EUROPEAN PARLIAMENT

DG INTERNAL POLICIES OF THE UNION

Policy Department: Economic and Scientific Policy

WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

(IP/A/ENVI/OF/2005-197)

Briefing Note

IP/A/ENVI/NT/2006-16 **PE 373.575**

This study was requested by the European Parliament's Committee on the Environment, Public Health and Food Safety.

Only published in English.

Author: Dr Frederic C. Daoud, MSc, Epidemologist
Medalliance
75, rue de Lourmel
F-75015 PARIS

Administrator: Mr Marcelo Sosa-Iudissa
Policy Department Economy and Science
DG Internal Policies
European Parliament
Rue Wiertz 60 - ATR 00K066
B-1047 Brussels
Tel: +32 (0)2 284 17 76
Fax: +32(0)2 284 69 29
E-mail: marcelo.sosa@europarl.europa.eu

Manuscript completed in January 2006.

The opinions expressed in this document do not necessarily represent the official position of the European Parliament.

Reproduction and translation for non-commercial purposes are authorised provided the source is acknowledged and the publisher is given prior notice and receives a copy. E-mail: poldep-esc@europarl.europa.eu.

EXECUTIVE SUMMARY

Compelling scientific evidence shows that tobacco consumption causes many severe diseases and death. The increased risk of lung cancer, other cancers and cardiovascular diseases is well documented. Pregnant women who smoke have a significantly higher risk of miscarriage and child disease. Exposure of non-smokers to other persons' environmental tobacco smoke (ETS) also results in an increased risk of diseases. Regarding ETS, although compelling epidemiological data has been gathered for lung cancer only, animal tests show that exposure increases the risk of other diseases as well.
In Europe, tobacco causes over 1.5 million deaths annually.

All Member States of the European Union (EU) are aware of this devastating problem and willing to reduce the harm, although the level of political commitment and ability to implement necessary reforms varies across Member States.

The EU has already adopted a number of legally-binding and non-legally binding measures for tobacco control, and individual Member States have undertaken measures beyond EU requirements. Ireland, Italy and Spain have banned smoking in all public places.

EU Member States have committed to implementing the WHO Framework Convention on Tobacco Control (FCTC) and its comprehensive approach to tobacco control. They now need to adopt further legally binding-measures to adhere to their commitment. Measures aim a reduction of tobacco product supply and of demand. These include:

- Control production, testing, sales, taxation and pricing of tobacco products
- Control of illicit tobacco trade
- Restriction on tobacco publicity and sponsoring
- Public information policies about the health risks of tobacco
- Programmes to facilitate tobacco consumption cessation, including medical care
- Cooperation between countries with communication of critical information and technology transfer to facilitate the implement all above measures globally.

The implementation of these measures by EU Member States involves political, legal and practical difficulties, but the human and financial benefit for European Nations is anticipated to be greater than the effort and cost.

CONTENTS

1. Background **1**
1.1. Consequences of tobacco consumption on public health 1
1.2. Current tobacco consumption summary 9

2. Milestones in WHO European tobacco control **10**

3. Challenges for the European Union **12**
3.1. EU coordination challenges 12
3.2. Challenges related to FCTC objectives 14

4. Conclusion **21**

APPENDICES **22**

REFERENCES **26**

1. Background

1.1. Consequences of tobacco consumption on public health

Tobacco and tobacco smoke contain thousands of chemicals, including nicotine, tar, carbon monoxide, acetaldehyde, hydrogen cyanides, arsenic, chromium, DDT, formaldehyde, benzene, N-nitrosamines, cadmium, nickel, beryllium and vinyl chloride. Many of these chemicals are well known to be toxic, carcinogenic, atherogenic, teratogenic and addictive; many have no known safe level of exposure. Nicotine is a highly toxic alkaloid that is both a ganglionic stimulant and depressant and Carbon monoxide is known to interfere with oxygen transport and utilization ([1]). Nicotine is the drug in tobacco that causes addiction; and it is also a psychoactive (mood altering) drug ([2]).

1.1.1. Consequences of direct tobacco consumption

Compelling scientific evidence has demonstrated that direct tobacco consumption is a high risk factor for the development of various diseases (*morbidity*), which in some cases, can lead to premature death (*mortality, reduced life expectancy*). It increases the risk of disorders in normal functions such as fertility, childbearing and lactation.

Direct transmission of tobacco by-products by mothers who smoke to foetus through umbilical circulation and to neonates through breast milk has been demonstrated.

The Facts 1 table provides a non-exhaustive list of the health effects of tobacco smoking, most of which can be reduced by tobacco consumption cessation.

Facts 1 : Effects of tobacco consumption and cessation

Disease – Function	Effect
Lung cancer	Increased risk (20 to 30 fold) with smoking. 80 to 90% of cases are smokers. The risk of lung cancer declines steadily in people who stop smoking, until, after 10 years, the risk becomes 30%–50% of that in continuing smokers.
Cancers of the oral cavity, larynx, pharynx, urinary bladder, pancreas, oesophagus, stomach, kidney, skin (squamous cell carcinoma), nasal sinuses, blood, uterine cervix, ovaries	Increased risk with smoking. Smoking cessation reduces the risk of many tobacco-related malignancies, including cancers of the larynx, oesophagus, pancreas and urinary bladder.
Breast cancer	Increased risk with smoking. Increased risk of lung metastasis.
Respiratory diseases (chronic bronchitis, emphysema, reduced lung capacity, asthma)	Increased risk with smoking. 80% of emphysema.
High blood pressure	Increased risk with smoking.
Coronary heart disease, heart attacks	Increased risk with smoking (3-fold in men, 6-fold in women). Smoking cessation cuts the risk of recurrence of heart attack by almost 2.
Congestive heart failure	Increased risk with smoking.
Abdominal aortic artery aneurysm	Increased risk with smoking. 80 to 90% of cases are smokers.
Carotid disease and stroke	Increased risk with smoking.
Lower limb artery disease, disability, gangrene, amputation.	Increased risk with smoking.
Osteoporosis, vertebral injury and fractures	Increased risk with smoking. First line preventive measure against further bone loss and progression.
Peptic ulcer & gastro-oesophageal reflux disease	Increased risk with smoking.
Male fertility	Decreased sperm count, increased frequency of abnormal sperm morphology, and an inferior quality of sperm. Delayed conception and reduced fertility rates. Impotence: Smokers are one and a half times more likely to suffer erectile dysfunction than non-smokers.
Female fertility & pregnancy disorders	With smoking: Decreased fertility ([3]) and shortened time to menopause by 1 to 2 years. Increased spontaneous abortion rate of chromosomally normal foetuses, increases the incidence of placental abruption, placenta *praevia*, bleeding during pregnancy, premature rupture of the membranes and stillbirths. All these risks to fertility and the outcome of pregnancy are minimized or absent in former smokers.
Smoking and oral contraception in women	Significant increase in risk of cardiovascular diseases

Disease – Function	Effect
Impact of smoking or exposure to Environmental Tobacco Smoke during: - pregnancy - breast feeding - childhood	Increased risk of : Spontaneous abortion, prematurity, placental abruption intrauterine growth retardation ([4]), premature delivery and low birth weights (35,[5]) and growth ([6],[7]). Perinatal mortality (up to 1.5 times the average), sudden infant death syndrome ([8],[9]). Reduced quality and frequency of breast feeding. Increased risk of congenital malformation (cleft lip/palate, clubfoot, limb defects, bronchial tree and pulmonary vasculature). Increased risk of eczema, asthma, respiratory disorders & infections, asthma ([10],[11],[12],[13],[14],[15],[16]), ears-nose-throat (ENT) infections ([17],[18]). Cancer & leukaemia*. Poor growth ([19],[20],[21]). Neurodevelopmental handicaps ([22]).

