

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

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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

1. At its third session (Durban, South Africa, 17–22 November 2008), the Conference of the Parties noted the information contained in the progress report¹ of the working group on Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (FCTC), and decided² to request the Convention Secretariat to invite WHO's Tobacco Free Initiative to undertake the following work:

- (1) submit a report for consideration by the Conference of the Parties at its fourth session which:
 - (a) identifies best practices in reporting to regulators as regards contents, emissions and product characteristics, including electronic systems;
 - (b) identifies best practices in informing the public;
 - (c) collects information on legal cases and analyses the legal issues related to tobacco product disclosures;
- (2) validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report of the working group, using the two smoking regimens set out in paragraph 18 of that report, and inform the Conference of the Parties through the Convention Secretariat on a regular basis of the progress made;

¹ Document FCTC/COP/3/6.

² See decision FCTC/COP3(9).

(3) monitor scientific progress; when appropriate, design and validate methods for testing and measuring the product characteristics identified in paragraph 33 of the progress report of the working group; and inform the Conference of the Parties, through the Convention Secretariat, on a regular basis of the progress made.

2. Pursuant to the decision of the Conference of the Parties, this report summarizes the activities of WHO's Tobacco Free Initiative on the requested work.

SELECTED CURRENT PRACTICES AND LEGAL ISSUES RELATED TO TOBACCO PRODUCT DISCLOSURES

3. In its progress report, the working group on Articles 9 and 10 of the WHO FCTC recognized that the purpose of disclosing product information is to give regulators sufficient information to take action and to inform the public about the harmful effects of tobacco use. Obtaining relevant, precise information on the contents, emissions and product characteristics of tobacco products is also useful for the elaboration and implementation of relevant policy measures, regulations and litigation and for countering tobacco industry arguments. It would be advisable for the regulatory authority for tobacco products to be a specialized agency within a ministry or government department, delegated to address such matters as issuing and enforcing the regulations that require manufacturers and distributors to: test the contents and emissions of tobacco products on a periodic basis; and disclose, on a periodic basis and according to a specified format, product characteristics of the tobacco product.

Reporting to regulators as regards contents, emissions and product characteristics, including electronic systems

4. This section does not provide an exhaustive analysis of all the tobacco product regulation practices currently in use globally. Rather, it provides an overview of selected current practices based on consultations with experts in tobacco product regulation and with the Key Facilitators of the working group on Articles 9 and 10 of the WHO FCTC.

5. Articles 9 and 10 of the WHO FCTC require Parties, where approved by competent national authorities and in accordance with national law, to adopt and implement effective legislative, executive, administrative or other measures for the testing and measuring of tobacco product contents and emissions, and for the disclosure of information about those contents and emissions to governmental authorities.

6. Canada has been identified by WHO's Tobacco Free Initiative and the WHO Study Group on Tobacco Product Regulation as having one of the most effective regimes for tobacco product regulation.¹ Canada's comprehensive Tobacco Reporting Regulations require the testing and measuring of tobacco product contents and emissions. Manufacturers and importers must submit detailed reports on their tobacco products to the Ministry of Health, including information on product composition and emissions. Disclosure of information is required for each product, by brand and type of tobacco product. Reports must be submitted (depending on the type of information they contain) monthly, quarterly, twice a year or annually and contain, inter alia, the following information:

¹ See WHO Study Group on Tobacco Product Regulation. *Best practices in tobacco control – regulation of tobacco products Canada report*. Geneva, World Health Organization, 2005.

- For cigarettes, cigarette tobacco, leaf tobacco, pipe tobacco, cigars, tobacco sticks, kreteks, bidis and smokeless tobacco:
 - information on all aspects of the products, including the tobaccos and other ingredients used in the manufacturing process, and on paper, tubes and filters. In addition, manufacturers must report information on the type and quantity of ingredients and their components, and provide information on certain specifications;
 - information on more than 20 constituents¹ of whole/unburned tobacco;
 - information on research projects undertaken by or on behalf of a manufacturer; applicable studies include those that examine the toxicity and health effects of tobacco products, their taste and flavour, the modification and development of tobacco products and the ingredients in tobacco products.
- For cigarettes, cigarette tobacco, leaf tobacco, tobacco sticks, and kreteks only:
 - information on more than 40 toxic emissions in both mainstream² and side stream³ smoke, under two smoking regimens – International Organization for Standardization (ISO) regular, and a modified ISO.

7. Canada's Tobacco Reporting Regulations also require disclosure of information on the toxicity testing of cigarette mainstream smoke.⁴ Furthermore, the disclosure of all ingredients⁵ and their components, by unit or by gram of product must be submitted on a three-monthly basis. The Regulations specify the method to be used for each analysis. Independent private laboratories, which must be accredited under ISO 17025, perform the analysis at the request of manufacturers. The tobacco inspectors of Canada's tobacco-control agency conduct selective audits of the reports that are submitted, but the agency does not itself perform laboratory verifications of the data. A pre-identified sampling methodology is used for tobacco product specimens being sent for testing to independent

¹ Nicotine, Nornicotine, Anabasine, Myosmine, Anatabine, Ammonia, Glycerol, Propylene glycol, Triethylene glycol, Nickel, Lead, Cadmium, Chromium, Arsenic, Selenium, Mercury, Benzo[a]pyrene, Nitrate, N-nitrosornicotine, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N-nitrosoanabasine, Triacetin, Sodium propionate, Sorbic acid, Eugenol [2-Methoxy-4-(2-propenyl)-phenol].

² Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-aminobiphenyl, 4-aminobiphenyl, Benzo[a]pyrene, Formaldehyde, Acetaldehyde, Acetone, Acrolein, Propionaldehyde, Crotonaldehyde, Butyraldehyde, Eugenol [2-Methoxy-4-(2-propenyl)-phenol], Hydrogen cyanide, Mercury, Lead, Cadmium, NO, NOx, N-nitrosornicotine, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N-nitrosoanabasine, Pyridine, Quinoline, Styrene, Hydroquinone, Resorcinol, Cathecol, Phenol, m+p-Cresol, o-Cresol, Tar, Nicotine, Carbon Monoxide, 1,3 Butadiene, Isoprene, Acrylonitrile, Benzene, Toluene.

³ Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-aminobiphenyl, 4-aminobiphenyl, Benzo[a]pyrene, Formaldehyde, Acetaldehyde, Acetone, Acrolein, Propionaldehyde, Crotonaldehyde, Butyraldehyde, Hydrogen cyanide, Mercury, Lead, Cadmium, NO, NOx, N-nitrosornicotine, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N-nitrosoanabasine, Pyridine, Quinoline, Hydroquinone, Resorcinol, Cathecol, Phenol, m+p-Cresol, o-Cresol, Tar, Nicotine, 1,3 Butadiene, Isoprene, Acrylonitrile, Benzene, Toluene, Styrene, Carbon Monoxide.

⁴ Bacterial Reverse Mutation Assay for Mainstream Tobacco Smoke, Neutral Red Uptake Assay for Mainstream Tobacco Smoke, In Vitro Micronucleus Assay.

⁵ The definition of "ingredient" in the Canadian regulations is: tobacco leaves and any substance used in the manufacture of a tobacco product or its components, including any substance used in the manufacture of that substance.

laboratories. A sample used for the purpose of determining the amount of a constituent or an emission must be selected in accordance with described procedures.¹

8. Brazil also has comprehensive regulations that require the testing and measuring of tobacco products and their emissions. These regulations establish the maximum content of tar, nicotine and carbon monoxide in cigarettes.² All distributors, importers and manufacturers must submit petitions requesting either the data registration or the renewal of registration for each tobacco product. These petitions must include analytical reports containing the following information on each product brand: tobacco composition, additives, the efficiency of the filter, mainstream smoke composition, side stream smoke composition, and compounds present in the total tobacco. Details of any changes made to products, including packaging and labelling, or any new tobacco product entering the market must be submitted to the regulatory agency for approval before market supply of the product. All data are collected electronically and stored in a database, along with hard copies of the documents. Testing and verification of tobacco products are currently carried out by the manufacturers. However, Brazil is constructing an official tobacco laboratory that will be able to perform counterproof analysis.

9. Turkey also employs a stringent set of reporting regulations. For tobacco products already on the market, importers and manufacturers test and report on their contents and emissions. Any changes made to existing products (except packaging and labelling) and any new tobacco product must first undergo contents and emissions testing, with the results subsequently reported to the regulator, before the product can be marketed. Details of the following must be provided: ingredient information, toxicology (if available), and tar, nicotine and carbon monoxide emissions. Independent and accredited laboratories are used to perform the testing and verification of tobacco products.³ Information is stored securely both electronically and in hard copy.

10. Australia has in place a formal voluntary agreement between the Australian Government and the three tobacco manufacturers in the country: Philip Morris Limited, British American Tobacco Australia Limited and Imperial Tobacco Australia Limited. These manufacturers provide ingredient data to the government under the Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes. Under the Voluntary Agreement, the three manufacturers provide the data listed below.

- By-brand variant lists of ingredients, including product weight and tobacco weight. Ingredients are listed in descending order of weight.
- Composite lists of tobacco ingredients (including flavourings) in alphabetical order. Quantities are listed as not exceeding the percentage of the product weight. Each ingredient's function (filler, flavour, humectant, preservative, binder, etc.) is included.
- Composite lists of non-tobacco ingredients in alphabetical order, each product's ingredients being listed separately. Quantities are listed as not exceeding the percentage of the product weight. Processing aids and preservatives are combined under each heading.

¹ The procedures described are those in items A and B of Table 1 of ISO 8243: 1991 (*Cigarettes – Sampling*).

² The maximum content per cigarette is: tar 10 mg, nicotine 1 mg, and carbon monoxide 10 mg.

³ Turkey uses the following testing standards: Tar (under ISO 4387), nicotine (under ISO 10315), and carbon monoxide (under ISO 8454). ISO 8243 is used for verification purposes.

11. Under the Voluntary Agreement, by-brand variant disclosure is structured to “protect the confidentiality of tobacco manufacturer trade secrets”. For each brand variant, the manufacturer must disclose the brand variant name; product weight; tobacco weight; ingredients added to tobacco.¹

12. The methods and formats used to report information to regulators vary greatly. Reports submitted with too much or too little information, in addition to those submitted as PDF files or in hard copy can make analysis of the data a challenge. Storage of the data in a useful format can also be problematic. A group of European Union Member States recently launched the Electronic Model Tobacco Control system, an electronic, web-based data reporting system that enables submission of tobacco ingredient data by tobacco companies to national authorities, i.e. the regulators. The system is partially funded by the European Commission Public Health Programme, and is based on a harmonized template used by the European Commission. There are currently 14 participating countries.² The data submitted to the Electronic Model Tobacco Control system are only accessible to national authorities and the European Commission. The national authorities of a Member State only have access to data submitted to their own Member State. In addition, the European Commission’s practical guide to reporting on tobacco product ingredients³ contains harmonized data collection methods that are based on a common format and definitions. Though not legally binding, the *Practical guide* contains common reporting formats for the submission of tobacco product ingredient information to regulators and to the general public. The common reporting formats aim to facilitate and improve the transmission of data from manufacturers and importers to Member States, and from them to the European Commission.

