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THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REGULATION

Second report of a WHO study group



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WHO Study Group on Tobacco Product Regulation

Stanford University, California, United States of America, 25–27
July 2007

Members

- Dr D.L. Ashley, Chief, Emergency Response and Air Toxicants Branch, Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America
- Dr D. Burns, Professor of Family and Preventive Medicine, School of Medicine, University of California at San Diego, San Diego, California, United States of America
- Dr M. Djordjevic, Program Director, National Cancer Institute, Division of Cancer Control and Population Sciences, Tobacco Control Research Branch, Bethesda, Maryland, United States of America
- Dr E. Dybing (*Chair*), Director, Division of Environmental Medicine, Norwegian Institute of Public Health, Oslo, Norway
- Dr N. Gray, Scientist, International Agency for Research on Cancer, Lyon, France
- Dr S.K. Hammond, Professor of Environmental Health Sciences, School of Public Health, University of California at Berkeley, Berkeley, California, United States of America
- Dr J. Henningfield, Professor (Adjunct), Behavioral Biology, Johns Hopkins University School of Medicine; Vice President, Research and Health Policy, Pinney Associates, Bethesda, Maryland, United States of America
- Dr M. Jarvis, Principal Scientist, Cancer Research UK, Health Behaviour Unit, Royal Free and University College London Medical School, London, England
- Dr K.S. Reddy, Professor of Cardiology, All India Institute of Medical Sciences, New Delhi, India

Dr C. Robertson, Senior Associate Dean for Faculty and Academic Affairs, School of Engineering, Stanford University, California, United States of America

Dr G. Zaatari, Professor, Department of Pathology and Laboratory Medicine, American University of Beirut, Beirut, Lebanon

Secretariat

Dr D.W. Bettcher, Coordinator, Framework Convention on Tobacco Control, and Director, a.i., Tobacco Free Initiative, WHO, Geneva, Switzerland

Ms E. Tecson, Administrative Assistant, Tobacco Free Initiative, WHO, Geneva, Switzerland

Ms G. Vestal, Legal Officer and Scientist, Framework Convention on Tobacco Control, Tobacco Free Initiative, WHO, Geneva, Switzerland

Preface

Tobacco product regulation — regulating the contents and emissions of tobacco products by testing, mandating disclosure of test results and regulating the packaging and labelling of tobacco products — is a pillar of any comprehensive tobacco control programme. The Contracting Parties to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) are legally bound by the treaty's provisions on tobacco product regulation, contained in its Articles 9, 10 and 11.

The information provided by the ad hoc WHO Scientific Advisory Committee on Tobacco Product Regulation, established in 2000 to fill gaps in knowledge on tobacco product regulation, served as the basis for the negotiations and the subsequent consensus on the language of the aforementioned articles of the treaty.

In November 2003, in recognition of the importance of regulating tobacco products, the WHO Director-General formalized the Scientific Advisory Committee into the WHO Study Group on Tobacco Product Regulation (TobReg). TobReg's membership comprises national and international experts on product regulation, treatment of tobacco dependence, laboratory analysis of tobacco contents and emissions and design features. Its work is based on current research, and it also conducts research and proposes testing to fill regulatory gaps in tobacco control. The Director-General reports to the Executive Board on the results and recommendations of the Study Group in order to draw the attention of Member States to WHO's efforts in tobacco product regulation.

This technical report was prepared by TobReg in accordance with the priorities of the WHO Tobacco Free Initiative and the provisions of the WHO FCTC concerning tobacco product regulation, in response to requests from Member States in which the population is affected by the issues addressed. The fourth meeting of TobReg was held at Stanford University, California, United States of America, on 25–27 July 2007. The agenda was prepared to respond partly to Decision 15 of the first session of the Conference of Parties to the WHO FCTC, held in Geneva, Switzerland, on 6–17 February 2006, when the Parties adopted templates for guidelines for implementing

Articles 9 and 10 of the Framework Convention. According to the template on regulations, the guidelines should be based on work performed by TobReg and the WHO Tobacco Free Initiative, which serves as TobReg's secretariat and coordinating body.

This report presents the conclusions and recommendations of the WHO Study Group on Tobacco Product Regulation (TobReg) from its fourth meeting which was held at Stanford University, California, United States of America (USA), on 25–27 July 2007. The agenda was prepared to respond partly to Decision 15 of the first session of the Conference of Parties to the WHO Framework Convention on Tobacco Control, held in Geneva, Switzerland, on 6–17 February 2006, when the Parties adopted a template for the development of guidelines for implementing Articles 9 and 10 of the Framework Convention. At this fourth meeting of WHO TobReg, the Study Group deliberated on a number of topics in the field of tobacco product regulation and produced the following advisory notes and recommendations:

- an advisory note on smokeless tobacco products: health effects, implications for harm reduction and research needs;
- an advisory note on 'fire safer' cigarettes: approaches to reduced ignition propensity;
- a recommendation on mandated lowering of toxicants in cigarette smoke: tobacco-specific nitrosamines and selected other constituents; and
- a recommendation on cigarette machine smoking regimens.

The four sections of this report address these four issues, and the Study Group's recommendations are set out at the end of each section. Its overall recommendations are summarized in section 5.

The Study Group's members serve without remuneration in their personal capacities and not as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

2. **Advisory note on ‘fire-safer’ cigarettes: approaches to reduced ignition propensity**

2.1 **Purpose**

This advisory note, formulated by TobReg, addresses growing concern about the loss of life, injury and property damage due to fires ignited by combusted tobacco products, and particularly by cigarettes. Its purposes are to provide guidance to WHO and its Member States about the risks related to fires caused by cigarettes and the measures that can be taken to mitigate those risks. The note also gives guidance to researchers and research agencies interested in facilitating better understanding of fire-related deaths and injuries associated with cigarettes.

2.2 **Background and history**

Cigarettes and other lighted tobacco products are a leading cause of fire-related deaths and injuries in countries throughout the world. In 2003, 25 600 cigarette-induced fires occurred in North America, resulting in an estimated 760 deaths, 1520 injuries and US\$ 481 million in direct property damage (Hall, 2006). A survey in 14 Member States of the European Union and Norway in 2005–2006 showed that in the countries that responded there were about 11 000 cigarette-caused fires, 520 deaths, 1600 injuries and € 13 million material damages each year (J. Vogelgesang, unpublished data, 2006). Extrapolation to the 25 countries of the European Union and Norway indicates that 12 900 fires, 650 deaths, 2400 injuries and € 48 million in material damages could be prevented. In New South Wales, Australia, 32 of 233 fire deaths were directly attributed to cigarettes, with an additional 63 possibly due to cigarettes. Annually, cigarettes cause 4574 fires across Australia and may be responsible for up to 78 894 more. Australia’s National Coroners Information system attributed 67 of 678 fire deaths in the period 2000–2005 directly to cigarettes. Further, an estimated 7% of all bush-fires in Australia are attributable to discarded cigarettes. Cigarette-related fires cost Australia AU\$ 80.6 million in 1998, which were projected to AU\$ 124 million in 2006 terms on the basis of the Consumer Price Index. In Canada, 3000 fires are started by smoking articles annually, which are

responsible for 70 fatalities, 300 injuries and CDN\$ 40 million in property damage (D. Choinière, unpublished data, 2006).

