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# **GREEN PAPER**

# Towards a Europe free from tobacco smoke: policy options at EU level

(presented by the Commission)

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# I. INTRODUCTION

Exposure to environmental tobacco smoke (ETS) – also called "second-hand smoke" and "passive smoking" - remains a widespread source of excess morbidity and mortality in the European Union, imposing significant costs on society as a whole.

A coordinated effort towards "smoke-free Europe" is one of the priorities of the Commission's public health, environment, employment and research policy. In its Environment and Health Action Plan (2004-2010), the Commission committed itself to "develop work on improving indoor air quality, in particular by encouraging the restriction of smoking in all workplaces by exploring both legal mechanisms and health promotion initiatives at both European and Member State level".

Substantial steps have already been taken to promote smoke-free environments in the EU. In the early nineties a number of EU health and safety at work directives defined certain restrictions on smoking at work. These were complemented by the Council Resolution of 1989<sup>1</sup> and the Recommendation on smoking prevention of 2002<sup>2</sup>, which called on Member States to provide protection from exposure to environmental tobacco smoke in indoor workplaces, enclosed public places, and public transport. In addition to legislative action, two anti-tobacco campaigns in the media – "Feel free to say no" (2001-2004) and "HELP: For a life without tobacco" (2005-2008) – have aimed at highlighting the hazards of passive smoking and at promoting tobacco-free lifestyles, particularly among young people.

National legislation differs widely across the Member States. The Commission welcomes the excellent example set by Ireland, Italy, Malta, Sweden and parts of the UK, and encourages all Member States to make rapid progress in introducing effective measures to protect their citizens from the harmful effects of passive smoking.

At international level, the WHO Framework Convention of Tobacco Control (WHO FCTC), signed by 168 and ratified by 141 Parties<sup>3</sup>, including the Community, "recognizes that scientific evidence has unequivocally established that exposure to tobacco smoke causes death, disease and disability". The Convention obliges the Community and its Member States to tackle exposure to tobacco smoke in indoor workplaces, public transport and indoor public places.

The aim of the present Green Paper is to launch a broad consultation process and an open public debate, involving the EU institutions, Member States and the civil society, on the best way forward to tackle passive smoking in the EU.

The Commission will analyse thoroughly the comments received in response to this Green Paper and on that basis decide on possible further action. The report summarising the consultation outcomes is expected for the first half of 2007. In parallel, the broader work on indoor air quality will be continued as a follow up to the Health and Environment Action Plan.

# II. JUSTIFICATION FOR ACTION

### 1. HEALTH CONSIDERATIONS

#### 1.1. Health burden of ETS exposure

ETS contains over 4 000 chemicals, including over 50 known carcinogens and many toxic agents. No safe level of ETS exposure has been established nor is there any expectation that further research will identify such a level.

ETS has been classified as a **known human carcinogen** by the US Environmental Protection Agency in 1993, by the U.S. Department of Health and Human Services in 2000 and by WHO International Agency for Research on Cancer in 2002. In addition, it has been classified as a **workplace carcinogen** by the Finish (2000) and German (2001) governments. Recently, the California Environment Protection Agency has classified tobacco smoke as a **"toxic air contaminant**".

Several recent reviews have confirmed the serious risks to health and life associated with passive smoking.<sup>4</sup> Chronic exposure to second-hand smoke has been established as a cause of many of the same diseases caused by active smoking, including lung cancer, cardiovascular disease, and childhood disease.

A review by the WHO-IARC found that non-smokers living with a smoker have a 20-30% greater risk of developing lung cancer. The extra risk of workplace exposure has been estimated at 12-19%.<sup>5</sup> The links between exposure to ETS and other types of cancer are less clear.

Living with a smoker has been shown to increase the risk of coronary heart disease among non-smokers by **25-30%**<sup>6</sup> (a recent study indicates that this figure may actually be higher)<sup>7</sup>. There is also growing evidence that passive smoking is causally linked to stroke in non-smokers, although further research is needed to estimate the risk.<sup>8</sup>

Passive smoking is associated with **respiratory disease**<sup>9</sup> and is a major source of exacerbation for people with asthma, allergies and chronic obstructive pulmonary disease, leading to social and work exclusion. A recent pan-European survey among people with symptoms of severe asthma found that one of their major wishes for the future was to be able to breathe healthy air.<sup>10</sup>

Second-hand smoke is especially dangerous for **young children and infants**, being associated with sudden infant death, pneumonia, bronchitis, asthma and respiratory symptoms as well as middle ear disease. ETS exposure in **pregnant women** can cause lower birth weight, foetal death and preterm delivery<sup>11</sup>.

The most recent research suggests that ETS exposure almost doubles the risk of developing age-related macular degeneration - the main cause of sight loss in the  ${\rm EU.}^{12}$ 

Most of the adverse health outcomes brought about by ETS show a linear doseresponse relationship – in other words the risk increases steadily with increasing exposure. The level of individual risk is lower compared to active smoking (e.g. 1.2 and 20, respectively, for lung cancer). Nevertheless, the fact that large numbers of people are exposed results in a substantial burden of disease.

In addition, the **dose-response relationship** for heart disease is **non-linear.** Secondhand smoking carries a risk of heart disease which is almost half that of smoking 20 cigarettes per day. Even very small amounts of tobacco smoke can have an immediate impact on clotting and thrombus formation, as well as long-term effects on the development of arteriosclerosis - all important factors in heart disease.<sup>13</sup> This is a source of major impact: heart disease is the most common cause of death in the EU, among both smokers and non-smokers.

