出國報告（出國類別：實習）

參與 106 年歐盟執委員衛生及食品安全總署國家專家專業訓練計畫(NEPTs)出國報告

服務機關：衛生福利部國民健康署
姓名職稱：胡祺苑技士
派赴國家：比利時
出國期間：**106** 年 **3** 月 **16** 日至 **6** 月 **15** 日
報告日期：**106** 年 **9** 月 **15** 日

(本出國經費由菸品健康福利捐支應**)**

摘　要

近年電子煙等新興菸品快速於世界各國市場氾濫，吸引青少年及兒童因好奇而嘗試；依衛生福利部國民健康署 2016 年青少年吸菸行為調查結果顯示，我國國、高中學生電子煙吸食率已由 2014 年的 2.0%與 2.1%，竄升至 2016 年 3.7%與 4.8%，增加近一倍，顯示電子煙的興起，已成為我國未來菸害防制重大課題。

為瞭解歐盟針對電子煙之管制內容，衛生福利部國民健康署於 2016 年第 28 屆「台歐盟諮商綜合及其他部門別會議」提案與歐盟進行電子煙法規及公衛合作，希望藉此平台建立雙邊合作機制及長期交流模式，後續能持續透過研討會或論譠方式，針對電子煙規範之執行現況、遭遇困難及解決方案等事項，進行經驗交流及分享。本提案獲歐方同意後，進一步透過駐歐盟及比利時代表處衛生組鄭組長慧文協助與歐盟執委會洽談聯繫，獲歐盟執委會衛生及食品安全總署(DG SANTE)同意提供國家專家專業訓練計畫(National Experts in Professional Training Programme，NEPTs)受訓名額，爰於 2017 年 3 月 16 日至 6 月 15 日推派受訓人員赴該總署第 B 司第 2 處參與訓練計畫。

見習期間主要任務為參與電子煙管制及監測工作，除了隨指導員參與相關討論會議外，並協助蒐集、彙整各國管理規範，摘要重要文獻及會議記錄，藉此機會瞭解歐盟電子煙立法重點、管制細節、各會員國遭遇之困難及最新發展。同時亦透過列席旁聽菸害防制政策各層級會議之機會，瞭解歐盟菸草指令(2014/40/EU)規範內容、創新策略及執行現況；單位處長及指導員更進一步安排與英國及瑞典會員國代表會面請益，詳談該 2 國菸害防制實務經驗及歐盟菸草指令落實現況，是十分難得且寶貴的經驗；期間更於單位會議上簡報我國菸害防制策略及執行現況，獲歐方大力讚許。

本次受訓經驗對於拓展國際視野及瞭解歐盟菸害防制政策極有助益，感謝國民健康署長官推薦及信任，菸害防制組同仁之協助與支持，期透過本報告記錄歐盟菸害防制現況並提出心得建議，作為日後我國菸害防制政策研擬之參考。

目　錄

壹、緣起與目的

近年電子煙等新興菸品，以各種香味料、創新設計及仿 3C 產品等模式進行行銷，快速於世界各國市場氾濫，並吸引青少年及兒童因好奇而嘗試，依衛生福利部國民健康署 2016 年青少年吸菸行為調查結果顯示，我國國、高中學生電子煙吸食率已由 2014 年的 2.0%與 2.1%，竄升至 2016 年 3.7%與 4.8%，增加近一倍，顯示電子煙的興起，已成為我國未來菸害防制重大課題。

歐盟方面，為加強歐盟各會員國間的菸品管制規範，考量近幾年已出現各種新的科學實證，加上電子煙及加味菸等產品氾濫，且世界衛生組織菸草控制框架公約陸續通過各法條之指導準則，業於 2012 年 12 月提出新版菸草指令草案，並於 2014 年通過 (Directive 2014/40/EU)，納入電子煙產品之管制規範。

爰此，衛生福利部國民健康署(下稱健康署)為進一步瞭解歐盟針對電子煙之管制內容，於 2016 年第 28 屆「台歐盟諮商綜合及其他部門別會議」提案與歐盟進行電子煙法規及公衛合作，希望藉此平台建立雙邊合作機制及長期交流模式，後續能持續透過研討會或論譠方式，針對電子煙規範之執行現況、遭遇困難及解決方案等事項，進行經驗交流及分享。本提案獲歐方同意後，健康署透過駐歐盟及比利時代表處衛生組鄭組長慧文協助，進一步與歐盟執委會洽談聯繫，獲歐盟執委會衛生及食品安全總署(DG SANTE)同意提供國家專家專業訓練計畫(National Experts in Professional Training Programme，NEPTs)受訓名額，於 2017 年 3 月 16 日至 6 月 15 日派員赴該總署參與訓練計畫，實質參與電子煙管制及監測工作，同時瞭解歐盟各項菸害防制政策之執行現況與創新策略。

貳、過程

見習期間獲安排於歐盟執委會衛生及食品安全總署(DG SANTE)第 B 司(Unit B-health systems, medical products and innovation)第 2 處(Unit B2- Health in all policies, global health and tobacco control)受訓學習，隨指導員參與菸害防制工作小組會議、處務會議、歐盟會員國菸害防制專家小組會議等，從中實質參與該部門菸害防制政策制定等實務工作，以下就歐盟各機構及衛生及食品安全總署之組織架構與業務職掌等簡述如下：

一、 歐盟(European Union)簡介

(一) 歐盟會員國組成

歐洲聯盟簡稱歐盟，目前共有 28 個會員國，24 種官方語言，土地範圍涵蓋了 4 百萬平方公里，人口數超過 5 億人，僅次於中國和印度，28 個會員國中，以法國土地面積最大，馬爾他最小[1]，人口數以德國最多(8 千多萬人)、法國次之(6 千多萬人)，馬爾他人口數最少(42 萬多人)。其中英國已於 2017 年 3 月向歐盟遞交脫歐法案，歐盟亦於同年 4 月訂定相關指引並成立專案，與英國展開協商，預計英國最晚將於 2019 年 3 月 30 日正式脫歐，其餘 27 國則已開始著手為英國脫歐後的各項挑戰作準備[2]。

歐盟最早是由 6 個創始會員國所組成的。1950 年代，歐洲各國正處於二次大戰後的戰後復甦期，為避免再度發生戰爭與衝突，建構經濟共同體並相互依存的概念應運而生，是年 5 月 9 日，時任法國外交部長之舒曼(Robert Schuman)於巴黎發表聲明，即舒曼宣言(Schuman declaration)，希望促成德國和法國之煤鋼共同生產計畫，並鼓勵其他歐洲國家加入，接著，法國、西德、比利時、荷蘭、義大利、盧森堡共 6 個國家於 1951 年 4 月 18 日共同簽署條約，建立煤鋼共同體(European Coal and Steal Community，ECSC)，是為歐盟之基礎，繼而於此基礎之上，6 國復於 1957 年簽署羅馬條約(Treaties of Rome，1958 年生效)，建立歐盟經濟共同體(European Economic Community，EEC) 及歐洲原子能共同體(European Atomic Energy Community，Euratom)，進一步讓彼此的國民、貨物和服務自由流通，此時已具歐盟雛形[3]。

後續歐盟版圖逐漸擴大，隨著不同國家的加入，便修正並簽署新的協定，將歐盟與會員國權責列於其中，並逐步建構政策運作模式，包括 1986 年簽署「單一歐洲法(Single European Act)」，1992 年簽署馬斯垂克條約(Maastricht Treaty)，此時歐洲共同體正式更名為「歐洲聯盟」，1997 年簽署「阿姆斯特丹條約(Treaty of Amsterdam)」，2001 年簽署「尼斯條約(Treaty of Nice)」，直至 2007 年 12 月簽署「里斯本條約」(2009 年 12 月 1 日生效)，賦予歐盟國際法人資格，可對外簽署國際條約並加入國際組織，此時已有 27 個會員國，最後加入歐盟的國家為克羅埃西亞

[1] Living in the EU https://europa.eu/european-union/about-eu/figures/living_en
[2] The 28 member countries of the EU https://europa.eu/european-union/about-eu/countries_en#28members
[3] The history of the European Union https://europa.eu/european-union/about-eu/history_en

(Croatia)，為 2013 年加入。目前仍有阿爾巴尼亞、蒙特內哥羅、塞爾維亞、馬其頓共和國及土耳其等國家申請加入歐盟。

圖 1、歐盟範圍及會員國概況

(二) 歐盟主要機構[4]

歐盟有 7 個主要機構以及其他機構間機關(bodies)，7 個主要機構包括歐盟理事會(European Council)、部長理事會(the Council of the European Union)、歐洲議會(European Parliament)、歐盟執委會(European Commission)、歐盟法庭(Court of Justice of the EU)，以及歐盟審計委員會(Court of Auditors)。

其中，歐盟理事會又稱歐洲首腦會議，為最重要的決策層級，由 28 個會員國元首、歐盟執委會主席，以及外交暨安全政策高級代表共同組成，每年例行召開四次會議，以決定歐盟政策之優先順序。現任主席為波蘭籍的圖斯克(Donald Tusk)，每任任期 2 年半。

另外，與歐盟立法息息相關的機構為部長理事會、歐洲議會及歐盟執委會。

- 部長理事會：成員為各會員國部會首長，其組成依議題涉及之政策領域而定，可針對歐盟執委會提出的法案提供修正建議，與歐洲議會共同享有立法權及預

[4] EU institutions and other bodies https://europa.eu/european-union/about-eu/institutions-bodies_en

算權，協商各國政策並制定歐盟之外交與安全政策。

- 歐洲議會：其成員由各會員國公民直接選出，享有立法權、預算權及監督權。目前共有 751 席議員，席次比例依各國人口數而定，現任議員以德國籍議員最多(96 席)；另依議題組成 8 大政黨，並以政黨形式運作，其中以歐洲議會人民黨團(Group of the European People's Party)為最大黨，佔 214 個席次。
- 歐盟執委會：為歐盟主要的法律提案單位，同時處理日常各項行政事務，並協助會員國落實法令之執行。依政策領域設有 31 個總署(Directorate-General)，負責發展、執行及管理歐盟各項政策、法律及計畫，另設 16 個服務部門(Service department)專責處理特殊事務，尚有 6 個執行機構(Executive agencies)負責管理各總署規劃之計畫。約有超過 3 萬 3 千名員工。

圖 2、歐盟主要機構

(三) 法律修訂與政策制定[5]：

歐盟法律可區分為初級立法及次級立法，條約(Treaties)屬於初次立法，為歐盟運作之基礎；次級立法則包括規則(Regulation)、指令(Directive)及決定(Decision)。規則(Regulation)具有拘束力，必須在整個歐盟實施；指令(Directive)則是設定一個應達成的目標，交由各會員國自行決定如何透過修訂本國法律以達到目標；決定(Decision)則是針對特定對象而訂定之規範，僅對該適用對象具有拘束力。另，執委會可發布建議(Recommendations)，提出行動方針，但對會員國未具約束力；意見(Opinions)則可由執委會、部長理事會或歐洲議會、區域委員會或歐洲經濟及社

[5] EU law https://europa.eu/european-union/law_en
How EU decisions are made https://europa.eu/european-union/eu-law/decision-making/procedures_en
Regulations, Directives and other acts https://europa.eu/european-union/eu-law/legal-acts_en

會委員會提出，亦同樣不具拘束力。

歐盟各項法律訂定及修正主要由歐盟執委會負責發動，但一般民眾、民間團體、歐洲議會或部長理事會亦可提案修訂法律。

一般來說，執委會研擬法律草案前，應先完成經濟、社會及環境評估，並徵詢民眾、民間團體及利益關係人之意見，各國國會亦可針對該法案內容及規範範圍提供意見；執委會依據各項意見擬定修法草案後，會同時送交部長理事會及歐洲議會進行審查，經兩個機構審查通過並生效後，各會員國應依法案性質而直接適用或轉化為各國法律，並由執委會及歐洲法庭共同監督各會員國落實執法情形。

當部長理事會針對各項討論必須做決定時，表決機制可分成三種[6]：

- 簡單多數決(simple majority)：超過 15 會員國通過即可；
- 條件多數決(qualified majority)：能夠代表 55%以上會員國及 65%以上歐盟人口；
- 一致決(unanimous vote)：所有人都同意。

隨著會員國越來越多，歐盟決策方式已漸漸由一致決改成條件多數決，然而遇到涉及外交、主權或較重要的議題，仍以一致決為主要決議方式。

見習期間參與的專家小組會議仍以一致決為原則，當有會員國專家提出異議時，該討論議題則暫時不作決議。舉例來說：當各國專家針對菸品瘦小包裝(Slim packaging)討論是否該訂定固定尺寸時，因有一個國家代表無法同意規格設定，該項議題便暫時擱置下次再議。

(四) 衛生及食品安全總署(DG Healthy and food safety，DG SANTE)[7]

1. 主要目標：

   - 保護和改善公共衛生
   - 確保歐洲的食物安全衛生
   - 保護動物之健康和福利
   - 保護作物和森林的健康

[6] Voting system http://www.consilium.europa.eu/en/council-eu/voting-system/
[7] 歐盟衛生及食品安全總署 http://ec.europa.eu/dgs/health_food-safety/index_en.htm

2. 組織架構及業務職掌：本總署主管衛生及食品安全政策制定等業務，共設7個司(A-G)，第一司負責法律、資訊、預算等一般事務，第二、三司負責醫藥衛生、危險因子及慢性病防治等業務，第四、五、六司則主責食品安全、動植物產品安全、動植物保護等業務，另設執行機構(The Consumers, Health, Agriculture and Food Executive Agency，Chefea)，負責管理及執行各司處規劃之專案計畫。
3. 第2司主責衛生體系、醫療產品及創新，而歐盟菸害防制政策制定及規劃則由第2司第2處負責(Unit B2-Health in all policies, global health and tobacco control)。該處約有15名員工，其中9位負責菸害防制業務，並依議題分工 。

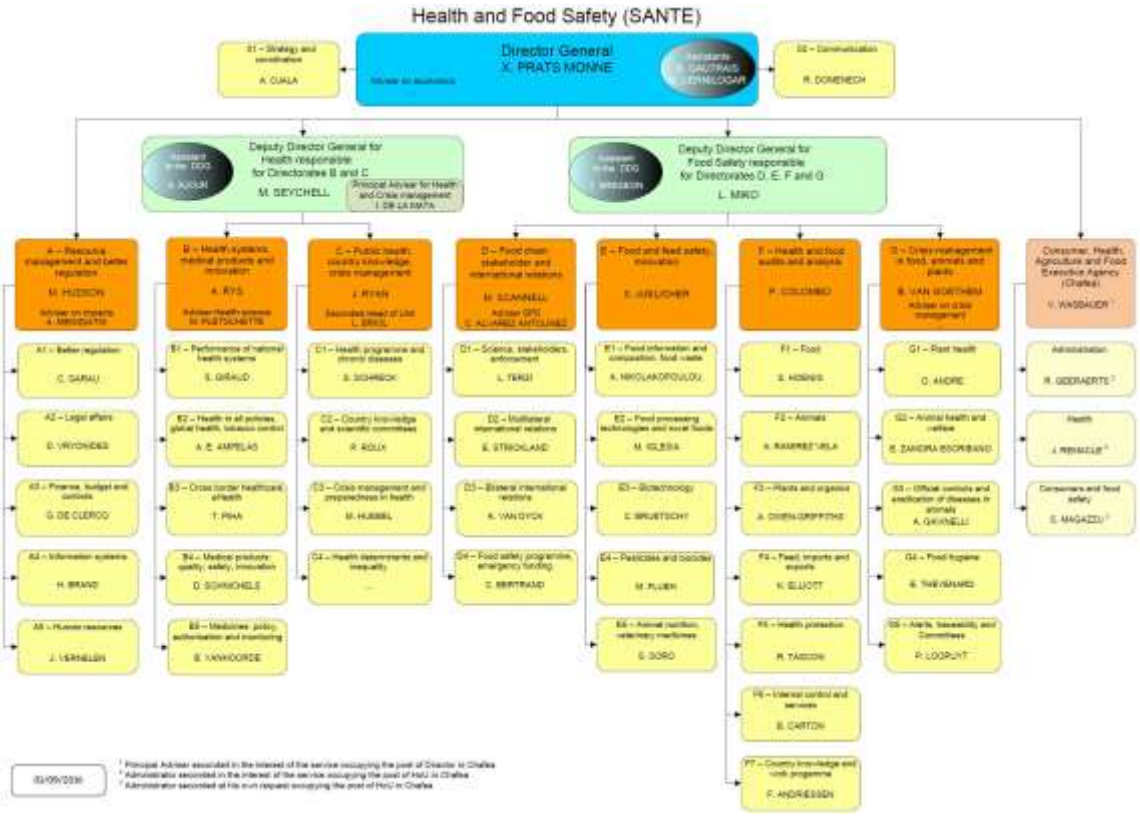

圖3、衛生及食品安全總署組織架構圖[8]