A significant proportion of the deaths, injuries and property destruction could be prevented by the introduction of fire-safety standards for cigarettes, which would mean that they were either self-extinguishing, i.e. would go out when not being puffed, or had altered smouldering characteristics, making a fire less likely. Cigarettes designed to comply with these standards are commonly referred to as 'fire-safe' or 'reduced ignition propensity' cigarettes.

In the USA, Congress enacted the Cigarette Safety Act of 1984 that required the creation of a technical study group within the Consumer Protection Agency to determine the technical, economic and commercial feasibility of designing a cigarette with minimum ignition propensity and to report its findings to Congress. In its final report, released in 1987, the group concluded that the goal was technically feasible and might be economically feasible. Congress subsequently passed the Fire Safe Cigarette Act of 1990, which charged the National Institute of Standards and Technology to design a standard method for determining the ignition propensity of cigarettes. It did not, however, give any government agency the authority to regulate the reduction of the propensity of cigarettes to cause fires.

The first performance standard is known as the 'mock-up furniture ignition test method', in which fabric and foam are used to simulate a piece of furniture and in which a burning cigarette is tested to determine whether it transfers enough heat to ignite these materials. The second performance standard is known as the 'cigarette extinction method', in which a set number of layers of filter paper are used to absorb heat, and a cigarette is tested to determine whether it generates enough heat to continue to burn on the paper. The cigarette extinction method is readily reproducible and takes less time per test than the mock-up furniture ignition test method. The cigarette extinction method was therefore refined and published by the American Society for Testing and Materials (2004) as the standard test method for measuring the ignition strength of cigarettes (ASTM E2187).

The tobacco industry claimed for years that cigarettes with reduced ignition propensity could not be made and even bribed fire service organizations to thwart the passage of laws. The tobacco industry itself, however, established that such cigarettes could be made and that their performance could be evaluated. More than 80 years of research by the industry and over 300 patents have addressed the design of 'fire-safe' cigarettes. The scientific basis is well advanced, and the tobacco industry and cigarette paper manufacturers continue their research and development.

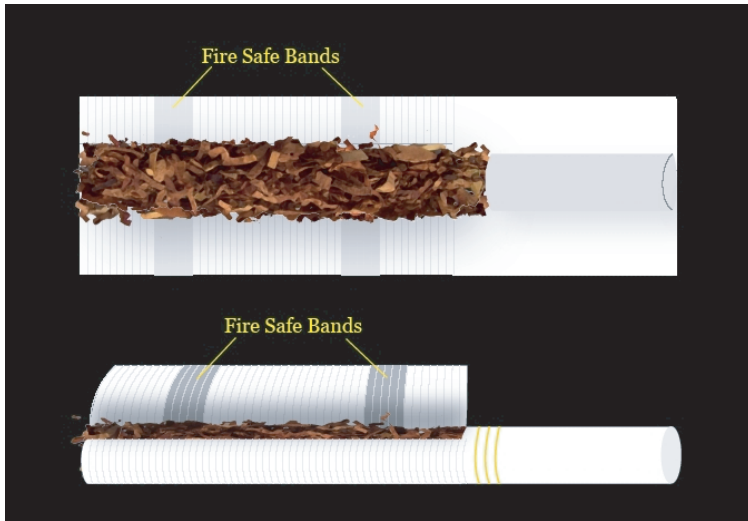
Philip Morris began exploring the design of ‘fire-safe’ cigarettes in 1974. Both RJ Reynolds and Brown & Williamson have had extensive testing programmes since the late 1970s or early 1980s. Lorillard began testing its cigarettes for ignition propensity at least as early as 1980. RJ Reynolds identified means of changing the burning rate of cigarette paper, which affects ignition propensity and developed prototypes throughout the 1980s that successfully reduced ignition propensity, using cigarette papers produced by the Ecusta Paper Company. The factors identified by RJ Reynolds in 1979 are nearly identical to those identified by the technical study group a decade later in their final report, released in 1987, which concluded that a ‘fire-safe’ cigarette was technically feasible and might be economically feasible (Gunja et al., 2002).

An internal Philip Morris document stated that: “Historical treatments of ignition-propensity results show that time to ignition measurements are related to the maximum temperatures which smouldering cigarettes will achieve on a standard fabric. Further analysis indicates that these maximum temperatures scale with the mass burn rates of the isolated cigarettes. This reduces the design problem to that of achieving target MBR’s [mass burn rates].” (Philip Morris, 1987).

The cigarette construction parameters identified by the technical study group and by industry as affecting the burning rate are wrapping paper properties, such as permeability, porosity, oxygen diffusion, chemical additives (e.g. citrate or chalk), cigarette circumference and tobacco density (Ohlemiller et al., 1993).

After the release of the technical study group report, RJ Reynolds refocused their research on ‘fire-safe’ cigarettes so as to target consumer acceptability. Other companies made similar progress in their ‘fire-safe’ cigarette projects. Brown & Williamson, Philip Morris and RJ Reynolds all obtained low-ignition paper from the Ecusta and Schweitzer paper companies from the early 1980s. In the 1980s, Brown & Williamson designed two cigarette prototypes with Schweitzer papers and tested a Kimberly-Clark banded cigarette paper. The method of banding most commonly used to reduce ignition propensity is that in which ultra-thin concentric bands are applied to traditional cigarette paper (Figure 2.1). These bands, sometimes compared with ‘speed bumps’, cause the cigarette to go out if it is not smoked, by restricting oxygen to the burning ember (Connolly et al., 2005). Banded cigarette paper is manufactured either in a water-based online process, referred to as ‘paper banding’, or by additional water- or solvent-based printing, referred to as ‘print banding’ (Thelen, 2006). In the early 1990s, Philip Morris designed a cigarette with bands that would extinguish the cigarette if it was not puffed. Banded cigarettes were tested as early as 1985, and in 2000 Philip Morris

Figure 2.1
Composition of a reduced ignition cigarette



released a banded cigarette with a ‘fire-safe paper select’ wrapper in the Merit brand (Gunja et al., 2002). Internal industry testing demonstrated that the width and location of the bands can be used to control ignition propensity, wider bands and lower inter-band width being associated with the greatest reduction. Internal studies by Philip Morris showed that the technique used to place the paper bands is very precise.

