Work in progress in relation to Articles 9 and 10 of the WHO FCTC

Report by WHO

INTRODUCTION

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) \(^1\) to the Convention Secretariat to invite WHO to:

   (a) monitor and follow closely the evolution of new tobacco products, including products with potentially “modified risks” and to report to the COP on any relevant development;

   (b) direct some of its activities towards section 12 of the background paper (Annex 3 of document FCTC/COP/5/9), which outlines aspects of addictiveness (or dependence liability) of both smoked and smokeless tobacco products that remain to be studied;

   (c) monitor and research the country experience and scientific development with respect to reduced ignition propensity cigarettes;

   (d) identify measures likely to reduce the toxicity of both smoked and smokeless tobacco products, describe the evidence supporting the effectiveness of such measures, and the experience of Parties on the matter for consideration by the COP;

   (e) compile, make available for Parties and update a non-exhaustive list of toxic contents and emissions of tobacco products, and advise about how such information could be best used by Parties;

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\(^1\) See decision FCTC/COP5(6).
(f) develop draft fact sheets on measures recommended in the *Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC*; and

(g) continue and report on progress in the validation of analytical chemical methods for testing and measuring cigarette contents and emissions.

2. This document is based in part on the discussions of the WHO Study Group on Tobacco Product Regulation (TobReg) during its seventh meeting in Rio de Janeiro, Brazil, on 4–6 December 2013. In addition, information on the availability and regulation of novel tobacco products and reduced ignition propensity cigarettes was collected through a WHO tobacco products survey submitted to all Member States. Ninety countries responded, representing approximately 77% of the world’s population. Four of these countries were State non-Parties.

NEW OR NOVEL TOBACCO PRODUCTS

Introduction

3. The following criteria were used by WHO to define “new” or “novel” tobacco products: in addition to containing tobacco, the product must meet at least one of the following criteria:

(a) the product employs new or unconventional technology, such as vaporization of tobacco into the lungs or use of menthol pellets in cigarette filter;

(b) the product type has been on the market for less than 12 years, such as dissolvable tobacco products recently introduced into some national markets;

(c) the product type has been on the market for a longer time, but market share has increased in countries/regions that traditionally did not use this type, as in the example of smokeless tobacco products being introduced into countries where they were not previously available.

(d) the product is marketed or work has been published to allow it to be marketed with the claim that these products have the potential to reduce exposure to harmful chemicals

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1 The WHO tobacco products survey on smokeless, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 WHO Member States, including 86 Parties to the WHO FCTC, had responded to the survey as at 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Bolivia (Plurinational State of), Botswana, Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Kenya, Kuwait, Lao People’s Democratic Republic, Latvia, Lebanon, Lithuania, Malaysia, Maldives, Mali, Mauritania, Mongolia, Morocco, Myanmar, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, United Arab Emirates, United States of America, Uruguay, Uzbekistan, Viet Nam, and Zambia.

2 A limitation of this survey is that some of those countries that did not respond probably did so due to lack of human resource capacity. Therefore the results may be biased towards countries with greater tobacco control capacity.

3 Products that represent a variation on traditional cigarettes, cigars, pipe tobacco, roll-your-own tobacco or oral tobacco in markets that traditionally carry these types of products were excluded. Also, for the purposes of this document electronic nicotine delivery systems (ENDS) and herbal cigarettes are not considered to be novel tobacco products. A separate report (document FCTC/COP/6/10) has been submitted to the COP on ENDS.
found in tobacco smoke. These potential reduced-exposure tobacco products (PREPs) include those employing modifications in tobacco processing (e.g. substituting burning for heating) and altered filter structure.

4. Novel products suggesting reduced risk of disease have been or are being marketed with implicit or explicit health claims. However, while the general concept of exposure reduction is constructive, assessment of the validity of claims of risk reduction for PREPs is challenging for many of these products. For this reason, criteria such as the product’s ability to (1) lower smoke components or toxicants in mainstream smoke, (2) modify toxicity tests and demonstrate a reduction in toxicity, (3) modify biomarkers of exposure in humans, (4) modify biomarkers of effect in humans (i.e. disease outcome), and (5) pass sensory evaluation such as test panels in controlled clinical studies, always need be evaluated by governments.

**Monitoring novel products**

5. There is no system to monitor the global expansion or emergence of specific novel products. An example of a globally expanding novel tobacco product is the water pipe, which has been traditionally associated with the Middle East and the elderly. New cumulative evidence shows shifts in this situation. Young people of both sexes are gradually taking up the habit, and it is becoming widely used in many regions other than the Middle East.

6. Examples of novel products identified in the WHO tobacco products survey that are emerging in some countries are the following:

   (a) Dissolvable tobacco products.\(^1\) These products were first introduced in 2001 and have undergone significant transformations since then to their packaging and formulations. For example, one brand of dissolvable products was initially introduced in “mellow” and “fresh” flavours but the latest version has been reformulated and comes in a single “mint” flavour. First versions of dissolvable products have also been shown to contain the lowest levels yet seen of the tobacco-specific \(N\)-nitrosamines (TSNA). More recently, slightly higher TSNA levels have been reported, although still leaving them in the “low-nitrosamine” category.\(^2\)

   (b) Menthol capsules embedded in the cigarette filter. The smoker can crush the capsule when desired and release it into the smoke for a direct “kick of freshness”.

   (c) Tobacco vaporizers. These products heat rather than burn tobacco by means of a handheld device that is used for warming tobacco pods in many different flavours. The user then inhales the warm tobacco aerosol.

7. The results of the WHO survey provide the information shown in Table 1.\(^3\)

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\(^1\) According to the 2013 WHO survey, these dissolvable products are available in seven countries, namely: China, Gabon, India, Republic of Korea, Thailand, Tunisia and United States of America.


