WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

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

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Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control

Report of the working group

1. At its fourth session (Punta del Este, Uruguay, 15–20 November 2010), the Conference of the Parties (COP) adopted partial guidelines for implementation of Article 9 (*Regulation of the contents of tobacco products*) and Article 10 (*Regulation of tobacco product disclosures*). The COP also decided[1] to mandate the working group on Articles 9 and 10 to:

- continue its work in elaborating guidelines in a step-by-step process, and to submit draft guidelines on addictiveness and toxicity to future sessions of the COP for consideration;
- continue to monitor areas such as dependence liability and toxicology; and
- examine the regulation of cigarette ignition propensity, as a product characteristic.

2. Areas for further development of the partial guidelines were chosen by the Key Facilitators of the working group on the basis of the responses received to a questionnaire that was circulated to the members of the working group in March 2011; several Parties also expressed interest in supporting the Key Facilitators in their task. At its seventh meeting (Geneva, Switzerland, 24–26 January 2012), the working group reviewed draft documents submitted by three drafting teams in the areas chosen: regulation of cigarette ignition propensity, as a product characteristic; disclosure to the public and confidentiality in relation to disclosure to the public; and tobacco addictiveness reduction. The Key Facilitators collected comments and views on the draft documents and implemented them accordingly.

[1] See decision FCTC/COP4(10).

After the draft text was made available to the Parties on 11 May 2012, comments from 12 Parties were received and considered by the Key Facilitators.

CONSIDERATIONS IN THE DEVELOPMENT OF PROPOSALS FOR INSERTION INTO THE DRAFT PARTIAL GUIDELINES ON ARTICLES 9 AND 10.

3. Bearing in mind the step-by-step development of the guidelines for the implementation of Articles 9 and 10[1], and considering the mandate assigned at the fourth session of the COP,[2] the working group presents two draft texts, attached as Annexes to the present document (Annex 1 on public disclosure and Annex 2 on product characteristics in relation to fire-risk). These are for insertion as indicated into the sections labelled "This section has been left blank intentionally" of the partial guidelines for implementation of Articles 9 and 10 as adopted at the fourth session of the COP. A background paper on tobacco addictiveness reduction (Annex 3) is also attached.

4. The draft text on public disclosure (Annex 1) does not yet include a definition of "constituents" for section 1.3 (Use of terms) of the partial guidelines, The working group will reconsider this matter at a future meeting following the fifth session of the COP, if it receives the mandate to do so.

5. The mandate of the working group provided by the COP at its fourth session included monitoring dependence liability and submitting draft guidelines on addictiveness. The working group agreed that drafting guidelines on addictiveness reduction would be premature; the development of such guidelines would be contingent on additional research and on country experience. Therefore, the working group opted to provide the COP with a background paper containing information on the current level of knowledge, as well as guidance on additional research that could be undertaken in this area, which is contained in Annex 3.

6. The working group has prepared a "white paper" listing some of the documents consulted in developing the three Annexes to the present report, and has asked the Convention Secretariat to make it available on the WHO FCTC web site to the Parties as background information.

RESOURCES AND RESEARCH

7. The working group noted the progress made by the Parties in regulating tobacco product contents and disclosures and the benefit of having additional country experience as new measures are implemented. However, more research is needed to enable the further development of the partial guidelines. The working group invites the COP to encourage Parties, international, regional and subregional organizations, international financial institutions and/or other development partners to assign resources to research that would support Parties in implementing Articles 9 and 10.

8. In reference to section 12 of the background paper on tobacco addictiveness reduction (Annex 3) which sets out a non-exhaustive list of aspects of addictiveness (and dependence liability) that remain to be studied, the working group invites the COP to encourage Parties to research, support research and/or monitor research in respect of the issues raised. The COP could request the

[1] As outlined in decision FCTC/COP3(9).

[2] See decision FCTC/COP4(10)

Convention Secretariat to invite WHO's Tobacco Free initiative to direct some of its activities towards the questions outlined in section 12 of the background paper (Annex 3).