According to the most recent – conservative - estimates by the partnership between the European Respiratory Society, Cancer Research UK and the Institut National du Cancer in France, **more than 79,000 adults** die each year as a result of passive smoking in the 25 countries of the EU. There is evidence that passive smoking **at work** accounted for over **7,000 deaths** in the EU in 2002, while exposure **at home** was responsible for a further **72,000 deaths**. These estimates include deaths from heart disease, stroke, lung cancer and some respiratory diseases caused by passive smoking. However they omit deaths in adults due to other conditions related to ETS exposure (such as pneumonia), deaths in childhood, and the significant serious morbidity, both acute and chronic, caused by passive smoking.<sup>14</sup>

# **1.2.** Levels of exposure

The main places for chronic and intensive ETS exposure are the **home** and the **workplace**.<sup>15</sup> According to the 1998 report by Information System on Occupational Exposure to Carcinogens (**CAREX**), ETS was the second most common form of exposure to carcinogens (after solar radiation) in the EU-15. Some 7.5 million European workers were exposed to second-hand tobacco smoke during at least **75%** of their working time in 1990-93.<sup>16</sup>

A study carried out in a range of public places in seven European cities in 2001-2002, showed that tobacco smoke was present in most of the studied public places studied, including leisure and hospitality venues, transport, hospitals and educational settings. The highest ETS concentrations were found in bars and discotheques, with a four-hour exposure in a discotheque being similar to that from living with a smoker for a month.<sup>17</sup> The finding that exposure levels are exceptionally high in hospitality venues has been confirmed by other studies, which found the average exposure of bar workers to be three or more times higher than the exposure sustained from living in a smoking household.<sup>18</sup>

Recently, smoke-free regulations have led to a near-total elimination of workplace exposure in some Member States and in some types of venues, while in countries with no comprehensive restrictions the exposure remains high, particularly in the hospitality and leisure sector.<sup>19</sup>

In order to estimate EU-wide exposure to ETS, the EU Expert Group on Human Biomonitoring<sup>20</sup> recommended to include cotinine (a major biomarker of ETS exposure) in the list of candidates for the future EU Pilot Project on Human Biomonitoring. Member States have supported this Recommendation on several occasions.

### **1.3.** Impact of smoke-free initiative

Action on smoke-free environments would not only protect people from the harm of ETS exposure but also contribute to the reduction of tobacco consumption in the whole population. The health effects of reduced passive and active smoking would include **reduced illness and mortality** from major disease types - in particular lung cancer, coronary heart disease, respiratory disease and stroke - and increased life expectancy. Although the full health benefits may take up to 30 years to be realised, major improvements, particularly in respiratory and cardiovascular health, can be expected to occur within 1-5 years.

The CHOICE project managed by WHO identified smoke-free public places as the **second most effective form of intervention** to reduce the mortality and morbidity related to tobacco use, after tax increases (see Annex I).

# 2. ECONOMIC CONSIDERATIONS

# 2.1. Economic burden

Data from Member States (UK, Ireland) and from outside the EU suggest that exposure to ETS imposes huge private and social costs although the overall burden on EU-27 has yet to be estimated. The burden to the **economy as a whole** includes the direct costs relating to increased healthcare expenditure on tobacco-related diseases, and the indirect costs linked to productivity losses and lost income tax and social security contributions among smokers and second-hand smoke victims who would otherwise be in paid employment.<sup>21</sup>

The economic burden is particularly high for **employers** and includes lower workers' productivity due to smoking breaks and increased sickness absence; fire damage caused by smoking materials as well as the additional cleaning and redecoration costs related to smoking.<sup>22</sup> In Canada, the annual cost per smoking employee, compared to a similar non-smoking employee, was estimated at \$2,565 in 1995 Canadian dollars. The loss to Scottish employers due to decreased productivity, higher rates of absenteeism and fire damage caused accidentally by smoking has been calculated at 0.51% to 0.77% of Scottish Gross Domestic Product (GDP) in 1997. In Ireland, the equivalent estimate was 1.1-1.7% of GDP in 2000.<sup>23</sup>

# 2.2. Impact of smoke-free initiative

In the longer term, the potential health improvement resulting from smoke-free policy could have a **major economic effect**. The regulatory impact assessments carried out by the UK Government estimated the long term net benefits of comprehensive smoke-free legislation at £1714-2116 billion annually.<sup>24</sup> In Scotland, Wales and Northern Ireland, the net benefits of smoking bans have been calculated, respectively, at £4.387 and £2.096 billion over a 30 year period and £1.101 billion over a 20 year period.<sup>25</sup>

# 2.3. Risk of unintended consequences

As smoke-free policies will motivate some smokers to give up smoking or to smoke less, there may be a **loss of profit to the tobacco industry** and, consequently, reductions in tobacco-related employment. However, jobs related to the tobacco industry represent a relatively small percentage of total EU employment. In 2000, employment in tobacco-related occupations (tobacco growing, processing and manufacturing) accounted for 0.13% of total EU15 employment.<sup>26</sup> Moreover, the money currently spent on tobacco is likely to be spent on other goods and services, generating employment in other sectors of the economy.

A reduction in the levels of active smoking will also mean a **loss of Member States revenue from taxes** (excise duty and VAT) on cigarettes. It should be noted, however, that in most EU countries, although cigarette taxation generates significant revenues, in terms of overall portion of the state budget it does not make up a significant share (1-5%). The exceptions are Czech Republic, Poland and Greece, where cigarette tax accounted for 6, 7 and 9 % respectively of government tax revenue in 1999.<sup>27</sup> In addition to a reduction of the societal costs associated with smokingthe disposable income of smoking households would increase if smoking bans were introduced, and the revenue from VAT accruing from alternative investments and expenditure by such households would partly off-set the revenue lost.

Some production losses can be expected from smokers who are currently allowed to smoke at work and will continue to smoke, taking smoking breaks outside the building.

