McDonald, David S

From: Nicolas Gagnon-Oosterwaal <n.gagnon@bluespike.ca>
Sent: November-02-14 12:35 PM
To: Office of the Legislative Counsel
Subject: BILL 60
Attachments: Addiction, Research report e-cig for smoking cessation, August 2014.pdf; Second Hand Smoke Study.pdf; Presentation Blue Spike_EVO_NS.pptx; WHO - Electronic Cigarette - Oct 2014.pdf

As a stakeholder in the proposed Bill 60, I would like to submit the attached PowerPoint presentation for your consideration.

We have also submitted some studies of which you are probably aware to support some points brought up in the brief presentation:

- Cessation aids are less effective than e-cigs or even quitting cold-turkey
- Second hand cigarette smoke is much more toxic than second hand smoke from e-cigarettes

We also attached the latest Tobacco Control Report from the World Health Organization which discusses and addresses its own recommendations regarding e-cigarettes.

I would be pleased to meet with the members of your cabinet to share in greater detail our experience and knowledge about the e-cigarette industry. We would like to express our point of view, shared by many in the scientific and medical communities, who strongly believe electronic cigarettes are an efficient tool to reduce the number of tobacco users in Canada and therefore should be regulated, though not necessarily through the Smoke-Free Places Act and Tobacco Access Act.

Regards,

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WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

Conference of the Parties to the WHO Framework Convention on Tobacco Control

Sixth session
Moscow, Russian Federation,13–18 October 2014

FCTC/COP/6/A/R/2
18 October 2014

Second report of Committee A

(Draft)

In addition to the decision on Item 4.2 contained in the first report of the Committee (document FCTC/COP/6/A/R/1), the Committee recommends to the Conference of the Parties the adoption of the following decisions:

Item 4.1	Status of the Protocol to Eliminate Illicit Trade in Tobacco Products
Item 4.3	Implementation of Article 19 of the WHO FCTC: "Liability"
Item 4.4.1	Smokeless tobacco products
Item 4.4.2	Electronic nicotine delivery systems, including electronic cigarettes
Item 4.4.3	Control and prevention of waterpipe tobacco products
Item 4.5	Economically sustainable alternatives to tobacco growing (in relation to Articles 17 and 18 of the WHO FCTC)
Item 4.6	Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC
Item 4.7	Impact assessment of the WHO FCTC
Item 4.8	Implementation of Article 5.3 of the WHO FCTC: evolving issues related to interference by the tobacco industry

Item 4.1

Status of the Protocol to Eliminate Illicit Trade in Tobacco Products

The Conference of the Parties (COP),

Taking into account Article 15 (*Illicit trade in tobacco products*) of the WHO FCTC;

Recalling its decision FCTC/COP5(1) by which the COP adopted the Protocol to Eliminate Illicit Trade in Tobacco Products;

Considering that the first session of the Meeting of the Parties will be held in conjunction with the next regular session of the COP following the entry into force of the Protocol;

Mindful of the importance of multisectoral cooperation and coordination among all relevant sectors of government, including health, customs, tax administrations, law enforcement, foreign affairs, trade and justice and other bodies as appropriate, for the implementation of the Protocol and Article 15 of the WHO FCTC,

1. CALLS UPON all Parties to the WHO FCTC to ratify, accept, approve, formally confirm or accede to the Protocol at the earliest opportunity, with a view to bringing the Protocol into force as soon as possible;

2. CALLS UPON all Parties to the WHO FCTC to advocate and support the entry into force of the Protocol, including through appropriate forums of the World Customs Organization (WCO), the United Nations Office on Drugs and Crime (UNODC), the World Trade Organization (WTO) and other relevant international organizations of which they are members;

3. REQUESTS the Convention Secretariat to:

(a) continue to promote ratification, acceptance, approval, formal confirmation and accession to the Protocol, including through multisectoral face-to-face and online meetings, and by promoting the use of the self-assessment checklist by all government sectors involved in Protocol implementation;

(b) identify and establish, as soon as possible, a panel of experts, composed of up to two experts per WHO region, with the mandate to support the Convention Secretariat to provide technical and legal advice upon request, including on customs, tax administration and enforcement, and facilitate exchanges of information, experiences and challenges among Parties, including on existing good practices and opportunities in implementation of the provisions of the Protocol;

(c) further engage with WCO, UNODC, WTO and other bodies, as appropriate, in order to identify means of accelerating the entry into force of the Protocol, particularly by facilitating multisectoral discussions;

(d) to continue to develop and make available the technical capacity required within the Secretariat to support Parties wishing to advance their work in the areas covered by Article 15 of the WHO FCTC and the Protocol;

(e) identify mechanisms of technical and financial support to Parties in implementation of the Protocol; and

(f) report on the activities carried out to the seventh meeting of the Conference of the Parties.

Item 4.3

Implementation of Article 19 of the WHO FCTC: "Liability"

The Conference of the Parties (COP),

Recalling the report by the Convention Secretariat on liability contained in document FCTC/COP/5/11;

Noting the report by the expert group on liability that was established pursuant to decision FCTC/COP5(9) contained in document FCTC/COP/6/8;

Recognizing that, as outlined in the expert group's report, "the marketing of an inherently deadly and addictive product, promoted as a lifestyle consumer good and subject to gradual and still evolving regulation has few, if any, historical parallels";

Recognizing that, as highlighted in the guiding principles of the WHO FCTC (Article 4.5), "issues relating to liability … are an important part of comprehensive tobacco control" and that Article 19 presents the Parties with an opportunity to hold the tobacco industry legally liable for the harms it causes;

Noting that, according to the expert group's report contained in document FCTC/COP/6/8, very few Parties have launched any criminal and/or civil liability action and even fewer have taken any legislative, executive, administrative and/or other action against the tobacco industry for full or partial reimbursement of medical, social and other relevant costs related to tobacco use in their jurisdiction, and that Parties require additional guidance to advance implementation,

(1) INVITES Parties to share, through the Convention Secretariat's information platform, relevant information regarding implementation of Article 19; experiences with issues related to tobacco liability; and expertise;

(2) REQUESTS the Convention Secretariat to:

(a) develop a database of public institutions and legal and scientific experts, nominated by Parties, with experience in tobacco litigation related to liability, and establish a mechanism for the recommendation of experts, at the request of Parties, engaged in relevant actions; and

(b) prepare, maintain and make available to Parties a comprehensive list of the existing resources that may assist Parties in dealing with civil and criminal liability and other legal challenges where necessary;

(3) DECIDES to extend the mandate of the expert group, which shall continue its work as set out in decision FCTC/COP5(9), and shall, prior to COP7, provide a final report on approaches that may assist Parties to strengthen civil liability mechanisms across a variety of legal systems. It shall also report on progress made in the other areas of its mandate;

(4) DECIDES that, with the aim of ensuring balanced representation from developed and developing nations, the expert group shall comprise 3 experts per WHO region, and two observers per WHO region with specific expertise in the area of the expert group invited by the Convention Secretariat;

(5) REQUESTS the expert group to take into account document FCTC/COP/6/8 in its deliberations;

(6) FURTHER REQUESTS the Convention Secretariat to make the necessary arrangements including budgetary arrangements, for the expert group to complete its work.

Item 4.4.1

Smokeless tobacco products

The Conference of the Parties (COP),

Recalling documents FCTC/COP/4/12 and FCTC/COP/5/12, and taking note of the report contained in document FCTC/COP/6/9;

Recognizing that the consumption of smokeless tobacco (SLT) products has become a matter of global public health concern with more than 80 Parties reporting the use of some form of SLT product;

Further recognizing that the WHO South-East Asia Region is home to nearly 90% of the world's 300 million users of SLT products;

Taking note of the fact that the prevalence of SLT use has seen an increase in most Parties;

Further taking note of the fact that SLT is a key causal risk factor for a number of noncommunicable diseases, especially oral cancer, heart disease and adverse reproductive outcomes, and that it increases all-cause mortality;

Commending the Parties that have adopted policies and programme measures to prohibit, restrict or reduce the consumption of SLT;

Taking note of the lack of adequate regulatory, enforcement or product-testing capacity to regulate SLT products or test for their constituents;

Agreeing that SLT control is no longer a regional issue and that it merits global level actions to strengthen policies, programmes and implementation;

Acknowledging the need to build a suitable communications strategy to denormalize SLT use, and to sensitize and educate policy-makers and the public on harms of SLT use, as well as the need to train health professionals on cessation of SLT use;

Taking note of Parties' commitment and support to the global effort to establish a knowledge hub on SLT products that builds upon the existing knowledge base and research capacity on SLT;

Agreeing on the need for:

(a) improvement in surveillance of SLT products and related indicators as part of regular health surveys;

(b) effective price and tax measures to be taken in line with Article 6 of the FCTC and the guidelines for its implementation and in line with other tobacco products such as cigarettes in accordance with national laws;

(c) operational and implementation research on opportunities and challenges in effective implementation of WHO FCTC provisions, and health and economic cost studies of specific SLT products;

(d) strict regulation of new and existing SLT products;

(e) strong efforts to reduce sales of SLT products to minors and their access to such products through strict application of relevant legislative and administrative measures;

(f) consideration of developing specific cessation support for people who use SLT and to assess the effectiveness of SLT cessation interventions in accordance with Article 14 guidelines;

(g) encouragement to all WHO regions to develop SLT strategies specific to regions and/or subregions;

(h) establishment of a global knowledge hub on SLT that serves as a repository of information, product-specific SLT burden, and research needs, including best practices and implementation challenges concerning SLT;

INVITES Parties to:

(a) consider, as appropriate, developing product specific policies and regulations to protect the health of their citizens, acknowledging the WHO FCTC provisions, especially on labelling, packaging, ingredients, sales arrangements, advertising, tax measures, or other strict regulations, such as prohibition of the import, manufacture and sale of identified SLTs in line with applicable legal provisions and public health priorities;

(b) to promote action for education and public awareness on the risks of use of these products, and offer cessation treatment;

DECIDES to request the Convention Secretariat to:

(a) include, as appropriate, a specific reference to and discussion of SLT issues in the ongoing working group discussions, especially in the working group on Articles 9 and 10 of the WHO FCTC;

(b) include, as appropriate, a separate examination of SLT issues as and when any of the existing guidelines are reviewed in future;

(c) in consultation with the WHO Secretariat, explore the feasibility of establishing a global knowledge hub on SLT.

Item 4.4.2

Electronic nicotine delivery systems[1] and electronic non-nicotine delivery systems[2]

The Conference of the Parties (COP),

Recalling its decision FCTC/COP4(14) to request the Convention Secretariat to prepare jointly with WHO's Tobacco Free Initiative a comprehensive report based on the experience of Parties on the matter of electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that vaporize a solution, which may include nicotine, or not, the user then inhales, for consideration at the fifth session of the COP;

Recalling its decision FCTC/COP5(10) to request the Convention Secretariat to invite WHO to identify options for the prevention and control of ENDS and examine emerging evidence on the health impacts of the use of such electronic systems; and report on the outcome to the sixth session of the COP;

Recognizing that the Parties have adopted various regulatory strategies with respect to ENDS, such as an outright ban on their sale, the adoption of regulation similar to that applicable to the marketing of medicines, their control as tobacco products, or no control at all;

Noting that the report by WHO to the COP at its sixth session (document FCTC/COP/6/10) summarizes the public health debate and limited nature of the evidence on ENDS and presents both general objectives and specific regulatory options for consideration by Parties,

1. WELCOMES the report contained in document FCTC/COP/6/10 and invites Parties to take careful note of it;

2. INVITES Parties, when addressing the challenge posed by ENDS/ENNDS, to consider taking measures such as those referred to in document FCTC/COP/6/10 in order to achieve at least the following objectives, in accordance with national law:

(a) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;

(b) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;

(c) prevent unproven health claims from being made about ENDS/ENNDS; and

(d) protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry;

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[1] Electronic nicotine delivery systems (ENDS), of which electronic cigarettes are the most common prototype, are devices that vaporize a solution.

[2] Electronic non-nicotine delivery systems (ENNDS).

3. INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;

4. URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS;

5. INVITES Parties and WHO to comprehensively monitor the use of ENDS/ENNDS, including the relevant questions in all appropriate surveys;

6. REQUESTS the Convention Secretariat to invite WHO to prepare an expert report, with independent scientists and concerned regulators, for the seventh session of the Conference of the Parties with an update on the evidence of the health impacts of ENDS/ENNDS, potential role in quitting tobacco usage, impact on tobacco control efforts and to subsequently assess policy options to achieve the objectives outlined in paragraph 2 of this decision and to consider the methods to measure contents and emissions of these products.

Item 4.4.3

Control and prevention of waterpipe tobacco products

The Conference of the Parties (COP),

Recalling the report submitted by the Convention Secretariat on the control and prevention of waterpipe tobacco products (document FCTC/COP/6/11);

Acknowledging that waterpipe use accounts for a significant and growing share of tobacco use globally and that misconceptions about the safety of waterpipe use compared to other smoked tobacco products have contributed greatly to its wide social and cultural acceptance and the observed sharp rise in its use globally;

Emphasizing that it is well documented that the tobacco used in waterpipe is as deadly as other tobacco products, causing a range of illnesses including cardiovascular diseases, different types of cancers, and respiratory and other illnesses;

Noting that the global tobacco industry and other commercial entities are investing in waterpipe production and that its distribution is no longer limited to local industries, which might increase its use and the related epidemic not only in countries traditionally known for waterpipe use but also at the global level;

Recognizing that Parties need clear guidance in relation to waterpipe and the regulatory peculiarities that are unique to its use;

Further emphasizing that establishing a mechanism for exchange of information on the different aspects of waterpipe tobacco products between Parties is vital to success in controlling its use,

1. INVITES Parties to:

   (a) include waterpipe tobacco products in surveillance systems and other relevant research at national level and develop national profiles, including consumers, products types, additives and sales channels, on waterpipe use;

   (b) strengthen their implementation of the WHO FCTC in relation to waterpipe tobacco products, through the integration of waterpipe prevention and control into tobacco-control measures;

2. REQUESTS the Convention Secretariat to:

   (a) Invite WHO to:

      (i) develop a report on policy options and best practices in the control of use of waterpipe tobacco products in light of the WHO FCTC to be submitted to the seventh session of the COP;

(ii) integrate reporting on use of waterpipe in all relevant data collection;

(b) review the reporting instrument of the WHO FCTC and integrate reporting on waterpipe use where appropriate;

(c) in consultation with the WHO Secretariat explore the possibility of including waterpipe use issues in a global knowledge hub;

(d) include, as appropriate, a specific reference to and discussion of waterpipe tobacco products in the ongoing working group discussions, especially in the working group on Articles 9 and 10 of the WHO FCTC.

Item 4.5

Economically sustainable alternatives to tobacco growing (in relation to Articles 17 and 18 of the WHO FCTC)

The Conference of the Parties (COP),

Taking into account Articles 17 (*Provision of support for economically viable alternative activities*) and Article 18 (*Protection of the environment and the health of persons*) of the WHO Framework Convention on Tobacco Control (WHO FCTC);

Reaffirming its decision FCTC/COP3(16) that established a working group on economically sustainable alternatives to tobacco growing in relation to Articles 17 and 18 of the WHO FCTC;

Recalling decisions FCTC/COP3(16) and FCTC/COP5(8);

Noting that the WHO FCTC does not aim to penalize tobacco farmers, but aims to promote economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers;

Considering that the success of the WHO FCTC will result in reducing consumption, and bearing in mind that Articles 17 and 18 of the WHO FCTC is aimed at increasing the number of livelihood options, with a view to assisting tobacco growers and workers;

Reaffirming the need to safeguard the livelihoods of tobacco farmers and workers;

Emphasizing that the aim of these policy options and recommendations is to assist Parties to meet their obligations under Articles 17 and 18 of the WHO FCTC,

1. ADOPTS the policy options and recommendations on economically sustainable alternatives to tobacco growing (in relation to Articles 17 and 18 of the WHO FCTC) contained in the Annex to this decision;

2. REQUESTS the Convention Secretariat to:

(a) support interested Parties in developing pilot projects and other initiatives that aim to implement these policy options and recommendations;

(b) promote international cooperation and exchange of information among interested parties;

(c) organize an international database, within the WHO FCTC information platform, of good practices, instruments and measures to support the implementation of these policy options and recommendations;

(d) invite support and collaboration from Parties and competent international organizations including WHO to raise awareness of the health, environmental and social harms and risks related to tobacco cultivation and manufacture and to promote the implementation of Articles 17

and 18 of the WHO FCTC in all relevant forums, including the discussion of the post-2015 development agenda;

(e) invite the Food and Agriculture Organization of the United Nations (FAO) to update its 2003 study "Projections of Tobacco Production, Consumption and Trade", considering the impact of the implementation of the WHO FCTC;

(f) invite the International Labour Organization to update data on jobs related to tobacco production and manufacturing in order to support Parties to the WHO FCTC to monitor the potential impact of the Convention on the livelihoods of tobacco growers and the economies of tobacco-growing regions;

(g) cooperate with FAO, in the context of the International Year of Family Farming, to support initiatives aimed at promoting alternatives to tobacco growing;

(h) request WHO to support interested Parties to develop guidelines for surveillance, prevention and early diagnosis of occupational harms and risks specific to tobacco cultivation and manufacture, in particular those related to green tobacco sickness;

(i) submit to COP7, a progress report on the implementation of the current decision. The progress report can make use of experiences and case studies from before and after this decision.

ANNEX

DRAFT POLICY OPTIONS AND RECOMMENDATIONS ON ECONOMICALLY SUSTAINABLE ALTERNATIVES TO TOBACCO GROWING (IN RELATION TO ARTICLES 17 AND 18 OF THE WHO FCTC)

1. INTRODUCTION

The WHO Framework Convention on Tobacco Control (WHO FCTC) enshrines a comprehensive range of multisectoral evidence-based measures that aim to reduce tobacco use and exposure to tobacco smoke. At the same time, it also recognizes the need to promote economically viable alternatives to tobacco production as a way to prevent possible adverse social and economic impacts on populations whose livelihoods depend on tobacco production. Moreover, Parties agreed to have due regard to the protection of the environment and the health of persons in respect of tobacco cultivation and manufacture.

1.1 The global tobacco production chain[1]

The global tobacco industry is a highly specialized oligopoly that depends on the cultivation of the tobacco crop *(Nicotiana tabacum* and to a much lesser extent *Nicotiana rustica).*

[1] The figures in this section will be updated/revised periodically, based on availability of data.

- The agricultural sector is composed of **tobacco growers and workers** who produced (in 2011) about 7 461 994 tonnes of raw tobacco on a total of 4 211 885 hectares[1] in about 120 countries.[2] The challenges of the agricultural sector related to contracting, extension, support and marketing/payment systems vary by region.

- The **primary processing** of the tobacco leaves is undertaken by specialized companies, called "first processors" or "leaf companies". Worldwide, only a few companies work in this sector. [3] The business model is a vertical integration of the tobacco growers and workers. The companies usually provide all the necessary inputs as well as loans for cropping.

- The **tobacco products industry** comprises facilities that manufacture cigarettes, cigars, smokeless tobacco (chewing, plug/twist, and snuff tobacco), loose smoking tobacco (pipe and roll-your-own cigarette tobacco), reconstituted (sheet) tobacco, and other tobacco products such as bidis, and that market them under different brands.

The farmers themselves earn very little for their crop in comparison with the final price obtained at the end of the value-added chain.[4] It is estimated that one ton of raw tobacco produced by a farmer and sold to the "first processor" increases in value 47.2 times[5] along the production chain until the point at which smokers buy cigarettes.

1.1.1 Global tobacco product consumption trends

Globally, the tobacco epidemic has expanded to, and become more focused on, the world's low- and middle-income countries, due largely to the expansion of the multinational tobacco industry's marketing efforts in eastern Europe, Asia, Africa, and Latin America.[6,7]

Ten years ago, it was predicted that any reduction in the number of smokers and in total tobacco consumption over the next 20 years would gradually. Half of this time has passed and there has been clear progress in WHO FCTC implementation and signs of reduction in tobacco demand.

In this context, the current scenario for global tobacco control needs to be better understood, taking into account its potential impact on the livelihoods of tobacco growers and the economics of tobacco-growing regions.

These new trends increase the urgency of considering measures to implement Article 17 by the Parties

[1] Food and Agriculture Organization of the United Nations. *FAOSTAT* (http://faostat.fao.org/site/567/default.aspx#ancor).

[2] Geist HJ, Chang K, Etges V, Abdallah JM. Tobacco growers at the crossroads: Towards a comparison of diversification and ecosystem impacts. Land Use Policy. 2009;26:1066-79.

[3] Van Liemt G. The world tobacco industry: trends and prospects. Geneva: International Labour Office; 2002 (Sectoral Activities Programme working paper No. 179).