[8] DG SANTE 組織架構圖 https://ec.europa.eu/info/sites/info/files/organisation-chart-dg-sante_en.pdf

(五) 歐盟國家專家訓練計畫及實習生制度：

歐盟訂有國家專家調派及專家訓練計畫(決定 C(2008) 6866[9])，調派國家專家(Seconded national experts，SNEs)係透過借調各會員國、地區或地方公務員方式，將他們的專業經驗帶給執委會，同時也將借調期間所獲得之知識帶回本國政府；除了公務員之外，國際間組織、大學、研究中心等之專家也可藉此借調方式，提供歐盟執委會需要之特殊專長及知識。另國家專家專業訓練(national experts in professional training，NEPTs)則開放與歐盟簽署自由貿易聯盟之成員國，或與歐盟簽署協定、談判之國家申請見習名額，此外，公共行政單位之工作人員亦得申請。我國在「臺歐盟雙邊諮商會議」架構下，獲歐方同意可於每年 3 月及 10 月，申請調派 4 名政府官員進行為期 3 個月之短期見習。

歐盟尚設有實習制度[10]，每年開放約 1300 個名額供歐盟各國年輕工作者申請，係屬為期五個月之有給職工作，月薪約 1160 歐元，又稱 Bluebook Trainees，根據官方統計，約有 95% Bluebook 見習生來自歐盟會員國，5%來自非歐盟國家；另設非典型實習生(Atypical Trainees)制度，由個人自行向各單位申請，為無給職，通常為期 3 個月，但可由各單位自行決定。這兩類實習制度除可讓各國職場新鮮人有機會接觸執委會工作內容，深入瞭解其日常運作模式外，實質上也為執委會人力不足之現況提供了重要的支援，見習期間遇有適當職缺，亦可參與就職考試並投遞履歷表申請。

在歐盟見習期間，同時於執委會見習之 Bluebook 實習生多達 50 位，來自於歐盟不同國家，此外亦有來自澳洲之見習生。歐盟人力總署針對實習生設立專責管理小組，由實習生組成社團群組，包括語言學習、辯論及活動規劃等，並設有編輯小組定期發行電子刊物，鼓勵各國見習生透過刊物分享交流各國文化及生活經驗；各總署亦設實習生群組，選出小組長定期辦理聚會、小組討論、研討會及參觀活動等，藉此鼓勵實習生相互交流。單位內即有 1 位 Bluebook 實習生及 2 位非典型實習生一同見習，透過共進午餐、聚會或共同執行交辦任務之機會，彼此交換工作心得、困境及解決方法，並分享生活旅遊各項實用經驗，著實平撫了身處異鄉的不安與孤獨感。

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[9] COMMISSION DECISION of 12.11.2008 laying down rules on the secondment to the Commission of national experts and national experts in professional training

[10] TRAINEESHIPS https://ec.europa.eu/stages/home_en

二、 見習期間工作內容

見習期間之主要任務為參與電子煙管制及監測，除了隨指導員參加相關會議外，並協助蒐集、彙整各國管理規範，摘要重要文獻及會議記錄，藉此機會了解歐盟電子煙立法重點，管制細節，各會員國遭遇之困難，及最新發展。此外，並透過列席旁聽菸害防制政策各類會議之機會，瞭解歐盟菸草指令規範內容，各會員國執行情形及挑戰，相關規範及重點整理將於下一章節詳述。

見習期間參與(旁聽)之重要會議包括：

1. 3 月 30 日，菸害防制政策專家小組會議(meeting of the group of experts on tobacco policy)[11]；
2. 5 月 15 日，菸品跟蹤及追溯系統利益關係人公聽會(Second stakeholder workshop on implementation of Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU)[12]；
3. 5 月 18 至 19 日，菸品跟蹤及追溯系統專家小組會議(meeting of the subgroup on traceability and security features)[13]
4. 5 月 31 日，世界無菸日研討會[14]
5. 6 月 1 日，加味菸獨立諮詢小組會議(The first meeting of the Independent Advisory panel for characterising flavours in tobacco products)[15]

另外，由於執委會主責為政策制定與法規修正，會員國才是落實執法之關鍵，處長及指導員為使我有機會瞭解各國菸害防制執行現況，特別協助聯繫各會員國菸害防制工作人員，居中安排與會員國代表會面請益的機會，雖最後因時間過短，能夠撥空訪談國家僅有英國及瑞典，但仍非常感謝處長及指導員的費心聯繫及安排。能與會員國進行實務上的分享與討論，更有助於瞭解實務執行現況及挑戰。

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[11] Summary report - Expert Group on Tobacco Policy established under Commission Decision C(2014) 3509 (30 March 2017) https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20170330_sr_en.pdf

[12] Stakeholder Workshop on implementation of Articles 15 & 16 of Directive 2014/40/EU https://ec.europa.eu/health/tobacco/2017_stakeholderworkshop_tpd_en

[13] Subgroup on Traceability and Security Features established by the Expert Group on Tobacco Policy https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20170518_sr_en.pdf

[14] World No Tobacco Day 2017: Europe United Race Against Tobacco http://ensp.org/2017/05/15/world-no-tobacco-day-2017-europe-united-race-against-tobacco/
World No Tobacco Day 2017 policy debate on "Tobacco: A Threat to Development" https://smokefreepartnership.eu/news/world-no-tobacco-day-2017-policy-debate-on-tobacco-a-threat-to-development

[15] 1st meeting - Independent Advisory Panel on characterising flavours in tobacco products https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20170601_ag_en.pdf

除了菸害防制相關會議之外，亦參與了歐盟白皮書討論會議(the Future of Europe)、第 B 司業務交流會議(ARGORA B)、世界衛生日午間研討會(Infopoint Lunchtime conference)等，讓視野拓展至菸害防制工作之外，有機會吸收不同議題之新知。單位同仁及實習生來自歐盟不同國家，在多元文化工作環境中，彼此分享工作及生活經驗，大大拓展了視野，同時並運用自身專業知識及工作經驗，與見習單位進行交流，於單位會議上分享我國菸害防制策略及執行成果，歐方大力讚許我國菸害防制成就。

三、 歐盟未來白皮書及歐洲日活動

今(2017)年適逢羅馬條約締約 60 周年，歐盟總部及各會員國特別舉辦規模大小不一的慶祝活動。值得一提的是關於歐盟未來白皮書之討論，以及辦理歐洲日活動：

(一) 歐盟未來白皮書(White paper on the future of Europe)：

對於歐盟未來白皮書的願景，歐盟執委會現任主席容克(Jean-Claude Juncker)表示：當我們歡慶羅馬條約締約 60 周年之際，27 個會員國應共同形塑出歐洲的未來與願景[16]。("As we mark the 60th anniversary of the Treaties of Rome, it is time for a united Europe of 27 to shape a vision for its future“(Jean-Claude Juncker, President of the European Commission, 1 March 2017)。

白皮書盤點了歐盟現今遭遇的挑戰與困境，包括新科技應用對就業市場及產業之衝擊，氣候變遷議題，邊境安全與移動自由，恐怖攻擊與歐盟境內外安全威脅，人口縮減與經濟衰弱，高失業率及高負債，人口老化，民粹主義與民族主義上升等。處於十字路口的歐洲，需要在此刻共同研商對策，以克服今日面臨的挑戰；白皮書又進一步列出 5 種情境供全體會員國及公民共同思考，並透過召開討論會議、公聽會、開放網路評論等方式，鼓勵各方提出意見及評論，希望能由會員國共同決定歐洲的未來。

見習期間也隨單位同仁參與其中一場討論會議，與會者均為衛生及食品安全總署同仁，針對白皮書的提問，來自不同業務單位的同仁依據其業務範疇提出建言，各方意見聽似各說各話，卻能歸納出共同訴求：衛生醫療政策仍應力

[16] White paper on the future of Europe
https://ec.europa.eu/commission/white-paper-future-europe-reflections-and-scenarios-eu27_en

求資訊透明，政策或服務應以民眾易於瞭解及取得為考量重點，更應進一步加強宣導推廣，提升民眾之知曉度及使用頻率，以提高各項政策的效益。

"Europe is at a crossroads and needs to decide how it wants to tackle the challenges of today."
"歐洲正處於十字路口，需要決定以何種方式克服今日面臨的挑戰。"

(二) 歐洲日活動[17]：

1950 年 5 月 9 日，時任法國外交部長舒曼(Robert Schuman)，於巴黎發表舒曼宣言(Schuman declaration)，提議建立煤鋼共同體(European Coal and Steal Community，ECSC)，為歐盟的最早雛形，是以歐盟將每年 5 月 9 日定為歐洲日。

為了慶祝歐洲日，歐盟各機構會在歐洲日前的周末辦理「歐洲日活動」，開放民眾進入各機構參觀，各機構內設有資訊攤位提供宣導單張或手冊，或設計各式活動或闖關遊戲，讓民眾除了親身體驗歐盟各機構平日運作模式之外，也能透過輕鬆有趣的方式瞭解各部會的政策推動現況。

見習期間亦把握歐洲日活動機會，進入歐洲議會、部長理事會及歐盟執委會大樓(Berlaymont Building)等機構參觀體驗，觀察到民眾對此類活動非常踴躍，每棟大樓均須排隊 30 分鐘以上方能入內參觀；此外，不同機構依其業務性質設計活動，如歐盟部長理事會為各國部會首長開會及辦公之場所，當日除開放各國部長專屬辦公室及會議室供民眾參觀外，一樓大廳亦安排 28 個會員國設置攤位，簡介其國情資訊及特色風情，各攤位均吸引大批家長陪同子女參觀同樂，是效益極高的政策宣導策略。歐洲議會則開放議場並定時安排辯論活動，由民眾模擬議員角色，針對設定議題發表看法，各黨團亦於大樓內設置攤位展示其政黨訴求及關切議題。歐盟執委會大樓(Berlaymont Building)則由各總署入駐設攤，依其業務性質發揮巧思設計攤位，讓參觀民眾彷若置身遊樂園，流連忘返，人力總署亦不忘趁機召募人才，詢問填表民眾絡繹不絕。

[17] Europe Day https://europa.eu/european-union/about-eu/symbols/archived-europe-day_en

嗣後有機會至歐洲議會大樓參加研討會，即使配有工作證亦被警衛攔阻，經詢問後才瞭解，平日歐洲議會安檢極為嚴格，實習生如欲進入，應由其指導長官或會議主辦人員陪同方能入內，先前把握住歐洲日活動進入議場參觀，並一睹各機關內部規劃，極為幸運！


圖 4、歐洲議會主議場

四、 業務交流會議及活動

見習單位第 B 司為促使該司各處員工有機會瞭解彼此業務，分享資源，促使互相交流合作，特別安排單位間交流活動，包括「AWAY DAY 活動」及「ARGORA B 會議」。「AWAY DAY 活動」係安排一天的署外活動，讓員工們走出辦公室，放下平日的工作習慣和思維，以研討會與聚會等較輕鬆的方式，讓不同處室員工相互交流，分享工作經驗，並從中媒合未來可能合作的機會。「ARGORA B 會議」則延續於「AWAY DAY 活動」之精神，由第 B 司各處輪流安排研討會議，邀請同仁利用簡短 7 分鐘的簡報時間，以各種創意方式呈現其業務重點，使其他處室同仁可藉機略知彼此的業務內容。

見習期間因參加人力總署簡介而來不及參與「AWAY DAY 活動」，「ARGORA B 會議」則有幸全程參與，藉此機會聆聽其他處室業務概要，進而簡略瞭解歐盟現階段優先推動之健康醫療政策及規劃，對入門新人來說頗有助益。此兩類活動鼓勵不同單位間之業務交流、資源共享流通，進而啟發新的思維及工作模式，值得仿效學習。

五、 世界無菸日研討會

5 月 31 日為世界無菸日，2017 年主題為「菸害對於國家永續發展的威脅」，當天參與了 2 場研討會：

(一) 「World No Tobacco Day 2017: Europe United Race Against Tobacco」

本場次研討會由歐洲菸害防制網絡 (European Network for Smoking and Tobacco Prevention，ENSP)主辦，主題為「與菸害賽跑(Europe United: the Race against Tobacco)」，邀請歐洲各國菸害防制合作夥伴，包括歐盟執委會、各會員國代表、菸草控制框架公約秘書處代表、世界衛生組織歐洲區代表及民間團體等共聚一堂，討論歐洲國家如何透過與世界衛生組織之合作，落實菸草控制框架公約以達成 2030 年永續發展目標；同時也盤點歐盟各國菸害防制工作之成就，以及未來必須共同面對的挑戰。(議程詳見附錄 2)

特別感謝 Anna-Eva 處長的信任，有機會偕同另一位實習生製作簡報，製作過程中，也對歐盟菸害防制之修法沿革與實施現況有更深刻的瞭解。

(二) 「World No Tobacco Day 2017 policy debate on "Tobacco: A Threat to Development"」

本場次由數個公共衛生組織所組成之無菸夥伴(Smoke Free Partnership，SFP)主辦，配合世界無菸日，主題訂為「菸害：永續發展的威脅」，邀請歐洲議會發展委員會主席 Linda McAvan 擔任主席，並邀請歐盟執委會衛生及食品安全總署署長 Dr. Vytenis Andriukaitis、世界衛生組織歐洲區辦公室菸害防制計畫管理經理 Kristina Mauer-Stender、歐盟執委會國際合作及發展總署(DG for International Cooperation and Development，DEVCO B4)處長 Aida Liha Matejicek，世界銀行衛生營養及人口專家 Patricio Marquez、菸害防制聯盟非洲區代表 Tih Ntiabang、非政府組織 Unfairtobacco 編輯及菸害防制專家 Ms Laura Graen、國際戒菸中心 Prof. Martin Raw 等，針對菸害與永續發展議題進行辯論，並以歐盟新版菸草指令內容、菸商干擾策略、提高菸稅策略、非洲菸害防制現況、戒菸服務等各面項議題，討論如何強化菸害防制策略，以促進永續發展目標之達成。(議程詳見附錄 2)