2.3 Regulatory responses

The first law to regulate ignition propensity was passed by the State of New York, USA, which mandated that all cigarettes sold in the State had to have reduced ignition propensity. The New York Fire Safety Standards for Cigarettes (Part 429, Title 18 of the *Official Compilation of Codes, Rules, and Regulations of the State of New York*) came into force on 28 June 2004. Since then, Canada and 19 states of the USA have mandated reduced ignition performance standards for cigarettes. All existing fire safety standards for cigarettes are modelled after the New York standards and require that cigarettes be manufactured or sold to meet an ignition propensity performance standard that makes them significantly less likely to cause fires if left unattended. Recently, the Australian Government prescribed regulations mandating a safety standard for cigarettes, covering performance, testing, packaging and marking requirements for cigarettes manufactured or imported into Australia. The Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008 came into force on 23 September 2008. South Africa’s Tobacco Products Control Act was

amended on 23 February 2008 to include authority to set regulations mandating a standard on the ignition propensity of cigarettes. Other countries, including New Zealand and Member States of the European Union, are considering similar policies, and the European Commission is examining the feasibility of proposing a standard.

Both the Canadian and the New York State laws incorporate the ASTM standard test method in which a lit cigarette is placed on multiple layers of standard filter paper in a draft-free environment (Figure 2.2). The paper cannot ignite to smouldering and draws its heat from the cigarette. The persistence of burning is an indication of the energy available to ignite soft furnishings. Thus, the indicator is whether the cigarette burns to its full length. The standard adopted in these two jurisdictions requires that no more than 25% of 40 test cigarettes placed on a thickness of 10 layers of filter paper undergo full-length burning. The techniques used by manufacturers to meet the standard are generally unrestricted. In 2006, Standards Australia published a draft standard test method for determining the extinction propensity of cigarettes, which is also based on the ASTM test method.

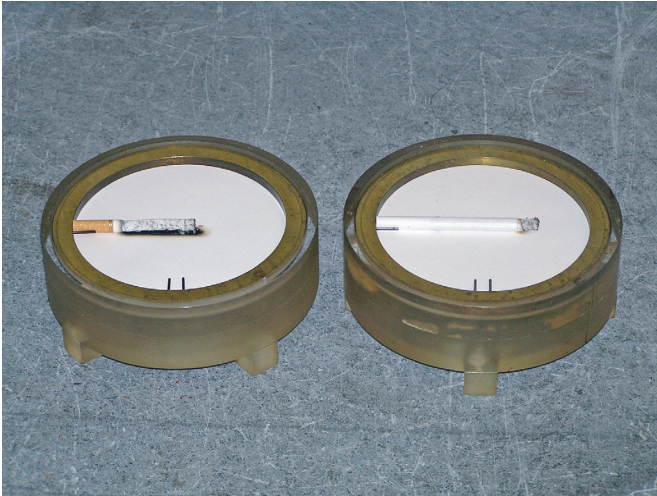
The New York Fire Safety Standards for Cigarettes include provisions regarding the reporting and investigation of cigarette-caused fires, the testing and certification of cigarettes, package labelling requirements, tax stamps and enforcement. The fire services must report all suspected cigarette-related fires within 14 days of completing an investigation and must provide information on the brand and style, marking as compliant, and the location and manner of purchase of the cigarette. Cigarette manufacturers are responsible under the New York Standards for testing each of their brands and for providing written certification to the Office of Fire Prevention and Control and to the Attorney General. The Office of Fire Prevention and Control is required to test cigarettes suspected of igniting fires and to retest any cigarettes to which a manufacturer makes a change that is likely to alter its compliance. Tax stamps may not be affixed to cigarette packages in New York State unless the cigarettes have been certified as meeting the Standards (J. Mueller, unpublished data, 2006).

The New York Office of Fire Prevention and Control is authorized to examine books, papers, invoices and other records and to impose civil penalties and suspensions. Enforcement includes penalties for false certification and for sale of non-compliant cigarettes. Public health officers are authorized to impose penalties on retail dealers. Officers of the Office of Fire Prevention and Control and of the Taxation and Finance Office are authorized to seize cigarettes not marked as compliant, and the seized cigarettes are to be destroyed (J. Mueller, unpublished data, 2006). Tobacco companies are required to pay for testing and stamping in all states of the USA. The fees for

Figure 2.2

Standard method for testing the ignition propensity performance standard of cigarettes, in which a lit cigarette is placed on multiple layers of standard filter paper (A) in a draught-free environment (B)

A.



B.

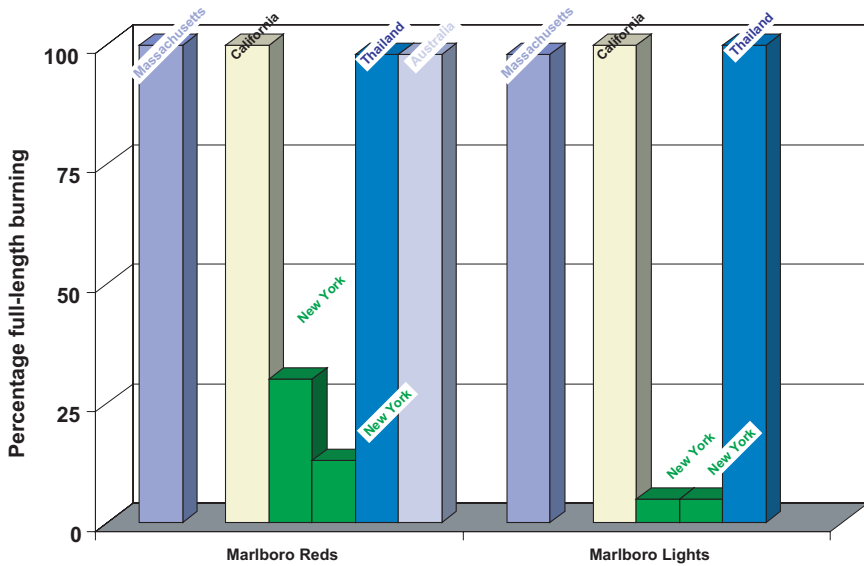


certification range from US\$ 100 to US\$ 1000 per cigarette brand or brand family and could increase.

Canada adopted the same standard as New York State when it introduced regulations requiring all cigarettes manufactured in or imported into Canada as of 1 October 2005 to satisfy the reduced ignition propensity standard.

Figure 2.3

Cigarette ignition propensity of major brands in California, Massachusetts and New York, USA, and in Australia and Thailand



From Tobacco Control Research Program, Harvard School of Public Health

Canada’s law applies at the manufacturing and importation levels, whereas the laws of states in the USA apply to the sale of cigarettes by retailers.

Approximately 1200 cigarette brands have been certified as compliant in New York State (New York Office of Fire Prevention and Control, 2008). Health Canada (2008a) has been sampling cigarettes from manufacturers and importers to determine whether they comply with the standard outlined in its regulations. As a result of ‘fire-safe’ cigarette laws, cigarette manufacturers in Canada have modified nearly all their brands (D. Choinière, unpublished data, 2006). The results of laboratory analyses of samples collected by Health Canada are posted on the Internet and updated periodically.