PROPOSED FUTURE WORK

9. At its third session (Durban, South Africa, 17–22 November 2008), the COP requested[1] the Convention Secretariat to invite WHO's Tobacco Free Initiative, among other work, to validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report (document FCTC/COP/3/6) of the working group. As indicated in document FCTC/COP/5/INF.DOC./1, that work is on track for completion in 2013. In view of that fact, the COP could mandate the working group to further develop the partial guidelines to include testing and measuring of contents and emissions using the validated analytical chemical methods.

10. In continuation of that work, the COP could assign to the working group the task of identifying other cigarette contents and emissions for which analytical chemical methods need to be validated, and/or of identifying the analytical chemical methods for which validation should be extended to include tobacco products other than cigarettes.

11. Should the COP decide to extend the mandate given to the working group "to continue to monitor […] toxicology" and "to submit draft guidelines on […] toxicity", the working group would recommend to the COP that its mandate include developing a background paper on toxicity reduction and to request the Convention Secretariat to invite WHO's Tobacco Free Initiative to direct some of its activities towards identifying and addressing key issues relating to the toxicity of tobacco products .

12. Members of the working group have also noted that the tobacco industry is constantly developing new technologies to induce the use of tobacco products and nicotine. The COP is invited to indicate whether the mandate of the working group should be extended to include monitoring new tobacco products and "modified risk" products (including the identification of harms and possible regulatory approaches).

13. Comments received from Parties highlight the fact that the partial guidelines do not address the possible false, misleading or deceptive conduct and/or representations with respect to tobacco products characteristics and/or performance relating to content regulation. The COP is invited to indicate whether the mandate of the working group should be extended to propose text to address this issue.

ACTION BY THE CONFERENCE OF THE PARTIES

14. The COP is invited to note the report of the working group, to review and consider adopting Annexes 1 and 2 proposed for insertion into the existing partial guidelines on Articles 9 and 10, to take note of Annex 3 and to provide further guidance.

[1] See decision FCTC/COP3(9).

ANNEX 1

PUBLIC DISCLOSURE – TOXIC CONSTITUENTS AND EMISSIONS

TEXT PROPOSED FOR INSERTION INTO THE PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC AS ADOPTED BY THE COP AT ITS FOURTH SESSION

INSERT after heading "1.2.3 Disclosure to the public"

Pursuant to Article 10, the primary objective of public disclosure of information about the toxic constituents and emissions of tobacco products is to inform the public of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke. This information may also assist the public in contributing to the development and implementation of relevant policies, activities and regulations.

INSERT after heading "2.7 Confidentiality in relation to disclosure to the public"

Parties should disclose information about the toxic constituents and emissions of tobacco products to the public in a meaningful way. Parties may determine in accordance with their national laws the information about the toxic constituents and emissions of tobacco products that should not be disclosed to the public.

INSERT after heading "3.5 Disclosure to the public"

3.5.1 Background

Many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality attributable to tobacco use and exposure to tobacco smoke. Complementing other measures relating to the reduction of demand for tobacco, Article 10 of the WHO FCTC requires that each Party shall adopt and implement effective measures for public disclosure of information about the toxic constituents of tobacco products and the emissions that they may produce. As stated in Article 4.1 of the WHO FCTC, Parties shall be guided by the principle that every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke.

3.5.2 Scope and means of public disclosure

3.5.2.1 Public access to information disclosed to governmental authorities

Detailed information about the toxic constituents and emissions of tobacco products is difficult to comprehend, and public disclosure of such information might not directly promote or protect public health. However, such information may assist other members of civil society, particularly academic institutions and nongovernmental organizations, in contributing to tobacco control policy.

In addition, other information disclosed to governmental authorities in accordance with these guidelines, such as information on ingredients, product characteristics and the market, may also contribute to raising public awareness and advancing tobacco control policy.

Recommendation:

Parties should consider, in accordance with their national laws, making information about the toxic constituents and emissions of tobacco products and other information disclosed to governmental authorities in accordance with these guidelines publicly accessible (e.g. via the Internet, or by request to a governmental authority) in a meaningful way.

