

Government Regulation of Tobacco Ingredients and Emissions

Lessons Learned and Issues that Remain to be Addressed

Linda L. Pederson, Ph.D. Joanna Cohen, Ph.D. Mary McKenna, Ph.D.

January 2009

Suggested Citation: Pederson, L.L., Cohen, J. and McKenna, M. *Government Regulation of Tobacco Ingredients and Emissions*. Toronto, ON: Ontario Tobacco Research Unit, Special Report, January 2009.

Acknowledgements

Diane van Abbe provided invaluable support in conducting literature searches on a wide range of topics. Drs. David Hammond and David E. Nelson read drafts of the document and gave thoughtful and useful suggestions and comments.

Table of Contents

Acknowledgements	iii
Table of Figures	vii
Executive Summary	
Background	
Possible Effects of Tobacco Ingredient and Emission Regulations: Positive, Negative	
and Unknown	5
Lessons Learned from Tobacco Control and Other Areas	7
Light and Mild Cigarettes	7
Potentially Reduced Exposure Products (PREPS):	
Ingredient Regulation in Food	9
A Framework for Issues that Remain to be Addressed	
Recommendations for Research	
The Agent	
The Vector	
The Host	
The Environment	
Some Final Thoughts	
References	

Table of Figures

Figure 1. F	nidemiologic	Model of Nicotine	Addiction and	Tobacco	Control	12
rigule 1. E	pluennologie	model of Micouile	Addiction and	TODACCO	Control	······ 12

Executive Summary

Recommendations of the WHO Study Group on "The Scientific Basis of Tobacco Product Regulation" (WHO, 2003; WHO, 2007) include two core proposals for governmental regulations:

- 1. Reduce the toxic substances present in tobacco smoke; and
- 2. Prohibit any marketing by the tobacco industry based on governmental regulation (WHO, 2007).

Despite the good intentions underlying the approach of reducing tobacco-related harm through the regulation of ingredients and emissions, there are questions about the population health impact of these interventions and the way in which the tobacco industry will respond to the regulations.

The purpose of this report is to:

- 1. Discuss potential results to population health, to smoking behaviour, to industry reactions and to health communication from changes in tobacco product ingredients and emissions; and
- 2. Apply an epidemiological framework to elucidate areas of product modification where research is needed before action can and should be taken.

While debate and discussion continue about possible legislative and regulatory approaches to reducing the harm from tobacco ingredients and emissions, questions remain about whether we have sufficient knowledge about possible unintended consequences of such changes. Questions also remain about how changes in ingredients (including nicotine) and emissions will affect peoples' smoking behaviour. We recommend a research agenda be developed and implemented, adding to information on users and potential users of tobacco products (the Hosts) and on the tobacco industry (the Vector), while continuing to monitor the products themselves (the Agent). This research can provide the basis for guiding policy and provide much needed information for the development of communication about ingredients and emissions (the Environment).

Background

The WHO Study Group on "The Scientific Basis of Tobacco Product Regulation" (WHO 2003; WHO, 2007) issued an important report in 2007 (WHO, 2007). Among the many recommendations, two core proposals were provided for governmental regulations:

- 1. Reduce the toxic substances present in tobacco smoke, on the basis that there is no justification for carcinogens and toxicants to be higher than the lowest levels of currently available products; and
- 2. Prohibit any marketing by the tobacco industry.

Burns et al. (2008) have discussed the rationale behind some of the recommendations, procedures for product monitoring, and concerns about the impact of communication to smokers about the regulations.

Many countries already place limits on tar and nicotine emissions and several countries have banned certain flavours that are added to cigarettes. The European Union, for example, has limits on tar, nicotine and carbon monoxide emissions under the ISO testing methods, although this has had little or no effect on population health to date (O'Connor et al, 2006a). Indeed, we did not locate any evidence that regulations of ingredients and emissions have reduced the risks of smoking. Canada has implemented two regulations related to the product (Reporting regulations and Reduced Ignition Propensity regulations, neither of which was intended directly to reduce the risks of tobacco use (Hammond, 2008). Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (FCTC) provide guidelines for implementation of regulations on tobacco products as well as industry disclosure of tobacco product information (WHO Framework Convention on Tobacco Control, 2008).

Proponents of ingredient regulations raise several compelling reasons for more careful consideration to be given to undertaking ingredient regulation (Burns et al., 2008; Hammond, 2008). Tobacco use will cause one in ten deaths around the world (WHO Tobacco Free Initiative, 2008) and is the second major cause of mortality globally. Given the overwhelming evidence of the harmfulness of tobacco and given what is known about the health risks from specific ingredients, any attempts to regulate ingredients that could result in decreased harm to the population by reducing the toxic ingredients in tobacco and reducing the appeal and addictiveness of tobacco should be considered. Some suggestions have been made about potential approaches. For example, Benowitz and Henningfield (1994) proposed establishing a threshold for nicotine in cigarettes as a way to control levels of addiction in established smokers and prevent initiation in young people, although, as they pointed out, smokers may increase exposure to other toxic ingredients in their attempts to regulate their nicotine intake. Using computer simulations, Tengs et al. (2004) demonstrated that there would ultimately be a reduction in smoking and very little negative impact on population mortality with the nicotine regulation approach, proposed by Benowitz and Henningfield. Additionally, the WHO study group (2007; Burns et al, 2008) suggested setting maximum limits for some toxicants, possibly using current median amounts of specific ingredients and emissions as the basis.

Respected scientific observers warn that ingredient regulation has the potential for deleterious consequences; however, many of these may not be readily obvious from a cursory analysis (Kozlowski, 2008). Further, there is still much to be learned about the health risks of the range of tobacco product ingredients and emissions (Hammond & O'Connor, 2008) and the interrelationships among them. Two quotations from Warner (2005), in a discussion of new tobacco products, summarize some of the relevant issues:

"Do the novel products represent a boon to health? No one knows. One might assume that reduced exposure to known toxins would reduce harm to smokers. However, as noted previously, cigarette smoke contains thousands of chemicals, with possibly hundreds of them hazardous to health. No one knows which chemicals, or which combinations, pose the greatest danger. Further, the novel products achieve their exposure reduction through a variety of techniques that may themselves pose risks, possibly new risks, to the health of their consumers. For example, one reduced-exposure brand of cigarettes uses palladium to achieve its objective. Is inhaling combusted palladium dangerous? No one knows."