\(^3\) In the 2013 WHO survey, novel tobacco products were defined as follows: “Novel tobacco products are such that they resemble conventional cigarettes but which claim to reduce the toxicity or addiction potential of the smoke generated by altering the tobacco used or the filter characteristics, or by adding new substances. Additionally, oral products that are offered as products less hazardous than cigarettes and make claims of reduced carcinogenic constituents of smoke and to reduce second hand smoke emissions should also be considered. Electronic cigarettes, water pipe, snus, and smokeless tobacco products should not be included as they will be addressed in a separate survey”.
Table 1. Number of countries (and percentage of world’s population residing in those countries) responding to questions in the 2013 WHO Tobacco Products Survey on novel tobacco products

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel tobacco products available for sale in the country</td>
<td>13 Member States (28%)(^1)</td>
<td>62 Member States (21%)</td>
<td>15 Member States (28%)</td>
<td>All 90 countries responded</td>
</tr>
<tr>
<td>Claims that products have attributes of modified risk, reduced risks, or harm-reduction</td>
<td>9 Member States (26%)</td>
<td>11 Member States (7%)</td>
<td>12 Member States (6%)</td>
<td>58 Member States (38%)</td>
</tr>
<tr>
<td>Production of novel tobacco products regulated</td>
<td>26 Member States (26%)</td>
<td>51 Member States (44%)</td>
<td>8 Member States (4%)</td>
<td>4 Member States (3%)</td>
</tr>
<tr>
<td>Distribution of novel tobacco products regulated</td>
<td>33 Member States (27%)</td>
<td>45 Member States (43%)</td>
<td>8 Member States (4%)</td>
<td>4 Member States (3%)</td>
</tr>
</tbody>
</table>

(a) Production, distribution, and sale of novel tobacco products are regulated in 26 countries (in which 26% of the world’s population lives), 33 countries (27%), and 39 countries (32%), respectively. However, only 13 countries (28%), report that novel tobacco products are available for sale. Regulation of production, distribution, and sale may be the cause of the limited availability reported by the countries. Of these 13 countries, novel products are made available by commercial manufacturing only in 1 country (3%), by importation in 7 countries (1%), by both local manufacturing and importation in 2 countries (21%), and by unknown sources in the remaining countries.

(b) Manufacturers and distributors in 9 countries (26%), claim that their products have the attributes of modified risk, reduced risks, or harm reduction. In one of these 9 countries and in five additional countries, characteristics and/or contents of novel tobacco products are being regulated as being potentially harmful. About 25% of the world’s population lives in these 6 countries.

(c) Governmental sale licences are required by 11 countries (28%), are not required in 19 countries (30%), and this information is unknown for the rest.

(d) Policies on sale of novel tobacco products to minors were reported in 44 countries (34%). Where specified, minimum required age for sale ranged from 16 to 21 years.

(e) Comprehensive tobacco advertising, promotion, and sponsorship bans on novel tobacco products are in place in 41 countries (35%). However, there is no ban on advertising, promotion, and sponsorship of novel tobacco products in 32 countries (38%).

Conclusions

8. There is a need to better monitor the availability and regulation of novel tobacco products entering international markets at national and global levels. There is also a need to systematically collect research data on these products, through the use of a survey instrument that has been tested and piloted to ensure consistency and applicability of results. Such information would be required to

\(^1\) The percentages in parentheses indicate the proportion of the world’s population that live in the number of countries preceding this figure in the text.
guide tobacco-control efforts and to understand the potential implications for public health. Examination of tobacco industry research indicates that more products and developments may be introduced in the near future.

9. The potential impact of the most novel tobacco products on public health is not clear. The major concerns include: (1) potential unrecognized toxicity; (2) increased or sustained prevalence of tobacco use through recruitment of new users, relapse of ex-smokers, or maintenance of tobacco use in current smokers who might otherwise have quit; (3) dual use of a novel tobacco product and cigarettes; and (4) potential initiating with a novel product and eventual switching to cigarette smoking (“gateway” effect).

10. Future research needs to be focused on such issues as the toxicity of the novel products, their addictive potential, and how they are perceived and used. Such information will help to enable a better understanding of novel products’ potential to reduce or induce harm at individual and population levels.

11. Parties may consider banning novel tobacco products for which there is no evidence that their harm is lower than existing combustible products on their markets.

**ADDICTIVENESS OR DEPENDENCE POTENTIAL: REDUCING NICOTINE**

**Introduction**

12. Nicotine is a highly addictive and potent drug, generating psychoactive and rewarding effects at acutely administered doses of less than 1 mg per cigarette and less than 0.1 mg per puff. Cigarettes provide a particularly effective form of nicotine delivery when compared with all other tobacco products and therefore are the main target of a nicotine reduction policy. Although nicotine is key to tobacco addictiveness, other factors and chemicals in tobacco contribute to dependence.

13. In considering reducing nicotine addiction in line with Article 5.2(b) of the Convention, Parties could consider a nicotine reduction regulatory strategy as outlined below. Such a strategy would aim to lower substantially the administered dose of nicotine in all cigarettes to levels that could not cause or sustain physiological and/or psychological dependence. It is important to differentiate this approach from the 20th century “light” and “low tar low nicotine” marketing for cigarettes that actually delivered dependence-producing doses to smokers.

14. Based on the weight of evidence, a nicotine reduction strategy has strong potential to:

   (a) reduce acquisition of smoking and progression to addiction among experimenters;
   (b) reduce smoking among some proportion of addicted smokers as a result of behavioural extinction; and
   (c) support increased quitting and a reduction in the number of smokers who relapse from quitting.

15. Although lowering nicotine under this policy is expected to substantially reduce addictiveness for most people, it should be recognized that such a policy may:

   (a) lead to an increase in use of alternative, less harmful sources of nicotine for people who are unable to give up nicotine completely. Whereas this is not the intent of a nicotine

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reduction policy, this possible consequence needs to be considered and planned for in the overall tobacco and nicotine policy of a country;

(b) not prevent some smokers from persistent use of very low nicotine products.