3.5.2.2 Public disclosure of constituents and emissions in the context of Articles 11 and 12 of the WHO FCTC

Information on how public disclosure is linked to Articles 11 and 12 of the WHO FCTC can be found in section 7, "LINKS TO OTHER ARTICLES OF THE WHO FCTC".

INSERT after heading "7 LINKS TO OTHER ARTICLES OF THE WHO FCTC"

7.1 Packaging suggesting the presence of a prohibited ingredient

INSERT after paragraph "7.1 Packaging suggesting the presence of a prohibited ingredient"

7.2 Information on relevant constituents and emissions on tobacco packaging

Tobacco product packaging and labelling are an effective means of public communication about constituents and emissions of tobacco products, as recognized in Article 11 of the WHO FCTC. Parties should refer to Article 11 and the guidelines for its implementation.

7.3 Information on relevant constituents and emissions in education, communication, training and other public awareness programmes

Parties should consider including messages about constituents and emissions of tobacco products in education, communication, training and other public awareness programmes. Such messages may reinforce efforts to inform the public of the health consequences, addictive nature and mortal threat posed by tobacco use and exposure to tobacco smoke in programmes established in accordance with Article 12 of the WHO FCTC and the guidelines for its implementation.

ANNEX 2

PRODUCT CHARACTERISTICS IN RELATION TO FIRE-RISK (REDUCED IGNITION PROPENSITY)

TEXT PROPOSED FOR INSERTION INTO THE PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC AS ADOPTED BY THE COP AT ITS FOURTH SESSION

INSERT after heading "3.3.2 Regulation"

3.3.2.1 *Cigarettes – Regulation in relation to fire-risk (reduced ignition propensity)*

(i) Background

Lit cigarettes that are laid down and left unattended smoulder and can ignite upholstery, other furniture, bedding and other textiles, or other material. This has been observed most often in cases of smoking in bed or smoking while under the influence of alcohol, illicit drugs or medication. Every year a considerable number of people around the world are injured or die (e.g. from burns or smoke gas poisonings) as a result of fires caused by cigarettes.

In order to prevent a significant number of such injuries and deaths, cigarettes can be designed in a way that the cigarette self extinguishes when not puffed or left unattended and thereby has a reduced risk of starting fires. These cigarettes are known as reduced ignition propensity cigarettes (RIP cigarettes).

Reductions in the number of cigarette fires and related victims have been observed in some jurisdictions that have mandated the replacement of conventional cigarettes with RIP cigarettes. Although RIP cigarettes do not self-extinguish in every case, they are expected to reduce the risk of a fire being ignited, and thus the risk of injuries and deaths. It is important to note that mandating an RIP standard is aimed at reducing the number of fires caused by lit cigarettes; it will not eliminate them.

There have been claims that RIP cigarettes may have a different toxicity than conventional cigarettes. Research suggests that RIP cigarettes are just as toxic as conventional cigarettes and equally dangerous to human health.

(ii) Regulating the ignition propensity of cigarettes

In regulating the ignition propensity of cigarettes, governmental authorities usually take a performance-based approach by adopting provisions that prescribe the test method to be used, and then provisions that set the pass/fail criteria (performance standard) applicable to the results obtained after conduct of the test (see Appendix 4).

In a number of cases, governmental authorities have also laid down requirements related to a specific technique for achieving RIP, namely banded paper technology, and requirements related to certification (see Appendix 5).

(iii) Recommendations

(i) Parties should require that cigarettes comply with an RIP standard, taking into account their national circumstances and priorities.

(ii) When implementing recommendation (i) of this paragraph, Parties should consider setting a performance standard that corresponds at a minimum to the current international practice, regarding the percentage of cigarettes that may not burn their full length when tested according to the method described in Appendix 4.

(iii) Parties should not allow any claims to be made suggesting that RIP cigarettes would be unable to ignite fires.

INSERT instead of "4.4 Deadline – prohibited or restricted ingredients"

4.4 Deadlines

4.4.1 Prohibited or restricted ingredients

(Text remains the same as in the current paragraph 4.4)

4.4.2 Reduced ignition propensity

Parties should specify a deadline following which the tobacco industry and retailers must only supply cigarettes that comply with the required RIP standard.

