Chapter 1
Overview of Handbook volume 13

IARC, which is part of the World Health Organization, coordinates and conducts research on the causes of human cancer and the mechanisms of carcinogenesis, and develops scientific strategies for cancer control. In Handbook Volume 13, IARC considered, for the first time, the effectiveness of public policies in its reviews. This IARC Handbook is focused on the effectiveness of tobacco control policies implemented to protect nonsmokers from secondhand tobacco smoke (SHS). The goal of smoke-free legislation is to eliminate involuntary exposure to SHS entirely.

In 2004, IARC published Monograph 83 - a definitive review of the carcinogenicity of exposure to SHS through involuntary smoking (IARC, 2004). This Handbook does not seek to update that review, as assessment of carcinogenicity is not the domain of the Handbooks[1]. Rather, the purpose is to focus on the effectiveness of the implementation of the health policy recommended by the WHO Framework Convention for Tobacco Control (FCTC). There are two relevant components to this. The first is a consideration of the strategies and evidence that opponents use to promote less than strict adherence to the recommended WHO FCTC legislative language. The second is consideration of the evidence for effectiveness of smoke-free legislation that has been implemented, as reported in the scientific literature and government reports. The first jurisdiction to implement a strict smoke-free policy, the US state of California, has 10 years experience with it; many others have close to five. It is timely to undertake an early review of the evidence and draw conclusions about the effectiveness of smoke-free policies. This Handbook will be useful for health professionals and policymakers in countries who are currently considering legislation to protect the population from SHS.

Secondhand smoke: the problem

SHS is defined as the smoke emitted either from the burning end of a tobacco product or by the exhalation of smoke-filled air by a smoker, both of which contain known human carcinogens (IARC, 2004). The ambient air in the immediate environment of a smoker quickly becomes contaminated with carbon monoxide; large quantities of particulate matter, as well as nitrogen oxides; several substances recognised as human carcinogens, such as formaldehyde, acetaldehyde, benzene, and nitrosamines; and possible human carcinogens, such as hydroquinone and cresol (IARC, 2004; U.S. Department of Health and Human Services, 2006). As these contaminants are absorbed (and later released) by materials in the environment (e.g. furniture covering, curtains), the potential for SHS exposure lasts considerably longer than the act of smoking. No safe level of SHS exposure has been identified.

Nonsmokers (and smokers) become exposed to SHS when they breathe this contaminated air. In addition to carcinogens, SHS contains compounds such as pyridine that produce unpleasant odors (National Cancer Institute, 1999), and particles such as nicotine, acrolein, and formaldehyde that cause mucosal irritation (Lee *et al*., 1993). However, the degree to which nonsmokers will notice and respond to SHS exposure is related to the age of the exposed person, their olfactory acuity, as well as their annoyance threshold (U.S. Department of Health and Human Services, 2006). Thus, harm may

[1] IARC will re-visit the carcinogenicity of involuntary tobacco smoke in its forthcoming Monograph volume 100 E (Lifestyle factors) during a meeting from September 29 to October 6 2009 in Lyon, France (http://monographs.iarc.fr/ENG/Meetings/index.php).

occur whether or not the individual realises that they are exposed.

Exposure to air that is not smoke-free will lead to the uptake of SHS contaminants. The dose of SHS contaminants that reach a target organ determines the risk of disease to that organ in the nonsmoker, as well as the smoker. The amount of exposure to a nonsmoker will vary with both the concentration of SHS in the ambient air and with the time that the individual spends in contact with it. Ventilation and air cleaning have been advocated as possible ways of reducing the exposure of nonsmokers to SHS. The dose of SHS contaminants that a nonsmoker receives varies with the number of cigarettes smoked per unit of time in an area, and is inversely proportional to the intensity of ventilation and the rate of cleaning or removal of SHS components from the air (Ott, 1999).