# **3. SOCIAL CONSIDERATIONS**

# 3.1. Public support for smoke-free laws

Nearly 70% of EU citizens do not smoke<sup>28</sup> and studies demonstrate that the majority of smokers want to stop smoking<sup>29</sup>.

According to the recent **Eurobarometer Survey** on the "Attitudes of Europeans towards Tobacco"<sup>30</sup>, three quarters of Europeans are aware that tobacco smoke represents a health risk for non-smokers, while 95% acknowledge that smoking in the company of a pregnant woman can be very dangerous for the baby.

The survey results demonstrate that **smoke-free policies are popular among EU citizens** (see Annex III). More than four out of five respondents are in favour of a ban on smoking in the workplace (86%) and any other indoor public place (84%). A majority of Europeans are also in favour of banning smoking in bars (61%) and restaurants (77%). Support for smoke-free pubs (over 80%) and restaurants (over 90%) is highest in the four Member States which have already banned smoking in hospitality venues. This is another indication that the support for smoke-free policies tends to increase during the build-up to their introduction, and grows still further after implementation.<sup>31</sup>

### **3.2.** Impact on tobacco consumption

An important indirect benefit of smoke-free policies is that they increase people's awareness of the dangers of active and passive smoking, contributing to the "denormalisation" of smoking within the society. The change in perception could be expected to lead to a change in smoking behaviour, and in particular to:

- Make it easier for smokers to decide to give up or reduce smoking and support them in the cessation process.<sup>32</sup>
- Discourage children and young people from taking up smoking.<sup>33</sup> Smoking bans in places of entertainment where young people often "experiment" with cigarettes could be expected to have the biggest impact.
- Deter smokers from smoking in the presence of non-smokers, in particular children and pregnant women, even when there are no regulatory restrictions in place (e.g. in homes and private cars).<sup>34</sup> This is important given that the main harm concerns children who are exposed to passive smoking in the home, which is an area that a regulation cannot address.

# **3.3.** Impact on social equity

Smoke-free policies could also help to reduce socio-economic inequalities in health. Given that the likelihood of being a smoker and being exposed to second-hand smoke is significantly increased for those who have a lower level of education, lower income and lower occupational class, an action on smoke-free environments might be expected to bring the biggest benefits to the most deprived groups in society.

#### 4. MOMENTUM FOR ACTION

As a Party to the WHO **Framework Convention on Tobacco Control (FCTC)**, the Community is under a legal obligation to take action on smoke-free environments. Under Article 8 of the FCTC each Party has undertaken to "adopt and implement (...) effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places." The first Conference of the Parties to the FCTC in February 2006 agreed to develop guidelines on smoke-free environments to be presented to the second Conference of the Parties due in the first half of 2007.

The **Council of the European Union** in its Recommendation of 2002 on the prevention of smoking and on the initiatives to improve tobacco control invited the Commission to "consider the extent to which the measures set out in this recommendation are working effectively, and to consider the need for further action, particularly if internal market disparities are identified in the areas covered by this recommendation". In addition, at a meeting of the **Tobacco Regulatory Committee**<sup>35</sup> in September 2005, Member States agreed that a Commission initiative in the form of a Green Paper or Communication would help disseminate good practice and bolster national efforts towards smoke-free environments.

The **European Parliament** welcomed "the Commission's willingness to act to put an end to smoking in enclosed spaces" and encouraged it "to designate environmental tobacco smoke a class 1 carcinogen" in its resolution on the Commission's Action Plan on Environment and Health in February 2005.<sup>36</sup>

The added value of EU action has also been recognised in the report "**Tobacco or Health in the European Union**" prepared for the Commission by a consortium of tobacco control experts.<sup>37</sup> The desirability of intervention at European level has been further highlighted by two pan-European projects on indoor air pollution, supported under the Community Public Health Programme. The **INDEX report** published by the EU Joint Research Centre established a list of five high-priority chemicals (all of which are present in tobacco smoke) that need to be regulated in indoor environments and recommended to "ban tobacco smoking in all indoor spaces under public jurisdiction, and working places".<sup>38</sup> The same recommendation has been formulated in the **THADE report**<sup>39</sup>, which identified ETS as the single largest contributor to indoor particulate concentration in buildings where tobacco smoking occurs.

# III. CURRENT REGULATORY ENVIRONMENT

# 1. NATIONAL PROVISIONS

There is a clear trend towards smoke-free environments throughout the Member States, driven – among other factors – by legal requirements at EU and international level. All Member States currently have some form of regulation aimed at limiting exposure to ETS and its harmful effects on health. The scope and character of these regulations vary widely.

Comprehensive bans on smoking in **all enclosed public places and all workplaces**, including bars and restaurants, have already been introduced in Ireland (March 2004) and Scotland (March 2006). In Northern Ireland, England and Wales, complete smoke-free legislation is due to come into force by summer 2007.

**Smoke-free legislation with exemptions** introduced in Italy (January 2005), Malta (April 2005) and Sweden (June 2005) permits employers to create special sealed-off smoking rooms with separate ventilation systems. Similar measures are set to come into effect in France in February 2007 (transition period for hospitality venues until

January 2008) and in Finland in June 2007. Lithuania is set to become smoke-free (with the exception of specially equipped "cigar and pipe clubs") as of January 2007.

A number of other Member States have banned smoking in all enclosed public places and all workplaces, with the **exception of the hospitality sector** where partial restrictions apply. These countries include for example Belgium, Cyprus, Estonia, Finland, the Netherlands, Slovenia and Spain.

Most Member States have regulations banning or restricting smoking in **major public places**, such as health care, educational and government facilities, theatres, cinemas and public transport. Restrictions of smoking at the workplace are less common. The force of the measures may range from a resolution or a voluntary agreement to a strict law with penalties for failure to comply.