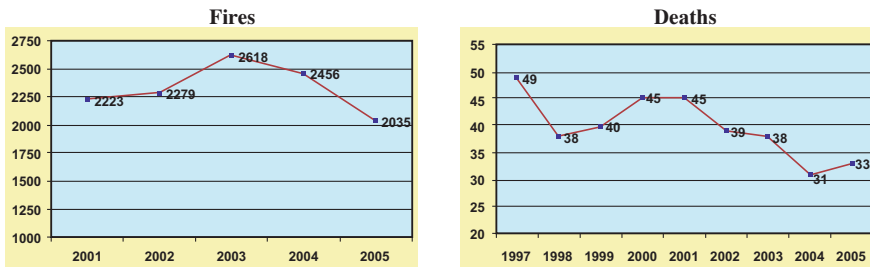
The ignition propensity of five brands of cigarettes sold in New York State after implementation of the Fire Safety Standards was tested with the cigarette extinction method; the full-length burning per brand was found to be 2.5–30.0% (Connolly et al., 2005). In contrast, the full-length burning of the same brands of cigarettes sold in Massachusetts and California, in New York before the law was passed, and in Australia and Thailand was 100% (Figure 2.3).

2.3.1 Effectiveness of regulatory measures in populations

Current regulatory measures are not expected to eliminate cigarette fire-related deaths but are intended to reduce such incidents over time, in the

Figure 2.4

Fires (left-hand panel) and deaths (right-hand panel) in fires due to smoking materials in New York State before and after application of fire-safety standards for cigarettes



From Mueller (2006)

expectation that future changes in cigarette design will continue to do so. At the same time, governments must improve data collection on the frequency of cigarette-related fires and design regulations to address the problem. Preliminary data suggest that governments will benefit by implementing regulations to reduce ignition propensity.

Compliance with standards based on the ASTM method should reduce the numbers of cigarettes that cause smouldering combustion and consequently ignite fires. The effectiveness of the standard should be monitored continuously by recording the incidence of cigarette-caused fires and the associated deaths, injuries and costs. Fire reporting is fraught with problems of quality, and the methods should perhaps be reconsidered. Reliable information on reductions in cigarette consumption, improved mattress standards and changing fire prevention standards is also difficult to obtain.

Preliminary data on the population effect of cigarettes with reduced ignition propensity that are on the market suggests that the numbers of smoking-related fires and fire deaths declined in New York during the first 2 years after implementation of the Fire Safety Standards (Figure 2.4).

In Canada, the regulatory impact assessment of reduced ignition propensity cigarettes predicted that a fire safety standard for cigarettes would reduce cigarette-caused fires by 34–68% (Health Canada, 2008b). As more countries regulate ignition propensity, it will become easier to evaluate the efficacy of such cigarettes.

2.3.2 **Regulatory considerations**

Emissions and biological assays

One concern is that changes in the design of cigarettes might lead to changes in exposure (by topography, burn temperature and emissions) that might

make these products more harmful than they already are. The preliminary data available do not indicate that this is a serious problem.

In the USA, under the Fire-safe Cigarette Act of 1990, the National Institute of Standards and Technology compared the yields of tar, nicotine and carbon monoxide of cigarettes with reduced ignition propensity from the Tobacco Institute Testing Laboratory with the yields of the 14 best-selling commercial cigarette brands. No significant differences were found (Ohlemiller et al., 1993). Preliminary data from Canada indicated small changes in the delivery of carbonyls, tar, carbon monoxide and nicotine (M.J. Kaiserman, unpublished data, 2006).

Internal industry testing of banded cigarettes has also shown them to be substantially the same as regular cigarettes with regard to a number of toxicological end-points, including mutagenicity and the concentrations of toxic chemicals in emissions (Theophilus et al., 2007a,b). Philip Morris assessed some toxicological aspects of banded cigarettes and found “no significant differences between the two cigarettes based on the chemical and biological assays used”. Similar findings have been published and presented at scientific meetings by other companies (Patskan et al., 2000; Appleton, Krauter, Lauterbach, 2003; Misra et al., 2005), including RJ Reynolds, which has long opposed regulations on reduced ignition propensity, claiming increased risk (Theophilus et al., 2007a,b). The tobacco industry claims that there is an unintended additional risk of ‘coal’ (a lightweight, short-lived bit) dropping off from banded cigarettes and has stated that 11% of consumer complaints about banded cigarettes in the USA in 2000 were related to coal drop-off. A publication from British American Tobacco in 1988 concluded that paper permeability had no influence on coal retention in the range tested (Dittrich, 1988).

When 42 smokers in Ontario, Canada, were asked to compare smoking their own brands before and after implementation of the cigarette ignition propensity law in 2005, no significant differences in puffing behaviour or exhaled carbon monoxide were found (Hammond et al., 2007).

Sense of security

Cigarette manufacturers have asserted that smoking ‘fire-safe’ cigarettes could give a false sense of security, which might increase fire-risk behaviour. According to a survey conducted before the coming into force of the cigarette ignition propensity regulation in Canada, 12% of current smokers had smoked a cigarette in bed in the past week, and 17% reported that they left lit cigarettes burning unattended on a daily basis (M.J. Kaiserman, unpublished data, 2006). In another survey in Ontario, Canada, nearly one in four smokers left burning cigarettes unattended, and 15% had smoked in bed in the past

30 days, indicating a high frequency of fire-risk behaviour (O'Connor et al., 2007); early data from follow-up studies showed little change in such behaviour after 1 year (O'Connor, 2008).

Economic effects

Research by the Harvard School of Public Health, USA, showed no decline in cigarette sales in New York State after implementation of the Fire Safety Standards for Cigarettes, confirming the conclusions of the technical study group in 1987 (Connolly et al., 2005). The results of a nationwide survey in the USA also showed that the New York Fire Safety Standards appeared to have had no discernable effect on how smokers perceived the taste of their cigarettes, smoking behaviour or intention to quit, countering arguments made by cigarette manufacturers that the law would have a negative effect on consumer acceptability (O'Connor et al., 2006).

Health Canada (2008c) estimated that if the cost of complying with measures for cigarette ignition propensity was absorbed entirely by cigarette manufacturers, the companies' operating profits would be reduced by 2.9–5.9%; they could raise their prices to offset the increased costs. While some price increase is likely, the extent to which individual manufacturers would raise their prices is uncertain and would depend on competitive forces in the tobacco products market. Given the degree of competition in that market, it is unlikely that prices would rise by the full amount of the estimated cost increase (i.e. US\$ 0.13–0.26 per carton).

Implementation and compliance

Approximately 1200 cigarette brands have been certified as compliant in New York State (New York Office of Fire Prevention and Control, 2008). Health Canada sampled products from manufacturers and importers to determine whether cigarettes in Canada comply with the standard outlined in its regulations and found that 'fire-safe' cigarette laws have resulted in modification of nearly all brands (D. Choinière, unpublished data, 2006). The results of laboratory analyses of samples collected by Health Canada are posted on the Internet and updated periodically.