"Even if a novel product truly poses less risk to smokers than do conventional cigarettes, the aggregate, or population, impact might be negative. This would occur if a reduced risk to the individual who consumes the product instead of smoking conventional cigarettes is outweighed by increased use of tobacco products, including the novel product, in the aggregate. That is, use might increase, possibly substantially, because the perceived relative 'safety' of the new product might lead some smokers to switch to the new product in lieu of quitting altogether. Similarly, former smokers who quit due to a concern about the relationship between smoking and lung cancer might relapse to a cigarette that promised 'reduced carcinogens.' Finally, some children who never would have smoked conventional cigarettes, for fear of their dangers, might experiment with the novel products, thereby joining the ranks of tobacco consumers. A subset of them, possibly quite large, might 'graduate' from the new products to 'better-tasting' conventional cigarettes."

Hence, it is necessary to proceed with caution in considering regulations that require changes in tobacco product ingredients and emissions.

The purpose of this report is to:

- Discuss potential results to population health, to smoking behaviour, to industry reactions and to health communication from changes in tobacco product ingredients and emissions; and
- 2. Apply an epidemiological framework to elucidate areas that can be acted upon immediately and to identify areas where research is needed before action can and should be taken.

Recommendations for research on the Agent (the tobacco products), Host (smokers and potential smokers), Vector (the tobacco industry) and Environment (legislative, social) are presented. In this document, reference to tobacco products and tobacco product use will include both combustible and non combustible products and does not distinguish among products within each category. Tobacco ingredients include all content and additives in the growing, curing and manufacture of products, including packaging, filters and paper. The term "emissions" refers to the compounds produced when tobacco products are burned for consumption purposes.

Possible Effects of Tobacco Ingredient and Emission Regulations: Positive, Negative and Unknown

Changes in tobacco ingredients and emissions might have several effects. Among them are:

- 1. Potential impacts on health;
- 2. Potential impacts on the behavior of the users, which can include changes in product use as well as use of multiple tobacco products;
- 3. Potential impacts on social norms, attitudes and beliefs and,
- 4. Potential responses from the tobacco industry to required product changes.

The major public health goal of tobacco product modification is to reduce health risks of users and nonusers exposed to tobacco. However, there are several possibilities that may preclude this from happening, given that nicotine in tobacco products is addictive and that continued sales and profits is the goal for the tobacco industry.

WHO (2007) has recommended that tobacco products be evaluated for addiction potential and consumer appeal, candy flavoured additives be prohibited, claims by manufacturers of risk reduction be prohibited, biomarkers for exposure be required and maximum limits for toxic constituents in smoke be established. The report notes that considerable time would be needed to follow smokers for many decades to determine the specific health effects of any product changes; during that time there would be, in all probability, modifications made to not only the products, but the packaging, the filters, the curing processes etc., all of which could contribute to the overall risks from the products. As a result, it would be difficult, if not impossible, to quantify any changes in health effects resulting from changes to specific ingredients and emissions. Although there is considerable evidence about the general harmfulness of a number of chemicals (e.g., arsenic, benzene, cadmium and formaldehyde), scientific evidence on the risks of products with lower levels of these chemicals is lacking and is particularly difficult to collect. A change in ingredients or emissions can result in at least three potential outcomes that defeat public health goals:

- 1. Products with a lower toxicity profile may nevertheless cause the same harm to individual smokers as a result of changes in use;
- 2. Products may reduce actual exposure to toxins, but the reduction is negligible or insufficient to reduce the health risks; and,
- 3. Products may reduce harm in those that use them (although they may either prolong use or result in greater uptake among previous non-users).

In addition to the lack of evidence about smokers' responses to changes in ingredients, another important consideration is the tobacco industry's response to regulation. For example, Wayne and Connolly (2004) have examined tobacco industry documents focusing on menthol in cigarettes. They found information on the physiological and pharmacological effects of menthol, its interaction

with nicotine and its toxicity cited in the documents, all of which demonstrates the potential types of topics that have been explored by the tobacco industry in developing products and in research on ingredients. The tobacco industry has access to a vast amount of information that could be used to undermine regulatory efforts.

In order for a regulation of toxic ingredients to be effective, even if it were possible to identify appropriate levels of ingredients and emissions, it would be necessary to be fairly specific about maximum levels of ingredients. But even the specification of maximum levels of ingredients could be ineffective because the tobacco industry might then modify or add other ingredients. The industry might modify or add other ingredients or change processes in order to counteract product modifications required by law (Gray & Boyle, 2002). Further, a required change in one ingredient might have an impact on other ingredients. Suppose, for example, regulation is enacted that requires the addition of a bitter tasting additive (bitrex) to tobacco products to make them less palatable. It is possible that the tobacco industry would add another ingredient to products in order to neutralize the effect of bitrex. We know from the experience with potentially reduced exposure products (PREPs) that smokers will not gravitate toward products that are not satisfying to them (e.g., taste that is unacceptable) (Pederson & Nelson, 2007), and that the industry can detect and capitalize on loopholes (follow the letter of the law rather than its intent). Therefore, it is certainly within the realm of possibility that the tobacco industry will somehow compensate for control over regulated ingredients.

Lessons Learned from Tobacco Control and Other Areas

Lessons learned from earlier experiences with cigarettes and other products can be useful in anticipating potential results from modifications to tobacco product ingredients and emissions. A discussion of light and mild cigarettes, and PREPs, both those that are burned and those that are not, provide some information, as do results from regulation of food products and additives.

There are at least two issues that should be kept in mind. First, there should be clear separation of modifications to products and the advertising of those modifications (Vladeck et al, 2004). It is certainly important that scientific evidence is available to support modifications leading to reduced health risks. But how that information is communicated to the general public is critically important. There is debate about the type of information needed for advertising the safety of products and who is responsible for providing that information, whether it be manufacturers or other groups (Kozlowski, 2002).