As a result of incomplete regulations or the lack of enforcement, national governments and employers have often faced litigation by citizens for damage to their health caused by passive smoking.<sup>40</sup>

In several Member States, nation-wide provisions are enhanced by more stringent regulations **at regional and/or local level**. The legal framework is also complemented by self-regulatory measures, with a growing number of workplaces, schools, hospitals, public transport facilities etc. going smoke-free on a voluntary basis. More and more is being done to support the staff in giving up smoking and to promote the concept of healthy indoor air as a basic right of every citizen and employee.

# 2. EXISTING COMMUNITY PROVISIONS

At EU level, the issue of smoke-free environments has been addressed in **nonbinding resolutions and recommendations**, which have encouraged Member States to provide adequate protection from exposure to ETS. In particular, the **1989 Council Resolution** 89/C 189/01<sup>41</sup> on smoking in public places invited Member States to adopt measures banning smoking in public places and on all forms of public transport. Most recently, the **Council Recommendation** 2003/54/EC<sup>42</sup> on the prevention of smoking and on initiatives to improve tobacco control called on Member States to implement effective measures that provide protection from exposure to environmental tobacco smoke in indoor workplaces, enclosed public places, and public transport.

The **Framework Directive on Health and Safety in the Workplace** (89/391/EEC)<sup>43</sup>, while not explicitly referring to tobacco smoke, covers all risks to the health and safety of workers<sup>44</sup> It requires the individual employer to assess the risks in the workplace and to introduce appropriate risk prevention and protection measures.

In addition, a number of individual occupational health and safety directives by setting out "minimum requirements" for specific risks contain certain provisions which ensure protection of workers from ETS (see paragraph below). These directives shall be transposed by Member States into national law and shall be

properly enforced. According to the Treaty, the Member States are allowed to introduce more stringent measures.

The **Directive on minimum safety and health requirements for the workplace**  $(89/654/\text{EEC})^{45}$  as well as the directives for temporary or mobile construction sites  $(92/57/\text{EEC})^{46}$ , mineral-extracting industries through drilling  $(92/91/\text{EEC})^{47}$  and mineral-extracting industries  $(92/104/\text{EEC})^{48}$  require employers to ensure ventilation and sufficient fresh air in enclosed workplaces and to protect non-smokers against discomfort caused by tobacco smoke in rest rooms and rest areas.

The **Carcinogens and Mutagens Directive**  $(2004/37/EC)^{49}$  and the **Asbestos Directive**  $(83/477/EEC)^{50}$  prohibit smoking in areas where, respectively, carcinogens/mutagens and asbestos are handled. The **Pregnant Workers Directive** (92/85/EEC) requires employers to take action to protect pregnant and breastfeeding women from exposure to carbon monoxide.

Certain components of ETS (such as arsenic, 1,3-butadiene, benzene and propylene oxide) are classified as carcinogenic under Annex 1 to the **Dangerous Substances Directive** (67/548/EEC)<sup>51</sup>. Tobacco smoke as such falls outside the scope of EU chemicals legislation since that legislation applies only to those substances and preparations that are **placed on the market** in the Member States.<sup>52</sup>

# IV. SCOPE OF SMOKE-FREE INITIATIVE

A key issue in developing an EU smoke-free initiative is its **scope**. Given the wide variety of settings where exposure to ETS occurs, an effective smoke-free policy should take a broad approach rather than relate only to certain types of businesses or premises.

The most comprehensive approach would consist in proposing a total ban on smoking in **all enclosed or substantially enclosed workplaces and public places**, including means of public transport. Restrictions could also be extended to outdoor areas around entrances to buildings and possibly to other outdoor public places where people sit or stand in immediate proximity to each other, such as open air stadiums and entertainment venues, bus shelters, train platforms etc. Very limited exceptions could be considered for places where people live on a day-to-day basis (e.g. designated rooms in residential premises, such as long-stay care homes, psychiatric units, prisons etc.).

A less stringent approach would consist in proposing a total ban on smoking in all enclosed or substantially enclosed workplaces and public places but with **exemptions granted to selected categories of venues**. Minimum requirements for enclosed smoking rooms, including ventilation standards, could be developed for exempted venues. Possible exemptions could include:

- the licensed hospitality sector (restaurants, pubs and bars),
- hospitality establishments which do not serve food.

Action on smoke-free environments would deliver the best results if complemented by **supporting measures** at EU and/or Member State level. Such "flanking policies"

could include awareness raising campaigns highlighting the right to smoke-free air and the dangers of passive smoking as well as increased access to cessation therapies (both behavioural and pharmacological) for persons who wish to stop smoking.

#### 1. COMPREHENSIVE SMOKE-FREE REGULATION

#### Advantages

Of all the options, this one would offer the **highest reductions in ETS exposure** and related harm, ensuring the equality of European citizens to protect their right to breathe healthy indoor air, as recognised by the WHO.<sup>53</sup>

Studies from smoke-free countries demonstrate that indoor air quality improved dramatically after the smoking bans went into effect. The drop in ETS exposure has been particularly spectacular in hospitality and leisure venues.<sup>54</sup> This has been mirrored by a significant improvement in the respiratory health of hospitality workers<sup>55</sup> and a considerable reduction in the incidence of and mortality from heart attacks<sup>56</sup> within months of policy implementation.

Comprehensive regulation would also have the biggest potential to **de-normalise smoking** in society, creating an environment that encourages smokers to cut back or give up smoking and discourages young people from taking up smoking.

