The TPA would not promote its products because its aim would be to reduce harm, rather than grow the market. Communication about products would focus on their harmful aspects. Demand for tobacco would

be further reduced through the RMM minimising image creation associated with marketing, by encouraging retail outlets to promote cessation and by restricting supply through restricting more harmful products and, over time, restricting the number of tobacco retail outlets.

7.3.1 Implementation Barriers

Borland (2003) identifies a number of likely barriers to implementing the RMM. He recognises that many people will need to be convinced that the tobacco problem warrants the proposed solution. He recognises that those who currently profit from the current market status quo will oppose the RMM and that there exists a significant undercurrent of suspicion of any government intervention in commerce and/or activities designed to influence personal choices.

International trade agreements such as those dealing with intellectual property and trademarks are also recognised as problematic, although he notes that further work is required in this area. Achieving truly generic packaging could, however, be difficult, particularly if compensation was not provided. The removal of trademarks could be more problematic for some countries than others. However, Borland (2003) suggests that the trademark issue could be addressed through making tobacco a controlled substance, thereby moving it outside ordinary commerce. He also suggests that trademark forfeiture could be achieved voluntarily (e.g. as part of agreed protection against future liability), or forcefully through litigation.

Borland (2003) acknowledges that governments may be nervous about becoming involved in the residual tobacco problem, particularly if over time the community loses sight of the reasons for government involvement and there is risk that governments are perceived as promoting tobacco. To address this possibility, he sees the need for symbolic as well as practical signals within the RMM which voice governments' disapproval of tobacco in an ongoing manner. Making tobacco a controlled substance and limiting its availability are seen as two mechanisms through which such messages would be communicated.

The risk of an illicit market, largely due to smuggling, is recognised, particularly if the RMM results in price increases of conventional products or mandates product modifications that make conventional products less appealing. Any capacity to import large quantities of tobacco products from areas outside the area controlled by the TPA is recognised as potentially problematic and the need to implement the RMM alongside a set of jurisdictions aimed at controlling smuggling is recognised.

7.4 Purchasing the Tobacco Industry

Callard, Thompson, & Collishaw (2005) take Borland's model further and propose tobacco industry reform at the most essential level; that is, the purchasing of the tobacco industry by public interest organisations tasked with managing the industry to eventually eliminate tobacco use. The legislation enabling such industry transformation would prohibit the manufacturer of tobacco products with one exemption, the public interest manufacturer.

Phasing out rather than banning tobacco use is seen as the objective, achieved by controlling how and by whom tobacco is sold. Rather than penalising users of tobacco, Callard et al (2005) argue that it is more appropriate to focus on removing the corporate behaviour and drivers that impede strategies aimed at reducing tobacco-related harm.

Callard et al (2005) argue that tobacco does not have to be sold by tobacco companies and point to many existing examples of goods and services being provided by public/government organisations and managed for the public good (e.g. building railroads, increasing steel production, building good security, reducing fossil fuel consumption). Existing regulatory tools used to meet such goals are identified to include tariffs, quotas, subsidies, licensing, protected oligopolies and monopolies, public ownership and bans on foreign ownership. Examples noted of where public control is used to reduce potential harm from existing products or behaviour include the control of the commercial trade of weapons, strategies to reduce greenhouse gas emissions and regulatory control of alcohol and gambling. The authors also cite many recent examples of legislative developments supporting new forms of social enterprise in Canada, Germany, Italy, Spain and Sweden. In reviewing this current context, the authors conclude that societies do have a choice and the available mechanism to shape a tobacco industry which helps to achieve public health goals rather than undermine them.

7.4.1 Public Interest Enterprise

The authors describe the public interest enterprise as the base organisational model for their strategy. Public interest enterprises in tobacco would supply the market with tobacco products while also working to decrease tobacco consumption; therefore working to support rather than undermine public health measures. Public interest enterprises could be in either the public or private sector; however, these would operate to meet public interest and social purpose objectives as well as economic objectives.

The non-profit businesses model is also seen as providing a useful framework for the reform strategy. Non-profit businesses are not operated for financial gain and are accountable for stating and then working in compliance to their stated business purpose. Identified examples include government enterprises such as water utilities, liquor distribution, petroleum products, waste collection and disposal.

Community Interest Corporations (CIC), a new business type recently formed in the UK, are also seen to provide a useful framework for development. CIC provide a structure for social enterprises wanting to use their profits and assets for the public good. The CIC structure also enables the use of the limited company framework without having a profit motive or charity status. CIC are seen as different from for-profit business corporations in relation to their motivations and accountability. They must pursue social objectives and must pass a community interest test by satisfying a regulator that their purpose would be regarded by a reasonable person as being in wide public interest.

7.4.2 Funding the Purchase

Callard et al (2005) propose that governments would purchase tobacco operations through a purchase agreement potentially financed by normal commercial debt borrowed at the government's borrowing rate. Using the Canadian tobacco market, as an example (estimated to be worth between \$3.4 to \$15 billion dollars), the authors propose that a proportion of the purchase cost could be re-paid by future tobacco product sales revenue. They note that a purchase cost of \$15 billion would only take two years of Canadian tobacco tax revenue to pay for. While recognising that revenue streams would reduce over time as smoking prevalence and sales declined, costs are also predicted to decline as revenue would no longer be needed for litigation¹², lobbying, marketing and promotion.

7.4.3 Barrier to Implementation

In respect to the Canadian context, Callard et al (2005) do not see anything in Parliamentary or legal statute that provides tobacco companies immunity from being purchased and transformed. They observe that any government is entitled to restrict and control sales of tobacco or any harmful substance. They further suggest that in the face of increasing litigation pressure, legal challenges by tobacco companies about reform may not be in the interests of tobacco company shareholders who may be better placed to accept a certain payment over an uncertain future.

The authors recognise that a big question for governments would be whether the proposed reform would be cheaper or more expensive than the status quo and doing nothing. They believe, however, that the cost of purchase would be significantly lower than the cost of doing nothing and that the investment would pay off primarily through greatly reduced health costs. Further to this point, key informant proponents now see value in conducting a cost benefit analysis of the structural reform approach. Such an analysis would compare the costs of continuing with current tobacco control strategies and the resultant costs of tobacco use against implementing the structural reform approach and the predicted decrease in prevalence. These informants feel that the value of the tobacco companies will continue to go down over time as litigation against the industry continues; with this perceived as having a positive impact on the cost-effectiveness of the approach.