* On the issue of childhood neoplasms, the pooled estimate of the relative risk of any childhood neoplasm from exposure to maternal smoking is 1.11 (95% confidence interval = 1.00-1.23, based on 11 studies), and that for leukaemia is 1.14 (95% confidence interval = 0.97-1.33, based on 8 studies) ([23]). There is suggestive evidence that parental smoking may increase the risk of some childhood cancers. However, the potential roles of preconceptional, *in utero*, and postnatal exposures are unknown.

1.1.2. Consequences of Environmental Tobacco Smoke exposure

Environmental Tobacco Smoke exposure (ETS) is generated by the combustion of tobacco products. It is composed of over 4000 compounds, including more than 40 known or suspected human carcinogens, such as 4-aminobiphenyl, 2-naphthylamine, benzene, nickel, and a variety of polycyclic aromatic hydrocarbons (PAHs) and N-nitrosamines. A number of irritants, such as ammonia, nitrogen oxides, sulfur dioxide and various aldehydes, and cardiovascular toxicants, such as carbon monoxide, nicotine and some PAHs, are also present. *In vitro* and animal *in vivo* ETS exposure tests have demonstrated:

- carcinogenic effect (52,[24],[25])
- mutagenic effect ([26],24,[27],[28],[29])
- cardiovascular effects and include promotion of atherosclerosis (in response to smoke exposure and individual PAH exposure), activation of platelets and leukocytes, exacerbation of ischaemia/reperfusion injury, and reduction of respiration by myocardial mitochondria ([30],[31],[32],[33],[34],[35],[36],[37],[38],[39],[40],[41]).

The risk in humans for some diseases in relation to exposure ETS has also been documented through epidemiological studies.

Lung cancer: Compelling epidemiological evidence shows that exposure to ETS is a risk factor for the development of lung cancer in individuals who live with smokers and who do not live with smokers (excess risk: 13 to 38%) ([42]).

Other malignancies: A review of epidemiological studies concerning ETS exposure-related risk for cancer in adults, concluded that there was suggestive evidence of an association with sinonasal cancer, no evidence of an association with bladder cancer, and equivocal evidence of associations with breast and cervical cancer ([43],[44],[45],[46],[47],[48],[49]).

Non-cancer respiratory diseases in children: At least 150 epidemiological studies on ETS and non-cancer respiratory health effects in children have been published in the last 25 years. Several reviews have already assessed the database, and there is strong consensus that ETS affects the developing respiratory system and causes an increased risk of the following health effects ([50],[51],[52],[53]):

- lower respiratory tract infections (e.g. bronchitis, bronchiolitis and pneumonia) in infants and young children;
- chronic middle-ear effusion in young children;
- increased frequency and severity of asthma attacks in asthmatic children;
- irritation of the upper respiratory tract; and
- reduced lung function.

Cardiovascular diseases: Many epidemiological studies on ETS and cardiovascular risks in adults have been published suggesting increased risk, but the level of evidence of most individual studies has been criticized, due to the possibility of confounding factors, exposure misclassification, publication bias, insufficient data or other methodological issues ([54]). However, a meta-analysis of 19 epidemiological studies of lifelong non-smokers living with a smoker reported a relative risk of ischaemic heart disease associated with exposure to ETS of 1.30 (95% confidence interval: 1.22–1.38) at 65 years of age. Detailed analyses indicated that dietary confounding could account for an excess risk of 6%, revising the excess risk due to ETS from 30% to 23% ([55]).

Quantification of exposure to ETS: The quantification of exposure to ETS is an important step in the quantification of risks for populations. The extent exposure to ETS in non-smokers can be estimated through nicotine and cotinine levels in the body. Cotinine is the major metabolite of nicotine, it is specific to tobacco and is a widely used short-term marker of exposure because of its relatively long half-life (about 20 hours), narrower fluctuations during exposure to tobacco smoke and convenient measurement in blood, urine and saliva ([56],[57]). Many population-based studies have demonstrated the association of cotinine levels in saliva, serum and urine with reported exposure to ETS ([58],[59],[60]). Cotinine measurements can provide an assessment of recent exposure to ETS, but they do not indicate the duration of exposure or the intake of other components of tobacco.

- **Adults:** a 10-country study conducted by the International Agency for Research on Cancer (IARC) collected data for non-smoking women from 13 cities, including 5 in Europe, showed mean urinary cotinine/creatine levels of 6.2 ng/mg for ETS exposure from husband's smoking, 2.4 ng/mg from workplace exposure, 9.0 ng/mg from husband and workplace, and 3.1 ng/mg from public places and other sources ([61],[62]).
- **Children:** Salivary cotinine concentrations measured in over 4 000 children aged 5 to 7 in the UK, have been found to correlate strongly with the smoking habits of their parents: 0.29 ng/mL in children with no reported exposure, 4.05 ng/mL in households where both parents smoked, and 9.03 ng/mL if both parents smoked over 20 cigarettes per day ([63]). It has been estimated from cotinine measurements that the total nicotine dose received by children whose parents are smokers is equivalent to their actively smoking between 60 and 150 cigarettes per year ([64]). Significant levels of cotinine in children from non-smoking households have been found ([65]). This indicates that children are exposed to tobacco smoke from sources other than their parents and that simply inquiring about parental smoking will underestimate a child's exposure. So-called 'unexposed' persons have been found to have on average 8.5 ng of cotinine per mL of urine ([66]). Since the only source of cotinine or nicotine in body fluids is tobacco products, primarily through exposure to smoke, it follows that 'unexposed' persons are also exposed to environmental tobacco smoke.

- ETS has been found to be carcinogenic in humans and to produce a substantial amount of morbidity and mortality from other serious health effects at levels of 1-10 $\mu g/m^3$ nicotine (taken as an indicator of ETS). Acute and chronic respiratory health effects on children have been demonstrated in homes with smokers (nicotine 1-10 $\mu g/m^3$) and even in homes with occasional smoking (0.1-1 $\mu g/m^3$). There is no evidence for a safe exposure level. The unit risk of cancer associated with lifetime ETS exposure in a home where one person smokes is approximately 1×10^{-3}.

Overall conclusion about risks:

Based on the combined evidence from several studies, WHO has estimated that some 9-13% of all cancer cases can be attributed to ETS in a non-smoking population of which 50% are exposed to ETS. The proportion of lower respiratory illness in infants attributed to ETS exposure can be estimated at 15-26%, assuming that 35% of the mothers smoke at home. Those estimates, when applied to the European population, will result in approximately 3000-4500 cases of cancer in adults per year, and between 300 000 and 550 000 episodes of lower respiratory illness in infants per year, which are expected to be related to ETS exposure ([67]).

Quantitative population estimates for cardiovascular disease mortality are less certain than those for lung cancer because (a) fewer epidemiological data are available, and (b) more risk factors for cardiovascular disease need to be included in adjustments in order to obtain a reliable risk estimate. In general, the relative risk estimates for cardiovascular disease from ETS exposure are similar to those for lung cancer; however, the baseline risk of death from cardiovascular disease in non-smokers is at least 10 times higher than the risk of lung cancer. Therefore, the population risks could be roughly 10 times higher as well. Thus, while there is more confidence in the presented estimates for lung cancer, the public health impact of ETS is expected to be substantially greater for cardiovascular disease.