圖 5、世界無菸日研討會

圖 6、參與專家會議、利益關係人公聽會及午間研討會議

叁、歐盟菸害防制策略

一、 歐盟菸害防制現況

(一) 歐盟菸害防制主軸包括[18]：

- 規範管制歐盟市場上菸草製品(如包裝、警示圖文及菸品成分)
- 限制菸草製品廣告，
- 營造無菸環境，
- 稅收措施和打擊非法貿易活動，
- 反菸宣導活動。

為落實各項策略之執行，歐盟訂有多項指令或決定，讓會員國據以納入國內法規或直接執行。重要法規包括：1990 年制定焦油含量指令，最早將菸品成分納管；2001 年發布第一版菸草指令(Directive 2001/37/EC)，據以管理歐盟菸品市場；隨後世界衛生組織於 2003 年開放簽署菸草控制框架公約(FCTC)，推薦具科學實證且全方位菸害防制策略，歐盟於 2003 年簽署加入後，亦陸續訂定禁止菸品廣告促銷指令及相關法規(Directive 2003/33/EC、Directive 2010/13/EU、Recommendation 2003/54/EC)；於 2005 年實施菸品包裝警示圖文相關法規及圖庫(library of 42 colour photographs and other illustrations, 2005、Commission Directive 2012/9/EU)；為避免二手菸害，歐盟執委會於 2009 年發布無菸環境建議書(Recommendation 2009/C 296/02)，促使各國修法規範室內禁菸場所及範圍；2011 年實施菸稅指令(Directive 2011/64/EU)，要求各會員國課徵之菸稅最少應佔菸品零售價之 60%，且每千支菸之價格不得少於 90 歐元；為加強各類菸品管理，於 2014 年通過新版菸草指令。綜觀之，歐盟係透過前揭各項法律條文，全面落實歐盟菸害防制策略。

圖 7、歐盟菸害防制措施沿革

[18] Policy priorities https://ec.europa.eu/health/tobacco/policy_en

(二) 歐盟民眾對吸菸與電子煙之態度調查(Attitudes of Europeans towards tobacco and electronic cigarettes)

歐盟為瞭解民眾菸品及電子煙使用情形，以及對菸品及電子煙之態度，每 2 年會針對 28 個會員國進行全面性的面對面問卷調查。最新一波調查於 2017 年 3 月間完成，共有 27,901 位民眾受訪，調查主題包括(1)菸品/電子煙使用情形；(2)開始吸菸/使用電子煙的年齡；(3)菸品消費型態(紙菸、雪茄或水菸等)；(4)開始吸菸以及停止吸菸的理由；(5)選擇紙菸或電子煙的影響因素；(6)工作場所及公共場所二手菸暴露情形；(7)電子煙廣告促銷情形；(8)電子煙危害認知；(9)民眾對菸品及電子煙政策之態度，調查結果於同年 5 月對外發布[19]。

依據 2017 年調查結果顯示，2017 年整體吸菸率為 26%，與 2014 年相較並未下降，然而，15-24 歲青少年族群吸菸率則由 2014 年的 25%上升至 2017 年的 29%。推測其上升原因，可能與新興菸品或具吸引力菸品推陳出新(如電子煙、加味菸)，以及菸商促銷策略等有關。常規電子煙使用者與 2014 年相較仍維持在 2%，曾經嘗試者則為 15%。

歐盟各國使用菸品情形存在顯著的健康不平等現象，吸菸率最高的國家為希臘(37%)、其次為保加利亞及法國(36%)、克羅埃西亞(35%)；吸菸率最低的國家則為瑞典(7%)及英國(17%)。

關於對菸品及電子煙控制措施的態度，大多數受訪者(63%)認為在禁止吸菸的地方應禁止使用電子煙；另有 46%贊成菸品素面包裝政策[20]。

二、 2014 年新版菸草指令(Directive 2014/40/EU)

(一) 修法緣由：

- 各類菸品健康危害已出現新的科學實證；
- 具實證基礎且有效之菸害防制策略；
- 因應各類新興菸品，各會員國管制規範不一，已造成歐盟內部市場流通之

[19] Special Eurobarometer 458
http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146

[20] World No Tobacco Day: More than one in four EU citizens still smoke
http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=3764&page=1&fullDate=Tue%2030%20May%202017&lang=default

混亂及阻礙；

- 世界衛生組織於 2005 年通過菸草控制框架公約後，歐盟及大部分會員國已簽署成為締約方，加上歷次締約方會議已通過 8 個實施準則及 1 個議定書，歐盟及各會員國有義務將相關內容納入歐盟法規及各國法規中；
- 歐盟議會及歐盟部長理事會多次要求修正法案。

(二) 修法歷程[21]：

- 2012 年 12 月提出修正草案：

本階段公布修法衝擊評估報告、修法重點文宣(包括新聞釋出、單張說明、圖表說明等)，並彙集民眾修正版本、徵詢公眾評論，同時徵求學術研究支持，包括修法影響評估，菸草、尼古丁等產品之市場經濟評估，吸菸責任及健康成本研究，健康警示圖文科學實證等，並召開多場專家小組會議及利益相關人會議。

- 2014 年 05 月 19 日，經過歐盟議會及部長理事會審議通過後，正式生效

期間送歐盟部長理事會及歐盟議會審議，經多次修正後，歐盟議會於 2014 年 2 月審核通過，部長理事會則於同年 3 月審核通過，該修正草案於同年 5 月 19 日生效。

- 2016 年 05 月 20 日前，完成各國法規修訂。

新版菸草指令生效後，各會員國應於 2016 年 5 月 20 日前，依其內容轉化為各國法制規範(Transposition)。歐盟執委會則以提供線上資訊、制定執行計畫、編撰指導文件及召開專家會議等方式，協助會員國完成轉化工作。

各會員國若未能於期限內完成轉化，或未能正確轉化為國內法律，歐盟執委會可啟動侵權程序(infringement procedure)要求修正，若還是無法確實完成轉化工作，則執委會可移請歐洲法院提起訴訟，要求該會員國繳交罰鍰。

根據統計，截至 2017 年 6 月，已有 22 個會員國完成國內法律轉化工作，另有 6 個會員國，其修法內容未能完全依照新版菸草指令進行修訂，歐盟執委

[21] Revision of the Tobacco Products Directive https://ec.europa.eu/health/tobacco/products/revision_en

會已提出修正建議，並將持續監督審查，如會員國仍未能完成國內法修訂，則執委會最終可向歐洲法院提起訴訟。

(三) 修法重點[22]

- 菸品成分申報
- 禁止加味菸
- 菸品容器警示圖文應大於 65%、禁止分裝及小包裝
- 禁止菸品、電子煙及草藥菸品出現促銷及使人誤導的元素
- 建立追蹤及追溯系統以對抗菸品非法貿易
- 禁止網路或跨境販售菸品及相關產品
- 建立電子煙安全及品質標準、市場監測機制及申報規範
- 強制要求新興菸品應於完成申報後方得於歐盟市場流通

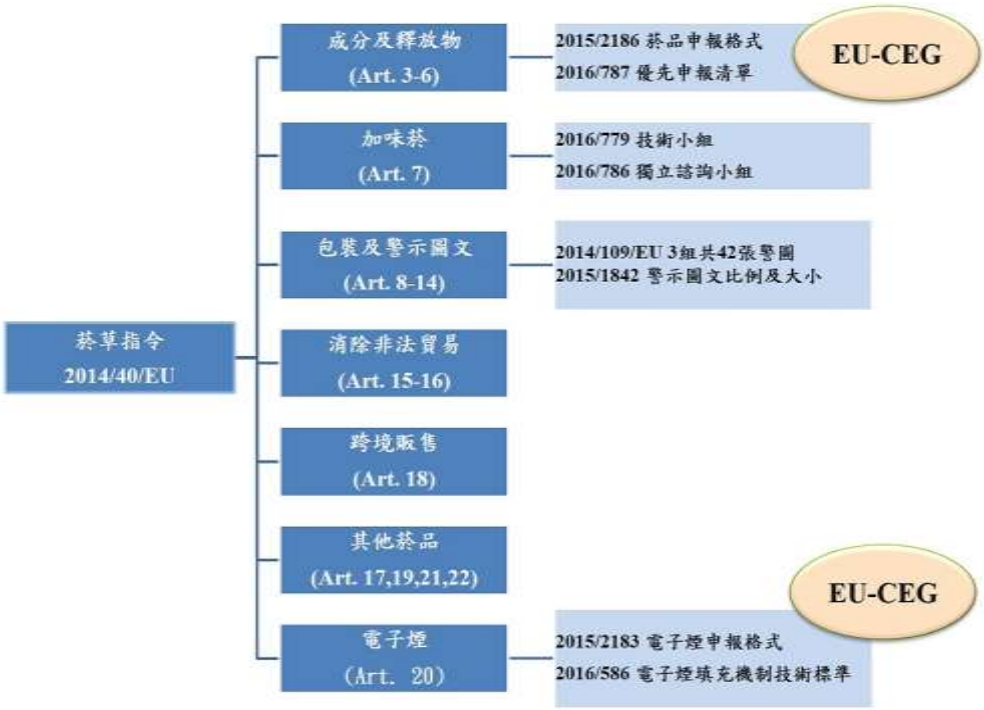


圖 8、新版歐盟菸草指令(2014/40/EU)法條及規範重點

(四) 報告

新版菸草指令於第 28 條揭示，各會員國於 2016 年 5 月完成國內法轉化後，執

[22] Product regulation https://ec.europa.eu/health/tobacco/products_en

委會最晚須於 5 年內(2021 年 5 月)提交指令執行報告，該報告應評估指令是否需依科學及技術發展(包括國際間針對菸草製品發展出的新法規或標準)，進而重新檢視或調整內容，並提出修正草案。

三、 電子煙管理

為避免電子煙危害並保障流通商品之安全性，於菸草指令第 20 條訂定電子煙管制相關規範，規範重點包括：產品之安全及品質要求，產品包裝及健康警示標示，以及市場監控、健康危害監測及定期報告等三大重點，規範內容包括：訂定尼古丁最高含量，產品上市審查機制，電子煙及煙油定期申報並提交市場監控報告，上市商品應含有使用說明書，確保消費者充分了解產品的危害性及安全使用方法，禁止 18 歲以下青少年購買電子煙，訂定電子煙廣告及促銷規範，同時，因目前電子煙健康危害證據不足，故指令特別要求廠商定期監測商品之健康危害，如上市商品經確認具有健康危害，則該商品不得販售。為確保電子煙填充產品之安全性，另訂定 Decision (EU) 2016/586 以訂定填充機制之技術標準。

此外，歐洲標準化委員會(European committee for standardization，CEN)已於 2015 年成立電子煙及煙油檢驗標準技術委員會(New CEN/TC 437[23])，其目的為因應快速增長的電子煙市場，開發必須且適合的測量技術，以保護使用者。該技術委員會由法國 AFNOR 擔任秘書處，透過成立工作小組及召開會議之方式，全面檢視電子煙及煙油檢測研究文獻及方法，進而研擬訂定歐洲電子煙及電子煙油之檢驗技術標準，針對電子煙之機械，溫控，電子和化學危害等訂定規範及檢驗標準，針對電子煙油之尼古丁、甲醛、重金屬及過敏原等之安全含量及分析方法設立檢驗技術，並提供所有化學成分之檢測及量化基準，以確保相關產品之安全性。該技術委員會截至 2017 年 6 月為止已召開 4 次會議，目前進展仍在蒐集相關文獻以研擬草案，預計將於 2018 年 02 月 28 日召開下一次會議。

[23] New CEN/TC 437 'Electronic cigarettes and e-liquids' https://www.cen.eu/news/brief-news/Pages/NEWS-2015-002.aspx ; Technical Bodies: CEN/TC 437 https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:1958025&cs=1076CCD77AC4703562C429855ED92DFA6

圖 9、第 20 條電子煙管理重點

四、 菸品及電子煙申報

菸草指令第 5 條規定，菸品應定期申報其成分及釋放物，並依 Decision (EU) 2015/2186 規範菸品申報格式；另於第 20(2)條規定，電子煙及電子煙油應完成內容物等成分申報並通過審查後方得上市，另訂 Decision (EU) 2015/2183 規範電子煙及煙油之申報格式。

為便於廠商申報及各國政府管控監測，歐盟執委會架設線上菸品申報系統(EU Common Entry Gate，EU-CEG)[24]，自 2016 年 5 月開始運作，旨在減少廠商及監管機構的行政負擔，並有助於數據比較。會員國亦可運用 EU-CEG 做為新興菸品、草藥菸品及無尼古丁電子煙等之申報系統。

截至 2017 年 3 月為止，已透過該系統申報 2 萬 3,246 項菸品，9 萬 6,541 項電子煙產品。

五、 加味菸管理

菸草指令第 7 條規定，菸品內不得添加特殊風味(Characterising flavour)，並將於 2020 年全面禁止薄荷菸。為協助會員國查核菸品是否含有特殊風味，依據指令

[24] EU-CEG 網址：https://ec.europa.eu/health/euceg/introduction_en

第 7(3)條訂定 Decision(EU) 2016/779，訂定加味菸檢測啟動流程；另依指令第 7(4)條訂定 Decision(EU) 2016/786，成立獨立諮詢小組及技術小組，以協助會員國進行菸品是否含有特殊風味之審核及判定。

目前已完成獨立諮詢小組之召募，並於 2017 年 6 月 1 日召開第一次小組會議，選出主席及副主席，接下來將展開文獻蒐集及方法學回顧，進而建立歐盟檢測標準及審核辦法，值得持續追蹤觀察。

獨立諮詢小組成員[25]：

- Prof. Andrea Buettner, Fraunhofer Institute for Process Engineering and Packaging, Freising, Germany and Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany
- Dr. Garmt Dijksterhuis, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands
- Dr. Jan van Amsterdam, Department of Psychiatry, Academic Medical Center, Amsterdam, The Netherlands
- Mr. Emmanuel Vanzeveren, It makes sense SPRL, Braine Le Comte, Belgium
- Dr. Wouter Visser, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands
- Assoc. Prof. Efthimios Zervas, Hellenic Open University, Patra, Greece

六、 菸品容器健康警示圖文

菸草指令第 2 章第 8 條至第 14 條，訂定菸品包裝規格、警示圖文面積及種類及菸品最小包裝等規範內容，另訂定 Decision(EU)2015/1842 明定菸品容器警示圖文之比例、大小及放置於菸盒上的位置，要求警示圖文前後面積平均不得小於 65%；另通過 Directive 2014/109/EU 建立警示圖文庫，內有 14 則警語 3 組警圖共 42 張圖片，要求會員國應每年更換一次菸盒包裝警示圖文，每次採用一組共 14 張警示圖文(14 則警語搭配其相對應之警圖)。

此外，自澳洲於 2012 年實施素面包裝措施之後，歐盟亦於菸草指令納入素面包裝規範基礎，鼓勵會員國實施素面包裝措施，目前歐盟有法國、英國、愛爾蘭、

[25] Independent Advisory Panel on characterising flavours in tobacco products
https://ec.europa.eu/health/tobacco/products/characterising_flavours/panel_en

匈牙利及斯洛維尼亞已實施或已通過素面包裝法案，除歐盟外，尚有挪威及紐西蘭等國即將實施素面包裝措施，詳如表 1。

圖 10、歐盟菸品容器警示圖文示意圖

圖 11、歐盟菸品容器警示圖庫

	國家	製造商實施日期	零售商實施日期
1.	Australia 澳洲	Oct. 1, 2012	Dec. 1, 2012
2.	France 法國	May 20, 2016	Jan. 1, 2017
3.	United Kingdom 英國	May 20, 2016	May 20, 2017
4.	Norway 挪威	July 1, 2017	July 1, 2018
5.	Ireland 愛爾蘭	Sept. 30, 2017	Sept. 30, 2018
6.	New Zealand 紐西蘭	Mar. 14, 2018	June 6, 2018
7.	Hungary *匈牙利	May 20, 2018	May 20, 2019
8.	Slovenia 斯洛維尼亞	Jan. 1, 2020	Jan. 1, 2020