[4] The top 5 largest international tobacco companies. (http://www.top5ofanything.com/index.php?h=fb59add3).

[5] Quotient of value of total volume of the tobacco market divided by estimated value of raw tobacco at farm gate.

[6] Shafey O et al. The tobacco atlas, 3rd ed. Atlanta (GA): American Cancer Society and World Lung Foundation; 2009.

[7] WHO report on the global tobacco epidemic, 2008. Geneva: World Health Organization; 2008.

in tobacco-growing regions, especially in those Parties where tobacco represents a significant source of income to the national economy.[1,2]

1.1.2 Labour demand in the tobacco production chain

The tobacco production chain demands labour in three different sectors, agriculture, manufacturing and services sector including sales and distribution. The agricultural sector is composed of tobacco growers and contractual, non-contractual, permanent or seasonal workers employed by the farmers.

Tobacco requires a lot of manual working units per hectare compared to many other crops, even on mechanized farms. A 2003 ILO report estimated that in 2003,100 million people worked in the tobacco industry, of whom only about 1.2 million were employed in manufacturing, 40 million worked in crop and leaf processing, and 20 million worked in home industries (such as hand-rolling bidis or kretek cigarettes in India and Indonesia, respectively). The remaining 38.8 million people worked in tobacco-related processes and industries including distribution, sales and promotion of tobacco use.[3] It is important, therefore, to recognize all of these people as tobacco workers (at least part-time) in so far as applicability of the draft policy options and recommendations are concerned.

1.2 Alternative crops and livelihoods

Many countries, including the world's largest producers, are taking steps to find alternatives to tobacco growing. Several economically sustainable alternatives to tobacco growing have been identified in studies in various regions of the world.[4] In order to find economically sustainable alternatives to tobacco growing, not only income and crop profitability but all aspects of farmers' livelihoods need to be addressed. A framework for alternative livelihoods that addresses the problem holistically could form a bridge between academic findings and policy decisions.

1.3 Occupational risks for tobacco workers and growers

Several occupational risks related to tobacco growing are well known, including green tobacco sickness and as in many other agricultural sectors, pesticide intoxication, respiratory and dermatological disorders and cancers. Green tobacco sickness,[5] the disease most specifically related to tobacco growing, results from dermal absorption of nicotine, which is exacerbated during the handling of wet leaves, but which may be preventable by the use of appropriate individual protective

[1] Reuters, 29 April 2014 (http://uk.reuters.com/article/2014/04/29/brit-am-tobacco-germany-idUKL2N0NE19820140429).

[2] Bloomberg, 25 April 2014 (http://www.bloomberg. com/news/2014-04-24/japan-tobacco-forecasts-17- profit-drop-on-restructuring-costs.html).

[3] International Labour Organization Newsroom, 18 September 2003 (http://www.ilo.org/global/about-the-ilo/newsroom/features/WCMS 071230/lang-en/index.htm).

[4] Summary of possible alternative crops. Paper presented at the third meeting of the working group (in relation to Articles 17 and 18 of the WHO FCTC), Geneva, Switzerland, 14-16 February 2012.

[5] Pereira Vasconcelos de Oliveira P, et al. First reported outbreak of green tobacco sickness in Brazil. Cadernos de Saúde Pública. 2010;26:2263-69.

equipment.[1] Furthermore, in the production of bidis, exposure to and inhalation of tobacco dust during manufacturing lead to respiratory problems. This is particularly so for women and children. In addition, bidi rolling requires the rollers to sit for long hours in a particular posture, which leads to musculoskeletal problems.

1.4 Impact on employment and social disruption

In some countries, two issues in particular exacerbate the social disruption and poverty caused by tobacco farming: bonded labour and child labour.[2] An overview of the social disruption caused by tobacco growing was given at the second meeting of the study group on economically sustainable alternatives to tobacco growing in Mexico City in 2008.[3]

The social disruption caused by tobacco growing must be addressed from a development perspective, taking into consideration poverty, unfair contracts, and child and bonded labour. Child labour and bonded labour must be tackled from a human rights perspective - these practices violate rights established in international law - in collaboration with relevant international organizations such as ILO, UNICEF and UNDP.

1.5 Environmental impact[4]

Forest degradation, deforestation to obtain the wood needed for the curing process, and deforestation as cultivators clear land (sometimes compensating for lost nutrient levels on existing cultivated land), leads to some of the major types of vegetation change associated with biodiversity losses that result from tobacco cultivation in many developing countries.[5]

Although the global share of agricultural land used for tobacco growing is less than 1%, its impact on global deforestation is higher.[6] In some countries, research suggests that tobacco growing may be up to 10 times more aggressive than the sum of all other factors in regard to deforestation. The cost of mitigating the socio-ecological losses is borne almost exclusively by farmers. Tobacco, being a mono-crop, depletes soil nutrients.[7] It is a high input-oriented crop and the per-acre requirement of pesticides and fertilizers is very high under certain conditions.[8] Tobacco ranks among the 10 crops with the highest fertilization rates.[9]

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[1] In Brazil research undertaken by the Federal University of Pelotas has shown that the personal protective equipment recommended by the Brazilian Tobacco Growers Association was not efficient in protecting workers from green tobacco sickness.

[2] International Labour Organization conventions on child labour.

[3] Otañez M. Social disruption caused by tobacco growing. Study conducted for the second meeting of the study group on economically sustainable alternatives to tobacco growing, Mexico City, 17-19 June 2008.

[4] This section is based on the corresponding section of document FCTC/COP/3/11 (page 4, paragraph 17).

[5] Yanda PZ. Impact of small scale tobacco growing on the spatial and temporal distribution of Miombo woodlands in Western Tanzania. Journal of Ecology and the Natural Environment. 2010;2:10-16.

[6] Geist H. Global assessment of deforestation related to tobacco farming. Tobacco Control. 1999;8:18-28.

[7] Goodland JA, Watson C, Ledec G. Environmental management in tropical agriculture. Boulder (CO): Westview Press; 1984.

[8] Fertilizer use by crop. Rome: Rome, Food and Agriculture Organization of the United Nations; 1999.

[9] Fertilizer use by crop. Rome, Food and Agriculture Organization of the United Nations; 2006.

1.6 Corporate practices undermining the implementation of sustainable alternatives to tobacco growing

The tobacco industry suggests that effective implementation of sustainable alternatives to tobacco growing as well as measures under the WHO FCTC for reducing demand would suddenly extinguish the economic benefits that tobacco growing brings. The economic contribution of tobacco growing to local and national economies, employment figures and the national balance of trade is usually mentioned by the tobacco industry.[1] In reality, annual consumption usually decreases by fractions of percentage points, thus allowing time for growers to diversify into other activities gradually and in combination with implementation of government adjustment programmes. Mechanization of tobacco growing and competition in international trade generally bear much more responsibility for decreasing employment.[2] Therefore, the suggestion by the tobacco industry is incorrect. Moreover, Parties shall act to protect the implementation of Articles 17 and 18 of the WHO FCTC against the commercial and vested interests (interference) by the tobacco industry in accordance with Article 5.3 of the Convention and the guidelines for its implementation.

2. PURPOSE, SCOPE AND APPLICABILITY

2.1 The purpose of these recommendations is to provide Parties with a general working framework within which they may adopt the comprehensive policies and effective measures required to fulfil their obligations under Articles 17 and 18 of the WHO FCTC.

2.2 The recommendations aim to guide Parties in implementing policies that promote the establishment of innovative mechanisms for the development of sustainable alternative livelihoods for tobacco growers and workers in relation to Articles 17 and 18 of the WHO FCTC.

2.3 Parties are recommended to build up development programmes connected with the promotion of food security and feasible markets that cover all aspects of the alternatives to tobacco growing, including economic viability and environmental protection. Government agencies, particularly those with a strong influence in rural areas, have an important role to play in supporting the diversification of livelihoods in tobacco-growing regions, through an array of policies and measures, including the provision of training for tobacco workers and growers and their families. International institutions and farmer organizations should also play an important role in the development and implementation of policy (see Principle 2 in *Guiding principles).*

2.4 Policies and programmes for promoting or shifting to alternative livelihoods may be planned in a time-bound and phased manner. Simultaneously, reconversion programmes for growers and workers should be developed and information in this regard shared with relevant stakeholders. The costs of adjusting supply as demand diminishes will be stretched out over decades. Thus, the transition costs will also be spread over a long period. Countries should orient educational programmes, and information campaigns backed by data and evidence in order to prevent any attempt to misinform farmers about the sustainable alternative livelihoods available to tobacco growers and workers. Tobacco-growing countries should fix realistic goals and targets depending on their

[1] Assunta M. Tobacco industry's ITGA fights FCTC implementation in the Uruguay negotiations. Tobacco Control, 26 May 2012. doi:10.1136/tobaccocontrol-2011-050222.

[2] Tobacco industry interference with tobacco control. Geneva: World Health Organization; 2008.

prevailing condition and capacity to implement strategies to provide alternative livelihoods for growers and workers.

2.5 While the measures recommended here should be applied by Parties as broadly as necessary, Parties are strongly encouraged to implement measures beyond those recommended when adapting them to their specific circumstances, in order to achieve the objectives of Articles 17 and 18 of the WHO FCTC, provided they do not harm the livelihoods of the tobacco growers and workers who find themselves with the need to shift to alternative activities/crops. The WHO FCTC does not aim to penalize tobacco growers and workers, but aims to promote economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers who will be affected by a reduction of tobacco consumption.

3. GUIDING PRINCIPLES

Principle 1: Livelihoods diversification should be the concept guiding implementation of economically sustainable alternatives to tobacco growing.

The concept of livelihood diversification is based on the fact that the more diversified a productive unit is, the more likely it is that farmers will have wider choices to diversify their economic and productive activities. The diversification of livelihoods approach does not merely mean growing other crops in the intervals between tobacco growing or associated with tobacco growing (intercropping). It goes beyond the idea of substituting one crop with another. It is a greater set of opportunities and alternatives that are fundamental to establishing successful strategies to livelihood diversification specially combat the various forms of vulnerability to which tobacco growing families are exposed to, particularly in poor rural areas. These alternatives should provide opportunities that would permit tobacco farmers to enhance their health and socioeconomic wellbeing. It is therefore important that diversification of livelihoods go beyond the farm level and be integrated into the broader development strategy to facilitate successful and sustainable implementation.

This means that policies for implementing Articles 17 and 18 should be holistic and encompass not just the economic and productive dimensions, but also aspects that can influence the welfare and quality of life of workers, as well as environmental protection. The livelihoods approach accordingly identifies five types of capital – natural (land or livestock), human (labour/education), physical (infrastructure), financial (savings, income) and social (network of social relations/social structure) – that households depend upon in the context of livelihood strategies.

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Principle 2: Tobacco growers and workers should be engaged in policy development concerning Article 17&18 in line with Article 5.3 of the WHO FCTC and its guidelines

Tobacco growers and workers should be engaged in the process of policy development concerning Article 17&18 and involved in implementation, in accordance with national laws, through a bottom up and territorial approach, making sure that their involvement is insulated from the commercial and vested interests of the tobacco industry

In order to take full advantage of the existing resources, public policies and intersectoral approaches are required. To better address these and other aspects, the involvement of farmers in decision-making processes should be guaranteed by providing adequate channels for them to voice their needs and concerns.

Principle 3: Policies and programmes to promote economically sustainable alternative livelihoods should be based on best practices and linked to sustainable development programmes

A successful shift from tobacco growing to alternative economic activities requires profitability, the provision of technical assistance, research, capacity building, the promotion of community organization, and market and social support, with special emphasis on the transition period. Where appropriate, financial mechanisms should be developed.

The alternatives should be developed under the principles of promoting sustainable development and poverty eradication, enhancing the ability of growers to manage natural resources sustainably with lower negative environmental impacts, increasing resource efficiency and reducing waste.

Policies to promote economically sustainable alternative livelihoods should be comprehensive, multisectoral, and consistent with the objective of the WHO FCTC, which means taking into account not just the short-term economic viability of the tobacco leaf business, but also the many hidden and external costs of tobacco growing and processing. Governments should consider to avoid measures that encourage new entries into tobacco growing or that discourage existing growers from seeking alternatives. Where appropriate, funding mechanisms should include special institutional arrangements for promoting alternative crops, education, communication and/or training. Efforts should also be made to integrate such policies into existing government schemes or programmes to promote sustainable development.

Principle 4: The promotion of economically sustainable alternative livelihoods should be carried out within a holistic framework that encompasses all aspects of the livelihoods of tobacco growers and workers (including the health, economic, social, environmental and food security aspects)

Diversification activities need to be incorporated into the policies of agrarian development, through appropriate public policies that guarantee quality of life to growers and the agrarian population as a whole. Such policies should aim at taking full advantage of the existing regional and local resources.

Every tobacco grower has the right to be duly informed about the risks that tobacco growing poses to his or her health and to the environment and about how to prevent them (see also section 4.2). National programmes and policies to protect workers' health and the environment should also address the risks related to tobacco production.

Adequate human, material and financial resources are required to establish and sustain the promotion of alternative livelihoods at local, municipal, national/federal, regional and international levels.

Principle 5: Policies promoting economically sustainable alternative livelihoods should be protected from commercial and other vested interests of the tobacco industry, including leaf companies, in accordance with Article 5.3 of the WHO FCTC and its guidelines.

There is a fundamental and irreconcilable conflict between the interests of the tobacco industry and public health. The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death, and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation, implementation and funding mechanisms to implement Articles 17 and 18 of the WHO FCTC from the tobacco industry to the greatest extent possible. The tobacco industry should be liable to the extent proven for the health and environmental harms related to tobacco growing and all activities connected with tobacco growing and the supply chain, and for ensuring respect for human rights for those working in connection with tobacco growing and the supply chain.

Principle 6: Partnership and collaboration should be pursued in the implementation of these policy options and recommendations, including in the provision of technical and/or financial assistance.

Adequate human, material and financial resources, where appropriate, should be available to establish and sustain the promotion of alternative livelihoods at local, municipal, national/federal, regional and international levels. To ensure sustainability of the programme, existing funding sources should be used and other potential sources explored, in accordance with Article 26 of the WHO FCTC. Where appropriate, parties should also consider to create incentives for promoting, supporting or shifting to alternate livelihoods and to avoid incentives for tobacco growing.

International cooperation, mutual support, cost-effective technology transfer and sharing of information, knowledge and relevant technical capacity are vitally important for strengthening the capacity of Parties to meet their obligations under Articles 17 and 18 of the WHO FCTC and to successfully counter the socioeconomic and environmental consequences of tobacco production at all levels. The obligation to cooperate in the development of effective measures, procedures and guidelines for implementation of the Convention, to cooperate with international and regional organizations and to use bilateral and multilateral funding mechanisms, derives from Articles 4.3, 5.4, 5.5, 20, 21 and 22 and 26 of the Convention.

4. IDENTIFYING AND DEVELOPING EFFECTIVE STRATEGIES FOR ALTERNATIVE CROPS AND LIVELIHOODS AND FOR PROTECTING TOBACCO GROWERS AND THE ENVIRONMENT FROM HARMS RELATED TO TOBACCO PRODUCTION.

Some of the reasons why farmers rely on tobacco cultivation include the following:

- delivery contracts are established between tobacco growers and first processors that give “security” to tobacco raw leaf sales, in some cases, first processors offer loans and other incentives for the cultivation of tobacco, and the tobacco industry creates a zone of comfort by ensuring a market and supplies;

- many agricultural communities are completely dependent on tobacco production and in many cases there is, at the local level, a symbiotic relationship between politicians, managers and the tobacco industry, which may explain, at times, lack of sufficient political will to develop alternatives at the local level;

- the belief among tobacco growers and workers that net profit from the tobacco crop is higher than for any other crop;

- beliefs and cultural habits - in some regions tobacco cultivation is carried out by succeeding generations, along with the transmission of cultural habits;

- uncertainties about alternative income opportunities and market opportunities for alternative crops, and lack of resources to invest in alternative crops;

- farmers are conservative in regard to changing established practices; and/or

- in regions where irrigation is inadequate or where there are adverse soil and climatic conditions, tobacco is grown because of its drought resistance and because under these agricultural conditions the net profit of tobacco is believed to be more than for any other.

Recommendations

Diversification strategies should include both agricultural and non-agricultural opportunities, including shifting from one agricultural product to another. Substitution of one economic activity by another does not, however, fully address the problem of the poverty and vulnerability of tobacco growers and workers, typical of economic agents from the primary sector.

Diversification strategies should encompass a vision of sustainable development of the agrarian sector. It should include diversified productive systems, e.g. production to achieve food security, short supply chains linked with local markets, and a combination of agricultural and non-agricultural activities.

Diversification strategies should increase the portfolio of activities and offered products - enlarging access to markets as an alternative to the seasonal constraints and stagnation of agricultural income. The strategies should also promote innovation and technical improvements on farms in order to save resources through new forms of handling and use of plants, livestock and land. This would result in an increase in the number of activities undertaken and in resources at farm level.

Diversification strategies should promote new forms of cooperation and local interaction that would reflect on scale of profits and reduction of transaction costs. These changes should produce new levels of satisfaction among the farmers, promote greater interaction with consumers/clients, and ensure more flexibility for adaptation.

Diversification strategies should be market demand driven and policies pursued should be based on market dynamics.

Regions with local diversified economic strategies should create environments favourable to sectoral integration between agriculture, commerce, industry and services. The regional diversity should produce greater stability and reduce vulnerabilities resulting from labour market fluctuations and

sources of income. Economies of scale should reduce the costs of transaction and produce positive territorial externalities.

This transition period from tobacco growing to an alternative livelihood also demands the implementation of intersectoral initiatives that provide farmers with a broader array of resources and opportunities. Such initiatives should have a market orientation and not be based upon protectionist assumptions. This transition should promote development strategies that strengthen farmers' autonomy, diversify agricultural and non-agricultural incomes, transform the technical basis to allow a transition to agro-ecology, recover soil fertility and preserve biodiversity, produce territorial externalities, and pay attention to public health objectives.

4.1 Promoting research

Research should be undertaken where needed in a comprehensive way and should cover all elements linked with tobacco growing, including profitability, but also the health, environmental and socioeconomic costs. Furthermore, the quality of life that farmers obtain through producing different crops should be quantified and included in the analysis. The demand and market size of tobacco and other alternative crops need to be compared. Research should take into account the issues of environmental impact, development and poverty alleviation. Decision-makers need to be actively involved in the work of researchers. International organizations should also be encouraged to provide technical support to country-level research.

Research should include feasibility studies covering the following aspects:

(a) **Identification of the profile and main features of the tobacco sector and economics of raw tobacco production.** This should include, where appropriate, a complete survey of all activities related to tobacco growing, including: number of tobacco growers and workers, size of holdings and number of tobacco growers and workers per size class, amount of tobacco production per holding and size class, age and gender distribution of the tobacco growers and workers, education level of the tobacco growers and workers, the tobacco variety produced, the number of tobacco workers employed by the tobacco farms, and the number of working days for family members and tobacco workers.

(b) **Demand forecast studies on food crops.** For each country, where appropriate, a forecast should be undertaken of future food requirements, and the potential impact of food crops, vegetables, fruits or any other alternative crop, along with a price forecast for food commodities. Governments should also identify opportunities, such as existing programmes of food acquisition, where appropriate. Data of land-use patterns should be collected in tobacco- growing areas, to find out if land used for food crops has been transformed into tobacco- growing land or vice versa.

(c) **Environmental and health impact studies** where appropriate. Each country should compare the impacts of tobacco growing to those of alternative crops, in respect of the levels of deforestation, forest degradation, water pollution, soil erosion and infertility levels, climate change effects, impact on wildlife and other ecological effects. The impacts should be linked to the fertilizers and agro-chemicals being used on tobacco and non-tobacco farms, to identify key sources of concern that policies need to address. Health impact assessment related to tobacco production should also be included as part of national health surveillance programmes.

(d) **Economics of raw tobacco production** where appropriate. Up-to-date studies of tobacco economics for each region and variety should be undertaken, along with a study of tobacco prices at

farm gate level for each country and each variety. Research should also focus on the economics of shifting to alternative land uses, including factors for tobacco growing or not growing as the case may be.

(e) **Standard information set for alternatives.** Where appropriate, for each identified alternative, a set of standard information should be obtained, including information on agricultural requirements, yield, value-added chain, standards, market, prices, international trade and other economic factors. For each identified alternative, where appropriate, a full feasibility study should be prepared. Internationally recognized experts may be invited to provide the required policy inputs on specific alternatives.

(f) **Priority list.** Based on the information obtained from steps (a) - (e), a priority list for each tobacco-growing region can be established of those alternatives that may be considered for field trials.