Second, we need to make the distinction between potential benefits to an individual and possible implications for population health overall. While a modification to a tobacco product may result in potential individual risk reduction for that user, it may also result in greater initiation of use, lower rates of cessation, and use of multiple tobacco products. Hence, overall there could be an increase in population health risks (Kozlowski, 2007, 2008). Scientific evidence for the impact on populations needs to be available and carefully considered.

Light and Mild Cigarettes

One of the first attempts by the tobacco industry to combat concerns about the health risks from smoking cigarettes can be found in the development of filters for cigarettes. Hammond (2008) provides a brief summary of the history of incorporation of filters in the design of cigarettes in the 1950's. He then goes on to describe the second major design change, which was the introduction of filter ventilation in the 1970's and 80's and thus the entrance into the market of light and ultra light cigarettes. The modified filters contained almost imperceptible ventilation holes that allowed for the dilution the smoke passing through the filter. Of course, as we came to learn, smokers were adept at adjusting their smoking strategies in order to maintain their level of nicotine (National Cancer Institute, 2001); an unexpected result was that these ventilated cigarettes were puffed more deeply, and have been linked to an increase in adenocarcinoma.

Interestingly, the use of the labels on the cigarettes implied lower risk and the industry marketed these products in ways that were intended to counteract health concerns of smokers (Pollay & Dewhirst, 2001, 2002). The marketing strategy appeared to work; smokers used these labels to determine health risks (National Cancer Institute, 2001). Several surveys of smokers have documented that smokers of light cigarettes were concerned about their health, they were interested

in quitting, and in general they believed theses cigarettes provided some health benefits (Ashley, Cohen & Ferrence, 2001; Pederson & Nelson, 2007). The lesson learned is two-fold: smokers are concerned about the health risks from smoking cigarettes and are amenable to adopting ways to reduce those risks, and second, that there has been no substantial reduction in health risks as a result, in part because smokers adapt the way that they use the products to maintain their level of nicotine exposure. There can even be increased population-level risks, since smokers who might have quit do not do so and some may initiate smoking under the mistaken belief that the risks are low.

The National Cancer Institute (2001) and the Ministerial Advisory Council on Tobacco Control (2002), after thorough examinations of the scientific evidence that had been accumulated regarding these products, concluded that light cigarettes provide no benefit to smokers' health. The European Union prohibited use of the terms "light" "mild" and similar terms from packaging and advertising in 2003 (Borland et al, 2008). Unfortunately, in spite of the high levels of misperception that exist among smokers, the ban did not appear to markedly change misperceptions to any great extent (Borland et al, 2008). Other measures such as removing tar and nicotine numbers from packages, restrictions on misleading pack design (i.e., plain packaging), prohibiting filter designs that produce misleading sensory perceptions and active educational campaigns may be needed beyond simply removing the misleading labels.

Potentially Reduced Exposure Products (PREPS):

Potentially Reduced Exposure Products (PREPs) were first introduced in the 1980s with RJ Reynolds' Premier brand (Stratton et al., 2001); tobacco companies in the U.S. have been involved with the development of modified cigarettes since that time. The development of these products and their potential impact on tobacco use have lead to the consideration of harm reduction products and approaches. Thoughtful discussions have addressed conceptual and definitional issues (Shiffman et al, 2002), research needs (Hatsukami et al, 2002), and potential benefits and risks (Warner, 2002), thereby illustrating the complexity of this approach to tobacco use. Pederson and Nelson (2007) summarized the history of PREPs products. In their review, they provide evidence that, while advertising for PREPs does not make specific health claims, they are marketed as being less harmful or less addictive than traditional cigarettes. There appeared to be no substantial differences in advertising strategies for PREPS and light cigarettes. Surveys of smokers again reveal that they believe there are health advantages in using PREPs compared to conventional cigarettes (Canada Gazette, 2007). In addition, focus groups conducted by the U.S. Centers for Disease Control and Prevention (Caraballo et al, 2006; O'Hegarty et al, 2007), found that smokers had tried PREPs products to reduce their risks. In a series of focus groups conducted by GlaxoSmithKline (Kemper, 2005), smokers appeared to be skeptical about or to have misunderstood the advertising claims for PREPs products. Even if some PREPs did have reduced health risks, perceptions of potential users, and those users who would have otherwise considered quitting altogether, would still be of concern.

It has been suggested that the primary motivation of tobacco companies in developing PREPs products was as a public relations effort by the tobacco industry to improve their image (Pederson & Nelson 2007). The lesson learned is that caution should be exercised when dealing with efforts by tobacco manufacturers to develop and market reduced risk products such as the low-nitrosamine smokeless products (Camel and Marlboro snus) currently entering the market (Pederson, 2008).

Experiences with changes in ingredients of other classes of products may provide some useful guidance in anticipating potential impacts of regulations of tobacco product ingredients and emissions. Therefore, we are going to discuss and review what happened with the substitution of aspartame for sugar and the removal of trans fats in food.

Ingredient Regulation in Food

Federal government agencies regulate many aspects of food, including safety, ingredients, additives, and supplements. The US Food and Drug Administration (FDA), for example, maintains an inventory of 'Everything Added to Food in the United States' (EAFUS) (US FDA, 2008). Substances such as food additives must be approved before they are marketed; they are evaluated for their composition, properties, anticipated consumption levels, and safety. For example, aspartame, a high intensity sweetener, is one of the most thoroughly tested additive substitutes (Health Canada, 2005; US Food and Drug Administration, 2008) and is on the EAFUS list.

In the past, some concerns were raised that brain cancer, leukemia, and lymphoma were linked to aspartame consumption. In 1996, the US Food and Drug Administration stated that data from the National Cancer Institute did not support the brain tumor association (US Food and Drug Administration, 1996, 1999). Recently, a safety evaluation by an expert panel funded by a manufacturer of aspartame found that current levels of consumption were well below Acceptable Daily Limits established by government agencies (Magnuson et al, 2007; American Cancer Society, 2007). Based on laboratory testing, animal experiments, epidemiological studies, and research from humans, the researchers found no credible evidence of carcinogenicity and no support for an effect of aspartame on the nervous system, learning, or behaviour (Magnuson et al, 2007).