The likelihood of legal challenge under various international trade agreements (e.g. GATS, TRIPS) is recognised (Callard et al, 2005); however, preparing for such is seen as due diligence in the development of a public interest tobacco manufacturer, while restricting imports and establishing a monopoly manufacturer might be considered to infringe various principles established under existing trade agreements. It is noted that countries are entitled to protect health with this right established under various other treaties (e.g. Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child).

Neither trade nor health-related treaties are considered subordinate one to the other, although it is noted that the convention is to give more recent treaties precedence. The recent Framework Convention on Tobacco Control is noted in this respect.

¹² Members, shareholders, directors and managers of the new organisation would be protected from lawsuits for the past wrongs of the for-profit tobacco industry

Key informant proponents also note that perhaps the critical issue is to determine whether governments are prepared to meet likely penalties from challenging trade agreements, rather than assuming that such agreements present insurmountable barriers.

“...that’s something that has been missing in discussions around trade issues and tobacco control. People will say you cannot do the following because of trade agreements where the more correct presentation of fact is that you cannot do the following without risking a decision by a trade tribunal and without risking a financial penalty as a result. But governments always have the authority to do it if they choose to pay the penalty.” (International key informant)

A New Zealand key informant agrees with this analysis, noting that the biggest barriers posed through international trade agreements may be the ‘hidden’ or diplomatic costs of change, for example, penalties and paybacks imposed as a consequence of imposed restrictions within tobacco trading markets.

7.5 Views on Purchasing the Tobacco Industry

Whilst acknowledging the concept of purchasing the tobacco industry as innovative, and not discounting the potential value of testing the approach in an appropriate market if this was possible, the feasibility of the concept is questioned by a number of key informants. Doubt is expressed that tobacco companies would ever allow such major reform to occur, particularly in core markets such as the USA. In acknowledging people smoke for a lot of reasons, fundamental doubts are also raised as to whether changing tobacco supply and the motives of the supplier will in fact change people’s reasons for wanting to smoke.

Key informants also question whether there would ever be the required level of political will to implement the strategy, particularly in the face of perceived uncertainties about the strategy’s efficacy. If such will does exist, it is suggested that a more proven and less risky approach would be to channel this into achieving higher and more systematic levels of regulatory control which operate from outside the tobacco industry and which focus on the core areas of product, price, placement and promotion. It is recognised that meaningful and comprehensive tobacco product regulation has never been implemented so therefore questions remain as to whether the extent of structural reform suggested is actually necessary.

“...if you had the political will to purchase the industry and only allowed tobacco to be sold by non-profits or a purchasing agency, imagine what you could do with that amount of political will through conventional channels. Tighten all aspects of regulation; put more money into mass communications. There is this jump that says we could fix everything by going from here to there and there is no discussion of the other things you do with the same amount or much less political will...” (International key informant)

Another view is that the goals of tobacco control are perhaps better served by working with the profit motive and tobacco industry market forces rather than trying to eliminate these. The near monopoly conventional tobacco products have in the market is seen as a key factor to address. Within the current

environment, tobacco companies are seen to have little incentive or motivation to change. It is suggested therefore that regulation should be used to build greater competition by encouraging innovative, cleaner forms of nicotine delivery.

“...I think that the profit motive is so engrained in so many cultures... if we like it or not, I think that there is more to be gained by trying to find a profit incentive for people to come up with an alternative that doesn't kill people...” (International key informant)

Under this approach, capitalism would therefore be used to drive competition and innovation in the tobacco market. However, regulation could still play a role in ‘distorting’ the market and addressing the profit/tobacco nexus by creating incentives to transfer from combustible products to cleaner forms of nicotine delivery. For example, using taxation policy to make smoked tobacco very expensive, limiting the supply of smoked tobacco, using de-marketing strategies and making alternatives less expensive but not so expensive that social use and initiation becomes a problem.

An international key informant notes that regulating combustible products to potentiate quitting would provide the tobacco industry with incentives to examine alternative, clean ways of delivering nicotine. More competition within the pharmaceutical market is also seen as beneficial, potentially achieved through encouraging manufacturers to introduce more novel and innovative NRT and alternative forms of nicotine delivery (e.g. nicotine patches in the form of tattoos as a way to appeal to young people).

Key informant proponents of structural reform note that the approach can seem radical in the context of the individual behavioural change strategies historically focused on within tobacco control. However, structural reform is considered less radical when assessed in the context of how other social issues are addressed in other disciplines. Geo-political reference points are also recognised as influential in how people respond to the idea. Those in de-regulatory environments more comfortable with the privatisation of state assets are reported to commonly struggle with the idea whereas those in more regulated environments, such as France or India, are reported to be more receptive.

“Political feasibility is very much measured by the current circumstances of the audience, it is a very subjective response.” (International key informant)

In recognising that such reform may be a longer-term proposition, key informant proponents report examining incremental ways to apply greater leverage over the way, and economic incentives under which, cigarettes are supplied. They report, for example, currently exploring possible incentives that can be provided to retailers to get them to assist in recruiting smokers for quitting. It is also recognised that ongoing implementation of other regulatory controls have a key role in moving towards a situation where total structural reform becomes more feasible.

7.6 New Zealand Considerations

International key informant proponents of structural reform see New Zealand offering particular potential as a market in which to take greater control of the tobacco supply. Factors perceived to be supportive of this include New Zealand's geography as an island state (offering relatively easy border control), the absence of domestic tobacco production, a relatively small consumer market (with possibly less resistance from the tobacco industry about such reform) and the existing progressive and supportive environment for tobacco regulation.

While New Zealand key informants acknowledge that structural reform ideas have not to date been seriously considered in New Zealand, some feel the country may actually be quite close to achieving the levels of democratic and political support that would be required to introduce such reform. High levels of identified public support for recent changes to the SFE Act are seen as evidence of this, as is recent public polling showing over the half the population supporting a total ban on tobacco. It is acknowledged, however, that to gain further public traction, structural reform ideas would need to be put on the public agenda and widely debated. Building public support would require a clear vision of the structural reform goal (e.g. sale of tobacco only through restricted outlets, sales only through the government) and promoting the vision as realistic and achievable. Building sufficient public support would be critical with political support contingent upon this.