(g) **Field trials.** Where appropriate, field trials can be used to establish the economic viability of alternative crops. They should be conducted in the field with tobacco growers and workers and not on an experimental basis in the agricultural fields of research institutes or universities. Regular studies on alternative crops need to be taken up simultaneously in the major tobacco-growing regions before any conclusion regarding crop shifting can be drawn. The field trials should follow a standardized approach and methodology.

(h) **Development of a business plan.** Where appropriate, once the field trials have been successfully concluded and the farmers convinced about the alternative, a business plan should be developed including the transformation of the raw products into value-added products (the value-added chain).

The involvement of relevant organizations, including nongovernmental organizations, is essential. Information and support centres (see section 4.8), where appropriate, should also be operative by this stage and included in planning, training, and delivering services, including the evaluation of the field trials.

All information derived from steps (a) to (h) will require standardization of methodology and approach, for example a standardized questionnaire, and should also be made available in an international database (see section 6.5). Efforts should be made to transform research into action. This should include undertaking further research to bridge knowledge gaps, improve and develop new applications and market studies, and in this way to improve the market opportunities for alternative crops in favour of the tobacco growers and workers. This can be a task, where appropriate, undertaken by the information and support centres.

Experiences, studies, projects, field trials, etc already made should be taken as well into account. The funds may be raised through various sources including revenues from tobacco, in accordance to national laws.

Expected results

1. Information obtained on the current situation and trends in the tobacco production and economic chain worldwide, based on a standardized questionnaire, including the number of people involved in all activities, types of labour, and tobacco growers' livelihoods, among other relevant information.

2. Updated studies prepared of the environmental and health impacts of tobacco growing by region in each country.

3. Updated forecasts obtained of the demand for various relevant crops in relation to food security by country.

4. Comprehensive database created of the economics of raw tobacco production by region and variety, based on a standardized methodology.

5. Economically viable alternatives to tobacco identified along with data related to their respective economic chains.

6. Priority list of alternatives to tobacco for the field trials defined for each country, supported by research results obtained by research institutes or universities, based on a standardized methodology.

7. Business plan developed regarding the value-added chain of each identified alternative to tobacco by country.

4.2 Developing educational and training programmes for workers and growers

It is essential to understand the composition of the target groups in terms of gender, age, ethnicity and education level, when developing educational programmes. Research should be conducted, where appropriate, in the affected countries, and before shaping educational programmes, two main points may be taken into account.

1. Training of trainers is the best means of providing the skills needed in relation to alternative crops for tobacco growers and workers. The purpose of "cascade training" is to pass knowledge and skills to colleagues who work at different levels (e.g. the district or local level). In order to teach a trainer how to train well, a "learning by doing" approach is best. Moreover, interaction is invaluable for effective training. Farmers' associations should be supported to develop the skills needed by farmers in the production of new crops.

2. Good Agricultural Practices (GAP) for the growing of economically viable alternative crops should be integrated into agricultural curricula and in farmers' field schools education/training in tobacco-growing regions and in the training programmes of competent authorities.[1] Tobacco growing, as is the case with other crops, should adhere to the concept of GAP, which is recognized, where applicable, in Parties in relation to all the operations in cropping systems, including soil management, pest management, water management, as well as the use and application of agrochemicals, fertilizers and machinery.

The educational programme should also follow the principles of sustainable development in its three dimensions (social, economic and environmental) and include the building of capacities for managing natural resources sustainably, and the managing of new activities with lower negative environmental impacts, increased resource efficiency and reduced waste.

[1] Good agricultural practices - a working concept. Rome: Food and Agriculture Organization of the United Nations; 2004 (FAO GAP Working Paper, No.5; http://www.fao.org/prods/gap/Docs/PDF/5- GAPworkingConceptPaperEXTERNAL.pdf).

Education programmes should include the dissemination of information on the harmful health and environmental effects of tobacco growing, as much for consumers as for tobacco growers and workers. Information should also be provided to farmers regarding the options available for alternative crops, vocations and livelihoods, technical support, net gains, and the health, social, and economic benefits.

4.3 Removing obstacles to diversification or the shift to alternatives to tobacco farming

The economic feasibility of alternative crops is often the key to inducing small tobacco growers and workers to switch away from tobacco production. However, since tobacco also generates substantial revenue for governments, especially local governments, the political will to promote crops alternative to tobacco may not exist even if an alternative cash crop is able to produce higher profit than tobacco for farmers. In some cases, the tobacco industry tries to pre-empt the implementation of Article 17 of the WHO FCTC by convincing local governments to join their proposed diversification programme, which could consist of growing a subsistence crop between tobacco harvest seasons.

Parties should, where appropriate, mitigate or remove any obstacles identified that prevent farmers from leaving tobacco farming, which may include tobacco-related debts, bonded labour, and/or child labour. Parties addressing such concerns include facilitating the creation of institutions to help in this regard, strengthening existing international instruments, such as ILO conventions, and providing the necessary options to farmers. There are three main obstacles:

1. Limited financial resources to maintain regional activities in states and municipalities. This barrier should be overcome by implementation of a long-term financial framework and/or by including diversification programmes in tobacco-growing areas in national rural development policy (see section 6.3).

2. Tobacco industry lobbying in legislatures and with policy-makers.

3. The socioeconomic situation of tobacco growers and workers. Most tobacco growers and workers, particularly in developing countries, have very limited land property or have access to arable land only through renting or share cropping. Therefore they need a crop with high profitability. In most cases, tobacco growers lack the funds to invest in their farms to make other crops viable. In addition many tobacco growers also receive loans and assistance from the first processors in concluding a supply contract for raw tobacco delivery. Such loans are strong incentives for the farmer to cultivate tobacco. It is possible that in any setting the farmers are vulnerable and trapped frequently by the tobacco industry in a vicious circle of debt. It is difficult to break that circle and it must be acknowledged as being one of the challenges to be overcome, mainly with the support of governmental programmes/policies.

4.4 Keeping coherence among the policies of different ministries/departments

Intersectoral coordination is desirable to ensure that all of the sectors involved in tobacco growing, support crop diversification and alternative livelihoods. Parties should make efforts to ensure coherence among the policies of different ministries/departments or equivalent bodies, in accordance with the WHO FCTC, to generate synergy in their activities.

Coherence and coordination among the various funding mechanisms and initiatives related to sustainable development are also crucial for supporting diversification in tobacco-growing areas.

Channels should be created for redirecting the funds into diversification and rural development activities, including alternative livelihoods. Public financing and incentives directly linked to tobacco growing should be discontinued, in accordance with national law and policies, taking into account possible adverse impact on tobacco growers.

Proposed actions

1. Tobacco-growing countries should not encourage and not provide any incentives to increase the acreage of land used for cultivating tobacco.

2. Tobacco-growing countries should consider reallocating public funds/subsidies used for tobacco production to alternative livelihoods activities.

4.5 Identifying and regulating tobacco industry strategies that promote tobacco farming and the manufacture of tobacco products

Where appropriate, Parties should develop policies that protect tobacco growers and workers from any tobacco industry practices that would fix prices or conditions that are disadvantageous to farmers, and from violations of labour rights and other malpractices carried out under the guise of "corporate social responsibility".

Civil society organizations can be important allies in monitoring and denouncing these malpractices.

Parties should, using appropriate instruments, create or improve regulatory mechanisms for the control and inspection of industry activities concerning labour relations and workers' health.

Parties should identify and regulate **crop production** practices that lead to environmental degradation. They should develop policies to promote farmers' autonomy, and apply corporate social responsibility rules in relation to farmers. It is important, therefore, to conduct awareness raising programmes for local partners and farmers on the benefits of alternative livelihood(s) in the short, medium and long term.

4.6 Mainstreaming alternative crops/livelihood options into government rural development programmes

Mainstreaming alternative crop and livelihood options, where appropriate, should be part of the wider agenda of governments and should be incorporated into multi-year planning in line with rural development policies and food security requirements. It is important to build mechanisms for promoting the effective participation of state and municipal governments, given their relevance to activities directly related to farmers. Governments should guarantee comprehensive and long-term governmental action in this regard, in line with Article 5 of the WHO FCTC.

4.7 Establishing mechanisms within the existing system to support alternative livelihoods

During the transition period from tobacco growing, the existence of public policies with intersectoral approaches is essential, in order to give full access to existing resources and opportunities. These policies must not assume any protectionist outline but should offer governmental support to the

farmers through mechanisms for strengthening the decision-making process and making easier the identification of challenges to be tackled and needs to be addressed.

Tobacco growers and workers should be involved in decision-making and must therefore be given adequate channels to voice their needs and concerns (see Principle 2 in *Guiding principles).*

The following is a non-exhaustive list of examples of measures that can be used to promote the shift to alternative livelihoods among tobacco growers and workers, as appropriate, in national settings.

- **Rural credit** (investment and defrayment of costs) - with an emphasis on credit for investment and with a grace period and terms consistent with the diversification or conversion programmes. Emphasis should be placed on credit programmes that enable value aggregation by the farmers themselves, by means of cooperative, associative or family agro-industries.

- **Food acquisition for food security programmes** - which should allow purchase for institutional markets (such as schools, hospitals and prisons), besides enabling purchases for simultaneous distribution and for the formation of buffer stocks.

- **Family farming price assurance** - as a way of securing income, and associated with family farming agrarian insurance.

- **Technical assistance and rural extension** - which should be comprehensive and qualified, and integrate state organizations, nongovernmental organizations and the farmers who are able to disseminate experience and knowledge.

- **Agrarian reform and credit** - taking into account the fact that many tobacco growers are partners and leaseholders, or owners of very small land areas.

- **Social and economic organization** - to find out which possible alternative crops/activities would be able to provide similar income to farmers or growers at similar levels of employment in tobacco-growing areas.

- **Infrastructure and services -** to ensure that tobacco growers willing to move from tobacco to other crops are given necessary support for this alternative value chain.

- **Crop and income insurance -** to create national crop insurance companies that promote economic stability of agriculture through a reliable and viable system of crop production.

- **Cooperatives** - programmes should be established to strengthen farmer cooperatives that facilitate the shift to alternative crops and livelihoods, especially through the involvement of nongovernmental organizations. It is strongly recommended that post-evaluations be conducted in respect of farmers who have successfully shifted to other crops, and that such information be made publicly available.

- **Promotion activities** – where appropriate, should be steered by a tobacco-alternative crops board, like the tobacco, coffee or tea boards that exist in some countries.

Productive diversification in tobacco-growing regions is a safe means of emancipating farmers from dependence on tobacco growing, especially the poorest ones. In order to successfully achieve this aim, the process must be sustained on the basis of: (a) the correct understanding of the decision-making process of farmers engaged in tobacco growing; (b) a strategy of intervention that encompasses actions supported by public policies that facilitate awareness raising and motivate farmers to enter into alternate livelihoods and new supply chains with sustained demands for their produce.

Appendix 2 describes the core elements of a methodological framework for building the dynamics of productive diversification in tobacco-growing regions.

4.8 Setting up information and support centres for alternative livelihoods

The need for alternative livelihoods for tobacco growers and workers differs among countries. The knowledge required for the cultivation, transformation, processing and marketing of food crops grown as alternatives to tobacco in the context of diversification for food security will usually be available in the countries concerned. The growing of already cultivated and known cash crops in these countries should also not present major problems. However, the growing of other alternative crops, such as those for biofuel, or new alternative cash crops, will require the establishment of information and support centres to provide cultivation and production expertise, technical assistance, market intelligence, and new varieties and breeds. The information and support centres should also act as background and reference laboratories.

As diversification of tobacco cultivation is a long-term task, financial support for the information and support centres undertaking this work should be ensured to be continued for several years to facilitate sustainable diversification and alternative livelihoods.

4.9 Ensuring the participation of civil society

The formulation, implementation and assessment of diversification programmes should involve the effective participation of family farming organizations and other civil society organizations that support the objective of the WHO FCTC. Nongovernmental organizations are likely to play an important role in the process of participatory planning in the methodological framework for building the dynamics of productive diversification in tobacco-growing regions (see Appendix 2).

Nongovernmental organizations can also be important allies in working in partnership with farmers to disseminate information about the numerous hidden economic, environmental and social costs of tobacco growing, besides monitoring and denouncing the abusive practices of the tobacco industry. They can also help farmers gain access to institutional and technical support and facilitate the creation of self-help groups and cooperatives, as well as disseminating the concept of agro-ecology among farmers.

4.10 Ensuring social, health and environmental protection in tobacco-growing regions

- **Tackling child labour and promoting decent work in tobacco-growing regions.** Any existing bonded labour or child labour in tobacco growing should be opposed and if possible ended. There are several relevant international instruments. Where applicable, Parties should promote the ILO Decent Work Agenda, and apply to the tobacco growing and industry the fundamental ILO conventions on the subject, Conventions 29 and 105, as well as Convention 182. These instruments

deal with the prohibition of forced or compulsory labour in all its forms, including for children aged less than 18 years. Parties should, if they have not yet done so, adapt their domestic legal frameworks to comply with relevant international instruments. They should reinforce labour inspections and sanctions against violations of such provisions in the agricultural sector, including tobacco. Simultaneously, solutions to this problem could be addressed by investigating and improving price-setting mechanisms (through collective bargaining and better contract practices, including the introduction and enforcement of labour rights in contracts). Further efforts should also be made to eliminate the exploitation of children and women, in particular.

- **Protecting tobacco growers' and workers' health.** Data generated by research on the harms caused by tobacco growing should be compiled and shared with all relevant stakeholders, including farmers. Effective education, communication and public awareness programmes on the occupational risks related to tobacco growing should be developed through a comprehensive multisectoral approach.

Initiatives in this area should include programmes of family health and training of community health workers in prevention, early diagnosis and treatment of cases of green tobacco sickness, pesticide poisoning, and other health problems related to tobacco growing.

Tobacco-growing harms should be included in the list of occupational diseases in the national public health system as well as in domestic legislation on security and health in rural work.

- **Protecting the environment from the harms of tobacco growing.** Parties should undertake, where appropriate, initiatives to monitor deforestation, and soil and water contamination with pesticides in tobacco-growing areas. Awareness-raising campaigns and educational programme on the harms posed by tobacco production to the environment should also be developed as part of national initiatives to promote diversification of production in tobacco-growing areas. In line with national law on environmental protection, Parties should undertake measures to prevent or to recover areas already damaged by tobacco production.

5. MONITORING AND EVALUATION

Monitoring and evaluation are key elements of the planning process for implementation of Articles 17 and 18. Article 17 aims to promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers in order to reduce economic dependence on tobacco. Article 18 aims to mitigate the health and environmental harms related to tobacco production.

For each policy to be implemented it is necessary to identify and diagnose the baseline situation which the policy is addressing to achieve a positive change. It is also important to identify who or what is affected by the problem, the needs among stakeholders and potential barriers to policy implementation, as well opportunities to overcome them. The measurable effects caused by the problem that could be mitigated by the intervention by the Party should be identified and monitored. It is also important to identify indicators against which the progress made by the policy/programme towards its main objectives can be monitored.

This involves using a systematic method for collecting, analysing, and using information to answer questions about the implementation of the policy/programme, and particularly about its expected

outcomes aiming at achieving continuous development and improvement.

In this context, three kinds of indicators are needed to monitor and evaluate progress in the implementation of Articles 17 and 18:

- situation analysis - baseline assessments;
- process to be undertaken to change the situation; and
- expected outcomes.

The monitoring elements presented in this chapter are only examples and are by no means exhaustive.

5.1. Implementation of Article 17 - development of an alternative livelihood model

For a complex task, such as implementing the methodological framework for building the dynamics of productive diversification in tobacco growing regions (see Appendix 2) within an agreed period of time, a good evidence base is a fundamental requirement. A first step is to make an analysis of the baseline situation of the problems to be addressed by the policy and to capture the elements needed to develop a strategic plan such as barriers and opportunities, including market information, region-specific conditions, and a better understanding of how farmers will decide on diversification alternatives, among other elements.

The following is a schematic example of a possible framework.

5.1(a) Conducting a baseline analysis of the problems to be addressed by the policy

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
Which data/research have been collected/undertaken in your country to obtain a better understanding of tobacco production economics, such as profitability, extent of land used, and characteristics/ dynamics of the tobacco productive chain?	Collect data for an inventory on the use of land for tobacco and for other crops and rural activities. Collect data on the economics of tobacco production in each region, including price monitoring and characteristics of the tobacco productive chain. Undertake modelling evaluation of socioeconomic impact of tobacco growing, including the impact on income, labour, health and environment for each tobacco growing region.	Analysis of the acreage of land used for tobacco, and for other crops and rural activities. Comprehensive database of the economics of raw tobacco by region and variety. Comprehensive analysis of how the tobacco production chain is organized.

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
Are there any data on the labour market in tobacco growing in your country?	Collect data on labour involved in tobacco and in other rural activities and the level of economic dependence on the tobacco productive chain among farmers.	Data on how many farmers are involved in tobacco growing, including their level of economic dependence on the tobacco productive chain.

5.1(b) Analysis of the main barriers and existing opportunities to be considered in the design of a strategic plan for implementation of Article 17

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
Are there any demand forecast data on food crops and on other rural activities to support diversification in your country?	Collect data and undertake modelling demand forecast.	Updated forecast of the demand for crops in relation to food security in the country.
Is there any standard information set for potential alternatives to tobacco growing in your country?	Develop feasibility studies on potential alternatives to tobacco growing, considering agricultural requirements, climate conditions, yield, value-added chain, standards, market, prices, international trade and other economic factors, and health, social and environmental impact. Develop field trials to establish economic viability of alternative crops. Conduct modelling evaluation of the socioeconomic impact of potential alternatives to tobacco growing including their impact on income, labour, health and the environment, for each tobacco growing region.	Standard information set for potential alternatives to tobacco growing. Models for implementing alternatives crops or other activities including an impact analysis of labour demand by alternative livelihood models in tobacco growing regions.
Which data/research were collected/ undertaken to acquire a better understanding of the livelihoods of tobacco	Map the key stakeholders in tobacco production and alternative activities. Conduct surveys among tobacco growers, policy-makers and other key	Analysis of the socioeconomic profile of tobacco growers and on their decision-making process as well as on the current relationship among stakeholders

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
growers and to map obstacles for diversification in your country? (see methodological framework **provided in Appendix 2)**	stakeholders in order to capture their beliefs, attitudes, behaviour and decision-making processes on tobacco growing and shifting to other activities. Perform needs assessment through research and regular consultation with stakeholders and with the people that will benefit from the policy, in a bottom-up approach to identify the needs and potential barriers to be overcome.	in tobacco production and in potential alternative activities. Analysis of the main barriers and opportunities to be considered for the strategic plan to promote alternatives to tobacco.
Which mechanisms exist in your country to support farmers and agricultural development? How accessible they are to farmers?	Collect information on how these mechanisms could or already operate to support diversification in tobacco growing regions. Collect data on how many tobacco growers and workers have already being supported by these mechanisms for diversification activities. Collect data on knowledge and perceptions of tobacco growers and other stakeholders on these mechanisms as well as on the existence of barriers to access them.	Analysis of the existing mechanisms to support diversification in tobacco growing areas, on how they are accessed by farmers, and on the numbers of tobacco growing farms that benefit from these mechanisms.
Does your country have information and support centres for alternative livelihoods for tobacco growing regions?	Collect information on the activities that the support centres undertake to promote alternative livelihoods in tobacco growing regions.	Report on the implementation of information and support centres in tobacco growing regions.
Does your country have a national programme to promote food security? Does it purchase food for institutional markets such as public schools, hospitals, prisons?	Collect data on national programmes to promote food security and purchasing policies.	Updated information on the existence of national programmes to promote food security and their potential to purchase products that result from the diversification process in tobacco growing areas.

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
Does the tobacco industry have channels to influence tobacco farming as part of agricultural development policies?	Take steps to insulate the agricultural policy from tobacco industry interference. Disseminate information on Article 5.3 as an obligation under the WHO FCTC, including in relation to implementation of Articles 17 and 18.	Increased level of awareness among tobacco growers and other stakeholders of Article 5.3, the guidelines for its implementation and its rationale.
Does your country have a national programme to promote and support diversification of activities in tobacco growing regions?	Collect information on existing national diversification programmes, what/who are the key institutions and actors, what are the main objectives and goals, how many tobacco growers have already been benefited, how are they financed and how much are their yearly budgets. Collect information on how these policies are disseminated among tobacco growers and other stakeholders. Develop and implement a national policy for implementing Article 17. Mainstream the national plan/programme/policy into the governmental rural development agenda and food security programmes.	Report on the implementation of the national programmes for diversification in tobacco growing areas. Number of tobacco growers shifted to alternative crops and other livelihoods. Level of dependence on the tobacco productive chain among the remaining tobacco growers. Improving human and working capital. Improved livelihood Better working conditions.
Does your country have a national programme to promote and support diversification of activities in tobacco growing regions?	Implement a long-term financial framework for the policy. Develop educational and training programmes for tobacco growers. Provide technical assistance and rural extension. Ensure the participation of civil society in line with Article 5.3 of the WHO FCTC.	Amount of tobacco acreage shifted to alternative crops or other activities. Number of tobacco growers and workers educated and trained (increased level of awareness and knowledge).