The US government recommends using non-caloric sweeteners as a strategy for weight loss (US Department of Health and Human Services, 2005), although Raben et al (2002) concluded there was no consensus on using artificial sweetener to achieve better weight control. A review by Vermunt et al (2003) also did not yield clear results. In two experiments, the consumption of aspartame-sweetened soft drinks was favourable to body weight control in adults of a healthy weight compared with caloric sweeteners. Epidemiological evidence suggests that the use of sweeteners might assist with weight maintenance in healthy weight people, but not with weight loss. In two weight loss experimental studies with obese participants, weight loss was similar among those consuming aspartame versus non-aspartame containing products. The aspartame users, however, maintained a weight loss during a two year follow-up, while the non-aspartame group re-gained all weight. The

American Diabetes Association accepts the US government position that sweeteners are safe and can be used to reduce calorie intake (American Diabetes Association, 2008). However, even with careful investigation, there continues to be concerns about its safety (see for example: http://www.cspinet.org/new/200706251.html and

http://www.cancer.org/docroot/ped/content/ped_1_3x_aspartame.asp). The lesson here is that even with all of the research conducted on aspartame, there are still questions remaining about the population impact of use of this substitute as a replacement for sugar. The implication for tobacco product regulation is that we may never have sufficient information to be sure that we are not causing new harms, and that no regulation may be better than uninformed regulation.

An example of food modification can be found with respect to fat and fatty acids. For example, in the 1990's numerous studies showed that trans fatty acids, found in semi-solid fats that are sold in margarines, cooking oils and process foods such as baked goods, increased levels of Low Density Lipoprotein cholesterol and the incidence of coronary heart disease (Eckel et al, 2007). The US federal government began to assist with information gathering about trans-fat levels in foods, by including trans fatty acids in the US nutrient database in 1994 and began national randomized sampling to derive trans fatty acid values in 2002. In 2005, labeling of trans fat content in food was required in Canada; a survey in the same year revealed that eight out of ten Canadians had heard of trans fats, were concerned about the health risks of trans fats and had modified their diets to reduce them (Leger Marketing, 2005).

Denmark in 2003 became the first country to limit trans fats on a national basis (American Heart Association, 2008), although we have not been able to find research evaluating this policy. In 2005, Canada was the first country in the world to institute mandatory nutrition labeling (including trans fats) on pre-packaged foods (Health Canada, 2007a). The US followed in 2006 with trans fat labeling and also developed nutrition claim regulations pertaining to trans fat (Eckel et al, 2007). Many food companies and restaurants responded by switching to reduce or eliminate trans fats, including: Nestle, Kraft Foods, Proctor & Gamble, Red Lobster, Wendy's, and McDonald's (Borra et al, 2007).

A report from the Pan American Health Association (2007) estimates that in the Americas, excluding the US and Canada, a reduction of 4.5 grams per day of trans fat (2% of total energy) would prevent between 30,000 and 130,000 Coronary Heart Disease events. A prospective study of nurses in the US found that those with the highest blood levels of trans fatty acids (intake 3.6 grams per day) compared with those with the lowest blood levels (intake 2.5 grams per day) were approximately three times more at risk for coronary heart disease, even after adjusting for other risk factors (Sun et al, 2007).

Although a survey by the American Heart Association in 2006 indicated that 84% of American adults had heard of trans fats, fewer than half the people could identify a food that contained trans fats, even when provided with a list (Eckel et al, 2007). Estimates of trans fat consumption vary. Consumption has decreased from 1980, when trans fatty acid consumption comprised 2.2% of total

energy intake to 1.5% in 1990 (Craig-Schmidt, 2006). Craig-Schmidt (2006) estimated that the decline would be sharper after 2006 following labeling requirements designed to increase consumer awareness. It is clear that regulation of trans fats and the labeling of products can impact population knowledge and behavior. However, questions about the impact on population health remain. For example, do people respond by replacing trans fats with other categories of fats? And if they do, what is impact on health in the general population?

From these food and beverage examples, it is apparent that changes can and do occur in knowledge and in behaviour. Considerable research was available on the risks or safety of ingredients in food and provided the basis for government regulation. However, even when there is government regulation, there is still much to be learned about the impact of these regulations on the health of the population. Because of the long-term nature of the follow ups that are needed, some uncertainty about the health implications remains. When applying lessons from the regulation of food products one must also recognize that one complication with tobacco products is that they contain nicotine which is addictive. Further, the risk of lowering some of the toxicants in tobacco products is that consumers will then assume cigarettes have met some sort of "safety standard" that is similar to other consumer products, which will never be the case for combustible tobacco products.

A Framework for Issues that Remain to be Addressed

There is much still to be learned about tobacco product ingredients and emissions and many questions can be raised. Among them are: What are population knowledge, attitudes and behaviors concerning product regulation and ingredients? What kinds of communication programs need to be designed if there are required changes to tobacco product ingredients and emissions? What do researchers and policy makers know and what information is needed in order to design effective messages? How might product ingredient regulation impact different population subgroups – by age, gender, SES, race/ethnicity, etc? What are the possible benefits and risks from product modification and/or regulation? What research needs to be conducted before any regulations can be recommended, particularly on a population level?

In order to examine issues surrounding ingredient regulation, we are proposing the adoption of a conceptual framework to provide guidance for and to organize research questions. The conceptual framework that provides the basis for some research recommendations was described by Giovino (2002) and is based on a conceptualization by Orleans and Slade (1993).



Figure 1: Epidemiologic Model of Nicotine Addiction and Tobacco Control

Briefly, the model has been used to provide a basis for understanding patterns of tobacco use and is based on the traditional epidemiologic model of agent, host, vector and environment. The agent here is the tobacco product; the host the smoker or tobacco user, with incidental hosts being individuals exposed to secondhand smoke; the vector refers to the tobacco industry; the environment is this case is specifically the legislated environment, but this construct can also include social norms, and influences from family, society, culture, politics, economics, and the media. Policies designed to regulate tobacco ingredients and emissions are environmental factors that need to be considered in the context of other environmental factors. Ingredients that are regulated are a component of the agent. All components of the model need to be addressed, including the specifics of tobacco product ingredients and emissions. The categories are not necessarily mutually exclusive; in the discussion that follows the interplay between them will be noted.

Recommendations for Research

The Agent

What are the impacts of changes to tobacco product ingredients and emissions on health?