INSERT instead of "4.6 Sampling and testing – prohibited or restricted ingredients"

4.6 Sampling and testing

4.6.1 Prohibited or restricted ingredients

(Text remains the same as in the current paragraph 4.6)

4.6.2 Reduced ignition propensity

Parties should consider having samples of cigarettes collected from manufacturers, importers or retailers. These samples should then be tested to ascertain whether they comply with the required RIP performance standard. Both sampling and testing should be carried out according to the method described in Appendix 4.

APPENDIX 4

Performance standard for reduced ignition propensity (RIP) cigarettes and related standard test methods

The performance standard for RIP cigarettes has been expressed as the percentage of cigarettes that, when ignited and laid down on a pre-determined substrate, do not burn through their whole length.

As of 2012, international practice is to require a not-burn-through rate of no less than 75%.

As of 2012, available standard test methods for sampling and verifying the conformity of cigarettes with the required not-burn-through rate include: ISO 12863:2010 "Standard test method for assessing the ignition propensity of cigarettes"; EN ISO 12863:2010 "Standard test method for assessing the ignition propensity of cigarettes"; AS 4830-2007 "Determination of the extinction propensity of cigarettes"; NZS/AS 4830:2007 "Determination of the extinction propensity of cigarettes"; and ASTM E2187-09 "Standard Test Method for Measuring the Ignition Strength of Cigarettes".

APPENDIX 5

Reduced ignition propensity cigarettes – additional information

a) Design of the cigarette paper

Where Parties have required banded paper technology, one of the practices with respect to both filter and non-filter cigarettes is for one band surrounding the tobacco column to be located not less than 15 mm from the lighting end of the cigarette, and for a second such band to be located not less than 10 mm from the filter end or, in the case of non-filter cigarettes, not less than 10 mm from the labelled end of the tobacco column.

(b) Certification approach

Where a self-certification approach has been adopted, the practice is to require the tobacco industry to file with the appropriate governmental authority a statement of conformity and/or declaration of truth, with the required RIP standard. An alternative approach would be to mandate third-party certification.

ANNEX 3

BACKGROUND PAPER ON TOBACCO ADDICTIVENESS REDUCTION

Contents

1. Introduction

At its fourth session, the Conference of the Parties decided "to mandate the working group to […] continue its work in elaborating guidelines in a step-by-step process, and to submit draft guidelines on addictiveness and toxicity to future sessions of the Conference of the Parties for consideration".[1]

Addressing the addictiveness[2] of tobacco products should be a critical component of a strategy to reduce tobacco use. As a first step that may eventually lead to guidelines, the working group has developed this background paper to help Parties better understand the challenges and opportunities surrounding this issue. Additional research will be necessary to support the development of guidelines on tobacco addictiveness.

2. What is tobacco addictiveness?

Tobacco addictiveness is not the same as tobacco addiction.[3] Tobacco addictiveness refers to the pharmacological potential of a tobacco product to affect an individual's physiological or psychological functions in such a way as to establish and sustain a tobacco addiction. The addictiveness of a tobacco product relates to its ability to instil a reward or a relief from withdrawal symptoms, or both.

Tobacco addictiveness is a complex problem that varies with the chemical nature of the tobacco product's emissions and its physical design features. Key elements include the dose, speed of absorption, metabolism, and physical and chemical features of the product.

For any given tobacco product, the risk of addiction in an individual also varies widely as a function of genetics, social environment, protective factors, perception of risk, availability of funds to pay for tobacco products, and so on.

3. What makes tobacco products addictive?

Nicotine is the main substance in tobacco that causes addiction. How nicotine is delivered to the central nervous system (CNS), its chemical form, the ease with which the dose may be adjusted to the user's needs, and tobacco product design characteristics that offer the user ease of administration all play a key role in developing and maintaining addiction. Given the association between drug delivery rate and addiction potential, the ability to deliver nicotine as rapidly as possible to the CNS may affect the addictive potential of a tobacco product.