New York State has taken the lead in validating industry reports by independent testing of cigarettes every 3 years and comparing industry reports with theirs. The cost of testing is US\$ 400–700 per brand but should fall as more countries become involved. Other states in the USA rely on New York State and have not conducted testing. Efforts are being made in the USA to coordinate state reporting and testing. The National Institute of Standards and Technology gives technical support to laboratories, including a reference cigarette (<http://firesafecigarettes.org/assets/files/niststandard.pdf>) and small

grants. There are currently six laboratories for testing. Brands that have been tested in New York State are listed online at <http://www.dos.state.ny.us/fire/cigarette.htm>.

The International Organization for Standardization (ISO) may adopt a standard that is identical to ASTM E2187, except in format. The alternative of drafting a guidance document that refers to the test method in the ASTM standard could take 1–2 years.

2.4 **Research needs**

2.4.1 ***Techniques***

Research is needed to ensure the effectiveness of any regulations on reduced ignition propensity and to provide a basis for future policy. The main approach used to modify burning rate and consequently to reduce ignition propensity is to decrease oxygen diffusion by lowering the permeability of cigarette paper. The techniques used by manufacturers to achieve this should be monitored, including the effects of measured differences among brands in band placement and other design features. Some researchers are using reverse engineering of products to examine their banding characteristics, such as the presence, number, width and spacing; filter ventilation and pressure drop; paper porosity and citrate content; tobacco weight and density and cigarette circumference.

Cigarette companies and paper manufacturers are conducting research in industry-based research and development and programmes to follow up the achievements of the National Institute of Standards and Technology and the New York State standards. Further research and reviews of the scientific literature, industry documents and other sources are important for monitoring industry findings on cigarette ignition propensity and performance.

Some of the patented designs for reducing ignition propensity are paper with very low porosity and added perforations, addition of fire retardant to the centre of the tobacco rod, cellulose bands on paper, application of chemicals outside the paper and addition of intumescent powder to the tobacco column. The last reduces the ignition propensity of tobacco by decreasing its density during heating (Stevenson, Graham, 1988).

2.4.2 ***Testing methods***

Methods are needed for testing ignition propensity performance, such as thermal imaging. Their potential use in effective, efficient testing might be included in regulations.

2.4.3 ***Surveillance and monitoring***

Fires and subsequent losses due to cigarettes should be surveyed and monitored in order to judge the success of policies and to determine whether the standards should be adopted. The New York State measures appear to be reducing the number of deaths due to cigarette-related fires, but high-quality fire incidence reporting and data are needed. The data must be accurate and timely and based on large enough numbers so that statistical significance can be assessed. The outcomes that should be monitored are the incidence of fires and the associated losses, injuries and deaths (D. Hemenway, unpublished data, 2006). The capacity of investigators at the scene of a fire must be improved to allow them to ascertain whether the fire was started by a cigarette and what other factors contributed to the severity of the fire.

The impact of measures to reduce ignition propensity should be followed up over time, on the basis of criteria such as population health and the optimum percentage reduction in fires.

The Fire Safety Standards for Cigarettes in New York State contain a provision that allows the Office of Fire Prevention and Control to review information on the incidence of fires in the light of technological changes after a period of 3–4 years and to consider revising the Standards. Other jurisdictions might wish to adopt a similar approach.

2.4.4 ***Exposure to emissions and smoking behaviour***

Further assessment of exposure to emissions and changes in smoking behaviour should include consideration of product design, emissions of tar, nicotine and carbon monoxide, puffing behaviour, filter analyses and biomarkers of exposure.

Population surveys with baseline and follow-up measures, such as those being conducted by the Roswell Park Cancer Institute and the Harvard School of Public Health in the USA, should include questions such as “Has a cigarette ever started a fire in your home?”, “How often does your cigarette go out on its own?” and “How often does the lit end or ash fall off your cigarette on its own?”. Such analyses should also assess the prevalence of fire-risk events in the 30 days before the survey. Information on fire-risk behaviour should include instances of burnt clothes, burnt furniture, burning cigarettes left unattended, dozing off and falling asleep while smoking and smoking in bed.

The tobacco industry has claimed that some methods of reducing the ignition propensity of cigarettes could increase the toxicity by increasing smoke delivery. There is no evidence that cigarettes with reduced ignition propensity increase the risk for disease from smoking. Cigarette smoke is a highly complex mixture, containing over 4000 chemicals, and the links between these

chemicals and the toxicity of the smoke are not well defined. It is probable that the smoke from cigarettes with reduced ignition propensity is just as toxic as that of unmodified cigarettes.

2.5 Findings and recommendations

Fires and fire deaths are caused by cigarettes.

Fires due to cigarettes and the related deaths are a major global public health problem. Although the number of deaths is far lower than that caused by smoking (900 deaths in the USA from fires and 460 000 from smoking), it is still high, and policies are needed to reduce the number.

Cigarettes with reduced ignition propensity should be mandatory.

As cigarettes are the principal cause of residential fires and related deaths and techniques exist to reduce ignition propensity and thus the likelihood of a cigarette igniting a fire, Member States should require reduced ignition propensity cigarettes, in line with the standard of the National Institute of Standards and Technology or any other that has been shown to be effective. Countries and jurisdictions within countries should retain the right to alter the standard on the basis of population-based data on its effectiveness.

While Canada has adopted measures for reducing ignition propensity within public health laws, Australia and most states of the USA implement such measures within laws on fire safety. In the European Union, such measures are being considered in the framework of consumer protection legislation.

The products covered by these measures should include not only cigarettes but also cigars and any other combusted tobacco product if evidence indicates that their ignition strength should be regulated. Considerations could include state or national monetary appropriations, identification of parties or agencies responsible for certification, the delay required for re-certification, identification of the agency responsible for auditing brands, the scope and frequency of audits, evaluation of the population impact, fees and fines, advisory committees and whether the regulations can be superseded by federal law. Countries should require tobacco manufacturers to test ignition strength, report the results to the responsible authority and pay a fee for implementation of the measures.

Independent laboratory testing capacity is currently minimal. It could be increased if countries adopted measures that require testing of ignition propensity by independent laboratories accredited according to ISO standard 17025, *General requirements for the competence of calibration and testing laboratories*. Industry-generated results should be validated by independent tests.

Legislation and regulatory measures should give the responsible authority the means to take appropriate legal action to ensure compliance with the standard.

No risk claims are permissible.

As reduced ignition propensity cigarettes must be made available to an entire population, manufacturers cannot be allowed to claim that they reduce the risk of fire. If they did, consumers might conclude that they reduced overall health risks. Public education campaigns are needed as part of any reduced ignition propensity programme, to inform consumers that all cigarettes are lethal and that smokers should quit. Such programmes should also include education campaigns to teach the public how to prevent fires.

The effectiveness of reduced ignition propensity cigarettes must be monitored.

Adequate, appropriate monitoring, reporting and archiving are needed to record the effectiveness of techniques for reducing ignition propensity for decreasing deaths, injuries and property damage due to cigarette-induced fires. Such assessments will increase public assurance and lead to more effective means of diminishing the needless losses that occur as a result of cigarette-ignited fires.