1.1.3. Smoking-attributable annual deaths in Europe

The Facts 2 table summarizes the estimated annual number (and percentage) of deaths attributable to smoking in the 25 countries of the EU ([68]). These estimates make the

conservative assumption that no death is attributable to smoking in the 0-34 year age group, which leads to an underestimation of total smoking-attributable deaths. This table also provides an estimate of the average number of years of life lost per patient.

Facts 2: Smoking-attributed annual deaths - EU 25 - year 2000 estimates

Mortality cause: number of cases (% of cases)	Age 35-69 years	Any Age
All causes	290 000 (25%)	655 000 (15%)
Men	244 000 (31%)	507 000 (23%)
Women	46 000 (11%)	148 000 (7%)
Cancer	144 000 (32%)	285 000 (25%)
Men	124 000 (45%)	239 000 (38%)
Women	20 000 (11%)	46 000 (9%)
Respiratory diseases	25 000 (50%)	112 000 (30%)
Men	19 000 (52%)	78 000 (40%)
Women	6 000 (34%)	34 000 (19%)
Vascular diseases	81 000 (23%)	183 000 (10%)
Men	68 000 (28%)	135 000 (16%)
Women	13 000 (12%)	48 000 (5%)
Average number of years of life lost per patient	22 years	14 years

The Facts 3 table shows the changes in the estimated percentage of deaths attributable to smoking in the 25 countries of the EU in women (68). It shows the increase in deaths attributable to smoking, particularly in women between 35 and 69 years of age.

Facts 3: Smoking-attributed annual deaths - EU 25 – Changes in Women

Mortality cause: number of cases (% of cases and variation)	Age 35-69 years	Any Age
All causes	**+1.2%**	**+0.5%**
Year 1995	45 000 (10.3%)	137 800 (6.1%)
Year 2000	45 600 (11.5%)	147 800 (6.6%)
Cancer	**+1.7%**	**+1.2%**
Year 1995	17 600 (9.3%)	39 800 (8.2%)
Year 2000	20 000 (11.1%)	46 000 (9.3%)
Respiratory diseases	**-0.4%**	**+0.1%**
Year 1995	6 400 (34.5%)	31 900 (19.1%)
Year 2000	6 100 (34.1%)	34 000 (19.2%)
Vascular diseases	**+1.0%**	**+0.2%**
Year 1995	14 600 (11.4%)	49 500 (4.5%)
Year 2000	12 500 (12.4%)	47 800 (4.7%)

It is estimated that approximately 30% of the adult population in the European Region of the World Health Organization (WHO) were regular smokers in 2001 ([69]). This results in a considerable "burden of illness" as defined in terms of number of life-years and healthy life-years lost for society (quantified in epidemiological studies "Disability-Adjusted Life Year" "DALY"). Owing to its longest exposure to tobacco smoking, the European Region of the WHO, with only 15% of the world's population, is facing nearly one third of the worldwide burden of tobacco-related diseases ([70]).
The standardized death rate for lung cancer among males had stabilized or was slightly decreasing in the central and western parts of the Region. The death rate among women was still increasing as they were, in general, exposed to tobacco later than men.

1.6 million deaths were estimated to be tobacco-related annually in 2000 ([71]).

1.2. Current tobacco consumption summary

Smoking prevalence survey compilations published in 2002 by the WHO (69) based on various national sources show:

- Alarming high levels and increase among teenagers over the 1993-1999 period.
- Alarming high levels and increase among adult women during the 1999-2001 period compared to the 1994-1998.
- Overall stagnation at the highest levels in adult men during the 1999-2001 period compared to the 1994-1998. Among them, prevalence decreased in 7 countries, increased in 3 countries and was stable in 15.

Facts 4: Tobacco-consumption - WHO European Region – 1997-2001 Period

Population	Prevalence and trends
Adults	Over the average adult smoking prevalence in countries of the WHO European Region has stabilized at around 30% of the adult population. Smoking prevalence shows signs of a decrease in the western part of the Region, both in males and in females, while in the eastern part it is stable (69).
Men	Nearly 38% smoked. Increasing prevalence gap between east and west: above 50% in at least 11 countries and below 30% in 4 countries.
Women	Nearly 23% smoked, with a slightly narrowing gap between east and west.
Youth	Among young people (15-18 years old): Around 30% for Europe as a whole, with a slight upward trend. No country showed a decrease in smoking prevalence in young people. According to data from the five countries, weekly smoking in 15-year-olds increased from 18% in 1993/1994 to 24% in 1997/1998. Smoking prevalence has increased among both boys by 5% and among girls by 6%. Smoking prevalence among young people aged 16-18 years is approximately 20% higher than among those aged 15-16 years ([72],[73]).
Vulnerable socio-economic groups	Nearly 23% smoked, with a slightly narrowing gap between east and west. Surveys show higher prevalence in lower income groups than in higher income groups, and in unemployed compared to the employed. No indication that the socioeconomic difference in tobacco use was being reduced ([74],[75]).

Given the criticality of these data for international stakeholders to weigh the importance of the problem, individual country prevalence rates of EU member States and the other countries of the WHO European Region are reported **Appendix 2** and Appendix 3.

2. Milestones in WHO European tobacco control

Various medical expert groups and several organizations dealing with public health acknowledged more than two decades ago the "devastating" consequences of tobacco consumption. The WHO, national authorities, "*regional economic integration organizations"* and other stakeholders have therefore developed policies and strategies to tackle this major public health concern: *"tobacco is a toxic and addictive substance and that the tobacco epidemic is one of the greatest public health challenges facing WHO's European Region, which therefore needs a joint response"* ([76]).

In 1987, Europe was the first of WHO regions to take the initiative of launching a regional action plan on tobacco. Since then, the WHO Regional Committee for Europe, individual countries of the European Region and the European Union (EU), have worked on several *"Action Plans"* and increasingly compelling policy protocols.

Facts 5: WHO Milestones

Period	Action plans and policy protocols
1987-1991	*First Action Plan For Tobacco Free Europe* ([77]) **Targets:** National comprehensive and multisectoral approach. Monitoring and evaluation of their anti-tobacco activities. **Outcomes:** Tobacco-control policies adopted/amended in 20 European countries. Tobacco consumption reduction observed in 12 countries only.
1988	First European Conference on Tobacco Policy (Madrid 1988): *Charter for Tobacco-Free Life* specifies 10 detailed strategies.
1992-1996	*Second Action Plan For Tobacco Free Europe* ([78]) **Targets:** 37 actions proposals. National financial commitments and capacity for tobacco control. Development of cooperation/alliances between European countries to support tobacco control policies. Priorities on the promotion of a smoke-free environment, non-smoking behaviour among young people and cessation activities. **Outcomes:** Implementation in most EU member States. Poor implementation in central and eastern Europe as Tobacco companies took advantage of economic and social changes to acquire interests in local tobacco production and increasing advertising.
1997-2001	*Third Action Plan For Tobacco Free Europe* ([79]) **Targets:** Evaluation of outcome of the First and Second Action Plans activities. Implement World Health Assembly resolutions for comprehensive tobacco control policies. Specific national targets to be achieved in the areas of pricing, availability, advertising, control of smuggling, product regulation, smoke-free environments, support for smoking cessation, public education and information, establishment of national action plans, coordinating committees and monitoring mechanisms. Highlight on the role of integrational, intergovernmental and nongovernmental organizations, as well as of the WHO Regional Office for Europe, in