While research shows that nicotine, the main alkaloid found in tobacco leaves, may not be the only substance in tobacco that affects its addictiveness, at least in smoked products, no other substance in tobacco that has this effect has been conclusively identified.

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[1] See decision FCTC/COP4(10) in document FCTC/COP/4/REC/1, available at http://apps.who.int/gb/fctc/E/E_cop4.htm.

[2] Addictiveness is sometimes referred to as dependence liability or addictive potential.

[3] See *Guidelines for implementation of Article 14 of the WHO Framework Convention on Tobacco Control* for a definition of "tobacco addiction/dependence." Tobacco addiction is used here interchangeably with nicotine addiction, tobacco dependence and nicotine dependence.

That said, tobacco contains more than 20 different, but related, pyridine alkaloids. The effects of several minor alkaloids (anabasine, anatabine, cotinine, myosmine and nornicotine) have been studied to determine whether they have reinforcing properties on their own or whether they enhance nicotine self-administration. It remains unclear whether one or more minor alkaloids are responsible for facilitating nicotine self-administration.

Researchers have found a marked decrease in the levels of monoamine oxidase (MAO) in the brains and peripheral organs of smokers. MAO is an important enzyme responsible for breaking down dopamine. The decrease in MAO results in higher dopamine levels and may be another reason that smokers continue to smoke, i.e. to sustain the high dopamine levels that lead to the desire for repeated drug use. It has been suggested that this change is likely to be caused by a substance in tobacco smoke other than nicotine. Certain tobacco constituents are reported to be MAO inhibitors, such as 2,3,6-trimethyl-1-4-naphthoquinone, and two β-carboline alkaloids, harman (1-methyl-β-carboline) and norharman (β-carboline). Not much is known about the influence of oral tobacco products use on the levels of MAO.

A few other substances in tobacco, such as acetaldehyde, have been tested for their ability to increase the likelihood of nicotine self-administration. A number of published papers show that acetaldehyde, formed during the combustion of organic material, exerts biological effects that may contribute to addiction.

Cultural, social, physical (sensorimotor) and economic factors are also reported to be associated with the sustained use of tobacco products.

4. How would reducing tobacco addictiveness benefit health?

The main health objective sought by mandating a reduction in the addictiveness of tobacco products is to prevent tobacco dependence, especially among youth experimenting with tobacco. A secondary health objective would be to help addicted tobacco users who struggle with attempts at quitting.

The overall benefit to public health from reducing tobacco addictiveness is to reduce the prevalence of tobacco use.

Any eventual reduction in the addictiveness of tobacco products would in no way suggest that those tobacco products are less dangerous to human health than conventional tobacco products.

5. Can degrees of tobacco addictiveness be measured?

No standardized method currently exists to measure the degree of addictiveness of a tobacco product. Therefore, regulatory agencies do not have at their disposal a performance-based standard that they could readily reference in legislation. That said, some research has been carried out into the feasibility of adapting abuse liability test methodology as used with regard to pharmaceutical products for this purpose.

Measuring the degree of addiction in tobacco users is a different matter. Several tools exist for measuring addiction (mainly among smokers), the most widely used being the Fagerström Test for Nicotine Dependence (also known as Fagerström Test for Cigarette Dependence) and the Diagnostic and Statistical Manual criteria for nicotine dependence. Both methods have limitations.

It is important to keep in mind that tobacco products are considered to be addictive (see the sixth preambular paragraph of the WHO Framework Convention on Tobacco Control). As with most addictive drugs, it is possible for some people to use tobacco products occasionally without developing addiction.

6. Can nicotine content be measured?

Nicotine is the dominant alkaloid in tobacco, making up about 88% of the total alkaloid content of some tobaccos. Nearly all the nicotine in tobacco is in the form of nicotine salts. A number of methods exist to measure nicotine in tobacco and tobacco products:

- A method validated by members of the WHO Tobacco Laboratory Network (TobLabNet) for determining nicotine in tobacco (see document FCTC/COP/4/INF.DOC./2, *Work in progress in relation to Articles 9 and 10 of the WHO Framework Convention on Tobacco Control: Report by WHO's Tobacco Free Initiative*, submitted to the fourth session of the Conference of the Parties).