5.1(c) Suggested Impact indicators for Article 17

- Number or percentage of tobacco growers impacted by these measures by diversification strategies and measures, fully shifted to alternative crops and other livelihoods.

- Number or percentage of tobacco growers impacted by these measures by diversification strategies and measures partially shifted to alternative crops and other livelihoods.
- The number of programs and policies that promote alternative livelihood for tobacco growers and workers
- Any other indicators showing changes of economic and social status impacted by these measures

5.2 Implementation of Article 18

Article 18 addresses health and environmental impacts related to tobacco production as well as social issues. Regarding the environment, a standardized approach should be developed by Parties for conducting audits of the environmental impact of tobacco growing, to be carried out in all countries concerned, to enable the correct actions to be carried out to achieve the positive effects expected. Information and support centres located in regions where tobacco is grown would enable growers to learn about the effects of tobacco on the environment as well as on their health and economic status. Initiatives to rehabilitate the affected regions, should be promoted, as appropriate, including reforestation programs. For the known health risks related to tobacco farming it is important to have a baseline analysis of the prevalence of green tobacco sickness and of other harms related to tobacco production so that the impact of the actions to be performed in relation to Article 18 can be monitored. For identified alternatives, environmental assessments should be also conducted to prevent a negative (their) environmental and health impact compared to tobacco.

The first step to achieving these aims is to analyse the baseline situation of the problems that will be addressed by the implementation of Article 18, as well as an analysis of the main barriers and existing opportunities to be considered in the design of a strategic plan for implementation of this policy. It is important to highlight the fact that the simultaneous implementation of Articles 17 and 18 should create synergy in motivating and supporting growers in moving towards diversification. All results of environmental audits and health data collection related to tobacco production and to identified alternatives should be made available through an international database. The following is a schematic example of a possible framework.

5.2(a) Making a baseline analysis of the problem to be changed by the policy

Situation analysis (How is it now?)	Process (Actions required to address the situation)	Outcome (Measurable progress)
Has your country executed studies on the health impact related to tobacco production in your country?	Collect data and information or develop studies on the impact of tobacco production on farmers' health.	Data concerning prevalence of green tobacco sickness and other harms related to tobacco production. Data concerning prevalence on use of personal protective equipment among tobacco farmers.

Situation analysis (How is it now?)	Process (Actions required to address the situation)	Outcome (Measurable progress)
Has your country executed studies on the environmental impact of alternatives to tobacco growing?	Model the impacts of alternative crops on fertilizer demand, pesticide use and deforestation in comparison with tobacco growing.	Impact analysis of the environmental impact of alternatives to tobacco growing.
Are there any data or information on the social impact of tobacco growing in your country?	Collect data on child labour and conditions of work involved in tobacco production.	Data on child labour and conditions of work involved in tobacco production.

5.2(b) Analysis of the main barriers and existing opportunities to be considered in the design of a strategic plan for implementation of Article 18.

Situation analysis (How is it now?)	Process (Actions required to address the situation)	Outcome (Measurable progress)
Does your country have a national programme or policies to address occupational risks related to tobacco growing and manufacturing?	Collect information on existing national initiatives to manage green tobacco sickness and other harms related to tobacco production as part of the national health workers policy or programme. Educate tobacco growers on the harms related to tobacco production. Promote or enhance the inclusion of green tobacco sickness and other harms related to tobacco production as part of national workers health policy or programme.	Harms and diseases related to tobacco production included as part of national health workers policy. Increased knowledge of health risks related to tobacco production and the use of personal protective equipment among tobacco growers and workers. Decrease in the prevalence of green tobacco sickness and other harms related to tobacco production.
Does your country include tobacco production in the inspection of compliance to national labour laws?	Include tobacco production in the national inspection of labour codes. Involve civil society organizations in monitoring of malpractices.	General improvement in the fairness of labour contracts and labour conditions in the tobacco productive chain.

Situation analysis (How is it now?)	**Process (Actions required to address the situation)**	**Outcome (Measurable progress)**
Does your country have a list of allowed pesticides for use in tobacco cultivation?	Compile such a list for pesticide use in tobacco cultivation according to environmental and toxicological risk assessment. Check the list to see if the allowed pesticides for tobacco cultivation is in accordance with the latest environmental and toxicological risk assessment.	Reduced environmental impact as the list of allowed pesticides for use in tobacco cultivation is updated according to the latest information on environmental and toxicological risk assessment.
Does your country have a monitoring system for soil and water contamination by pesticides and fertilizers.	Execute a monitoring in tobacco growing regions and compare it with other regions where tobacco is not grown.	Impact analysis on soil and water contamination.
Has your country executed studies on the extent to which deforestation or forest degradation is due to tobacco cultivation?	Collect data and quantify deforestation and forest degradation due to tobacco cultivation (change of land use and for curing purposes).	Impact analysis of deforestation and forest degradation based on tobacco cultivation requirements.
Does your country have a national programme or policy or legislation on environmental protection?	Collect information on existing national initiatives and legislation to audit and mitigate environment harms. Promote the inclusion of tobacco growing areas in the list of areas to be audited by national programmes to mitigate environmental harms.	Tobacco production audit included in legislation, programme or policy controlling deforestation, water and soil contamination and the amount of pesticide residues in or on tobacco crops and the contamination of the tobacco crops and fertilizers by heavy metals. Reduction in forest degradation and deforestation, and improvement of the conditions of natural resources and the environment in tobacco-growing areas as well in the alternative crops areas.

5.2(c) Suggested impact indicators for Article 18

1. Prevalence of green tobacco sickness and of other harms, e.g. pesticide poisoning, specifically linked to tobacco production in tobacco growing areas.

2. Number or percentage of child labour in tobacco growing areas.

3. Percentage of the loss of forest area due to forest degradation and deforestation in tobacco growing areas and in alternative crop areas.

6. INTERNATIONAL COOPERATION

Parties to the WHO FCTC have already made several important commitments with respect to international cooperation, including those found in Article 4 (Guiding principles), Article 5 *(General obligations)*, Article 19 *(Liability)*, Article 20 *(Research, surveillance and exchange of information)*, Article 21 *(Reporting and exchange of information)*, Article 22 *(Cooperation in* the scientific, technical, and legal fields and provision of related expertise), and Article 26 *(Financial resources)*.

International cooperation should also be guided by the provisions of United Nations General Assembly resolution A/RES/66/288, "The future we want".

In the context of the commitments contained in the WHO FCTC and of these policy options and recommendations, international cooperation should include the aspects described below.

6.1 Promotion of opportunities for economically sustainable livelihoods and development of markets in the context of sustainable development and poverty eradication

Parties should exchange information and experiences, including best practices, to promote economically sustainable alternative livelihoods. Parties should also make efforts to establish relationships with actors in domestic, regional and global markets, with a view to understanding the relevant supply and demand considerations, including the market requirements for alternative crops. Any alternative crop should be in harmony with efforts to ensure sustainable management of natural resources.

6.2 Cooperation with relevant national, regional and international organizations

Parties may consider, in cooperation with relevant national, regional and international organizations, neither encouraging nor promoting tobacco production, in line with Article 5.3 of the WHO FCTC.

International cooperation should facilitate mechanisms for implementation of alternatives to tobacco growing and should also promote global efforts to ensure higher production of agricultural commodities and therefore enhance food security.

Proposed actions:

1. Regional and international organizations, within their respective mandates, , upon request,

support tobacco-growing countries in implementing alternatives to tobacco growing including, when necessary the convergence of global efforts to ensure higher production of food commodities.

2. Regional and international organizations, within their respective mandates, upon request, support and cooperate with tobacco-growing countries in reinforcing or strengthening the implementation of relevant existing and applicable international instruments relating to labour, the environment, health and human rights.

6.3 Assistance and cooperation in capacity building

Parties should cooperate with each other directly and/or through competent international organizations, in providing training and technical and financial assistance, and should cooperate in scientific, technical and technological matters, including the transfer of expertise or appropriate technology in the field of economically alternative livelihoods, such as crop production and market intelligence. It is important that international organizations with specific expertise participate in capacity building for economically sustainable alternative livelihoods, especially agencies that have recognized expertise in this area, such as the Food and Agriculture Organization of the United Nations (FAO), the International Fund for Agricultural Development (IFAD), Worldbank, UNCTAD and ILO. Parties may request support from competent international organizations.

Parties are encouraged to enter into bilateral, multilateral or any other agreements or arrangements in order to promote training, technical assistance and cooperation in scientific, technical and technological matters, taking into account the needs of developing country Parties and Parties with economies in transition. Financial resources are an essential part of such cooperation. Parties are also encouraged to allocate funds to promote alternatives to tobacco growing, as the case may be, considering that currently governments have allocated less than 0.5% of global tobacco tax revenue.

Proposed action: Parties should implement the measures proposed in Article 26 of the WHO FCTC *(Financial resources)*.

6.4 International information exchange

Parties should, in cooperation with relevant international organizations and the Convention Secretariat, establish and implement an information exchange system on sustainable alternative livelihoods and global tobacco leaf demand. This information exchange would draw on official information made available by Parties and international organizations and should be coordinated by the Convention Secretariat. This should lead to the creation of a database or similar resource on available best practices in different countries, so that these experiences may be used by other countries. Parties should use the WHO FCTC reporting instrument to report on implementation of Articles 17 and 18 of the Convention within the framework of the already established reporting cycle.

Expected results: Information available in Parties' implementation reports on best practices in relation to Articles 17 and 18 is made available to Parties for further research.[1]

[1] The database is available at http://apps.who.int/fctc/reporting/database/.

6.5 International cooperation and the role of the Convention Secretariat

The Convention Secretariat facilitates collaboration between Parties and intergovernmental and nongovernmental organizations, and should ensure that it does so in regard to the effective implementation of Articles 17 and 18. The Secretariat should invite international organizations with specific expertise in this area to participate in the activities of the working group or other future intergovernmental mechanisms established by the COP, especially agencies that have recognized expertise in this area, such as FAO. The Secretariat should also work with relevant networks and institutions, in different geographical settings and in cooperation with FAO and other international organizations that are engaged in research on alternative crops, at global, regional and subregional levels. The Convention Secretariat should coordinate information exchange, which would draw on official information made available by Parties and international organizations. In order to bring synergy to such activities and efforts, the Secretariat should actively engage interested Parties and to appropriate institutions and networks in order to facilitate a systematic and comprehensive approach to implementation of Articles 17 and 18.

APPENDIX 1

PROPOSED LIST OF STANDARDIZED TERMS IN RELATION TO ECONOMICALLY SUSTAINABLE ALTERNATIVES TO TOBACCO GROWING

• **Cropping system:**[1,2] Describes how a producer grows crops. Cropping systems include: crop rotation, multiple cropping, mixed-cropping, strip-intercropping and related agronomic practices.

• **Diversification:** The creation of a strategy portfolio that allows the reduction of dependence on a single crop and instability in the process of reproduction caused by faults in production activities, such as losses of harvest due to droughts or floods, and the variability of seasonal income throughout the year.

• **Economically sustainable alternatives:** Aim to meet human needs while preserving the environment so that these needs are met not only in the present, but also for generations to come.

• **Environmental audit:**[1] A process to verify the effectiveness of the environmental management programme, ensure that environmental objectives and targets are being met, and evaluate how the environmental management system should be modified and expanded in the context of future business expansion, new environmental legislation, and emerging environmental issues.

• **Environmental impact assessment:**[2] A procedure for evaluating the likely impact of a proposed activity on the environment.

• **Environmental monitoring:** Site-specific continuous assessments of changes to environmental quality.

• **Environmental restoration:** Deliberate attempt to speed recovery of damaged ecological areas.

• **First processor or leaf company:** Buyer of the raw tobacco from farmers for a first transformation of the tobacco leaves, grading the raw tobacco into different qualities.

• **Food security:**[3] The availability of food and people's access to it.

• **Good Agricultural Practices:**[4] Practices that ensure that agricultural products are of high quality, safe and produced in an environmentally and socially responsible way.

• **Green tobacco sickness:** Nicotine poisoning that results from the absorption of nicotine through the skin from contact with tobacco plants during cultivation and harvesting. Nicotine is a water and lipid-soluble alkaloid that dissolves in any water on the leaves of the green tobacco plant.[5]

• **Human capital:** The stock of competencies, knowledge and personality attributes embodied in the ability to perform labour so as to produce economic value; the attributes gained by a person through education and experience.

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[1]Source: United Nations Environment Programme.

[2]Source: United Nations Environment Programme.

[3]Trade reforms and food security. Rome: Food and Agriculture Organization of the United Nations; 2003.

[4]World programme for the census of agriculture: A system of integrated agricultural censuses and surveys (FAO Statistical Development Series). Rome: Food and Agriculture Organization of the United Nations; 2005.

[5]Arcury TA, Quandt SA. Health and social impacts of tobacco production. Journal of Agromedicine. 2006;11:71-81.

• **Impact on the environment:**[1] Any effect caused by a proposed activity on the environment including on human health and safety, flora, fauna, soil, air, water, climate, landscape and historical monuments or other physical structures, or the interaction among these factors; it also includes effects on cultural heritage or socioeconomic conditions resulting from alterations to those factors.

• **Individual capacities/capabilities:** A process through which individuals strengthen and maintain their capabilities to set and achieve their own development objectives over time.

• **Intercropping** is the practice of growing two or more crops in proximity. The most common goal of intercropping is to produce a greater yield on a given piece of land by making use of resources that would otherwise not be utilized by a single crop.

• **Row cropping** involves arranging the associated crops in rows whereby one crop is alternated with one or multiple rows of another crop.

• **Crop rotation** is the practice of growing a series of dissimilar/different types of crops in the same area in sequential seasons. Crop rotation gives various benefits to the soil. A traditional element of crop rotation is the replenishment of nitrogen through the use of green manure in sequence with cereals and other crops. Crop rotation also mitigates the build-up of pathogens and pests that often occurs when one species is continuously cropped, and can also improve soil structure and fertility by alternating deep-rooted and shallow-rooted plants.

• **Intersectoral approach:** Works across different sectors - social, economic and institutional.

• **Livelihoods:** Refers to the process in which rural families build a diversified portfolio of activities and abilities of social support in order to survive and improve living conditions.

• **Productive system:** A system that transforms inputs into an output. Inputs into a productive system include human resources, land, equipment, buildings and technology. Outputs include the goods and services that are provided for customers and clients.

• **Tobacco crop:** Cultivation of *Nicotiana tabacum* and *Nicotiana rustica* for sale either under a contractual arrangement, non-contractual arrangement\open-market or a quota system.

• **Tobacco industry:**[2] Tobacco manufacturers, wholesale distributors and importers of tobacco products.

• **Tobacco products:**[3] Products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.

Tobacco worker: A person working on a tobacco farm, in tobacco processing, or tobacco or bidi manufacturing, with or without a contractual arrangement based on the labour laws of the country in which s/he is employed.

[1] Source: United Nations Environment Programme.

[2] Definition taken from the WHO FCTC.

[3] Definition taken from the WHO FCTC.

APPENDIX 2

METHODOLOGICAL FRAMEWORK FOR BUILDING THE DYNAMICS OF PRODUCTIVE DIVERSIFICATION IN TOBACCO GROWING REGIONS

1. Introduction

This appendix aims to present the core elements and the sequence of the actions of a methodological template for productive diversification in tobacco growing regions. This methodology is based on the premises that farmers should be free to build life projects that emancipate and fulfil them, that this intent must be supported by public policy and that the success of redesigning productive systems depends on the active participation of relevant social and economic actors.

2. Methodological guidelines

2.1 Bottom-up approach

Considering that the decision to undertake productive diversification is, first and foremost, to be taken by the farmers, there is no possibility of success without their participation in setting the strategy to be followed.

2.2 Networks of stakeholders

Agriculture is not an isolated socio-productive phenomenon, but a phenomenon involving different and interdependent social agents articulated around supply chains and local conglomerates. Thus, a process of productive diversification involves, besides farmers, a number of other subjects, which may have congruent interests and, to the extent that they are called upon to participate, are able to join forces for constructing new chains and marketing channels.

2.3 Integration of different levels of government (local, regional and national)

Productive diversification requires a range of supporting policies and actions that encompass all levels of government, in order to join efforts and leverage resources for reaching more meaningful results.

2.4 Participatory planning and implementation

The success of this process depends on the active participation of relevant socioeconomic factors and actors at all stages. Thus, its implementation must be triggered on the basis of a set of articulations that select, prioritize and commit the parties to the planned strategy with the participation of all relevant stakeholders.

2.5 Territorial approach

While working with diversification, it should be clear that the various agricultural products fall into chains of production and consumption, which in most cases reach beyond the local circuit. Thus, both in terms of allocation of resources and scale of production, infrastructure and distribution, as well as the viability of markets for the products, the territorial regional approach allows stakeholders to involve and mobilize the necessary resources.

2.6 Ongoing monitoring and evaluation

The productive diversification, according to the methodology in question, is embodied in a participatory process that triggers a set of activities, which, in turn, are dependent on public policy. Therefore, as they involve different actors with different responsibilities and expectations, ongoing monitoring and evaluation are essential to ensure ongoing participation and commitment of the parties, with benchmarking and rescheduling of activities.

3. Getting started in the process: chaining actions

3.1 Mobilization

Considering that participatory planning, monitoring and evaluation are core elements of this methodological framework, its starting point depends on a presentation of the purposes and strategies for productive diversification, seeking convergences of interests among stakeholders of the communities involved.

Therefore both awareness raising by mass media (radio, television, press, etc.) and visits to civil society organizations and farms should be employed to raise awareness and provide information. As a general guideline, it is important to seek collective debate and dialogue in spaces such as community meetings, meetings with civil society organizations, meetings with representatives of local government, etc. Once information and procedures are agreed among stakeholders, a common agenda for action and monitoring should be established.

3.2 Analysis of the situation

To reach the objectives of productive diversification it is crucial to have specific information for the identification of goals, resources, responsibilities, deadlines, etc. Thus, the planning should start from an analysis of the agrarian system of tobacco growers and workers. Based on this information, an analysis should be made of the decision-making process of farmers, taking into account their plans, constraints, perspectives, orientation on tobacco growing, and possibilities.

From this perspective, it is important to consider that, on the one hand, the productive systems employed by farmers derive from objective parameters such as availability of means of production and profitability of crops, and on the other hand, from subjective and social questions.

Such an analysis can be developed by using a questionnaire, and, if experimental data are available, carrying out an impact assessment addressing multidimensional issues through the following key parameters:

- family composition;
- availability of natural resources;
- availability of means of production;
- agricultural and livestock production systems on the property (except tobacco);
- subsistence goods produced;

- financial income from the marketing of different products (other than tobacco);
- system of production and financial performance related to tobacco;
- access to services and public policies;
- access to credit and other banking services;
- organization and social participation;
- economic and social partners;
- family and community values and priorities;
- health status, labour and the environment;
- satisfaction with their present condition;
- plans for the property.

3.3 Information sharing and participatory planning

After data from the questionnaire and from mobilization meetings are tabulated and analysed, a strategy should be pursued to share these data with the stakeholders in communities, according to a logic of successive involvement that could lead to referential and territorial planning, which identifies:

- situation analysis;
- prioritization;
- strategies and activities;
- goals and deadlines;
- sources of funds;
- framework of public policies;
- roles and responsibilities;
- process of monitoring, evaluation and reprogramming.

3.4 Participatory implementation

Considering the information coming from the debates in communities and territories and the establishment of a steering group for the territorial planning of productive diversification, stakeholders involved in this management process are responsible for promoting the consolidation of collaborative networks and partnerships with social subjects and public officials to provide the requisites for setting up a dynamic.

All stakeholders at community level and public officials shall participate in the implementation and management of alternative livelihoods in an open, transparent and participatory manner. The participation shall be facilitated by all relevant information, inputs and incentives.

Sensitization and training of social workers and farmers are the conductors of the process, which, given the active social participation, should move towards the government for allocation of public policies to support productive activities prioritized in discussions with the communities.

3.5 Continuous monitoring, analysis, evaluation and initiation of a new cycle of actions

The territorial process of productive diversification in tobacco growing regions should include the establishment of a steering group to coordinate and monitor the implementation of activities. This monitoring should be done in a coordinated way among all stakeholders and communities involved, providing instruments to collect data for evaluation and especially ensuring the hierarchy of community meetings to review results and re-programme actions. Thus, prioritization of social participation, and community ownership and transparency of information, can encourage dynamic sustainability of livelihoods diversification in a sustainable manner.