In most homes, ventilation occurs by a natural exchange of indoor and outdoor air. However, public and commercial buildings generally have systems for ventilation and air exchange. These heating, ventilating, and air conditioning systems often distribute SHS throughout a building in the process of air exchange, thereby potentially magnifying the number of nonsmokers who are exposed to SHS (U.S. Department of Health and Human Services, 2006). Measurements of ambient nicotine concentrations have confirmed that current ventilation systems are insufficient to eliminate SHS from indoor air (Repace & Lowrey, 1993). Further, in the presence of multiple indoor smoking episodes, reducing SHS to very low levels by ventilation has generally not been considered feasible because of the high cost of installing the necessary ventilation system and the impairment of comfort levels that implementing such a system would entail (e.g. by making the air less thermally tolerable). Given the strength of cigarettes, and other combusted tobacco products, as a source of toxic particles and gases indoors, air cleaning has also been judged to be ineffective for controlling SHS exposure (American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc., 2005; U.S. Department of Health and Human Services, 2006; WHO, 2007b).

The need for policies to protect nonsmokers

Unlike many indoor pollutants that cause disease, exposure to SHS can be completely prevented by removing the source - tobacco smoke. This requires public policy. Early steps have focused on banning smoking from areas in which smokers and nonsmokers might congregate. An example was seen in 1970 when the World Health Assembly banned smoking in meeting rooms (WHO, 1970). By 1975, a number of countries had banned smoking in hospitals and schools, public transport, libraries, theaters, and concert halls. By the end of the 1980s, some countries had even banned smoking in government offices. The first jurisdiction to mandate a smoke-free workplace was California, where most workplaces were legislated to be smoke-free by 1995, but establishments serving alcohol were not covered until 1998. However, unlike many other types of public health legislation, there were no similar laws passed in other jurisdictions until 2002.

A landmark event for the protection of nonsmokers from SHS occurred when WHO agreed to negotiate and promote a Framework Convention for Tobacco Control (FCTC). The first big success was that this treaty was negotiated in 2003 and ratified by so many member nations. The second success was that the WHO FCTC developed evidence-based model language for smoke-free legislation, which is embodied in Article 8. WHO's FCTC marked a new epoch where tobacco control was seen as a global problem with global solutions. Since the ratification of the treaty, there has been rapid progress in countries implementing smoke-free workplaces using language similar to that recommended by Article 8. Under the FCTC, "smoke-free" air means that a nonsmoker will not be able to see, smell, or sense tobacco smoke, nor will components of tobacco smoke be able to be measured in the air.

Measurement of SHS

The issue of how exposure to SHS is measured is central to the discussion on the health consequences of SHS and the effectiveness of policies to reduce exposure among nonsmokers. There are several comprehensive reviews of this field, such as that of the California Environmental Protection Agency (California Environmental Protection Agency: Air Resources Board, 2005); this Handbook does not add to this literature. The most common methods of measurement of SHS exposure are self-reported

questionnaires, atmospheric markers, and biomarkers of exposure within individuals. A table listing these measures, along with identified advantages and disadvantages, is presented in Appendix 1. A summary of this literature is provided to assist readers with different chapters in this Handbook.

Self-reported questionnaires

Measuring exposure to SHS by self-reported questionnaires is a method frequently used in studies, whether the exposure data are collected retrospectively or prospectively. Self-reported measures can be useful for determining if any SHS exposure has taken place and for determining the location of exposure (Borland *et al*., 1992; Matt *et al*., 1999). However, they have limitations because of respondents' inability to accurately assess and then recall the duration and intensity of SHS exposure, or of ventilation or air conditioning practices in a particular environment (U.S. Department of Health and Human Services, 2006). As mentioned earlier, there is significant individual variability in sensitivity to smells and irritants that will add inconsistencies to anything more detailed than broad exposure assessment. More credibility is given to self-reported exposure in the home than to exposure in other multiple locations.

Individual biomarkers

An individual's exposure to SHS can be assessed objectively using the same biomarkers as are used for assessing active smoking. The most commonly used biomarkers are body fluid concentrations of nicotine (Benowitz, 1999), its more stable metabolite cotinine (Feyerabend & Russell, 1980; Pierce *et al*., 1987), and urinary concentrations of 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanol (NNAL) - a potent tobacco specific carcinogen (Hecht & Hoffmann, 1988; Hecht, 2002). Hair and toenails also take up nicotine, and gradients in concentration across tissue have been detected allowing for an estimate of longer-term exposure to SHS (Al-Delaimy, 2002; Al-Delaimy *et al*., 2002a,b). Levels of these biomarkers should be zero among people unexposed to tobacco smoke; any detectable level indicates exposure. The change in nicotine, cotinine, and NNAL are sensitive to even short-term exposure.