International collaboration is necessary.

International collaboration between interested institutions and authorities is needed to coordinate education, advocacy, testing, research and evaluation of reduced ignition propensity cigarettes and for implementation of such measures in all WHO regions.

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Annex 2.1 Model legislation

THE CIGARETTE FIRE SAFETY STANDARD AND FIREFIGHTER PROTECTION ACT

1. **Title.** This Act shall be known and may be cited as the ‘Fire Safety Standard and Firefighter Protection Act’.

2. **Findings.**

The Legislature finds and declares that:

- a. Cigarettes are the leading cause of fire deaths in this State and the nation;
- b. Each year in the United States, 700–900 persons are killed due to cigarette fires and 3000 are injured in fires ignited by cigarettes, while in this State [] residential fires and [] fatalities were attributable to cigarettes in years [____-2005];
- c. A high proportion of the victims of cigarette fires are non-smokers, including senior citizens and young children;
- d. Cigarette-caused fires result in billions of dollars of property losses and damages in the United States and millions of dollars in this State;
- e. Cigarette fires unnecessarily jeopardize firefighters and result in avoidable emergency response costs for municipalities;
- f. In 2004, New York State implemented a cigarette fire safety regulation requiring cigarettes sold in that State to meet a fire safety performance standard; in 2005, Vermont and California enacted cigarette fire safety laws directly incorporating New York’s regulation into statute; and, in 2006, Illinois, New Hampshire and Massachusetts joined these states in enacting such laws.
- g. In 2005, Canada implemented the New York State fire safety standard contained in the other state laws, becoming the first nation to have a cigarette fire safety standard;
- h. New York State’s cigarette fire safety standard is based upon decades of research by the National Institute of Standards and Technology, Congressional research groups, and private industry;
- i. This cigarette fire safety standard minimizes costs to the State and minimally burdens cigarette manufacturers, distributors and retail sellers, and, therefore, should become law in this State; and

- j. It is therefore fitting and proper for this State to adopt the cigarette fire safety standard that is in effect in New York State to reduce the likelihood that cigarettes will cause fires and result in deaths, injuries and property damages.

3. **Definitions.** For the purposes of this Act:

- (a) ‘Agent’ shall mean any person authorized by the [State entity that administers cigarette tax stamps] to purchase and affix stamps on packages of cigarettes.
- (b) ‘Cigarette’ shall mean:
 - (1) any roll for smoking, whether made wholly or in part of tobacco or any other substance, irrespective of size or shape, and whether or not such tobacco or substance is flavored, adulterated or mixed with any other ingredient, the wrapper or cover of which is made of paper or any other substance or material, other than leaf tobacco; or
 - (2) any roll for smoking wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette as described in subparagraph 1 above.
- (c) ‘Director’ shall mean the Director of the [State entity responsible for administering the provisions of this Act].
- (d) ‘Manufacturer’ shall mean:
 - (1) any entity which manufactures or otherwise produces cigarettes or causes cigarettes to be manufactured or produced anywhere that such manufacturer intends to be sold in this State, including cigarettes intended to be sold in the United States through an importer; or
 - (2) the first purchaser anywhere that intends to resell in the United States cigarettes manufactured anywhere that the original manufacturer or maker does not intend to be sold in the United States; or
 - (3) any entity that becomes a successor of an entity described in paragraph (1) or (2) of this subsection.
- (e) ‘Quality control and quality assurance program’ shall mean the laboratory procedures implemented to ensure that operator bias, systematic and nonsystematic methodological errors, and equipment-related

problems do not affect the results of the testing. Such a program ensures that the testing repeatability remains within the required repeatability values stated in paragraph (6) of subsection (a) of Section 4 of this Act for all test trials used to certify cigarettes in accordance with this Act.

- (f) ‘Repeatability’ shall mean the range of values within which the repeat results of cigarette test trials from a single laboratory will fall 95 percent of the time.
- (g) ‘Retail dealer’ shall mean any person, other than a manufacturer or wholesale dealer, engaged in selling cigarettes or tobacco products.
- (h) ‘Sale’ shall mean any transfer of title or possession or both, exchange or barter, conditional or otherwise, in any manner or by any means whatever or any agreement therefor. In addition to cash and credit sales, the giving of cigarettes as samples, prizes or gifts, and the exchanging of cigarettes for any consideration other than money, are considered sales.
- (i) ‘Sell’ shall mean to sell, or to offer or agree to do the same.
- (j) ‘Wholesale dealer’ shall mean any person other than a manufacturer who sells cigarettes or tobacco products to retail dealers or other persons for purposes of resale, and any person who owns, operates or maintains one or more cigarette or tobacco product vending machines in, at or upon premises owned or occupied by any other person.

4. Test Method and Performance Standard.

- (a) Except as provided in subsection (g) of this section, no cigarettes may be sold or offered for sale in this State or offered for sale or sold to persons located in this State unless the cigarettes have been tested in accordance with the test method and meet the performance standard specified in this section, a written certification has been filed by the manufacturer with the [State entity responsible for administering the provisions of this Act] in accordance with section 5 of this Act, and the cigarettes have been marked in accordance with section 6 of this Act.
 - (1) Testing of cigarettes shall be conducted in accordance with the American Society of Testing and Materials (‘ASTM’) standard E2187-04, “Standard Test Method for Measuring the Ignition Strength of Cigarettes.”
 - (2) Testing shall be conducted on 10 layers of filter paper.

- (3) No more than 25 percent of the cigarettes tested in a test trial in accordance with this section shall exhibit full-length burns. Forty replicate tests shall comprise a complete test trial for each cigarette tested.
 - (4) The performance standard required by this section shall only be applied to a complete test trial.
 - (5) Written certifications shall be based upon testing conducted by a laboratory that has been accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization ('ISO'), or other comparable accreditation standard required by the [State entity responsible for administering the provisions of this Act].
 - (6) Laboratories conducting testing in accordance with this section shall implement a quality control and quality assurance program that includes a procedure that will determine the repeatability of the testing results. The repeatability value shall be no greater than 0.19.
 - (7) This section does not require additional testing if cigarettes are tested consistent with this Act for any other purpose.
 - (8) Testing performed or sponsored by the [State entity responsible for administering the provisions of this Act] to determine a cigarette's compliance with the performance standard required shall be conducted in accordance with this section.
- (b) Each cigarette listed in a certification submitted pursuant to section 5 of this Act that uses lowered permeability bands in the cigarette paper to achieve compliance with the performance standard set forth in this section shall have at least two nominally identical bands on the paper surrounding the tobacco column. At least one complete band shall be located at least 15 millimeters from the lighting end of the cigarette. For cigarettes on which the bands are positioned by design, there shall be at least two bands fully located at least 15 millimeters from the lighting end and 10 millimeters from the filter end of the tobacco column, or 10 millimeters from the labeled end of the tobacco column for non-filtered cigarettes.
 - (c) A manufacturer of a cigarette that the [State entity responsible for administering the provisions of this Act] determines cannot be tested in accordance with the test method prescribed in paragraph (1) of subsection (a) of this section shall propose a test method and performance standard for the cigarette to the [State entity responsible for