Item 4.6

Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC

The Conference of the Parties (COP),

Taking into account Article 7 (*Non-price measures to reduce the demand for tobacco*), Article 9 (*Regulation of the contents of tobacco products*) and Article 10 (*Regulation of tobacco product disclosures*) of the WHO FCTC;

Recalling its decision FCTC/COP1(15) to establish a working group to elaborate guidelines for implementation of Article 9 and Article 10 of the WHO FCTC, and its decision FCTC/COP2(14) to extend the work of the working group to include product characteristics, such as design features, to the extent that they affect the objectives of the WHO FCTC;

Recalling its decision FCTC/COP4(10) to adopt partial guidelines for implementation of Article 9 and Article 10 of the WHO FCTC, and its decision FCTC/COP5(6) to adopt further partial guidelines, and to mandate the working group to continue its work;

Noting the progress report of the working group to the COP at its sixth session (document FCTC/COP/6/13) and its Annexes, which contain proposals for consideration in relation to possible future work on the partial guidelines, entitled Constituents – Disclosure (Annex 1), Emissions – Disclosure (Annex 2) and Use of terms – Constituents (Annex 3); and

Recognizing the significant work of the laboratories that have contributed, through the WHO Tobacco Laboratory Network, to the validation of analytical chemical methods,

1. WELCOMES the report of WHO's Department for Prevention of Noncommunicable Diseases to the COP on the work in progress in relation to Articles 9 and 10 of the WHO FCTC (document FCTC/COP/6/14);

2. REQUESTS the Convention Secretariat:

(a) to make accessible, via the WHO FCTC website, the standard operating procedures and related documentation published by WHO;

(b) to invite WHO to:

(i) finalize, within one year, the validation of the analytical chemical methods for testing and measuring cigarette contents and emissions in accordance with the progress report presented by WHO to COP at its fifth session (document FCTC/COP/5/INF.DOC./1);

(ii) assess, within two years, whether the standard operating procedures for nicotine, tobacco-specific *N*-nitrosamines (TSNAs) and B[a]P in cigarette contents and emissions

are applicable or adaptable, as appropriate, to tobacco products other than cigarettes, including smokeless tobacco and waterpipe smoke;

(iii) prepare a report based on scientific evidence on specific cigarette characteristics of interest, including slim/super slim designs, filter ventilation, and innovative filter design features including flavour-delivering mechanisms such as capsules, to the extent that those characteristics affect the public health objectives of the WHO FCTC, for consideration by the working group at its first meeting following the sixth session of the COP;

(iv) continue to monitor and follow closely the evolution of new tobacco products;

(v) prepare a report on the toxic contents and emissions of waterpipe and smokeless tobacco products;

and

(vi) report back to the COP through the Convention Secretariat;

3. DECIDES to mandate the working group to:

(a) continue its work in elaborating guidelines in a step-by-step process, and to submit draft partial guidelines or a progress report on the disclosure, testing and measuring of contents and emissions to the next session of the COP, taking into account:

(i) the analytical chemical methods for testing and measuring cigarette contents and emissions validated by WHO; and

(ii) the draft text prepared by the Key Facilitators followed by discussions of the working group at its eighth meeting;[1]

(b) explore possibilities for defining "constituents" in a way that is meaningful and acceptable to the COP, taking into account the alternative possible definitions discussed by the working group at its eighth meeting[2] and continue work on other definitions in the area of product regulation;

(c) continue to monitor areas such as dependence liability and toxicology, including for smokeless tobacco products and waterpipe tobacco products, and in particular take stock of information obtained from WHO in relation to these areas, examine relevant issues, and report back to the next session of the COP;

(d) consider specific cigarette characteristics of interest, including slim/super slim designs, filter ventilation, and innovative filter design features including flavour-delivering mechanisms such as capsules, to the extent that those characteristics affect the objectives of the WHO FCTC,

[1] See Annexes 1 and 2 of document FCTC/COP/6/13.

[2] See Annex 3 of document FCTC/COP/6/13.

and submit further draft partial guidelines or a progress report in relation to these issues to the next session of the COP;

4. INVITES Parties, international, regional and subregional organizations, international financial institutions and/or other development partners to assign resources to, and to coordinate, the conduct of research that would support Parties in implementing Articles 9 and 10 of the WHO FCTC;

5. ENCOURAGES Parties to address infrastructure and capacity issues for laboratories, including on a regional basis, and share best practices and tools used in the disclosure of contents and emissions of tobacco products;

6. ALSO DECIDES, in accordance with decision FCTC/COP4(10):

(a) to request the Convention Secretariat to provide assistance and make the necessary arrangements, including budgetary arrangements, for the working group to continue its work, and to ensure, in consultation with the Bureau of the COP, that Parties have access to the draft text (for example, via a protected website) and can provide comments before the circulation of the draft guidelines to the COP;

(b) to adopt the timeline set out below:

Draft guidelines, if any, made available by the Secretariat for comments by the Parties	At least six months before the opening day of the seventh session of the COP
Submission of the final report by the working group to the Secretariat	At least three months before the opening day of the seventh session of the COP
Circulation to the COP	At least 60 days before the opening day of the seventh session of the COP in accordance with Rule 8 of the Rules of Procedure of the COP

Item 4.7

Impact assessment of the WHO FCTC

The Conference of the Parties (COP),

Recalling decision FCTC/COP5(12), requesting the Convention Secretariat to prepare a report outlining options for conducting an impact assessment of the WHO FCTC after its first 10 years of operation;

Welcoming the implementation reports submitted by the Parties in the 2014 reporting cycle, which serve as an important source of information concerning the progress in implementation made at country, regional and global levels;

Recognizing that the impact assessment should be performed by independent experts;

Having considered the report of the Secretariat, *Impact assessment of the WHO FCTC*, as contained in document FCTC/COP/6/15,

DECIDES:

(1) that an impact assessment of the WHO FCTC will be conducted, under the guidance of the Bureau, and as outlined under option A in paragraph 27 of document FCTC/COP/6/15;

(2) that the purpose of the impact assessment should be to assess and examine the impact of the WHO FCTC on implementation of tobacco control measures and on the effectiveness of its implementation in order to assess the impact of the Convention as a tool for reducing tobacco consumption and prevalence after its first 10 years of operation;

(3) to mandate the Bureau, based on an initial screening by the Secretariat, to establish a group of seven independent experts, to conduct the impact assessment. The group should be selected from nominations made by Parties and non-governmental organizations accredited to the COP and ensure there is regional balance. The group should include expertise in programme evaluation, including, but not limited to, evaluation of tobacco-control policies and legislation, treaty law, epidemiology and public health;

(4) to mandate the independent expert group to examine in three Parties selected in consultation with the Bureau, on a voluntary basis, within each of the four different levels of economic development as prescribed by the World Bank, including an analysis considering gender, children and vulnerable socioeconomic groups, where relevant data are available, the impact of the WHO FCTC by seeking the views of relevant stakeholders, organizations and actors in tobacco control in the respective jurisdictions, and through desk reviews, as part of its work; including identification of indicators and methodologies on consumption and prevalence;

(5) to request the Secretariat to assist the independent expert group to fulfil its mandate;

(6) to request the expert group to report on the outcome of the impact assessment and make possible recommendations, as appropriate, on how to strengthen the impact of WHO FCTC, to be presented for final consideration at the seventh session of the COP.

Item 4.8

Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry

The Conference of the Parties (COP),

Emphasizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco-control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on implementation of the WHO FCTC;

Recalling the resolution of the United Nations General Assembly in A/RES/66/2, which recognized the fundamental conflict of interest between the tobacco industry and public health, and United Nations Economic and Social Council (ECOSOC) resolution E/RES/2012/4, which recognized the same in relation to the work of the United Nations;

Acknowledging with appreciation the report of the Secretary-General to the ECOSOC at its substantive session in 2013 (E/2013/61), which recommended that the United Nations adopt guidelines to ensure objectivity in its work, in line with the principles of Article 5.3 of the Convention and its implementing guidelines;

Noting that global progress reports on implementation of the WHO FCTC, based on the reports of the Parties, reveal that tobacco industry interference remains one of the greatest obstacles to implementation of the Convention;

Recognizing that the tobacco industry is well-resourced and will continue to undermine tobacco-control efforts internationally, particularly for developing country Parties and Parties with economies in transition;

Noting with concern recent experiences indicating that tobacco industry strategies and tactics go beyond national borders as well as initiatives of the tobacco industry advising governments to challenge other countries' tobacco-control measures at national and international levels;

Reiterating that international cooperation is essential to prevent interference by the tobacco industry in the formulation of public health policies on tobacco control, as recommended in the guidelines for implementation of Article 5.3 and also in line with Articles 22, 23.5(g), 24.3(c), (d), (e), and Article 25 of the WHO FCTC;

Acknowledging the task requested to the Convention Secretariat in operative paragraph 2, the Convention Secretariat might consider to seek external expertise, in line with past practice,

1. DECIDES to:

(1) urge Parties to strengthen their implementation of Article 5.3 and intensify collaborative action to address tobacco industry efforts internationally; and

(2) urge Parties to raise awareness and adopt measures to implement Article 5.3 and its implementing Guidelines among all parts of government including diplomatic missions;

2. REQUESTS the Convention Secretariat, in coordination with the WHO to:

(1) examine the level of tobacco industry engagement in key international organizations which are in a position to contribute to WHO FCTC implementation, prepare a report on their impact on multisectoral collaboration for the implementation of the WHO FCTC, and make appropriate recommendations;

(2) seek collaboration with pertinent international organizations, including regional, and subregional organizations, to raise awareness of their role in contributing to Parties' implementation of Article 5.3 and that their administrative, financial and other decisions affect implementation of Article 5.3 of the WHO FCTC, by promoting the principles of Article 5.3 and its implementing Guidelines, including rejection of any direct or indirect contributions, technical and financial, from the tobacco industry;

(3) propose tools that will facilitate where appropriate raising awareness and assisting with implementation of Article 5.3 among all parts of government;

(4) identify and recommend options and sustainable mechanisms international cooperation on, and exchange of information related to, tobacco industry interference, building on the existing WHO Tobacco Industry Monitoring database or through a knowledge hub, in order to strengthen effective implementation of Article 5.3 of the WHO FCTC;

(5) stimulate the reporting of Parties' experiences in implementing Article 5.3 of the Convention through the reporting instrument of the WHO FCTC, and facilitate exchange of best practices through the establishment of a virtual community on the WHO FCTC information platform;

(6) develop and promote monitoring tools that would encourage voluntary and timely sharing of further information in order to enhance the monitoring of tobacco industry interference, including at the international level and regularly report on findings to Parties;

(7) continue to develop, and make available on a continuous basis, the technical capacity required to carry out the tasks listed above and provide technical assistance to Parties upon their request, to implement Article 5.3 of the Convention;

(8) report on its findings and activities to the seventh session of the COP.

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BREUVAGES

bluespike

BEVERAGES

Document presented to the cabinet of the
Health Minister of Nova Scotia

October 31, 2014

Presentation

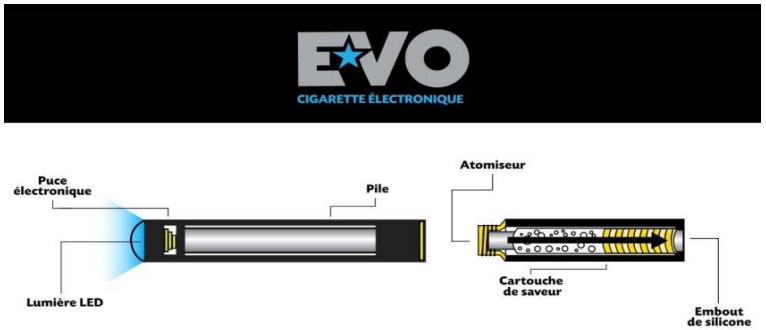
- Blue Spike Beverages
- The Product : Disposable Electronic Cigarettes (EVO)
- Identified Industry Problems
- Legislative Supervision
- Conclusion

Blue Spike Beverages

- Founded in 2003, the company is based in Montreal and now employs roughly 100 people.
  - The company has extensive experience in product development
  - They own recognized and respected brands
- Operate in the field of electronic cigarettes as well as the highly regulated field of alcoholic beverages.
- E-cigarettes solely sold via retailers with tobacco licenses. No online sales and no sales of nicotine; tobacco enhanced sales to comply with all current federal and provincial legislation.
- Second largest supplier of disposable electronic cigarettes in Canada, with market share of 40%.

The Product: Disposable Electronic Cigarettes

- EVO is composed of three (3) simple components: an atomizer, a cartridge, and a battery.
- EVO contains only 4 ingredients:
  - Artificial flavouring
  - Vegetable Glycerin
  - Propylene glycol
  - Water
  - EVO contains no nicotine or tobacco. *



- Lit traditional cigarettes release more than 7000 compounds.
- A recent study by the University of Southern California, published in August 2014, showed second hand smoke of e-cigs had close to zero organic carcinogens.
- Although more testing may be needed, the vast majority of the scientific and medical communities agree that e-cig smoke is much less toxic than traditional cigarettes.

** As demonstrated in laboratory tests performed by the Canadian Cancer Society, May 2013.*

The Product: Disposable Electronic Cigarettes

- EVO Flavours:
  - Tobacco, Menthol, Strawberry, Watermelon, Blueberry

- Nicorette Flavours:
  - Fresh Mint, Ice Mint, Fresh Fruit, Cinnamon, Extreme Chill

- To best assist smokers to kick their habit, they must be offered various options that can appeal to their specific taste. In offering a variety of options, smokers are more likely to find an appealing means to help them end their habit of smoking. If this was not the case, Nicorette would simply offer tobacco flavoured gum.

- Over 70% of sales are in the Menthol and Tobacco flavour which indicates purchases by current smokers as a substitution to traditional cigarettes.

- Studies have shown that the patch is only 2% more effective than quitting cold turkey. E-cigs offer a more potent aid to quit smoking and flavours are a part of this.

The Product: Disposable Electronic Cigarettes

Distribution

- EVO products are available in renowned points of sale:

... and other independent retailers.

- Retail sales only (no direct sales to the consumer via the Internet).

The Product: Disposable Electronic Cigarettes

Promotion

- Target Market: 19 years +
  - Blue Spike encourages its retailers to ID EVO customers.
- The product aims to be an alternative to the traditional cigarette.
  - Provides the 'mouth-feel' of traditional cigarettes
  - Allows social networks / social habits to be retained
  - Aids in ending an addiction to nicotine since this product contains none unlike other cessation aids
- E-cigarettes allow smokers to more easily quit smoking by touching multiple facets of smoking that the patch or gum can not.
  - Supported by the fact that Blue Spike receives numerous emails every week from customers who have stopped smoking by using EVO

Identified Industry Problems

- Proliferation of the "vape-shops" which do not seem to respect Provincial and Federal laws; the majority of them openly sell products containing nicotine.
- Proliferation of the online retailers which do not seem to respect Provincial and Federal laws; the majority of them openly selling products containing nicotine.
- No mechanism to ensure only adults purchase electronic cigarettes in vape-shops or online
- For certain e-cig distributors, there are no quality control standards, nor do they adhere to CFIA labeling guidelines since they act illegally. However, the major distributors in Canada who sell legal product, like Blue Spike, adhere to CFIA guidelines and continuously monitor products to ensure quality and reliability.
- The e-cig industry is not sufficiently regulated in Canada due to insufficient information on its properties, a rapid market growth, and confusion about its side effects.

Legislative Supervision

1. **Market and trade**

- Blue Spike suggests regulations similar to the ones used for alcoholic beverages instead of regulations similar to tobacco products for the sale, promotion, and advertising of e-cigs.
  - Visibility, education, and promotion is required to convert smokers to e-cigarettes.
  - Alcoholic advertising regulations can be effective to ensure minors are not impacted.
  - All agree e-cigs are not as harmful as combustible cigarettes.
- Continuing to permit the marketing and promotion of e-cigs will:
  - Allow consumers to educate and familiarize themselves with this technology.
  - Likely decrease the number of smokers of traditional cigarettes as more people learn about this offering.
    - Decrease the sales of Nicorette (decrease cost for the Provinces health care system).

Legislative Supervision

2. **Distribution**
   - The application of a law prohibiting the sale to minors.
   - Impose criminal and administrative penalties for sales of electronic cigarettes to minors.
   - Only tobacco licensed retailers should have the right to sell e-cigs.
     - Such retailers already ID their customers for cigarettes
3. **Product**
   - Ensure that the contents do not contain ingredients dangerous for the health and that all ingredients are stated on the labels.
   - Flavors are not harmful and are an integral part of the product.

Legislative Supervision

4. **Approved Advertisement and Packaging**

   - Blue Spike suggests all packaging and ads be approved by the Government, following enforceable and clear guidelines (similarly to what is done for alcoholic beverages in Quebec – see attached documentation).
   - Fees could be charged to finance further studies on the use of e-cigs.

5. **Identification**

   - All manufacturers and importers should require a license at the provincial and federal level to be allowed to sell e-cigs.
     - This would allow the monitoring, testing, and taxation of e-cig industry members

Conclusion

Key elements:

- Blue Spike believes in the imposition of clear, binding and taxable rules. The company is honorable, responsible and ethical.
- The company wishes to participate in the discussion concerning the supervision of the regulations for the sale and marketing of electronic cigarettes.
- Blue Spike would be ready to participate financially in studies to increase the current knowledge on the effects of the electronic cigarette without nicotine in Canada.
- The company wants to maintain a dialogue with the cabinet of the Health Minister to offer its experience and knowledge and to allow an appropriate supervision of the regulations for the sale and marketing of electronic cigarettes.

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ORIGINAL INVESTIGATION

Secondhand Exposure to Vapors From Electronic Cigarettes

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ABSTRACT

Introduction: Electronic cigarettes (e-cigarettes) are designed to generate inhalable nicotine aerosol (vapor). When an e-cigarette user takes a puff, the nicotine solution is heated and the vapor is taken into lungs. Although no sidestream vapor is generated between puffs, some of the mainstream vapor is exhaled by e-cigarette user. The aim of this study was to evaluate the secondhand exposure to nicotine and other tobacco-related toxicants from e-cigarettes.

Materials and Methods: We measured selected airborne markers of secondhand exposure: nicotine, aerosol particles ($PM_{2.5}$), carbon monoxide, and volatile organic compounds (VOCs) in an exposure chamber. We generated e-cigarette vapor from 3 various brands of e-cigarette using a smoking machine and controlled exposure conditions. We also compared secondhand exposure with e-cigarette vapor and tobacco smoke generated by 5 dual users.

Results: The study showed that e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants. The air concentrations of nicotine emitted by various brands of e-cigarettes ranged from 0.82 to 6.23 μg/m^3. The average concentration of nicotine resulting from smoking tobacco cigarettes was 10 times higher than from e-cigarettes (31.60 ± 6.91 vs. 3.32 ± 2.49 μg/m^3, respectively; $p = .0081$).

Conclusions: Using an e-cigarette in indoor environments may involuntarily expose nonusers to nicotine but not to toxic tobacco-specific combustion products. More research is needed to evaluate health consequences of secondhand exposure to nicotine, especially among vulnerable populations, including children, pregnant women, and people with cardiovascular conditions.

INTRODUCTION

Passive smoking, also referred to as exposure to secondhand smoke (SHS), happens when a person inhales a mixture of toxic compounds released from burning cigarettes (California Environmental Protection Agency, 2005; Nelson, 2001; Wallace-Bell, 2003). Despite the comprehensive smoke-free regulations introduced in many countries, passive smoking remains a global health problem. It has been estimated that passive smoking causes more than six hundred thousand deaths every year around the world (Oberg, Jaakkola, Woodward, Peruga, & Prüss-Ustün, 2011). Current laws and regulations do not adequately protect vulnerable populations, including children, pregnant women, and those with preexisting health conditions, from exposure to SHS. Based on data from 192 countries, Oberg et al. (2011) estimated that 40% of children had been exposed globally to SHS. SHS (also referred to as environmental tobacco smoke, ETS) is comprised primarily of sidestream smoke released from burning cigarettes during puff breaks and smoke exhaled by smokers after each puff. While SHS may contain the same toxic substances as mainstream smoke, it contains higher concentrations of many toxic and carcinogenic compounds than mainstream smoke. Although toxicants released from burning cigarettes are diluted in the indoor air, passive smokers are often exposed to secondhand smoke for prolonged periods of time.