16. The implementation of a nicotine reduction policy would need to be supported by a comprehensive programme involving:

(a) a health communication and public education strategy. Before the introduction of the policy and during its implementation, educating the population and health professionals is necessary to communicate risks and ensure compliance and support for the law;

(b) availability of effective and affordable treatment and of alternative forms of nicotine to help dependent smokers who experience adverse effects or withdrawal;

(c) capacity for market surveillance and product testing. A nicotine reduction strategy is not appropriate in the absence of developed capacity for market surveillance and product testing;

(d) continued research efforts to assess, among other things:

(i) likely use and effects of reduced nicotine cigarettes among non-smoking adolescents, non-smoking adults, and non-dependent smokers and their potential to serve as gateway products among adolescents for other forms of nicotine or drugs of abuse; and

(ii) long-term use of reduced nicotine cigarettes, and long-term impact on smoking behaviours.

Nicotine performance standard

17. The actual maximum nicotine content of cigarettes that carries a risk of dependence varies across individuals, and is likely to be lower for youth. Thus, a precautionary principle urges that the maximum nicotine content should be as low as is technically feasible: currently, that is approximately 0.1 mg nicotine per approximately 1 gram of tobacco. WHO TobReg recommends that this be established as the standard. It must be emphasized that this standard is based on actual nicotine content and not ISO ratings. Most cigarettes with ISO ratings of 0.1 mg delivery actually contain many times those levels of nicotine and enable cigarette smokers to readily obtain nicotine doses that can cause and sustain dependence.

18. There is strong evidence in favour of the feasibility of saleable commercial brands of very low nicotine cigarettes with relatively strong subjective ratings from users, despite technical challenges to maintaining smoke sensory characteristics and appeal to smokers. Such a policy would clearly be a restriction on cigarettes that carry a very high risk of dependence or addiction; however this is not the same as a cigarette ban.

19. Compensatory smoking behaviours evident with use of highly ventilated cigarettes are not demonstrated in the case of cigarettes with reduced nicotine content at 0.1 mg nicotine per 1 gram of tobacco. This is in contrast to the well-documented compensatory smoking that occurs in cigarettes

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1 WHO Tobacco Laboratory Network (TobLabNet) has produced an analytical method standard operating procedure for measuring nicotine in cigarette tobacco filler. See http://who.int/tobacco/publications/prod_regulation/789241503907/en/
with low ISO ratings but which are actually designed to enable smokers to obtain high and
dependence-producing levels of nicotine by more intense smoking behaviour.

20. Nevertheless, the implementation of reduced nicotine policy requires close monitoring of
product design factors to avoid the manipulation of physical or chemical parameters of cigarette
construction leading to harmful behavioural changes.
Conclusions

21. Mandated nicotine reduction for all cigarettes at real nicotine levels below 0.1 mg per gram of tobacco should receive very serious consideration by Parties to the WHO FCTC and, when implemented, take place within the context of a comprehensive programme of regulation of all nicotine- and tobacco-containing products, as described above in paragraph 16.

22. The introduction of a nicotine reduction policy below the established performance standard on one single target date rather than gradually, for example, over 10 years, is preferred for practical reasons. Although science supports this rapid approach, the evidence is not definitive on whether gradual or abrupt reduction is theoretically least likely to be associated with unintended consequences.

23. WHO TobReg will continue to assess available scientific evidence to provide information on questions raised in Annex 3 of document FCTC/COP/5/9.

REDUCED IGNITION PROPENSITY CIGARETTES

24. Reduced ignition propensity (RIP) cigarettes are designed to be either (a) self-extinguishing when left unpuffed for an extended period of time and/or (b) have altered smouldering characteristics thus making a fire less likely even if they are dropped on to inflammable items, such as mattresses and upholstered furniture. An RIP standard provides the maximum percentage of RIP cigarettes in a sample allowed to fail to self-extinguish, in order to reduce the likelihood of causing fires. RIP standards are addressed in section 3.3.2.1 of the Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC, which recommend in Section 3.3.2.1(iii) that Parties should require cigarettes to comply with a universal RIP standard.

Results of the WHO survey

25. All 50 US states, Australia, Canada, Iceland, South Africa, and all 28 European Union Member States have adopted policies requiring RIP cigarettes. These countries represent approximately 20% of the world’s population, consuming approximately 20% of the cigarettes manufactured globally and on the whole are high-income countries. The additional cost of manufacture of RIP cigarettes has been marginal and has been paid for by manufacturers.

26. Among the 90 respondent countries to the WHO Tobacco Products Survey, 18 reported having a legal mandate that requires cigarettes on the market to have RIP characteristics. Nineteen countries (5% of the world’s population) – 18 countries with such a mandate plus one without such a mandate – in four of the six WHO regions reported that they have adopted technical standards for RIP. This means that not all countries with policies on RIP have adopted technical standards.

27. RIP cigarettes are made available by commercial manufacture in 13 countries (8%) and by importation in 19 countries (8%). Exporters identified through the survey are Canada, China, Czech Republic, Hungary, Lithuania, Netherlands, New Zealand, Republic of Korea, and the United States of America.

28. Fires and/or deaths in fires due to smoking materials are recorded in 24 countries (7%).

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1 Connolly GN, O’Connor RJ. Research and monitoring and scientific development with respect with respect to Reduced Ignition Propensity cigarettes. Prepared for the 7th Meeting of the WHO Study Group on Tobacco Product Regulation, Rio de Janeiro, Brazil, 3-5 December, 2013 (p.2).