A New Zealand key informant sees the need for a two-part vision and strategy. It is acknowledged that further reductions in smoking prevalence and the further de-normalising of smoking is important. In the first part of the strategy, shorter-term strategies to achieve the end goal of the elimination of tobacco harm are continued (e.g. elimination of visible sales, the licensing and restrictions of sales outlets, graphic warnings, and elimination of additives). Concurrently, efforts are made to convince the public that there is an end point to ongoing regulation (i.e. the elimination of tobacco) and that this is achievable. It is within this context that the feasibility and efficacy of big structural reforms are then positioned as a means to reach the end point goal. An integrated plan, concurrently involving both product and content level and structural level regulation, is therefore described.

Thomson, Wilson, & Crane (2005) have written in support of a dedicated tobacco control agency and structural reform in New Zealand as suggested by Borland (2004) and Liberman (2003). A key informant supporter of this direction sees the initial establishment of a dedicated agency as the required first stage of moving towards eventual structural reform. Such an agency would have a key role in determining appropriate options and direction for reform. In an ideal scenario, the regulatory authority would not allow any commercial interests or products into the market. In the short to immediate term, the authority may decide which parts of the supply chain it needs to control and which parts could still have commercial interests involved in it. In this respect, Borland's (2004) regulated market model is seen as a potentially appropriate first move.

Another New Zealand key informant voices fundamental opposition to structural reform ideas; principally because they are seen as deviating from the core public health goal of reducing tobacco deaths. It is felt that substantial resources would be required to achieve reform, with outcomes uncertain and not necessarily as effective as other regulatory approaches. It is noted that regulated cigarette sales will still kill thousands each year, and that there is no guarantee of significantly reduced sales without a reduction in nicotine content, a policy direction a takeover body may not be mandated to take.

“I think it would be very dangerous to run the industry down. At present the industry reliably delivers nicotine to three-quarters-of-a-million people, wherever they live in New Zealand, to the brand formulation they are used to and so forth. If you are going to take over that and your managerial capacity fails or anything like that, the government, particularly the political elements in government most friendly to tobacco control who backed such legislation, gets blamed for not supplying addicts with their drug... A vertically integrated industry with intact distribution can assist in selling smokeless and other addictive nicotine alternatives in the fast-moving convenient goods sector, in a way that pharmacies cannot with NRT. ” (New Zealand key informant)

8. IMPLEMENTATION

This following section considers the organisational type and nature that may be required to implement an overall tobacco regulatory framework.

8.1 Dedicated Tobacco Regulatory Agency

A number of authors believe that standalone, dedicated tobacco regulatory agencies are required to deliver effective tobacco product regulation (WHO, 2005; Thomson, Wilson, & Crane, 2005; Liberman, 2003; Royal College of Physicians of London, 2002; Raw, 1997).

In the UK, the Royal College of Physicians of London (2002) calls for a permanently staffed agency for tobacco and nicotine regulation, funded from tobacco duty and sitting outside the Department of Health. Transferring regulatory functions to a new agency is seen as one way such an agency could be developed. The establishment of the Medicines Control Agency (MCA) is cited as an example of this occurring. The College also note the Food Standards Agency (FSA) having being formed through new enabling legislation and powers, with the FSA having an independent role and powers conferred by its own legislation, the Food Standards Act, 1999. Another option considered for forming an agency is through adding tobacco regulation to the mandate of an existing body, amending its enabling legislation if necessary. In the UK, the FSA or the MCA are considered as possible bodies through which this could occur. The College also calls for a re-examination of existing legislation as a possible means of creating specific powers to regulate tobacco. The Consumer Protection Act 1987 or the newly adopted General Product Safety Regulations are both seen as offering potential in this regard (Royal College of Physicians of London, 2002).

The College sees a dedicated tobacco regulatory agency being mandated with a range of responsibilities, including regulatory activity as well as other components of tobacco control (e.g. cessation, second hand smoke). Core regulatory activity is suggested to include:

Product Regulation and Consumer Protection

- Enforcing legislation
 - Establishing standards for alternative products and formulating proposals for regulation of constituents of tobacco products and smoke
-

- Managing disclosure of additives and publishing of public data
- Managing testing and disclosure of toxicity data for smoke and ingredients
- Conducting market surveillance
- Advising on warnings and consumer protection information required on packs
- Challenging misleading risk communication and advising on appropriate public communication
- Evaluating, approving or challenging health claims

Non-tobacco Nicotine Products

- Advice on the public health consequences of licensing non-tobacco nicotine products

Research and Evidence Clearing House

- Development of expertise on the science, law, economics and other policy aspects of tobacco
- Conduct of required research and monitoring

Marketing Activity

- Control and supervision of industry marketing activities
- Enforcement of advertising legislation.

Economic and Trade Regulation

- Control in relation to areas such smuggling, under-age sales, illegal sales, and vending machines.

Raw (1997) also proposes a 'nicotine regulatory authority' which would have oversight of all forms of nicotine delivery. The agency would control testing, stipulate allowable levels of toxic constituents and would set standards for licensing, labelling, packaging, sales and marketing (cited in WHO, 2001).

The IOM committee concludes that a regulatory agency charged with regulating PREPs should have a public health orientation and should be given authority over all tobacco products, including conventional production (Stratton et al, 2001). The agency would be empowered to set performance standards for all classes of products and enforcement powers would be commensurate with its public health mission. It would have an analytical laboratory capable of testing a wide range of conventional and modified tobacco products. A product surveillance programme would be staffed with epidemiologists and data management experts. Other staff would include molecular biologists, pharmacologists, toxicologists, physicians, epidemiologists, statisticians, scientists experienced in the technology of tobacco product design and manufacture, social scientists, marketing experts, enforcement and legal staff.

8.1.1 Organisations for Structural Reform

In furthering his discussion on removing the profit motive from the tobacco industry, Liberman (2003) also proposes a dedicated tobacco regulatory agency. He sees an agency being established by legislation and being required to operate under strict harm-reduction-focused criteria and values. Its core goal would be the minimisation of population harms caused by tobacco products, with sub-goals such as reducing uptake and encouraging cessation. A core role of the agency would be the supply of tobacco products to those who want them, but without having any economic incentive for sales.