Ingredient reporting is one way to monitor the Agent. Another approach is to conduct computer simulations based on specific sets of assumptions about ingredients, changes in ingredients and population variables. Several recent examples can be found that illustrate this approach. The first is the Tobacco Policy Model (Tengs et al, 2004) that has estimated changes in population smoking given specific changes in nicotine content in cigarettes. They concluded that even if regulations to make lower nicotine cigarettes result in smoking being more attractive to smokers, reduction of nicotine could prevent new smokers from becoming addicted and provide a net gain in population health. A second example is found in the Australian simulation study on use of smokeless tobacco to replace cigarette smoking (Gartner et al, 2007), which demonstrated the amount of replacement needed to impact population health. Glantz (2008) demonstrated the population impacts that could potentially result from recommending smokeless tobacco (ST) as a harm reduction strategy. Similar approaches could be adapted to model different outcomes (population initiation, prevalence, and morbidity and mortality) under a range of different ingredient and emission requirements (e.g., nicotine levels, carbon monoxide levels and various combinations of the two). While such studies would, of necessity, only estimate the impacts of product modifications, they could provide important information more quickly than waiting for results from cohort studies on health effects.

The Vector

How can the activities of the tobacco industry be monitored and influenced?

One of the challenges surrounding regulation is that the tobacco industry may be conducting research and developing products that can address a variety of product modifications and may, in fact, neutralize their impact. Researching the activities of the tobacco industry can prove fruitful. Since 1998, with the availability of internal tobacco industry documents (Master Settlement Agreement, 1998), it has been possible to examine industry policies and activities in some depth (e.g., Ling & Glantz, 2005).

The regulations in place in Canada related to the tobacco industry cover reporting regulations and ignition propensity, neither of which was intended directly to reduce the health risks of tobacco use (Hammond, 2008). The one exception is reduced ignition propensity (RIP) cigarettes, which were intended to reduce fire risks; the Cigarette Ignition Propensity Regulations require all cigarettes manufactured in or imported for sale into Canada on or after October 1, 2005 to meet an ignition propensity standard (Health Canada, 2007b). When cigarettes in New York State were required to meet reduced propensity standards in 2004 (Connolly et al, 2005), NY smokers were more likely than smokers in other jurisdictions to report that cigarettes went out between puffs, but there were

no differences in cigarettes sales or prices. In addition, the changes in ignition propensity did not appear to affect reports of cigarette taste, intentions to quit or quit attempts (O'Connor et al, 2006b). Under the Reporting regulations, tobacco manufacturers and importers must provide Health Canada with annual reports which include their sales data, manufacturing information, tobacco product ingredients, toxic constituents, toxic emissions, research activities and promotional activities, although these data are not normally available to researchers outside of Health Canada.

It could also be useful to develop a system for surveillance of activities using business and trade publications. Nelson and Pederson (2008) demonstrated the utility of this approach in a preliminary analysis of material on PREPs from a range of publications. Knowledge of three categories could be obtained from tobacco specific publications, general marketing publications and business periodicals: (1) information on product development, rollouts and terminations; (2) information on marketing and advertising strategies by the tobacco industry; and, (3) information and projections from business analysts.

Several additional sources are available for monitoring the tobacco industry (David Sweanor, 2008 personal communication). Among them are:

- The Tobacco Merchants Association (TMA)
- The US Securities and Exchange Commission (10-K and 10-Q filings and insider trading reports)
- The Ontario Securities Commission for companies operating in Canada
- Hoover's Reports for UK companies
- Financial websites
- Brokerage account websites
- Competitive intelligence from individual companies
- Current and former employees
- Convenience store associations

In addition there are several publications that routinely cover the activities and developments of the tobacco industry (Diane vanAbbe, personal communication 2008).

- Canadian Tobacco Grower, http://www.canadiantobaccogrower.com/
- Cigar Aficionado, http://www.cigaraficionado.com/Cigar/Home/
- Cigar Life, http://www.cigarlife.com/
- Pipes and Tobacco, http://www.pt-magazine.com/
- Roll Your Own Magazine, http://www.ryomagazine.com/
- Smoke Magazine Online, http://www.smokemag.com/
- SmokeShop Magazine, http://www.smokeshopmag.com/
- Tobacco Farm Quarterly, http://www.tobaccofarmquarterly.com/
- Tobacco International, http://www.tobaccointernational.com/
- Tobacco Outlet Business ,http://www.tobonline.com/
- Tobacco Reporter, http://www.tobaccoreporter.com/
- Tobacco Retailer, http://www.tobaccoretailer.com/
- Tobacconist Magazine, http://www.tobacconistmagazine.com/

To effectively use business and trade publications and internet sources to monitor the tobacco industry, it would be necessary to determine the type of data to be collected and to design and test a coding scheme for a formal content analysis, along with a mechanism for communicating the information. In addition, strategies for inclusion of websites and newspaper reports would need to be developed and could provide important background and contextual material. While not a replacement for the tobacco industry documents, this proposed approach means that new product developments and activities could be monitored, described and summarized. Such an approach would mean that tobacco control efforts could be more proactive when information emerged about product development, marketing, and corporate strategies. To be best prepared to overcome tobacco industry strategies, it would also be important to capture and understand the tobacco industry's internal behaviour.

In addition to the approach described, requiring the tobacco industry to provide data on specific ingredients and emissions provides information on the vector as well as the agent. Some suggestions for surveillance and monitoring of mandated reductions in toxicants in cigarette smoke come from the WHO TobReg proposal, summarized by Burns et al (2008). Among these are specific ingredients that have been suggested as targets for lowering: N'-Nitrosonornicotine (NNN), 4- (methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), acetaldehyde, carbon monoxide and formaldehyde (see Burns et al., 2008 for the complete list of recommendations). There are lower levels of some toxic ingredients in products imported from the U.S. (e.g., benzo(a)pyrene); levels of other ingredients are higher in imported cigarettes (e.g., tobacco-specific nitrosamines) (Hammond & O'Connor, 2008). While ingredient and emission regulation is complex and multifaceted, as discussed above, a regular report to governments of particularly dangerous ingredients, many of which are already being reported by tobacco manufacturers to Canadian authorities through the Tobacco Products Reporting Regulations (Hammond & O'Connor, 2008) provides a means for determining whether the mandated restrictions are being followed.