2 The African Region, the Region of the Americas, the European Region and the Western Pacific Region.
Table 2. Number of countries (and percentage of world’s population residing in those countries) responding to questions in the 2013 WHO Tobacco Products Survey on RIP

<table>
<thead>
<tr>
<th>Legally mandate that cigarettes are required to be sold with RIP characteristics</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Member States (5%)</td>
<td>65 Member States (70%)</td>
<td>5 Member States (1%)</td>
<td>2 Member States (1%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technical standards for RIP cigarettes in place</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 Member States (5%)</td>
<td>61 Member States (70%)</td>
<td>6 Member States (1%)</td>
<td>4 Member States (1%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fires and/or deaths in fires due to smoking materials are recorded</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>No response</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 Member States (7%)</td>
<td>31 Member States (30%)</td>
<td>24 Member States (12%)</td>
<td>11 Member States (27%)</td>
<td></td>
</tr>
</tbody>
</table>

Country experience in RIP policy adoption and implementation

29. Experience obtained in countries in which RIP laws have been introduced suggests that there are several key steps necessary for the successful passage of such laws: (1) formation of a coalition of relevant groups including scientists, consumer groups, public health and fire safety officials to collect data on cigarette-related fires, to formulate appropriate legislative proposals and to interact with policy makers; (2) uniformity in the standard across legislative entities, enabling easier adoption and eliminating industry arguments of the need to design multiple RIP cigarettes; (3) availability of hard data on the harm caused by cigarette fires; and (4) legislation that requires compliance with a uniform standard, but which does not dictate actual cigarette design.

30. RIP compliance data has been collected in those countries in which RIP laws have been introduced. Data from Canada indicate substantial, sustained compliance among large manufacturers, and increased compliance among smaller manufacturers. Large manufacturers, comprising 97% of the market in Canada, readily met the performance target of 25% or fewer of the cigarettes in a sample failing to meet the standard, soon after the RIP law was implemented. With all manufacturers, 10% or fewer of samples failed to reach the standard within a few years of the RIP law being enacted.

31. Evaluation of the impact of RIP standards on cigarette-caused fire incidence and related casualties has been hampered by a number of factors including lack of data or poor quality of fire reporting, relatively short length of time in which the RIP standards have been in force, a general decline in fire incidence over recent decades, introduction of clean air laws, and reduced flammability of substrates (e.g. mattresses, soft furnishings). Despite these limitations, there are some rigorous studies available from two countries that indicate an approximate 30% reduction in cigarette-caused fires as a result of RIP regulations.

Conclusions

32. Consistent with Section 3.3.2.1(iii) of the Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC, it is recommended that Parties require cigarettes to comply with a universal RIP standard, taking into account their national circumstances and priorities. If implemented by Parties, RIP design should be adopted by manufacturers as standard manufacturing practice for cigarettes.

33. It is recommended that all costs related to implementation of RIP be borne by the manufacturers. However, countries with limited capacity for compliance testing should consider

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1 See http://www.who.int/fctc/guidelines/adopted/article_9and10/en/
requesting manufacturers to file with government a statement of conformity or use third party certification.

34. It is strongly recommended that the RIP performance standard be set at 10%, which available evidence suggests is entirely feasible. It is recognized that this will most likely require an increase in the sample size tested for conformity to ensure adequate power of the test.

35. Implementation of these recommendations will require close collaboration between agencies and fire departments, the establishment of a central clearing house for RIP standards, a survey of Parties to the WHO FCTC and fire officials on the impact of RIP standards, introduction of a consistent standard for reporting of fires and identification of how these activities will be funded.

36. It is recommended that research continue in order to obtain data from all countries and regions in which RIP laws have been introduced on the population impact of RIP legislation on cigarette fires, deaths and injuries.

REGULATION OF TOBACCO PRODUCT TOXICANTS

37. Tobacco smoke contains more than 7000 individual chemical constituents of which at least 70 cause cancer. The next section of this report discusses the possible implementation of a toxicant regulatory strategy, and identifies a priority list of 38 toxicants.

Regulatory strategy and public health significance

38. The purpose of a toxicant regulatory strategy is to reduce the concentrations of carcinogens currently present in tobacco products to the lowest levels readily achievable with existing techniques. The purpose of the toxicant regulatory strategy, however, is not to reduce risk or harm by shifts from one tobacco product to another, nor to produce recommendations on whether some tobacco products should be endorsed as a harm reduction strategy. It merely establishes the basis for control and alternate manufacturing practices.

39. Science has not established that reduction of any individual toxicant in machine-measured cigarette smoke will reduce actual human exposure or disease risk. Mandating lower levels of toxicants and removing some brands with higher levels from the market must not imply that the remaining brands are safe or less hazardous than the brands that have been removed, nor should it represent government approval of the safety of the products that remain on the market.

40. A toxicant regulatory strategy does not require that, for each substance under consideration, there be proof of a specific link between a lower level (amount) of any individual toxicant and a lower level of human disease (response). Such a strategy simply requires that the substance be known to be harmful and that processes exist for its diminution or removal. Correspondingly, compliance with these regulations does not support a claim that a given brand is safe or less hazardous than other brands.

41. Under such a strategy, regulatory authorities have an obligation to ensure that the public is not misled by the results of the recommended testing and regulatory strategy, given the existing scientific limitations.

Selecting toxicants for regulating maximum limits

42. There is strong evidence on what substances are harmful in tobacco but there is a paucity of data on the harm reduction effectiveness of lowering specific compounds. Furthermore, Parties’ experiences of specific toxicant level reduction measures are extremely limited.

43. In order to characterize the inherent hazard of tobacco constituents, it is necessary to know both the level of the particular constituent in smoke and the toxic potency (strength) of that component, as well as its interactions with other components in the smoke. Our understanding of these complex relationships, however, remains incomplete, since the known toxic potency of smoke explains only a part of the observed disease effects in humans.