Period	Action plans and policy protocols
	strengthening and coordinating tobacco control policy in the Region. **Outcomes:** At the end of 2001, uneven implementation throughout European countries. About 80% of European countries had bans or restrictions on smoking in public places and workplaces (significant differences in the degree of implementation) and made available common nicotine replacement therapy (*NRT*) products without prescription in pharmacies. NRT products were not made widely affordable. Three quarters of countries had established intersectoral coordinating committees but less than half of them had drawn up national action plans and introduced partial restrictions or bans on both direct and indirect forms of advertising of tobacco products. One third of countries had sustainable and gender-based public information campaigns. Less than one quarter had earmarked tobacco taxes and restricted access to tobacco products for people under 18 years (also eliminating all major impersonal modes of sale). Very few countries reimbursed the cost of treatment of tobacco dependence, published comprehensive national reports on tobacco control, or had introduced health warnings and requirements for tar & nicotine at the levels recommended by the Third Action Plan.
February 2002	*Warsaw Declaration for a Tobacco-free Europe* by the Ministers & Representatives of the States participating in the WHO European Ministerial Conference (76) **Commitment by country representatives:** To adopt a *Fourth Action Plan For Tobacco-Free Europe* (2002-2007) where: - Tobacco control is at the top of public health priorities to protect the health of individuals, with special emphasis on children, young people, women, and persons from vulnerable socioeconomic and minority groups. - Tobacco-consumption is defined as addictive, lethal, and as an epidemic. - Tobacco control involves a combat that takes into account the tactics of tobacco industry, based on comprehensive policies that include: information to individuals about the danger of tobacco, high taxes, bans on tobacco advertising, sponsorship and promotion, protection against involuntary exposure to environmental tobacco smoke in public places and workplaces, access to cessation measures and strict controls on smuggling. - The need to promote and subsidies viable alternative economic activities for those who rely on growing tobacco. To support the *WHO Framework Convention on Tobacco Control (FCTC)* (81): - With WHO European Region & European Union countries are stakeholders To urge for the development of Member States and intergovernmental organizations: - To strengthen European partnership and solidarity for tobacco control with appropriate instruments in all key fields: scientific/technical information, legal, policy, mutual support. To require continued *WHO Regional Director for Europe* for guidance, coordination and facilitation in all relevant areas, including financial.
2002-now	*Fourth Action Plan : European Strategy for Tobacco Control (ESTC)* ([80]) **Targets:** 37 actions proposals. National financial commitments and capacity for

Period	Action plans and policy protocols
	tobacco control. Development of cooperation/alliances between European countries to support tobacco control policies. Priorities on the promotion of a smoke-free environment, non-smoking behaviour among young people and cessation activities. **Outcomes:** Implementation in most EU Member States. Poor implementation in central and eastern Europe as Tobacco companies took advantage of economic and social changes to acquire interests in local tobacco production and increasing advertising.
2003-now	*WHO Framework Convention on Tobacco Control (FCTC)* ([81]) Entered into force on 27 February 2005. Ratified by EU and 20 of 25 Member States (pending on 31 December 2005: CR, CZ, IT, GR, PL) Appendix 4.

3. Challenges for the European Union

The European Community has signed the FCTC (81) as a *"regional economic integration organization"*:

Article 35 "[…] *an organization that is composed of several sovereign states, and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters* […]. *In the case of those organizations, one or more of whose Member States is a Party to the Convention, the organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the Convention. In such cases, the organization and the Member States shall not be entitled to exercise rights under the Convention concurrently."*

3.1. EU coordination challenges

The specific issues faced by the European Union fulfilling its commitment with respect to the FCTC are to agree with Member States on the coordination of the implementation of the various articles of the FCTC.

The legitimacy of this role is confirmed in FCTC Article 2: "[…] *The provisions of the Convention and its protocols shall in no way affect the right of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or additional to the Convention and its protocols, provided that such agreements are compatible with their obligations under the Convention and its protocols*"

There are differences between EU Member States in current efforts applied to curb tobacco consumption and in views on actions that should/can be conducted in order to achieve Tobacco-Free Europe policy.

European Institutions therefore faces strategic challenges related to coordinating the Member States' participation effectively and cost-effectively.

The European Institutions' approach to coordinate Member States' fulfilment of FCTC goals, can be analyzed as six aspects with each a predominant type of difficulty (Table 1).

Table 1 : EU Coordination strategic challenges

Coordination feature	Potential difficulties
Feature 1: Agreement of 25 Member States on a common EU interpretation and concrete objectives of the FCTC articles.	Political & legal (a review of current status necessary)
Feature 2: Modifying legally-binding EU documents in order to clear potential obstacles to implementing the FCTC.	Political, legal, financial, practical
Feature 3: Commitment of 25 Member States to a common basic package of national measures aiming at initiating the implementation of all FCTC articles (demand reduction, supply reduction, protection of environment, liability) within national boundaries. The basic package should cover those aspects of one Member State's tobacco control that are likely to affect tobacco consumption in other Member States (e.g. tobacco exports). Aspects that do not affect other countries (e.g. smoking in bars) may not have their place in such a basic package.	Practical & psychological (i.e. citizen psychology), political, legal
Feature 4: Agreement of the 25 Member States on a program and financial mechanisms to assist each Member State, according to its needs, in achieving the economic transition where tobacco-related economic activities are abandoned, and replacing by viable long-term economic activities.	Financial, practical, political, legal
Feature 5: Definition of a program and budget for the 25 Member States' Scientific and technical cooperation and communication for information (implementation of the cooperation concept of the FCTC).	Few intrinsic challenges expected. Difficulties should arise as they affect Features 3 & 4
Feature 6: Agreement and adherence of the 25 Member States to a common code of conduct with non-EU States: - For a single voice on the international scene as regards FCTC implementation to build EU credit/leadership within WHO strategy. Intended benefit: Self-confidence of Europeans and support from/to non-EU States. - To prevent EU-based tobacco businesses from transferring their activities to non-EU States (especially economically/socially vulnerable countries) for new production sites, as well as local markets.	Political, financial and practical

3.2. Challenges related to FCTC objectives

The list of potential challenges related to achieving specific FCTC objectives is long. Table 2 is a non-exhaustive approach to those challenges. It compares and discusses:

- FCTC objectives that are likely to be critical for the EU's tobacco-free strategy,
- Features of current EU legally binding documents that have an impact on EU's tobacco-free strategy,
- Difficulties that might be met and possible aspects of implementation. Loopholes and individual-related issues are considered.