Electronic nicotine delivery systems (commonly referred as electronic cigarettes or e-cigarettes) are new consumer products designed to generate nicotine aerosol (vapor) without combustion of tobacco. A typical e-cigarette is composed of three essential parts: the battery, the heating element or atomizer, and a cartridge or tank that holds a nicotine solution. The product contains nicotine dissolved in propylene glycol, glycerin, or the mixture of the two. When an e-cigarette user takes

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a puff, the nicotine solution is heated and the vapor can be inhaled into lungs. E-cigarettes are designed to deliver nicotine without toxic constituents of tobacco or tobacco combustion toxicants and carcinogens. Studies have shown that vapor generated from e-cigarettes contains nicotine and that the devices might be effective in delivering nicotine to the body. There is also some evidence that the vapor may contain some toxic compounds like carbonyls, traces of nitrosamines, or particles of heavy metals (Bullen et al., 2010; Dawkins & Corcoran, 2013; Etter & Bullen, 2011; Goniewicz, Knysak, et al., 2013; Goniewicz, Kuma, Gawron, Knysak, & Kosmider, 2013; Trehy et al., 2011; Vansickel & Eissenberg, 2013; Vansickel, Cobb, Weaver, & Eissenberg, 2010; Williams, Villarreal, Bozhilov, Lin, & Talbot, 2013).

Analysis of global e-cigarette marketing indicates that the products are promoted to circumvent smoke-free policies and to reduce exposure to secondhand smoke (Grana & Ling, 2013). Although no sidestream vapor is generated from e-cigarettes between puffs, some of the vapor is exhaled by the user. A study by Schripp, Markewitz, Uhde, and Salthammer (2013) showed that ultrafine particles, volatile organic compounds (VOCs), and nicotine are released with exhaled vapor. McAuley, Hopke, Zhao, and Babaian (2012) investigated emissions and indoor air concentrations of common tobacco smoke by-products from four different vaporized nicotine solutions and found that they emitted traces of carbonyls, polyaromatic hydrocarbons, tobacco-specific nitrosamines, and glycols. There is limited evidence whether passive "vaping" exposes nonusers to nicotine. One study showed that 1-hr exposure to secondhand cigarette smoke and to exhaled "secondhand" e-cigarette vapors generated similar effects on serum cotinine levels (Flouris et al., 2013).

As the popularity of e-cigarettes increases, it is becoming important to further investigate patterns and levels of passive exposure to nicotine and other toxicants from e-cigarettes. The present study explores various factors that might contribute to emission of chemicals from e-cigarettes. It also aims to compare the passive exposure to nicotine, particulates, carbon monoxide (CO), and VOCs from electronic and tobacco cigarettes.

MATERIALS AND METHODS

Study Protocols

We conducted two studies to assess emissions from e-cigarettes. The first study (Study 1) was designed to evaluate major factors that might affect exposure patterns. We generated vapor from three different models of e-cigarettes and released the vapor into an experimental exposure chamber. The aim of the second study (Study 2) was to compare emissions from e-cigarettes and cigarette smoke generated by experienced users of both products. Both studies are described in details below.

Study With Machine-Generated Vapors (Study 1)

Study 1 consisted of 12 experiments (Table 1; Experiments 1–12) conducted in an exposure chamber, each one lasting 2 hr. During the first hour, background levels of all analyzed markers were taken. During the second hour, vapor from e-cigarettes was generated using a smoking machine and released into the exposure chamber. We measured 1-hr average concentrations of nicotine, aerosol particles ($PM_{2.5}$), CO, and selected VOCs. We also monitored changes in $PM_{2.5}$ and CO levels over 2 hr.

Electronic Cigarettes

We studied three different models of e-cigarettes selected from the popular brands in Poland: (a) Colinss Age with Camel High atomized cartridge (cartomizer) (Colins Poland; EC1); (b) Dekang 510 Pen with SGC Regular cartridge (Ecigars Polska; EC2); and (c) Mild M201 Pen with Marlboro cartridge (Mild Poland; EC3). Although all cartridges were labeled as containing 18 mg of nicotine, our previous study showed that they differed in nicotine levels: Colinss Camel contained 11 mg, SGC Regular contained 18 mg, and Mild Marlboro contained 19 mg of the drug (Goniewicz, Kuma, et al., 2013). All products were purchased from online stores or shopping mall kiosks, and e-cigarettes batteries were charged for 24 hr before the experiments.

Exposure Chamber

A 39-m^3 laboratory room (3.4×4.1×2.8 m) was equipped as an exposure chamber. The chamber had plain acrylic painted walls and tiled floor, with no windows, carpets, linings, or curtains inside. It was equipped with a regulated exhaust, ventilation system, and two fans for mixing the indoor air. Inside the chamber, there was a sampling station equipped with pumps and monitors, a smoking machine for generating e-cigarette vapors (see Generation of Vapors From E-Cigarettes section), and two chairs. The sampling station was located 1 m from a smoking machine and 10 cm above the level of e-cigarettes.

The air exchange rates were determined before each experiment using a ventilation marker (methane) released into the exposure chamber according to the method described previously (Czogala & Goniewicz, 2005). The ventilation rate during the study varied from 1.37 (low) to 12.6 (high) air changes per hour (see also Supplementary Materials). Before each experiment, all surfaces inside the chamber were decontaminated by wiping with 10% aqueous solution of ethanol and intensive ventilation. Only one person, who operated the smoking machine and sampling station, was allowed inside the exposure chamber during Study 1.

Generation of Vapors From E-Cigarettes

In order to generate vapors from the e-cigarettes, a smoking machine was placed in the exposure chamber. We used an automatic single-channel piston-operated smoking machine Palaczbot (Technical University of Lodz) designed to generate vapor from e-cigarettes (Goniewicz, Knysak, et al., 2013; Goniewicz, Kuma, et al., 2013). In all experiments, the vapors from e-cigarettes were generated using the following puffing conditions: puff volume of 70 ml, puff duration of 1.8 s, and intervals between puffs of 10 s. Two doses of vapor (see Generation of Vapors From E-Cigarettes section) were released into the exposure chamber with 30-min interval.

Vapors were generated from each of the three e-cigarettes under two variants of ventilation (intensive vs. restricted) and two variants of emission pattern (high vs. low) (3 brands × 2 variants of ventilation × 2 variants of emission). Ventilation of the exposure chamber was controlled during each experiment and adjusted by operating the exhaust. During the experiments with intensive ventilation, exhaust from the exposure chamber was fully opened, while it was partly closed during the experiments with restricted ventilation.

Table 1. Changes in Nicotine, Aerosol Particles ($PM_{2.5}$), and Carbon Monoxide (CO) Air Concentration Inside Exposure Chamber After Use of E-Cigarette

Experiment	Exposure level	Ventilation	E-cigarette brand	Nicotine (µg/m³)		$PM_{2.5}$ (µg/m³)		CO (ppm vol/vol)	
				Baseline	E-cigarette	Baseline	E-cigarette	Baseline	E-cigarette
Experiments with smoking-machine (Study 1)									
1	Low	High	EC1	BLD	0.82	12.7	33.0	1	1
2	Low	High	EC2	BLD	1.13	85.0	80.0	1	1
3	Low	High	EC3	BLD	3.42	25.3	29.0	1	1
4	Low	Low	EC1	BLD	0.88	33.0	43.7	1	1
5	Low	Low	EC2	BLD	2.52	59.7	63.0	2	2
6	Low	Low	EC3	BLD	2.38	12.0	15.0	2	2
7	High	High	EC1	BLD	0.92	11.3	15.3	2	2
8	High	High	EC2	BLD	2.45	71.3	85.0	2	2
9	High	High	EC3	BLD	4.52	50.7	64.3	2	2
10	High	Low	EC1	BLD	0.95	12.0	15.0	1	1
11	High	Low	EC2	BLD	4.15	17.3	23.3	2	2
12	High	Low	EC3	BLD	6.23	6.6	69.7	1	1
Average (Experiments 1–12)				BLD	2.53 ± 1.75[a]	33.1 ± 26.9	44.7 ± 26.4[a]	1.50 ± 0.52	1.50 ± 0.52

		Nicotine (µg/m³)			$PM_{2.5}$ (µg/m³)			CO (ppm vol/vol)		
		Baseline	E-cigarette	Tobacco cigarette	Baseline	E-cigarette	Tobacco cigarette	Baseline	E-cigarette	Tobacco cigarette
Experiments with dual product users (Study 2)										
13	Smoker 1	BLD	0.65	26.9	80.0	63.3	690.0	1	1	3
14	Smoker 2	BLD	0.85	38.1	8.0	123.0	726.0	2	2	5
15	Smoker 3	BLD	5.02	25.6	13.3	91.3	661.3	2	2	3
16	Smoker 4	BLD	3.87	25.6	44.0	208.3	802.0	1	1	4
17	Smoker 5	BLD	6.23	41.8	16.7	272.7	1217.3	1	1	4
Average (Experiments 13–17)		BLD	3.32 ± 2.49[a,b]	31.6 ± 7.8	32.4 ± 30.0	151.7 ± 86.8[a,b]	819.3 ± 228.6	1.40 ± 0.55	1.40 ± 0.55[b]	3.80 ± 0.84

Note. BLD = below limit of detection (0.22 µg/m³).
[a]Significant difference with baseline ($p < .05$).
[b]Significant difference with tobacco cigarette ($p < .05$).

In order to modify exposure patterns, vapors from e-cigarettes were generated using 7 or 15 puffs, for low and high exposure, respectively. The rationale for using two levels of exposure (low vs. high) was to examine various doses of nicotine released with secondhand vapor. Although studies have shown that e-cigarette vapors contain significant amounts of nicotine, there are some controversy as to whether this nicotine is effectively absorbed in the lungs (Zhang, Sumner, & Chen, 2013). If there is little absorption, vapor exhaled by e-cigarette users might contain high levels of the drug. We assumed that if an e-cigarette user takes 15 puffs, and no nicotine is absorbed, then the entire amount of nicotine would be exhaled. If e-cigarettes effectively deliver nicotine to the bloodstream, exhaled vapors will contain only some of nicotine inhaled by the user. By releasing 7 puffs, we simulated the scenario in which approximately half of the nicotine from 15 puffs is absorbed and the balance is exhaled.

Analytical Procedures

Nicotine was measured using gas chromatography with nitrogen–phosphorus detector following active sampling on XAD-4 sorption tubes (SKC Inc.) according to the National Institute of Occupational Safety and Health reference method 2551 (National Institute of Occupational Safety and Health, 2003) with a detection limit of 0.22 μg/m^3. Aerosol particles ($PM_{2.5}$) were measured continuously with a SidePak AM510 Personal Aerosol Monitor. CO was also measured continuously with a Q-Trak Indoor Air Quality 8550 monitor (both instruments from TSI Inc.). The Sidepak was used with a calibration factor setting of 0.32, suitable for secondhand smoke (Jiang et al., 2011; Klepeis, Ott, & Switzer, 2007). VOCs were analyzed using gas chromatography with mass spectrometry following active sampling on Anasorb CSC sorption tubes (SKC Inc.) according to the Occupational Safety and Hazards Agency reference method (Occupational Safety and Hazards Agency, 2000). The method allowed us to measure 11 compounds: benzene, toluene, chlorobenzene, ethylbenzene, m,p-xylene, o-xylene, styrene, naphthalene, 1,2-dichlorobenzene, 1,3-dichlorobenzene, and 1,4-dichlorobenzene. Each monitor was calibrated according to manufacturer's recommendations, and all analytical procedures were validated and described in details in the Supplementary Materials.

Study With Human-Generated Vapors and Smoke (Study 2)

Subjects

We recruited five volunteers (all male; average age 37.6 ± 16.0; body mass index 23.4 ± 2.1; nicotine dependence by Fagerström Test for Nicotine Dependence 5.8 ± 2.9), who were dual users of e-cigarettes and conventional tobacco cigarettes. The subjects reported using e-cigarettes on average 14 ± 7 times a day for at least 8 months (12.0 ± 4.2) and additionally smoking on average 11 ± 6 cigarettes per day for at least 5 years (18.2 ± 14.1). Two subjects reported using M201 pen-style e-cigarette (18 mg/ml; Mild brand), two others used eGo model (16 mg/ml; Janty brand), and one used M401 model (18 mg/ml; Nicore brand, Atina Poland). Three volunteers smoked L&M Blue Label brand of cigarettes (ISO yields/cigarette: nicotine 0.6 mg; tar 8 mg; CO 9 mg), and two smoked Marlboro Gold brand (nicotine 0.5 mg; tar 7 mg; CO 7 mg). All volunteers who participated in experiments were not given any money, gifts, or other economic incentives. Study 2 protocol was reviewed and approved by the Institutional Review Board at the Medical University of Silesia, Poland.

Emission of E-Cigarettes Vapors and Tobacco Smoke

Study 2 comprised five experiments (Table 1; Experiments 13–17), each lasting for 3 hr. After background measures were taken for 1 hr, a volunteer entered the room. Each volunteer used *ad libitum* their own e-cigarette twice for 5 min with a 30-min interval. Then, the room was decontaminated as described above and ventilated for 5 min. In the last hour, each subject smoked *ad libitum* entire tobacco cigarettes of their own brand. As with e-cigarettes, volunteers smoked two cigarettes lighting the second cigarette 30 min after the first. One-hour average concentrations of nicotine, aerosol particles ($PM_{2.5}$), CO, and VOCs were determined as described above (baseline, e-cigarette, and tobacco cigarette). $PM_{2.5}$ and CO levels were also monitored continuously over 3 hr of each experiment. Only two persons were allowed in the exposure chamber during Study 2: volunteer and operator of the sampling station.

Statistical Analysis

We compared average concentrations of each airborne marker using a nonparametric Mann–Whitney test. For both studies, we assessed the differences between baseline measures and each test condition (e-cigarette and tobacco cigarette). For Study 2, we also assessed differences in average indoor concentrations of each marker between electronic and tobacco cigarettes. For all tests, Statistica 10.0 software (StatSoft Inc.) was used. The significance level was established as $p < .05$.

RESULTS

Secondhand Exposure to Nicotine From E-Cigarettes

Study 1

Nicotine was detected in the air during all experiments where e-cigarette vapor was generated with the smoking machine and released into the exposure chamber. Mean 1-hr concentration of nicotine was 2.51 ± 1.68 μg/m^3 and ranged from 0.82 to 6.23 μg/m^3. Comparison of average indoor air nicotine concentrations in the exposure chamber from three e-cigarette brands are presented in Figure 1. Changes between baseline values and an average nicotine concentration after emission of machine-generated vapors from e-cigarettes are presented in Table 1.

Study 2

Figure 2 shows baseline concentrations of nicotine and 1-hr medium concentrations after using e-cigarettes or after smoking tobacco cigarettes by volunteers. The average concentration of nicotine resulting from smoking tobacco cigarettes was 10 times higher than from e-cigarettes (31.60 ± 6.91 vs. 3.32 ± 2.49 μg/m^3, respectively; $p = .0081$).

Secondhand Exposure to $PM_{2.5}$ From E-Cigarettes

Study 1

Aerosol particles were detected in the air during all experiments with vapor generated with the smoking machine and released into the exposure chamber. Mean concentration of $PM_{2.5}$ was 33.1 ± 26.9 μg/m^3 and ranged from 6.6 to 85.0 μg/m^3.

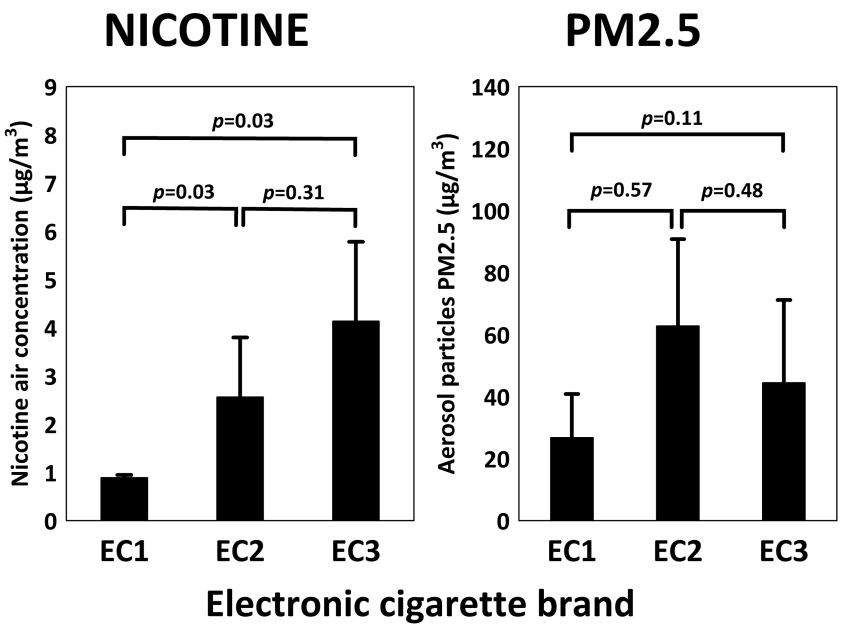

Figure 1. Effect of e-cigarette brand on nicotine (left) and aerosol particle (right) concentration in the air inside exposure chamber.

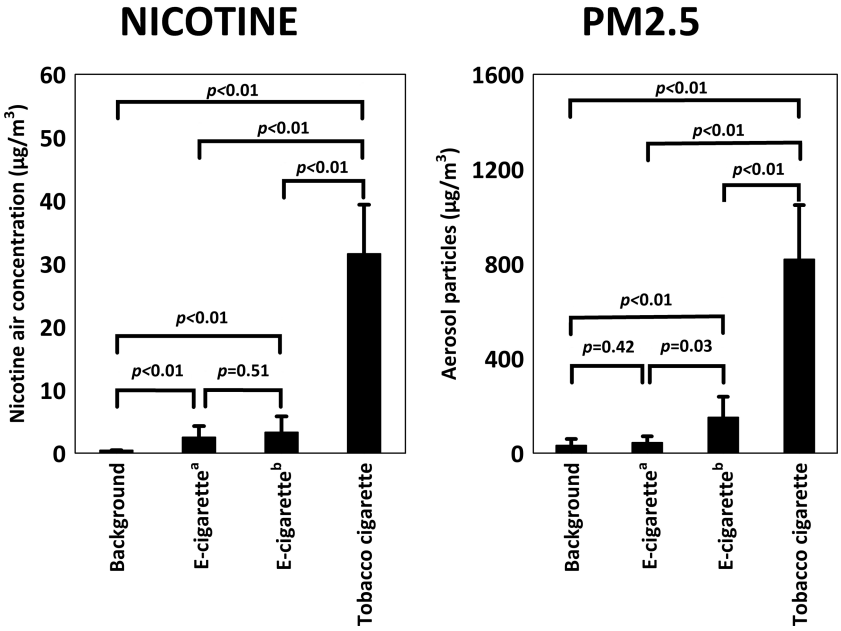

Figure 2. Comparison of indoor air nicotine (left) and aerosol particle (right) concentrations released from e-cigarette with background values and tobacco cigarette smoking.
Note. [a]Vapor generated with smoking machine (*Study 1*); [b]Vapor exhaled by users (*Study 2*).

Comparison of average indoor air $PM_{2.5}$ levels in exposure chamber from three e-cigarette brands are presented on Figure 1. Changes between baseline values and mean $PM_{2.5}$ levels after emission of machine-generated vapors from e-cigarettes are presented in Table 1.

Study 2

Figure 2 shows baseline concentrations of $PM_{2.5}$ and 1-hr mean concentrations after using e-cigarettes or after smoking tobacco cigarettes by volunteers. The mean concentration of $PM_{2.5}$ resulting from smoking tobacco cigarettes was 7 times higher than from e-cigarettes (819.3 ± 228.6 vs. 151.7 ± 86.8 µg/m^3, respectively; $p = .0081$). Figure 3 shows changes in $PM_{2.5}$ concentration in the exposure chamber during one of the experiments in Study 2 (Experiment 15; see Table 1).

Secondhand Exposure to CO From E-Cigarette

Studies 1 and 2

There were no changes in CO concentration after using e-cigarettes in both studies ($p > .05$). However smoking of two tobacco cigarettes in Study 2 increased CO concentration in the

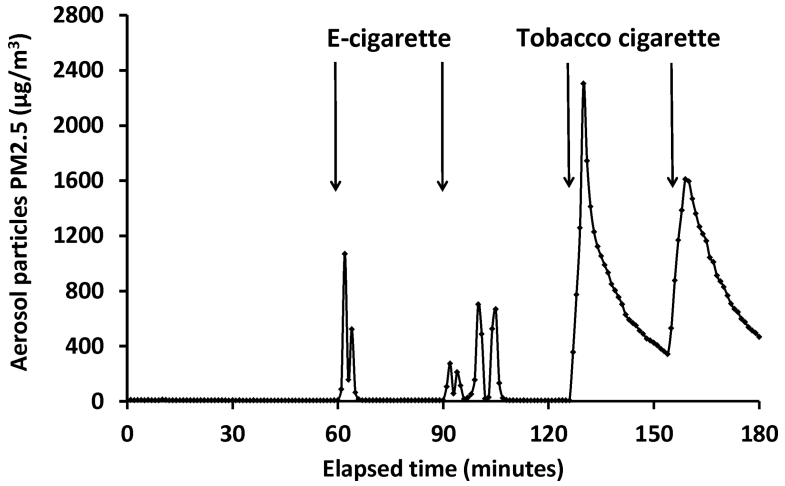

Figure 3. Changes of aerosol particle $PM_{2.5}$ concentrations during experiment of e-cigarette use and tobacco cigarette smoking in exposure chamber.

exposure chamber on average by 2 to 3 ppm (vol/vol) (Table 1; $p < .05$).