administering the provisions of this Act]. Upon approval of the proposed test method and a determination by the [State entity responsible for administering the provisions of this Act] that the performance standard proposed by the manufacturer is equivalent to the performance standard prescribed in subsection (a) (3) of this section, the manufacturer may employ such test method and performance standard to certify such cigarette pursuant to section 5 of this Act. If the [State entity responsible for administering the provisions of this Act] determines that another state has enacted reduced cigarette ignition propensity standards that include a test method and performance standard that are the same as those contained in this Act, and the [State entity responsible for administering the provisions of this Act] finds that the officials responsible for implementing those requirements have approved the proposed alternative test method and performance standard for a particular cigarette proposed by a manufacturer as meeting the fire safety standards of that state's law or regulation under a legal provision comparable to this section, then the [State entity responsible for administering the provisions of this Act] shall authorize that manufacturer to employ the alternative test method and performance standard to certify that cigarette for sale in this State, unless the [State entity responsible for administering the provisions of this Act] demonstrates a reasonable basis why the alternative test should not be accepted under this Act. All other applicable requirements of this section shall apply to the manufacturer.

- (d) Each manufacturer shall maintain copies of the reports of all tests conducted on all cigarettes offered for sale for a period of three years, and shall make copies of these reports available to the [State entity responsible for administering the provisions of this Act] and the Attorney General upon written request. Any manufacturer who fails to make copies of these reports available within sixty days of receiving a written request shall be subject to a civil penalty not to exceed \$10,000 for each day after the sixtieth day that the manufacturer does not make such copies available.
- (e) The [State entity responsible for administering the provisions of this Act] may adopt a subsequent ASTM Standard Test Method for measuring the Ignition Strength of Cigarettes upon a finding that such subsequent method does not result in a change in the percentage of full-length burns exhibited by any tested cigarette when compared to the percentage of full-length burns the same cigarette would exhibit when tested in accordance with ASTM Standard E2187-04 and the performance standard in subsection (a)(3) of this section.

- (f) The [State entity responsible for administering the provisions of this Act] shall review the effectiveness of this section and report every three years to the Legislature [the State entity's] findings and, if appropriate, recommendations for legislation to improve the effectiveness of this Act. The report and legislative recommendations shall be submitted no later than June thirtieth following the conclusion of each three-year period.
- (g) The requirements of subsection (a) of this section shall not prohibit:
 - (1) wholesale or retail dealers from selling their existing inventory of cigarettes on or after the effective date of this Act if the wholesale or retailer dealer can establish that State tax stamps were affixed to the cigarettes prior to the effective date and the wholesale or retailer dealer can establish that the inventory was purchased prior to the effective date in comparable quantity to the inventory purchased during the same period of the prior year; or
 - (2) the sale of cigarettes solely for the purpose of consumer testing. For purposes of this subsection, the term 'consumer testing' shall mean an assessment of cigarettes that is conducted by a manufacturer (or under the control and direction of a manufacturer), for the purpose of evaluating consumer acceptance of such cigarettes, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment, and in a controlled setting where the cigarettes are either consumed on-site or returned to the testing administrators at the conclusion of the testing.
- (h) This Act shall be implemented in accordance with the implementation and substance of the New York Fire Safety Standards for Cigarettes.

5. Certification and Product Change

- (a) Each manufacturer shall submit [to the State entity responsible for administering the provisions of this Act] a written certification attesting that:
 - (1) each cigarette listed in the certification has been tested in accordance with section 4 of this Act; and
 - (2) each cigarette listed in the certification meets the performance standard set forth in section 4.
- (b) Each cigarette listed in the certification shall be described with the following information:
 - (1) brand, or trade name on the package;

- (2) style, such as light or ultra light;
 - (3) length in millimeters;
 - (4) circumference in millimeters;
 - (5) flavor, such as menthol or chocolate, if applicable;
 - (6) filter or non-filter;
 - (7) package description, such as soft pack or box;
 - (8) marking pursuant to section 6 of this Act;
 - (9) the name, address and telephone number of the laboratory, if different than the manufacturer that conducted the test; and
 - (10) the date that the testing occurred.
- (c) The certifications shall be made available to the Attorney General for purposes consistent with this Act and the [State entity responsible for administering the State cigarette tax act] for the purposes of ensuring compliance with this section.
- (d) Each cigarette certified under this section shall be re-certified every three years.
- (e) For each cigarette listed in a certification, a manufacturer shall pay to the [State entity responsible for administering the provisions of this Act] a \$250 fee. The [State entity responsible for administering the provisions of this Act] is authorized to annually adjust this fee to ensure it defrays the actual costs of the processing, testing, enforcement and oversight activities required by this Act.
- (f) There is established in the [State treasury] a separate, nonlapsing fund to be known as the 'Fire Safety Standard and Firefighter Protection Act Enforcement Fund'. The fund shall consist of all certification fees submitted by manufacturers, and shall, in addition to any other monies made available for such purpose, be available to the [State entity responsible for administering the provisions of this Act] solely to support processing, testing, enforcement and oversight activities under this Act.
- (g) If a manufacturer has certified a cigarette pursuant to this section, and thereafter makes any change to such cigarette that is likely to alter its compliance with the reduced cigarette ignition propensity standards required by this Act, that cigarette shall not be sold or offered for sale in this State until the manufacturer retests the cigarette in accordance with the testing standards set forth in section 4 of this Act

and maintains records of that retesting as required by section 4 of this Act. Any altered cigarette which does not meet the performance standard set forth in Section 4 of this Act may not be sold in this State.

6. Marking of Cigarette Packaging

- (a) Cigarettes that are certified by a manufacturer in accordance with section 5 of this Act shall be marked to indicate compliance with the requirements of section 4 of this Act. The marking shall be in eight point type or larger and consist of:
 - (1) Modification of the product UPC Code to include a visible mark printed at or around the area of the UPC Code. The mark may consist of alphanumeric or symbolic characters permanently stamped, engraved, embossed or printed in conjunction with the UPC; or
 - (2) Any visible combination of alphanumeric or symbolic characters permanently stamped, engraved or embossed upon the cigarette package or cellophane wrap; or
 - (3) Printed, stamped, engraved or embossed text that indicates that the cigarettes meet the standards of this Act.
- (b) A manufacturer shall use only one marking, and shall apply this marking uniformly for all packages, including but not limited to packs, cartons, and cases, and brands marketed by that manufacturer.
- (c) The [State entity responsible for administering the provisions of this Act] shall be notified as to the marking that is selected.
- (d) to the certification of any cigarette, a manufacturer shall present its proposed marking to the [State entity responsible for administering the provisions of this Act] for approval. Upon receipt of the request, the [State entity responsible for administering the provisions of this Act] shall approve or disapprove the marking offered, except that the [State entity responsible for administering the provisions of this Act] shall approve:
 - (1) any marking in use and approved for sale in New York pursuant to the New York Fire Safety Standards for Cigarettes, or
 - (2) the letters 'FSC', which signifies Fire Standards Compliant appearing in 8 point type or larger and be permanently printed, stamped, engraved or embossed on the package at or near the UPC code.