Liberman (2003) describes the agency having the authority to impose strict controls over tobacco manufacturers and retailers, either through licensing or contractual arrangements. Strict parameters would be set defining how manufacturers and retailers would operate to serve the agency. For examples, controls would be set over what products and ingredients were permitted in the market, allowable packaging, display, sales outlets and consumer communication (focused on relative harms and addictiveness of different products). Where appropriate, the agency would use communication strategies and pricing policy to encourage use of less harmful products and would create incentives for the development of less harmful products.

Liberman sees governance of the agency through a board comprising a mix of experts (e.g. in epidemiology, toxicology, pharmacology, health economics, communications, law, drug policy, business and public health). The agency would have sufficient distance from government to ensure independence and all actions and decisions would be publicly available.

Borland (2004) places a proposed monopsonistic agency, the Tobacco Products Agency (TPA) at the centre of his Regulated Market Model (RMM). While tobacco companies would retain the right to manufacture tobacco, the TPA would take over marketing and distribution of tobacco products, operating under the goal of minimising tobacco-related harm by making tobacco as unattractive as possible. The TPA is also described as requiring independence from government and open governance, operating under a charter that clearly spells out its objectives. It would be a non-profit (or non-profit maximising) organisation, either raising its operating costs from tobacco sales or operating under government funding. To separate revenue raising from harm-reduction functions and to reduce the likelihood of governments seeking to raise revenue through tobacco sales, revenue-related decision-making would lie outside the TPA (e.g. through Treasury).

Callard et al (2005) also envision a new tobacco agency within their proposal to purchase the tobacco industry. While the agency would still manufacture, distribute and sell cigarettes, it would do so with the aim of reducing tobacco consumption rather than selling more tobacco. Core activities of the new organisation are described as including the:

- cessation of all advertising and promotion;
 - delivery of de-marketing campaigns to reduce demand;
 - use of pricing strategies to reduce demand;
-

- adjustment of cigarette design to encourage quitting and discourage uptake;
- gradual transformation of the retail environment to one more appropriate to addiction treatment.

To illustrate the range of possible options for establishing the agency, they describe three organisational models: a private sector/public interest model; a Crown Corporation model; and a Licensing Commission Model.

The private sector/public interest model would involve two private sector non-profit organisations, fully independent of government. One would purchase tobacco, manufacture cigarettes and sell them to distributors while the other would receive all revenues in excess of costs and would distribute them to various tobacco consumption reduction initiatives. Under the Crown Corporation model, two Crown agencies would be created. One would be responsible for all short-term and long-term operations in managing the supply of and demand for tobacco, while the other would manage revenue surpluses and deficits and ensure proper operation of incentive schemes to discourage consumption. Both organisations would operate at arm's length from government and from each other. The Licensing Commission Model would involve a government agency, operating at arm's length from government, with regulatory authority over the entire system of tobacco supply. The agency would control the supply of all products and would be tasked with achieving specified targets in reduced prevalence. The agency would directly control those parts of the supply chain where this was felt appropriate and provide indirect controls over those parts seen as best managed through partnerships with others (e.g. non-profit agencies, other government agencies, other levels of government, private sector).

8.2 New Zealand Considerations

The establishment of a New Zealand Tobacco Authority in line with the regulatory models suggested by Borland (2004) and Liberman (2003) is proposed by Thomson, Wilson, & Crane (2004). Under this model, a non-profit organisation (funded by a levy on the suppliers of tobacco to the Authority) would sit between tobacco manufacturers and retailers. Manufacturers would only be able to sell tobacco products to the Authority, thus removing the ability of companies to sell branded products to retailers or customers. This structure is seen as enabling the Authority to better control the nature of the product (e.g. through specifying product constituents), product price, the distribution and retail structure, including number of tobacco retail outlets (with this evolving to a structure more appropriate to the sale of an addictive, dangerous drug) and the provision of alternative nicotine delivery devices. An Authority would require independence from political interference, a stable funding flow, the ability to focus on achieving health and equity gains and the ability to withstand expected attacks by the tobacco industry and its allies.

Thomson et al (2005) also suggest further regulatory development to minimise the tobacco industry's planning and executive abilities¹³. Improved knowledge about the industry through increased industry monitoring and powers of disclosure is seen as enabling more proactive tobacco control and as potentially leading to increased public and political willingness to control or prevent industry behaviour adverse to

¹³ Recognised as less necessary if Tobacco Authority control of marketing and product design was introduced

health. They note precedent of this approach in the various powers of the Commerce Commission; for example authority to access documents and to obtain evidence from witnesses. They argue that if such control over financial markets is justified, similar control within a market seriously affecting our health should also be possible.

Allen & Clarke (2003) also suggest that New Zealand could further examine the setting up of a government body to regulate nicotine and products containing nicotine. Other options identified include bringing nicotine under the administration of a single existing regulatory body or formalising links between existing agencies so as to avoid duplication of resources and to ensure the development of consistent policy and regulation.

A number of New Zealand key informants see value in some form of Tobacco Authority. There is, however, recognition that what is ultimately required and appropriate needs to be determined in the context of decisions made about the overall direction of tobacco control in New Zealand. Further to this point, there is a view that should New Zealand elect not to go down a product modification pathway and elect instead to work towards the eventual banning of smoked sales, there would be little need for a large, separate Authority. It is felt that with some 'small print' modifications, existing powers under the SFE Act would provide the bulk of the regulatory framework required to pursue this strategy (e.g. through activating existing powers under Section 31 of the Act to name nicotine as a harmful constituent).

Reasons given by key informants in favouring the establishment of a Tobacco Control Authority include that:

- The conceptual frame for regulating tobacco is seen as different to other consumer products. To ensure the uniqueness of tobacco as a product is recognised, a degree of independence is seen as needed in how tobacco regulation is approached, governed and implemented.
- An Authority would allow for a dedicated focus on tobacco control and would not be distracted by other issues to which it is held politically responsible.
- An Authority could provide fairness to manufactures, consumers, and the public generally by determining and regulating product availability on the basis of degree of harmfulness (e.g. cigarettes would be the most restricted, NRT the least restricted).
- Symbolically, the establishment of a dedicated Authority would send a message to both the general public and the tobacco industry that New Zealand is serious about reducing harm to health caused by tobacco.
- The Framework Convention for Tobacco Control (FCTC) essentially requires the establishment of such an authority.