A review of 35 studies on the effectiveness of smoke-free policies concluded that comprehensive public clean air laws have the potential to reduce smoking prevalence of the whole population by about 10%.<sup>57</sup> A review of 26 workplace studies also suggested that totally smoke-free workplaces are associated with a reduction in smoking prevalence of 3.8% and 3.1 fewer cigarettes smoked per day per continuing smoker.<sup>58</sup>

That comprehensive smoking bans are associated with **reductions in active smoking** has been confirmed by the evidence from smoke-free countries, where the fall in tobacco sales (e.g. by 8% in Italy and 14% in Norway) has been coupled with a significant increase in attempts to give up smoking shortly after the introduction of the new regulations.<sup>59</sup> In Ireland, 80% of ex-smokers cited new legislation as the motivation to quit smoking while 88% declared that the law had helped them not to start again. <sup>60</sup> Despite concerns to the contrary, the bans on smoking in all public venues appear to have reduced the levels of smoking in the home, especially around young children.<sup>61</sup> In Ireland, the proportion of smoke-free households increased by 8% after the ban came into effect.<sup>62</sup>

In terms of social impact, the benefits of this option would be concentrated on people in **lower socio-economic groups**, who are more likely to smoke and to be employed in the hospitality sector.

As regards **enforcement**, a comprehensive smoking ban would be easier to implement than partial restrictions. Over 90% compliance in Italy and Ireland demonstrates that a total smoking ban is almost entirely self-enforcing as social pressure becomes a powerful curb on smoking and drastically reduces the need for enforcement by formal authorities.

# Disadvantages

A total ban on smoking in all public places and workplaces would be likely to arouse **opposition** in some Member States, and may therefore be more difficult to adopt and enforce. This option is also the one that the tobacco and the majority of the hospitality industry have made clear they favour least.

There have been concerns about **possible harm to the hospitality industry** from bans on smoking in pubs and restaurants. However, evidence from smoke-free jurisdictions demonstrates no overall negative impact on employment or revenue in the sector.<sup>63</sup> In Ireland, the volume of sales in pubs and bars increased slightly (by 0.1%) in 2005, thus reversing a declining trend which had started before smoke-free legislation came into force.<sup>64</sup> It could be worth recalling some statistics even if they concern States not belonging to the EU. For instance, in Norway, there has been a slight fall of 0.8% in sales in eating and drinking establishments but this is likely to be due to a number of other factors, including the weather.<sup>65</sup> In New York City and California, most hospitality industries appear to have benefited from smoke-free regulations.<sup>66</sup> This is consistent with an international review of 97 studies, which failed to find any negative economic impact in studies based on objective data such as sales tax and employment figures.<sup>67</sup>

### 2. SMOKE-FREE REGULATION WITH EXEMPTIONS

### Advantages

The reduction in both active and passive smoking as well as the de-normalisation of tobacco use under this option could be expected to be greater than if no measures were taken.

Legislation with exemptions could be more acceptable in some Member States, especially to the industry, and therefore a compromise could be more feasible. At the same time, individual Member States would be free to adopt, or to continue, more stringent national legislation where exemptions do not apply.

Exemptions could be complemented by minimum requirements for enclosed smoking rooms, including ventilation standards.

# Disadvantages

In terms of health and social benefits, this measure would be less effective than comprehensive smoke-free regulation.

Some of the most vulnerable groups would continue to be exposed to ETS. Incomplete regulation could pose the risk of the Member States and/or employers being subject to litigation by citizens for damage to their health caused by passive smoking.

Exemptions would reduce the effect of de-normalising smoking which could be achieved by a total ban. International evidence suggests that regulations which allow smoking in some areas have about half the effect on smoking behaviour in comparison with totally smoke-free policies.<sup>68</sup>

Different provisions for different establishments would also be more complicated and expensive to enforce than a comprehensive ban, necessitating increased signage requirements and inspections.

# 2.1. Exemption for the licensed hospitality sector

Owing to heavy ETS exposure, hospitality employees are at particular risk from passive smoking, with a 50% greater risk of lung cancer<sup>69</sup>. This occupational group would continue to be exposed to second-hand smoke. The same health risk would apply to customers of drinking and eating venues.

According to the Labour Force Survey figures for 2004, almost 4.3 million individuals were employed in the bars, restaurants and the catering sector (HORECA) in 15 Member States of the EU, which accounted for 3% of the total employment in these countries (no data for the remaining 10 MS). Significant proportions of young people and women are employed in the hospitality sector.<sup>70</sup>

The regulatory impact assessment conducted by the Scottish Executive estimated the drop in deaths due to reduced active and passive smoking under this option to be, respectively, one half and one quarter of the drop in deaths due to a totally smoke-free option.<sup>71</sup>

### 2.2. Exemption for pubs and bars not serving food

This option would fail to protect the most vulnerable occupational groups from exposure to second-hand smoke. The customers of pubs and bars would not be protected either. It would also create a risk of pubs giving up serving food to circumvent the smoking ban.

In addition, there would be a risk of widening existing health inequalities: recent studies from the UK show that the levels of ETS exposure are significantly higher in pubs in deprived communities than in pubs in more affluent areas.<sup>72</sup> Moreover, the majority of licensed premises not serving food are located in deprived areas and pubs in these areas will have stronger incentives to switch to serving only alcohol.<sup>73</sup>

The regulatory impact assessment carried out by the UK Government estimated the health benefits of this option at 40 per cent of the benefits of a total ban (based on an assumption that 10-30% of the pubs do not currently serve food).<sup>74</sup>

#### 2.3. Enclosed, separately ventilated smoking rooms

The evidence demonstrates that currently used technologies (based on mixing and dilution) have a limited impact on the levels of ETS pollutants in the hospitality industry and other indoor environments.<sup>75</sup> In addition, studies conducted in controlled environments, such as the EU INDOORTRON 'environmental chamber' found that increasing the air exchange rate would not lead to a meaningful improvement of indoor air quality.<sup>76</sup> While displacement ventilation has been reported to be more effective in some recent case-studies funded by the tobacco industry<sup>77</sup>, complete elimination of tobacco smoke using ventilation is not possible.<sup>78</sup>