Secondhand Exposure to VOCs From E-Cigarettes

Study 1

During the study with machine-generated e-cigarette vapor, only toluene was detected in the exposure chamber. No statistical difference was found between average toluene concentration after release of e-cigarette vapor and baseline values (6.63 ± 0.21 vs. 4.15 ± 2.69 µg/m^3, respectively; $p = .1582$).

Study 2

As with Study 1, toluene was the only VOC detected in the exposure chamber, and the use of e-cigarette did not change the concentration of toluene (3.79 ± 2.16 vs. 4.09 ± 2.12 µg/m^3, respectively; $p = .8513$). Smoking two tobacco cigarettes increased the concentration of four compounds: toluene, ethylbenzene, m,p-xylene, and o-xylene ($p < .05$). For toluene, the average concentration after smoking tobacco cigarettes was 3.5-fold higher than after using e-cigarettes (14.75 ± 6.02 vs. 4.15 ± 2.69 µg/m^3, respectively; $p < .05$). The average concentrations of ethylbenzene, m,p-xylene, and o-xylene after smoking tobacco cigarettes were 1.17 ± 1.44, 1.94 ± 1.14, and 0.48 ± 0.95 µg/m^3, respectively; $p < .05$).

DISCUSSION

Principal Findings

The key finding of this study is that e-cigarettes emit significant amounts of nicotine but do not emit significant amounts of CO and VOCs. We also found that the level of secondhand exposure to nicotine depends on the e-cigarette brand. However, the emissions of nicotine from e-cigarettes were significantly lower than those of tobacco cigarettes.

Strengths and Limitations of the Study

To our knowledge, this is one of the first studies to measure the concentrations of nicotine, $PM_{2.5}$, CO, and VOCs emitted by e-cigarettes and to compare the emissions of electronic and conventional tobacco cigarettes in a conventionally ventilated, full-sized room. By comparing e-cigarette vapors generated with a smoking machine to those generated by experienced e-cigarette users in a controlled setting allowed us to control for potential factors that may affect exposure patterns.

Results from experiments with human subjects who used both electronic and tobacco cigarettes allowed us to compare the emissions and the potential exposures by the two products. One of the most important aspects of our study is that the e-cigarette vapors and tobacco smoke were generated by long-term dual users of the products, and we did not modified the way volunteers were typically using the products.

Our findings are supported by results from study by McAuley et al. (2012) who examined the chemical composition of freshly generated vapor collected in a small emission chamber and found that the total air emission concentrations for many pollutants from e-cigarettes were very low. Our study examined the potential effect of various e-cigarette brands on patterns of exposure, whereas McAuley et al. (2012) studied vapors generated from the same model of e-cigarette with varying nicotine solutions and found that the chemical composition of the vapors from different solutions differed in levels of nicotine and other chemicals. Our study showed that the level of exposure also differs between e-cigarette brands. These findings are also consisted with our previously reported data showing high variability in composition of freshly generated vapors among the products (Goniewicz, Kuma, et al., 2013). These findings should be taken into careful consideration when exposure to e-cigarette vapors is considered.

The study has several limitations. An important limitation of our study is that we measured a limited number of chemicals that might be contained within e-cigarette vapors. We reported previously that e-cigarette vapors contain significant levels of carbonyls, including toxic and carcinogenic formaldehyde, acetaldehyde, and acrolein (Goniewicz, Knysak, et al., 2013). These compounds were not measured in this study. Studies by Schripp, Markewitz, Uhde, and Salthammer (2013) and McAuley et al. (2012) found that there is a risk of exposure to carbonyls from e-cigarettes, although the levels of the compounds were lower than those in SHS. We did not investigate

other significant factors affecting exposure to e-cigarette vapors, for example, room volume and number of e-cigarettes used simultaneously in a single room. The exposure chamber input air was not filtered during the experiments, and ventilation air exchange rates of exposure chamber were higher than residential rates (Yamamoto, Shendell, Winer, & Zhang, 2010). Finally, the study assessed concentrations of several markers in the air but not serum concentrations in people exposed to secondhand vapors. These airborne concentrations do not necessarily reflect the serum concentration and the impact on health of people exposed to these vapors.

Unanswered Questions and Future Research

This study did not test potential health effects associated with secondhand exposure to vapors from e-cigarettes. To date, there are few studies that have tested the acute effects of brief exposure to secondhand e-cigarette vapors. One study by Flouris et al. (2012) found that acute passive "vaping" of e-cigarettes did not influence complete blood count in human subjects. Another study by the same authors found that controlled 1-hr exposure to e-cigarette vapors did not significantly affect lung function in human subjects (Flouris et al., 2013). We found no publications on the cardiovascular effects of passive exposure to e-cigarette vapors or on the health effects of secondhand exposure to e-cigarette vapors among vulnerable population, including children, pregnant women, and people with cardiovascular conditions.

There is some discrepancy between our findings and results reported recently by Flouris et al. (2013) on secondhand exposure to nicotine. Our data suggest that secondhand exposure to nicotine from e-cigarettes is on average 10 times less than from tobacco smoke. However, Flouris et al. (2013) found that e-cigarettes and tobacco cigarette generated similar effects on serum cotinine levels after 1-hr passive exposure (2.4±0.9 vs. 2.6±0.6 ng/ml, respectively; $p < .001$). Future research should look for correlation between indoor air levels of nicotine from e-cigarettes and its uptake by passive smokers to explain this discrepancy.

Future research should also study exposure patterns over extended periods of time and the potential health effects of long-term exposure to secondhand e-cigarette vapors. Data are also needed from the field studies conducted in homes and public places where e-cigarettes are in use. Moreover, this study only focused on nicotine and a limited number of chemicals released from e-cigarettes. Further research is needed to explore emission and exposure to other toxicants and carcinogens identified in e-cigarettes, for example, carbonyl compounds (Goniewicz, Knysak, et al., 2013).

It remains unclear whether concentration of $PM_{2.5}$ will be a suitable and reliable airborne marker to evaluate emission and exposure to secondhand vapors from e-cigarettes. Although some studies suggest that e-cigarette vapor and SHS have comparable aerosol particle size distribution and deposition patterns, we found that concentration of e-cigarette aerosol particles tends to decrease rapidly when diluted in the air. Figure 3 shows that there is a significant particle mass signal from e-cigarette vapor but that it dissipates much more rapidly than cigarette smoke. This may be due to the evaporation of the aerosol in addition to deposition on the surfaces and removal by ventilation. There is a need for developing an accurate methodology to assess e-cigarette vapor indoor concentrations. Finally, the vapor from e-cigarettes might be easily deposited on surfaces to form "thirdhand" e-cigarette vapor, and studies are needed to assess the deposition rate, potential formation of toxic derivatives, and human exposure.

Implications for Policy Makers

The study showed that e-cigarettes might involuntarily expose nonsmokers and people who do not use e-cigarettes to nicotine. In the past, secondhand exposure to nicotine has been primarily associated with exposure to ETS. E-cigarettes have created the new scenario under which bystanders might be exposed to low levels of nicotine but not to the other toxins found in tobacco smoke. It remains unclear whether exposure to low levels of nicotine indoors causes any harm to bystanders, including children, pregnant women, and person with cardiovascular conditions.

Besides nicotine, e-cigarette vapor contains significant amounts of propylene glycol and vegetable glycerin. Although both compounds are considered to be safe, there is lack of data on health risk associated with prolonged exposure to their vapors. Propylene glycol has been shown to cause upper airway irritation (Vardavas et al., 2011). Some volatile carbonyl compounds have been also identified in the vapor of e-cigarettes (Goniewicz, Knysak, et al., 2013). More research is needed about the health risk associated with exposure to toxic constituents of the vapors. The physicochemical changes may also occur after vapors are released into ambient air. It has been shown that such changes increase toxicity of tobacco smoke two- to four-fold (Schick & Glantz, 2006). These data are needed to inform regulators whether e-cigarettes should be included under smoke-free policies to protect nonusers from inhaling the toxicants.

E-cigarettes are promoted to circumvent smoke-free policies (Grana & Ling, 2013). Exempting e-cigarettes from smoke-free regulations, besides creating secondhand exposure to nicotine, might have additional implications for public health. It remains unclear whether observation of smokers using e-cigarettes, especially by young people, might reverse the denormalization of smoking behavior as a social norm. Cigarette smokers might use e-cigarettes as additional sources of nicotine in places with smoking bans. Data are needed to determine whether dual use of the products (e-cigarettes in addition to tobacco cigarettes) results in reinforcement of nicotine addiction.

SUPPLEMENTARY MATERIAL

Supplementary Material can be found online at http://www.ntr.oxfordjournals.org

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DECLARATION OF INTERESTS

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Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study

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ABSTRACT

Background and Aims Electronic cigarettes (e-cigarettes) are rapidly increasing in popularity. Two randomized controlled trials have suggested that e-cigarettes can aid smoking cessation, but there are many factors that could influence their real-world effectiveness. This study aimed to assess, using an established methodology, the effectiveness of e-cigarettes when used to aid smoking cessation compared with nicotine replacement therapy (NRT) bought over-the-counter and with unaided quitting in the general population. **Design and Setting** A large cross-sectional survey of a representative sample of the English population. **Participants** The study included 5863 adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only ($n = 464$), NRT bought over-the-counter only ($n = 1922$) or no aid in their most recent quit attempt ($n = 3477$). **Measurements** The primary outcome was self-reported abstinence up to the time of the survey, adjusted for key potential confounders including nicotine dependence. **Findings** E-cigarette users were more likely to report abstinence than either those who used NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93, 20.0 versus 10.1%] or no aid (OR = 1.38, 95% CI = 1.08–1.76, 20.0 versus 15.4%). The adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid. **Conclusions** Among smokers who have attempted to stop without professional support, those who use e-cigarettes are more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Keywords Cessation, cross-sectional population survey, e-cigarettes, electronic cigarettes, nicotine replacement therapy, NRT, quitting, smoking.

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INTRODUCTION

Smoking is one of the leading risk factors for premature death and disability and is estimated to kill 6 million people world-wide each year [1]. The mortality and morbidity associated with cigarette smoking arises primarily from the inhalation of toxins other than nicotine contained within the smoke. Electronic cigarettes (e-cigarettes) provide nicotine via a vapour that is drawn into the mouth, upper airways and possibly lungs [2,3]. These devices use a battery-powered heating element activated by suction or manually to heat a nicotine solution and transform it into vapour. By providing a vapour containing nicotine without tobacco combustion, e-cigarettes appear able to reduce craving and withdrawal associated with abstinence in smokers [2,4,5], while toxicity testing suggests that they are much safer to the user than ordinary cigarettes [3].

E-cigarettes are increasing rapidly in popularity: prevalence of ever-use among smokers in the United

States appears to have increased from approximately 2% in 2010 to more than 30% in 2012, and the rate of increase appears to be similar in the United Kingdom [6–9]. Although there are concerns about their wider public health impact relating to the renormalization of smoking and promotion of smoking in young people, crucially two randomized controlled trials have suggested that e-cigarettes may aid smoking cessation [10,11]. However, there are many factors that influence real-world effectiveness, including the brand of e-cigarette, the way they are used and who chooses to use them [12]. Therefore, it is a challenge to establish probable contribution to public health through randomized efficacy trials alone. Moreover, this kind of evidence will take many years to emerge, and in the meantime the products are developing rapidly and countries require evidence on effectiveness to inform decisions on how to regulate them [13–19]. As a result, there is an urgent need to be able to make an informed judgement on the real-world effectiveness of currently popular brands as chosen by the millions of smokers across the world who are using them in an attempt to stop smoking [6–9].

Several studies have attempted to examine the relationship between the use of e-cigarettes and smoking status in the real world by surveying regular e-cigarette users [20–27]. These studies—including one using a longitudinal design [27]—have found that users consistently report that e-cigarettes helped them to quit or reduce their smoking. However, because the samples were self-selected, the results have to be interpreted with caution. In more general samples the evidence is less positive. One national study of callers to a quitline, which assessed the cross-sectional association of e-cigarette use and current smoking status at a routine follow-up evaluation of the quitline service, found that e-cigarette users compared with never users were less likely to be abstinent [28]. In a longitudinal study of a general population sample, e-cigarette users at baseline were no more likely to have quit permanently at a 12-month follow-up despite having reduced their cigarette consumption [29]. However, neither of these studies adjusted for important potential confounding variables and both evaluated the association between quitting and the use of e-cigarettes for any purpose, not specifically as an aid to quitting. It is crucial to distinguish between the issue of whether use of e-cigarettes in a quit attempt improves the chances of success of that attempt from the issue of whether the use of e-cigarettes, for whatever purpose, such as aiding smoking reduction or recreation, promotes or suppresses attempts to stop. In determining the overall effect on public health both considerations are important, but they require different methodologies to address them.

An ongoing national surveillance programme (the Smoking Toolkit Study) has been tracking the use of e-cigarettes as a reported aid to cessation among the general population in England since July 2009 [30]. This programme has established a method of assessing real-world effectiveness of aids to cessation by comparing the success rates of smokers trying to quit with different methods and adjusting statistically for a wide range of factors that could bias the results, such as nicotine dependence [31]. The method has been able to detect effects of behavioural support and prescription medications to aid cessation and found a higher rate of success when using varenicline than prescription nicotine replacement therapy (NRT) [32,33], supporting findings from randomized controlled trials and clinical observation studies [34–37]. This method cannot achieve the same level of internal validity as a randomized controlled trial, but clearly has greater external validity, so both are important in determining the potential public health contribution of devices hypothesized to aid cessation, such as e-cigarettes.

Given that smokers already have access to licensed NRT products, it is important to know whether e-cigarettes are more effective in aiding quitting. This comparison is particularly important for two reasons. First, buying a licensed NRT product from a shop, with no professional support, is the most common way of using it in England, and secondly, previous research has found that this usage was not associated with greater success rates than quitting unaided in the real-world [33]. It is therefore important to know whether e-cigarettes can increase abstinence compared to NRT bought over-the-counter.

The current study addressed the question of how effective e-cigarettes are compared with NRT bought over-the-counter and unaided quitting in the general population of smokers who are attempting to stop.

METHODS

Study design

The design was cross-sectional household surveys of representative samples of the population of adults in England conducted monthly between July 2009 and February 2014. To examine the comparative real-world effectiveness of e-cigarettes, the study compared the self-reported abstinence rates of smokers in the general population trying to stop who used e-cigarettes only (i.e. without also using face-to-face behavioural support or any medically licensed pharmacological cessation aid) with those who used NRT bought over-the-counter only or who made an unaided attempt, while adjusting for a wide range of key potential confounders. The surveys are part of the ongoing Smoking Toolkit Study, which is designed to provide information about smoking

prevalence and behaviour in England [30]. Each month a new sample of approximately 1800 adults aged ≥16 years are selected using a form of random location sampling, and complete a face-to-face computer-assisted survey with a trained interviewer. The full methods have been described in detail and shown to result in a sample that is nationally representative in its socio-demographic composition and proportion of smokers [30]. Approval was granted by the ethics committee of University College London, UK.

Study population

For the current study, we used aggregated data from respondents to the survey in the period from July 2009 (the first wave to track use of e-cigarettes to aid cessation) to February 2014 (the latest wave of the survey for which data were available), who smoked either cigarettes (including hand-rolled) or any other tobacco product (e.g. pipe or cigar) daily or occasionally at the time of the survey or during the preceding 12 months. We included those who had made at least one quit attempt in the preceding 12 months, assessed by asking: 'How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year'. We included respondents who used either e-cigarettes or NRT bought over-the-counter during their most recent quit attempt, and an unaided group defined as those who had not used any of the following: e-cigarettes; NRT bought over-the-counter; a prescription stop-smoking medication; or face-to-face behavioural support. We excluded those who used either e-cigarettes or NRT bought over-the-counter in combination with one another, a prescription stop-smoking medication or face-to-face behavioural support.

Measurement of effect: quitting method

The use of different quitting methods were assessed for the most recent attempt by asking: 'Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?' and included: (i) e-cigarettes; (ii) NRT bought over-the-counter; (iii) no aid (i.e. had not used any of e-cigarettes, NRT bought over-the-counter, a prescription stop-smoking medication or face-to-face behavioural support).

Measurement of outcome: self-reported non-smoking

Our primary outcome was self-reported non-smoking up to the time of the survey. Respondents were asked: 'How long did your most recent serious quit attempt last before you went back to smoking?'. Those responding 'I am still not smoking' were defined as non-smokers. Previous research has shown that self-reported abstinence in surveys of this kind is not subject to the kind of biases observed in clinical trials where there is social pressure to claim abstinence [38].

Measurement of potential confounders

We measured variables potentially associated with the different quitting methods and that may also have an effect on the outcome. These potential confounders were chosen a priori. The most important factor was nicotine dependence, for which we used two questions. First, time spent with urges to smoke was assessed by asking all respondents: 'How much of the time have you felt the urge to smoke in the past 24 hours? Not at all (coded 0), a little of the time (i), some of the time (ii), a lot of the time (iii), almost all of the time (iv), all of the time (v)'. Secondly, strength of urges to smoke was measured by asking: 'In general, how strong have the urges to smoke been? Slight (i), moderate (ii), strong (iii), very strong (iv), extremely strong (v)'. This question was coded '0' for smokers who responded 'not at all' to the previous question. In this population these two ratings have been found to be a better measure of dependence (i.e. more closely associated with relapse following a quit attempt) than other measures [32,33,39]. The demographic characteristics assessed were age, sex and social grade (dichotomized into two categories: ABC1, which includes managerial, professional and intermediate occupations; and C2DE, which includes small employers and own-account workers, lower supervisory and technical occupations, and semi-routine and routine occupations, never workers and long-term unemployed). We also assessed the number of quit attempts in the last year prior to the most recent attempt, time since the most recent quit attempt was initiated (either more or less than 6 months ago), whether smokers had tried to quit abruptly or gradually and the year of the survey.

Analysis

Bivariate associations between the use of different quitting methods and potentially confounding socio-demographic and smoking history variables were assessed with χ^2 tests and one-way analyses of variance (ANOVA)s for categorical and continuous variables, respectively. Significant omnibus results were investigated further by *post-hoc* Sidak-adjusted χ^2 tests and *t*-tests.

Our measure of dependence (strength of urges to smoke) assumed that the score relative to other smokers would remain the same from pre- to post-quitting [32,33]. If a method of quitting reduced the strength of

urges to smoke more than another method, this would tend to underestimate the effectiveness of that intervention because the smokers using this method would appear to be less dependent. To test for this bias, we used an analysis of covariance (ANCOVA) to examine whether the difference in strength of urges to smoke in smokers versus non-smokers depended upon the method of quitting, adjusting for the time since the quit attempt started.

In the analysis of the associations between quitting method and abstinence, we used a logistic regression model in which we regressed the outcome measure (self-reported non-smoking compared with smoking) on the effect measure (use of e-cigarettes compared with either NRT bought over-the-counter or no aid). The primary analysis was an adjusted model that included the potential confounders listed above and two interaction terms: (i) between time since last quit attempt and time spent with urges, and (ii) between time since last quit attempt and strength of urges to smoke. These interaction terms were used to reflect the fact that urges to smoke following a quit attempt are influenced by whether an individual is currently abstinent and the duration of abstinence [32,33]. In addition to the model from the primary analysis ('fully adjusted model'; model 4), we constructed a simple model including only the effect measure ('unadjusted model'; model 1), a model that included the effect measure, year of the survey and all potential confounders except for the two measures of tobacco dependence, and a model that included all variables from the previous model and the two measures of tobacco dependence but without their interaction terms ('partially adjusted models'; models 2 and 3, respectively) to assess the extent of confounding by dependence. As *post-hoc* sensitivity analyses, the models were re-examined using different potential confounders from the ones specified a priori and reported in previous publications using the same methodology [32,33]. First, the time since the initiation of the quit attempt was included using the following six categories: 'in the last week'; 'more than a week and up to a month'; 'more than 1 month and up to 2 months'; 'more than 2 months and up to 3 months'; 'more than 3 months and up to 6 months'; and 'more than 6 months and up to a year'. Secondly, an additional index of dependence—the heaviness of smoking index (HSI) [40]—was included. The HSI was assessed by asking current smokers to estimate current cigarettes per day and time to first cigarette (the two items comprising HSI) and by asking non-smokers to recall these behaviours prior to their quit attempt. Finally, in *post-hoc* subgroup analyses all models were repeated (i) among those reporting smoking one or more than one cigarette per day (CPD) to determine whether inclusion of very light smokers might have had an influence on the results; (ii) among those completing the survey between 2012–14 once e-cigarette usage had become prevalent; and (iii) in the two subsamples of respondents who had started their most recent quit attempt less or more than 6 months ago, in order to assess the interplay between long-term effectiveness and the occurrence of differential recall bias. All analyses were performed with complete cases.