A key consideration raised by key informants is how best to balance core requirements for both action and accountability. There is a view that accountability may be best delivered working through existing government departments; this structure may also guard against the agency becoming isolated or vulnerable to under-funding or political cut-backs to regulatory authority. It is recognised that the regulation of tobacco is inevitably political, and thus any agency must be part of the inner circle of Ministries. Risk is

seen in developing a Public Health Commission type model separate from government with little power without going back to Parliament each time new initiatives are sought.

Some informants see a more independent body potentially allowing for quicker, more flexible and responsive action to be taken. However, there is another view that the same challenges and obstacles to regulatory reform will face a Tobacco Authority and that faster progress is not necessarily guaranteed under this model.

Possible structural options put forward for an Authority include:

- an independent Crown entity model which would have independence from the political process (e.g. like Commissioner for Children, Electricity Commissioner);
- a statutory position within the current Ministry of Health with statutory independence as well as authority to recommend policy direction;
- a Land Transport Safety Authority (LTSA) or Pharmac type model.

It is noted that any Authority must be driven by public health imperatives and must be empowered with an appropriate level of power and influence, including access to the Minister and to government. A Reserve Bank type model is suggested; while not of an unduly large size, the Bank is seen as a highly influential agency supported by highly skilled and effective staff.

Identified tasks of a Tobacco Authority are identified by key informants as including:

- overall responsibility for all nicotine-containing products (e.g. cigarettes, PREPS, smokeless, NRT etc);
- to lead and recommend regulatory control at the product and content level;
- to further investigate structural reform options and direction;
- to regulate the availability of tobacco, including point of access, price, packaging, advertising and product claims.

Despite enthusiasm for the concept, some informants note reluctance by the current Government for more regulatory agencies and therefore do not consider the current political environment to necessarily be supportive of such a move.

9. CONCLUSIONS

This research has examined models or frameworks of tobacco product regulation that could minimise harm in New Zealand from tobacco and nicotine products. Regulatory models or frameworks that could be feasible and sustainable have been explored, along with different regulatory options. The potential role and fit of PREPs within a regulatory framework has also been examined. Finally, the research has considered the organisational type and infrastructure that could be required to implement and monitor the regulation framework.

In many areas of tobacco product regulation, there is a lack of empirical evidence which can be used to definitively assess the likely impact and outcomes of pursuing various regulatory options. There are some common areas of agreement about appropriate direction as well as many areas where there are different views and perspectives. The ability to draw further conclusions about regulation will also require further discussion and then clarity on desired future goals for tobacco product regulation in New Zealand. With the emerging debate about tobacco harm-reduction, it is timely to have this discussion. Decisions about intent will have implications for what sort of regulatory control is required, with this in turn implicating the level and type of regulatory infrastructure required.

While it is difficult in this context to reach definitive conclusions about the way forward, some broad conclusions on this can be drawn. A number of foundation principles to guide future decision making are also identified and these are summarised in the conclusions below.

Many questions are raised about tobacco product regulation and this document will be successful if it serves to inform this debate constructively. Is there now a need to re-consider the ultimate goal for tobacco control in New Zealand? Should the goal now be explicitly stated as totally eliminating smoked tobacco? How close is New Zealand to this proposition and how feasible is it? Is the possible introduction of new, non-combustible nicotine alternatives justified in the context of a harm-reduction approach focused on achieving the elimination of smoked tobacco? What is the future role for ongoing regulation and the ever-increasing control of tobacco products at the product and content level? Will such an approach achieve desired reductions in smoking prevalence over desired timeframes? What risk is there that such direction ties up scarce regulatory resources and acts to extend the total timeframe to the eventual elimination of smoked tobacco?

In seeking answers to the above, two 'givens' seem clear. Regulation should exist as part of a comprehensive tobacco control strategy and priority must be given to public health goals. The de-normalising of tobacco use is an essential strategy and this focus should not be compromised through regulatory developments. Preventing smoking initiation and providing affordable and effective cessation are also fundamental and

regulation also must not undermine these strategies. Not smoking or stopping smoking are the most effective ways of reducing tobacco-related harm and the evidence suggests that the value of investing in prevention and cessation is considerable.

Proponents of comprehensive tobacco control strategy suggest that what is needed to more effectively reduce smoking-related harm is more investment in de-normalisation, prevention and cessation strategies. This fundamental issue must be considered in the New Zealand context, particularly if there is any potential for regulatory developments to impact on the amount of funding likely to be available for these strategies. For example, there is a view that cessation services to Maori require further attention to ensure that appropriate services are being purchased and delivered effectively.

Some broad conclusions can be reached about any tobacco product regulatory framework. A comprehensive regulatory framework, covering all nicotine delivery systems, would seem appropriate. In turn, it seems appropriate that the regulatory framework recognise the differences between different delivery systems, particularly the differences in resultant harms from combustible and non-combustible nicotine products.

Key questions are raised as to the appropriate balance between regulatory control at the product and content level, that which controls at the structural and 'system' level and that which explicitly aims to eliminate the sale of smoked tobacco as quickly as possible. In reality, an integrated approach developing control at all these levels may provide the most feasible way forward. For example, significant structural regulation and/or moves towards prohibiting the eventual sale of smoked tobacco in New Zealand may only be possible through the continued tightening of tobacco supply through regulation at the product and content level. Supply side controls restricting the supply of tobacco are important in de-normalising tobacco use and in addressing the range of marketing strategies used by the tobacco industry. Further control at this level may be required to build the public and political support required to implement regulations at other levels. Ultimately, the appropriate strategy balance requires clarity about the overall goal for tobacco control in New Zealand and how quickly it is felt this goal should and can be achieved.

Proponents of increased government intervention and control of the supply of tobacco products suggest a range of mechanisms to do this. This include establishing a centralised agency responsible for marketing and promotion and government ownership of the tobacco industry. A central issue in considering regulation of this type is the relationship between government and the industry. Questions also remain as to whether structural reform might genuinely and ultimately contribute to harm-reduction.