Proposed markings shall be deemed approved if the [State entity responsible for administering the provisions of this Act] fails to act within 10 business days of receiving a request for approval.

- (e) No manufacturer shall modify its approved marking unless the modification has been approved by the [State entity responsible for administering the provisions of this Act] in accordance with this section.
- (f) Manufacturers certifying cigarettes in accordance with section 5 of this Act shall provide a copy of the certifications to all wholesale dealers and agents to which they sell cigarettes, and shall also provide sufficient copies of an illustration of the package marking utilized by the manufacturer pursuant to this section for each retail dealer to which the wholesale dealers or agents sell cigarettes. Wholesale dealers and agents shall provide a copy of these package markings received from manufacturers to all retail dealers to which they sell cigarettes. Wholesale dealers, agents and retail dealers shall permit the [State entity responsible for administering the provisions of this Act], the [State entity responsible for administering the provisions of the State cigarette tax act], the Attorney General, and their employees to inspect markings of cigarette packaging marked in accordance with this section.

7. Penalties.

- (a) A manufacturer, wholesale dealer, agent or any other person or entity who knowingly sells or offers to sell cigarettes, other than through retail sale, in violation of section 4 of this Act, shall be subject to a civil penalty not to exceed one hundred (\$100) dollars for each pack of such cigarettes sold or offered for sale provided that in no case shall the penalty against any such person or entity exceed one hundred thousand (\$100,000) dollars during any thirty-day period.
- (b) A retail dealer who knowingly sells or offers to sell cigarettes in violation of section 4 of this Act shall be subject to a civil penalty not to exceed one hundred (\$100) dollars for each pack of such cigarettes sold or offered for sale, provided that in no case shall the penalty against any retail dealer exceed twenty-five thousand (\$25,000) dollars for sales or offers to sell during any thirty-day period.
- (c) In addition to any penalty prescribed by law, any corporation, partnership, sole proprietor, limited partnership or association engaged in the manufacture of cigarettes that knowingly makes a false certification pursuant to section 5 of this Act shall be subject to a civil penalty of at least seventy-five thousand (\$75,000) dollars and not to exceed

two-hundred fifty thousand (\$250,000) dollars for each such false certification.

- (d) Any person violating any other provision in this Act shall be subject to a civil penalty for a first offense not to exceed one thousand (\$1,000) dollars, and for a subsequent offense subject to a civil penalty not to exceed five thousand (\$5,000) dollars for each such violation.
- (e) Any cigarettes that have been sold or offered for sale that do not comply with the performance standard required by section 4 of this Act shall be subject to forfeiture [under the pertinent provision of State law having to do with forfeiture of contraband]. Cigarettes forfeited pursuant to this section shall be destroyed; provided, however, that prior to the destruction of any cigarette forfeited pursuant to these provisions, the true holder of the trademark rights in the cigarette brand shall be permitted to inspect the cigarette.
- (f) In addition to any other remedy provided by law, the [State entity responsible for administering the provisions of this Act] or Attorney General may file an action in [name of court] for a violation of this Act, including petitioning for injunctive relief or to recover any costs or damages suffered by the State because of a violation of this Act, including enforcement costs relating to the specific violation and attorney's fees. Each violation of this Act or of rules or regulations adopted under this Act constitutes a separate civil violation for which the [State entity responsible for administering the provisions of this Act] or Attorney General may obtain relief.
- (g) Whenever any law enforcement personnel or duly authorized representative of the [State entity responsible for administering the provisions of this Act] shall discover any cigarettes that have not been marked in the manner required by section 6 of this Act, such personnel is hereby authorized and empowered to seize and take possession of such cigarettes. Such cigarettes shall be turned over to the [department of taxation and finance], and shall be forfeited to the State. Cigarettes seized pursuant to this section shall be destroyed; provided, however, that prior to the destruction of any cigarette seized pursuant to these provisions, the true holder of the trademark rights in the cigarette brand shall be permitted to inspect the cigarette.

8. Implementation.

- (a) The [State entity responsible for administering the provisions of this Act] may promulgate rules and regulations, pursuant to the [State administrative procedures act], necessary to effectuate the purposes of this Act.

- (b) The [State entity responsible for administration of the State cigarette tax act] in the regular course of conducting inspections of wholesale dealers, agents and retail dealers, as authorized under the [State cigarette tax act] may inspect such cigarettes to determine if the cigarettes are marked as required by section 6 of this Act. If the cigarettes are not marked as required, the [State entity responsible for administration of the State cigarette tax act] shall notify the [State entity responsible for administering the provisions of this Act].
9. **Inspection.** To enforce the provisions of this Act, the Attorney General, the [State department of taxation and finance] and the [State entity responsible for administering the provisions of this Act], their duly authorized representatives and other law enforcement personnel are hereby authorized to examine the books, papers, invoices and other records of any person in possession, control or occupancy of any premises where cigarettes are placed, stored, sold or offered for sale, as well as the stock of cigarettes on the premises. Every person in the possession, control or occupancy of any premises where cigarettes are placed, sold or offered for sale, is hereby directed and required to give the Attorney General, the [State department of taxation and finance] and the [State entity responsible for administering the provisions of this Act], their duly authorized representatives and other law enforcement personnel the means, facilities and opportunity for the examinations authorized by this section.
10. **Cigarette Fire Safety Standard and Firefighter Protection Act Fund.** There is hereby established in the State Treasury a special fund to be known as the ‘Cigarette Fire Safety Standard and Firefighter Protection Act Fund’. The fund shall consist of all monies recovered as penalties under section 7 of this Act. The monies shall be deposited to the credit of the fund and shall, in addition to any other monies made available for such purpose, be made available to the State entity responsible for administering the provisions of this Act to support fire safety and prevention programs.
11. **Sale Outside of [State name].** Nothing in this Act shall be construed to prohibit any person or entity from manufacturing or selling cigarettes that do not meet the requirements of section 4 of this Act if the cigarettes are or will be stamped for sale in another state or are packaged for sale outside the United States and that person or entity has taken reasonable steps to ensure that such cigarettes will not be sold or offered for sale to persons located in this State.
12. **Preemption.** This Act shall be repealed if a federal reduced cigarette ignition propensity standard that preempts this Act is adopted and becomes effective.

13. **Effective Date.** This Act shall take effect on the first day of the thirteenth month after enactment.

Hyperlink to New York State Regulations:

<http://www.dos.state.ny.us/fire/amendedcigaretterule.htm>

Hyperlink to Canada Cigarette Ignition Propensity Regulations:

<http://canadagazette.gc.ca/partII/2005/20050629/html/sor178-e.html>