13. As countries craft the language of their tobacco product regulations, it is crucial not only that potential loopholes are pre-empted, but also that allowance is made for the regular revision of the regulations to take into account any new knowledge that may emerge about any tobacco product or its modified or re-engineered version.

14. In Canada, enforcement measures, up to prosecution, may be taken where non-compliance to the Tobacco Reporting Regulations is observed. In Brazil, non-compliance may result in penalties from a simple notification to monetary fines or even the cancellation of a product registration by the regulatory agency and the consequent banning of sale of the product. In Turkey, monetary penalties for non-compliance with disclosure regulations are prescribed under national law.

Informing the public

15. Article 10 of the WHO FCTC requires Parties to adopt and implement effective measures for public disclosure of information about the toxic constituents of tobacco products and their emissions. In its progress report the working group on Articles 9 and 10 of the WHO FCTC recognized the

¹ Ingredients added to tobacco must be listed in descending order by weight of ingredient as added, except that: flavourings that give each brand variant its unique characteristics need not be disclosed individually but may be grouped as natural, and/or artificial flavours in the by-brand variant list; and processing aids and preservatives that are not significantly present in and do not functionally affect the finished product need not be disclosed individually but may be grouped as processing aids, and/or preservatives in the by-brand variant list. All ingredients added to tobacco must be individually disclosed in the composite list of ingredients added to tobacco. Each manufacturer must disclose the criteria it applied (including quantitative cut-offs) to determine which flavourings it included in the by-brand variant lists.

² See: <http://ec.europa.eu/eahc/projects/database.html?prjno=2007312>.

³ *Reporting on tobacco product ingredients, practical guide*. Brussels, European Commission, 2007 (http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf).

consumer's right to know, and considers that the main objective of disclosure to the public is to inform and educate them about the harmful effects of tobacco.

16. The Brazilian authorities do not release information to the public regarding tobacco contents and emissions given the lack of evidence of how such information is understood by the public. The Brazilian regulations rather work in accordance with the guidelines for the implementation of Article 11 of the WHO FCTC¹ concerning pictorial health warnings. There is a federal regulation, under the mandate of the Ministry of Finance, that obligates cigarette manufactures to stamp the maximum content of tar, nicotine and carbon monoxide onto the packaging and labelling of cigarettes. However, the regulatory agency of Brazil, ANVISA, argues that such information alone might be misleading as it is used by manufacturers as a marketing tool to promote one brand as being less harmful than another.

17. The Canadian authorities have released information collected from tobacco companies on cigarette constituents and emissions in each product brand to the public. The information provides the amounts of selected toxic substances found in tobacco and cigarette smoke. These data are available on request.² Currently only data for 2004 are available, but data sets for other years are currently being processed.

18. The Australian authorities also release information they have collected from tobacco manufacturers to the public. The annual reports submitted by manufacturers containing by-brand variant ingredients data are posted on the web site of the Australian Department of Health and Ageing.³ A recent qualitative research study⁴ undertaken by the Australian Department of Health and Ageing evaluated the effectiveness, including public health value, of releasing data on emissions and ingredients. Tobacco-control stakeholders, smokers and non-smokers who participated in the study saw access to disclosed tobacco product information as a consumer right. However, they also reported that currently disclosed information about emissions and ingredients was incomprehensible, uninteresting, incomplete and difficult to access. The study found that it was unlikely that the health of Australians would be directly promoted and protected by disclosing tobacco product information to the public. It suggested instead that this objective would be more likely to be met by using the disclosed information to inform Government policy, public health initiatives and communication, tobacco-control research and future tobacco product regulation. Furthermore, it was reported that the information most wanted by both smokers and non-smokers was a description of the health effects and function of each ingredient, and of each chemical in the emissions lists.

19. The guidelines for the implementation of Article 11 of the WHO FCTC recognize that well-designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means of increasing public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption. The synergistic effect of Articles 10 and 11 of the Convention is apparent here. Public disclosure of information about the toxic constituents of tobacco products and the emissions that they may produce, as required under Article 10, could be made more accessible by

¹ Adopted by the Conference of the Parties in decision FCTC/COP3(10).

² See <http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/indust/constitu-eng.php#request>.

³ See <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-drugs-tobacco-ingredients.htm>.

⁴ *Public health value of disclosed cigarette ingredients and emissions data*. Department of Health and Ageing, 2009 (<http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-tobacco-phv-cig-ing-em-data>).

translating their health effects into pictorial health warnings. Evidence demonstrates that pictorial warnings are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. They are also particularly effective in communicating health effects to populations with low literacy rates, children and young people. WHO's Tobacco Free Initiative maintains a database of pictorial health warnings, including a section on toxins and constituents.¹

Legal analysis of cases related to tobacco product disclosures

20. In meeting their obligations under Article 10 of the WHO FCTC, Parties require tobacco companies to disclose information about the contents and emissions of tobacco products to governmental authorities in two main ways. Although some countries have voluntary disclosure agreements with tobacco manufacturers, those passing legislation that makes these disclosures mandatory are increasing in number. While the tobacco industry has yet to launch legal challenges to any government's understanding of voluntary disclosure agreements, legislation is preferable for the following reasons: voluntary agreements may not cover all tobacco companies, such as those entering the market after the agreement came into force. Furthermore, because such agreements are voluntary in nature, a tobacco company may renounce the agreement at will, especially if it perceives that there is a competitive disadvantage in relation to a new entrant not subject to the agreement.