The feasibility of any of these options needs to be assessed against the:

- likelihood of tobacco industry support;
 - likelihood of public and political support for government involvement in, or ownership of, the tobacco industry;
 - ability of government to become successful managers within the tobacco industry. Many issues would conspire against this including the complexity of the issue, associated difficulties in public communication, and a lack of industry expertise.
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In sum, the current feasibility of successfully lobbying government to adopt a direct role in the industry seems remote. In marketing terms, it seems more realistic to continue to advocate for government to act as a competitor, not in products necessarily, but for positive health outcomes. In setting goals for intervention, establishing this role for government not only offers politicians an attractive, feasible and realistic proposition, but also establishes a clear framework for strategy development.

A harm-reduction approach within any regulatory framework is perhaps most risky if it is undertaken within the context of accepting smoked tobacco and that smoked tobacco has a long-term future. Many doubts are now raised about the efficacy and value of regulating conventional cigarette content in the pursuit of achieving a 'safer' cigarette. This review covers issues regarding regulation of the addictiveness and palatability of combustible products. The evidence is unclear about the value of reducing addictiveness, given that there is a real possibility of compensatory smoking to maintain nicotine levels. However, reduction in palatability is a real possibility and may work in favour of minimising initiation. The key risk in this strategy, however, remains scientific evidence that reduction in palatability will not result in the potential for further harms. The industry itself is not likely to provide this data either willingly and/or accurately.

Doubts about the efficacy of any PREP involving the combustion of tobacco are also raised and the evidence reviewed points away from the pursuit of combustible PREPs. Although these may be most appealing to smokers, as they require the lowest level of behaviour change, the potential for harm-reduction is far from proven and existing evidence indicates harm-reduction could be negligible. Furthermore, in the absence of independent scientific evidence and faced with an industry with a dubious track record and focused on profitability, the risks to allowing combustible PREPs are significant and numerous.

The evidence reviewed suggests that non-combustible alternative nicotine products such as snus, NRT and pure nicotine may provide greater promise as harm-reduction tools. However, given the complications and many questions surrounding PREPs and limits to available tobacco control resources, further discussion is needed on the value of investing in a PREP-based strategy in the New Zealand context. For example, proponents for PREPs predominantly argue on the basis of harm-reduction for the core target group, particularly on the assumption that there will be a proportion of smokers who can not or will not quit. Notably, however, the size of this group of intractable cigarette users, if indeed it exists, has not been established. Further analysis of the broader addiction literature and expert consultation may assist in estimating what proportion of smokers may be 'unreachable'. A targeted market study may also be useful. The question over PREPs however, will be significantly helped if we better understand what proportion of smokers can not, or will not quit. The value of investing time and resources into a PREP based strategy can then be further assessed against the expected quantum of individuals a harm-reduction strategy may potentially benefit,

These additional analyses are further indicated when we consider the proposition that conventional tobacco control strategies offer the smoker the opportunity to 'quit or die'. This assertion is, in the first instance, a highly emotive one and in the second, a harsh truth, but a truth nevertheless. Whether or not it is regulators that make this offer is, however, a dubious proposition, as the alternatives are in reality

offered by those who develop, market and distribute the product and can hardly be attached to those who oppose and regulate against cigarette use. The 'quit or die' positioning more likely moves market perceptions and regulators closer in favour of the tobacco industry, an industry that likely seeks greater longevity (and profitability) through the chance to develop and market PREPs as an alternative to cessation. These points aside, however, there is no current evidence that the availability of PREPs in New Zealand will result in any significant product switching, and the potential to influence intractable smokers is unknown.

Many concerns about harm-reduction and PREPs are identified in the literature and by tobacco control experts and stakeholders. The risks that harm-reduction and the introduction of PREPs causes further harms is real. Any PREP-based strategy will need to carefully manage the potential contradictions between this approach and core tobacco control goals.

A number of 'bottom-line' requirements are identified should any PREP-based strategy be considered further. The onus, accountability and cost to demonstrate, and then monitor (over the short and long term) the safety and impact of any PREP, should as much as possible lie with the manufacturer of these products. Any regulatory system will require high standards of performance, defined through best possible scientific evidence, with these standards needing to be met as a condition of any product introduction. If any reduced exposure or reduced harm claim is to be made about any PREP, claims must be supported and verified by scientifically sound and independently verified evidence.

There are many challenges and difficulties in developing the testing, evaluation and monitoring systems that would be required to ensure that PREPs are safe and do not lead to greater rather than reduced harms to individual and population health. Many initial questions remain unanswered and comprehensive pre- and post-market research and surveillance is considered essential within any PREP-based strategy. A carefully targeted research programme would therefore be essential in any further examination of PREPs and their potential impact and outcome in the New Zealand context.

The cost, infrastructure requirements and feasibility of developing the required testing, evaluation and monitoring systems are themselves core issues which must be considered when assessing the potential role for PREPs within a regulatory framework. In addition, it is acknowledged that with current available science and understanding, there will always be some degree of uncertainty about PREP impacts and outcomes. While post-hoc research, market surveillance and appropriate regulatory control is considered essential in quickly identifying and responding to any unanticipated consequences, the unknown risks need to be carefully considered. For example, once marketers establish a product presence and dependent market, questions arise as to whether and how effectively regulatory control could implement further change should this be required. The lessons learnt throughout the history of the introduction of combustible tobacco products should be carefully considered in this respect.

The inherent risks in PREPs help to draw out a number of foundation principles which are suggested to guide decision-making, particularly in relation to the possible introduction of PREPs. In general, harm-reduction must not undermine comprehensive tobacco control programmes. This would include:

- ensuring that this approach is not interpreted as a signal that the tobacco problem is solved;
- maintaining a baseline message that all tobacco products are unsafe;
- sustaining an ongoing focus on de-normalising tobacco use;
- not weakening or diverting resources from a core focus on preventing smoking initiation and on providing affordable, accessible and effective cessation services;
- ensuring that PREPs do not increase youth uptake, increase young adult prevalence, decrease quit attempts, lead to increased relapse of former smokers, or lead to wide misuse.