Table 2 : Challenges related to specific FCTC objectives

FCTC	EU legally-binding texts	Potential difficulties & aspects of implementation
Tobacco products - tobacco content - Cooperation Article 1: *"[…] means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing"* Article 9: *"[…] guidelines for testing and measuring the contents and emissions of tobacco"* Article 22: *"[…] Cooperation in the scientific, technical, and legal fields and provision of related expertise"*	The definition in Directive 2003/33/EC ([82]), Article 2 (c) covers all aspects of this FCTC definition. Directive 2001/37/EC ([83]) addresses some aspects intended to be covered by FCTC Article 9.	The European institutions will play a central role in achieving these objectives as it involves a trans-European "investing in people" programme. Significantly technical knowledge and know-how will need to be developed throughout Member States with the support of appropriate regulations. This aspect of the FCTC will raise mainly practical difficulties. Particular scientific attention will be required to analyse methods used to enhance addictive features of tobacco products, and use this knowledge to develop tobaccological know-how. This will require international scientific cooperation and training of health care/social/educational workers. Cooperation with non-EU Member States will be necessary to help curb imports but also to protect vulnerable countries from dumping by European-owned tobacco industries seeking new markets and production sites.
Tobacco control Article 1*: "[…] means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke"*	No legally-binding approach to this definition in Council Recommendation 2003/54/EC ([84]) but legally binding definition.	Such a comprehensive definition involves two critical concepts - Elimination of tobacco consumption or exposure - Demand and harm reduction strategy The development of such definition will raise mainly legal and political issues.

Tobacco advertising and promotion – Packaging and Labelling Article 1: *"[…] means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly"* Proposed in measures in Article 10, Article 12 Article 13.	These FCTC objectives are relatively well addressed by Directive 2003/33/EC (82) Among the various discrepancies found: the definition in Directive article 2 (b) does not include two words *"recommendation or action"*	The main issues concern the practical implementation by all 25 Member States. Discrepancies such as those in the definition are a source of loopholes: - Publicity by smokers themselves (user-mediated publicity, e.g. in schools, bars) - Publicity though art (esp. movies, television series) where smoking is associated to independence, glamour, strength, glorious during. European institutions' main issues are to ensure compliance by all 25 Member States with Directive 2003/33/EC on the long run. Indeed, the risk of short-term-only implementation of the directive is the greatest risk.
Sponsorship Article 1: *"[…] means any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly"* Proposed in measures in Article 13.	FCTC objectives fairly well addressed by Directive 2003/33/EC (82)	Similar comments as those for advertising and promotion. Sponsorship can be the most difficult to detect form of pressure due to its potentially confidential aspect thus involving penal responsibility with respect to illegal financial transactions. Permanent repression and penalties against indirect or concealed sponsorship requires the highest level of commitment by individuals who hold government, elected and private managerial responsibilities.

Illicit trade Article 1: *"[…] means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity"* Article 15*: "[…] elimination of all forms of illicit trade in tobacco products, including smuggling […] manufacturing and counterfeiting* *[…] implement legislative, executive, administrative or other measures […] (to) determining the point of diversion […] control the movement of tobacco* *[…] require that […] tobacco products for retail and wholesale […] carry the statement: "Sales only allowed in (insert name of the country, subnational, regional or federal unit)" or carry any other effective marking indicating the final destination* *[…] developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit* *[…] collect data on cross-border trade in tobacco products, including illicit trade, and exchange information among customs, tax and other authorities"*	A common definition of "illicit trade" applicable to tobacco throughout the EU has not been identified in the preparation of this review. Reviewed EU legally-binding texts do not enable the implementation of many of FCTC requirements of article 15	The adoption by EU Member States of: - Harmonized and matched definitions of illicit exports and illicit imports, - Measures to implement the requirements of FCTC article 15, including traceability of tobacco products and communication of information for smuggling and illegal trade repression is necessary to leverage current efforts by individual Member States. Political, legal and practical issues. The implementation of FCTC requirements against illicit trade involves the coordination and further development of existing legally binding and non-binding EU texts including Directive 2001/37/EC (83) and Directive 2003/33/EC (82). Political, diplomatic and financial efforts will need to be deployed to promote the willingness of non-EU economically vulnerable States to participate in this effort.

Strong political commitment Article 4	Obviously present at EU level.	Initial and permanent commitment of a wide range of individuals at government/elected positions is essential. To ensure complete independence of the individuals who hold positions *vis-à-vis* tobacco businesses would require a total prohibition of any form of incentive, donation or sponsorship proposed by tobacco businesses (or intermediaries), as it is the case with narcotic dealers. This involves intense and permanent political pressure.
Comprehensive multisectoral strategies Article 5: *"Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes* *[…] measures and responses to reduce consumption of all tobacco products at the national, regional and international levels"*	Current range of texts: -Directive 2001/37/EC (83) -Directive 2003/33/EC (82) -Decision 2003/641/EC ([85]) -Regulation No 546/2002 ([86]) -Recommendation 2003/54/EC (86) -Regulation No 1648/2000 ([87])	Further EU developments for tobacco control need to place particular emphasis coordination mechanisms to: - Leverage the various legally-binding and non-binding actions related undertaken until now. - But also to ensure that all aspects of FCTC strategy are addressed in an effectiveness and cost-effectiveness manner.
Liability Article 19: *"Parties shall […] consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate* *[…] cooperate […] in exchanging information […] on the health effects of the consumption of tobacco products and exposure […] and […] on legislation and regulations in force as well as pertinent jurisprudence* *[…] afford one another assistance in legal proceedings relating to civil and criminal liability consistent with this Convention"*	This aspect has not been a covered by EU legally-binding texts until now.	This topic is delicate considering the penal consequences for many individuals and the considerable amount of claims. Public perception and legal difficulties need to be surmounted for a fair liability recognition program to be established. Among these, the need to clear fallacious perception of public benefit through tax revenue: - Information about national burden due to medical costs, productive life-years lost, and to social damage caused by tobacco consumption, compared to tax earnings. - Legal definition of taxes on tobacco to fund the consequences, prevent consumption and enable the economic conversion of households with tobacco-related revenues.

Price and tax measures Article 6: *"The Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young person* *[…] implementing tax policies […], price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption; and... prohibiting or restricting … sales to and/or importations by international travellers of tax- and duty-free tobacco products.* *[…] provide rates of taxation for tobacco products and trends in tobacco consumption in their periodic reports to the Conference of the Parties, in accordance with Article 21."*	European institutions made several attempts to use taxation as a means of reducing tobacco consumption and converting tobacco production farms to other activities. The failure of measures in the past decade led to adoption of Council Regulation No 546/2002 (86).	The development of a harmonized tax and pricing throughout the EU is key for the sustainable achievement of FCTC implementation. Key difficulties are: - For EU Member States that are net tobacco producers/exporters to collaborate with net importers on tobacco-free economic growth based on business diversification. - To curb legal tobacco imports from non-EU States. - To coordinate price and tax measures with anti-smuggling measures. Such measures will have an impact on the long run maintaining confidence and credit on the long run requires a reduction in demand for tobacco products.
Protection from exposure to tobacco smoke Article 8: *"[…] adoption and implementation of 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."*	Although no EU legally-binding document with these requirements have been published until now, several individual EU Member States (e.g. Ireland, Italy, Spain) have adopted such measures.	This measure is of significant value as it provides protection the majority of the population, who is non-smoker. It also has a direct restrictive impact on smokers. The development of harmonized EU legally-binding texts for that implement this FCTC requirement is unavoidable. The social diversity of EU Member States that have adopted these measures is an indicator of feasibility.