44. WHO has selected a list of toxicants for assessing potential mandated toxicity lowering, based on data on animal and human toxicity, toxicity indices, variation in toxicants across brands, potential for the toxicant to be lowered, and inclusion of constituents from both the particulate and the gas phases of smoke and from different chemical classes in cigarette smoke. This list includes compounds implicated in cardiovascular and pulmonary toxicity as well as carcinogenicity. The most important criterion for selecting compounds for regulation was evidence of toxicity.\(^1\) As our knowledge of smoke chemistry expands and the demonstration of the toxicity of smoke toxicants becomes more complete, the list of candidate toxicants for mandated lowering may change.\(^15\)

45. A working group was established by WHO TobReg and the International Agency for Research on Cancer (IARC) to define maximum limits for tobacco smoke toxicants.\(^2\) The initial nine toxicants recommended for mandatory lowering and the initial regulatory levels recommended from existing data are listed in Table 3. A modified machine-testing regimen with more intense puffing parameters, in which all the holes in cigarette filters are blocked, was used to generate these values, and TobReg recommended use of that regimen by regulators in implementing the proposed regulatory strategy. The mandated lowering for NNK and NNN was set at below the median of the data set analysed. An initial level of 125% of the median value was recommended for the other toxicants, reflecting the somewhat greater uncertainty about the extent to which these toxicants can be reduced with existing approaches.

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Table 3. Toxicants recommended for mandated lowering

<table>
<thead>
<tr>
<th>Toxicant</th>
<th>Level in µg/mg nicotine</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>International brands&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Canadian brands&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>NNK</td>
<td>0.072</td>
<td>0.047</td>
</tr>
<tr>
<td>NNN</td>
<td>0.114</td>
<td>0.027</td>
</tr>
<tr>
<td>Acetaldehyde</td>
<td>860</td>
<td>670</td>
</tr>
<tr>
<td>Acrolein</td>
<td>83</td>
<td>97</td>
</tr>
<tr>
<td>Benzene</td>
<td>48</td>
<td>50</td>
</tr>
<tr>
<td>Benzo[a]pyrene</td>
<td>0.011</td>
<td>0.011</td>
</tr>
<tr>
<td>1,3-Butadiene</td>
<td>67</td>
<td>53</td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td>18400</td>
<td>15400</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>47</td>
<td>97</td>
</tr>
</tbody>
</table>

NNK, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone; NNN, N’-nitrosonornicotine

<sup>a</sup> Based on data from Counts et al., 2005

<sup>b</sup> Based on the data reported to Health Canada minus brands with levels of NNN per mg nicotine > 0.1 ng, which eliminates most US and Gauloise brands. (http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/reg/indust/constitu_e.html)

46. While this is identified as an approach for regulating cigarettes, reducing the concentrations of toxicants present in smokeless tobacco (SLT) products is a logical scientific extension of this regulatory strategy. It is both desirable and feasible to regulate smokeless tobacco by setting regulatory limits on the concentrations of selected carcinogens. The regulatory limit recommended for TSNA (NNN plus NNK) is a maximal concentration of 2 µg/g dry weight of tobacco while for benzo[a]pyrene is a maximal concentration of 5 ng/g dry weight of tobacco. The following toxicants were identified in SLT that meet the criteria as IARC group 1 carcinogens (“sufficient” evidence of carcinogenicity in humans): benzo[a]pyrene, formaldehyde, NNN, NNK, arsenic, nickel compounds, polonium-210, uranium-235, uranium-238, beryllium, cadmium, and chromium.<sup>1</sup>

47. In addition, heavy metals have been found in tobacco leaf, processed tobacco (both cigarettes and smokeless tobacco) as well as tobacco smoke and smokeless tobacco emissions. These metals are absorbed from the soil, occur in air pollution, and derive from agricultural treatments during tobacco growing, curing and processing. Therefore the amounts of metals in tobacco products vary widely, depending on the geographical location in which the tobacco leaf was grown. The biological effects of metals with carcinogenic and other toxic effects delivered directly to the lung or oral mucosa is of great concern, especially when delivered in combination with other known carcinogens, sensitizers (such as polycyclic aromatic hydrocarbons, nickel, cobalt, and some forms of chromium) and toxicants in smoke. Among the metals identified in some tobacco products that have been shown to be carcinogenic are arsenic, cadmium, lead, nickel, and the radioactive substances polonium-210 and lead-210.

Conclusions

48. The reduction of toxicant levels in tobacco products is possible for some toxicants. It relies on measures of clearly established toxicants as they appear in tobacco smoke generated under standardized conditions. However, this strategy is neither based on nor relies on measures of actual or

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estimated human exposure or risk, and so cannot be used to quantify reductions in human exposure, risk or disease.

49. The implementation of any toxicity regulatory approach should only be considered if:

(a) it specifically prohibits use of the results of the proposed testing in marketing or other communications with the consuming public, including product labelling;

(b) manufacturers are prohibited from making statements that a brand has met government regulatory standards or from publicizing the relative ranking of brands by testing level;

(c) the government monitors the accuracy of news reports and tobacco industry marketing and pursues vigorously whatever corrective action is necessary to prevent consumers from being misled.

50. The implementation of any toxicity regulatory approach also requires:

(a) manufacturers testing mandated toxicants and disclosure to the appropriate government authority;

(b) governmental monitoring of tobacco blends in both combustible and non-combustible products verifying the manufacturers’ reports.

51. If individual countries wish to pursue a toxicity regulatory approach, they are advised to set mandated reduction levels based on the products sold in their own markets with an anticipated outcome of a marketplace that excludes those brands and products with the highest levels of toxicants.

PRIORITY LIST OF TOXICANTS

52. At its meeting in Rio de Janeiro in December 2013, WHO TobReg identified a priority list of 38 toxicants among the more than 7000 chemicals found in cigarette smoke. See Table 4. The priority list of toxicants was drawn from eight existing, non-exhaustive lists of toxicants (Health Canada, RIVM, USA FDA, Counts, Dybings and Fowles, Hoffman analytes, Philip Morris-Australian brands, and Philip Morris-Canadian brands) with an eye towards balancing the concerns identified with the practical reality of a regulatory structure.