There is also a view that PREPs should not be marketed to the general public and should only be made available to existing smokers. Core questions remain whether the principles above could be adhered to while also achieving the level of alternative product uptake that would be required to result in sufficient reductions in harm. Unless couched completely in the context of cessation (albeit a long-term solution), it seems unlikely that such levels of uptake could be achieved without significant marketing on the basis of a benefit to the consumer, that benefit being the potentiality for reduced harm. A range of further regulatory measures are also likely to be required to encourage a shift between products. While some of these would likely comprise a continuation of current supply side regulatory strategies to reduce the availability of tobacco, others, such as an eventual ban on the sale of smoked tobacco, are untested and would require very careful further deliberation in the New Zealand context.

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11. APPENDICES

APPENDIX ONE: Letter to Key Informant Research Participants

APPENDIX TWO: Tobacco Product Regulation Research –
Key Informant Discussion Guide

Appendix One: Letter to Key Informant Research Participants

30 March 2006

Dear [Research Participant],

Gravitas Research and Strategy Ltd have been contracted by the Smoke-free Coalition and Action on Smoking and Health (ASH) (New Zealand) (the ‘sponsors’) to develop a discussion document and policy/literature review on tobacco product regulation in New Zealand.

The research is exploring options for tobacco product and industry regulation in New Zealand and will assist the sponsors to form an evidence-based position on tobacco product regulation. The research will also assist in identifying future possible tobacco control legislation opportunities in New Zealand.

The two key research questions are:

What models/frameworks of tobacco product regulation¹⁴ would most effectively minimise harm in New Zealand from tobacco and nicotine products?

What models/frameworks of tobacco product regulation are most likely to be feasible and sustainable in New Zealand?

In addition to reviewing the recent national and international literature on tobacco product regulation, the research team is conducting a series of key informant interviews with national and international experts on tobacco product regulation. The consultation aims to ensure that recent national and international experience informs decisions on appropriate direction for New Zealand.

You have been identified by the sponsors as a key person in the field and we are writing to seek your agreement to participate in an interview as part of the research.

Your participation will involve a telephone interview of approximately 1 to 1.5 hours. All interviews will be arranged at a time to best suit you.

¹⁴Note: the term tobacco product regulation is used generically to denote regulation at the product as well as the tobacco industry level

Information from your interview will be integrated with that from other interviews conducted as well as the reviewed literature. The research team will deliver a written report as well as a verbal presentation of the findings to the sponsors.

Your participation can be anonymous if you wish (i.e. information from your interview will not be attributed to you and you will not be identified through your participation). If you are willing for information to be attributed to you, we will discuss with you how you wish for this to be managed. For example, you may wish to review/comment on key findings from your interview before these are reported.

Overview of Interview

The following provides a brief overview of the issues we wish to discuss with you.

- Your role, experience and interest in relation to tobacco product regulation
- Core features, concepts and definition related to tobacco product regulation (e.g. aims and objectives, key principles, conceptual frameworks)
- Essential features/requirements for a regulator and regulatory framework under which to develop and implement tobacco product regulation
- Developments and recommended directions for regulation at both the tobacco industry and tobacco product level
- The place and role of PREPs generally within an overall tobacco regulation framework
- Recommended direction for tobacco product regulation development and implementation in New Zealand, with particular consideration to feasibility, appropriateness and sustainability.

We have identified a number of key themes and issues from the tobacco product regulation literature and will seek to discuss and expand on these as part of the interview.

Thank you for considering this request to participate in the research. In the first instance, could you please indicate by email whether you will be able to take part and provide some indication as to when this will best work for you. We will then follow you up further to finalise details for the interview. To meet our project deadlines, all interviews will need to be completed by 21st April 2006.

Please do not hesitate to contact me if you have any questions about the research. If you wish to speak to one of the research sponsors, Becky Freeman, Director of ASH New Zealand can be contacted on 00 64 09 520 4866 or freeman@ash.org.nz

Thank you again and we look forward to talking with you soon.

Yours sincerely
Michael Blewden
Gravitas Research and Strategy Ltd

Appendix Two: Tobacco Product Regulation Research – Key Informant Discussion Guide

1. Introduction

Background to Research	An exploration of framework options for tobacco product and industry regulation in New Zealand. The research involves review of the literature and key informant interviews with national and international experts. To date, a preliminary review of the literature has been completed to inform the interviews
Research Purpose	To assist ASH/Smoke-free Coalition form an evidence-based position on tobacco product regulation in New Zealand
Interview Purpose	To examine key issues in tobacco product regulation and implementation, drawing on experience and expertise and considering development and implementation in New Zealand
Interview Length	Approximately 1.0 to 1.5 hour
Use of findings	Contribute to a final written report to be prepared for ASH/the Smoke-free Coalition
Confidentiality	Discuss re: identification and attribution to material provided.
Audio tape	Consent to tape
Any questions?	

2. Introduction to Interview

Note: Will use the general term ‘tobacco product regulation’ (TPR) to denote both regulation at the tobacco product level as well as at the industry level

Seems widespread agreement on need for tobacco industry regulation apparent

- *areas of consensus and disagreement*
- *much potential and possibilities*
- *many questions and unknowns*

Interested in your views within this context. As appropriate, will concentrate on specific areas of interest/expertise

3. Participant Background

Background participant’s position, role and experience in relation to

- tobacco control generally
- tobacco product regulation

Identify any areas of particular involvement or interest in tobacco product regulation

4. TPR Context/Background

Check conceptualisation and definition of the term ‘tobacco product regulation’

- anything specifically included /not included in definition

What should we be seeking to achieve through TPR? (e.g. harm-reduction, reducing supply, structural reform of tobacco industry, mix of all these).

- different objectives for TPR over time?

Ultimately what role and fit for TPR within overall tobacco control strategy?

How important is TPR in the overall mix of a comprehensive tobacco reduction plan?

Harm-reduction

Literature grapples with the place, role and merits of a harm-reduction approach within TPR

Broad arguments for: *e.g. a ‘new era’ of harm-reduction is inevitable – a moral and ethical imperative to develop – new potential to deliver on the harm-reduction promise*

Broad argument against: *e.g. harm-reduction approach to tobacco fundamentally flawed – we have sufficient tools to address tobacco, need appropriate resourcing and implementation*

EXPLORE participant’s general position on harm-reduction

- pros and cons of HR approach

Is/should HR be the leading priority for tobacco control?