Public awareness & Demand reduction Article 12: *"[…] educational and public awareness programmes on the health risk"* Article 14: *"[…] promoting the cessation of tobacco use, in educational […], health care […], workplaces […] diagnosis […] treatment of […] dependence […] with […] health […] and social workers […] facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products."*	Although no EU legally-binding document with these requirements have been published until now, several individual EU Member States (e.g. Ireland, Italy, Spain) have adopted such measures.	Relay actions in the population, that involve direct consumer/potential consumer contact are essential for the "shock" of press and broadcast communication campaigns to have an effect on individual demand for tobacco products. The key features that need to be dealt with by direct contact actions are: - To greatly increase the level of tobaccological knowledge and know-how, material resources, motivation/incentive among Health care professionals'/educators'/social workers'. - To develop the credibility among tobacco consumers of tobaccological competence. - To offer solutions to the personal reasons for which individuals smoke despite the knowledge of risks, such as the need for relaxation, the image they wish to project (self-assurance, independence, glamour, etc.), or the fear to put on weight after cessation. - To maintain the highest level of mutual confidence and respect between smokers, non-smokers, tobaccology professionals and Authorities, to prevent crisis around tobacco control and cessation. These various actions will require mostly practical and financial efforts. The guidance of European institutions is key in this respect.

4. Conclusion

Populations of the European Union are badly harmed by tobacco. All Member States of the EU are aware of this devastating problem and are willing to reduce the harm, although there are variations between Member States in their level of political commitment and ability to implement the necessary reforms.

The EU has already adopted a number of legally-binding and non-legally binding measures for tobacco control, and individual Member States have undertaken measures beyond EU requirements.

EU Member States have committed to implementing the WHO Framework Convention on Tobacco Control (FCTC) and its comprehensive approach to tobacco control. They now need to adopt further legally binding-measures to adhere to their commitment. This involves political, legal and practical difficulties, but the human and financial benefit for European Nations is anticipated to be greater than the effort and cost.

Appendices

Appendix 1: Terminology

Term	Definition
DALY	Disability Adjusted Life Year.
EC	European Communities
EU	European Union
FCTC	Framework Convention on Tobacco Control
WHO	World Health Organisation

Appendix 2: Smoking prevalence among young people – Country Estimates

Country	ESPAD 1995	ESPAD 1999	HBSC 1993-1994	HBSC 1997-1998
Austria			30%	33%
Bulgaria		36%		
Croatia	23%	28%		
Czech Republic	26%	36%	13%	20%
Denmark	23%	32%	19%	24%
Estonia	25%	27%	14%	18%
Finland**	35%	39%	28%	27%
France*			24%	29.5%
Germany*			25%	30.5%
Greece			27%	18.5%
Hungary	28%	28%	22%	32%
Iceland	27	25%		
Ireland	37%	34%		25%
Israel			9%	19%
Italy	25%	25%		
Latvia		30%	23.5%	28%
Lithuania	20%	35%	9.5%	17%
Malta	19%	20%		
Norway	25%	33%	20.5%	25.3%
Poland	20%		18%	23.5%
Portugal	13%	17%		16.5%
Russian Federation*	42%	14%	23%	
Slovakia	20%	30%	12%	23%
Slovenia	16%	26%		
Spain				23.5%
Sweden	28%	25%	17%	21%
Switzerland			17.5%	25%
Ukraine	29%	29%		
United Kingdom	27%	26%		

* In the HBSC surveys, France, Germany & Russian Federation are represented by regions.

** Smoking prevalence among 14-18-year-olds in Finland was 25.5 in 1995 and 24.5 in 1999.

Appendix 3: Smoking prevalence and trends among adults – Country Estimates

Country	men 1994-1998	men 1999-2001	women 1994-1998	Women 1999-2001	total adults 1994-1998	total adults 1999-2001
Austria	29.6%		18.7%		23.9%	29%
Belgium	34%	36%	27%	26%	30%	31%
Croatia	34.1%	34.1%	31.6%	26.6%	32.6%	30.3%
Cyprus						
Czech Republic	43%	36.2%	31%	22%	36%	29.1%
Denmark	39%	32%	35%	29%	37%	30%
Estonia	52%	44%	24%	20%	36%	29%
Finland	29%	27%	19%	20%	24%	23%
France	35%	33%	21%	21%	28%	27%
Germany	43.2%	38.9%	30%	30.6%		34.5%
Greece	46%	46.8%	28%	29%	37%	37.6%
Hungary	44%	53.1%	27%	30.4%		41.75%
Ireland	32%		31%		31%	
Italy	38%	32.4%	26%	17.3%	32%	25%
Latvia	53%	49.1%	18.4%	13%		29.2%
Lithuania	43.3%	51%	6.3%	15.8%		32%
Luxembourg	39%		27%		32%	
Malta	33.7%		14.9%		24.1%	
Netherlands	36%	37%	29%	29%	33%	33%
Poland	44%	42%	24%	23%		
Portugal	29.4%		6.4%		17.2%	
Slovenia	34.7%	28%	22.7%	20.1%	28.7%	23.7%
Spain	42.1%		24.7%		33.1%	
Sweden	17%	17%	22.3%	21%	19.1%	19%
United Kingdom	29%	29%	28%	25%	28%	27%
Andorra	52.3%		35.6%			
Monaco						
Albania	44.4%	60%	6.6%	18%		39%
Armenia	63.7%				29%	
Azerbaijan		30.2%			26.5%	
Belarus	54.8%	53.7%	3.6%	4.8%	27.5%	26.3%
Bosnia & Herzegovina						
Bulgaria	49.2%		23.8%		35.6%	
Georgia	53.2%	54.4%	11.92%	15%	32.56%	
Iceland	30.3%	25.3%	30.6%	22.9%	30.4%	24.1%
Israel	32%		25%		28%	
Kazakhstan	60%		7%			
Kyrgyzstan						
Norway	36%	31%	36%	32%	36%	32%
Rep. of Moldova	43.9%	46%		18%		
Romania	61.7%		25%			
Russian Federation	63.2%		9.7%		36%	
San Marino						
Slovakia	44.1%		14.7%		29%	
Switzerland	39%		28%		33%	
Tajikistan						
Former Yugoslav Rep. of Macedonia						
Turkey						
Turkmenistan						
Ukraine	48.5%	51.1%	20.5%	19.5%		
Uzbekistan						
Yugoslavia						

Appendix 4: EU-25 - FCTC Ratification status – on 31 December 2005

Country	Signature date	Ratification date
European Community	16/6/03	30/6/05
Austria	28/7/03	15/9/05
Belgium	22/1/04	1/11/05
Croatia	2/6/04	Pending/to confirm
Cyprus	24/5/04	26/10/05
Czech Republic	16/6/03	Pending/to confirm
Denmark	16/6/03	16/12/04
Finland	16/6/03	24/1/05
France	16/6/03	19/10/04
Germany	24/10/03	16/12/04
Greece	16/6/03	Pending/to confirm
Hungary	16/6/03	7/4/04
Ireland	16/6/03	7/11/05
Italy	16/6/03	Pending/to confirm
Latvia	10/5/04	10/2/05
Lithuania	22/9/03	16/12/04
Luxembourg	16/6/03	30/6/05
Malta	16/6/03	24/9/03
Netherlands	16/6/03	27/1/05
Poland	14/6/04	Pending/to confirm
Portugal	9/1/04	8/11/05
Slovakia	19/12/03	4/5/04
Slovenia	25/9/03	15/3/05
Spain	16/6/03	11/1/05
Sweden	16/6/03	7/7/05
United Kingdom	16/6/03	16/12/04

References

[1]. Holbrook, J.H. Nicotine addiction. In: Braunwald, E., et al., eds. Harrison's principles of internal medicine, 14th ed. New York, McGraw-Hill, 1998:2516.