Atmospheric markers

The level of SHS in an environment is commonly measured by concentrations of either airborne nicotine or particulate matter (PM). About 95% of the nicotine in SHS is in the vapour phase (Leaderer & Hammond, 1991). Vapour-phase nicotine in the air can be passively collected in a sorbent tube or a filter treated with sodium bisulphate, and then analysed by gas chromatography. PM is defined as solid particles or liquid droplets suspended in the atmosphere. They can remain suspended for varying amounts of time depending on their properties and prevailing atmospheric conditions. PM is produced primarily from combustion processes originating from many different indoor and outdoor sources, including cooking and heating appliances and combustion engines. The rate of deposition of PM increases with the square of the particle diameter for particles >1 μm (Hinds, 1982). Therefore, larger particles (over 5 μm in diameter) tend to remain suspended for shorter periods, while smaller particles (submicrometric) can remain suspended for hours or even days (Institute of Medicine, 2001).

Although PM is not a specific marker of SHS, the amount of PM pollution generated by smoking can be extremely high in indoor environments (Repace & Lowrey, 1980). The typical metric for particulate matter is the mass concentration of particles of a given size, for example $PM_{2.5}$ (the mass of particles equal or less than 2.5 μm in diameter per unit of volume). This is the standard size measured as the majority of particles in SHS are within this diameter (Institute of Medicine, 2001). PM concentrations can be determined gravimetrically by collecting particles on a filter medium and then weighing them to provide a single integrated value for the sampling period. They can also be assessed in real time using optical or light-scattering monitors, which are capable of taking measurements every second, thus allowing exposure peaks to be recorded (Invernizzi *et al*., 2002).

Other measures of SHS exposure have included determinations of airborne carbon monoxide and polycyclic aromatic hydrocarbons (Chuang *et al*., 1999; Klepeis, 1999).