The **first Conference of the Parties** to the Framework Convention for Tobacco Control has (unanimously) agreed that "there is conclusive evidence that engineering approaches do not protect against exposure to tobacco smoke."<sup>79</sup> Likewise, the American Society of Heating, Refrigerating, and Air Conditioning Engineers (**ASHRAE**) – an international standard-setting body for indoor air quality and ventilation – adopted a position document in 2005 on approaches to controlling second-hand smoke, which concluded that the only effective way of eliminating health risks associated with ETS exposure is to ban smoking in indoor environments.<sup>80</sup>

Physical separation of smokers and non-smokers in the form of an **enclosed smoking room** can increase the effectiveness of ventilation systems in the non-smoking section of the premises.<sup>81</sup> However, this approach does not protect the occupants of the smoking room and the staff (e.g. waiters or cleaners) that must enter the room as part of their job.

A further concern relating to smoking rooms is the significant **financial cost**, which could create an uneven playing field for the smaller operators<sup>82</sup> In addition, the operating and maintenance of ventilated smoking rooms require an extensive **inspection and monitoring** infrastructure. Evidence shows that, where ventilation systems are used, they often fail to meet the standards set by the law.<sup>83</sup>

If ventilated smoking rooms were to be considered as a viable option for the exempted venues, they would have to fulfil the following requirements:

- be completely enclosed and isolated from non-smoking areas,
- be equipped with a separate ventilation system from non-smoking areas,
- have negative air pressure to prevent the diffusion of tobacco smoke into other areas,
- no activity other than smoking should be allowed there in order to minimise the need for employees to perform work-related activities in those areas.<sup>84</sup>

In Malta, Italy and Sweden, which allow for the creation of separately ventilated smoking rooms, most of the operators have chosen not to make use of this option.

# V. POLICY OPTIONS

Several **different policy options** are available to achieve the smoke-free objectives. The aim should be to find an option that best achieves the objectives while minimising costs and burdens. The regulatory options described below are listed in an order reflecting an increasing level of possible EU intervention (from continuing the current level of activity to developing a new binding framework based on EU legislation).

These policy options are **not mutually exclusive** and might complement each other. For example, a Commission recommendation could be an incentive for selfregulatory initiatives among stakeholders and Member States. Self-regulatory instruments, on the other hand, could serve as groundwork and/or supplement to binding legal regime (e.g. covering the venues where the legislation is not yet in force or those exempted from the smoking ban).

It should be noted that the scope of the various policy instruments would differ. Thus, while EU worker protection legislation would apply to public places in so far as they are workplaces given the limits provided by the Treaty, a comprehensive ban on smoking in all public places could be encouraged through non binding measures (such as Commission or Council Recommendation), legislative measures adopted by Member States and/or by voluntary measures adopted by stakeholders.

In order to be effective, any regulatory instrument should also be equipped with a viable means of **enforcement** and a transparent **monitoring** regime. The introduction of regulatory measures, either at EU or at national/sub-national level, should also be accompanied by prior **public consultation and information campaigns** as well as an **impact assessment**.

### 1. NO CHANGE FROM THE STATUS QUO

This option would mean no new activity on the part of the EU, while **continuing the current work** on second-hand smoke under the different Community programmes (Public health, Research, Employment). Regulatory developments in this area would be left to the Member States and the FCTC process.

The resources saved from developing and implementing any new policy initiative could be used to ensure proper enforcement of existing EU recommendations and occupational health and safety directives. In particular, guidance for employers, employees and Member States' competent authorities could be developed in order to ensure a better application of the Framework Directive (89/391/EEC) which – while not explicitly referring to ETS - already covers all risks to workers' health and safety, including tobacco smoke.

Efforts could also be devoted to promoting smoke-free environments through means other than legislation, such as information and education campaigns, networking initiatives etc. The current anti-tobacco "HELP" campaign will run until 2008 and might be followed by another awareness raising initiative thereafter.

In addition, work on indoor air quality, including ETS, will continue as a follow-up to Action 12 of the Environment and Health Action Plan. The necessary resources for the various projects in this area will come the from the Life+ multi-annual strategic programme 2007-2010<sup>85</sup>, the Seventh Framework Programme of the European Community for research<sup>86</sup> and the Public Health Programme<sup>87</sup>.

Member States would retain the right to decide whether and how to introduce smokefree measures depending on national circumstances and cultural differences. The trend towards smoke-free environments would most probably continue, reinforced by the drafting and publication of the FCTC guidelines. A number of national governments, including those of Denmark, Germany, Latvia, Portugal and Slovenia, have already announced their intentions to strengthen national smoke-free regulations in the near future. However, of all the options this one could be expected to be the least effective in reducing ETS exposure and related harm. The progress in different Member States is likely to be patchy. As a result of incomplete regulations, many vulnerable groups would remain exposed to ETS in indoor environments under public jurisdiction. This could present the risk of litigation by citizens for damage to their health caused by passive smoking.

Given the widespread expectations for EU smoke-free initiative, there would be a risk of disappointing the public. Continuing with the status quo would also be a lost opportunity to build on the current political momentum towards smoke-free areas in the EU.

#### 2. VOLUNTARY MEASURES

This option would consist in encouraging stakeholders to adopt common voluntary guidelines at European level to make more places smoke-free. Sectoral approaches (e.g. in the leisure and catering industry) could be promoted. Corporate social responsibility could be used as a basis for development in this area.