[2]. The tobacco health toll. WHO Regional Office for the Eastern Mediterranean. © World Health Organization 2005. ISBN: 978–92–9021–443–4.

[3]. Howe, G., Westoff, C., Vessey, M., et al. Effects of age, cigarette smoking, and other factors on fertility:findings in a large prospective study. *BMJ* 1985; 290: 1697–700.

[4]. Cooke, R.W. Smoking, intra-uterine growth retardation and sudden infant death syndrome. *Int J Epidemiol* 1998; 27: 238–41.

[5]. Kramer, M.S. Determinants of low birth weight: methodological assessment and metaanalysis. *Bulletin of the World Health Organization* 1987; 65: 663–737.

[6]. Department of Health and Human Services. The health consequences of involuntary smoking: a report of the Surgeon General. Washington, DC, Government Printing Office, 1986 (Publication no. DHHS (CDC)87–8398).

[7]. National Research Council, Committee on Passive Smoking. Environmental tobacco smoke: measuring exposure and assessing health effects. Washington, DC, National Academy Press, 1986.

[8]. Steele, R., Langworth, J.T. The relationship of antenatal and postnatal factors to sudden unexpected death in infancy. *Canadian Medical Association Journal* 1966; 94: 1165–71.

[9]. Haglund, D., Cnattingius, S. Cigarette smoking as a risk factor for sudden infant death syndrome: a population based study. *American journal of public health* 1990; 80:29–32.

[10]. Fielding, J.E., Phenow, K.J. Health effects of involuntary smoking. *New England journal of medicine* 1988; 319: 1452–60.

[11]. Weitzman, M., et al. Maternal smoking and childhood asthma. *Paediatrics* 1990; 85: 505–11.

[12]. Barker, D.J., Osmond, C. Childhood respiratory infection and adult chronic bronchitis in England and Wales. *British medical journal* 1986; 293: 1271–5.

[13]. Harlap, S., Davies, A.M. Infants' admissions to hospital and maternal smoking. *Lancet* 1974; 1: 529–32.

[14]. Colley, J.R., Holland, W.W., Corkhill, R.T. Influence of passive smoking and parental phlegm on pneumonia and bronchitis in early childhood. *Lancet* 1974; 2: 1031–4.

[15]. Murray, A.B., Morrison, B.J. Passive smoking by asthmatics: its greater effect on boys than on girls and on older than younger children. *Paediatrics* 1989; 84: 451–9.

[16]. Murray, A.B., Morrison, B.J. It is children with atopic dermatitis who develop asthma more frequently if the mother smokes. *Journal of allergy and clinical immunology* 1990; 86: 732–9.

[17]. Said, G., et al. Paternal smoking related to adenoidectomy and tonsillectomy in children. *Journal of epidemiology and community health* 1978; 32:97–101.

[18]. Iversen, M., et al. Middle ear effusion in children and the indoor environment: an epidemiological study. *Archives of environmental health* 1985; 40: 74–9.

[19]. Asmussen, I. Fetal cardiovascular system as influenced by maternal smoking. *Clinical cardiology* 1979; 2: 246–56.

[20]. Rona, R.J., Chinn, S., Flory, C.D. Exposure to cigarette smoking and children's growth. *International journal of epidemiology* 1985; 14: 402–9.

[21]. Berkey, C.S., et al. Passive smoking and height growth of preadolescent children. *International journal of epidemiology* 1984; 13: 454–8.

[22]. Candy, D., Davies, E.G., Ross, E. Clinical paediatrics and child health, 1st ed. Philadelphia, WB Saunders, 2001: 15.

[23]. Boffetta, P., Tredaniel, J., Greco, A. Risk of childhood cancer and adult lung cancer after childhood exposure to passive smoke: a meta-analysis. *Environ Health Perspect* 2000; 108: 73–82.

[24]. Tobacco smoking. Lyon, International Agency for Research on Cancer, 1986 (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 38).

[25]. Bernfeld, P., et al. Cigarette smoke inhalation studies in inbred Syrian golden hamsters. *Journal of the National Cancer Institute* 1979; 63: 675–89.

[26]. Claxton, L.D., et al. A genotoxic assessment of environmental tobacco smoke using bacterial bioassays. *Mutation research* 1989; 222: 81–99.

[27]. DeMarini, D.M. Genotoxicity of tobacco smoke and tobacco smoke condensate. *Mutation research* 1983; 114: 59–89.

[28]. Ong, T.M., et al. A simple in situ mutagenicity test for detection of mutagenic air pollutants. *Mutation research* 1984; 139: 177–181.

[29]. Löfroth, G., et al. Public exposure to environmental tobacco smoke. *Mutation research* 1988; 202: 103–10.

[30]. Glantz, S.A., et al. Passive smoking and heart disease. *Circulation* 1991; 83: 1–12.

[31]. Glantz, S.A., et al. Passive smoking and heart disease: mechanisms and risk. *Journal of the American Medical Association* 1995; 273: 1047–53.

[32]. Penn, A., et al. Inhalation of steady-state sidestream smoke from one cigarette promotes arteriosclerotic plaque development. *Circulation* 1994; 90: 1363–7.

[33]. Penn, A., et al. Inhalation of sidestream cigarette smoke accelerates development of arteriosclerotic plaques. *Circulation* 1993; 88: 1820–15.

[34]. Zhu, B.Q., et al. Passive smoking increases experimental atherosclerosis in cholesterol-fed rabbits. *Journal of the American College of Cardiologie* 1993; 21: 225–32.

[35]. The health benefits of smoking cessation. A report of the Surgeon General. Washington, DC, US Department of Health and Human Services, 1990 (DHHS Pub. No. (CDC) 908416).

[36]. Sun, Y.P., et al. Metoprolol does not attenuate atherosclerosis in lipid-fed rabbits exposed to environmental tobacco smoke. *Circulation* 1994; 89: 2260–5.

[37]. Lehr, H.A., et al. Vitamin C prevents cigarette smoke-induce leukocyte aggregation and adhesion to endothelium in vivo. *Proceedings of the National Academy of Sciences of the United States of America* 1994; 91: 7688–92.

[38]. Zhu, B.Q., et al. Exposure to environmental tobacco smoke increases myocardial infarct size. *Circulation* 1994; 89: 1282–90.

[39]. Prentice, R.C., et al. Recent exposure to cigarette smoke increases myocardial infarct size (abstract). *Journal of the American College of Cardiology* 1989; 13: 124A.

[40]. Gvozdjakova, A., et al. Smoke cardiomyopathy: disturbance of oxidative processes in myocardial mitochondria. *Cardiovascular research* 1984; 18: 229–32.

[41]. Gvozdjakova, A., et al. Effect of smoking on the oxidative processes of cardiomyocytes. *Cardiology* 1992; 81: 81–4.

[42]. Hacksaw, A.F., et al. The accumulated evidence on lung cancer and environmental tobacco smoke. *BMJ* 1997;315: 980–8.

[43]. Tredaniel, J., et al. Environmental tobacco smoke and the risk of cancer in adults. *European journal of cancer* 1993; 29A: 2058–68.

[44]. Zheng, W., et al. Risk factors for cancers of the nasal cavity and paranasal sinuses among white men in the United States. *American journal of epidemiology* 1992; 138: 965–72.

[45]. Hirayama, T. Lung cancer and other diseases related to passive smoking: a large-scale cohort study. In: Gupta, P.C. et al., ed. Control of tobacco-related cancers and other diseases. Bombay, Oxford University Press, 1992.