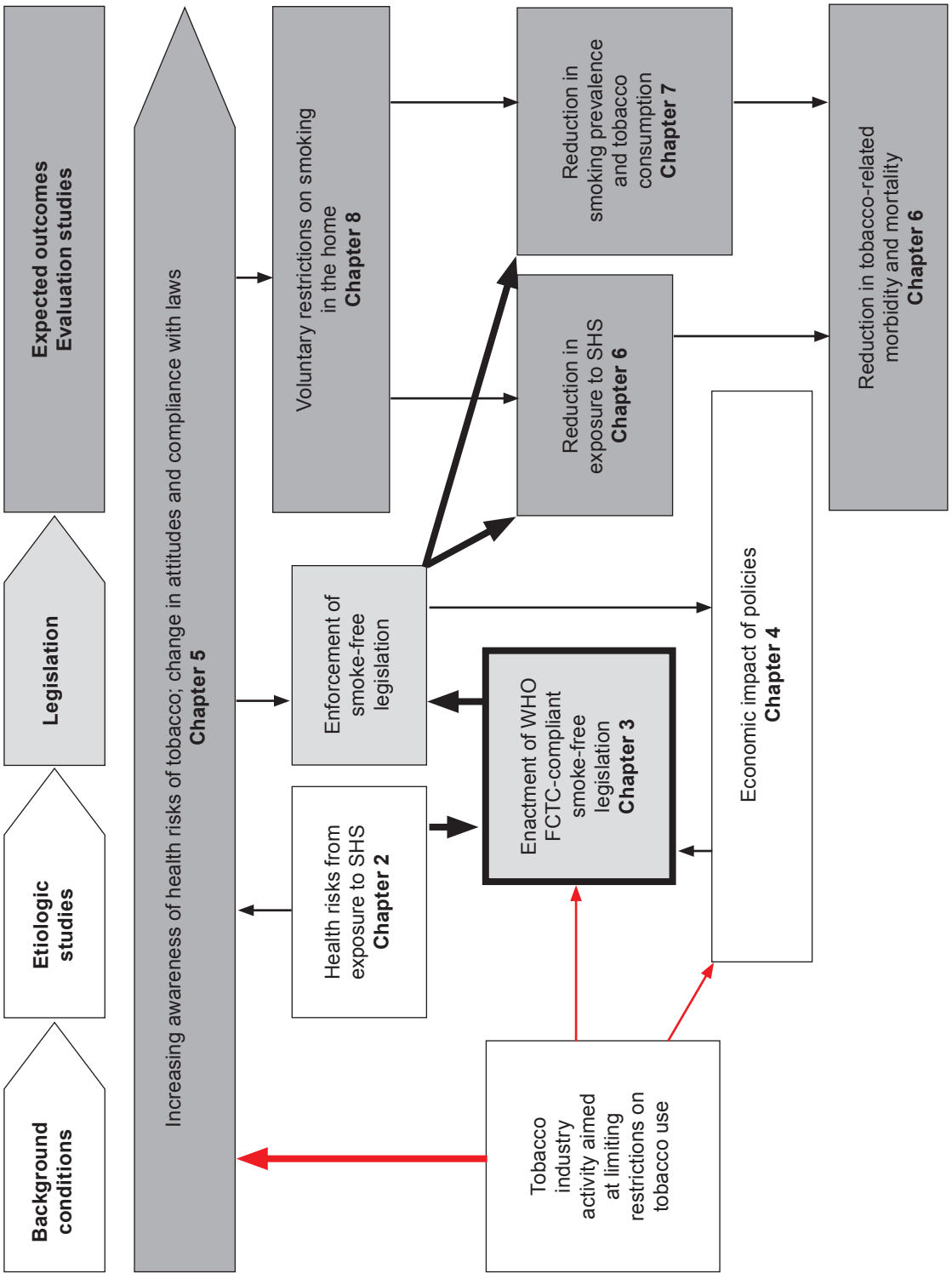

Figure 1 A logic model for SHS legislation

Outline of the Handbook

The logic model used for this Handbook is presented in Figure 1. This volume focuses on the enactment of smoke-free legislation, displayed in the middle of the figure. We consider the forces associated with the passage of such legislation, as well as the evidence for the effect of the enacted laws. Prior to consideration of public health legislation, there are a series of etiologic studies conducted which document health risks. Public awareness and acceptance of these risks will be accompanied by advocacy for protective action, which will be critical to gaining the necessary political support to enact the legislation. Meaningful restrictions on smoking will not only protect nonsmokers from the health consequences of exposure to SHS, but also may reduce the magnitude of the cigarette business within the jurisdiction. Accordingly, it is to be expected that the tobacco industry will be active in opposing the legislation in order to maintain their cigarette business. The tobacco industry strategies to oppose this legislation were uncovered in the 1990s, when the previously secret "Brown and Williamson" documents were released publicly (Glantz *et al.*, 1995; 1998). Further public releases occurred with legal discovery as part of lawsuits against the industry.

Public and legislator acceptance of the need for legislation is influenced by tobacco industry activities. One key concern prior to passing a policy is the potential economic impact on a given jurisdiction. Legislation for a policy also needs to consider the level of necessary enforcement; oftentimes a budget for inspections and policing of the policy is not available. It is presumed that social norms alone will be sufficient to enforce the new laws.

Once legislation has been enacted, the effectiveness can be evaluated. Such effectiveness will be related to the level of compliance with the law which depends on public awareness and acceptance.

Chapter 2: The health effects of exposure to secondhand smoke

It is important to establish the scientific basis for SHS policy. Acceptance of the health consequences from exposure to SHS is central to efforts to promote legislation to protect the public's health, and, therefore, in the logic model in Figure 1, it precedes legislative efforts. Research on SHS has been ongoing for decades, with the first reviews of the evidence undertaken in the mid 1980s. Since then, authoritative scientific bodies have revisited the data at regular intervals particularly focusing on the evidence that exposure to SHS causes cancer, cardiovascular disease, and respiratory disease. These reviews have carefully considered the published epidemiological studies; they have reviewed the evidence on the suggested mechanisms for the effects of SHS and have considered potential confounding from other risk factors, as well as exposure misclassification. A summary of this body of evidence is provided in this chapter accompanied by results of both published and *de novo* meta-analyses, establishing the strong scientific basis for urgent public health action to protect nonsmokers from exposure to SHS.