表 1、目前已實施或將實施素面包裝措施之國家[26] (截至 2016.10)

七、 營造無菸環境

為避免人民暴露於二手菸環境中，歐盟執委會於 2009 年發布無菸環境建議書 (Council Recommendation on smoke-free environments (2009/C 296/02))，建議各會員國將工作場所、室內公共場所、公眾運輸工具及其他公共區域納入禁菸場所範圍，並要求 2012 年完成各國立法。依據 2012 年調查結果顯示，酒吧二手菸暴露率已自 2009 年的 46%降至 2012 年 28%，並有 17 個國家訂定全面性禁菸場所規範，其中愛爾蘭、英國、希臘、保加利亞、馬爾他、西班牙及匈牙利採用最嚴格的規範。

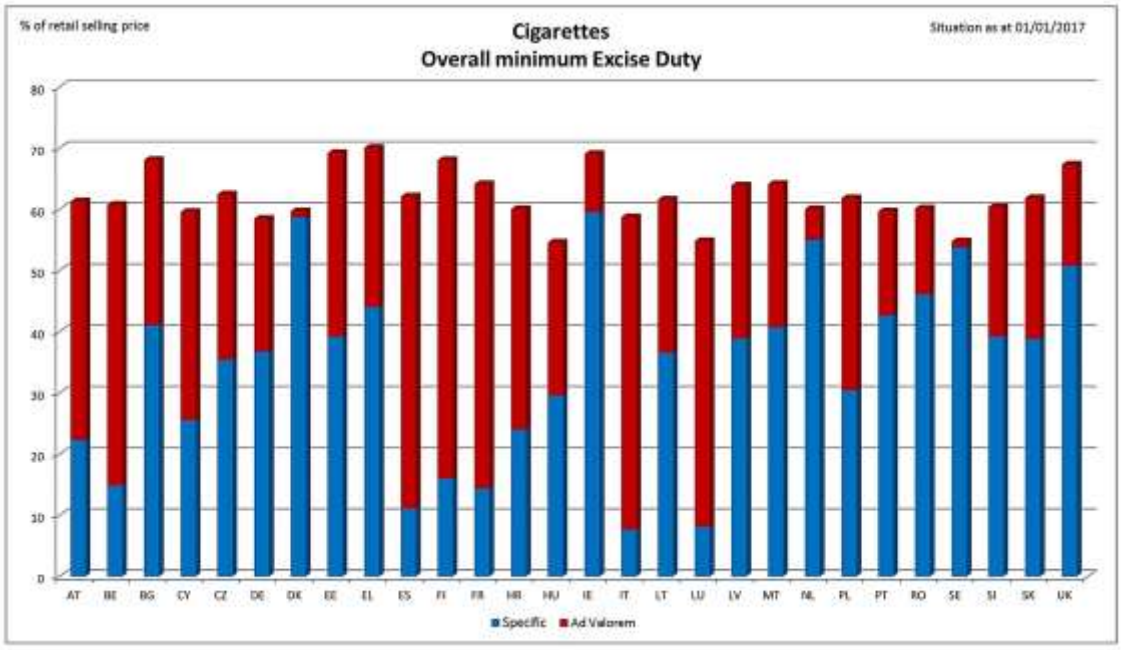
根據 2017 年菸品及電子煙使用態度調查 (Special Eurobarometer 458)[27]結果顯示，2017 年餐廳二手菸暴露率為 9%，酒吧二手菸暴露率為 20%，較 2014 年為低，然而，希臘、克羅埃西亞、捷克等國之二手菸暴露率分別為 87%、77%及 73%，仍高達 70%以上。

八、 菸稅政策[28]

[26] Plain Packaging http://ensp.org/policies/resources/plain-packaging/
[27] Special Eurobarometer 458 http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146
[28] Excise Duties: Cigarettes https://ec.europa.eu/taxation_customs/business/excise-duties-alcohol-tobacco-energy/excise-duties-tobacco/excise-duties-cigarettes_en

依菸稅指令(Directive 2011/64/EU)規定，各會員國課徵菸稅最少應佔菸品零售價之60%，且每千支菸之價格不得少於 90 歐元(若每千支菸價格大於 115 歐元，則菸稅比率可不須大於 60%)。

依 2017 年 1 月 1 日統計結果，歐盟各國平均菸價為每千支菸 230 歐元，平均菸稅佔零售價比率為 62%，觀察各國菸稅佔零售價比率現況，以希臘 70.5%最高，愛沙尼亞、愛爾蘭、保加利亞、芬蘭及英國等國均大於 65%，而匈牙利 54.6%最低，應於 2017 年 12 月前達到 60%。另觀察各國菸價現況，以愛蘭蘭每千支菸 484 歐元最高，英國 442 歐元次之，保加利亞 125 歐元最低。



AT	奧地利	BE	比利時	BG	保加利亞	CY	賽普勒斯	CZ	捷克
DE	德國	DK	丹麥	EE	愛沙尼亞	EL	希臘	ES	西班牙
FI	芬蘭	FR	法國	HR	克羅埃西亞	HU	匈牙利	IE	愛爾蘭
IT	義大利	LT	立陶宛	LU	盧森堡	LV	拉脫維亞	MT	馬爾他
NL	荷蘭	PL	波蘭	PT	葡萄牙	RO	羅馬尼亞	SE	瑞典
SI	斯洛維尼亞	SK	斯洛伐克	UK	英國				

圖 12、歐盟各國課徵菸稅現況(統計至 2017.1.1)

九、 其它菸害防制措施

(一) 防止菸草製品非法貿易：為防止菸品走私等非法貿易，歐盟已於 2012 年簽署菸草控制框架公約防止菸草製品非法貿易議定書，並依據相關內容於新版菸草指令第 15、16 條訂定菸品標誌、追蹤及追溯系統之規範，擬透過標籤條碼系

統追蹤菸品流向(製造、倉儲、批發、販賣)，以防止走私菸品竄流市面。目前正積極召開業者及相關利益關係人公聽會、會員國專家小組討論會議等，預計將訂定 Decision 以作為具體規範，最快將於 2018 年底開始推動相關措施。

(二) 新興菸品：菸商持續推出創新商品以吸引青少年嘗試吸菸。近幾年加熱式菸品如 iQOS 等，亦出現於歐盟市場，如依新版菸草指令之規範內容，有三種可能的管理方式：(1)視為無煙菸品；(2)視為電子煙；(3)視為新興煙品，然而各國對於該產品之分類、管理機制及應課徵稅則等部分尚未有定論，相關討論仍在持續進行中。

(三) 禁止跨境販售菸品：因各會員國允許或禁止販售的菸品種類不同，新版菸草指令第 18 條增訂禁止菸品跨境販售之規範，要求零售商如欲跨境販賣菸品，應完成商家地址、網站網址及網站資料等註冊手續，同時依各國最低買菸年齡限制，建立年齡鑑別系統。

十、 歐盟菸害防制工作之挑戰

(一) 菸商市場策略及新興產品：菸商透過創新市場策略，如社群行銷、零售店廣告及名人代言等，新型態菸品不斷推陳出新，不僅刻意避免現有法令規範，更造成各國管制規範之不一致，容易造成市場的混亂。

(二) 健康不平等：歐盟 28 個會員國因應國情、風俗民情及菸商干擾等狀況，各國菸害管制強度不一，造成健康不平等情形，需要更多的督促及其他會員國協助，以落實各項菸害防制策略。

(三) 聯合國永續發展目標：依據聯合國永續發展目標(SDG 3.a)，各國應落實菸草控制框架公約之執行，歐盟及其他大部分會員國已簽署成為締約方，將持續依據公約及相關實施準則，落實各項政策之執行。

(四) 各會員國間最低買菸年齡不一，有些國家甚至允許採用自動販賣機賣菸，各會員國間如何建立購菸年齡鑑別機制，考驗各國管理單位之智慧及落實策略。

(五) 電子煙安全標準及檢測：新版指令雖訂有電子煙及煙油填充設備之技術標準，然仍需訂定電子煙產品之檢測技術標準及檢驗流程，以協助會員國稽查檢驗並確保產品安全。

(六) 口嚼菸(snus)管理：目前歐盟境內僅瑞典開放口嚼菸之銷售，其他國家均禁止販售，然而瑞典針對其他國家的口嚼菸禁售法令，已向英國法庭及歐洲法庭提起訴訟，未來是否會修改口嚼菸管制規範仍有待觀察。

十一、 歐洲各國菸害防制實地觀察現況

見習期間走訪歐洲幾國，順勢觀察菸害防制現況，簡述如下：

(一) 禁止於航空器內使用電子煙：飛往歐盟航班及境內航班，已全面禁止於航空器內使用電子煙，並透過機上廣播及安全指引卡加強宣導。

(二) 營造無菸環境：以車站禁菸為例，在台灣，車站內包括月台全面禁菸。然而比利時車站僅在售票站體內禁菸，月台上抽菸問題十分嚴重，許多乘客一下車便點菸，讓候車的民眾頗為困擾；荷蘭火車站月台上則設置吸菸區，以玻璃隔板區隔非吸菸者與吸菸者。

(三) 菸商贊助：德國與杜拜機場內設有室內吸菸室，吸菸室外設有大幅菸品廣告，顯見菸商贊助問題嚴重。

(四) 禁止菸品展示：英國零售店已禁止菸品展示，僅以告示牌告知顧客此處賣菸，然而，電子煙油卻如一般商品般，十分容易取得。

圖 13、德國菸品自動販賣機

圖 14、航空器禁止使用電子煙

圖 15、英國零售商店禁止菸品展示

圖 16、英國商店販售電子煙及煙油

圖 17、菸商贊助設立機場吸菸室

圖 18、機場內大幅菸品廣告
(阿拉伯聯合大公國杜拜機場、德國法蘭克福機場)

肆、心得與建議

見習三個月期間，有幸參與各項菸害防制實務工作，出席旁聽專家討論會議，與英國、瑞典等國代表會面請益，實地觀察歐盟國家等，心得與建議如下：

(一) 電子煙管理規範值得參考，然仍存有許多漏洞尚待補足：

1. 依菸草指令第 20 條規定，電子煙應於上市前完成申報並通過審核後方能上市，以確保電子煙之安全性及品質。然而，若無標準檢驗流程及技術標準，執法人員稽查時無判定依據及工具。為解決此一困境，歐盟標準化委員會已成立技術小組，刻正訂定相關產品之規格、檢驗流程及技術標準。建議可進一步瞭解歐盟有關電子煙成分申報規範及成分與釋放物等之檢測技術，並持續追蹤最新進展，以作為未來建立相關檢測技術之參考。
2. 因應電子煙安全性不明，菸草指令要求廠商應定期監測其產品之健康危害情形，一旦發生危害健康之情事，廠商應即刻將產品下架，然而，產品危害性未明情況下若貿然開放，具有潛在的健康危害風險，且世界衛生組織建議應採取嚴格的規範管制電子煙，建議應持續蒐集電子煙之健康危害相關研究文獻，以評估其健康風險。
3. 菸草指令要求電子煙張貼警示圖文，然而究竟要黏貼於吸食器或煙液之外包裝，或產品外部，仍未有定論。另電子煙如不含尼古丁或不含衍生自菸草之尼古丁，則未納入電子煙管制範圍內，為實務管理之漏洞，可持續觀察歐盟各國落實情形，納入政策參考。

4. 為訂定歐盟電子煙及煙油檢驗標準技術，歐洲標準化委員會已成立電子煙及煙油檢驗標準技術委員會(New CEN/TC 437)，並將於 2018 年 2 月召開第 5 次討論會議，建議可透過歐盟執委會衛生及食品安全總署持續追蹤相關技術標準訂定現況及預定實施時程。
5. 建議與歐方建立長期交流模式，持續保持交流及互動，如透過研討會或論譠方式，針對電子煙規範執行現況、面對各不同利益團體時遭遇之困難及解決方案，進行經驗交流及分享。

(二) 提高菸價政策：

歐洲各國菸品價格不一，歐盟指令雖訂有菸稅比率及菸品最低價格(菸稅最少應佔菸品零售價之 60%，每千支菸價格不得少於 90 歐元)，然而，因部分國家未禁止菸品促銷行為(如盧森堡)，且跨境買菸問題嚴重，因此，單靠部分國家提高菸價並無法改善買低價菸之情形，加強菸品走私查緝及防制菸品非法貿易等工作亦同等重要。

圖 19、盧森堡高速公路休息站菸品促銷及廣告

(三) 防制菸品非法貿易：

為防制菸品非法貿易，歐盟於新版菸草指令第 15、16 條訂定菸品標誌、追蹤及追溯系統之規範，擬透過標籤條碼系統追蹤菸品流向(製造、倉儲、批發、販賣)，以防止走私菸品竄流市面；我國方面，財政部已成立「菸品刊印二維條碼及查緝作業專案小組」，規定菸品包裝應黏貼含防偽機制與查驗碼之查驗條，期透過條碼上之數位控管及資訊管控等查驗碼追蹤菸品流向，建議財政部亦可持續觀察歐方追蹤及追溯系統建置及運作狀況，作為我國防制菸品非法貿易之參考。

圖 20、財政部推出菸品二維條碼追蹤菸品流向

(四) 以實證為基礎的政策制定模式、跨部門合作各司其職、借重專業協助，橫向溝通無障礙：

見習部門衛生及食品安全總署第 B 司第 2 處，其主要職責為菸害防制政策之制定及法規修訂，同仁多為法律背景專業人員，為了強化政策效益，制定以實證為基礎的政策，與不同單位間之互動及合作十分密切頻繁，例如，透過與健康及食品執行機構(Chafea)及聯合研究中心(JRC)之合作，蒐集各項科學研究及實證數據；透過與法律部門合作，監督各會員國法律執行現況，並解決爭訟案件；設立機構外獨立諮詢小組協助會員國建立加味菸檢測及審議機制等，可觀察到各部門分工細緻各司其職，可全力發揮專業長才，亦可借重專業協助，無障礙的橫向溝通及互助，有事半功倍之效。

(五) 歐盟執委會負責政策制定，會員國負責落實執行：

實際參與執委會日常工作，才發現其角色主要為制定政策並訂定相關法規，法規之落實及稽查實務工作則由各會員國負責，執委會扮演居中協調的角色，另有關戒菸服務及菸害教育宣導等工作，亦多由會員國制定推動，建議未來可透過執委會之媒介，爭取至會員國工作實習之機會，透過實務工作參與深入瞭解政策落實現況及執行困境。

後記：

有機會參與本次訓練計畫，要特別感謝國民健康署王英偉署長及諸位長官玉成，菸害防制組羅素英組長的鼓勵及信任，駐歐盟及比利時代表處衛福組鄭慧文組長協助洽談並在比利時撥冗關懷及照顧，食品藥物管理署吳明美專門委員毫無保留的經驗分享，更要感謝出國見習期間，菸害防制組所有同仁的支援，尤其是正處於菸害防制法修法期間壓力最大的法制科同仁，因為有這群堅強的後盾，才能心無罣礙順利結業，期間還受到署內其他組室同仁協助、外交部同仁經驗分享，在此一併感謝。

在歐盟見習期間，非常感謝處長 Ms Anna Eva 及指導員 Ms Agnieszka 之耐心指導，並感謝其他同仁之協助及解惑，同期實習生之互助與扶持。最後，要感謝我的家人，有句客家諺語是這麼說的：「敢去一擔柴」，感謝父母和姊妹和家人們給予的勇氣與無後顧之憂的支持，願習得的經驗得以分享，願經歷的甘苦化作養分，成為繼續往前的動力。