21. In some countries that have passed legislation requiring disclosures, foreign companies have occasionally chosen to withdraw brands that do not conform to regulations from the market,² or have considered withdrawal.³ Legislation has also caused the tobacco industry to reformulate the ingredients of some cigarette brands when faced with having to reveal the contents of that brand.⁴

22. WHO's Tobacco Free Initiative has conducted a comprehensive study of legal cases and negotiations related to tobacco product disclosures. Following detailed analysis of the legal issues pertaining to the cases, the study found that seven factors were cited by the tobacco industry in opposing disclosure legislation: (1) lack of jurisdiction; (2) domestic property rights; (3) technical barriers to trade; (4) international intellectual property rights; (5) privacy rights; (6) burden; and (7) vagueness.

(1) Lack of jurisdiction

23. Every state limits the legal jurisdiction of its governmental bodies. In federated countries the tobacco industry may argue that the government has acted outside its constitutional jurisdiction. The simplest argument is a claim that under the country's constitutional division of powers, the subject matter appropriately resides solely with another level of government and cannot be regulated by the

¹ The toxins and constituents section can be found at:
<http://www.who.int/tobacco/healthwarningsdatabase/toxins/en/index.html>.

² Hur RK. Takings, trade secrets, and tobacco: mountain or molehill? (2001), *Stanford Law Review*, 2000, 53:447–490. See page 488.

³ Webb W. Thailand: Marlboro Ingredients Modification. 7 Jun 1995. Philip Morris. Bates No. 2050890222.

⁴ Examples include RJ Reynolds' reformulation of its cigarettes sold in Canada subsequent to a Canadian brand-by-brand ingredients disclosure requirement. See Camel taste odd? Blame gov't. *Edmonton Journal*, 1 April 1989. See also Philip Morris' reformulation in response to Thailand's ingredient disclosure law: Philip Morris Worldwide Regulatory Affairs, Ingredient Disclosure – Compliance with Thai regulation, undated but faxed on 10 October 1998, Philip Morris Bates No. 2072522486.

level attempting to do so. In challenging the province of British Columbia's disclosure law in Canada, for example, a tobacco company argued that a provincial ingredient disclosure law amounted to the de facto regulation of interprovincial trade, and therefore should be nullified for infringing on federal jurisdiction.¹

24. A second type of constitutional argument is that even if the governmental level has jurisdiction, the manner in which the government has chosen to apply the disclosure requirement infringes upon the constitutional jurisdiction of some other level of government. In the British Columbia challenge mentioned above, one industry argument focused on the burden being placed on tobacco manufacturers resident elsewhere in the country as grounds for finding that federal jurisdiction was infringed.² Although the tobacco industry was initially successful in these challenges, Canada remedied the problem by passing laws at the federal level. After the Government of Canada passed a federal law mandating disclosures, the tobacco industry attempted the converse argument that disclosure was, this time, beyond federal jurisdiction. The Canadian courts rejected the argument and upheld the federal law.³

25. Enabling legislation gives the regulator the power to make legally binding regulations. One argument the tobacco industry has employed is that requiring disclosure exceeds the agency's jurisdiction because the enabling legislation did not expressly delegate that extent of power to the agency. Another argument is that the regulations violate or exceed the scope of the regulatory authority's enabling legislation. In the British Columbia case, the industry argued that the mandatory disclosure regulation was invalid because it conflicted with the enabling legislation. In its view, disclosing ingredient information in the manner required could mislead the public and did not provide information consumers could use to reduce risks to their health.⁴ Both arguments might be remedied by writing enabling legislation with a specific delegation of authority to the agency to mandate disclosures.

26. In an argument that overlaps with the industry's claims to property rights (see below), the industry often also argues that disclosures are trade secrets, and that regulations infringe on the company's property rights. In the British Columbia case, the industry also argued that the public dissemination portion of the regulation went beyond the scope of the enabling legislation because there was no express authorization for public disclosure of trade secrets in the enabling legislation.⁵ Governments may pre-empt this argument by including such authorization in the enabling legislation and by putting into place a reliable system that legally protects bona fide trade secret information from being released through required disclosures.

¹ *RJR-Macdonald v. A.G. British Columbia*, Statement of Claim No. A982885, 30 October 1998, amended 30 July 1999, at paragraphs 4(b) and 15.

² *RJR-Macdonald v. A.G. British Columbia*, Statement of Claim No. A982885, 30 October 1998, amended 30 July 1999, at paragraphs 16–19.

³ See *JTI-Macdonald v. Canada* (Que Ct Appeal), 2005 QCCA 726, at paragraphs 175–180.

⁴ *RJR-Macdonald v. A.G. British Columbia*, Statement of Claim No. A982885, 30 October 1998, amended 30 July 1999, at para. 12.

⁵ *RJR-Macdonald v. A.G. British Columbia*, Statement of Claim No. A982885, 30 October 1998, amended 30 July 1999, at para. 14.

(2) Domestic property rights

27. The constitutions and legislation of many countries protect property rights from expropriation, which is the taking of property or reduction in its value by a person other than the owner. Such laws normally entitle the property owner to just compensation when the property is expropriated. Trade secrets are special forms of intellectual property in that their value comes from their protected contents. Unlike other types of property which are expropriated when another person damages the property or takes physical possession of it, a trade secret is expropriated when the public or a competitor gains knowledge of the secret's contents.