In order to facilitate discussions, a wide platform process could be set up, bringing together the civil society and economic operators as well as the representatives of EU Institutions, Member States and international organisations. Such platform has been established last year in the area of diet and physical activity. A similar process has recently been proposed for the development of an EU-wide strategy on alcohol.

Another option would be to encourage the European social partners (employers and trade union organisations) to negotiate an autonomous agreement on workplace smoking based on Article 138 of the Treaty. Self-regulation through European social dialogue has resulted in a variety of outcomes, including the adoption of over 300 joint texts by the European social partners.

Ideally, self-regulation might be quicker and more flexible than traditional legislative channels, and provide for the sectors and businesses concerned an opportunity to have more direct influence on the policies adopted. It also has the potential to create a sense of responsibility and ownership among stakeholders. However, the progress achieved depends on the stakeholders' willingness to comply with the agreed commitment and the effectiveness of enforcement mechanisms. Evidence from the Member States suggests, unfortunately, that voluntary agreements have not been effective in the area of tobacco control. Specifically in the leisure and hospitality sector, voluntary measures have not met the key target of significantly reducing ETS exposure.

For instance, in the UK, after five years of a voluntary agreement between the Department of Health and the key hospitality associations, fewer than 1% of bars were found to be smoke-free.88 In Spain, the 2006 legislation gave bars and restaurants below 100 m<sup>2</sup> the option to become smoke-free on a voluntary basis. The early evidence suggests that only around 10% of eligible establishments have decided to do so.89 In Paris a voluntary scheme aimed at encouraging city's 12,452 cafes, bistros and brasseries to declare themselves smoke-free zones had been adopted by barely 30 establishments<sup>90</sup>.

# **3. OPEN METHOD OF COORDINATION**

This option would involve coordinating Member States' efforts on smoke-free environments using the so-called "open method of co-ordination". Member States would thus be encouraged to make their smoke-free laws more convergent without there being a need for direct harmonisation (although this would remain a possibility).

This could include the following elements:

Sharing experiences and **best practices** of establishing effective smoke-free policies at national, sub-national and local level,

- Agreeing common EU targets and guidelines based on successful experiences both within Member States and outside the EU. These could be accompanied by relevant deadlines, together with the conditions for monitoring and enforcement,
- Translating these guidelines into national action plans to reduce ETS exposure with specific timetables for achieving the goals in the short, medium and long terms,
- Periodic monitoring, evaluation and peer review, for example in the form of annual reports from the Member States.

A number of jurisdictions have already gone smoke-free and a number of others have declared their intention to do so. Member States also face common challenges, such as opposition from industry, public scepticism, and non-compliance with existing requirements. EU coordination might be instrumental in bringing about a process of mutual learning and sharing of best practices between Member States.

However, the commitment to smoke-free objectives would remain voluntary and there would be no sanctions for non-compliance with the agreed targets. The effectiveness of the scheme would depend on the strength of multilateral surveillance and peer pressure.

#### 4. COMMISSION OR COUNCIL RECOMMENDATION

This option would consist in encouraging Member States to adopt national smokefree legislation steered by a comprehensive Commission or Council Recommendation on smoke-free environments based on Article 152 EC, which would set out suggested courses of action. It could be used independently or as part of the self-regulatory schemes among Member States (option 3) and/or industry (option 2).

While it would not have binding force, such a recommendation would be a clear statement on the part of the Commission or Council that action should be taken to eliminate passive smoking in Europe. It would bring the issue onto the political agenda at a high priority level in all EU Member States and thus provide support for Member States' actions.

The effectiveness of this option would depend to a large degree on the clarity of EU guidelines and the reporting requirements. Clear targets accompanied by specific timelines and indicators (e.g. a recommendation that a specific percentage of workplaces be made smoke-free by a given year and sector) would certainly have a greater impact than recommendations of a more general nature. Likewise, the requirement to implement a monitoring regime and make the results publicly available would create public pressure for stronger enforcement and the development of more stringent policy.

While this option would offer flexibility to Member States, the main risk would be that some Member States might chose not to act at all.

#### 5. **BINDING LEGISLATION**

A Community action in this field could include the adoption of binding legislative measures. Binding legislation would impose a comparable, transparent and enforceable basic level of protection from the risk of ETS exposure throughout the Member States.

On the one hand a legislative process ensures formal consultations and thorough negotiations involving all parties, which can make the resulting policy more robust. On the other hand, the legislative route is likely to be relatively lengthy and the end result could be difficult to predict.

The exact legal basis of the legislation could only be determined once the exact nature and scope of the instrument will be defined and this choice will have to take into account the results of this public consultation.

A few options can already at this stage be mentioned, without prejudice to the outcome of the public consultation.

- Revision of the existing directives based on the Framework Directive on workplace safety and health 89/391/EEC. This option could include, in particular, extending the scope of the Carcinogens and Mutagens Directive 2004/37 (to cover ETS) and/or strengthening the requirements for the protection of workers from tobacco smoke in Directive 89/654/EEC on minimum health and safety requirements.
- Another option would be to enact a separate directive on workplace smoking.
- Although not directly related to the protection form second-hand smoke, a possible option to consider would be the amendment of Dangerous Substances Directive (67/548/EEC)91 to classify ETS as a carcinogen. This would automatically bring ETS under the scope of the Carcinogens and Mutagens Directive.

The first two options would be restricted in scope to workplace environment. They could apply either to all workplaces or to certain categories of workplaces and would have to ensure that workers who are exposed to dangerous levels of ETS are adequately covered.

Finally the adoption of a legislative instrument within the remits of the Treaty would not preclude the Community to adopt flanking measures whose nature would be non binding and that could contribute to ensure the overall aim of protection from ETS across all sectors.