圖 21、與 DG SANTE Unit B2 同仁合影

由左至右為：

Ms Marta LEGNAIOLI, Ms Patricia MURRAY, Ms Katja BROMEN, Ms Katarina DVORSKA, Ms Anna Eva AMPELAS, Mr Matus FERECH, Mr. Jan HOFFMANN, Mr. Filip Borkowski

附錄 1、歐盟菸害防制相關法規

歐盟菸草指令

- DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0040

歐盟菸稅指令

- COUNCIL DIRECTIVE 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:176:0024:0036:EN:PDF

電子煙相關法規

- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D2183
- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.101.01.0015.01.ENG
- Commission Report COM(2016) 269 final - Report from the Commission to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes. http://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=1&year=2016&number=269&version=ALL&language=en

加味菸相關法規

- Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down

uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavor
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.131.01.0048.01.ENG

- Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour.
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.131.01.0079.01.ENG
- Independent Advisory Panel on characterising flavours in tobacco products
  https://ec.europa.eu/health/tobacco/products/characterising_flavours/panel_en
- Technical Group of sensory and chemical assessors
  https://ec.europa.eu/health/tobacco/products/characterising_flavours/technical_group_en

菸品健康警示圖文相關法規

- COMMISSION DELEGATED DIRECTIVE 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0109
- COMMISSION IMPLEMENTING DECISION (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking (notified under document C(2015) 6729)
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2015_267_R_0003

菸品申報管理相關法規

- Tobacco products(菸品)–implementing decision (Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products)
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2015_312_R_0003
- e-cigarettes and refill containers(電子煙及煙油) – implementing decision (Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common

format for the notification of electronic cigarettes and refill containers (notified under document C(2015) 8087))
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D2183

- 歐盟菸品申報系統 EU Common Entry Gate (EU-CEG)
  https://ec.europa.eu/health/euceg/introduction_en

無菸環境建議書

- Recommendation 2009/C 296/02 Council Recommendation of 30 November 2009 on smoke-free environments
  http://eur-lex.europa.eu/legal-content/en/ALL/?uri=OJ%3AC%3A2009%3A296%3ATOC

禁止菸品廣告促銷相關法規

- DIRECTIVE 2003/33/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:152:0016:0019:EN:PDF
- DIRECTIVE 2010/13/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive)
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:095:0001:0024:en:PDF
- Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (2003/54/EC)
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32003H0054

附錄2、世界無菸日研討會議程

TOBACCO: A THREAT TO DEVELOPMENT

Lunch reception and debate hosted by Linda McAvan MEP, Chair of the European Parliament Development Committee (DEVE)

31 May 2017, 12:00-15:00, European Parliament, room ASP 5E2

Draft agenda

12:30-13:00 – Standing lunch, followed by the announcement of the World No Tobacco Day Awards

- Welcome and introduction by Linda McAvan MEP
- WNTD Awards presentation by Kristina Mauer-Stender, Program Manager for Tobacco Control, World Health Organisation Regional Office for Europe

13:00-15:00 – Policy debate chaired by Linda McAvan MEP, Chair of the EP DEVE Committee

Introduction by Linda McAvan MEP

13:05-13:55 Keynote speeches followed by Q&A:

- Dr. Vytenis Andriukaitis, European Commissioner for Health and Food Safety
- High level representative of DG for International Cooperation and Development (TBC)
- Representative of the FCTC Secretariat (TBC)
- Patricio Marquez, Lead Health Specialist, Health, Nutrition and Population Global Practice, The World Bank

Panel debate, followed by Q&A

- Tih Ntiabang, Framework Convention Alliance Regional Coordinator for the AFRO Region
- Laura Graen, Journalist and tobacco control expert, Unfairtobacco
- Prof. Martin Raw, Director, International Centre for Tobacco Cessation (TBC)

Conclusions and closing by chair

Register here

AGENDA

EUROPE UNITED: THE RACE AGAINST TOBACCO

High level meeting on tobacco control

On the occasion of World No Tobacco Day - 31st of May 2017, focussing on Tobacco - A threat to development

PRESS CLUB EUROPE BRUSSELS

Co-sponsored by World Health Organization - WHO European Region Office

		SECTION 1 - „THE RACE AGAINST TOBACCO ORGANIZING COMMITTEE"					SECTION 2 - „INTRODUCING THE RACE AGAINST TOBACCO TEAM"	SECTION 3 – THE RACE AGAINST TOBACCO PLEDGE AND CLOSING	
09:15-10:00	**10:00-10:10**	**10:10-10:15**	**10:15-10:20**	**10:20-10:30**	**10:30-10:35**	**10:35-10:45**	**10:45-11:45**	**11:45**	**11:50-12:00**
GUESTS REGISTRATION	WELCOME SPEECH **PRESENTER** James Crisp – Freelance journalist, Political editor at EurActiv.com H.E. Vytennis Andriukaitis – EU Commissioner for Environment, Public Health and Food Safety - via Video message	Goal 1 WNTD 2017: Highlight the links between the use of tobacco products, tobacco control and sustainable development **PRESENTER** Gilles Pargneaux – Vice-Chair, Committee on the Environment, Public Health and Food Safety, European Commission	Goal 2 WNTD 2017: Encourage countries to include tobacco control in their national responses to 2030 Sustainable Development Agenda **PRESENTER** Anna Eva Ampelas – Head of Unit, B2 Health in All Policies, Global Health and Tobacco Control, DG Sante, European Commission	Goal 3 WNTD 2017: A 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years in line with the NCD Global Action Plan Targets **PRESENTER** Kristina Mauer-Stender – Program Manager for Tobacco Control, WHO Regional Office for Europe	Goal 4 WNTD 2017: Support Member States and civil society to combat tobacco industry interference in political processes **PRESENTER** Sonja von Eichborn – Unfairtobacco.org	Goal 5 WNTD 2017: Encourage broader public and partner participation in national, regional and global efforts to develop and implement development strategies and plans and achieve goals that prioritize action on tobacco control **PRESENTER** Prof. Guy Joos – European Respiratory Society President Francisco Rodriguez Lozano – European Network for Smoking and Tobacco Prevention President	European Best practices and Commitment – Europe United tobacco control display lightning and the handing of the individual countries Race Team packs. Presenting Europe WHO countries achievements in 2016 and individual countries priorities for the Race against Tobacco till 2030. ENSP 20 Years Anniversary Tobacco Control Awards Session **PRESENTER** James Crisp – Freelance journalist, Political editor at EurActiv.com Co-hosted by Oxana Domenti, President of the Committee for Social Protection, Health and Family, Parliament of the Republic of Moldova Presented by Cornel Radu-Loghin, ENSP General Secretary	„Europe United - The Race Against Tobacco Pledge" **PRESENTER** James Crisp – Freelance journalist, Political editor at EurActiv.com	CLOSING SPEECHES **PRESENTER** Prof. Guy Joos – European Respiratory Society President Francisco Rodriguez Lozano – European Network for Smoking and Tobacco Prevention President

附錄3、歐盟新版菸草指令(2014/40/EU)

I

(Legislative acts)

DIRECTIVES

DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 3 April 2014

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 53(1), 62 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Directive 2001/37/EC of the European Parliament and of the Council ([4]) lays down rules at Union level concerning tobacco products. In order to reflect scientific, market and international developments, substantial changes to that Directive would be needed and it should therefore be repealed and replaced by a new Directive.

(2) In its reports of 2005 and 2007 on the application of Directive 2001/37/EC the Commission identified areas in which further action was considered useful for the smooth functioning of the internal market. In 2008 and 2010 the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) provided scientific advice to the Commission on smokeless tobacco products and tobacco additives. In 2010 a broad stakeholder consultation took place, which was followed by targeted stakeholder consultations and accompanied by studies by external consultants. Member States were consulted throughout the process. The European Parliament and the Council repeatedly called on the Commission to review and update Directive 2001/37/EC.

(3) In certain areas covered by Directive 2001/37/EC, Member States are legally or in practice prevented from effectively adapting their legislation to new developments. This is in particular relevant for the labelling rules, where Member States have not been permitted to increase the size of the health warnings, change their location on an individual packet ('unit packet') or replace misleading warnings on the tar, nicotine and carbon monoxide (TNCO) emission levels.

([1]) OJ C 327, 12.11.2013, p. 65.
([2]) OJ C 280, 27.9.2013, p. 57.
([3]) Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and decision of the Council of 14 March 2014.
([4]) Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

(4) In other areas there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco and related products which present obstacles to the smooth functioning of the internal market. In the light of scientific, market and international developments these discrepancies are expected to increase. This also applies to electronic cigarettes and refill containers for electronic cigarettes ('refill containers'), herbal products for smoking, ingredients and emissions from tobacco products, certain aspects of labelling and packaging and to cross-border distance sales of tobacco products.

(5) Those obstacles should be eliminated and, to this end, the rules on the manufacture, presentation and sale of tobacco and related products should be further approximated.

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the entire Union in only a small number of production plants within the Union and the resulting significant cross-border trade of tobacco and related products calls for stronger legislative action at Union rather than national level to achieve the smooth functioning of the internal market.

(7) Legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control ('FCTC') of May 2003, the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people.

(9) It is necessary to establish a number of new definitions in order to ensure that this Directive is uniformly applied by Member States. Where different obligations imposed by this Directive apply to different product categories and the relevant product falls into more than one of those categories (e.g. pipe, roll your-own tobacco), the stricter obligations should apply.

(10) Directive 2001/37/EC established maximum limits for tar, nicotine and carbon monoxide yields of cigarettes that should also be applicable to cigarettes which are exported from the Union. Those maximum limits and that approach remain valid.

(11) For measuring the tar, nicotine and carbon monoxide yields of cigarettes (hereinafter referred to as 'emission levels'), reference should be made to the relevant, internationally recognised ISO standards. The verification process should be protected from tobacco industry influence by using independent laboratories, including State laboratories. Member States should be able to use laboratories situated in other Member States of the Union. For other emissions from tobacco products, there are no internationally agreed standards or tests for quantifying maximum levels. The ongoing efforts at international level to develop such standards or tests should be encouraged.

(12) As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness.

(13) In order to carry out their regulatory tasks, Member States and the Commission require comprehensive information on the ingredients and emissions from tobacco products to assess the attractiveness, addictiveness and toxicity of tobacco products and the health risks associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be strengthened. Additional enhanced reporting obligations should be provided for in respect of additives included in a priority list in order to assess, inter alia their toxicity, addictiveness and carcinogenic, mutagenic or reprotoxic properties ('CMR properties'), including in combusted form. The burden of such enhanced reporting obligations for SMEs should be limited to the extent possible. Such reporting obligations are consistent with the obligation placed on the Union to ensure a high level of protection for human health.

(14) The use of differing reporting formats, as is currently the case, makes it difficult for manufacturers and importers to fulfil their reporting obligations and burdensome for the Member States and the Commission to compare, analyse and draw conclusions from the information received. Therefore, there should be a common mandatory format for the reporting of ingredients and emissions. The greatest possible transparency of product information should be ensured for the general public, whilst ensuring that appropriate account is taken of the trade secrets of the manufacturers of tobacco products. Existing systems for the reporting of ingredients should be taken into account.

(15) The lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. Some Member States have adopted legislation or entered into binding agreements with the industry allowing or prohibiting certain ingredients. As a result, some ingredients are regulated in certain Member States, but not in others. Member States also take differing approaches as regards additives in the filters of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles to the smooth functioning of the internal market are expected to increase in the coming years, taking into account the implementation of the FCTC and the relevant FCTC guidelines throughout the Union and in the light of experience gained in other jurisdictions outside the Union. The FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

(16) The likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than one of tobacco, which could facilitate initiation of tobacco consumption or affect consumption patterns. Measures introducing unjustified differences of treatment between different types of flavoured cigarettes should be avoided. However, products with characterising flavour with a higher sales volume should be phased out over an extended time period to allow consumers adequate time to switch to other products.

(17) The prohibition of tobacco products with characterising flavours does not preclude the use of individual additives outright, but it does oblige manufacturers to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, should be allowed, as long as they do not result in a characterising flavour or increase the addictiveness, toxicity or CMR properties of the product. An independent European advisory panel should assist in such decision making. The application of this Directive should not lead to discrimination between different tobacco varieties, nor should it prevent product differentiation.

(18) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health risks or increase mental alertness and physical performance. These additives, as well as additives that have CMR properties in unburnt form, should be prohibited in order to ensure uniform rules throughout the Union and a high level of protection of human health. Additives that increase addictiveness and toxicity should also be prohibited.

(19) Considering this Directive's focus on young people, tobacco products other than cigarettes and roll-your-own tobacco, should be granted an exemption from certain requirements relating to ingredients as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people.

(20) Given the general prohibition of the sale of tobacco for oral use in the Union, the responsibility for regulating the ingredients of tobacco for oral use, which requires in-depth knowledge of the specific characteristics of this product and of its patterns of consumption, should, in accordance with the principle of subsidiarity, remain with Sweden, where the sale of this product is permitted pursuant to Article 151 of the Act of Accession of Austria, Finland and Sweden.

(21) In line with the purposes of this Directive, namely to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people, and in line with Council Recommendation 2003/54/EC ([1]), Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures that lay down and enforce age limits.

(22) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the use of combined health warnings consisting of a picture and a text, information on cessation services and promotional elements in and on unit packets.

(23) Such disparities are liable to constitute a barrier to trade and to impede the smooth functioning of the internal market in tobacco products, and should, therefore, be eliminated. Also, it is possible that consumers in some Member States are better informed about the health risks of tobacco products than consumers in other Member States. Without further action at Union level, the existing disparities are likely to increase in the coming years.

(24) Adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. The provisions on misleading information will complement the general ban on misleading business to consumer commercial practices laid down in Directive 2005/29/EC of the European Parliament and of the Council ([2]).

Member States that use tax stamps or national identification marks for fiscal purposes on the packaging of tobacco products may, in some cases, have to provide for these stamps and marks to be repositioned in order to allow for the combined health warnings to be at the top of the principal display areas, in line with this Directive and the FCTC guidelines. Transitional arrangements should be put in place to allow Member States to maintain tax stamps or national identification marks used for fiscal purposes at the top of unit packets for a certain period after transposition of this Directive.

(25) The labelling provisions should also be adapted to new scientific evidence. For example, the indication of the emission levels for tar, nicotine and carbon monoxide on unit packets of cigarettes has proven to be misleading as it leads consumers to believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings comprised of a text warning and a corresponding colour photograph are more effective than warnings consisting only of text. As a consequence, combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the surface of unit packets. Minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness.

([1]) Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (OJ L 22, 25.1.2003, p. 31).

([2]) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).

(26) For tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers and small groups of the population, it should be possible to continue to grant an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people. The labelling of these other tobacco products should follow rules that are specific to them. The visibility of health warnings on smokeless tobacco products should be ensured. Health warnings should, therefore, be placed on the two main surfaces of the packaging of smokeless tobacco products. As regards waterpipe tobacco, which is often perceived as less harmful than traditional tobacco products for smoking, the full labelling regime should apply in order to avoid consumers being misled.

(27) Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for-one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products.

(28) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimensions of the health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including the shape and opening mechanism. When prescribing a cuboid shape for a unit packet, rounded or bevelled edges should be considered acceptable, provided the health warning covers a surface area that is equivalent to that on a unit packet without such edges. Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned.

(29) Considerable volumes of illicit products, which do not fulfil the requirements laid down in Directive 2001/37/EC, are placed on the market and there are indications that these volumes might increase. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. In addition, the FCTC requires the Union to combat illicit tobacco products, including those illegally imported into the Union, as part of a comprehensive Union policy on tobacco control. Provision should, therefore, be made for unit packets of tobacco products to be marked with a unique identifier and security features and for their movements to be recorded so that such products can be tracked and traced throughout the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not tobacco products are authentic.