The Host

What are population knowledge, attitudes and behaviors concerning tobacco product ingredients and emissions? What do researchers and policy makers know about ingredients and emissions and what information is needed for regulations?

Several population surveys have documented that, while smokers do understand that cigarette smoking is harmful to health (Hammond, 2008), their knowledge of health risks from different types of products is superficial. In addition, individuals have very little understanding of tobacco ingredients and their specific health risks, nor do they understand information that is provided on tobacco packs and warning labels about ingredients (Cohen, 1996). One only has to consider the results of surveys in the mid 1990's that revealed a third of smokers felt that low tar cigarettes were no more harmful than not smoking and another third were not sure about the health risks. When product constituent information is added to pack labels, smokers are able to report that information,

but it is not apparent that they understand the meaning of it or what its health impact might be (O'Connor et al., 2006c). Therefore, careful development of interventions to increase knowledge is a necessary early step in the process, along with regular monitoring of population knowledge about ingredients and their health impacts. Canadian cigarette packs contain some information, but as has been noted above, knowledge by the population is less than optimal. One wonders whether tobacco users would continue to use the products if they possessed comprehensive and comprehensible information about the ingredients. More research is needed to determine what, if any, ingredient and emissions information is needed and what modalities should be used to communicate that information.

It is recommended that in depth information be collected from both smokers and non smokers of all ages to determine their understanding of ingredients. What types of information, if any, might have an impact on their behavior? Qualitative methods could be used initially to provide that basis for the design of interventions for health communication and instruments to monitor populations.

The Environment

What regulations of ingredients and emissions are needed that will result in changes in smoking behaviour and ultimately in population health? What types of health communication messages are necessary to inform tobacco product users about the regulations and modifications?

Included in this category are legislation, regulations, and health communication campaigns. While legislation refers specifically to laws that are enacted by the federal or provincial government, regulations are developed from legislation and are often required in order to implement a law. How the legislative measures are interpreted and implemented may result in less than optimal ingredient regulation. The delineation of different responsibilities for enactment and enforcement needs to be acknowledged and determined.

There are other environmental components that may be worth investigating, such as the impact of cultural, familial, social and media influences on tobacco use. More can be learned about these influences through the use of qualitative interviews and quantitative surveys. The basis for campaigns in this context can come from tobacco users and potential users as described in the section considering the Host.

Data should be collected on what type of information users would like to have access to, and their attitudes toward different types of regulations and modification s; i.e., what regulations and modifications will ultimately lead to changes in tobacco use behaviour and eventually in population health. It might be necessary to provide different types of information and modes of communication for different population subgroups. Implementation of campaigns about ingredient and emission regulations and the reasons for them need to be carefully designed and monitored, in order to avoid unintended consequences.

There is ample evidence that health communication campaigns can increase knowledge of the health risks of tobacco use, change attitudes toward smoking and smokers, and even modify behavior. One only needs to consider the changes that have occurred in the past 50 years with regard to smoking. Following the Surgeon General's Report in 1964 (US Public Health Service, 1964) and the coverage of the findings, the general population became increasingly aware of the health risks of cigarette smoking. Also, while early research on the health effects of second hand smoke exposure was not readily accepted, even by the scientific community, by 2006 a rigorous and comprehensive review of the scientific evidence lead to the conclusion that exposure to secondhand smoke was a serious health risk (US Department of Health and Human Services, 2006). Media campaigns the U.S. have resulted in local and national legislation restricting where smoking is permitted (National Cancer Institute, 2008). Clear, concise and understandable communication can have an impact. It is critical that health communication messaging be repeated, comprehensible, convincing and believable.

Some Final Thoughts

In considering the population impacts of changes to tobacco product ingredients and emissions, there are important issues that need to be considered. First, credible scientific information on the complex relationships of ingredients and emissions and toxicity and addiction is needed. The situation is not straightforward. There are there are many chemical ingredients that we know are harmful, but there is also an assumption that altering a few of them in isolation will have a negligible impact on overall harm and could have important ramifications for the population. The question then becomes: should we risk consumer misperceptions and undertake elaborate regulations to make negligible differences to the product? In fact, there are many who would argue that virtually all of the modifications that are feasible will collectively have little impact on harm; in other words, there may be no feasible way to "clean" smoke to any significant extent. Second, what is also needed more research that provides evidence that consumers are aware of, understand and are trying to do something about their risks from tobacco products. Both quantitative and qualitative investigations can help inform policy and public education campaigns. Third, examination and attention need to be paid to addressing profits made by those who manufacture and sell tobacco products. What would it take to make them direct their attention to protecting public health? What type of incentives would be required, and how could they be implemented, to ensure that profits do not come at the expense of public health?

While the debate and discussion continue about possible legislative and regulatory approaches to reducing the harm from tobacco ingredients and emissions (see for example Chapman, 2008; Gray et al., 2005; Borland, 2003; Myers, 2006; Burns et al, 2008; Hammond, 2008), questions remain about whether we know about possible unintended consequences, and whether more information is needed from the general population about how changes in ingredients (including nicotine) and emissions will affect their smoking behaviour. It is necessary to determine what criteria are needed to help policymakers move forward and regulate ingredients and emissions. Some of this information will emanate from research designed to address different and interrelated aspects of the framework discussed. We recommend that a research agenda be developed regarding the health implications of changes to tobacco product ingredients and emissions and on the types of changes required for reducing the harm, addiction and attractiveness of tobacco products in consultation with experts in pharmacology, survey research, public policy, and health communication among others.

References

American Cancer Society. Aspartame, 2007 Available from: http://www.cancer.org/docroot/ped/content/ped_1_3x_aspartame.asp?sitrea=PED,2007 Accessed August 2008.

American Diabetes Association. Sweetners and Desserts. Available from: http://www.diabetes.org/nutrition-and-recipes/nutrition/sweeteners.jsp Accessed July 2008.

American Heart Association. A History of Trans Fats. Behind the Label, 2008. Available from: http://www.americanheart.org/presenter.jhtml?identifier=3048193 Accessed September 2008.