# VI. CONCLUDING REMARKS

Taking into account the unequivocal scientific evidence of the harm caused by second-hand smoke and the impact of clean indoor air policies on the overall reduction in tobacco use, the Commission considers that the policy of the widest scope would bring the biggest benefit to the public health of the population. It would also create a level playing field for all operators. Several successful examples of comprehensive smoke-free policy now in force around the world have proved that this option is viable and enforceable,

The desirable level of EU involvement in promoting smoke-free legislation is an open question, and is also linked to the current evolutions in Member States, some of them having recently decided to take action to ban smoking in public spaces.

The Commission calls on all the EU institutions, the Member States and all interested citizens, parties and organisations to submit responses to the issues raised in this Green Paper. The Commission is particularly interested in stakeholders' views on the following questions:

# Questions

- (1) Which of the two approaches suggested in Section IV would be more desirable in terms of its scope for smoke-free initiative: a total ban on smoking in all enclosed public spaces and workplaces or a ban with exemptions granted to selected categories of venues? Please indicate the reason(s) for your choice.
- (2) Which of the policy options described in Section V would be the most desirable and appropriate for promoting smoke-free environments? What form of EU intervention do you consider necessary to achieve the smoke-free objectives?
- (3) Are there any further quantitative or qualitative data on the health, social or economic impact of smoke-free policies which should be taken into account?
- (4) Do you have any other comments or suggestions on the Green Paper?

The replies to these questions should be sent by 1 May 2007, to the following address (preferably by e-mail):

European Commission

Directorate-General Health and Consumer Protection

Unit C6 – Health Measures

E-mail: sanco-smoke-free-consultation@ec.europa.eu

Postal address: B-1040 Brussels

Fax: (+32) 2 298 42 04

All responses to this Green Paper will be published on the Commission's website unless respondents make a declaration to the contrary.

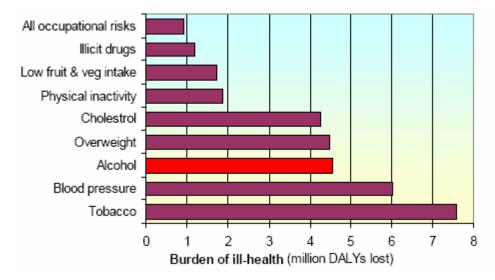
# VII. ANNEXES

Annex 1. Cost effectiveness of various tobacco-control measures in European Region A					
Interventions: Codes_and Descriptions	Cost per year (I\$, millions) per one million_population [i.e. cost per capita]	DALYs** averted per year per one million population	Average Cost per DALY averted		
TOB-2: Excise tax on tobacco products: 80% of supply price (global average)	0,22	1 939	111		
TOB-3: Excise tax on tobacco products: 300% of supply price (highest regional rate)	0,22	4 641	46		
TOB-4: Excise tax on tobacco products: 600% of supply price (double the highest regional rate)	0,22	6 723	32		
TOB-5: Clean indoor air law enforcement	0,67	742	908		
TOB-6: Comprehensive ban on tobacco advertising	0,27	561	473		
TOB-7: Information dissemination	0,55	670	816		
TOB-8: Nicotine replacement therapy	2,35	670	3 511		
TOB-9: Combination (TOB4 + TOB7)	0,76	7 093	107		
TOB-10: Combination (TOB4 + TOB5 + TOB7)	1,43	7 467	192		
TOB-11: Combination (TOB4 + TOB6 + TOB7)	1,03	7 372	139		
TOB-12: Combination (TOB4 + TOB6)	0,48	7 032	68		
TOB-13: Combination (TOB4 + TOB5 + TOB6)	1,15	7 415	156		
TOB-14: Combination (TOB4 + TOB5 + TOB6 + TOB7)	1,70	7 725	220		
TOB-15: Combination (ALL)	4,05	7 981	508		

#### Source:

WHO-CHOICE webpage: http://www.who.int/choice/results/tob\_eura/en/index.html

- \* **European Region A**: Andorra, Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Slovenia, Spain, Sweden, Switzerland
- \*\* **DALYs** = Disability Adjusted Life Years (the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

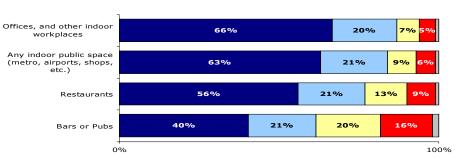


# Annex II: Global burden of ill-health

Source: WHO's Global Burden of Disease Study 2004

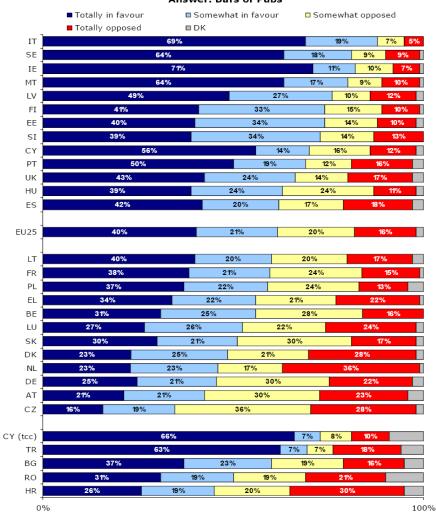
### Annex III: Support for smoke-free policies

#### Q8. Are you in favour of smoking bans in the following places? (EU25)



■ Totally in favour ■ Somewhat in favour ■ Somewhat opposed ■ Totally opposed ■ DK

#### Q8.2 Are you in favour of smoking bans in the following places? Answer: Bars or Pubs



#### Source:

"Attitudes of Europeans towards tobacco", Special Eurobarometer 239, January 2006, http://ec.europa.eu/health/ph\_information/documents/ebs\_239\_en.pdf

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