28. The tobacco industry commonly argues that regulations requiring public disclosure on ingredients force them to divulge trade secrets, resulting in expropriation. It also argues that for trade secrets, removing the secrecy of some key part of the brand, even if other parts remain secret, may reduce the trade secret value. Tobacco companies also contend that public disclosure of ingredients on a brand basis achieves this destruction of secrecy by providing potential competitors with valuable information they could otherwise safeguard for their own exclusive use.

29. In drafting legislation to pre-empt this issue, the threshold for the government to publicly disclose ingredients is an important factor. A case from the State of Massachusetts in the United States of America, is illustrative. The court found the disclosure law unconstitutional, considering that the threshold for justifying public dissemination was too low (the statutory test to justify dissemination was when public disclosure "could" reduce health risks).¹

30. While trade secrets have been a contentious issue in European efforts to regulate ingredient disclosure, Directive 2001/37/EC of the European Parliament and of the Council sets a more liberal standard. It requires members to implement disclosure laws but does not make full public disclosure of the information mandatory. Member States can take account of laws protecting trade secrets, but are left with the latitude to disclose information by all appropriate means with a view to informing consumers.² In implementing Directive 2001/37/EC, legislation in the Netherlands provided for dissemination of ingredient disclosures to the public in their entirety.³ In 2005, the Dutch court upheld this law against an industry challenge, ruling that while ingredient information constitutes a trade secret, trade secrets do not enjoy absolute protection.⁴ The result of the 2005 decision was that tobacco companies were required to submit detailed brand information.

31. Although full public disclosure of ingredients is preferable, in order to prevent a legal challenge on a trade secret issue, a country may restrict the list of ingredients to be disclosed to the public. Ensuring that only certain ingredients, or certain classes of ingredients, are disclosed may protect trade secrets and public health simultaneously. The issue may also be avoided by releasing brand-specific information not as to the ingredients in the manufactured product, but as they exist upon combustion or mastication. The manufacturers' property rights may extend to what they put into their products, not what they produce when ignited or chewed.

¹ *Philip Morris v. Reilly*, 113 F.Supp.2d 129 (D.Mass 2000), at 140.

² Directive 2001/37/EC, OJ L 194/26, 18/07/2001, at Art. 6.2.

³ Staatsblad van het Koninkrijk der Nederlanden 2003(89), 06 February 2003.

⁴ Rechtbank/Gravenhage, HR 21 December 2005, NJ 548, (ann. DJV).

(3) Technical barriers to trade

32. In accordance with Article 2.2 of the Agreement on Technical Barriers To Trade,¹ technical regulations “shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create”. British American Tobacco argued that Thai ingredients disclosure regulation was in breach of Article 2.2 of the Agreement, being more trade restrictive than necessary to achieve the public health objective. British American Tobacco argued that ingredient disclosure could gravely harm their research and development activities if information made its way to competitors and would, therefore, constitute a barrier to their ability to trade in the Thai market.²

33. In order to counter these arguments of the tobacco industry, countries may write a carefully crafted objective into their national legislation, tailoring it such that the objective can only be reached through the disclosure of ingredients, ideally with public dissemination. The aim would be to write the legislative purpose such that it makes ingredient disclosure “necessary”, for example, to inform and educate the public about the harmful effects of tobacco. In addition, the Preamble to the Agreement states, *inter alia*: “Recognizing that no country should be prevented from taking measures necessary ... for the protection of human, animal or plant life or health ... at the levels it considers appropriate”. Countries can argue that ingredient disclosure helps protect health at a level they consider appropriate. However, under the Agreement the measures taken are subject to the requirement that they are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and that they are otherwise in accordance with the provisions of the Agreement.

(4) International intellectual property rights

34. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement that protects intellectual property. The most comprehensive legal arguments made in regard to the TRIPS Agreement occurred in a dispute between Thailand and British American Tobacco, and focused on two issues: trademarks and protecting undisclosed information.

35. In a detailed note sent to the Prime Minister of Thailand, British American Tobacco contended that mandatory disclosure of ingredient information, without guarantees of confidentiality, would violate Article 16 of the TRIPS Agreement.³ To counter such arguments, countries could simply ensure that trademarks continue to be allowed to be registered and unauthorized use by third parties prohibited.

36. In an argument similar to that used with regard to trade secrets, as detailed above, British American Tobacco claimed that releasing ingredient information on a by-brand basis would reduce the value of the trademark associated with those brands. However, it is notable that British American Tobacco did not specify how a reduced trademark value in itself related to Article 16 of the

¹ See the web site of the World Trade Organization: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm.

² British American Tobacco – Thai Ingredients Law: The Current Position, 05 June 1997, BAT Bates No. 770003794-804 (<http://legacy.library.ucsf.edu/tid/mji45a99>).

³ A Critical Analysis of the Ministerial Regulations to be Issued Pursuant to Section 11 of the Tobacco Products Control Act 1992, As Acknowledged by the Council of Ministers on 16 May 1995, 31 May 1995, BAT Bates No. 502575535 (<http://legacy.library.ucsf.edu/tid/pqn45a99>).

TRIPS Agreement, which deals with the right of trademark use and preventing others from using that trademark. British American Tobacco also argued that public dissemination of information on ingredients would facilitate unauthorized use by their competitors of that valuable and otherwise secret information, and that this would be “contrary to honest commercial practices” as per Article 39.2 of the TRIPS Agreement.¹

37. In countering this argument, the same approach suggested in the domestic property rights section above may be helpful, i.e. the release of brand-specific information not as to the ingredients in the manufactured product, but as they exist upon combustion or mastication. In addition, a country could publicly disseminate brand-specific information for only a portion of the disclosed ingredients, especially if the limited ingredient information chosen yielded a significant benefit for public health and did not reveal sufficient new information to permit unfair competition.