[46]. Coker, A.L., et al. Active and passive cigarette smoke exposure and cervical intraepithelial neoplasia. *Cancer epidemiology, biomarkers & prevention* 1992; 1: 349–56.

[47]. Wells, A.J. Breast cancer, cigarette smoking, and passive smoking (letter). *American journal of epidemiology* 1991; 133: 208–10.

[48]. Smith, S.J. et al. Alcohol, smoking, passive smoking and caffeine in relation to breast cancer risk in young women. *British journal of cancer* 1994; 70: 112–9.

[49]. Morabia, A. et al. A population-based case-control study of tobacco smoke and breast cancer (abstract). *American journal of epidemiology* 1994; 139: S28.

[50]. Respiratory health effects of passive smoking: lung cancer and other disorders. Washington, DC, US Environmental Protection Agency, 1992 (EPA/600/6-90/006F).

[51]. National Research Council. Environmental tobacco smoke: measuring exposures and assessing health effects. Washington, DC, National Academy Press, 1986.

[52]. The health consequences of involuntary smoking. A report of the Surgeon General. Washington, DC, US Department of Health and Human Services, 1986 (DHHS Pub. No. (PHS) 87-8398).

[53]. Spitzer, W.O., et al. Links between passive smoking and disease: a best evidence synthesis. A report of the working group on passive smoking. *Clinical and investigative medicine* 1990; 13: 17–42.

[54]. Chapter 8.1 Environmental tobacco smoke. Air Quality Guidelines - Second Edition. ©WHO Regional Office for Europe, Copenhagen, Denmark, 2000.

[55]. Law, M.R., et al. Environmental tobacco smoke exposure and ischaemic heart disease: an evaluation of the evidence. *BMJ* 1997; 315: 973–80.

[56]. Department of Health and Human Services. The health consequences of involuntary smoking: a report of the Surgeon General. Washington, DC, Government Printing Office, 1986 (Publication no. DHHS (CDC)87-8398).

[57]. National Research Council, Committee on Passive Smoking. Environmental tobacco smoke: measuring exposure and assessing health effects. Washington, DC, National Academy Press, 1986.

[58]. Wald, N.J., et al. Urinary cotinine as a marker of breathing other people's tobacco smoke. *Lancet* 1984; 1: 230–1.

[59]. Jarvis, M.J., et al. Factors determining exposure to passive smoking in young adults living at home: quantitative analysis using saliva cotinine concentrations. *International journal of epidemiology* 1991; 20: 126–31.

[60]. Tunstall-Pedoe, H., et al. Tea drinking, passive smoking, and serum cotinine in the Scottish heart health study. *Journal of clinical epidemiology* 1991; 44: 1411–14.

[61]. Riboli, E., et al. Exposure of non-smoking women to environmental tobacco smoke: a 10-country collaborative study. *Cancer causes & control* 1990; 1: 243–252.

[62]. Becher, H., et al. Passive smoking in Germany and Poland: comparison of exposure levels, sources of exposure, validity, and perception. *Epidemiology* 1992; 3: 509–14.

[63]. Cooke, D.G., et al. Passive exposure to tobacco smoke in children aged 5-7 years: individual, family, and community factors. *BMJ* 1994; 308: 384–9.

[64]. Working Party of the Royal College of Physicians. Smoking and the young. London, Royal College of Physicians, 1992.

[65]. Strachan, D.P., Jarvis, M.J., Feyerabend, C. The relationship of salivary cotinine to respiratory symptoms, spirometry and exercise-induced bronchospasm in seven-year old children. *American review of respiratory disease* 1990; 142: 147–51.

[66]. Wald, N., Ritchie, C. Validation of studies on lung cancer in non-smokers married to smokers. *Lancet* 1984; 1: 1067.

[67]. WHO European Centre for Environment and Health. Concern for Europe's tomorrow. Health and the environment in the WHO European Region. Stuttgart, Wissenschaftliche Verlagsgesellschaft mbh, 1995.

[68]. Peto, R., Alan, D., Lopez, A.D., Jillian Boreham, J., Thun, M. Mortality from smoking in developed countries 1950−2000. Enlarged eu (25 countries − EU25). Revised 09−Dec−2005.

[69]. World Health Organization Regional Office for Europe - Copenhagen. The European Report on Tobacco Control Policy. Review of implementation of the Third Action Plan for a Tobacco-free Europe 1997–2001. © World Health Organization – 2002.

[70]. World Health Organization Regional Office for Europe - Copenhagen. European Strategy for Tobacco Control. © World Health Organization – 2002.

[71]. The world health report 2002: reducing the risks, promoting healthy life (http://whqlibdoc.who.int/publications/9241562072.pdf). Geneva, World Health Organization, 2002 (accessed 14 March 2003).

[72]. The 1999 ESPAD Report and The 1995 ESPAD Report. Stockholm. The Swedish Council for Information on Alcohol and Other Drugs (CAN), 2000. (http://www.can.se, accessed 2 November 2001).

[73]. Currie, C., et al. ED. Health and health behaviour among young people. Copenhagen, WHO Regional Office for Europe, 1999 (Health Policy for Children and Adolescents Series, No. 1).

[74]. Poverty and Health – Evidence and action in the WHO's European Region. Copenhagen, WHO Regional Office for Europe, 2001 (document EUR/RC51/8).

[75]. Aliaga, C. Le tabac: vingt ans d'usage et de consommation. Paris, INSEE Premiere, No 808 (2001).

[76]. WHO European Ministerial Conference for a Tobacco-free Europe (Warsaw, 18–19 February 2002), Warsaw Declaration for a Tobacco-free Europe.

[77]. Resolution EUR/RC37/R9. In: Report of the thirty-seventh session of the WHO Regional Committee for Europe. Copenhagen, WHO Regional Office for Europe, 1987.

[78]. Resolution EUR/RC42/R2. In: Report of the forty-second session of the WHO Regional Committee for Europe. Copenhagen, WHO Regional Office for Europe, 1992 (document EUR/RC42/REC1).

[79]. Resolution EUR/RC47/R8. Third Action Plan for a Tobacco-Free Europe 1997–2001 Regional Committee For Europe, Forty-seventh session, Istanbul, 15 – 19 September 1997. Copenhagen, WHO Regional Office for Europe. (document EUR/ICP/LVNG 01 04 01).

[80]. WHO European Strategy for Smoking Cessation Policy. Revision 2004. Copenhagen, WHO Regional Office for Europe. © World Health Organization 2004.

[81]. WHO Framework Convention on Tobacco Control. © World Health Organization 2003, updated reprint 2004, 2005. ISBN 92 4 159101 3.

[82]. Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (text with EEA relevance).

[83]. Directive 2001/37/EC of The European Parliament and of The Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

[84]. Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (2003/54/EC).

[85]. Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages (notified under document number C(2003) 3184) (Text with EEA relevance).

[86]. Council Regulation (EC) No 546/2002 of 25 March 2002 fixing the premiums and guarantee thresholds for leaf tobacco by variety group and Member State for the 2002, 2003 and 2004 harvests and amending Regulation (EEC) No 2075/92.

[87]. Council Regulation (EC) No 1648/2000 of 25 July 2000 laying down detailed rules for the application of Council Regulation (EEC) No 2075/92 with regard to the Community Tobacco Fund and repealing Regulation (EEC) No 2427/93.

+++