Ashley MJ, Cohen JE, Ferrence R. 'Light' and 'mild' cigarettes: Who smokes them? Are they being misled? *Canadian Journal of Public Health* 2001;92:407-11.

Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. The implications for tobacco regulation. *New England Journal of Medicine* 1994;33:1123-5.

Borland R. A strategy for controlling the marketing of tobacco products: A regulated market model. *Tobacco Control* 2003;12:374-82.

Borland R, Fong GT, Yong HH, Cummings M, Hammond D, King B et al. What happened to smokers beliefs about light cigarettes when "light/mild" brand descriptors were banned in the UK? Findings from the international tobacco control (ITC) four country survey. *Tobacco Control* 2008;17:256-262.

Borra S, Kris-Etherton PM, Dausch JG, Yin-Piazza S. An update of fat reduction in the American diet. *Journal of the American Dietetic Association* 2007;107:2048-50.

Burns DM, Dybing E, Gray N, Hecht S, Anderson C, Sanner T, O'Connor R, et al. Mandated lowering of toxicants in cigarette smoke: A description of the World Health Organization TobReg proposal. *Tobacco Control* 2008;17:132-41.

Canada Gazette. Promotion of tobacco products and accessories regulations (Prohibited Terms). Department of Health, Government of Canada. *Canada Gazette* August 4, 2007;141.

Caraballo R, Pederson LL, Gupta N. New tobacco products: Do smokers like them: *Tobacco Control* 2006;15:39-44.

Chapman S. Benefits and risks in ending regulatory exceptionalism for tobacco. *Tobacco Control* 2008;17:73-4.

Cohen JB. Smokers' knowledge and understanding of advertised tar numbers: Health policy implication. *American Journal of Public Health* 1996;86:8-24.

Connolly G, Alpert H, Rees V, Carpenter C, Wayne G, Vallone D, Koh H. Effect of the New York State cigarette fire safety standard on ignition propensity, smoke constituents, and the consumer market. *Tobacco Control* 2005:14;321-327.

Craig-Schmidt MC. World-wide consumption of trans fatty acids. *Atherosclerosis Supplements* 2006; 7:1-4.

Eckel RH, Borra S, Lichtenstein AH, Yin-Piazza SY. Understanding the complexity of trans fatty acid reduction in the American diet: American Heart Association trans fat conference 2006: Report of the trans fat conference planning group. *Circulation* 2007;115:2231-2246.

Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AK, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modeling study. *Lancet* 2007;369:2010–14.

Glantz S. Innovative approaches to harm reduction. Presented at the Society for Research on Nicotine and Tobacco Annual Meeting. 2008. Portland, Oregon.

Gray N, Henningfield JE, Benowitz,NL, Connolly GC, Dresler C, Fagerstrom K, Jarvis MJ, Boyle P. Toward a comprehensive long term nicotine policy. *Tobacco Control* 2005;14:161–5.

Gray N, Boyle P. Regulation of cigarette emissions editorial. Annals of Oncology 2002;13:19-21.

Giovino G. Epidemiology of tobacco use in the United States. Oncogene 2002;21:7326-40.

Hammond D. Product modification and regulation. Non Smokers' Rights Association Roundtable on Long-term Policy Options to Regulate the Tobacco Industry and it Products. January 25, 2008.

Hammond D, O'Connor RJ. Constituents in tobacco and smoke emissions from Canadian cigarettes. *Tobacco Control* 2008;17(Suppl I):i24-i31.

Hatsukami DK, Slade J, Benowitz NL, Giovino GA, Gritz ER, Leischow S, Warner KE. Reducing tobacco harm: Research challenges and issues. *Nicotine & Tobacco Research* 2002:4;S89-S101.

Health Canada. Food and Nutrition. Aspartame. Available from: http://www.hc-sc.gc.ca/fn-an/securit/addit/sweeten-edulcor/aspartame_e.html. Accessed March 2008.

Health Canada. Healthy Living. Trans Fat. It's Your Health. (2007a.) Available from: http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/trans-eng.php. Accessed September 2008. Health Canada. Responsibilities under the Tobacco Act. Government of Canada, (2007b) Available from

http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/reg/coming-avenir/pcipr-prpic-eng.php Accessed July 2008.

Kemper K. Perception IS reality: The truth about "reduced risk" tobacco. American Public Health Association Annual Meeting 2005; Philadelphia USA

Kozlowski LT. Harm reduction, public health, and human rights: smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Research* 2002;4:S55-S60.

Kozlowski LT. Effect of smokeless tobacco product marketing and use on population harm from tobacco use: Policy perspective for tobacco-risk reduction. *Preventive Medicine* 2007;33:S379–86.

Kozlowski LT. The proposed tobacco regulation: the triumph of hope over experience? *Tobacco Control* 2008;17:74-5.

Leger Marketing. Canadians and Transfats. 2005. Available from: http://www.legermarketing.com/documents/spclm/051003ENG.pdf. Accessed March 2008.

Ling PM, Glantz SA. Tobacco industry consumer research on socially acceptable cigarettes. *Tobacco Control* 2005;14:1–16.

Magnuson BA, Burdock GA, Doull J, Kroes RM, Marsh GM, Pariza MW, Spencer PS, Waddell WJ, Walker R, Williams GM. Aspartame: A safety evaluation based on current use levels, regulations, and toxicological and epidemiological studies. *Critical Reviews in Toxicology* 2007; 37:629-727.

Master Settlement Agreement. 1996. Available from: http://ag.ca.gov/tobacco/msa.php 1998. Accessed March, 2008.

Ministerial Advisory Council on Tobacco Control: Canadian Expert Report. *Putting an End to Deception: Proceedings of the International Expert Panel on Cigarette Descriptors.* Ottawa, ON: Ministerial Advisory Council on Tobacco Control, January, 2002.

Myers ML. Government tobacco regulation: opportunity for change. The Lancet 2006;368:268-270.

National Cancer Institute (NCI). *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine*. National Cancer Institute Monograph 13, National Institutes of Health, 2001. National Cancer Institute (NCI). *The Role of the Media in Promoting and Reducing Tobacco Use*. National Cancer Institute Monograph 19, National Institutes of Health, 2008.