38. In 2001 a Ministerial Declaration² was adopted on the TRIPS Agreement and public health which states, inter alia: “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health ...”.

39. Article 39.3 of the TRIPS Agreement states, inter alia, that “... Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use”. If the principle in Article 39.3 is applicable to tobacco products, two points are relevant: (i) the standard is “necessary to protect the public” and (ii) it is disjunctive, that is, the government can disclose either when it is necessary or when they have taken steps to prevent unfair commercial use. Article 39.3 suggests an alternative, which is to justify public disclosure on the basis of necessity to protect the public, and the Ministerial Declaration, described above, clarifies that public health is an interest that warrants protection.

(5) Privacy rights

40. Courts have quickly dismissed the argument that required disclosures violate privacy rights.³ Although courts have determined that a disclosure is a de facto seizure, they have ruled that is reasonable given that cigarette companies are aware that they are part of a highly regulated industry. The industry has not often raised this argument. In one instance, a tobacco company argued that making reporting of ingredients mandatory is equivalent to a seizure of that information and that doing so without prior authorization for each disclosure, or without demonstrated reasonable grounds, makes

¹ Dillard, JE, Comment on Draft Guidance on Listing of Ingredients in Tobacco Products, 13 November 2009, FDA-2009-D-0524. A generalized version of a TRIPS Article 39 argument exists in an internal industry document dealing with the Massachusetts disclosure law. Author unknown, undated but faxed on 21 January 1997, BAT Bates No. 700367478-483 (<http://legacy.library.ucsf.edu/tid/azu92a99/pdf>). See page 481.

² The declaration on the TRIPS agreement and public health (document WT/MIN(01)/DEC) is available on the WTO web site at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

³ *JTI Macdonald v. Canada* [2002] 102 C.R.R. (2d) 189, at paragraphs 501–508; *JTI Macdonald v. Canada* (Que Ct Appeal), [2005] QCCA 726, at paragraphs 185–192.

it an unreasonable seizure (something that is prohibited in privacy legislation in many countries). Courts at trial and on first appeal quickly have dismissed this argument.¹

(6) Burden

41. The “burden” argument appeals to the notion that there should be some sort of balance between what the State asks in compliance with the benefit to be derived from that compliance. Countries should not require huge private efforts to be undertaken for minor public gains. In the British Columbia challenge outlined above, the tobacco industry argued this with a focus on the economic cost of complying. They maintained that ingredient disclosure imposed “excessive, disproportionate and unjustifiable costs” on the manufacturer.²

(7) Vagueness

42. Specificity is crucial in drafting disclosure requirements for procedural reasons. When a law or regulation is overly broad, many legal systems will invalidate it because “[t]he requirements appear so vague and susceptible to multiple interpretations that it would be unfair to impose criminal penalties for failing to comply”.³ In the Massachusetts case described above, an American constitutional guarantee that the legal process provide the defendant with a reasonable opportunity to be heard led to the court invalidating the disclosure law in question.⁴ In Thailand, the industry alleged that there was imprecision in the disclosure regulation, contending that lack of specificity in testing and sampling methods to be used by manufacturers, and by enforcement officials, would not permit the manufacturers to know when they were in compliance.³

VALIDATION OF ANALYTICAL CHEMICAL METHODS

43. Pursuant to decision FCTC/COP3(9), WHO’s Tobacco Free Initiative has begun work on validating the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report of the working group on Articles 9 and 10 of the WHO FCTC, using the two smoking regimens set out in paragraph 18 of that report.

44. WHO’s Tobacco Free Initiative, as the Secretariat and Coordinating Body of the WHO Laboratory Network (TobLabNet), is working with the TobLabNet member laboratories to validate the following:

- (1) Methods for testing and measuring cigarette contents: (a) one for nicotine; (b) one for ammonia; and (c) one for humectants (propane-1,2-diol, glycerol (propane-1,2,3-triol), triethylene glycol (2,2’-ethylenedioxybis(ethanol)).

¹ *JTI Macdonald v. Canada* [2002] 102 C.R.R. (2d) 189, at paragraphs 501–508; *JTI Macdonald v. Canada* (Que Ct Appeal), [2005] QCCA 726, at paragraphs 185–192.

² *JTI Macdonald v. Canada* [2002] 102 C.R.R. (2d) 189, at paragraphs 501–508; *JTI Macdonald v. Canada* (Que Ct Appeal), [2005] QCCA 726, at paragraph 15.

³ A Critical Analysis of the Ministerial Regulations to be Issued Pursuant to Section 11 of the Tobacco Products Control Act 1992, As Acknowledged by the Council of Ministers on 16 May 1995, 31 May 1995, BAT Bates No. 502575535-544 (<http://legacy.library.ucsf.edu/tid/pqn45a99>). See page 538.

⁴ *Philip Morris v. Reilly*, 113 F.Supp.2d 129 (D. Mass 2000); see especially 145 and 148.

- (2) Methods for testing and measuring cigarette emissions in mainstream smoke: (a) one for tobacco-specific nitrosamines (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and *N*-nitrosonornicotine (NNN)); (b) one for benzo[*a*]pyrene; (c) one for aldehydes (acetaldehyde, acrylaldehyde (acrolein), and formaldehyde); and (d) one for volatile organic compounds (benzene, 1,3-butadiene, and carbon monoxide).