53. The non-exhaustive priority list of tobacco content and emissions of cigarette smoke was based on the following criteria:

2 See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3084482/
3 See http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm
8 See http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/reg/indust/constitu_e.html
(c) presence of specific chemicals in cigarette smoke at levels that are toxic for smokers as determined by well-established scientific toxicity indices;

(d) variations of concentrations between different cigarette brands that are substantively greater than the variation in repeat measurement for the toxicant for a single brand; and

(e) availability of technologies to reduce a given toxicant in smoke should mandating of upper limits of a toxicant be implemented.

Conclusions

54. It is recommended that the list below be used by Parties to start monitoring the contents and emissions of cigarettes on their markets and eventually regulating contents and emission as required by Article 9 of the WHO FCTC. This priority list should be periodically re-evaluated as new knowledge becomes available.

55. Although the priority list of contents and emissions has been recommended for standard cigarettes, the same list of priority emissions can be used for other smoked tobacco products such as nonstandard cigarette (slims for example), cigars, water pipe, pipe, and roll/make-your-own.

56. Any monitoring and regulation of content and emissions should be done in conjunction with the existing validated TobLabNet methods.\textsuperscript{1} Among methods that do not exist yet, priority should be given for TobLabNet to develop standardized testing methods for the measurement of:

   (f) cadmium and lead content;

   (g) nicotine in smoke of water pipe (shisha);

   (h) nicotine, TSNAs and B[a]P in smokeless tobacco products.

57. It is recommended that countries do not regulate tar. While several Parties include tar in their regulatory policies, tar is not included in the priority list of toxicants with respect to tobacco smoke emissions since the composition of tar is qualitatively and quantitatively variable per product which poses a limitation for validated testing and measurement.

58. It is reiterated that the data for each brand and each content and emission should be delivered by the tobacco industry, and that the cost of compliance testing should also be covered by the tobacco industry as already agreed upon in the \textit{Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC}.

Table 4. Priority list of toxic contents and emissions of tobacco products

<table>
<thead>
<tr>
<th>Acetaldehyde</th>
<th>Acetone</th>
<th>Acrolein</th>
<th>Acrylonitrile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Aminonaphthalene</td>
<td>2-Aminonaphthalene</td>
<td>3-Aminobiphenyl</td>
<td>4-Aminobiphenyl</td>
</tr>
<tr>
<td>Ammonia</td>
<td>Benzene</td>
<td>Benzo[a]pyrene</td>
<td>1,3 Butadiene</td>
</tr>
<tr>
<td>Butyraldehyde</td>
<td>Cadmium</td>
<td>Carbon monoxide</td>
<td>Catechol</td>
</tr>
<tr>
<td>m-+p-Cresol</td>
<td>o-Cresol</td>
<td>Crotonaldehyde</td>
<td>Formaldehyde</td>
</tr>
<tr>
<td>Hydrogen cyanide</td>
<td>Hydroquinone</td>
<td>Isoprene</td>
<td>Lead</td>
</tr>
<tr>
<td>Mercury</td>
<td>Nicotine</td>
<td>Nitric oxide</td>
<td>N-nitrosoanabasine</td>
</tr>
<tr>
<td>N- nitrosoanatabine</td>
<td>4-(methylNitrosamino)-1-(3-</td>
<td>N’-nitrosonornicotine</td>
<td>Nitric oxide (NOx)</td>
</tr>
</tbody>
</table>

\textsuperscript{1} See document FCTC/COP/6/14 Add.1
FACT SHEETS ON MEASURES RECOMMENDED IN ARTICLE 9 AND 10 PARTIAL GUIDELINES

59. A draft RIP cigarettes fact sheet is attached as Annex 1 to the present document and a draft fact sheet on ingredients in tobacco products is attached as Annex 2. The draft fact sheets have been developed on the basis of measures recommended in the Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC. They were presented during the meeting of the working group on Articles 9 and 10 in January 2014, shared with the Key Facilitators of the working group, and revised based on discussions during that meeting.

PROGRESS OF THE VALIDATION OF ANALYTICAL CHEMICAL METHODS FOR TESTING AND MEASURING CIGARETTE CONTENT AND EMISSIONS

60. A separate document will be provided as an addendum to this report.

ACTION BY THE CONFERENCE OF THE PARTIES

61. The COP is invited to note this report and to provide further guidance.
ANNEX 1

DRAFT REDUCED IGNITION PROPENSITY (RIP) CIGARETTES FACTSHEET

What are reduced ignition propensity (RIP) cigarettes?

Reduced ignition propensity (RIP) cigarettes, also known as “fire-safer” cigarettes, are cigarettes which have been designed to self-extinguish when left unpuffed. However, RIP cigarettes are no safer with respect to the health consequences of smoking than their traditional cigarette counterparts. Their primary utility compared to other types of cigarette is the reduced incendiary feature to prevent fires caused from burning cigarettes.

Conventional cigarettes are designed to continue burning when left unattended. An unfortunate consequence of this is that if they are dropped on mattresses, upholstered furniture, or other combustible material while still burning, they have a high propensity to start fires. Smoking is a leading cause of fires in many countries, producing an estimated 10% of global fire death burdens. 1

Smoking generates an estimated global fire cost of US$ 27.2 billion per year.2

What are the benefits of regulating the ignition propensity of cigarettes?

Ultimately, the most effective method for reducing fire incidence and fire-related mortality from smoking is to reduce the total number of smokers and the volume of flammable cigarettes available on the marketplace. Nevertheless, the introduction of fire safety technical standards for cigarettes and the adoption of legislation to ensure compliance with these standards could help to prevent a significant number of deaths, injuries, and property damage. In fact, there is good evidence to suggest that the implementation of RIP standards can yield a measurable reduction in fire deaths caused by smoking material. A 2013 report by the United States National Fire Protection Association suggests that the adoption of the RIP standard by US states appears to be the “principal reason for a 30% decline in smoking material fire deaths from 2003 to 2011” and a key contributing factor to the lowest levels of smoking-material related fire incidents and deaths since 1980.3 In Estonia, the number of deaths in fires due to smoking materials had dropped from 73 to 54 3 in 2012, the first full year of implementation of legislation requiring that only RIP cigarettes be sold on the marketplace.4 Finally, in Massachusetts, the Cigarette Fire Safety law adopted in 2008 was associated with a 28% reduction in the likelihood of residential fires.4

How are cigarettes which are less prone to initiating fires made?