- does it fit within TPR framework? – where/how?

On what grounds/basis do we ultimately move forward?

5. Potential Reduced-Exposure Products (PREPs)

PREPs defined to include: modified cigarettes; high-tech pseudo-cigarettes; smokeless tobacco products; new tobacco products; nicotine pharmaceuticals; non-pharmaceutical products delivering nicotine only

Literature provides compelling arguments for and against PREPs. For: e.g. ethical and moral imperative – favourable risk-use equilibrium particularly for NRT and snus

Against: e.g. diversion from core public health goals (prevent initiation, cessation) – we have sufficient and effective tools (but need to implement properly) – endorsement of tobacco industry products and need to work with the industry

Substantial information and research needs identified. Many unknowns/questions. A key challenge is sufficiently predicting likely individual and population level benefits and harms.

EXPLORE general position and view on PREPs

- where debate up to/developments in thinking?
- on what grounds/basis are we able to move forward?

NRT

On the basis of evaluating proposed benefits, possible harms, population wide impacts and effects, case for NRT seems particularly strong – there are calls for:

- *Increased/easier access*
- *More favourable regulatory framework (e.g. easier entry to market)*
- *Increase range of approved indications for use*

EXPLORE responses/views on NRT

- recent developments
- feasibility–supportive factors?
- requirements to develop further
- barriers/constraints?

EXPLORE feasibility in New Zealand

- supportive factors?
- requirement to develop further
- barriers/constraints
- risks/concerns

Considerable support in the literature for Snus – particularly on the grounds of relative safety (compared to tobacco smoking)

EXPLORE responses/views on SNUS

- recent developments
 - feasibility – supportive factors
 - requirements to develop further
 - barriers/constraints to development/implementation
-

EXPLORE feasibility/potential in New Zealand

- supportive factors
- requirements to develop further
- barriers/constraints
- risks/concerns

Regulation and Implementation of PREPs

Literature suggests a number of general or overall conditions/requirements for regulating and developing PREPs (EXPLORE views/responses to each)

- *Need to retain focus on preventing initiation and cessation – ensuring appropriate communication etc*
- *Prohibit any harm-reduction claims?*
- *Harm reducing claims allowable when backed by sufficient data?*
- *Mandate minimum standards to overcome problem of messages about reduced risk?*
- *Likely impossibility of ever concluding absolutely that a PREP is harm reducing. Is it acceptable to proceed on this basis? What minimum requirements for understanding/information required to proceed?*

EXPLORE any other views on place/role of PREPs within overall TPR regulation framework. How would this work/what would it look like ideally?

6. Other Product Regulation

*Can we talk further about **tobacco product regulation** – ie. specific aspects of tobacco design/ modification, production, packaging, distribution, sales and marketing.*

Note: Beyond scope of interview and time available to discuss all areas of regulation at the product level.

However do you consider any other areas of product regulation to be of particular priority/ importance within an overall TPR framework? For example, reduced-toxicity strategies, control/ regulation of additives/ingredients, reduced-nicotine and tar strategies?

For those identified:

EXPLORE:

- Reasons for attributed priority/importance
 - Any recent progress
 - in thinking (e.g. aims and objectives)
 - feasibility/potential
 - development/implementation
 - evidence/prediction of efficacy
-

Any product modification areas of less priority/importance or those we should be steering clear of?
EXPLORE fully reasons why.

7. Industry Regulation

Can we talk more specifically now about tobacco industry regulation. By this I mean TPR aimed at increasing control over the tobacco industry generally and regulation which achieves structural level reform, including the proactive shaping of the industry and markets (as opposed to regulation focusing more specifically and reactively at the product level)

The literature appears particularly focused on regulation at the product level, including product modification. There appears less written consideration of regulation as means to proactively achieve overall industry/structural reform

EXPLORE perceived reasons for this situation (e.g. just more written down about product regulation, more accessible, acceptable and feasible way to progress TPR, structural reform in 'too hard' basket)

EXPLORE

- strengths/weaknesses of 'product lead' approach
- implications for overall development of TRP framework
- lessons/implications for New Zealand? EXPLORE fully

Industry regulation strategies identified through the literature include (all part of same general plan to increase control over the industry)

e.g.

- *Removal of the profit motive*
- *Control/removal of the marketing function from tobacco industry – regulated market model*
- *Purchasing of the tobacco industry*
- *Minimisation of the industry's planning and executive abilities – increasing monitoring of the records and planning of tobacco companies*

EXPLORE knowledge of strategies – any particularly preferred

For known/preferred strategy:

EXPLORE any recent progress

- in thinking (e.g. aims and objectives)
 - in development/implementation
 - evidence/prediction of efficacy
-

EXPLORE

- feasibility
- requirements to develop further
- barriers/constraints

EXPLORE feasibility in New Zealand

- existing supportive factors
- requirements to develop further
- barriers/constraints

8. TRP Framework

Can we talk now about how do we deliver on all this...

There is a call in the literature for a unique regulator and regulatory framework for tobacco – it is felt that existing regulatory frameworks/models (e.g. foodstuffs, consumer products, drugs) may be inappropriate for tobacco

Discuss participant's initial response/views on this proposition (e.g. agree, disagree)

What ideally would a unique regulator and regulatory framework look like?

EXPLORE:

- aims/objectives
- roles and responsibilities
- structure/organisation
- requirements and needs (e.g. agreed standards, testing, monitoring and surveillance, research and information)

Examine any national/international developments/progress.

How feasible such a framework model in New Zealand?

- what would be required to achieve and sustain?
 - existing enabling factors?
 - existing barriers/constraints
 - requirement to develop over time? – if so, should we distinguish short/mid/longer term objectives?
-

Literature suggests important 'macro' level features of an overall TPR framework/approach

e.g.

- Global response and common regulatory framework
- Integrated within comprehensive tobacco strategy
- Retention of prevention and cessation imperative
- Rejection of prohibition
- Dedicated tobacco regulation authority
- Criticality of research, information, monitoring and surveillance

EXPLORE responses/reflections on these broad requirements

Explore any other 'macro' level features considered important when determining overall TPR framework

- role/function
- reason for importance

9. Other

Any others comments/thoughts?

Agreement on attribution to information, anonymity and confidentiality

Thank and close