(30) An interoperable tracking and tracing system and security features should be developed at Union level. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow manufacturers of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and security features becoming applicable to those other products.

(31) In order to ensure independence and transparency of the tracking and tracing system, manufacturers of tobacco products should conclude data storage contracts with independent third parties. The Commission should approve the suitability of those independent third parties and an independent external auditor should monitor their activities. The data related to the tracking and tracing system should be kept separate from other company related data and should be under the control of, and accessible at all times by, the competent authorities from Member States and the Commission.

(32) Council Directive 89/622/EEC ([1]) prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC reaffirmed that prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants Sweden a derogation from the prohibition. The prohibition of the sale of tobacco for oral use should be maintained in order to prevent the introduction in the Union (apart from Sweden) of a product that is addictive and has adverse health effects. For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use.

(33) Cross-border distance sales of tobacco products could facilitate access to tobacco products that do not comply with this Directive. There is also an increased risk that young people would get access to tobacco products. Consequently, there is a risk that tobacco control legislation would be undermined. Member States should, therefore, be allowed to prohibit cross-border distance sales. Where cross-border distance sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are appropriate to ensure the effectiveness of this Directive. Member States should, in accordance with Article 4(3) of the Treaty on European Union (TEU) cooperate with each other in order to facilitate the implementation of this Directive, in particular with respect to measures taken as regards cross-border distance sales of tobacco products.

(34) All tobacco products have the potential to cause mortality, morbidity and disability. Accordingly, their manufacture, distribution and consumption should be regulated. It is, therefore, important to monitor developments as regards novel tobacco products. Manufacturers and importers should be obliged to submit a notification of novel tobacco products, without prejudice to the power of the Member States to ban or to authorise such novel products.

(35) In order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive.

(36) Electronic cigarettes and refill containers should be regulated by this Directive, unless they are - due to their presentation or function - subject to Directive 2001/83/EC of the European Parliament and of the Council ([2]) or to Council Directive 93/42/EEC ([3]). Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

(37) Member States should ensure that electronic cigarettes and refill containers comply with the requirements of this Directive. Where the manufacturer of the relevant product is not established in the Union, the importer of that product should bear the responsibilities relating to the compliance of those products with this Directive.

(38) Nicotine-containing liquid should only be allowed to be placed on the market under this Directive, where the nicotine concentration does not exceed 20 mg/ml. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set.

(39) Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market under this Directive. Delivery of nicotine doses at consistent levels under normal conditions of use is necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses.

(40) Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child- and tamperproof, including by means of child-proof labelling, fastenings and opening mechanisms.

([1]) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use (OJ L 359, 8.12.1989, p. 1).

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([3]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(41) In view of the fact that nicotine is a toxic substance and considering the potential health and safety risks, including to persons for whom the product is not intended, nicotine-containing liquid should only be placed on the market in electronic cigarettes or in refill containers that meet certain safety and quality requirements. It is important to ensure that electronic cigarettes do not break or leak during use and refill.

(42) The labelling and packaging of these products should display sufficient and appropriate information on their safe use, in order to protect human health and safety, should carry appropriate health warnings and should not include any misleading elements or features.

(43) Disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. Without further action at Union level, those disparities are likely to increase over the coming years, also taking into account the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national provisions on advertising and sponsorship of those products having cross-border effects, taking as a base a high level of protection of human health. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers.

(44) In order to perform their regulatory tasks, the Commission and Member States need comprehensive information on market developments as regards electronic cigarettes and refill containers. To this end manufacturers and importers of these products should be subject to reporting obligations on sales volumes, preference of various consumer groups and mode of sales. It should be ensured that this information is made available to the general public, taking the need to protect trade secrets duly into account.

(45) In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors operate an appropriate system for monitoring and recording suspected adverse effects and inform the competent authorities about such effects so that appropriate action can be taken. It is warranted to provide for a safeguard clause that would allow Member States to take action to address serious risks to public health.

(46) In the context of an emerging market for electronic cigarettes, it is possible that, although complying with this Directive, specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional appropriate measures could involve the prohibition of the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. The Commission should be empowered to do so, when at least three Member States have prohibited the products concerned on duly justified grounds and it is necessary to extend this prohibition to all Member States in order to ensure the smooth functioning of the internal market for products complying with this Directive but not presenting the same health risks. The Commission should report on the potential risks associated with refillable electronic cigarettes by 20 May 2016.

(47) This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance with Directive 98/34/EC of the European Parliament and of the Council [1].

[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

(48) Moreover, this Directive does not harmonise the rules on smoke-free environments, or on domestic sales arrangements or domestic advertising, or brand stretching, nor does it introduce an age limit for electronic cigarettes or refill containers. In any case, the presentation and advertising of those products should not lead to the promotion of tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so.

(49) The regulation of herbal products for smoking differs between Member States and these products are often perceived as harmless or less harmful despite the health risk caused by their combustion. In many cases consumers do not know the content of these products. In order to ensure the smooth functioning of the internal market and improve information to consumers, common labelling rules and ingredients reporting for these products should be introduced at Union level.

(50) In order to ensure uniform conditions for the implementation of this Directive implementing powers should be conferred on the Commission concerning the laying down and updating of a priority list of additives for enhanced reporting, the laying down and updating of the format for the reporting of ingredients and for the dissemination of that information, determining whether a tobacco product has a characterising flavour or has increased levels of toxicity, addictiveness or CMR properties, the methodology for determining whether a tobacco product has a characterising flavour, the procedures for the establishment and operation of an independent advisory panel for determining tobacco products with characterising flavours, the precise position of health warnings on pouches of roll-your-own tobacco, the technical specifications for the layout, design, and shape of combined health warnings, the technical standards for the establishment and operation of the tracking and tracing system, for ensuring the compatibility of the systems for the unique identifiers and for the security features, as well as establishing a common format for notification of electronic cigarettes and refill containers and the technical standards for the refill mechanisms for such products. Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [1].

(51) In order to ensure that this Directive is fully operational and to adapt it to technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting and adapting maximum emission levels and methods for measuring those emissions, setting maximum levels for additives that result in a characterising flavour or that increase toxicity or addictiveness, withdrawing certain exemptions granted to tobacco products other than cigarettes and roll-your-own tobacco, adapting the health warnings, establishing and adapting the picture library, defining the key elements of the data storage contracts to be concluded for the purposes of the tracking and tracing system, and extending measures adopted by Member States to the entire Union concerning specific electronic cigarettes or refill containers or a type of electronic cigarette or refill container. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(52) The Commission should monitor the developments as regards the implementation and impact of this Directive and submit a report by 21 May 2021, and when necessary thereafter, in order to assess whether amendments to this Directive are necessary. The report should include information on the surfaces of unit packets of tobacco products that are not governed by this Directive, market developments concerning novel tobacco products, market developments that amount to a substantial change of circumstances, market developments concerning, and the consumer perception of, slim cigarettes, of waterpipe tobacco and of electronic cigarettes and refill containers.

The Commission should prepare a report regarding the feasibility, benefits and impact of a European system for the regulation of ingredients in tobacco products, including the feasibility and benefits of establishing a list of

[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

ingredients at Union level that can be used, or present in or added to tobacco products (so-called 'positive list'). In preparing that report, the Commission should evaluate, inter alia, the available scientific evidence on the toxic and addictive effects of ingredients.

(53) Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive.

(54) Moreover, in order to take into account possible future market developments, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in the Member State concerned and provided the provisions are justified by the need to protect public health, taking into account the high level of protection achieved through this Directive. Member States should notify such stricter national provisions to the Commission.

(55) A Member State should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the TFEU and do not jeopardise the full application of this Directive. Accordingly and under those conditions, a Member State could, inter alia, regulate or ban paraphernalia used for tobacco products (including waterpipes) and for herbal products for smoking as well as regulate or ban products resembling in appearance a type of tobacco or related product. Prior notification is required for national technical regulations pursuant to Directive 98/34/EC.

(56) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council [1].

(57) This Directive is without prejudice to Union laws governing the use and labelling of genetically modified organisms.

(58) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents [2], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(59) The obligation to respect the fundamental rights and legal principles enshrined in the Charter of Fundamental Rights of the European Union is not changed by this Directive. Several fundamental rights are affected by this Directive. It is therefore necessary to ensure that the obligations imposed on manufacturers, importers and distributors of tobacco and related products not only guarantee a high level of health and consumer protection, but also protect all other fundamental rights and are proportionate with respect to the smooth functioning of the internal market. The application of this Directive should respect Union law and relevant international obligations.

(60) Since the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).
[2] OJ C 369, 17.12.2011, p. 14.

sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

TITLE I

COMMON PROVISIONS

Article 1

Subject matter

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;

(c) the prohibition on the placing on the market of tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the obligation to submit a notification of novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;

in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC').

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

(2) 'pipe tobacco' means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;

(3) 'roll-your-own tobacco' means tobacco which can be used for making cigarettes by consumers or retail outlets;

(4) 'tobacco products' means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

(5) 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

(6) 'chewing tobacco' means a smokeless tobacco product exclusively intended for the purpose of chewing;

(7) 'nasal tobacco' means a smokeless tobacco product that can be consumed via the nose;

(8) 'tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

(9) 'tobacco products for smoking' means tobacco products other than a smokeless tobacco product;

(10) 'cigarette' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU [1];

(11) 'cigar' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 4(1) of Directive 2011/64/EU;

(12) 'cigarillo' means a small type of cigar and is further defined in Article 8(1) of Council Directive 2007/74/EC [2];

(13) 'waterpipe tobacco' means a tobacco product that can be consumed via a waterpipe. For the purpose of this Directive, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;

(14) 'novel tobacco product' means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and

(b) is placed on the market after 19 May 2014;

(15) 'herbal product for smoking' means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

(16) 'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

(17) 'refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

(18) 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

(19) 'nicotine' means nicotinic alkaloids;

(20) 'tar' means the raw anhydrous nicotine-free condensate of smoke;

(21) 'emissions' means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

(22) 'maximum level' or 'maximum emission level' means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;

(23) 'additive' means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;

(24) 'flavouring' means an additive that imparts smell and/or taste;

(25) 'characterising flavour' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

(26) 'addictiveness' means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both;

[1] Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco (OJ L 176, 5.7.2011, p. 24).

[2] Council Directive 2007/74/EC of 20 December 2007 on the exemption from value added tax and excise duty of goods imported by persons travelling from third countries (OJ L 346, 29.12.2007, p. 6).

(27) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;

(28) 'substantial change of circumstances' means an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level;

(29) 'outside packaging' means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

(30) 'unit packet' means the smallest individual packaging of a tobacco or related product that is placed on the market;

(31) 'pouch' means a unit packet of roll-your own tobacco, either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch;

(32) 'health warning' means a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages, as provided for in this Directive;

(33) 'combined health warning' means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, as provided for in this Directive;

(34) 'cross-border distance sales' means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person: if he or she has his or her place of business in that Member State;

(b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State;

(35) 'consumer' means a natural person who is acting for purposes which are outside his or her trade, business, craft or profession;

(36) 'age verification system' means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements;

(37) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;

(38) 'import of tobacco or related products' means the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement;

(39) 'importer of tobacco or related products' means the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of the Union;

(40) 'placing on the market' means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;

(41) 'retail outlet' means any outlet where tobacco products are placed on the market including by a natural person.

TITLE II

TOBACCO PRODUCTS

CHAPTER I

Ingredients and emissions

Article 3

Maximum emission levels for tar, nicotine, carbon monoxide and other substances

1. The emission levels from cigarettes placed on the market or manufactured in the Member States ('maximum emission levels') shall not be greater than:

(a) 10 mg of tar per cigarette;

(b) 1 mg of nicotine per cigarette;

(c) 10 mg of carbon monoxide per cigarette.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to decrease the maximum emission levels laid down in paragraph 1, where this is necessary based on internationally agreed standards.

3. Member States shall notify the Commission of any maximum emission levels they set for emissions from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes.

4. The Commission shall adopt delegated acts in accordance with Article 27 to integrate standards agreed by the parties to the FCTC or by the WHO relating to maximum emission levels for emissions from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes into Union law.

Article 4

Measurement methods

1. The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide.

The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO standard 8243.

2. The measurements referred to in paragraph 1 shall be verified by laboratories which are approved and monitored by the competent authorities of the Member States.

Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

Member States shall communicate to the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and shall update that list whenever any change is made. The Commission shall make those lists of approved laboratories publicly available.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the methods of measurement of the tar, nicotine and carbon monoxide emissions, where this is necessary, based on scientific and technical developments or internationally agreed standards.

4. Member States shall notify the Commission of any measurement methods they use for emissions from cigarettes other than the emissions referred to in paragraph 3 and for emissions from tobacco products other than cigarettes.

5. The Commission shall adopt delegated acts in accordance with Article 27 to integrate standards agreed by the parties to the FCTC or by the WHO for measurement methods into Union law.

6. Member States may charge manufacturers and importers of tobacco products proportionate fees for the verification of the measurements referred to in paragraph 1 of this Article.

Article 5

Reporting of ingredients and emissions

1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities the following information by brand name and type:

(a) a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco products;

(b) the emission levels referred to in Article 3(1) and (4);

(c) where available, information on other emissions and their levels.

For products already placed on the market that information shall be provided by 20 November 2016.

Manufacturers or importers shall also inform the competent authorities of the Member States concerned, if the composition of a product is modified in a way that affects the information provided under this Article.

For a new or modified tobacco product the information required under this Article shall be submitted prior to the placing on the market of those products.

2. The list of ingredients referred to in point (a) of paragraph 1 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall also indicate the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council [1] as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council [2].

3. The list referred to in point (a) of paragraph 1 shall also be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects.

Furthermore, for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, shall be submitted by the manufacturer or importer.

Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4(4), manufacturers and importers shall indicate the methods of measurement of emissions used. Member States may also require manufacturers or importers to carry out studies as may be prescribed by the competent authorities in order to assess the effects of ingredients on health, taking into account, inter alia, their addictiveness and toxicity.

4. Member States shall ensure that the information submitted in accordance with paragraph 1 of this Article and of Article 6 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available. Member States shall require manufacturers and importers to specify, when submitting the information pursuant to paragraph 1 of this Article and Article 6, the information which they consider to constitute trade secrets.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

5. The Commission shall, by means of implementing acts, lay down and, if necessary, update the format for the submission and the making available of information referred to in paragraphs 1 and 6 of this Article and Article 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

6. Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Member States shall also require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015. Member States shall provide any other sales volume data that is available to them.

7. All data and information to be provided to and by Member States under this Article and under Article 6 shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the Commission and other Member States have access to that information for the purposes of applying this Directive. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

8. Member States may charge manufacturers and importers of tobacco products proportionate fees for receiving, storing, handling, analysing and publishing the information submitted to them pursuant to this Article.

Article 6

Priority list of additives and enhanced reporting obligations

1. In addition to the reporting obligations laid down in Article 5, enhanced reporting obligations shall apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list. The Commission shall adopt implementing acts laying down and subsequently updating such a priority list of additives. This list shall contain additives:

(a) for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the properties set out in points (a) to (d) of paragraph 2 of this Article; and

(b) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to paragraphs 1 and 3 of Article 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2). A first list of additives shall be adopted by 20 May 2016 and shall contain at least 15 additives.

2. Member States shall require manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list provided for in paragraph 1, to carry out comprehensive studies, which shall examine for each additive whether it:

(a) contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;

(b) results in a characterising flavour;

(c) facilitates inhalation or nicotine uptake; or

(d) leads to the formation of substances that have CMR properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

3. Those studies shall take into account the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned. Manufacturers or importers using the same additive in their tobacco products may carry out a joint study when using that additive in a comparable product composition.