Common ways to reduce the ignition propensity of cigarettes include altering the wrapping paper properties, decreasing the thickness and/or density of the cigarette, and the application of extinguishing bands to the cigarette paper. The method of banding is most commonly used to reduce ignition propensity. Banding involves the application of ultra-thin concentric bands to traditional cigarette paper. These bands cause the cigarette to go out if it is not smoked, by restricting oxygen to

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3 2013 WHO tobacco product survey unpublished country reported data.
the burning ember. The tobacco industry has had the advanced science base and technology to make all cigarettes less likely to cause fires since the early 1990s but only began to market some RIP brands around the year 2000.

Technical standards for the testing of reduced ignition strength and the production of modified fire resistant cigarettes have been developed. Examples include the American Society for Testing and Materials E2187 (Standard Test Method for Measuring the Ignition Strength of Cigarettes), European Committee for Standardization’s standard CEN: EN 16156:2010 (Cigarettes–Assessment of the ignition propensity–Safety requirement), Australian Standard AS 4830-2007 (Determination of the extinction propensity of cigarettes), the US National Institute of Standards and Technology NIST SRM 1082 (Cigarette Ignition Strength Standard) and NIST SRM 1196 (Standard Cigarette for Ignition Resistance Testing), and International Organization for Standardization ISO 12863 (Standard test method for assessing the ignition propensity of cigarettes). These standards have been adopted by various countries.

**Where have reduced ignition propensity standards been implemented?**

Currently, all 50 US states, Australia, Canada, Iceland, South Africa, and all 28 European Union Member States have adopted policies requiring RIP cigarettes. These countries represent approximately 20% of the world’s population, consuming approximately 20% of the world manufactured cigarettes and on the whole are mostly large high income nations.

The regulatory framework for RIP laws has varied on a country to country basis. While Canada has adopted measures for reducing ignition propensity within public health laws, Australia and most US states implement such measures within laws on fire safety. In the European Union, similar measures have been implemented within the framework of consumer protection legislation.

The scientific evidence shows that, compared to conventional non-RIP cigarette smokers, those using RIP cigarettes do not change smoking behaviour (e.g. puff volume, puff duration, interval between puffs) or increase fire-risk related behaviour, such as leaving burning cigarettes unattended or smoking in bed. In addition, studies on emissions tend to show no substantial differences between conventional cigarettes and RIP cigarettes and risk assessment studies have indicated no evidence of increases in toxicant exposures among smokers. Finally, economic studies have shown no decline in cigarette sales after implementation of the fire safety standards for cigarettes, contrary to tobacco industry claims.

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3. Connolly GN, O’Connor RJ. Research and monitoring and scientific development with respect with respect to Reduced Ignition Propensity cigarettes. Prepared for the 7th Meeting of the WHO Study Group on Tobacco Product Regulation, Rio de Janeiro, Brazil, 3-5 December, 2013.
What can governments do to regulate the ignition propensity of cigarettes?

Effective tobacco product regulation may contribute to reducing tobacco-attributable disease and premature death by reducing the attractiveness of tobacco products, reducing their addictiveness or reducing their overall toxicity. So far, Parties to the WHO FCTC have adopted the partial guidelines for implementation of some of the measures contemplated in Articles 9 and 10 of the Convention. These guidelines encourage Parties to reduce the likelihood of cigarette-caused fires by:

- 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;
- requiring tobacco manufacturers to test ignition strength, report the results to the responsible authority and pay for implementation of the measures;
- requiring that all cigarettes comply with a RIP standard and establishing the necessary enforcement mechanisms; but
- avoiding any claims suggesting that RIP cigarettes would be unable to ignite fires.

As more countries adopt RIP legislation, it will be important to obtain accurate data on the impact this has in helping to reduce fire deaths and injury. In order to do so, more standardized and comparable information regarding the trends and patterns in incidence of fire- and cigarette fire-related deaths and injuries should be collected.

Summary

While the number of deaths caused by cigarette fires is significantly lower than the number of deaths caused by smoking, it is a serious problem that must and can be addressed. A small number of countries have adopted RIP standards for their cigarettes in order to save lives. Countries which have adopted RIP standards and enacted RIP laws have reported reductions in smoking material fire deaths. In this way, reduced ignition propensity cigarettes offer a measurable public health impact. The adoption of RIP laws and strict enforcement of these laws to ensure compliance will ensure manufacturers review the current design of cigarettes in the marketplace and adopt international standards for RIP cigarettes. The tobacco industry should universally adopt RIP cigarette design as part of good manufacturing practice and reduce the deaths, injuries, and property destruction caused by cigarette-induced fires.

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1 Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC. Available at http://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf
References

- Connolly GN, O’Connor RJ. Research and monitoring and scientific development with respect to Reduced Ignition Propensity cigarettes. Prepared for the 7th Meeting of the WHO Study Group on Tobacco Product Regulation, Rio de Janeiro, Brazil, 3-5 December, 2013
ANNEX 2

DRAFT FACTSHEET ON INGREDIENTS IN TOBACCO PRODUCTS

What are tobacco product ingredients?