45. Of the seven cigarette testing methods above, TobLabNet will present two validated methods to the Conference of the Parties at its fourth session. The first method, for tobacco-specific nitrosamines (NNN and NNK, both of which are widely known human carcinogens) in cigarette emissions underwent validation with the participation of nine TobLabNet laboratories from eight countries.¹ At the time of writing of this report (early June 2010), the second method, for testing and measuring cigarette contents for nicotine in tobacco was undergoing completion with the participation of 21 laboratories in 16 countries.² A short summary is provided below of both method validations. A more detailed version of these method validations will be presented in a non-paper to the Conference of the Parties at its fourth session.

46. Following a WHO Tobacco Free Initiative convened working group meeting in Singapore in July 2010 of TobLabNet member laboratories involved in the methods validation project, it was decided that the validation of the other five cigarette testing methods will occur in the following order:

- (1) humectants in tobacco;
- (2) ammonia in tobacco;
- (3) benzo[*a*]pyrene in mainstream smoke;
- (4) aldehydes in mainstream smoke;
- (5) volatile organic compounds in mainstream smoke.

47. Depending on the availability of the necessary technical and financial resources, WHO's Tobacco Free Initiative will strive to deliver three validated methods to the Conference of the Parties at its fifth session in 2012, and the remaining two at its sixth session in 2014.

Validation of a method for the determination of tobacco specific nitrosamines in mainstream cigarette smoke³

48. The method validation for the determination of tobacco-specific nitrosamines in mainstream cigarette smoke began by first identifying the methodology and a TobLabNet laboratory to lead the study. The US Centers for Disease Control and Prevention (CDC) served as the lead laboratory for this method validation. CDC circulated the Standard Operating Procedure among TobLabNet members to edit and revise. The Standard Operating Procedure was then revised to incorporate all suggestions from TobLabNet members into a final draft. Afterwards, the final draft was distributed to all

¹ Canada, China, France, Germany, Japan, Netherlands, Singapore, United States of America (two laboratories).

² Brazil, Burkina Faso, Canada, China (two laboratories), France, Germany, Greece, Indonesia, Japan, Lithuania, Netherlands (two laboratories), Singapore, Slovak Republic, Spain, Ukraine, United States of America (four laboratories).

³ A copy of the validated method is available on request. E-mails should be addressed to: tfi@who.int.

TobLabNet labs and WHO elicited participants for the study. During the initial round, CDC made revisions to the Standard Operating Procedure in response to feedback from participants that resulted in an updated draft that all laboratories adhered to during the full evaluation.¹

49. In late January 2010, samples were shipped to laboratories participating in the full evaluation. Laboratories smoked five sample varieties² employing either a linear or rotary smoking machine³ and implementing ISO and Intense smoking regimes. A smoking plan in accordance with ISO 4387:2000 was followed resulting in each laboratory generating seven replicates per sample variety⁴ for the full evaluation. Total particulate matter from mainstream cigarette smoke was collected onto Cambridge filter pads. A solution containing a mixture of two (or four) isotopically-labelled internal standards was spiked onto the pad and subsequently extracted with ammonium acetate. The extract was filtered and analysed by high performance liquid chromatography (HPLC) – tandem mass spectrometry (MS/MS) using electrospray ionization. Analyte ions were detected using multiple-reaction-monitoring (MRM) mode. The reconstructed ion chromatogram peak area ratio of native analyte-to-labelled internal standard was compared to a calibration curve created by analysis of standards with known concentrations of tobacco-specific nitrosamines to determine the amount of tobacco-specific nitrosamines in each unknown sample. CDC advised on technical issues and answered questions about the Standard Operating Procedure, and provided additional samples throughout the method validation process. Laboratories were instructed to send results to WHO following completion of the method validation. WHO subsequently forwarded coded results to the lead laboratory.⁵

50. By May 2010, results for the determination of NNN and NNK in the mainstream cigarette smoke of all cigarette varieties were received from all nine laboratories. Currently, CDC is performing a statistical evaluation of raw data in accordance with ISO 5725. Results for this method validation will be delivered in a WHO report. A peer-reviewed manuscript on this global collaborative study is also expected to be published.

Validation of a method for the determination of nicotine in tobacco⁴

51. The second method validated by TobLabNet members was for the determination of nicotine in tobacco. The same round-robin procedure was followed as with the first method validation with the exception of an initial round. The Food and Consumer Product Safety Authority (VWA) of the Netherlands served as the TobLabNet method validation lead laboratory. Following identification of the methodology, VWA circulated the Standard Operating Procedure among TobLabNet laboratories to edit and revise by mid-February 2010. Subsequently, VWA composed a final draft of the Standard Operating Procedure, incorporating all suggestions from TobLabNet members, by the beginning of March 2010, and WHO elicited participants for the study. At the beginning of April 2010, CDC shipped one pack each of three reference cigarettes (1R5F, 3R4F, CM6) and two commercial brands

¹ Nine laboratories delivered 3R4F results. Initial round results were shared between CDC and WHO; however, participants were not notified of their performance only that they would participate in the full evaluation.

² Three reference cigarettes (1R5F, 3R4F, CM6) and two commercial brands (Marlboro Full-Flavor and Player's).

³ Six laboratories used linear smoking machines and three laboratories used rotary smoking machines.

⁴ Table 2 of the Standard Operating Procedure. During the initial round, all participants followed the Standard Operating Procedure for determination of tobacco-specific nitrosamines in mainstream cigarette smoke but did not follow a smoking plan since only one sample was evaluated.

⁵ The Standard Operating Procedure for the overall seven validations called for the coding of results by WHO so that the lead laboratory performing the analysis would not know which laboratory the result came from.