- The International Organization for Standardization (ISO) method ISO 2881:1992 "Tobacco and tobacco products – Determination of alkaloid content – Spectrometric method".

- Health Canada's Official Method T-301 (Determination of Alkaloids in Whole Tobacco), published in December 1999.

- CORESTA Recommended Method No. 35, "Determination of Total Alkaloids (as Nicotine) in Tobacco by Continuous Flow Analysis *(second updated edition)*" (2010); and Recommended Method No. 62, "Determination of Nicotine in Tobacco and Tobacco Products by Gas Chromatographic Analysis" (2005).

- Centers for Disease Control and Prevention's Revised Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products, published in: Federal Register/Vol. 74, No. 4/ Wednesday, January 7, 2009/Notices.

A number of other methods have been used and reported on by researchers in the scientific literature.

7. What levels of nicotine are found in leaf tobacco and in tobacco products?

The levels of nicotine in leaf tobacco and tobacco products vary widely. Tobacco leaves used in commercial tobacco products come mainly from the species *Nicotiana tabacum*. A very small number of products use leaves from the species *Nicotiana rustica* (e.g. Sudanese "toombak"). From a random examination of 152 cultivated varieties of *Nicotiana tabacum*, researchers have reported alkaloid variation between 1.7 and 49.3 mg/g.

Some of the prominent factors that determine the levels of nicotine in a leaf tobacco include tobacco type (e.g. sun-cured oriental, flue-cured Virginia, air-cured Burley, and air-cured dark tobacco), leaf position on the plant, agricultural practices, fertilizer treatment, and degree of ripening. Researchers have reported that tobacco leaves harvested from the bottom of Virginia tobacco plants contain the lowest amount of nicotine, whereas the leaves from the top contain the highest amount (37.4 and 60.4 mg/g dry tobacco, respectively).

Tobacco products that are combusted

There is a wide variation in nicotine content in cigarette tobacco sold worldwide. The amount of nicotine in a blended cigarette is usually 8 to 15 mg (per cigarette). The nicotine concentration in a sample of 48 international brands ranges from 13.8 to 23.2 mg/g (dry tobacco).

The concentration of nicotine in the tobacco of 12 brands of bidi ranges from 15.3 to 27.1 mg/g.

Tobacco products that are heated

The nicotine concentration in commercial tobacco preparations used in waterpipe smoking (also known as arghileh, narghileh, narguila, hookah, sheesha, chicha, gozah) ranges from 1.8 to 6.3 mg/g in flavoured products (also known as mua'sel); in unflavoured products, the range is from 30 to 41 mg/g.

Tobacco products that are taken orally or nasally

A recent survey of international oral tobacco products reports the following ranges of nicotine level (mg/g, wet weight): gul, 34.1–33.4; zarda, 9.55–30.4; khaini, 2.53–4.79; gutkha, 0.91–4.20; naswar, 10.5–14.2; toombak, 10.3–28.2; snuff, 1.17–14.9; snus, 7.76–17.2; chimó, 5.29–30.1. [1]

8. Can the nicotine content of leaf tobacco, and of tobacco products, be reduced?

Nicotine can be reduced either by chemically removing it from the leaf tobacco or through genetic engineering.

Removing nicotine from tobacco leaves can be done through a process known as supercritical fluid extraction, a high-pressure carbon dioxide process used to decaffeinate coffee. This process reportedly removes about 97% of nicotine. In the early 1990s, a manufacturer in the United States of America used this method to process the tobacco leaves used to make a brand of cigarettes marketed as "denicotinized". These cigarettes each reportedly contained 0.03 mg nicotine per gram of dry tobacco.

Another approach to nicotine reduction is to use leaf tobacco that has been genetically modified to produce very low nicotine content. Traditional genetic manipulation has been able to reduce nicotine levels about tenfold.