RESULTS

A total of 6134 respondents reported a most recent quit attempt in the last 12 months that was either unaided ($n = 3477$) or supported by NRT bought over-the-counter ($n = 2095$), e-cigarettes ($n = 489$) or both ($n = 73$). Those using both were excluded as were those using a prescription stop-smoking medication or face-to-face behavioural support in combination with either NRT bought over-the-counter ($n = 173$) or e-cigarettes ($n = 25$). Thus, the study population consisted of 5863 smokers who had made an attempt to quit in the previous year, of whom 7.9% (464) had used e-cigarettes, 32.8% (1922) had used NRT bought over-the-counter and 59.3% (3477) had used no aid to cessation. Quitting method did not differ by sex or the number of quit attempts in the past year but was associated with age, social grade, time since the quit attempt started, CPD, smoking less than one CPD, the measures of dependence (time with and strength of urges and HSI) and whether the attempt had begun abruptly (see Table 1). The *post-hoc* comparisons showed that those who used either e-cigarettes or no aid were younger than those using NRT over-the-counter, and that those who used NRT over-the-counter or no aid were more likely to hold a lower social grade than those using e-cigarettes. As would be expected, given the recent advent of e-cigarettes, the quit attempts of e-cigarette users were less likely to have begun more than 6 months previously than those using NRT over-the-counter or no aid. Those using NRT bought over-the-counter smoked more cigarettes and scored higher than either of the other two groups on all measures of dependence. E-cigarette users smoked more cigarettes, and were more dependent by the strength of urges measure and HSI than those using no aid. Finally, those using no aid were more likely to have smoked less than one CPD and stopped abruptly than the other two groups.

Strengths of urges to smoke were higher in smokers than in non-smokers (see Table 2). However, the mean differences in strength of urges between smokers and non-smokers were similar across method of quitting: the interaction between smoking status (smokers versus non-smokers) and method of quitting in an ANCOVA of the strength of urges adjusted for the time since quit attempt started was not significant ($F_{(2,\ 5856)} = 1.50$, $P = 0.22$).

Non-smoking was reported among 20.0% (93 of 464) of those using e-cigarettes, 10.1% (194 of 1922) using

Table 1 Associations between characteristics of the sample and use of different quitting methods.

	E-cigarettes (n = 464)	*NRT over-the-counter[§] (n = 1922)*	*No aid (n = 3477)*	*P*
Mean (SD) age	39.0 (15.6)[a]	41.2 (15.3)[ab]	37.5 (16.2)[b]	***
% (*n*) Female	47.2 (219)	51.1 (982)	48.9 (1699)	NS
% Social grade C2DE	59.3 (275)[cd]	65.9 (1266)[c]	65.5 (2277)[d]	*
Mean (SD) cigarettes per day[¶]	12.6 (8.0)[ef]	13.8 (8.5)[eg]	10.9 (8.1)[fg]	***
% (*n*) < 1 cigarettes per day[¶]	0.7 (3)[h]	0.8 (15)[i]	2.8 (94)[hi]	***
% (*n*) Time since quit attempt started >26 weeks	23.7 (110)[jk]	36.4 (700)[j]	36.5 (1269)[k]	***
Mean (SD) quit attempts in the past year	1.6 (0.9)	1.6 (0.9)	1.5 (0.9)	NS
Mean (SD) time spent with urges to smoke (0–5)	1.9 (1.3)[l]	2.2 (1.3)[lm]	1.8 (1.3)[m]	***
Mean (SD) strength of urges to smoke (0–5)	2.0 (1.2)[no]	2.2 (1.1)[np]	1.8 (1.1)[op]	***
Mean (SD) heaviness of smoking index[†]	2.0 (1.5)[qr]	2.3 (1.5)[qs]	1.6 (1.5)[rs]	***
% (*n*) Abrupt attempt (no gradual cutting down first)	50.4 (234)[t]	52.5 (1010)[u]	59.0 (2051)[tu]	***

Different pairs of superscript letters indicate a significant difference ($P < 0.05$) between two groups after Sidak adjustment for multiple comparisons. *$P < 0.05$; ***$P < 0.001$; NS = not statistically significant ($P \geq 0.05$). [§]A subgroup of those using nicotine replacement therapy (NRT) over-the-counter provided information about the form of NRT ($n = 975$): 60.0% (585) used a patch, 21.0% (205) gum, 14.9% (145) an inhalator, 6.2% (60) lozenges, 1.2% (12) microtabs and 1.0% (10) nasal spray. NB: response options were not mutually exclusive and 11.1% (108) reported using more than one form. [¶]Data were missing for 156 respondents (e-cigarettes: 22; NRT over-the-counter: 34; no aid: 100). [†]Data were missing for 172 respondents (e-cigarettes: 23; NRT over-the-counter: 36; no aid: 113). SD = standard deviation.

Table 2 Differences between smokers and non-smokers in strength of urges to smoke by method of quitting.

Method of quitting	*n*	*Mean (SD) strength of urges to smoke in smokers*	*n*	*Mean (SD) strength of urges to smoke in non-smokers*	*Mean difference (95% CI) in strength of urges to smoke*
E-cigarettes	371	2.3 (1.1)	93	0.8 (1.1)	1.4 (1.2–1.7)
NRT over-the-counter	1728	2.3 (1.0)	194	1.2 (1.3)	1.2 (1.0–1.3)
No aid	2942	2.0 (1.0)	535	0.7 (1.1)	1.3 (1.2–1.4)

NB: the mean differences are calculated from exact rather than the rounded figures presented in columns 3 and 5 of this table. The mean difference in strength of urges to smoke was not different across the methods of quitting ($F_{(2, 5856)} = 1.50$, $P = 0.22$ for the interaction term between smoking status and method of quitting adjusted for the time since the quit attempt started). SD = standard deviation; CI = confidence interval; NRT = nicotine replacement therapy.

NRT over-the-counter and 15.4% (535 of 3477) using no aid. The unadjusted analyses indicated that e-cigarette users were more likely to be abstinent than either those using NRT bought over-the-counter [odds ratio (OR) = 2.23, 95% confidence interval (CI) = 1.70–2.93) or those who used no aid (OR = 1.38, 95% CI = 1.08–1.76; see model 1, Table 3). The primary analyses revealed that the fully adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.17–2.27) times higher compared with users of NRT bought over-the-counter and 1.61 (95% CI = 1.19–2.18) times higher compared with those using no aid (see model 4, Table 3). The relative magnitudes of the ORs from the fully adjusted model with the other three unadjusted and partially adjusted models illustrate the confounding effects of dependence (see Table 3).

In *post-hoc* sensitivity analyses, the associations between quitting method and non-smoking were re-examined using models including different potential confounders. In a model including the more fine-grained assessment of time since the initiation of the quit attempt than the measure presented in Table 1, the adjusted odds of non-smoking in users of e-cigarettes were 1.58 (95% CI = 1.13–2.21) times higher compared with users of NRT bought over-the-counter and 1.55 (95% CI = 1.14–2.11) times higher compared with those using no aid. In another model that included another measure of dependence (HSI; missing data 3%, $n = 172$), the adjusted odds of non-smoking in users of e-cigarettes were 1.63 (95% CI = 1.15–2.32) times higher compared with users of NRT bought over-the-counter and 1.43 (95% CI = 1.03–1.98) times higher compared with those using no aid.

In *post-hoc* subgroup analyses, very light smokers were shown to have little influence on the pattern of results: in repeated analyses among those 5595 smokers reporting smoking one or more than one CPD the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.13–2.26) and compared with those using no aid (OR = 1.63, 95% CI = 1.18–2.24). Similarly, the exclusion of respondents

Table 3 Associations between quitting method and abstinence.

	(1) e-Cigarettes	*(2) NRT over-the-counter*	*(3) No aid*	*(1) versus (2)* *Model 1: OR (95% CI)* *Model 2: OR (95% CI)* *Model 3: OR (95% CI)* *Model 4: OR (95% CI)*	*(1) versus (3)* *Model 1: OR (95% CI)* *Model 2: OR (95% CI)* *Model 3: OR (95% CI)* *Model 4: OR (95% CI)*
Full sample (n = 5863)					
% (n) Self-reported non-smoking	20.0 (93/464)	10.1 (194/1922)	15.4 (535/3477)	2.23 (1.70–2.93)***	1.38 (1.08–1.76)*
				1.88 (1.40–2.52)***	1.21 (0.92–1.58)
				1.63 (1.17–2.28)**	1.62 (1.19–2.19)**
				1.63 (1.17–2.27)**	1.61 (1.19–2.18)**
Subsample: quit attempt started ≤26 weeks (n = 3784)					
% (n) Self-reported non-smoking	20.3 (72/354)	11.0 (135/1222)	14.6 (323/2208)	2.06 (1.50–2.82)***	1.49 (1.12–1.98)**
				1.80 (1.27–2.55)***	1.39 (1.01–1.90)*
				1.56 (1.06–2.29)*	1.88 (1.32–2.68)***
				–	–
Subsample: quit attempt started >26 weeks (n = 2079)					
% (n) Self-reported non-smoking	19.1 (21/110)	8.4 (59/700)	16.7 (212/1269)	2.56 (1.49–4.42)***	1.18 (0.72–1.94)
				1.98 (1.11–3.53)**	0.91 (0.54–1.55)
				1.64 (0.83–3.24)	1.10 (0.59–2.06)
				–	–

Model 1 = unadjusted; model 2 = adjusted for age, sex, social grade, time since quit attempt started, quit attempts in the past year, abrupt versus gradual quitting and year of the survey; model 3 = adjusted for the variables from model 2 and time spent with urges to smoke and strength of urges to smoke; model 4 = adjusted for the variables from model 3 and the interaction terms time since last quit attempt started × time spent with urges and time since last quit attempt started × strength of urges to smoke. NB: for the two subsample analyses, model 4 is redundant, as there is no variation in the time since quit attempt. *P < 0.05; **P < 0.01; ***P < 0.001. OR = odds ratio; CI = confidence interval; NRT = nicotine replacement therapy.

during a time when e-cigarette usage was relatively rare (2009–11) had little effect on the results: among those 2306 smokers responding between 2012–14 the adjusted odds of non-smoking in users of e-cigarettes were higher compared with users of NRT bought over-the-counter (OR = 1.59, 95% CI = 1.05–2.42) and those using no aid (OR = 1.46, 95% CI = 1.04–2.05). In a final subgroup analysis the models were re-examined among those who started their quit attempt more or less than 6 months ago: there was only evidence among those who began their attempts less than 6 months ago of higher odds of non-smoking in users of e-cigarettes compared with users of NRT bought over-the-counter or those using no aid in the fully adjusted models (see Table 3).

DISCUSSION

Respondents who reported having used an e-cigarette in their most recent quit attempt were more likely to report still not smoking than those who used NRT bought over-the-counter or nothing. This difference remained after adjusting for time since the quit attempt started, year of the survey, age, gender, social grade, abrupt versus gradual quitting, prior quit attempts in the same year and a measure of nicotine dependence.

The unadjusted results have value in that they demonstrate self-reported abstinence is associated with quitting method among those who use these methods to aid cessation in real-world conditions. However, this was not a randomized controlled trial and there were differences in the characteristics of those using different methods. For example, more dependent smokers tended to be more likely to use treatment, and smokers from lower social grades were less likely to use e-cigarettes. Although the adjustments go beyond what is typically undertaken in these types of real-world studies [28,29,41–44], it was not possible to assess all factors that may have been associated with the self-selection of treatment and we cannot rule out the possibility that an unmeasured confounding factor is responsible for the finding. For example, motivation to quit is likely to have been associated positively with the use of treatment. However, previous population studies have found that the strength of this motivation is not associated with success of quit attempts once started, so it is unlikely to explain our findings [45]. There are other variables which are typically related to abstinence that may also be related to the selection of treatment; for example, those using e-cigarettes may have been less likely to share their house with other smokers, had better mental health or greater social capital of a kind not measured by social grade. These possibilities mean the associations reported here must be interpreted with caution. Nevertheless, the data provide some evidence in forming a judgement as to whether the advent of e-cigarettes in the UK market is likely to be having a

positive or negative impact on public health, in a way that a randomized controlled trial is unable to do.

The finding that smokers who had used an e-cigarette in their most recent quit attempt were more likely to report abstinence than those who used NRT bought over-the-counter, and that the latter did not appear to give better results than not using any aid [33], contributes to the debate about how far medicine regulation can go in ensuring that products used for smoking cessation are or continue to be effective in the real world [14–17]. Randomized controlled trials are clearly important in identifying potential efficacy, but real-world effectiveness will depend upon a number of other contextual variables. The current study, together with previous randomized trials, suggests that e-cigarettes may prove to be both an efficacious and effective aid to smoking cessation [10,11]. In so far that this is true, e-cigarettes may substantially improve public health because of their widespread appeal [6–9] and the huge health gains associated with stopping smoking [46]. This has to be offset against any detrimental effects that may emerge, as the long-term effects on health have not yet been established. However, the existing evidence suggests the associated harm may be minimal: the products contain low levels of carcinogens and toxicants [3] and no serious adverse event has yet been reported in any of the numerous experimental studies. Regardless, the harm will certainly be less than smoking, and thus of greater importance is the possible long-term effect of e-cigarettes on cigarette smoking prevalence beyond helping some smokers to quit. For example, it has been suggested that e-cigarettes might re-normalize smoking, promote experimentation among young people who otherwise may not have tried smoking or lead to dual use together with traditional cigarettes, and thereby deter some smokers from stopping [47]. The current data do not address these issues. However, the rise in e-cigarette prevalence in England since 2010 has coincided with continued reduction in smoking prevalence [48].

If e-cigarette use is proving more effective than NRT bought over-the-counter, a number of factors may contribute to this [49]. A greater similarity between using e-cigarettes and smoking ordinary cigarettes in terms of the sensory experience could be one factor. Greater novelty is another. It is also possible that users of e-cigarettes use their products more frequently or for a longer period than those using NRT without professional support. These are all issues that need to be examined in future research.

This study was not designed to assess the comparative effectiveness of e-cigarettes and NRT or other medications obtained on prescription or behavioural support. The evidence still favours the combination of behavioural support and prescription medication as providing the greatest chance of success [33,34,37], which is currently offered free at the point of access by the NHS stop smoking services in the United Kingdom.

A major strength of the current study is the use of a large, representative sample of the English population. Additionally, the study benefits from having begun to track the use of e-cigarettes as an aid to cessation at a time when e-cigarettes were only an emerging research issue. The importance of adjusting for nicotine dependence in real-world studies of smoking cessation is illustrated by the difference in the ORs between the models with and without this adjustment. The optimal method of adjusting for dependence would be to assess this in all participants prior to their quit attempt. However, in a wholly cross-sectional study, we believe the particular method used to adjust for dependence, established in two previous studies, is valid [32,33]. One of the most commonly used alternative measures of dependence—HIS—relies upon the number of cigarettes smoked and time to first cigarette of the day [40]. When smokers relapse they tend to do so with reduced consumption, which can lead to a false estimation of prior dependence in cross-sectional studies. This potential confound was avoided in the primary analysis by using a validated measure involving ratings of current urges to smoke and statistical adjustment of the urges for the time since the quit attempt was initiated [39]. The value of strength of urges as a measure of dependence in cross-sectional research would be limited if different methods of stopping were linked differentially to lower or higher levels of urges in abstinent compared with relapsed smokers. For example, a method of stopping that led to a relatively higher reduction in urges could underestimate the effectiveness of that method by making it seem that those using it were less dependent. However, we have not previously found evidence in this population data set that urges to smoke in smokers versus quitters differs as a function of method [33], and it was true again in this study. Regardless, the pattern of results remained the same in both a sensitivity analysis that also included HSI and in a subgroup analysis that excluded very light smokers. It is unlikely, therefore, that differential dependence between the users of different treatments has led to a substantial over- or underestimation of the relative effectiveness of e-cigarettes in the current study. Nevertheless, future studies may be able to draw stronger inferences by including a broader array of dependence measures or assessing dependence prior to a quit attempt.

The study had several limitations. First, abstinence was not verified biochemically. In randomized trials, this would represent a serious limitation because smokers receiving an active treatment often feel social pressure to report abstinence. However, in population surveys the

social pressure and the related rate of misreporting is low and it is generally considered acceptable to rely upon self-reported data [38]. A related issue is the assessment of abstinence by asking respondents whether they were 'still not smoking'. This definition classified as abstinent those who had one or more lapses but resumed not smoking. This limitation would be serious if the rate of lapsing was associated with method of quitting, and should be assessed in future studies. By contrast, advantages of this measure were the assessment of prolonged abstinence, as advocated in the Russell Standard, and a clear relationship to the quit attempt in question. An alternative approach, with a view to survival analysis, may have been to assess the length of abstinence since quit date among all respondents, including those who had relapsed by the time of the survey. However, this assessment would have added noise and potential bias with smokers needing to recall the time of relapse and having different interpretations of their return to smoking (i.e. first lapse, daily but reduced smoking, or smoking at pre-quit level). The strength of our approach is that smokers only needed to know whether they were currently still not smoking.

Secondly, there was a reliance upon recall data. The assessment of the most recent quit attempt involved recall of the previous 12 months and introduced scope for bias. The bias associated with recall of failed quit attempts would be expected to reduce the apparent effectiveness of reported aids to cessation because quit attempts using such aids would be more salient than those that were unaided [31]. Therefore, recall bias should militate against finding a benefit of e-cigarettes compared with no aid to cessation. Consistent with this explanation, the effect size for e-cigarettes compared with no aid appeared lower in smokers who started their quit attempt more than 6 months ago than in smokers who started their quit attempt less than 6 months ago. Although the power to detect the associations in these subgroups was limited, the explanation that the lack of effect in the more distant attempts was related to differential recall bias is also supported by the absolute rate of non-smoking being higher in those making unaided attempts more than 6 compared with less than 6 months ago. Alternatively, the finding may reflect a reduced long-term effectiveness of e-cigarettes. Future longitudinal studies of e-cigarettes as aids to cessation in the general population may differentiate these explanations and would represent a valuable improvement upon the current study.

Thirdly, NRT over-the-counter and e-cigarettes both represent heterogeneous categories. In particular, there is considerable variability in nicotine vaporization between different types of e-cigarette [50,51]. Similarly, the simple definition of using one or the other aid to support an attempt is likely to have masked variability in how heavily, frequently and how long either NRT over-the-counter or e-cigarettes were used by different smokers [12,52–54]. It is also possible that there were differences between the groups in their experience of unanticipated side effects. It is precisely because of all these factors—type/brand of NRT over-the-counter or e-cigarette, intensity and frequency of usage and experience of unanticipated side effects—that it is important to examine real-world effectiveness. However, it also means that we cannot make more exact statements about relative effectiveness of different products and ways in which they may be used. Given this huge variability it may be many years before one could accumulate enough real-world data to address these questions. Finally, the prevalence of e-cigarettes has been increasing in England over the study period and this may affect real-world effectiveness. Although the evidence does not yet suggest an 'early adopters' effect—the current results persisted after adjusting for the year of survey and in a subgroup analysis limiting the data to a period when e-cigarette usage had become prevalent—these findings will need to be revisited to establish whether or not the apparent advantage of e-cigarettes is sustained.

In conclusion, among smokers trying to stop without any professional support, those who use e-cigarettes are more likely to report abstinence than those who use a licensed NRT product bought over-the-counter or no aid to cessation. This difference persists after adjusting for a range of smoker characteristics such as nicotine dependence.

Declaration of interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: JB's post is funded by a fellowship from the UK Society for the Study of Addiction; R.W. is funded by Cancer Research UK; Cancer Research UK, the Department of Health and Pfizer funded data collection for this study (including a Pfizer investigator initiated award), and that at the outset data collection for the Smoking Toolkit Study was also supported by GlaxoSmithKline and Johnson and Johnson; J.B., D.K. and E.B. have all received unrestricted research grants from Pfizer; R.W. undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis and Sanofi-Aventis); there are no other financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, particularly electronic cigarette companies, and there are no other relationships or activities that could appear to have influenced the submitted work. Funding was provided for the conduct of this research and preparation of the manuscript. The funders had no

final role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication. All researchers listed as authors are independent from the funders and all final decisions about the research were taken by the investigators and were unrestricted.

Transparency declaration

J.B. affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

STROBE statement

All authors declare that study hypotheses arose before any inspection of the data and that all STROBE recommendations were followed.

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