4. Manufacturers or importers shall establish a report on the results of these studies. That report shall include an executive summary, and a comprehensive overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive.

Manufacturers or importers shall submit these reports to the Commission and a copy thereof to the competent authorities of those Member States where a tobacco product containing this additive is placed on the market at the latest 18 months after the additive concerned has been included in the priority list pursuant to paragraph 1. The Commission and the Member States concerned may also request supplementary information from manufacturers or importers regarding the additive concerned. This supplementary information shall form part of the report.

The Commission and the Member States concerned may require these reports to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions. The information received shall assist the Commission and Member States in taking the decisions pursuant to Article 7. The Member States and the Commission may charge manufacturers and importers of tobacco products proportionate fees for those peer reviews.

5. Small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC [1] shall be exempted from the obligations pursuant to this Article, if a report on that additive is prepared by another manufacturer or importer.

Article 7

Regulation of ingredients

1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, provided those additives do not result in a product with a characterising flavour and do not increase to a significant or measureable degree the addictiveness, toxicity or the CMR properties of the tobacco product.

Member States shall notify the Commission of the measures taken pursuant to this paragraph.

2. The Commission shall, at the request of a Member State, or may, on its own initiative, determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3. The Commission shall adopt implementing acts laying down uniform rules for the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

4. An independent advisory panel shall be established at Union level. Member States and the Commission may consult this panel before adopting a measure pursuant to paragraphs 1 and 2 of this Article. The Commission shall adopt implementing acts laying down the procedures for the establishment and operation of this panel.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

5. Where the content level or concentration of certain additives or the combination thereof has resulted in prohibitions pursuant to paragraph 1 of this Article in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to set maximum content levels for those additives or combination of additives that result in the characterising flavour.

6. Member States shall prohibit the placing on the market of tobacco products containing the following additives:

(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

[1] Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

(e) additives that have CMR properties in unburnt form.

7. Member States shall prohibit the placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine.

8. Member States shall ensure that the provisions and conditions laid down in Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

9. Member States shall, on the basis of scientific evidence, prohibit the placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measureable degree.

Member States shall notify to the Commission the measures they have taken pursuant to this paragraph.

10. The Commission shall, at the request of a Member State, or may, on its own initiative, determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 9. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2) and shall be based on the latest scientific evidence.

11. Where an additive or a certain quantity thereof has been shown to amplify the toxic or addictive effect of a tobacco product, and where this has resulted in prohibitions pursuant to paragraph (9) of this Article in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to set maximum content levels for those additives. In this case, the maximum content level shall be set at the lowest maximum level that led to one of the national prohibitions referred to in this paragraph.

12. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

13. The Member States and the Commission may charge proportionate fees to manufacturers and importers of tobacco products for assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product concerned.

14. In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3 % or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.

15. This Article shall not apply to tobacco for oral use.

CHAPTER II

Labelling and packaging

Article 8

General provisions

1. Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in this Chapter in the official language or languages of the Member State where the product is placed on the market.

2. Health warnings shall cover the entire surface of the unit packet or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

3. Member States shall ensure that the health warnings on a unit packet and any outside packaging are irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. On

unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall remain intact when opening the unit packet other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

4. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

5. The dimensions of the health warnings provided for in Articles 9, 10, 11 and 12 shall be calculated in relation to the surface concerned when the packet is closed.

6. Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings, except for health warnings pursuant to Article 11.

7. When adapting a health warning pursuant to Articles 9(5), 10(3) and 12(3), the Commission shall ensure that it is factual or that Member States shall have a choice of two warnings, one of which is factual.

8. Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter.

Article 9

General warnings and information messages on tobacco products for smoking

1. Each unit packet and any outside packaging of tobacco products for smoking shall carry one of the following general warnings:

'Smoking kills – quit now'

or

'Smoking kills'

Member States shall determine which of the general warnings referred to in the first subparagraph is to be used.

2. Each unit packet and any outside packaging of tobacco products for smoking shall carry the following information message:

'Tobacco smoke contains over 70 substances known to cause cancer.'

3. For cigarette packets and roll-your-own tobacco in cuboid packets the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings shall have a width of not less than 20 mm.

For packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into two when the packet is open, the general warning and the information message shall appear in their entirety on the larger parts of those split surfaces. The general warning shall also appear on the inside of the top surface that is visible when the packet is open.

The lateral surfaces of this type of packet shall have a height of not less than 16 mm.

For roll-your-own tobacco marketed in pouches the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings. For roll-your-own tobacco in cylindrical packets the general warning shall appear on the outside surface of the lid and the information message on the inside surface of the lid.

Both the general warning and the information message shall cover 50 % of the surfaces on which they are printed.

4. The general warning and information message referred to in paragraphs 1 and 2 shall be:

(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the font size, provided that the font size specified in national law ensures that the relevant text occupies the greatest possible proportion of the surface reserved for these health warnings; and

(b) at the centre of the surface reserved for them, and on cuboid packets and any outside packaging they shall be parallel to the lateral edge of the unit packet or of the outside packaging.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the information message laid down in paragraph 2 to scientific and market developments.

6. The Commission shall, by means of implementing acts, determine the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

Article 10

Combined health warnings for tobacco products for smoking

1. Each unit packet and any outside packaging of tobacco products for smoking shall carry combined health warnings. The combined health warnings shall:

(a) contain one of the text warnings listed in Annex I and a corresponding colour photograph specified in the picture library in Annex II;

(b) include smoking cessation information such as telephone numbers, e-mail addresses or Internet sites intending to inform consumers about the programmes that are available to support persons who want to stop smoking;

(c) cover 65 % of both the external front and back surface of the unit packet and any outside packaging. Cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65 % of their respective half of the curved surface;

(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;

(e) appear at the top edge of a unit packet and any outside packaging, and be positioned in the same direction as any other information appearing on that surface of the packaging. Transitional exemptions from that obligation on the position of the combined health warning may apply in Member States where tax stamps or national identification marks used for fiscal purposes remain mandatory, as follows:

(i) in those cases, where the tax stamp or national identification mark used for fiscal purposes is affixed at the top edge of a unit packet made of carton material, the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp or national identification mark;

(ii) where a unit packet is made of soft material, Member States may allow for a rectangular area to be reserved for the tax stamp or national identification mark used for fiscal purposes of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings.

The exemptions referred to in points (i) and (ii) shall apply for a period of three years from 20 May 2016. Brand names or logos shall not be positioned above the health warnings;

(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;

(g) in the case of unit packets of cigarettes, respect the following dimensions:

(i) height: not less than 44 mm;

(ii) width: not less than 52 mm.

2. The combined health warnings are grouped into three sets as set out in Annex II and each set shall be used in a given year and rotated on an annual basis. Member States shall ensure that each combined health warning available for use in a given year is displayed to the extent possible in equal numbers on each brand of tobacco products.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to:

(a) adapt the text warnings listed in Annex I taking into account scientific and market developments;

(b) establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments.

4. The Commission shall by means of implementing acts define the technical specifications for the layout, design and shape of the combined health warnings, taking into account the different packet shapes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

Article 11

Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco

1. Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. In that event, and in addition to the general warning provided for in Article 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Annex I. The general warning specified in Article 9(1) shall include a reference to the cessation services referred to in Article 10(1)(b).

The general warning shall appear on the most visible surface of the unit packet and any outside packaging.

Member States shall ensure that each text warning is displayed to the extent possible in equal numbers on each brand of these products. The text warnings shall appear on the next most visible surface of the unit packet and any outside packaging.

For unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open.

2. The general warning referred to in paragraph 1 shall cover 30 % of the relevant surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and to 35 % for Member States with more than two official languages.

3. The text warning referred to in paragraph 1 shall cover 40 % of the relevant surface of the unit packet and any outside packaging. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with more than two official languages.

4. Where the health warnings referred to in paragraph 1 are to appear on a surface exceeding 150 cm^2, the warnings shall cover an area of 45 cm^2. That area shall be increased to 48 cm^2 for Member States with two official languages and 52,5 cm^2 for Member States with more than two official languages.

5. The health warnings referred to in paragraph 1 shall comply with the requirements specified in Article 9(4). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

The health warnings shall be surrounded by a black border of a width of not less than 3 mm and not more than 4 mm. This border shall appear outside the surface reserved for the health warnings.

6. The Commission shall adopt delegated acts in accordance with Article 27, to withdraw the possibility of granting exemptions for any of the particular product categories referred to in paragraph 1 if there is a substantial change of circumstances as established in a Commission report for the product category concerned.

Article 12

Labelling of smokeless tobacco products

1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

'This tobacco product damages your health and is addictive.'

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 9(4). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

In addition, it shall:

(a) appear on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the surfaces of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning laid down in paragraph 1 to scientific developments.

Article 13

Product presentation

1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:

(a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

(b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;

(c) refers to taste, smell, any flavourings or other additives or the absence thereof;

(d) resembles a food or a cosmetic product;

(e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

Article 14

Appearance and content of unit packets

1. Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.

2. A unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.

Article 15

Traceability

1. Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps or price marks, or by the opening of the unit packet. In the case of tobacco products that are manufactured outside of the Union, the obligations laid down in this Article apply only to those that are destined for, or placed on, the Union market.

2. The unique identifier shall allow the following to be determined:

(a) the date and place of manufacturing;

(b) the manufacturing facility;

(c) the machine used to manufacture the tobacco products;

(d) the production shift or time of manufacture;

(e) the product description;

(f) the intended market of retail sale;

(g) the intended shipment route;

(h) where applicable, the importer into the Union;

(i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;

(j) the identity of all purchasers from manufacturing to the first retail outlet; and

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

3. The information referred to in points (a), (b), (c), (d), (e), (f), (g) and, where applicable, (h) of paragraph 2 shall form part of the unique identifier.

4. Member States shall ensure that the information mentioned in points (i), (j) and (k) of paragraph 2 is electronically accessible by means of a link to the unique identifier.

5. Member States shall ensure that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

6. Member States shall ensure that all natural and legal persons engaged in the supply chain of tobacco products maintain complete and accurate records of all relevant transactions.

7. Member States shall ensure that the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph 8.

8. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the Commission.

The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to access.

Member States shall ensure that the Commission, the competent authorities of the Member States, and the external auditor have full access to the data storage facilities. In duly justified cases the Commission or the Member States may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law.

9. Recorded data shall not be modified or deleted by an economic operator involved in the trade of tobacco products.

10. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.

11. The Commission shall, by means of implementing acts:

(a) determine the technical standards for the establishment and the operation of the tracking and tracing system as provided for in this Article, including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data;

(b) determine the technical standards for ensuring that the systems used for the unique identifier and the related functions are fully compatible with each other across the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to define the key elements of the data storage contracts referred to in paragraph 8 of this Article, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts.

13. Paragraphs 1 to 10 shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

Article 16

Security feature

1. In addition to the unique identifier referred to in Article 15, Member States shall require that all unit packets of tobacco products, which are placed on the market, carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.

Member States requiring tax stamps or national identification marks used for fiscal purposes may allow that they are used for the security feature provided that the tax stamps or national identification marks fulfil all of the technical standards and functions required under this Article.

2. The Commission shall, by means of implementing acts, define the technical standards for the security feature and their possible rotation and adapt them to scientific, market and technical developments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3. Paragraph 1 shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

CHAPTER III

Tobacco for oral use, cross-border distance sales of tobacco products and novel tobacco products

Article 17

Tobacco for oral use

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Article 18

Cross-border distance sales of tobacco products

1. Member States may prohibit cross-border distance sales of tobacco products to consumers. Member States shall cooperate to prevent such sales. Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited. Member States which do not prohibit such sales shall require retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State, where the retail outlet is established, and in the Member State, where the actual or potential consumers are located. Retail outlets established outside the Union shall be required to register with the competent authorities in the Member State where the actual or potential consumers are located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities when registering:

(a) name or corporate name and permanent address of the place of activity from where the tobacco products will be supplied;

(b) the starting date of the activity of offering tobacco products for cross-border distance sales to consumers by means of Information Society services, as defined in point 2 of Article 1 of Directive 98/34/EC;

(c) the address of the website or websites used for that purpose and all relevant information necessary to identify the website.

2. The competent authorities of the Member States shall ensure that consumers have access to the list of all retail outlets registered with them. When making that list available, Member States shall ensure that the rules and safeguards laid down in Directive 95/46/EC are complied with. Retail outlets may only start placing tobacco products on the market via cross-border distance sales when they have received confirmation of their registration with the relevant competent authority.

3. The Member States of destination of tobacco products sold via cross-border distance sales may require that the supplying retail outlet nominates a natural person to be responsible for verifying — before the tobacco products reach the consumer — that they comply with the national provisions adopted pursuant to this Directive in the Member State of destination, if such verification is necessary in order to ensure compliance and facilitate enforcement.

4. Retail outlets engaged in cross-border distance sales shall operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination. The retail outlet or natural person nominated pursuant to paragraph 3 shall provide to the competent authorities of that Member State a description of the details and functioning of the age verification system.

5. Retail outlets shall only process personal data of the consumer in accordance with Directive 95/46/EC and those data shall not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to other third parties. Personal data shall not be used or transferred for purposes other than the actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

Article 19

Notification of novel tobacco products

1. Member Stes shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with Article 5. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the competent authorities with:

(a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions;

(b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers;

(c) other available and relevant information, including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception.

2. Member States shall require manufacturers and importers of novel tobacco products to transmit to their competent authorities any new or updated information on the studies, research and other information referred to in points (a) to (c) of paragraph 1. Member States may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information. Member States shall make all information received pursuant to this Article available to the Commission.

3. Member States may introduce a system for the authorisation of novel tobacco products. Member States may charge manufacturers and importers proportionate fees for that authorisation.

4. Novel tobacco products placed on the market shall respect the requirements of this Directive. Which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking.

TITLE III

ELECTRONIC CIGARETTES AND HERBAL PRODUCTS FOR SMOKING

Article 20

Electronic cigarettes

1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with this Directive and with all other relevant Union legislation.

This Directive does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

2. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

(a) the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;

(b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;

(c) toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;

(d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;

(e) a description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

(f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;

(g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Where Member States consider that the information submitted is incomplete, they shall be entitled to request the completion of the information concerned.

Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted to them.

3. Member States shall ensure that:

(a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;

(b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;

(c) the nicotine-containing liquid does not contain additives listed in Article 7(6);

(d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture;

(e) except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;

(f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;

(g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

4. Member States shall ensure that:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information on:

(i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

(ii) contra-indications;

(iii) warnings for specific risk groups;

(iv) possible adverse effects;

(v) addictiveness and toxicity; and

(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:

(i) include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

(ii) without prejudice to point (i) of this point, do not include elements or features referred to in Article 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and

(iii) carry one of the following health warnings:

'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.

or

'This product contains nicotine which is a highly addictive substance.'

Member States shall determine which of these health warnings is to be used;

(c) health warnings comply with the requirements specified in Article 12(2).

5. Member States shall ensure that:

(a) commercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market;

(b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;

(c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited;

(d) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

(e) audiovisual commercial communications to which Directive 2010/13/EU of the European Parliament and of the Council [1] applies, are prohibited for electronic cigarettes and refill containers.

6. Article 18 of this Directive shall apply to cross-border distance sales of electronic cigarettes and refill containers.

7. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:

(i) comprehensive data on sales volumes, by brand name and type of the product;

(ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;

(iii) the mode of sale of the products; and

(iv) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.

8. Member States shall ensure that the information received pursuant to paragraph 2 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available.