More recently, tobacco has been genetically engineered to produce very low nicotine levels. Researchers used molecular biological technologies in the late 1990s at North Carolina State University in the USA to develop a tobacco line with nicotine levels of about 0.05 mg nicotine per gram of tobacco (measurements made from cigarettes produced in the USA that used leaves from this line).

[1] See Glossary (on the last page).

9. Has a threshold level been established for nicotine in tobacco products that would not cause or sustain addiction?

There is no consensus yet on what threshold level of nicotine in tobacco products would not cause or sustain addiction in all tobacco users. Research initiated in North America involving cigarettes with various levels of nicotine may help to provide further information in this regard. That said, experts in this area believe that tobacco products in which nicotine is virtually absent will not cause or sustain addiction.

10. How do reduced nicotine content tobacco products relate to "compensation"?

The phenomenon known as "compensation" is discussed in the context of smoked tobacco products, such as cigarettes.

Smokers are able to smoke cigarettes with more or less intensity, thus obtaining different doses of nicotine each time. A concern expressed with regard to cigarettes that have so-called reduced nicotine (smoke) yield is that smokers will smoke more cigarettes and/or smoke them more intensively to "compensate" for lower nicotine levels in the smoke they inhale. This increases their exposure to carcinogens and other toxic emissions in the smoke.

A similar concern has been expressed about reductions in the nicotine content of cigarettes: that smokers will also compensate for reduced nicotine by smoking more cigarettes and/or smoking them more intensively (see also section 11, below).

Cigarettes typically marketed as having "low yields" are low yield not because their nicotine content has been reduced, but because of the lower levels of nicotine and tar in the smoke[1] when the smoke is produced under "ISO" conditions. Generally, low-yield cigarettes have nicotine content similar to regular cigarettes; the lower yields measured in their smoke are generally a result of specific cigarette design features,[2] not an actual reduction in nicotine content.

11. Would it be more beneficial to public health to have a gradual reduction or a one-time reduction in the nicotine content of smoked tobacco products?

There is no consensus on whether a gradual, stepwise reduction of nicotine or a single, rapid reduction would be more beneficial to public health.

One proposed approach is to gradually reduce the nicotine content of tobacco products in order to reach very low levels over time, in a stepwise fashion. It has been suggested that such gradual reduction in smoked tobacco products may lead to compensatory behaviour. A small-scale, short-term clinical study in which the levels of nicotine in cigarettes were gradually reduced showed some initial compensatory smoking behaviour at initial dose reductions. At very low doses, researchers observed no compensatory behaviour or increased exposure to toxicants. They also noted a reduction in the

[1] Nicotine in cigarette smoke is measured after first extracting smoke by smoking machines according to a set of predetermined smoking parameters, such as those found in applicable ISO standards, and then by applying analytical chemistry tools to measure the amount of nicotine in the extracted smoke.

[2] These design features generally deal with mainstream smoke dilution through filter ventilation and paper porosity.

level of dependence and an increase in the potential facilitation of cessation in smokers who are uninterested in quitting. These findings are consistent with a larger-scale study which revealed that progressively reducing the nicotine content of cigarettes over six months is associated with a progressive reduction in nicotine intake by the smokers, with no increase in cigarettes smoked per day and no significant increase in exposure to tobacco smoke combustion products.

The other proposed approach is to rapidly reduce nicotine content (through a one-time reduction) to very low levels. One study examined the effects of using reduced-nicotine cigarettes with smokers interested in quitting smoking. In the study, subjects who immediately switched to smoking substantially reduced-nicotine cigarettes showed reduced toxicant exposure, reduced dependence, no compensatory behaviour, and a cessation rate similar to, if not slightly higher, than that found with medicinal nicotine-based cessation products.

It has been suggested that addicted tobacco users who are not willing to quit would be likely to face acute nicotine deprivation if forced to use only tobacco products with very low nicotine content. However, some studies have suggested that this may not be the case for all dependent smokers. Acute nicotine deprivation in physically dependent tobacco users can precipitate withdrawal symptoms that can be severely disruptive to behaviour, emotions, cognitive function, and physiological health. It is possible that acute nicotine abstinence might precipitate symptoms of depression in people with histories of major depressive disorders, exacerbate symptoms of other forms of psychiatric illness, or complicate the management of other forms of drug dependence treatment, but this has not been well studied.