Chapter 3: The evolution of smoke-free policies

In 2003, WHO achieved consensus that a key to protecting people from the harmful consequences of exposure to SHS was legislation creating smoke-free environments - one of the pillars of the WHO FCTC. It was also recognised that such legislation can be written in a manner that appears to meet the public health goal, but contains clauses that do not protect the public from exposure to SHS as initially envisioned. Accordingly, specific model language was proposed in Article 8 of the WHO FCTC, which is presented in this chapter. Legislation is initiated by a governmental entity that has the power to both implement and enforce laws within its jurisdiction. Such an entity is a national or federal government, a sub-national government (state or province), or, in some countries, it can be a lower level of government, such as a local city or county government.

There is a long history of attempting to restrict smoking behaviour in different locations starting from the early days of the cigarette smoking epidemic. As cigarette smoking became more prevalent, nonsmokers' ability to maintain their rights disappeared. It was not until after the health consequences of smoking were accepted that restrictions on smoking began to be considered again. The Working Group briefly reviewed this history noting some of the landmarks

and also noting that the diffusion was faster in some parts of the world than in others. Prominent reports concluding that exposure to SHS has serious health consequences for nonsmokers started in the mid 1980s; a paper in a major scientific journal appeared in 1992 calling for public health action to ensure a smoke-free workplace (Borland *et al*., 1992). The first jurisdiction to implement a smoke-free workplace was the US state of California. Legislation was passed in 1994, but not fully enacted until 1998. Following WHO's initiative on the FCTC, smoke-free workplaces started to rapidly disseminate. The first country with nation-wide smoke-free workplaces was Ireland in 2004. The chapter summarises the rapidity of the diffusion of this important SHS legislation throughout this period. It also presents details of the legislation, including evidence of enforcement, for some of the key jurisdictions.

Chapter 4: Impact of smoke-free policies on businesses, the hospitality sector, and other incidental outcomes

In many jurisdictions, legislators, as well as residents, put a high value on ensuring that laws are "business friendly," meaning that enactment will not have a negative impact on business in the community (i.e. their profit margins) or on the taxation base of the community. As most community members, including legislators, will have little personal experience with which to judge the likely impact of the new policies, they will rely quite heavily on the economic reports from other places that have introduced similar legislation. Thus, research that addresses the evidence of economic impact of smoke-free legislation can have an important impact on whether a given jurisdiction initiates SHS legislation or not, a link depicted in the logic model. The tobacco industry has generated much of this literature, disseminating reports favorable to their vested interest. However, the methodological rigor used by many of these tobacco industry-sponsored studies leaves much to be desired. Indeed, these methodologically unsound studies have often led to conclusions that are quite the opposite of those studies that used appropriate scientific methodology. Unfortunately, the findings from these studies, particularly those that focus on the hospitality industry, have been promoted widely by the tobacco industry, thus leading to the appearance of scientific controversy. This chapter lays out the methodological criteria for a study that can contribute to the science. It also discusses the consistency of the findings on the economic impact of smoke-free legislation on the hospitality industry from available scientifically-appropriate studies accessible up to April 2008.

Chapter 5: Public attitudes towards smoke-free policies - including compliance with policies

The passage of smoke-free legislation in any jurisdiction occurs within both a social and political context. It requires the multi-level support of stakeholders and potentially difficult negotiations in order to ensure enough votes for passage. A major determinant to the ease of passage of legislation will be the level of awareness and concern in the community on the issue and the strength of support for restrictions on smoking to protect nonsmokers from exposure to SHS. Community awareness and concern will also dictate the level of compliance with legislation that has been introduced. Thus, in the logic model, community awareness and attitudes are presented as an important variable that acts across the continuum from background conditions to the outcomes following implementation and enforcement of SHS legislation (Figure 1). This chapter reviews the evidence for the level of community attitudes and support for smoke-free policies, as well as changes in these that occur after enactment of legislation.

Chapter 6: Reductions in exposure to secondhand smoke and effects on health due to restrictions on smoking

Prior to the passage of smoke-free legislation, many workplaces within a jurisdiction will already have voluntary restrictions on smoking behaviour, some of which will require smoke-free settings. Voluntary smoke-free workplaces, as well as jurisdictions that have smoke-free legislation, have been studied. There is now 10 years of follow-up for the jurisdiction with the first smoke-free legislation. Thus, there is a sufficient research base to allow an assessment of the short- and long-term effectiveness of the legislation in protecting nonsmokers from exposure to SHS, as indicated in the logic model (Figure 1).