Nelson DE, Pederson LL. Using Business and Trade Periodicals to Monitoring Tobacco Industry Marketing Activities: The Case of Potentially Reduced Exposure Products (PREPS). Unpublished manuscript.

Orleans CT, Slade J. *Nicotine Addiction: Principles and Management*. 1993. New York: Oxford University Press, p. ix.

O'Connor RJ, McNeil A, Cummings KM, et al. How did UK cigarette makers get their brand to 10 mg 'Tar' or less? *British Medical Journal* 2006a;332:302.

O'Connor RJ, Giovino GA, Fix BV, Hyland A, Hammond D, Fong GT, Bauer U, Cummings KM. Smokers' reactions to reduced ignition propensity cigarettes. *Tobacco Control* 2006b: 15;45-49.

O'Connor RJ, Kozlowski LT, Borland R, Hammond D, McNeil A. Relationship between constituent labeling and reporting of tar yields among smokers in four countries. *American Journal of Public Health* 2006c;28:324–32.

O'Hegarty M, Richter P, Pederson LL. What do adult smokers think about ads and promotional materials for PREPs? *Journal of Health Behavior* 2007;31:526-34.

Pan American Health Association. *Report of the Pan American Health Association/WHO Task Force on Trans Fats Free Americas.* Washington DC, April 26-27 2007.

Pederson LL. Why smokeless tobacco use is not a public health strategy for reducing societal harm from cigarette smoking. National Smokeless and Spit Tobacco Summit. Oklahoma City, March, 2008.

Pederson LL, Nelson DE. Literature review and summary of perceptions, attitudes, beliefs and marketing of Potentially Reduced Exposure Products: Communication implications. *Nicotine & Tobacco Research* 2007;9:525-34.

Pollay RW, Dewhirst T. Marketing cigarettes with low machine-measured yields. In: *Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*. National Cancer Institute Monograph 13 National Institutes of Health, 2001.

Pollay RW, Dewhirst T. The dark side of marketing seemingly "light" cigarettes: Successful images and failed fact. *Tobacco Control* 2002;11(Suppl1):i18-i31.

Raben A, Vasilara TH, Moller AC, Astrup A. Sucrose compared with artificial sweeteners: Different effects on ad libitum food intake and body weight after 10week of supplementation in overweight subjects. *American Journal of Clinical Nutrition* 2002;76:721-9.

Shiffman S, Gitchell JG, Warner KE, Slade J, Henningfield JE, Pinney JM. Tobacco harm reduction: Conceptual structure and nomenclature for analysis and research. *Nicotine & Tobacco Research* 2002:4;S113-S129.

Stratton, K, Shetty, P, Wallace, R, Bonurant S, editors. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*. Washington DC: Institute of Medicine, National Academy Press, 2001.

Sun Q, Ma J, Campos H, Hankinson SE, Manson JE, Stampfer MJ, Rexrode KM, Willett WC, Hu FB. A prospective study of trans fatty acids in erythrocytes and risk of coronary heart disease. *Circulation* 2007;115:1858-1865.

Tengs TO, Ahmad S, Savage JM, Moore R, Gage E. The AMA proposal to mandate nicotine reduction in cigarettes: a simulation of the population health impacts. *Preventive Medicine* 2004; 40:170-80.

U.S. Department of Health and Human Services. A Healthier You: Based on the Dietary Guidelines for Americans. 2005. Available from:

http://www.health.gov/dietaryguidelines/dga2005/healthieryou/html/chapter5.html. Accessed August 2008.

U.S. Department of Health and Human Services. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General.* U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006.

U.S. Food and Drug Administration. FDA talk paper (T96-75),1996. Available from: http://www.cfsan.fda.gov/~lrd/tpaspart.html. Accessed July 2008.

U.S. Food and Drug Administration: Center for Food Safety and Applied Nutrition. EAFUS: A Food Additive Database, 2008. Available from: http://vm.cfsan.fda.gov/~dms/eafus.html. Accessed July 2008.

U.S. Food and Drug Administration. Sugar Substitutes: Americans Opt for Sweetness and Lite, 1999. Available from: http://www.fda.gov/FDAC/features/1999/699_sugar.html. Accessed March 2008.

U.S. Public Health Service. *The Health Consequences of Smoking: A Report of the Surgeon General*, Public Health Service Publication Number 1103; 1964.

Vermunt SH, Pasman WJ, Schaafsma G, Kardinaal AF. Effects of sugar intake on body weight: a review. *Obesity Review* 2003;4:91-99.

Vladeck D, Webber G, Gostin LO. Commercial speech and the public's health: Regulating advertisements of tobacco, alcohol, high fat foods and other potentially hazardous products. *The Journal of Law, Medicine & Ethics* 2004;4:32-4.

Warner KE. Tobacco harm reduction: Promise and perils. *Nicotine & Tobacco Research* 2002:4;S61-S71.

Warner KE. Will the next generation of "safer" cigarettes be safer? *Journal of Pediatric Hematology and Oncology* 2005;27:543-50.

Wayne GF, Connolly GN. Application, function and effects of menthol in cigarettes: A survey of tobacco industry documents. *Nicotine and Tobacco Research* 2004; 6:S43-S54.

World Health Organization. *The Scientific Basis of Tobacco Product Regulation: Report of a WHO Study Group.* WHO Technical Report Series 945, Geneva, Switzerland: World Health Organization Press, 2007.

World Health Organization. *WHO Framework Convention on Tobacco Control*. Conference of the parties to the WHO Framework Convention on Tobacco Control, Third Session. Durban, South Africa, 2008. Available from http://www.who.int/gb/fctc/PDF/cop3/FCTC_COP3_6-en.pdf Accessed January 2009.

World Health Organization. *WHO Tobacco Free Initiative. Information on Global Tobacco Use;* (2008) Available from: http://www.who.int/tobacco/health_priority/en/index.html Accessed March 2008.

World Health Organization Scientific Advisory Committee on Tobacco Product Regulation (SACTob) *Statement of Principles Guiding the Evaluation of New or Modified Tobacco Products;* 2003. Available from: http://www.who.int/tobacco/global_interaction/tobreg/brisbane_2002_modified/en/index.html Accessed March 2008.