Member States shall, upon request, make all information received pursuant to this Article available to the Commission and other Member States. The Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

9. Member States shall require manufacturers, importers and distributers of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with this Directive, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Directive, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

Member States may also request additional information from the economic operators, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

10. The Commission shall submit a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

[1] Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

11. In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where a competent authority ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health, it may take appropriate provisional measures. It shall immediately inform the Commission and the competent authorities of other Member States of the measures taken and shall communicate any supporting data. The Commission shall determine, as soon as possible after having received that information, whether the provisional measure is justified. The Commission shall inform the Member State concerned of its conclusions to enable the Member State to take appropriate follow-up measures.

Where, in application of the first subparagraph of this paragraph, the placing on the market of specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container has been prohibited on duly justified grounds in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to extend such a prohibition to all Member States, if such an extension is justified and proportionate.

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning in paragraph 4(b) of this Article. When adapting that health warning, the Commission shall ensure that it is factual.

13. The Commission shall, by means of an implementing act, lay down a common format for the notification provided for in paragraph 2 and technical standards for the refill mechanism provided for in paragraph 3(g).

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

Article 21

Herbal products for smoking

1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:

'Smoking this product damages your health.'

2. The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.

3. The health warning shall comply with the requirements set out in Article 9(4). It shall cover 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and to 35 % for Member States with more than two official languages.

4. Unit packets and any outside packaging of herbal products for smoking shall not include any of the elements or features set out in Article 13(1)(a), (b) and (d) and shall not state that the product is free of additives or flavourings.

Article 22

Reporting of ingredients of herbal products for smoking

1. Member States shall require manufacturers and importers of herbal products for smoking to submit to their competent authorities a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type. Manufacturers or importers shall also inform the competent authorities of the Member States concerned when the composition of a product is modified in a way that affects the information submitted pursuant to this Article. The information required under this Article shall be submitted prior to the placing on the market of a new or modified herbal product for smoking.

2. Member States shall ensure that the information submitted in accordance with paragraph 1 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available. Economic operators shall specify exactly which information they consider to constitute a trade secret.

TITLE IV

FINAL PROVISIONS

Article 23

Cooperation and enforcement

1. Member States shall ensure that manufacturers and importers of tobacco and related products provide the Commission and the competent authorities of the Member States with complete and correct information requested pursuant to this Directive and within the time limits set out herein. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in the Union. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside the Union and the importer is established inside the Union. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside the Union.

2. Member States shall ensure that tobacco and related products which do not comply with this Directive, including the implementing and delegated acts provided for therein, are not placed on the market. Member States shall ensure that tobacco and related products are not placed on the market if the reporting obligations set out in this Directive are not complied with.

3. Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures that are necessary to ensure that these penalties are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial administrative penalty that may be imposed as a result of an intentional infringement may be such as to offset the economic advantage sought through the infringement.

4. The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the correct application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive in a uniform manner.

Article 24

Free movement

1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.

3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.

Article 25

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

4. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 26

Competent authorities

Member States shall designate the competent authorities that shall be responsible for the implementation and enforcement of the obligations provided for in this Directive within three months of 20 May 2016. Member States shall inform the Commission about the identity of the designated authorities without delay. The Commission shall publish that information in the *Official Journal of the European Union*.

Article 27

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall be conferred on the Commission for a period of five years from 19 May 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Articles 3(2) and(4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 28

Report

1. No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

When drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information at its disposal.

2. In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:

(a) the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;

(b) market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19;

(c) market developments which constitute a substantial change of circumstances;

(d) the feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products, including the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products, taking into account, inter alia, the information collected in accordance with Articles 5 and 6;

(e) market developments concerning cigarettes with a diameter of less than 7,5 mm, and consumer perception of their harmfulness as well as the misleading character of such cigarettes;

(f) the feasibility, benefits and possible impact of a Union database containing information on ingredients and emissions from tobacco products collected in accordance with Articles 5 and 6;

(g) market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours;

(h) market developments and consumer preferences as regards waterpipe tobacco, with a particular focus on its flavours.

The Member States shall assist the Commission and provide all available information for carrying out the assessment and preparing the report.

3. The report shall be followed-up by proposals for amending this Directive, which the Commission deem necessary to adapt it - to the extent necessary for the smooth functioning of the internal market - to developments in the field of tobacco and related products, and to take into account new developments based on scientific facts and developments concerning internationally agreed standards for tobacco and related products.

Article 29

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 May 2016. They shall forthwith communicate to the Commission the text of those provisions.

The Member States shall apply those measures from 20 May 2016, without prejudice to Articles 7(14), 10(1)(e), 15(13) and 16(3).

2. When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. The Member States shall determine how such reference is to be made and how that statement is to be formulated.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 30

Transitional provision

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until 20 May 2017:

(a) tobacco products manufactured or released for free circulation and labelled in accordance with Directive 2001/37/EC before 20 May 2016;

(b) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016;

(c) herbal products for smoking manufactured or released for free circulation before 20 May 2016.

Article 31

Repeal

Directive 2001/37/EC is repealed with effect from 20 May 2016, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of that Directive.

References to the repealed Directive shall be construed as references to this Directive and read in accordance with the correlation table in Annex III to this Directive.

Article 32

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 33

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 3 April 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

ANNEX I

LIST OF TEXT WARNINGS

(referred to in Article 10 and Article 11(1))

(1) Smoking causes 9 out of 10 lung cancers

(2) Smoking causes mouth and throat cancer

(3) Smoking damages your lungs

(4) Smoking causes heart attacks

(5) Smoking causes strokes and disability

(6) Smoking clogs your arteries

(7) Smoking increases the risk of blindness

(8) Smoking damages your teeth and gums

(9) Smoking can kill your unborn child

(10) Your smoke harms your children, family and friends

(11) Smokers' children are more likely to start smoking

(12) Quit smoking – stay alive for those close to you

(13) Smoking reduces fertility

(14) Smoking increases the risk of impotence

ANNEX II

PICTURE LIBRARY

(REFERRED TO IN ARTICLE 10(1))

[To be established by the Commission pursuant to Article 10(3)(b).]

ANNEX III

CORRELATION TABLE

Directive 2001/37/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3(1)	Article 3(1)
Article 3(2) and (3)	—
Article 4(1)	Article 4(1)
Article 4(2)	Article 4(2)
Article 4(3) to (5)	—
Article 5(1)	—
Article 5(2) point (a)	Article 9(1)
Article 5(2) point (b)	Article 10(1) point (a) and 10(2), Article 11(1)
Article 5(3)	Article 10(1)
Article 5(4)	Article 12
Article 5(5) first subparagraph	Article 9(3) fifth subparagraph Article 11(2) and (3) Article 12(2) point (b)
Article 5(5) second subparagraph	Article 11(4)
Article 5(6) point (a)	Article 9(4) point (a)
Article 5(6) point (b)	—
Article 5(6) point (c)	Article 9(4) point(b)
Article 5(6) point (d)	Article 8(6) and Article 11(5) second subparagraph
Article 5(6) point (e)	Article 8(1)
Article 5(7)	Article 8(3) and (4)
Article 5(8)	—

Directive 2001/37/EC	This Directive
Article 5(9) first subparagraph	Article 15(1) and (2)
Article 5(9) second subparagraph	Article 15(11)
Article 6 (1) first subparagraph	Article 5(1) first subparagraph
Article 6 (1) second subparagraph	Article 5(2) and (3)
Article 6 (1) third subparagraph	—
Article 6(2)	Article 5(4)
Article 6(3) and (4)	—
Article 7	Article 13(1) point (b)
Article 8	Article 17
Article 9(1)	Article 4(3)
Article 9(2)	Article 10(2) and (3) point (a)
Article 9(3)	Article 16(2)
Article 10(1)	Article 25(1)
Article 10(2) and (3)	Article 25(2)
Article 11 first and second subparagraphs	Article 28(1) first and second subparagraphs
Article 11 third subparagraph	Article 28(2) first subparagraph
Article 11 fourth subparagraph	Article 28(3)
Article 12	—
Article 13(1)	Article 24(1)
Article 13(2)	Article 24(2)
Article 13(3)	
Article 14(1) first subparagraph	Article 29(1) first subparagraph

Directive 2001/37/EC	This Directive
Article 14(1) second subparagraph	Article 29(2)
Article 14(2) and (3)	Article 30 point (a)
Article 14(4)	Article 29(3)
Article 15	Article 31
Article 16	Article 32
Article 17	Article 33
Annex I (List of additional health warnings)	Annex I (List of text warnings)
Annex II (Time-limits for transposition and implementation of repealed Directives)	—
Annex III (Correlation table)	Annex III (Correlation table)

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE 2014/109/EU

of 10 October 2014

amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC [1], and in particular Article 10(3)(b) thereof,

Whereas:

(1) Article 10 of Directive 2014/40/EU provides that each unit packet and any outside packaging of tobacco products for smoking is to carry combined health warnings unless exempted in accordance with Article 11. The combined health warnings are to contain, inter alia, one of the text warnings listed in Annex I and a corresponding colour photograph specified in the picture library in Annex II to that Directive.

(2) Directive 2014/40/EU also empowers the Commission to adopt delegated acts to establish and adapt the picture library in Annex II taking into account scientific and market developments.

(3) Therefore, Annex II to Directive 2014/40/EU should be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2014/40/EU is replaced in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 May 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 20 May 2016.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

[1] OJ L 127, 29.4.2014, p. 1.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 10 October 2014.

For the Commission
The President
José Manuel BARROSO

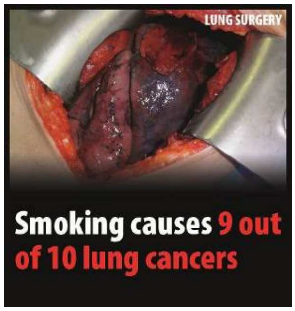
ANNEX

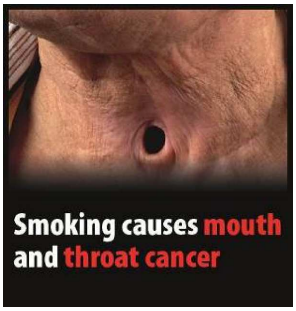
'ANNEX II

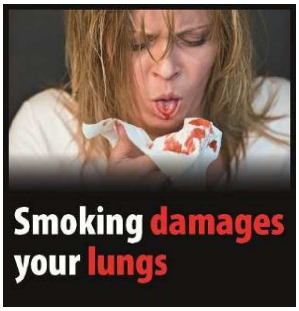
Picture Library (of combined health warnings)

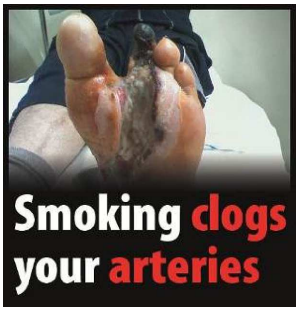
(referred to in Article 10(1))

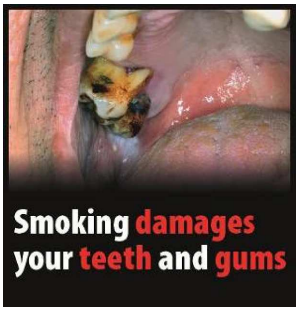
Set 1

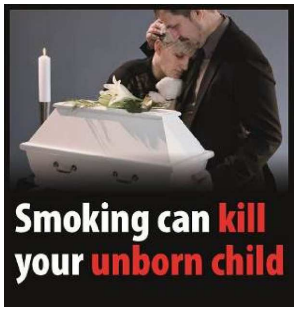


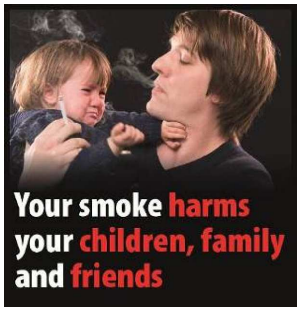










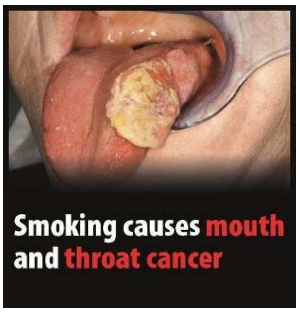



Smoking
reduces fertility


Smoking increases
the risk of impotence

Set 2


Smoking causes 9 out
of 10 lung cancers


Smoking causes mouth
and throat cancer

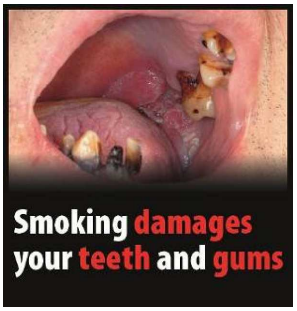

OPEN WOUND AFTER
LUNG SURGERY
Smoking damages
your lungs

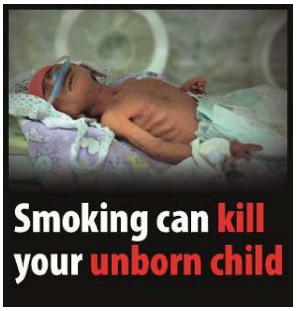

Smoking causes
heart attacks


Smoking causes
strokes and disability


Smoking clogs
your arteries


Smoking increases
the risk of blindness

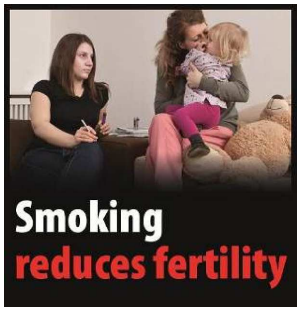

Smoking damages
your teeth and gums


Smoking can kill
your unborn child


Your smoke harms
your children, family
and friends


Smokers' children
are more likely
to start smoking

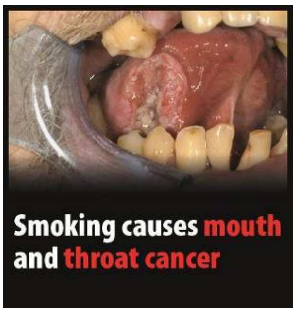

Quit smoking –
stay alive for those
close to you

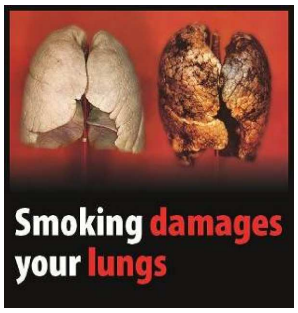

Smoking
reduces fertility


Smoking increases
the risk of impotence

Set 3

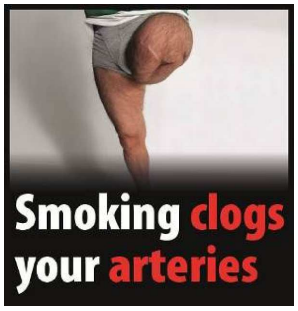

Smoking causes 9 out
of 10 lung cancers

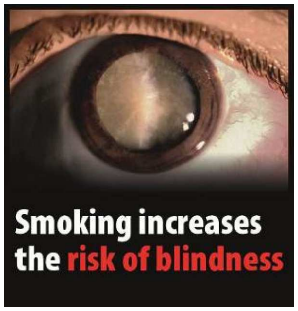

Smoking causes mouth
and throat cancer


Smoking damages
your lungs


Smoking causes
heart attacks


Smoking causes
strokes and disability


Smoking clogs
your arteries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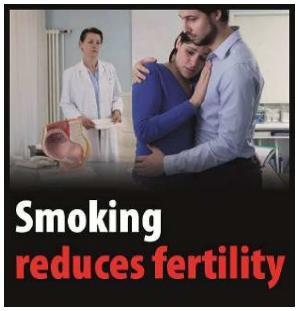
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