Given that some of the health consequences of exposure to SHS have short-term onset, there has

been considerable research interest in the change in prevalence of respiratory symptoms, and even acute coronary events, following reduction or elimination of SHS resulting from the implementation of smoke-free legislation. It is too early to assess any long-term health benefits, such as a change in the incidence of lung cancer. This chapter reviews the research documenting changes in exposure to SHS following smoke-free legislation and draws conclusions on the change in short-term health consequences following the implementation of a smoke-free workplace.

Chapter 7: The effect of mandated smoking restrictions on smoking behaviour

Restrictions on smoking behaviour to protect nonsmokers can also provide health benefits to smokers, by limiting their opportunity to smoke, reducing their level of consumption, and encouraging them to quit. Indeed, restrictions may also have a role in preventing young people from progressing to the same level of nicotine dependence that they may have done otherwise (Pierce *et al.*, 1991). Reductions in population level nicotine dependence can be expected to modify both the short- and long-term health consequences of smoking in the community. These outcomes need to be considered in any assessment of the effectiveness of this public policy action (see Figure 1).

The literature is consistent that lung cancer, as a consequence of smoking, can be predicted from a power function of both the duration and intensity of smoking (Doll & Peto, 1978; Flanders *et al.*, 2003). Thus, both cessation behaviour and consumption level of continuing smokers need to be part of the assessment of the effectiveness of smoke-free legislation. There are a number of studies that compare smoking behaviour in workplaces with total, partial, and no restrictions on smoking. In this chapter, we review these studies and draw conclusions on the role of smoke-free workplaces in modifying smoking behaviour in the community.

Chapter 8: Home smoking restrictions: effects on exposure to secondhand smoke and smoking behaviour

One key measure of the degree of acceptance of smoke-free policies is the extent to which community members implement their own voluntary restrictions in their homes, particularly smoke-free homes. In Figure 1, this relation is shown by connecting attitudes and compliance with voluntary restrictions on smoking in the home. Jurisdictions in which smokers live in smoke-free homes can be expected to require less enforcement of smoke-free policies, as the societal norms will be more aligned with the legislation. Further, a high proportion of smokers living in smoke-free homes and working in smoke-free workplaces is expected to be associated with a lower population level of nicotine dependence in continuing smokers. Smoke-free homes might also be associated with a reduction in the probability of smoking initiation by the children in the home. Finally, as mentioned in the previous chapter, a reduction in smoking behaviour (proportion of smokers and their level of smoking intensity) should result in a reduction in tobacco-related morbidity and mortality.

This chapter reviews and draws conclusions from the available studies that report on voluntary home smoking restrictions, the protection of nonsmokers, and smoking behaviour among continuing smokers. This is a relatively new area of research; it can be expected that the scientific basis for conclusions will increase significantly over the next years.

Summary of findings of the Handbook

In each of the above chapters, the Working Group conducted a comprehensive examination of the peer-reviewed literature and publicly accessible government reports since 1990. Having completed that, the Working Group assessed the quality of the evidence in each of the areas and voted on it for a series of findings listed in the Evaluation chapter. The scale for the quality of evidence lists “sufficient” as the highest classification, indicating that the association was highly likely to be causal; a lesser classification of “strong” indicates that the association is consistent, but evidence of causality is limited. Three additional classification criteria were available when judging the strength of the evidence. Finally, the Working Group proposed several public health and research recommendations. On the basis of the evidence reviewed, an overall recommendation made by the Working Group is that governments enact and implement smoke-free

policies that conform to the WHO FCTC. A short report of the Working Group's findings was published shortly after the conclusion of the Handbook meeting in Lyon. This report summarised the findings as follows: "Implementation of such policies can have a broader population effect of increasing smoke-free environments. Not only do these policies achieve their aim of protecting the health of non-smokers by decreasing exposure to secondhand smoke, they also have many effects on smoking behaviour, which compound the expected health benefits. These benefits will be greater if these policies are enacted as part of a comprehensive tobacco-control strategy that implements all of the provisions called for by the WHO FCTC." (Pierce & Leon, 2008).