Certain addicted tobacco users who experience substantial withdrawal symptoms will be likely to seek out alternative forms of tobacco or nicotine and/or accept treatment to help them cope with the new environment.

12. What issues could be considered for further research in tobacco addictiveness?

Useful information could be gained from studying the following issues:

A. What health, behavioural and social impacts would a market-wide nicotine content reduction measure have on addicted tobacco users and on non-addicted tobacco users, both positive and negative? And what would be the impact on prevalence and consumption, as well as morbidity and mortality?

B. What impact would a market-wide nicotine content reduction measure have on initiation?

C. What approach to tobacco addictiveness reduction would provide the most benefit to public health? D. Considering the existence of addictiveness models for some drugs, is it necessary to develop a tobacco addictiveness model, and if so, is it feasible?

E. In reference to the answer to section 3 (“What makes tobacco products addictive?”), what more can we learn about the role of substances other than nicotine in sustaining tobacco addiction? How could governmental authorities monitor these substances and, eventually, regulate them?

F. How can we test whether the lowest nicotine levels in leaf tobacco achieved so far, by supercritical fluid extraction or genetic manipulation, can sustain addiction?

G. What would be the essential elements of a monitoring and surveillance plan that would accompany a nicotine content reduction measure?

H. Which additives enhance the addictiveness of tobacco products, what is their role and how do they act?

I. Are there any lessons to be learnt from how hemp and marijuana (two forms of the same plant species *Cannabis sativa* but with different THC levels) are regulated in various jurisdictions? Are there other examples?

J. What impacts other than health, behavioural or social could result from a market-wide nicotine content reduction measure?

Glossary[1]

***Chimó*:** Tobacco paste made from tobacco leaves, sodium bicarbonate, brown sugar, ashes from the Mamón tree (*Melicocca bijuga*), vanilla and anisette flavours. *Chimó* is specific to Venezuela.

Dry snuff*:** Fire-cured, fermented tobacco powder that may contain aroma and flavour additives. See also ***khaini.

***Gul*:** Mixture of tobacco powder, molasses and other flavouring ingredients sold as a powder and used as a dentifrice.

***Gutkha*:** Commercially prepared betel quid which consists of sun-dried or roasted finely chopped tobacco mixed with areca nut, slaked lime, catechu and flavouring ingredients. Also spelled *gutka*.

***Khaini*:** Mixture of sun-dried, coarsely cut tobacco leaves crushed into smaller pieces and mixed with slaked lime. Also known as *chada*, *chadha* or *sada*, or as *surti* in Nepal and neighbouring parts of India.

***Moist snuff*:** Air- and fire-cured tobacco, including stems and leaves, that is powdered into fine particles or strips containing 20–55% moisture by weight. Also includes flavouring agents and chemical buffering agents.

***Naswar*:** Mixture of powdered tobacco, ash, flavouring and colouring agents, oil and sometimes lime. Also known as *niswar*, *nass*, *nasswar*.

***Snuff*:** General term for finely cut or powdered, flavoured tobacco. Snuff can be prepared as three types: moist snuff, fine-cut or long-cut tobacco particles, and dry snuff.

***Snus*:** Swedish-type moist snuff consisting of finely ground dry tobacco mixed with aromatic substances, salt, water, humidifying agents and chemical buffering agents.

***Toombak*:** Fermented tobacco and sodium bicarbonate rolled into a ball, used in Sudan. Also known as *saffa*.

***Zarda*:** Flaked tobacco leaves boiled in water with lime and spices until evaporation, then dried and coloured with vegetable dyes, generally chewed mixed with finely cut areca nut and spices. Also known as *dokta*.

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[1] Glossary extracted from *Smokeless tobacco and some tobacco-specific N-Nitrosamines.* Lyon, World Health Organization/International Agency for Research on Cancer, 2007 (Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 89); available at http://monographs.iarc.fr/ENG/Monographs/vol89/mono89-8.pdf.