Tobacco product ingredients are the substances, components and raw materials that when put together make up a tobacco product ready to be used. The ingredients of tobacco products are:

- the processed tobacco leaf;
- the material that holds together the processed tobacco leaf and usually gives shape to the tobacco product, such as paper and wrappers, and the filter if the product has one;
- the processing aids and residual substances following storage and processing of the tobacco leaf;
- the substances that migrate from the packaging material into the product; and
- the substances intentionally added to increase the attractiveness of the product to the consumer. Among these are substances that enhance the palatability, the product’s colour and physical appearance as well as substances which may create the false impression that tobacco products have health benefits or increase energy and vitality.

Ingredients, with the exception of water, that are added during the course of manufacture of a tobacco product, including preservatives, humectants, flavours, and processing aids are called additives.

What are some of the benefits derived from regulating tobacco product ingredients?

Ingredients in tobacco products may increase their attractiveness, addictiveness and toxicity. The use of ingredients to do so is contrary to the objective of the WHO Framework Convention on Tobacco Control, namely to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke. Therefore, regulating ingredients in tobacco products is essential to an effective national tobacco control programme as part of the regulation of the contents and emissions of tobacco products and the disclosure of this information to the appropriate governmental bodies and to the public.

Why are tobacco ingredients of public health concern?

Ingredients in tobacco products may affect public health in several ways such as increasing the attractiveness, addictiveness, and toxicity of a well-established harmful drug.

**Attractiveness**

Many ingredients are used by the tobacco industry to make cigarettes and other tobacco products more attractive to both existing and potential users. Ingredients that mask the harshness of its products, mimic flavours traditionally found in candy, gum and foods, or create the impression that products have health benefits or increase the consumer’s vitality play an important role in encouraging the continued use of products among existing users and in appealing to new consumers.

**Addictiveness**

In addition to increasing attractiveness, many ingredients are intentionally manipulated or added to optimize addictive potential. Of great concern is the fact that modern cigarettes have been
extensively engineered to be delivery devices for nicotine and other ingredients. In doing so, some ingredients such as ammonia compounds have been used to increase free-base nicotine and addiction potential in addition to masking the harsh taste of products.

The addictive properties may also be indirectly enhanced by the inclusion of ingredients such as eugenol, menthol and cocoa. Ingredients such as eugenol and menthol numb the throat so the smoker cannot feel the smoke’s aggravating effects. Because of its local anaesthetic properties, menthol allows a deeper inhalation of the irritating tobacco smoke and as such, more smoke to be inhaled and deeper puffs to be attained, resulting in a higher nicotine dose per puff. With products like menthol-flavoured cigarettes, individuals can inhale more tobacco smoke while experiencing less of the harsh taste. Therefore, along with the added fresh taste, menthol has significant physiological effects on breathing. Similarly, additives such as cocoa may be used to dilate the airways allowing the smoke an easier and deeper passage into the lungs, exposing the body to more nicotine and higher levels of tar.

Toxicity
Another reason for concern is that some ingredients may be toxic when used alone or in combination with other substances found in tobacco products. Examples include ammonia, caffeine, and taurine. In some cases, colouring agents added for aesthetic purposes may affect the overall toxicity of the resulting product. In addition, some ingredients have the ability to change the physical properties of tobacco smoke, including particle size of the emitting smoke. Particle size affects absorption levels of nicotine and other tobacco constituents in the lungs which can in turn increase blood nicotine levels. Furthermore, when ingredients are burned, new products of combustion are formed and these may be toxic or pharmacologically active. A key example is acetaldehyde, a known carcinogen produced from the burning of sugars added as sweeteners. Acetaldehyde works synergistically with nicotine to enhance the addictive potential of these products.

What can countries do to regulate and monitor tobacco product ingredients?
Effective tobacco product regulation may contribute to reducing tobacco-attributable disease and premature death by reducing the attractiveness of tobacco products, reducing their addictiveness or reducing their overall toxicity. So far, Parties to the WHO FCTC have adopted the partial guidelines for implementation of some of the measures contemplated in Articles 9 and 10 of the Convention. These guidelines encourage Parties to reduce the attractiveness of tobacco products by prohibiting the use of ingredients in such products associated with energy and vitality. To reduce attractiveness, Parties are also urged to prohibit or restrict ingredients used to increase palatability, that may create the impression that they have a health benefit, and that add colour to tobacco products, except when used for tax-related markings or for health warnings and messages. In addition, measures to reduce

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6 Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC. Available at http://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf
attractiveness should include those mentioned in Articles 11 and 13 of the WHO FCTC and its guidelines relating to packaging and labelling of tobacco products and banning tobacco advertising, promotion, and sponsorship.

The guidelines also indicate that Parties should require that manufacturers and importers of tobacco products disclose to governmental authorities information on the ingredients used in the manufacture of their tobacco products with an indication of the purpose of the ingredient. This disclosure of information should be done at specified intervals by product type and for each brand within a brand family.

Despite strong opposition by the tobacco industry, countries are making progress in limiting the use and exploitation of tobacco ingredients. For example, in 2012 Brazil became the first country to ban menthol and almost all other additives in tobacco products. Similarly, Canada has recently taken steps to curb the widespread use of additives and other flavouring ingredients on their domestic tobacco market. In 2010, most flavouring agents along with other specified ingredients were no longer permitted for use within Canada’s borders. The European Union has revised its Tobacco Products Directive:1 under the new Directive, cigarettes and roll-your-own tobacco with characterizing flavours are prohibited. Certain additives, such as vitamins, caffeine, etc. are also prohibited. The Directive makes it possible to prohibit products with additives that increase toxicity or addictive effects. In addition, electronic reporting by the tobacco industry on ingredients has been substantially reinforced, in particular in regard to certain additives identified on a priority list.

Summary

Prohibiting or restricting the use of ingredients that increase tobacco product attractiveness can contribute to reducing the prevalence of tobacco use and dependence among new and continuing tobacco users with a view to reducing disease, suffering and death from tobacco. Immediate adoption of the measures detailed in the Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC is a positive and tangible step, which countries should take.

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1 See http://ec.europa.eu/health/tobacco/products/revision/
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