(Marlboro Full-Flavor and Marlboro Lights, UK) to participants. This shipment included repeat samples to be used if needed. Laboratories were directed to send results to WHO following completion of the method validation.

52. The protocol for this method validation projected a study close date of 28 May 2010. However, by early June, results from only 8 out of 20 labs had been received. Therefore, the study was extended by several additional weeks to allow more participants to complete the method validation. Once the study has been completed, VWA will statistically evaluate all raw data sent from participants in accordance with ISO 5725. Statistical procedures and reporting of results will be followed in the same manner as the method validation of tobacco-specific nitrosamines in mainstream cigarette smoke. CDC will assist with data analysis if needed and in the composition of WHO's report on results. A peer-reviewed manuscript describing this global collaborative study is also expected to be written by either VWA or CDC and co-authored by all study participants.

SCIENTIFIC PROGRESS

53. Electronic Nicotine Delivery Systems designed for nicotine delivery to the respiratory system is a designation which encompasses products that contain tobacco-derived substances but in which tobacco is not necessary for operation. Electronic Nicotine Delivery Systems are marketed under a variety of brand names and descriptors, of which the terms "electronic cigarettes" or "e-cigs" are the most common. As reported by many countries, electronic cigarettes are witnessing a significant increase in global distribution and sales coinciding with the implementation of Article 8 of the WHO FCTC and the introduction of smoke-free environments. As market penetration of "e-cigs" continues to rise, policy-makers and regulators in many countries have sought guidance from WHO's Tobacco Free Initiative on the scientific evidence-base and optimal regulatory approaches with regard to these products.

54. WHO's Tobacco Free Initiative continues to be increasingly concerned about the significant questions that remain to be answered in relation to the safety and efficacy of this class of products.¹ For example, there is a lack of understanding surrounding the organic compounds or vaporization products in the electronic cigarette, in addition to the absence of any published studies demonstrating efficacy and safety of any electronic cigarettes. Furthermore, WHO's Tobacco Free Initiative is not aware of any set of data that establishes the safety of nicotine and other constituents of the product to confer the claimed cigarette-mimicking sensory characteristics, when heated and delivered to the lung. WHO's Tobacco Free Initiative also remains unconvinced of the precise nature and the quantity of constituents in the emissions; as there are many variants of electronic cigarettes, there is also concern about the variety and lack of uniformity of these products.

55. The WHO Quality Assurance and Safety of Medicines team and WHO's Tobacco Free Initiative jointly convened a teleconference on 24 February 2010 with representatives of major regulatory authorities to investigate the process for developing a uniform strategy to address Electronic Nicotine Delivery Systems. The participants in this teleconference included the US Food and Drug Administration, the European Commission, ANVISA (Brazil), Health Canada, the Saudi Food and Drug Authority, and SwissMedic. All participants were in agreement that a consultation

¹ WHO Study Group on Tobacco Product Regulation. *Report on the scientific basis of tobacco product regulation: third report of a WHO study group*. Geneva, World Health Organization, 2010. The report provides scientific and regulatory recommendations on ENDS.

hosted by WHO to examine strategies to regulate electronic cigarettes would be crucial in determining appropriate scientific and regulatory approaches to this class of products.

56. The WHO Regulatory Consultation on the Safety of Electronic Nicotine Delivery Systems was held on 6 and 7 May 2010. The purpose of this meeting was to share regulatory country experiences, raise awareness of potential safety concerns related to Electronic Nicotine Delivery Systems, consider present and future approaches to regulation of these products, which includes the potential for standardization, and map out a way forward in order to promote and protect public health research priorities and regulatory guidelines. The meeting was attended by delegates,¹ invited experts in the field of tobacco product regulation, some members of the WHO Study Group on Tobacco Product Regulation, and from WHO.

57. During the first meeting, participants began work on a set of seven recommendations, outlined below.

- (1) Nicotine is a highly toxic and addictive substance that poses a serious risk to health. Nicotine and nicotine products for human use should be regulated.
- (2) There is an emerging group of products called Electronic Nicotine Delivery Systems that may or may not deliver nicotine. These products, commonly including e-cigarettes, may be used to deliver other potentially toxic chemicals and drug ingredients. These products are often accompanied by inaccurate information. Regulators are concerned that the quality and safety of these products has not been established.
- (3) Regulators of medical and tobacco products should collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) Electronic Nicotine Delivery Systems to protect public health.
- (4) Where health and/or therapeutic claims are being made or implied, quality, safety and efficacy data substantiating those claims should be presented to the regulator.
- (5) National regulators are encouraged to inform the public and other interested parties about concerns related to these products, including their safety and misleading marketing.
- (6) National regulators are encouraged to share information among themselves about these products, including research findings and related policies.
- (7) National regulators encourage WHO to facilitate information exchange between tobacco-control and medical products regulators.

¹ Delegates came from Australia, Brazil, Canada, the European Commission, New Zealand, Saudi Arabia, Serbia, Singapore, South Africa, Switzerland, Thailand, Turkey, Ukraine, and the United States of America.

58. Participants agreed that the draft recommendations should be sent to all participants, by WHO, for additional comments. This was done in May 2010. At the time of the writing of this report, in early June 2010, final comments on the draft were expected. In addition, two working groups were established, each to develop an information document specific to Electronic Nicotine Delivery Systems addressing both national regulators and the general public. The outputs of these working groups are also currently being formulated.

ACTION BY THE CONFERENCE OF THE PARTIES

59. The Conference of the Parties is invited to note this report.

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